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EVOLUT™ TAVR CUSP OVERLAP TECHNIQUE

PRECISION & CONTROL

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Procedural Optimization to Minimize Interaction With the Left Ventricular Conduction System During Self-Expanding TAVR

The inception of the cusp overlap technique: rationale and development.

By Hemal Gada, MD, MBA, and Amit N. Vora, MD, MPH

Transcatheter aortic valve replacement (TAVR) with the self-expanding, supra-annular CoreValve and Evolut R bioprostheses (Medtronic) has been associated with the need for permanent pacemaker implantation (PPI) in 15.7% to 28.6% of patients within 30 days after the procedure.\textsuperscript{1-9} The frequent requirement for PPI has been one of the main challenges influencing an operator’s willingness to perform TAVR with this bioprosthesis. We present a novel method that describes a series of procedural steps designed to provide a controlled implantation depth and minimize the interaction of the bioprosthesis with the atrioventricular (AV) conduction system, potentially reducing the subsequent clinical sequelae of conduction disturbances.

Traditional deployment of the CoreValve and subsequently Evolut bioprosthesis had relied upon obtaining a three-cusp coplanar view and then adjusting the gantry angle, generally caudal, to eliminate parallax from the capsule marker band. Subsequently, Piazza and colleagues demonstrated that the three-cusp technique with marker adjustment distorted the native anatomy on fluoroscopy.\textsuperscript{10} Using the three-cusp technique, the operator often deployed the valve without a clear representation of the location of the native annulus relative to the conduction system. The location of the conduction system was obscured by the radiographic foreshortening of the left ventricular outflow tract in noncusp overlap views.

Figure 1. Cusp overlap view. The left panel illustrates the cusp overlap position with the NCC (yellow), RCC (green), and left coronary sinus (red). The right panel shows the volume rendering of the cusp overlap view showing the commissure of the non- and right coronary sinus (courtesy James Harvey, MD).
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To develop a strategy that minimizes the risk of interaction of the conduction system with the bioprosthesis, a better understanding of the location of the conduction system relative to the aortic annulus basal plane was needed. The noncoronary cusp (NCC), the most inferiorly oriented cusp in the left ventricular outflow tract (LVOT), is isolated from the left coronary cusp (LCC) and the right coronary cusp (RCC) using the cusp overlap technique. Below the non-right commissure, the membranous septum houses the conduction system. More ventricular to the membranous septum, which may be of variable length, these conduction fibers become more superficial in the muscular septum. If the transcatheter heart valve (THV) is deployed below the membranous septum, there is a greater chance of interaction with the conduction system. Jilaihawi et al described the variation in PPI rates depending on the length of the membranous septum and the depth of the THV. Their series suggested that when a THV is deployed below the membranous septum, the risk of PPI was increased.4

CUSP OVERLAP METHOD

Our method demonstrates that by isolating the NCC and overlapping the NCC/RCC commissure along the basal annular plane, the implantation view can be optimized during THV deployment. This view can be easily identified during computed tomography (CT) reconstruction (3Mensio, Pie Medical Imaging) and contribute to preprocedural case planning (Figure 1). The cusp overlap view unforeshortens and elongates the LVOT and accentuates the NCC/RCC commissure in the center of the fluoroscopic view, creating an implant that references the conduction system and separates it from the annular plane. Given the unforeshortening of the LVOT, there is also a greater distance between the NCC insertion and the compact AV node (Figure 2). This fluoroscopic view may lead to a more precise 3-mm implantation depth, thereby minimizing the risk of interaction with the conduction system.

In addition to the cusp overlap view, several procedural steps have been embedded in this technique to further reduce interaction with the conduction system during TAVR deployment. We now focus on more of a “top-down” deployment of the THV, starting with the catheter marker band positioned at the midportion of the pigtail in the NCC (Figure 3). With retraction of the nitinol capsule, the inflow of the prosthesis advances across the annulus and is positioned at 3 mm below the annulus. This maneuver avoids traumatic advancement of the bioprosthesis into the ventricle with inflow flaring deeper within the left ventricle, resulting in subsequent maneuvers to move it more aortic and interacting with the muscular septum and conduction system. We also use a stiffer, double-curved, Lunderquist wire (Cook Medical) in most cases to maintain a wire position in the non-right commissure and begin the prosthesis deployment along the posterior aspect of the annular plane. The stiffer wire may result in more symmetrical deployment and is especially valuable when deploying larger-sized THVs. Using the cusp overlap view to maintain a reference to the native annular plane, the marker band on the THV delivery catheter does tend to lose parallax when approaching the valve plane. The loss of parallax of the marker band is the result of the delivery catheter following the stiff left ventricular wire that is generally positioned in the NCC/RCC commissure. This approach may lead to more confidence in the initial positioning of the THV in relation to the

Figure 2. Location of the AV node and basal annular plane. The blue AV node is shown best in the cusp overlap view (A) with an increased distance from the AV node to the basal annular plane. The three-cusp coplanar view generally requires caudal angulation to remove the parallax from the marker band and the AV does appear closer to the basal annular plane due to foreshortening of the LVOT (B). The LAO view shows the AV node with overlaps the RCC and NCC and isolates the LCC (C). The LVOT is also foreshortened in this view.
insertion of the NCC and a better assessment at the point of no-recapture. We also favor sufficient pacing during the deployment to minimize cardiac output and the occurrence of premature ventricular contraction burden, allowing for a stable bioprosthesis deployment. Finally, once we are at 80% deployment, we rotate the gantry to an LAO projection to visualize the LCC and ensure that the inflow is supra-annular. We aim for an implantation depth of 3 mm, and no deeper than 5 mm, below the NCC to reduce our risk of conduction disturbance. We occasionally aim for shallower deployment in patients at high risk for conduction system abnormality but recommend recapture for bioprosthesis positions < 1 or > 5 mm within the ventricle. Once final positioning is confirmed, we retract the left ventricular wire, centralize the nose cone, and slowly release the delivery catheter from the bioprosthesis by the release of the frame paddles. We are cautious to avoid interaction of the delivery catheter and the bioprosthesis as the delivery catheter is retracted into the aorta.

THE UPMC PINNACLE EXPERIENCE WITH CUSP OVERLAP

After starting with routine use of the cusp overlap technique in October 2015, we have observed a significant decline in the post-TAVR PPI rates at our institution, especially with the Medtronic CoreValve and Evolut platforms. In the Medtronic Low Risk trial, the rate of PPI 30-days post-TAVR was 17.4%, with wide site-specific variability (Figure 4). Our single-center experience utilizing cusp overlap found that only one (1.5%) in 65 patients required permanent pacing. As the highest enrolling center in the Evolut low-risk trial, we attribute this difference to the comprehensive use of the cusp overlap technique at our institution.

We have also analyzed our experience in 134 patients without antecedent PPI who underwent placement of the 34-mm Evolut R THV, which has been shown to be a predictor of PPI, independent of membranous septum length. After preprocedural computed tomography (CT) planning to determine the optimal cusp overlap projection angle, we were able to achieve the projected cusp overlap gantry view on CT reconstruction in 88% of patients, and a near cusp overlap projection in the remaining patients. In this series, we obtained an effective 30-day PPI rate of 5.2%. In addition, the new-onset left bundle branch block rate was 10.9%, below contemporary rates previously published. When compared to previous studies (Figure 5), we believe that the cusp overlap view contributed to the lower rate of PPI rates in our series. The Optimize PRO study (NCT04091048) will provide additional insights into the safety and efficacy of this method in a broader array of patients at multiple centers.

PROCTORING EXPERIENCE IN ADOPTION OF CUSP OVERLAP

Prior to the adoption of the cusp overlap technique as the standard for Medtronic self-expanding THV deployment, we
were able to teach the cusp overlap technique successfully to several international centers, including those in the United States. A focused didactic experience involving several Latin American centers was initiated in July 2018.12 There were eight formal encounters with Latin American physicians, involving didactics through programmatic lecture, proctored and presented cases, as well as case observation at our institution. We analyzed the results of these experiences extending to October 2019.12 Fourteen implanting physicians from seven countries performed consecutive procedures on 114 patients. Each physician implanted only 22.6 ± 10.9 THVs the previous year, with a lifetime experience of 129 ± 110 THVs. Of the 114 patients, 105 (92%) did not have a prior PPI. In this series, the in-hospital rate of new PPI post-THV was 5.7%. During the 30-day follow-up that included 85 patients, no additional patients required a new permanent pacemaker. These results suggest that the use of the cusp overlap in lower volume operators resulted in reduced rates of PPI and may be useful to potentially shorten the learning curve for this self-expanding bioprosthesis.

**OPTIMIZING POSTPROCEDURAL MANAGEMENT**

Our institution has focused on optimizing postprocedural management over the past several years, which has included an effort to reduce resource utilization during the hospitalization period. Our institution experienced a reduction in the 2019 TAVR mean length of stay (LOS) to 1.23 days after 386 TAVR procedures, at least partially due to a reduction in the need for new PPI implantation. More specifically, an analysis of 567 TAVR cases performed at our institution between July 2015 and June 2018 included 34 patients who required PPI during their hospital stay. The average cost of PPI was $4,415, but the patients who went onto receive PPI had a significantly longer LOS than those who did not (4.49 vs 1.75 days), resulting in a modified contribution margin differential of $12,654 per case. Although the reasons for this reduction in LOS differential were multifactorial, a primary reason was related to the reduced postprocedural conduction disturbances and the need for a temporary or permanent pacemaker. For example, patients who developed temporary conduction disturbances requiring temporary pacing were not placed on the “fast track” protocol and early ambulation. In those patients who required permanent pacing, usually on postprocedural day 1, an additional 24-hour period of bed rest was needed, leading to slower periprocedural recovery and increased resource utilization to facilitate suitable disposition.

**LIMITATIONS AND MITIGATIONS**

There are three potential limitations for the cusp overlap method that will be informed by additional single and
multicenter studies, including the Optimize PRO study. One concern relates to higher implantation of the self-expanding bioprosthesis with its 13- to 14-mm skirt height that raises concerns for coronary access. Preprocedural CT planning can mitigate this risk by assessing the heights of the coronary arteries and placing the bioprosthesis at a position to allow coronary access after TAVR.

Another potential limitation of the cusp overlap technique is the operator’s anxiety that a shallow TAVR implantation may lead to a higher rate of valve embolism (“pop-outs”), potentially resulting in increased procedural complexity and patient morbidity. In our experience, we have not found this to be the case, and required the use of a second THV in only one (0.5%) of approximately 200 cases. In fact, the cusp overlap technique may facilitate a better understanding of the true THV depth relative to the NCC, and importantly, the target 3-mm implantation depth in relation to the NCC is standard for use for all THV platforms. Because the LVOT is elongated in this particular view, our assessment of the depth assessment is likely more accurate. In a non-cusp overlap view, the LVOT is foreshortened, leading to the false perception that THV is positioned shallower relative to the NCC insertion. Another reason to position the THV at a 3-mm implantation depth is that if postdilation is indicated, there is a buffer for the potential shortening of the THV during postdilatation.

A third limitation is the use of a stiff Lunderquist wire. Our technique supports the use of the double-curved Lunderquist wire in most ventricular anatomies. We believe that the stiffer wire provides several advantages, including biasing the valve toward the posterior aspect of the annular plane, eliminating parallax in the marker band, increasing efficiency, and providing a more predictable deployment. Like all ventricular wires, the possibility of ventricular perforation is always a consideration. We deploy the Lunderquist through a pigtail catheter established toward the apex of the left ventricle. After unsheathing the wire, there is no forward manipulation, thereby reducing the possibility of trauma.

Innovation and Impact Without Device Iterations

Our description of the novel cusp overlap technique includes both optimization of the CT image reconstruction to define an ideal implant angle, and simplification of the procedure to minimize the interaction of the transcatheter bioprosthesis and the conduction system. The simplified cusp overlap technique has the potential to enhance clinical outcomes by focusing on procedural modifications rather than to rely on new technology or expanded infrastructure for clinical improvements. In our institution, the cusp

Figure 5. Rate of PPI in the UPMC Pinnacle 34-mm Evolut R series. Using the cusp overlap technique, the lowest reported rate of 30-day PPI with the 34-mm Evolut R was achieved.\(^9\)
As transcatheter aortic valve replacement (TAVR) is now approved in lower-risk, younger patients, lifetime management of this population is becoming more important. In surgical aortic valve replacement (SAVR), after excision of the native valve leaflets, commissural alignment of the new prosthesis is guaranteed. This has been demonstrated by Fuchs et al who studied SAVR implantation and found that all commissures were within 30° of native commissures. Cardiac surgeons never intentionally rotate the valve off its native axis nor do they compromise the depth of annular sutures.

Because the prevalence of significant coronary artery disease is 40% to 75% in patients with severe aortic stenosis undergoing TAVR, one must consider the need for coronary reaccess when placing a TAVR valve. In one study of 779 patients undergoing TAVR, 4.7% had acute coronary syndrome within 1 year after TAVR and 10% did during a median follow-up of 25 months. These patients were on average younger than the total population. Our group has studied optimal commissural alignment with the cusp overlap technique using self-expanding Evolut valves (Medtronic) to decrease likelihood of future coronary access challenges.

**COMMISSURAL ALIGNMENT FOR CORONARY REACCESS**

Barriers to coronary reaccess after TAVR include the native aortic valve leaflets, the stent frame (whose distal end extends above the sinotubular junction), and the commissures if not properly aligned. The likelihood of the frame interfering with coronary reaccess is highest when there is a small angle to the commissure and short inflow to ostium distance.

Ochiai et al studied coronary positioning with computed tomography (CT) after implantation of 66 Evolut R/Evolut PRO valves from December 2015 to November 2017. Coronary reaccess was considered unfavorable if the ostium ended up below the 13/14-mm skirt (depending on valve size implanted) or if the transcatheter heart valve (THV) commissure landed near the ostium. Results showed that the skirt eclipsed the left coronary artery (LCA) in 12.8% of cases and the right coronary artery (RCA) in 3% of cases. The reason for no immediate hemodynamic collapse was that there was, on average, 4.2 to 4.8 mm of horizontal distance between the coronary ostia and the skirt blocking them. Coronary access was also obscured when the commissural triangle (up to 26 mm at the posts) blocked the LCA in 22.7% of cases and the RCA in 21.2%. This led to the inability to selectively engage the coronaries during coronary angiography or percutaneous coronary intervention after TAVR.

Similarly, Abdelghani et al looked at 101 patients from October 2015 to June 2019 who had Evolut R/PRO

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**Figure 1.** C-tab loaded 90° clockwise from the “Hat” marker in the Evolut TAVR system.
implantation with pre- and post-TAVR CTs. They found that in 10.8% of cases, a commissure was facing the LCA and in 9.7% of cases it was facing the RCA.\textsuperscript{10}

In our ALIGN-TAVR study, we looked at 245 patients between March 2016 and September 2019 at five centers that had Evolut placement. We used the coregistration technique between fluoroscopy and the coplanar angle on pre-TAVR CT using 3mensio software (Pie Medical Imaging).\textsuperscript{12} Commissural overlap was considered severe if it was within 20° of the coronary ostium. Evolut orientation at initial deployment was categorized by the position of the radiopaque “Hat” marker on the delivery device; it was either on the outer curve (OC), center front (CF), inner curve (IC), or center back (CB) of the aorta (Figure 1). The same four designations were used for the final C-tab position of the valve. As the study progressed, less commissural overlap with the coronaries was found when the “Hat” marker was placed on the OC of the descending aorta/annulus.\textsuperscript{12} This orientation was more common when the flush port of the delivery catheter was placed at the 3 o’clock position during insertion (versus the 12 o’clock position), so a change was made at our institution in March 2019 to implant the next 107 valves this way (Figure 2). In the overall cohort, having the “Hat” marker at the OC/CF position conferred significantly less ($P < .001$) commissural overlap than the IC/CB positions: 15.7% versus 66.0% for the LCA, 7.1% versus 51.1% for the RCA, 2.5% versus 40.4% for both coronaries, and 20.2% versus 76.6% for one or both coronaries (Figure 3).

CUSP OVERLAP IMPLANT VIEW TO MINIMIZE THE RISK OF INTERACTION WITH THE CONDUCTION SYSTEM

To increase the accuracy of implantation depth with Evolut valves, at our institution we obtain a cusp overlap view in addition to the three-cusp coplanar view. To do this, we obtained a more right anterior oblique (RAO) caudal view to overlap the left and right coronary cusps and position the “Hat” marker of the Evolut delivery catheter toward the CF during initial deployment.\textsuperscript{13} The valve is then deployed with contact from the non-coronary cusp to the overlapped left and right cusps, which enables higher implantation relative to the non-coronary cusp without valve “pop-out.”\textsuperscript{13} The approach in our facility
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is to optimize overlap without needing another arterial puncture, one pigtail can be placed in the right coronary cusp and another pigtail, a 0.035-inch J wire or an 0.018-inch nitinol wire in the left coronary cusp, which is then removed once the cusp overlap view is confirmed.13

With improved visualization of the nadir of the non-coronary cusp using the cusp overlap technique, permanent pacemaker implantation (PPI) can be reduced.

CLINICAL EXAMPLES

Case 1
A 72-year-old man presented with severe aortic stenosis. He was deemed a low surgical risk and appropriate for a 29-mm Evolut valve as part of the Evolut low-risk randomized trial. The delivery catheter was inserted with the flush port at the 3 o’clock position and the “Hat” marker was OC as seen in the left anterior oblique (LAO) 14°/caudal (CAU) 22° image (Figure 4A). The valve was implanted in the three-cusp view. Commissural alignment was confirmed on post-TAVR CT (Figure 4B). One week later, the patient returned with anginal symptoms. Secondary to commissural alignment, coronary access was straightforward and no coronary obstruction was identified in this case (Figure 4C).

Case 2
An 81-year-old woman who presented with symptomatic severe aortic stenosis (AS) had favorable anatomy for implantation of a 23-mm Evolut Pro. Fluoroscopic images were obtained in both the three-cusp view (LAO 0°/CAU 9°) and the RAO cusp-overlap view (RAO 23°/CAU 26°). The “Hat” marker in the cusp-overlap

Figure 4. “Hat” marker in the OC position (A). Commissural alignment confirmed on post-TAVR CT (B). Straightforward coronary access with commissural alignment (C).

Figure 5. Three-cusp and cusp-overlap views. “Hat” marker at the CF position (A). C-tab at the inner curve with ideal commissural alignment (B).
view was in the CF position on cusp-overlap and the C-tab landed at the inner curve, with ideal commissural alignment after deployment (Figure 5A, B). Having the “Hat” marker at the OC position in the three-cusp view or CF in the RAO cusp-overlap view allows for optimal results.

CONCLUSION
Although the self-expanding Evolut valve has tall commissural posts, we have found a valve positioning methodology that lowers risk of coronary obstruction while reducing the risk of interaction with the conduction system. This is increasingly important in the lifetime management of lower-risk and younger patients. By inserting the flush port away from the operator, we are able to control the “Hat” marker in the OC/CF position > 90% of the time to facilitate future coronary engagement. Using the cusp overlap technique, we bring precision to valve deployment to achieve the target implantation depth, providing physicians the tools to reduce the risk of TAV interaction with the conduction system.

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To minimise the risk of interaction with the conduction system, precise sizing, positioning, and expansion of the Evolut valve (Medtronic) are required. An ideal valve position would include a position just below the annular plane, and coaxial alignment with the left ventricular outflow tract (LVOT). This would ensure the maximum expansion diameter within the annulus to minimise the risk of paravalvular leak, and a high implantation depth would reduce the chance of compression of the conduction system, and the subsequent need for a permanent pacemaker.

However, in practice, upward displacement of the valve can occur during release, due to systolic ejection, valve shortening during expansion, and melon seeding when the LVOT is narrow—and if the valve is placed too high at the outset, a ‘pop-out’ can occur. Furthermore, coaxial alignment may be difficult to achieve due to the differing axes of the ascending aorta (adopted by the valve) and the LVOT (of which the annulus is its proximal cross-section).

In practice, the best results are therefore achieved by minimising the depth of the device below the noncoronary cusp (the deepest cusp), whilst allowing for a small degree of upward movement during expansion. This requires precise positioning, as well as control of the device during deployment.

**Judging the Prosthesis Depth**

Medtronic’s previous guidance for placement of the Evolut valve has been to first align the lowest points of the three cusps to create an annular plane three-cusp view. From transfemoral access, the device is often poorly aligned in this view, meaning that different sides of the expanded valve will occupy different depths with respect to a line joining the base of the cusps (the annular plane). It is, therefore, not possible in this view to be confident that the expanded valve will be below all three cusps. Medtronic’s guidance has therefore been to add either caudal angulation (common in the United Kingdom) or left anterior oblique (LAO) angulation (common in the United States) to this three-cusp view to achieve a device plane. Using these device plane projections, the operator can adjust the device position so that it is below the left and noncoronary cusps. These angulations have the effect of elevating the right coronary cusp (RCC) above the remaining left and noncoronary cusps and so, if the device is deployed below the still visible non-coronary cusp (NCC) and left coronary cusp (LCC), the operator can then be confident that the device will deploy below all three cusps, thereby minimizing the risk of a pop out.

However, the problem with this approach has been uncertainty regarding the true depth of the valve using off-annular plane projections. A potential solution was first proposed by Piazza et al, who realized that the annulus remained in-plane in a range of views with different relative cusp positions, described by an S curve, and that the device plane could similarly be imaged from different angiographic angles, described by a second S curve. From transfemoral access, Piazza et al described how these two S curves intersect in an RAO caudal view in most cases. This view, being the unique projection in which both the device and annulus are in-plane, allows the true device depth below the annulus to be assessed.¹

Determining the S curve of the annulus is easily accomplished using computed tomography (CT) imaging software, such as 3mensio (Pie Medical Imaging BV) at the time of procedural planning. However, determining the S curve of the device requires image analysis at the time of the procedure and is not routinely available. This led to initial difficulties adopting this technique.

However, operators realized that the solution could be estimated by simply choosing an eccentric RAO caudal angle from the annular S curve generated from the CT data and that this view not only aligned the device and annular planes but frequently also overlapped the LCCs and RCCs along the annular plane, leading to the term cusp overlap view (COV). Medtronic has now adopted use of this view, in addition to other procedural tweaks, to create the current procedural guidance.

**Manchester Experience**

When we transitioned from a Sapien-only centre (Edwards Lifesciences) to include the Evolut R valve in 2015, we had
been used to only implanting in the three-cusp annular plane view (as per Edwards Lifesciences instructions for use). We, therefore, felt uncomfortable coming off the annular plane and were attracted to ways to visualise both the valve and annulus in plane. After experimentation with RAO caudal annular projections predicted by the CT analysis, we similarly adopted the cusp overlap view as a convenient place to start. We were pleased by how often the cusp overlap technique aligned both the annulus and device and were struck by the low rate of pacemaker implantation, trending to be lower than our Sapien experience (N = 487; Evolut, 4.6%; Sapien 3, 8% pacemaker at 30 days) and the low rates of perivalvular leak (Figure 1).²,³

In the lab, we have found that the COV has been a very workable view with both RAO and caudal angulations < 30° in roughly 80% of cases. In the remaining cases, we have found that a less extreme view derived from the CT annular S curve in between the three-cusp and cusp overlap views works well with good device alignment.

Furthermore, as the COV puts the lowest point of the NCC lateral to the valve, rather than behind the valve (as in the three-cusp view and modifications) visualisation of its position is further simplified (Figure 2). With the pigtail firmly at the base of this cusp, the device can be easily adjusted relative to the base of the pigtail. We have also been confident that when the valve is below the NCC in the COV it will be below all three cusps in almost all cases. As Medtronic now recommends, we aim to place the valve at a target implantation depth of 3 mm, with a range of 1 to 5 mm; shallower implantations may lead to pop-outs during postdilation, whereas deeper implants increase the pacemaker rates. This cusp overlap technique has allowed us to greatly simplify deployment (Figure 2).

The effect of caudal and LAO angulation off the annular plane has been further examined in a modeling study.³ This study showed that the valve was elevated above the annular plane in a similar way with respect to the RCC whenever caudal or LAO angulation was applied (Figure 3). We’ve calculated that each 10° of caudal or LAO angulation off the

1. Image in three-cusp view to verify S curve angles from CT. Apply any difference from CT angle to all subsequent views.
2. Switch to COV. With the pigtail at the base of the NCC, slowly unsheath the valve (up to a point before annular contact) while keeping the base of the valve approximately 1 mm horizontally below the base of the pigtail. This will be approximately 3 mm below the annular plane, defined as the line joining the base of the NCC and LCC.
3. We then deploy the valve to 80% in the cusp overlap view, under rapid pacing to reduce cardiac output and minimize the likelihood of movement. During deployment aim to keep the valve 1 mm horizontally below the base of the pigtail held at the base of the NCC and LCC at 80%—aiming for 2-4 mm below this line. Consider recapture if < 1 or > 5 mm.
4. Assess expansion and depth below the LCC in this view.
5. Check in the LAO cranial view to judge tension on the valve before release, with the aim of a mid aortic position. Check device below LCC, risk of coronary obstruction, degree of aortic regurgitation in this view. Check degree of valve expansion in both views.
6. Do not release unless a good position is achieved. Recapture and reposition the valve, if necessary, to obtain an optimal position.
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Currently, approximately one-third (16 of 46) of the valve and the device are in plane. However, in the RAO caudal views, both the valve and the device are not in plane. The sheath is withdrawn, exposing the valve level with the base of the pigtail. Further withdrawal, flaring of the valve with its base 3 mm below the annular plane, is then followed by deployment to 80% (double arrow) under rapid ventricular pacing, and then subsequent release.

Figure 3. In the three-cusp annular plane view the valve is not in plane. However, in the RAO caudal views, both the valve and the device are in plane. The sheath is withdrawn, exposing the valve level with the base of the pigtail. Further withdrawal, flaring of the valve with its base 3 mm below the annular plane, is then followed by deployment to 80% (double arrow) under rapid ventricular pacing, and then subsequent release.

This minimises interaction with the conduction system and helps sit the frame in the optimum position. If the LVOT size is smaller than the annulus, some forward pressure can be applied to fix the valve in place.

For experienced implanters used to implanting at 0 to 1 mm in the caudal or LAO off annular views, it is important to be aware that the valve will look lower in the RAO caudal view and that 1 to 2 mm is the minimum depth in this view. Additional observations include the annular plane being more vertical in the COV, and that, following expansion, the valve may look more constrained as this view approximates more closely to the short diameter of the LVOT.

SUMMARY

LAO and caudal angulation from the three-cusp view leads to the valve looking higher in a similar way to the RCC. Failure to recognize this effect can contribute to a deep implantation. Using the cusp overlap technique (COT) the true depth of the device beneath the annular plane is seen by aligning both the annulus and the prosthesis in the same view. Deployment from 0% to 80% can be performed without moving from the COV, and a target 3-mm placement below the annular plane usually equates to 1 mm below a pigtail placed at the base of the NCC in this view. It is advised to consider recapture if the device is < 1 or > 5 mm below the NCC in this view. Following this, it is important to check in the LAO cranial view with the device aligned before final release. This technique simplifies deployment, has been associated with a reduction of pacemaker rates, and is now recommended by Medtronic.

REFERENCE

1. Piazza N. Obtaining the correct depth of implant using the FluoroCT Double S curve. Presented at PCR London Valves 2015.

EXPERIENCE WITH CUSP OVERLAP TECHNIQUE IN THE UNITED KINGDOM

National data from the United Kingdom show significantly higher pacemaker rates (16%-18%) for the Evolut valve compared to those for the balloon-expandable Sapien valve (6%-8%).4 Currently, approximately one-third (16 of 46 centers) across the United Kingdom are using the cusp overlap technique, with most centers having started within the last 6 to 12 months and not all operators in these centers adopting the technique. Anecdotally we believe that the current adoption of the cusp overlap technique is low in the United Kingdom, but this is very likely to change in light of the recent (and ongoing) data and increased awareness of the technique.

ADDITIONAL RECOMMENDATIONS

Those new to the Evolut valve can follow the simplified scheme described previously, which allows rapid deployment with accurate results and is especially useful when hemodynamics are compromised during placement. It is recommended to start flaring the valve above the annulus and, once partially flared, advance to the desired position.

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Cusp Overlap Technique in TAVR

Transcatheter aortic valve replacement (TAVR) is a safe and effective alternative to surgical aortic valve replacement for the treatment of symptomatic severe aortic valve stenosis across all surgical risk categories. In 2007, when TAVR was first commercialized in Europe, such a statement would have not seemed possible for a nascent technology that was plagued by high rates of three important complications: postprocedural paravalvular leak, vascular complications, and new permanent pacemaker implantation (PPI). Progressive iterations of transcatheter heart valve (THV) design, preprocedural planning, and implantation technique have seen these complications become less frequent. Higher rates of new PPI have been the most challenging issues to address due to the anchoring mechanism of most THV technology (radial force) and the proximity of the implantation site to the cardiac conduction system. Current rates of new PPI range from 2% to 36% depending on the THV design and the patient population studied. Although the clinical impact of new PPI after TAVR has been somewhat controversial, meta-analyses have suggested an increased risk of all-cause mortality at 1 year in patients receiving a new permanent pacemaker. Certainly, the requirement for PPI is associated with longer hospital stay and increased costs.

The cusp overlap implantation technique has the potential to lower the risk of interaction with the conduction system by providing a more accurate assessment of THV depth. In this article, we review the rationale and practicalities of using this technique.

**THE IMPORTANCE OF IMPLANTATION DEPTH**

The proximity of the aortic valve and the cardiac conduction system explains the occurrence of new conduction disturbances with TAVR (Figure 1). The conduction system continues from the atrioventricular node toward the bundle of His and then splits into the left and right bundle branches. Located caudal to the commissure between the right (RCC) and noncoronary cusps (NCC), the bundle of His emerges at the surface of the interventricular membranous septum (MS), with the left bundle branch emerging and traversing the superficial crest of the interventricular septum within the interleaflet triangle separating the NCC and RCC. Kawashima et al described three variants of bundle of His anatomy: (1) the bundle courses within the right half of the MS in 50% of cases, (2) within the left half of the MS in 30%, and (3) coursing on to the MS just under the endocardium in 20%. The latter two anatomic variances would increase the risk of new conduction disturbances during TAVR.

Figure 1. The aortic valve and conduction system. AA, ascending aorta; BH, bundle of His; LBB, left bundle branch; LCC, left coronary cusp; LV, left ventricle; MS, interventricular membranous septum; NCC, noncoronary cusp; RA, right atrium; RBB, right bundle branch; RCC, right coronary cusp; RV, right ventricle.
The depth at which a THV is implanted in the left ventricular outflow tract (LVOT) has been consistently associated with the requirement for new PPI for both balloon- and self-expandable THVs. This is axiomatic because the deeper the THV is implanted the greater the risk of contact between the THV and the conduction tissue. Such interaction induces either direct or indirect (localized edema, hematoma, etc.) injury to the conduction tissue. A shallower THV implantation in the LVOT is therefore among the simplest ways to reduce new PPI rates. It is, however, important to implant the THV at a sufficient depth to avoid pop-up of the valve into the aorta and to ensure anchoring and sealing. Each valve has specific guidance regarding implantation depth; for example, the recommended Evolut TAV (Medtronic) implantation depth is 3 mm depth below the aortic annulus. Because a few millimeters in implantation depth can make a big difference for PPI rates, accurate imaging of the aortic root during valve implantation is crucial to achieving the correct implantation depth and a low PPI rate. Recently, Jilaihawi et al described the Minimizing Depth According to the membranous Septum (MIDAS) approach for the deployment of self-expandable THVs, aiming for an implantation depth of less than the MS length, which in their experience reduced the incidence of new conduction disturbances and requirement of new PPI.

Device implantation is optimally performed in an angiographic projection that is perpendicular to the virtual plane of the aortic annulus and has parallax removed from the delivery system. In other words, it is recommended to implant in an angiographic view where there is no foreshortening of either the patient’s anatomy or the delivery system. Traditionally, with self-expandable devices that have a marker band at the distal tip of the delivery capsule, it was uncommon to have both the anatomy and device in plane together, and hence, there were two options: (1) implant in an angiographic view where the anatomy was in the correct imaging plane and accept that the device was not perfectly aligned, or (2) implant in an angiographic view where the device was in-plane and accept that the anatomy was not perfectly aligned. Neither of these implantation techniques is ideal because the presence of parallax in either the anatomy or the device renders the relationship between them (implant depth) unclear.

To address this problem, Piazza and Thériault-Lauzier developed the double S-curve implantation technique using bespoke multislice CT (MSCT) software (FlurooCT). Using this software program, the operator could construct the S-curve of the annular plane in the usual way and then...
To construct the S-curve of the delivery catheter once it was sitting in the aortic root of the patient during the TAVR procedure. The software generates the delivery catheter S-curve once a left anterior oblique (LAO) and a right anterior oblique (RAO) projection (> 20º separation) with the delivery catheter in-plane are input into the system (Figure 2). The junction of the aortic annulus S-curve and the delivery catheter S-curve gives the angiographic projection where both the anatomy and delivery catheter are simultaneously in-plane. Thus, in this angiographic view, the distance between the base of the NCC (pigtail catheter) and the bottom of the THV (the implant depth) can be trusted to be accurate because there is no foreshortening of either structure. Importantly, in 90% of cases, the junction of these two S-curves (hence the title of double S-curve technique) was in an RAO-caudal projection, with the remaining cases being either an anteroposterior-caudal or a shallow LAO-caudal projection.\cite{15,16}

Further understanding of the fluoroscopic anatomy of the heart, described as chamber anatomy, reveals why the RAO-caudal implantation view removes parallax from both the anatomy and delivery catheter: in this projection, the heart is imaged in a three-chamber view (echocardiographic nomenclature) with the LVOT elongated (no foreshortening). On the other hand, in an LAO-cranial view, the heart is imaged in a four-chamber view with the LVOT foreshortened (Figure 2). Thus, if a catheter is placed in the LVOT, it is foreshortened in the LAO-cranial projection but not in the RAO-caudal projection. If the LAO-cranial view is used for THV implantation, the delivery catheter appears to be closer to the anatomy (represented by the NCC pigtail) than it actually is, and therefore, the depth of implantation appears to be less than it actually is. This does not occur if the RAO-caudal projection is used for THV implantation.\cite{17}

Although the double-S technique was used successfully in several centers, the requirement for dedicated MSCT software and the time required to generate the S-curve of the delivery catheter in the LVOT during TAVR meant that widespread adoption of the double-S implantation technique did not occur.

**Cusp Overlap Technique**

Because the double-S curve implantation view occurs in the RAO-caudal projection in 90% of cases, a “modified double-S” can be achieved by simply selecting an RAO-caudal implantation view from the annular S-curve and then adjusting this angle slightly during the procedure (if required) to ensure that the marker band at the base of the delivery catheter is in-plane.

More recently, Gada and colleagues recognized that in the RAO-caudal implant view, the RCC and the left coronary cusp (LCC) are superimposed on MSCT, leaving the NCC isolated. This two-cusp view, or cusp overlap view, is distinct from the traditional three-cusp view that is found usually in an LAO-cranial projection (Figure 3). This important observation affords TAVR operators the ability...
CUSP OVERLAP TECHNIQUE

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CUSP OVERLAP TECHNIQUE IN DAILY PRACTICE

While the transition from a traditional three-cusp view to the cusp overlap view for THV implantation is relatively straightforward, it can require several cases to become familiar with the technique. During this transition, we would suggest that operators start with patients with straightforward anatomy and good renal function so that additional aortography can be performed during implantation if required. In our daily practice with self-expanding THV, we will identify the cusp overlap view and an LAO-cranial view before starting the case. We then place the delivery system across the stenotic aortic valve. At this point, we perform our first aortography to assess the selected implantation view and initial device depth. A careful deployment of the THV, which starts at mid pigtail, is performed with occasional 3 to 5 mL contrast injections until annular contact on the left side is achieved. We then proceed to the point of no recapture, 80% of THV deployment, and assess implantation depth in the cusp overlap view before moving the C-arm to the predefined LAO-cranial view to assess depth on the LCC and the amount of tension in the delivery system, before performing final release.

CONCLUSION

The cusp overlap implantation technique has the potential to lower the risk of interaction with the conduction system. In an RAO-caudal view, identified simply using the cusp overlap technique, the relationship between the native anatomy and delivery catheter can be accurately determined and thus the true implant depth assessed. Large, prospective studies are being performed to confirm the risks and benefits of this new implant strategy.


...
(Continued from page 7) overlap technique has been associated with reproducibly low PPI rates and improved clinical outcomes through what we believe is a rational, evidence-based, and intuitive approach that is supported by sound principles in anatomy and pathophysiology.


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