Transcatheter intervention for a failed surgical mitral bioprosthesis was first described over a decade ago and filled an unmet need for inoperable or high-risk, symptomatic patients requiring reintervention. Initially, these procedures were undertaken via a transapical approach, which demonstrated acceptable and reproducible results. The first successful transseptal mitral valve-in-valve (VIV) procedure was reported in 2011 using a balloon expandable, 26-mm Sapien XT valve (Edwards Lifesciences, Irvine, CA). However, in this initial description, despite dilatation of the interatrial septum (IAS) with a 10-mm-diameter balloon, the Sapien XT on the Novaflex system (Edwards Lifesciences) failed to cross the septum, requiring the transcatheter heart valve (THV) to be removed from the body and further septal dilatation with a larger balloon before a successful reattempt. Although earlier systematic reviews did not identify a procedural success or mortality advantage of transseptal over transapical procedures, more recent data from the Society of Thoracic Surgeons — American College of Cardiology, Transcatheter Valve Therapy (STS-ACC TVT) Registry in 1529 patients undergoing transseptal or transapical procedures have shown a lower 1-year mortality rate with transseptal access, leading to a recommendation for transseptal access in most patients.

The technique for transseptal delivery of the Sapien 3 valve (Edwards Lifesciences) for mitral VIV and valve-in-ring (VIR)
**Results:** From January 2018 to March 2022, a total of 12 consecutive patients who underwent transseptal mitral valve-in-valve (9) or valve-in-ring (3) procedures were identified. Three patients (25%) required repeat septostomy on the buddy wire after initial THV crossing failure. Crossing of the IAS and successful deployment in the mitral valve with the THV was achieved in all cases, without removal from the body or need for an additional wire or septal puncture. No access-site bleeding, stroke, tamponade, ventricular arrhythmia, intraprocedural death, or 30-day vascular complication occurred.

**Conclusions:** The planned buddy-wire technique was successful in all cases and facilitated successful crossing of the IAS and deployment of the THV in the mitral position without removal from the body, additional wires, or septal punctures, with no adverse events.

The purpose of the current study was to examine the safety, efficacy, feasibility, and utility of a planned, modified buddy-wire technique to facilitate crossing of the interatrial septum and a failing mitral valve bioprosthesis with the Sapien 3 valve during transseptal mitral VIV or VIR procedures.

**Materials and Methods**

**Study population and variables**

Between January 2018 and March 2022, we identified 12 consecutive patients undergoing transcatheter mitral VIV or VIR procedures from our institutional database. This number represents all patients undergoing transcatheter mitral VIV and VIR procedures for surgical mitral valve and/or ring failure at our institution during this period. In all cases, a planned buddy-wire technique was attempted. All patients were discussed by our heart team and were deemed to be at high risk for repeat surgical management but suitable candidates for transcatheter intervention with implantation of the balloon-expandable Edwards Sapien 3 THV. All patients provided written informed consent for this procedure. As this was a retrospective study using a standard technique at our institution, ethical approval was not required by our institutional review board, and no special consent was required.

The following were recorded: demographics, including age and gender; surgical risk as expressed by Euroscore II; initial surgical device (bioprosthetic valve or annuloplasty ring) and year of implantation; pathology of device failure; size of the Sapien 3 valve selected for implantation; diameter of septostomy balloon; need for repeat septostomy; need for pacing; and antithrombotics used at discharge.

**Endpoints**

The primary endpoint was a composite of successful delivery of the buddy wire and deployment of the Sapien 3 valve within the mitral valve without THV removal from the body, additional interatrial septal puncture, or placement of a further buddy wire. Secondary outcomes included safety endpoints—access-site bleeding, tamponade, stroke, intra-procedural death, sustained ventricular dysrhythmia, and 30-day vascular complications (Mitral Valve Academic Research Consortium [MVARC] definitions).

**Statistical analysis**

Categorical data are presented as numbers and percentages. Continuous data are expressed as medians and interquartile ranges (IQRs). Statistical analysis was done using R, version 4.1.1 (R Foundation for Statistical Computing, Vienna, Austria).

**Technique**

Patients underwent a gated cardiac computed tomography scan for THV size selection and to assess the risk of left ventricular outflow tract (LVOT) obstruction. A predicted neo-LVOT area of < 1.7 cm² has been shown to carry a high sensitivity and specificity for post-procedural LVOT obstruction. All procedures were performed under general anesthesia with transesophageal echocardiography (TEE) and fluoroscopic guidance. A single access was made to the right femoral vein using ultrasound guidance and a micropuncture needle. One or two Perclose Proglide closure devices (Abbott Laboratories) were then placed in a "pre-close technique" to facilitate suture-mediated closure of the puncture site following removal of the large-bore access sheath. The mode of transseptal puncture changed during the study period. Initially, we used a mechanical transseptal needle (January 2018 to October 2021). However, since it became commercially available in Europe in late 2021, we now favour the...
VersaCross RF transseptal system (Boston Scientific, Marlborough, MA). The reasons for this preference are primarily safety, ease of use, less need for guidewires exchange, targeted and controlled transseptal puncture, and increased efficiency. All transseptal punctures were performed with TEE guidance. Following access to the left atrium, an 8.5-F small-curve steerable Agilis NxT sheath (Abbott, St Paul, MN) was placed in the left atrium. Through this, 2 extra-small-curve, 275-cm long, 0.035” Safari wires (Boston Scientific) were advanced to the LV apex through a 7-F multipurpose guiding catheter positioned in the LV (Figure 1, A and B; Video 1, view video online). One Safari wire is used for delivery of the THV (the “delivery wire”). The second Safari wire (the “buddy wire”) is used to facilitate advancement of the THV through the septum. Over the delivery wire (Fig. 2, A and B), an E-Sheath (Edwards Lifesciences) was then advanced and secured in place. A 14-Fr E-Sheath was selected for the 23-mm and the 26-mm S3 (Edwards Lifesciences) and a 16-Fr E-Sheath was selected for the 29-mm S3. Over the buddy wire, an 11-cm 7-Fr sheath was advanced and secured in place (Fig. 2C). A purse-string suture was placed around the 2 sheaths and pulled taught using a 3-way stopcock to reduce any ooze through the puncture site during the procedure, and it was left in place overnight to reduce the risk of access-site bleeding. Through the 7-Fr sheath and over the buddy wire, a 12- or 14-mm x 40-mm balloon was advanced and inflated across the IAS for septostomy (Fig. 3A). A 12-mm balloon was used for the 23-mm and the 26-mm THV, and a 14-mm balloon was used for the 29-mm THV. Generally, the balloon is kept inflated for 45-60 seconds and redilated, followed by flossing of the IAS with the balloon deflated, to confirm unobstructed passage. The Sapien 3 was crimped on the Commander delivery catheter (Edwards Lifesciences) in reverse configuration for retrograde transcatheter aortic valve replacement procedures. The crimped THV on the Commander delivery system was advanced into the inferior vena cava, where it was loaded on the deployment balloon in standard fashion under fluoroscopic guidance. The Commander catheter is then rotated 180 degrees to orient the flush port on the delivery catheter toward the operator. Flex is applied to the Commander catheter as the Sapien 3 is advanced through the interatrial septum with the buddy wire in place (Fig. 3B).
The THV is then positioned in the prosthetic mitral valve or ring. After confirmation of satisfactory THV positioning, the buddy wire is retracted from the LV into the right atrium to prevent it from being trapped on deployment of the THV in the mitral prosthesis. The THV is then deployed under fluoroscopic guidance (Fig. 3C), generally without pacing, but in 2 cases in which excessive movement of the THV occurred, burst pacing was undertaken via the Safari delivery wire to stabilize the THV at deployment. Following THV deployment (Fig. 3D), the result was assessed angiographically, as well as with TEE. The IAS was reviewed for shunt assessment, and generally closure was not performed if a small left-to-right shunt or bidirectional shunting was observed.

After a successful result was confirmed, the equipment and wires were withdrawn from the body via the multipurpose guide catheter, and the single femoral vein-access site was closed using Proglide sutures (Abbott Laboratories, Chicago, IL). The purse-string suture was tightened and left in place overnight. Elective patients were discharged the next day in the absence of complications.

### Results

Between January 2018 and March 2022, a total of 12 consecutive patients underwent transcatheter transseptal mitral VIV or VIR procedures. A planned buddy-wire technique was attempted in all cases. The mean patient age was 74.9 years, and 5 patients (42%) were male (Table 1). Nine cases were undertaken due to failing bioprosthetic mitral

| Table 1. Baseline characteristics |
|----------------------------------|
| Characteristic                  | Value                  |
| Age, y                          | 79.5 (77–82)           |
| Male gender                     | 5 (42)                 |
| Diabetes                        | 2 (17)                 |
| Hypertension                    | 4 (33)                 |
| Coronary artery disease         | 3 (25)                 |
| Atrial fibrillation             | 5 (42)                 |
| LV ejection fraction, %         | 58 (55–60)             |

Continuous variables are presented as median and 25th and 75th percentiles. Categorical variables are presented as number and percentage.

LV, left ventricular.
The primary composite endpoint was met in all cases. The buddy wire was successfully delivered in all cases. In all cases, the THV was successfully passed through the IAS with the buddy wire in place and successfully deployed in the failed mitral valve prosthesis. No patient required additional interatrial septal puncture, and no further buddy wires were required. No patient required removal of the first intended THV from the body (Table 3).

In 9 cases, the THV was successfully passed across the septum on the initial attempt after predilatation of the septum with an appropriately sized balloon (12- or 14-mm diameter).

In 3 cases (cases 1, 9, 10), an initial failure to cross the septum with the THV occurred, despite adequate predilatation of the septum and multiple crossing attempts (Video 2, view video online). In all 3 cases, repeat dilatation of the septum was undertaken on the buddy wire with a 14-mm diameter balloon. However, in 2 cases (cases 9 and 10), repeat septostomy alone did not result in successful crossing of the septum by the THV but a balloon-assisted passage was successful (buddy balloon) in both cases (Fig. 4, A-C; Video 3, view video online).

Regarding the secondary endpoints—no access-site bleeding, stroke, tamponade, intraprocedural death, sustained ventricular arrhythmia, or 30-day access-site complication occurred. Two deaths occurred at 30 days. Patient 8, an 85-year-old woman with severe pulmonary hypertension, developed fatal pneumonia. Patient 9, a 25-year-old woman, died following insertion of a left ventricular assist device for severe heart failure. Ten patients had the procedure electively and were discharged the following day. We did not identify any intraprocedural complications related to use of the buddy wire.

The average pressure gradient across the mitral valve, as assessed by TEE at the conclusion of the procedure, was 3.4 mm Hg. No evidence was seen of moderate or severe paravalvular leak in any case. In one case, a 25-year-old patient with very severe biventricular dysfunction, a decision was made to close the interatrial septum with a closure 25-mm Amplatzer device (Abbott Laboratories) following THV deployment, as the patient was to undergo implantation of a ventricular assist device.

**Discussion**

In this single-centre study, we demonstrate the safety, ease of use, and utility of a planned buddy-wire technique in 12 consecutive, transseptal mitral VIV and VIR procedures. This technique facilitates successful passage of the THV through the IAS while using a single venous femoral puncture and a single IAS puncture in a time-efficient, reproducible manner.

Several techniques have been described to overcome the problem of the initial difficulty in crossing the IAS with the Sapien 3 for transseptal procedures. One of these techniques involves placement of a 24/26-F, 65-cm Gore Dryseal sheath (W.L. Gore & Associates, Flagstaff, AZ) directly into the left atrium, through which a balloon-mounted Sapien 3 can be passed, overcoming any difficulty of IAS crossing with a "bare" Sapien 3. This technique has been described for treatment of pulmonary valves with the Sapien 3, as a means to minimize the risk of tricuspid valve injury.13 However, this

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**Table 2. Procedural characteristics**

| Patient | Age, y | Gender | Euroscore II, % | MV pathology | MV device size (mm); type; (implant year) | Transseptal puncture device | 1st balloon septostomy diameter, mm | Repeat septostomy | Pacing | Post MV PG, mm Hg | Antithrombotic at discharge |
|---------|--------|--------|----------------|--------------|----------------------------------------|-----------------------------|---------------------------------|----------------|--------|----------------|----------------------------|
| 1       | 81     | M      | 5.76           | S            | 31; Perimount valve (2007)             | MN                          | 14                              | Y              | Z      | 5.5            | Warfarin                   |
| 2       | 79     | M      | 7.72           | R            | 27; Perimount valve (2008)             | MN                          | 14                              | Y              | Z      | 6.28           | Warfarin                   |
| 3       | 83     | F      | 7.46           | S/R          | 26; Edwards Physio II ring (2018)     | MN                          | 12                              | Y              | Z      | 4.18           | Apixaban                   |
| 4       | 80     | M      | 15.46          | R            | 29; Edwards Physio II valve (2012)    | MN                          | 12                              | Y              | Z      | 5              | Warfarin                   |
| 5       | 78     | M      | 5.2            | R            | 15.46                                  | MN                          | 12                              | Y              | Z      | 5.9            | Warfarin                   |
| 6       | 85     | F      | 19.38          | S/R          | 26; Edwards Physio II valve (2010)    | MN                          | 12                              | Y              | Z      | 3.5            | Warfarin                   |
| 7       | 78     | M      | 19.38          | S/R          | 26; Edwards Physio II valve (2009)    | MN                          | 12                              | Y              | Z      | 3.5            | Warfarin                   |
| 8       | 85     | F      | 20.96          | S/R          | 26; Edwards Physio II valve (2011)    | MN                          | 12                              | Y              | Z      | 3.5            | Warfarin                   |
| 9       | 78     | M      | 15.46          | S/R          | 26; Edwards Physio II valve (2013)    | MN                          | 12                              | Y              | Z      | 3.5            | Rivaroxaban                 |
| 10      | 83     | M      | 10.09          | R            | 26; Hancock II valve (2013)           | VC                          | 12                              | Y              | Z      | 2              | Rivaroxaban                 |
| 11      | 73     | F      | 5.79           | R            | 29; LivaNova ring (2018)              | VC                          | 12                              | Y              | Z      | 2.8            | Warfarin                   |
| 12      | 78     | F      | 6.54           | R            | 27; Epic (2008)                        | VC                          | 12                              | Y              | Z      | 3.5            | Warfarin                   |

F, female; M, male; MN, mechanical needle; MV, mitral valve; N, no; PG, pressure gradient; R, regurgitation; S, stenosis; VC, VersaCross Radio Frequency system; Y, yes.
A buddy-wire technique to facilitate the crossing of the IAS with the Sapien S3 has been previously described. 14–16 However, in all prior cases, an Amplatz Super Stiff (Boston Scientific) was placed in the left atrium or pulmonary vein, rather than in the left ventricle. Furthermore, in 2 of these earlier reports, the buddy wire was placed in the left atrium as a bailout strategy only after failed initial crossing of the IAS with the THV, necessitating either recrossing of the original interatrial puncture or creation of a new transseptal puncture to place the buddy wire. 4,16

The technique described in this study has several advantages over previous buddy-wire techniques in which a stiff buddy wire was placed in the left atrium or pulmonary vein. First, the proposed technique is time-efficient and simple to perform, compared with previous bailout buddy-wire techniques. The described technique delivers a buddy wire to the LV at the same point in the procedure as the passage of the THV delivery wire and takes little additional time to perform. The previously described techniques add complexity, significantly lengthen the procedure, and potentially increase the risk of complications. Second, the proposed technique requires only one transseptal puncture, as opposed to recrossing the original transseptal puncture or undertaking a new puncture as described in earlier reports. Third, the current technique involves only a single femoral vein puncture, in contrast to earlier techniques, and therefore potentially reduces the risk of vascular complications. Fourth, the described technique places the buddy wire in the LV, rather than the left atrium or pulmonary vein, thereby minimizing the risk of injury from the buddy wire. Placement of a stiff buddy wire in the thin-walled left atrium or pulmonary vein likely carries a greater risk of wall/vessel injury and risk of pericardial tamponade. Fifth, difficulty is experienced occasionally in crossing a stenosed, degenerate mitral bioprosthetic valve with the Sapien 3 valve, due to non-coaxial alignment and interaction between the THV and valve struts when a single wire is placed in the LV. The buddy wire may assist in the passage of the THV through a degenerate mitral bioprosthetic valve itself, but it may also allow use of a “buddy balloon” to assist in the crossing of the mitral bioprosthetic valve in this situation. This maneuver cannot be undertaken with a buddy wire in the LA or pulmonary vein, and placement of a bailout buddy wire in the LV at this point would likely require an addition femoral venous access and septal puncture, adding to procedure time, complexity, and risk. Finally, the proposed technique eliminates the scenario of having to remove the THV from the body in the event of failure to cross the septum or the mitral bioprosthesis with the THV. Although a crimped Sapien 3 can be retrieved via the E sheath and more readily via a larger bore Dryseal sheath, reuse of the same THV is inadvisable, as the manufacturer’s 15-minute crimp time would likely be exceeded, or the valve may be damaged via its passage through the sheath.

This technique, apart from the additional cost incurred, appears to have few disadvantages. The maneuver adds little additional time to the standard procedure. No additional risk is incurred, as the same wire for delivery is placed in the same location. A potential concern with this technique is the increased risk of bleeding at the venous access site, due to placement of 2 sheaths through a single puncture. However, we observed no troublesome ooze through the single puncture and attribute this to placement of a controllable-tension

Table 3. Primary and secondary endpoint rates

| Endpoint                              | n (%) |
|---------------------------------------|-------|
| Primary (composite)                   |       |
| Buddy-wire delivery success           | 12 (100) |
| THV deployment success                | 12 (100) |
| Freedom from additional IAS puncture  | 12 (100) |
| Freedom from additional buddy wire    | 12 (100) |
| Secondary                             |       |
| Access-site bleeding                  | 0     |
| Tamponade                             | 0     |
| Stroke                                | 0     |
| Ventricular arrhythmia                | 0     |
| Intraprocedural mortality             | 0     |
| 30-day vascular complication          | 0     |

IAS, interatrial septum; THV, transcatheter heart valve.

![Image](https://via.placeholder.com/502x245)

**Figure 4.** (A) A 26-mm Sapien 3 transcatheter heart valve (THV; Edwards Lifesciences, Irvine, CA) failed to traverse the septum after septostomy with a 12-mm balloon, despite multiple maneuvers. Further dilatation was performed with a 12-mm balloon. A significant waist was noted on the balloon, indicating “recoil” of the elastic septum. (B) A further attempt to pass the THV failed, but a “buddy balloon” technique was successfully employed to pass the THV through the septum. (C) The Sapien 3 was successfully deployed in the Hancock II (Medtronic, Minneapolis, MN) after removal of the buddy wire.)
purse-string suture, which has been shown to be a safe and effective method for controlling bleeding at large-bore venous access sites.\textsuperscript{17} Pre-close with Proglide sutures is also an effective means of hemostasis for large-bore venous access with good safety.\textsuperscript{18} As evidenced in this report, difficulty crossing the septum with the Sapien 3 is largely unpredictable and occurred in 25\% of patients. None of the 3 patients who required redilatation of the IAS after an initial failed crossing had any septal abnormality that would have predicted the difficulty in crossing. None of the patients had prior surgery or intervention to the IAS, and computed tomography did not identify septal thickening. In this study, 3 patients required re-balooning of the IAS after a failed initial attempt. In how many of the other 9 cases the presence of a buddy wire alone circumvented difficulty crossing the septum by the THV is unclear. Although we did not experience difficulty crossing the degenerate mitral bioprosthesis with the THV in this study, we are aware that this difficulty can occur. The buddy wire may reduce this problem, in itself, and it allows use of a buddy-balloon technique to be readily employed, if required, without the need for additional femoral access or transseptal puncture.

In all likelihood, use of transcatheter mitral valve interventions with the Sapien 3 THV for failing annuloplasty rings and mitral valve bioprostheses will continue to grow. Transseptal access, as compared with transapical access, is associated with similar technical success and in-hospital mortality but a significantly shorter length of stay and lower 1-year mortality.\textsuperscript{7} Thus, transseptal access for these procedures probably will become the dominant access route.

**Limitations**

Our study has several limitations. Firstly, this is a retrospective study, and as such, it is subject to bias. Second, the population is small. Third, the absence of a comparative arm means that unequivocal ascertainment that a planned buddy-wire technique is more efficacious than the standard technique is not possible. However, the rate of failure to cross the septum, without additional maneuvers, has not been reported previously. Our data suggest that the standard technique may fail in the delivery of the THV in up to one quarter of attempts. The bailout options are time consuming and may introduce additional risk; hence, the proposed solution to this problem may be attractive.

**Conclusion**

The planned buddy-wire technique is a safe, efficacious, and time-efficient technique for transseptal mitral VIV and VIR procedures and may be considered for use as an alternative to placement of a single wire in the LV. The dual advantage of this technique is to overcome both the difficulty of IAS crossing with the Sapien 3 valve and of the passage of the Sapien 3 through a degenerate mitral bioprosthesis. The utility of a planned buddy wire, we believe, outweighs the disadvantages of the increased cost and the potentially increased risk of access-site bleeding.

**Funding Sources**

The authors have no funding sources to declare.

**Disclosures**

S.N.D. is a proctor for Edwards LifeSciences and Boston Scientific and has received speaker fees from Boston Scientific, Medtronic, and Abiomed. The other authors have no conflicts of interest to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit CJC Open at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2022.07.006.