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Aortic valve replacement with sutureless and rapid deployment aortic valve prostheses

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Abstract

Aortic valve stenosis is the most common valve disease in the western world. Over the past few years the number of aortic valve replacement (AVR) interventions has increased with outcomes that have been improved despite increasing age of patients and increasing burden of comorbidities. However, despite such excellent results and its well-established position, conventional AVR has undergone great development over the previous two decades. Such progress, by way of less invasive incisions and use of new technologies, including transcatheter aortic valve implantation and sutureless valve prostheses, is intended to reduce the traumatic impact of the surgical procedure, thus fulfilling lower risk patients’ expectations on the one hand, and extending the operability toward increasingly high-risk patients on the other. Sutureless and rapid deployment aortic valves are biological, pericardial prostheses that anchor within the aortic annulus with no more than three sutures. The sutureless prostheses, by avoiding the passage and the tying of the sutures, significantly reduce operative times and may improve outcomes. However, there is still a paucity of robust, evidence-based data on the role and performance of sutureless AVR. Therefore, strongest long-term data, randomized studies and registry data are required to adequately assess the durability and long-term outcomes of sutureless aortic valve replacement.

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1 Introduction

With an ever increasing disease prevalence, aortic valve stenosis is the most common valve disease in the developed world.^[1,2] Aortic valve replacement (AVR) via a median sternotomy approach, has been largely shown to be safe and long-term efficacious, and thus currently represents the “gold-standard” approach for aortic stenosis treatment.^[3] Over the past two decades the number of AVR interventions has dramatically increased with outcomes that have improved despite the increasing age of patients that carry a growing burden of comorbidities.^[4,5] Nevertheless, data from Euro Heart Survey have suggested that 30% of patients with severe aortic stenosis are not referred to surgery because deemed inoperable due to presence of multiple comorbidities.^[6] This observation has recently triggered the development of minimally

invasive interventions such as percutaneous transcatheter aortic valve implantation (TAVI). Compared to optimal medical therapy, TAVI has shown to provide a 26.8% absolute reduction in mortality at 3-year follow-up in inoperable patients,^[7,8] and has demonstrated great potential for high-risk surgical candidates.^[9] While the uptake and growth for TAVI has been enthusiastic and widespread in Europe and North America, concerns still exist surrounding paravalvular leakage, vascular complications, stroke, optimal access sites, long-term valve durability and economic sustainability meaning that the optimal treatment of high-risk operable patients remains controversial and requires further long-term follow-up and critical assessment.^[9–12]

Over the last years, minimally invasive techniques are progressively challenging traditional approaches for aortic valve surgery. Minimally invasive incisions, by allowing reduced surgical dissection, may lead to lower blood loss, wound complications, postoperative pains, improved postoperative respiratory recovery, earlier mobilization and functional recovery. In this setting, recent technological developments have led to an alternative minimally invasive surgical option which avoids the placement and tying of

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sutures, known as “sutureless” or rapid deployment aortic valves. While the sutureless concept of aortic valve implantation came up in the early sixties,^[13] New sutureless valve prostheses have been redeveloped in the last few years based on modern experience with TAVI. Sutureless or rapid deployment aortic valve replacement (SU-AVR), by avoiding placement and tying of sutures after annular decalcification, has shown to minimize cross-clamp and cardiopulmonary bypass (CPB) durations.^[14,15] Shortened operational durations of SU-AVR may help reduce post-operative mortality and morbidity and improve cost-effectiveness, particularly in high risk patients as well as in those undergoing complex or concomitant procedures.^[16]

2 Sutureless and rapid deployment aortic valves

Sutureless and rapid deployment aortic valves are biological, pericardial prostheses that anchor within the aortic annulus with no more than three sutures. There are two types of sutureless aortic prostheses which are currently available on the market, including Perceval S (Sorin, Saluggia, Italy) and Intuity Elite (Edwards Lifesciences, Irvine, USA) sutureless valves.

The Perceval sutureless valve was CE approved in 2011. It comprises a biological component of bovine pericardium fixed in a metal cage made of a super-elastic alloy. The cage design is characterized by two ring segments, on the proximal and distal end, and 9 vertical struts, with the dual task of supporting the valve and holding it in place without any permanent suture. Its elastic properties allow the stent to adapt to the anatomy of the aorta and to follow its movements, relieving the stress on the leaflets. The valve is collapsed with an atraumatic device compression, assuring that the valve leaflets are not affected. Perceval is lowered until the correct position and then self-expands back to its original diameter (Figure 1A).

The design of the Edwards Intuity Elite valve, CE ap-

proved in 2012, is based on the Perimount valve family. A balloon expandable stainless steel cloth-covered frame is incorporated into the inflow aspect of the valve. The valve is implanted with the aid of a delivery system, which incorporates a balloon catheter used to expand the frame within the left ventricular outflow tract. The expandable frame works in conjunction with the sewing ring to position and stabilize the valve at implant. The system reduces to three the number of sutures required to secure the valve, while establishing the seal between the aortic annulus and the frame (Figure 1B).

3 SU-AVR: surgical technique

SU-AVR can be performed using standard full sternotomy or minimally invasive approaches. Minimally invasive incisions involve the upper mini-sternotomy, extended to the 2nd, 3rd or 4th intercostal space, or the right anterior mini-thoracotomy, usually at the 2nd intercostal space. Similarity to the traditional AVR, SU-AVR does not avoid CPB and aortic cross-clamping (Figure 2). After cardioplegic arrest, the diseased valve is excised and the annulus is accurately decalcified to allow for the sutureless prosthesis to be deployed and positioned. The nature of sutureless valves is that these do not require extensive placement and tying of sutures. Therefore, subsequent to diseased valve excision, the sutureless and rapid deployment valve prostheses are sized and deployed using delivery systems that make the procedure extremely rapid (Figure 3). This may translate into reduced operation duration, especially when a minimally invasive access is used to approach the aortic valve, the latter traditionally associated with longer operative times due to increased surgical complexity in narrow working spaces and learning curve.^[17-20]

The sutureless surgical approach provides direct visualization of the implantation and target orifice location, in contrast to TAVI where visualization is achieved indirectly via the use of fluoroscopy. Both in SU-AVR and TAVI, an

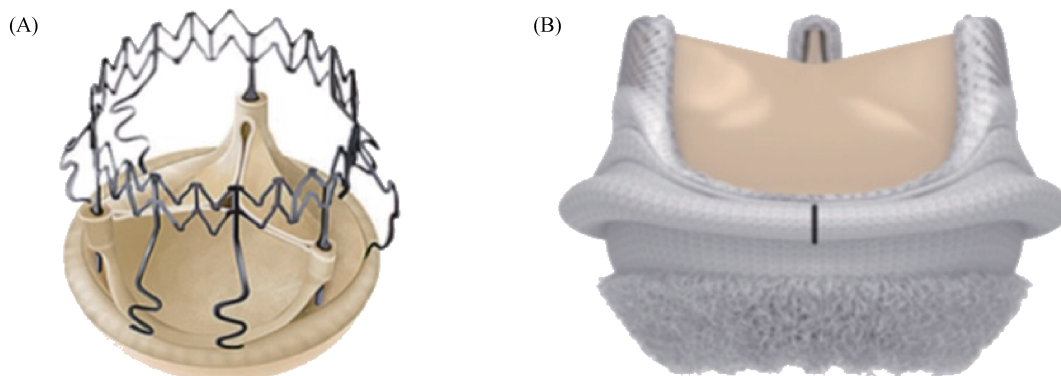


Figure 1. Sutureless and rapid deployment valves. (A): Perceval sutureless aortic valve (Sorin, Saluggia, Italy); (B): Edwards Intuity Elite rapid deployment aortic valve (Edwards Lifesciences, Irvine, USA)

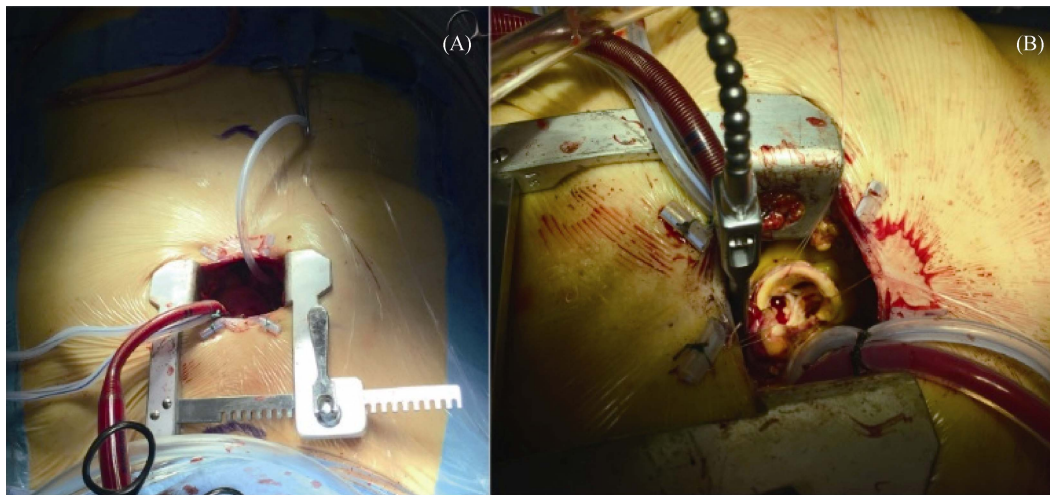


Figure 2. SU-AVR through ministernotomy. (A): minimally invasive SU-AVR through an upper J ministernotomy extended to the 3rd intercostal space; (B): aortic valve exposure. SU-AVR: sutureless aortic valve replacement.

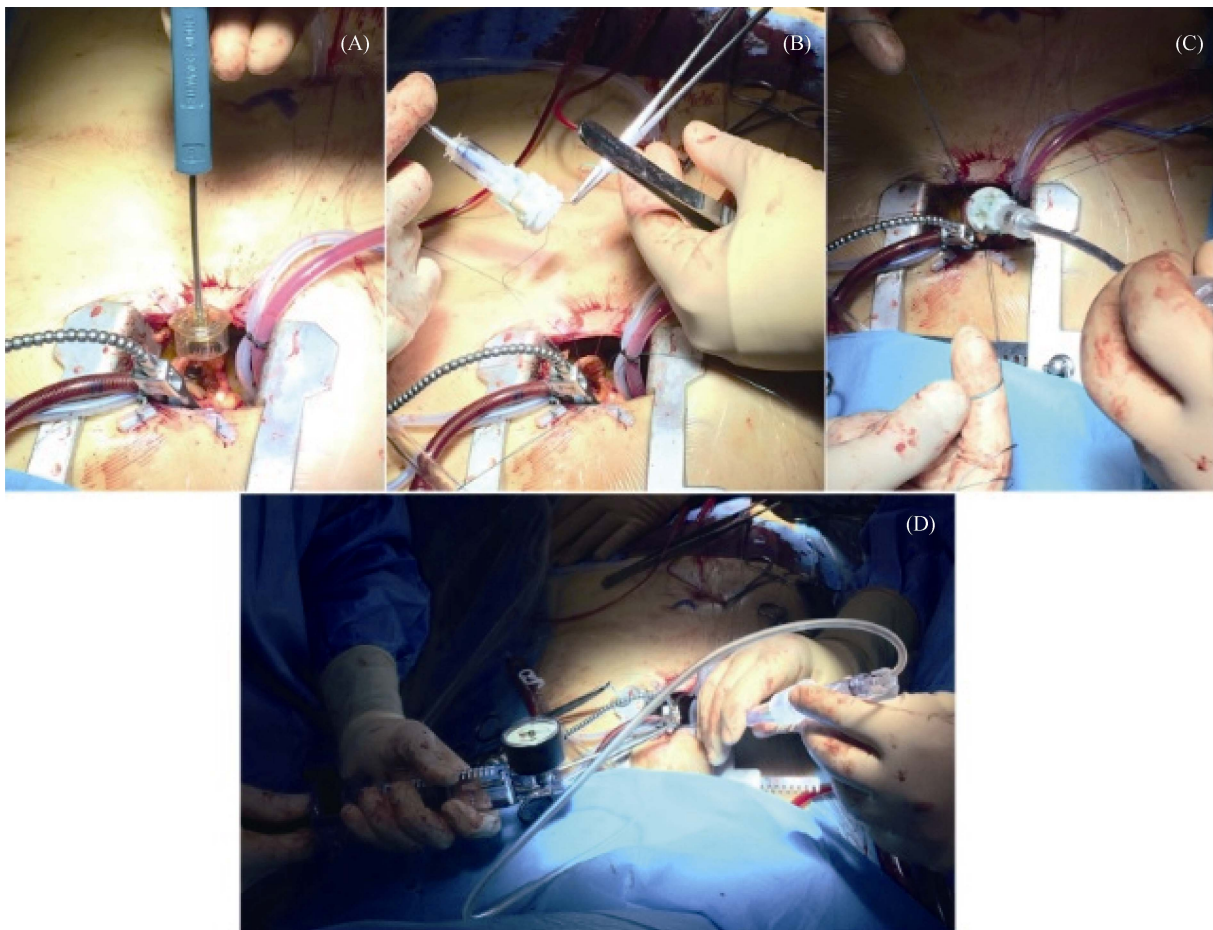


Figure 3. Minimally invasive SU-AVR using Edwards Intuity elite valve system. (A): sizing of the aortic valve annulus; (B) & (C): guiding sutures placement and valve seating; (D): valve deployment. SU-AVR: sutureless aortic valve replacement.

accurate valve sizing is pivotal to avoid catastrophic complications such as paravalvular leaks, valve migration, and root dehiscence. During SU-AVR procedure, this is per-

formed under direct vision using standard surgical valve sizers, which seems to be more accurate than CT-derived measurements used for TAVI. Moreover TAVI protocols do

Table 1. Differences between SU-AVR and TAVI procedures.

	SU-AVR	TAVI	Clinical implications
Surgical incisions	Yes	No	Increase surgical trauma for SU-AVR
CPB and cardioplegic arrest	Yes	No	Increase surgical trauma for SU-AVR
Valve excision	Yes	No	Less paravalvular leak and embolic strokes
Sizing	Surgical	CT-based	More accurate with SU-AVR
Valve deployment	Under direct vision with a still heart	Under fluoroscopy and rapid pacing	More accurate with SU-AVR

CPB: cardio-pulmonary bypass; SU-AVR: sutureless aortic valve replacement; TAVI: trans-catheter aortic valve implantation.

not involve excision of the diseased calcified aortic valve, in contrast to SU-AVR. Calcium remove in sutureless aortic valve surgery may be effective in reducing paravalvular leaks and brain embolic showers and injuries in comparison to TAVI; however, this hypothesis remains to be demonstrated in clinical studies. Whilst sutureless valves are in principle based on a similar technology to TAVI prosthesis, the former do not require crimping of the pericardium, which may translate in superior long-term valve durability. Furthermore the valve deployment appears more accurate during SU-AVR than TAVI. The former is performed under direct vision with a still heart in contrast to TAVI where the deployment is performed under fluoroscopy and rapid pacing (Table 1).

4 SU-AVR: when and why?

In cardiac surgery, prolonged CPB and cross-clamp durations are strong independent risk factors for post-operative mortality and morbidity.^[21,22] Their detrimental effect becomes further amplified when operations are performed in patients burdened by advanced age and other serious comorbidities. In a recent retrospective analysis of 979 patients with aortic valve stenosis, Ranucci, *et al.*,^[16] showed that aortic cross-clamp time was a significant independent predictor of cardiovascular morbidity. The cross-clamp time reduction decreased the risk of operative mortality, acute kidney injury, stroke and low postoperative cardiac output. Therefore, any technique that shortens cross-clamp or CPB time will have the potential to decrease the risk of complications and reduce long-term mortality. The sutureless prostheses, by avoiding the passage and the tying of the sutures, significantly reduce operative times and may improve outcomes.^[23] In a recent meta-analysis, Phan, *et al.*,^[14] reported a pooled cross-clamp and CPB duration for SU-AVR of 56.7 and 33 min, respectively, showing that sutureless valves, compared to sutured valves, halves CPB and cross clamping times with interesting positive prognostic implications for elderly and high risk patients. Therefore, the indication for SU-AVR is appealing in higher risk patients and may become standard of care once long-term results have demonstrated efficacy and durability. Additionally, the use

of SU-AVR may be particularly reasonable in higher risk patients who need to undergo AVR with concomitant cardiac surgery or complex operations with multiple interventions to minimize operational durations and improve outcomes.

SU-AVR may facilitate minimally invasive approach. Minimally invasive aortic valve replacement (MI-AVR) has been introduced in the nineties^[24] and has slowly gained acceptance as a less traumatic alternative compared to median sternotomy.^[25,26] However, due to the technical challenges involved and the lack of data showing a substantial survival benefit and a reduced occurrence of major post-operative complications from MI-AVR over conventional management,^[25,27,28] this approach has not been universally adopted. Opponents of minimally invasive AVR claim that potential advantages (reduced surgical chest trauma and improved cosmesis)^[26] are counterbalanced by longer cross-clamp and CPB duration, which are associated with poorer outcomes. In a recent meta-analysis, Phan, *et al.*,^[25] showed that, despite longer operative times, MI-AVR is associated with reduced transfusion incidence, postoperative renal failure, intensive care stay, and hospitalization. In terms of mortality MI-AVR was not inferior to conventional AVR, but there was no data suggesting it was superior. In MI-AVR, the placement and tying of sutures may be challenging and time consuming compared to standard approach. In this setting, sutureless and rapid deployment aortic valves, by avoiding sutures and minimizing cross-clamp and CPB times may simplify the MI-AVR procedure and improve outcomes, particularly in critically ill patients at the highest operative risk. Recently, a prospective, multicentric, randomized trial comparing outcomes in patients undergoing minimally invasive SU-AVR using Edwards Intuity Elite valve, with those undergoing conventional full sternotomy AVR revealed a significant cross-clamp time reduction in patients undergoing SU-AVR, despite the minimally invasive approach.^[29]

Consistent with the data reported by Others,^[30-32] Borger and colleagues, also demonstrated excellent hemodynamic performance of the SU-AVR prostheses compared to conventional AVR.^[29] At three months, the mean gradient was significantly lower for the SU-AVR prosthesis than for the

conventional valves (8.5 vs. 10.3 mmHg; $P = 0.04$). The authors speculated that the balloon-deployable frame, which is expanded in the inflow aspect of the left ventricular outflow tract, combined with the lack of annular suture material, allows for maximum hemodynamic performance of this prosthesis. Moreover, no severe patient-prosthesis mismatch (PPM) was observed for the SU-AVR group compared to six patients (15%) in the conventional AVR group ($P = 0.01$). Patient-prosthesis mismatch, as is known, has been associated with worse haemodynamic function, less regression of left ventricular hypertrophy, more cardiac events, and an increase in all-cause and cardiac-related mortality over long-term follow-up.^[33,34] Patients who are particularly at risk of PPM include those with smaller annulus.^[35,36] As such, aortic root enlargement and use of stentless prostheses may assist in reducing PPM complications; however, these interventions add technical complexity, and certainly extend operative duration significantly, thus translating into increased surgical risk.

Therefore, as stated in a recent expert consensus document with regard to the use of sutureless, rapid deployment valves and stented bioprosthesis in AVR,^[37] SU-AVR should be considered for isolated AVR in patients with comorbidities, old age, small aortic annulus, delicate aortic wall conditions such as calcified root, as well as for concomitant procedures to reduce cross-clamp time. There is a contraindication for bicuspid valves only for type 0 (according to Sieveres, *et al.*^[38]) and for annular abscess or destruction due to infective endocarditis.^[38]

5 Results

Current evidence on SU-AVR is limited to observational studies with short-term follow-up. In the largest institutional study comparing 164 mini-thoracotomy versus 117 mini-sternotomy SU-AVR patients,^[39] it was found that in-hospital mortality (0.7%), strokes (1.8%) and overall survival rate (90%) over one-year follow-up was acceptable and safe. Cardiopulmonary bypass (81 min) and cross-clamp (48 min) durations were low and excellent mean postoperative gradients were achieved. In a large multicentric study on sutureless valves,^[40] analysis of 314 patients showed acceptable early survival in high-risk patients (1-year survival: 90.5%) and low paravalvular leak rates (0.6%).

Despite the above retrospective analyses, there is still a paucity of prospective data, propensity-score matched analyses and randomized controlled trials on SU-AVR to adequately determine long-term survival outcomes and to compare between different minimally invasive interventions.

Haverich, *et al.*^[41] reported on 287 patients with aortic stenosis, enrolled in a prospective multicentric study, underwent rapid deployment AVR using Edwards Intuity Elite Valve. Early mortality was 1.7%. The main complications included stroke (2.8%) and major paravalvular leak (0.7%). At three years the prevalence of severe patient-prosthesis mismatch was 3%.

Recently, Shrestha, *et al.*^[42] reported the combined results of three multicentre, prospective, non-randomized clinical trials designed to evaluate the sutureless Perceval aortic valve prosthesis in 731 elderly patients. Early mortality was 3.4% and postoperative stroke occurred in 1.6% of patients. Overall survival was 92.1% and 74.7% at one and five years respectively. No structural valve degeneration was found during follow up.

In a propensity-matched study by D'Onofrio, *et al.*,^[43] 38 matched pairs of SU-AVR versus TAVI showed that both approaches were equally efficacious, but SU-AVR was associated with lower incidence of paravalvular leak and similar transprosthetic gradients. In a similar study by Santarpino, *et al.*^[44] SU-AVR demonstrated a significantly higher survival rate than the TAVI group, lower paravalvular leak incidence, shorter procedural durations and non-significant increase in permanent pacemaker implantations. Gilmanov, *et al.*^[45] published a propensity-matched analysis of 133 pairs of patients undergoing MI-AVR, using conventional and sutureless prostheses. CPB and cross-clamp time was significantly shorter in the sutureless group, whilst in-hospital mortality, perioperative strokes and pacemaker implantations were comparable. At median follow-up of 21 months, there was similar actual survival rate for all patients, but survival was 2-fold higher in octogenarian patients with sutureless compared to sutured valves (100% vs. 50%, $P = 0.02$). This is likely due to this group susceptible to high mortality risk and morbidities under the duress of conventional AVR compared to more rapid minimally invasive sutureless surgery. In another propensity-matched analysis of 164 pairs receiving sutureless and conventional sutured valves, Pollari, *et al.*^[23] demonstrated reduced procedural time in the SU-AVR cohort, that significantly correlated with shorter hospitalization, reduced postoperative atrial fibrillation, respiratory complications and hospital costs. The only randomized multicentric trial published to date on minimally invasive SU-AVR vs. conventional AVR, showed that SU-AVR was associated with significantly lower cross-clamp durations (41.3 vs. 54 min), but similar CPB time (68.8 vs. 74.4 min). There was no difference in early clinical outcomes, but SU-AVR patients had superior mean transvalvular gradients.^[29]

In a recent meta-analysis pooled results from 1037 pa-

tients undergoing SU-AVR were analyzed.^[14] Cross-clamp and CPB duration for isolated SU-AVR was 56.7 and 46.5 min, respectively. Several experienced valvular centers have reported cross-clamp and cardiopulmonary bypass durations as low as 22 and 46 min, respectively.^[15] These operative durations are much shorter compared to the reported durations of isolated conventional AVR, and suggest potential benefits from sutureless technology in different settings: higher risk or elderly patients, complex or time-consuming combined operations, and minimally invasive surgery. Pooled 30-day and 1-year mortality rates were 2.1% and 4.9%, respectively, while the incidences of strokes (1.5%), valve degenerations (0.4%) and paravalvular leaks (3.0%) were satisfactory. On the other hand, there have also been reports of post-operative conduction disorders following implantation of the Perceval S sutureless valve. Shrestha, et al.^[42] reported a pacemaker implantation rate of 6% (44/731). In an observation study of 31 patients who underwent Perceval S implantation, four patients (13.3%) required permanent pacemaker implantation due to total atrioventricular block.^[46] Furthermore, there are also concerns around “stent fatigue” in sutureless valves, which may lead to longer-term paravalvular leak complications.^[47] However, the relative paucity of clinical data on the long-term safety, efficacy and hemodynamic profiles of SU-AVR requires further critical assessment.

6 Conclusions

Current evidence suggests SU-AVR may be a safe and effective alternative to conventional AVR allowing for shortened CPB and cross-clamp times. Sutureless and rapid deployment prostheses seem to provide excellent haemodynamic results together with reduced surgical trauma by facilitating minimally invasive approach. However there is still a paucity of robust, evidence-based data on the role and performance of sutureless AVR on the long term. Therefore, strongest long-term data, randomized studies and registry data are required to adequately assess the durability and long-term outcomes of SU-AVR.

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