



## Intentional combination of ProGlide and Angio-Seal for femoral access haemostasis in transcatheter aortic valve replacement☆



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### ABSTRACT

**Background:** To describe and evaluate the intentional combination of Angio-Seal (AS) and Perclose ProGlide (PP) in achieving haemostasis in patients undergoing transfemoral transcatheter aortic valve replacement (TAVR).

**Methods:** This study cohort was divided into two groups: dual PP versus one AS with one PP (AS + PP) used for common femoral artery haemostasis. The baseline, procedural characteristics and all outcomes (defined according to VARC-2 criteria) were prospectively collected and retrospectively compared.

**Results:** Overall, a total of 151 consecutive patients (68 men;  $80.9 \pm 7.3$  years old) were evaluated. Of these, 51 patients (33.8%) underwent TAVR using the dual PP, and 100 (66.2%) using one AS with one PP. There were no significant differences in the baseline characteristics of both patient groups, except higher incidence of chronic pulmonary disease in dual PP group (21.6% vs 7%,  $P = 0.009$ ). Patients in AS + PP group had lower rate of arterial stricture (21.6% vs 8%,  $P = 0.017$ ), arterial dissection (13.7% vs 4.0%), requiring endovascular intervention for puncture site issues (21.6% vs 9.0%,  $P = 0.031$ ). Less procedural time ( $139.8 \pm 36.9$  vs  $97.9 \pm 31.4$  min,  $P < 0.001$ ) & contrast medium consumption ( $223.9 \pm 88.3$  vs  $174.1 \pm 49.7$  ml,  $P < 0.001$ ) were also observed in AS + PP group. There were no statistically significant differences between 2 groups in regards of closure device failure, major and minor vascular complications, nor major and minor bleeding.

**Conclusions:** Intentional combination of one PP and one AS for femoral access haemostasis in patients undergoing TAVR is feasible and safe, with low risk of vascular and bleeding complications.

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### 1. Introduction

The development of fully percutaneous transfemoral transcatheter aortic valve replacement (TF-TAVR) requires the use of vascular closure devices allowing effective haemostasis after large-bore arteriotomy. Vascular complications in femoral access site are associated with prolonged hospitalization and higher morbidity/mortality after TAVR [1–4]. Use of suture-mediated closure devices, such as 1 Prostar XL or 2 Perclose ProGlide (PP) (both Abbott Vascular Inc., Santa Clara, Ca, USA), are routine for this purpose [5,6] and the results on vascular complications and outcome after TF-TAVR had been reported [7,8]. However, excessive suturing may increase the risk of femoral artery stenosis, especially in patients with small vessel size and/or mild

stenosis. Collagen-based Angio-Seal (AS) (St. Jude Medical, St. Paul, MN, USA) had been used as an adjunctive bail-out, when routine dual PP failed to achieve complete haemostasis after TF-TAVR [9]. Intentional combination of one AS and one PP to seal 9 Fr arteriotomy wound has been described before [10]. The objective of the present study was to describe this new hybrid vascular closure technique to achieve haemostasis in patients undergoing TF-TAVR, and evaluate its procedural and clinical outcomes.

### 2. Methods

#### 2.1. Patient population and data collection

Patients treated before October 2013 were not included to eliminate the learning curve impact. A total of 159 consecutive patients undergoing TAVR in National Taiwan University Hospital from October 2013 to March 2018 were analysed retrospectively. Of these, 8 patients were excluded from analysis: 1 trans-aortic approach, 1 trans-apical approach, 3 trans-femoral approach with surgical cut-down, 1 trans-femoral approach with internal endoconduit method [11], and 2 conversion to emergent open surgery. Dual PP was used in all patients from October 2013 to August 2015. Since August 2015, we

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gradually switched to intentional combination of one AS with one PP as routine practice. Therefore, among the 151 patients analysed, two PP devices (dual PP group) were used in 51 (33.8%) to achieve haemostasis after TF-TAVR, and intentional combination of one AS and one PP device (AS+ PP group) were used in 100 (66.2%). All data were collected prospectively.

## 2.2. Vascular access and evaluation

Before TAVR, peripheral access evaluation and measurement was accomplished with pre-procedural multi-detector computed tomography (MDCT). During the procedure, cross-over angiography was routinely performed for access vessel evaluation and arterial puncture guidance. Vessel tortuosity and calcification were evaluated as previously described (2). The tortuosity score was defined as follows: 0 = no tortuosity; 1 = mild tortuosity (30° to 60°); 2 = moderate tortuosity (60° to 90°); and 3 = marked tortuosity (>90°). The calcification score was evaluated under fluoroscopy before contrast injection or by MDCT, and defined as follows: 0 = no calcification; 1 = mild calcification; 2 = moderate calcification; and 3 = marked calcification.

One PP was deployed after puncture with the suture knot secured. In dual PP cases, the second PP was deployed at about 45° rotation to the first one. Unfractionated heparin was administered after large sheath insertion to achieve activated clotting time (ACT) of 250–300 s throughout the procedure. After large sheath removal at the end of the procedure, the access site was evaluated, both externally and through selective cross-over angiogram, for any vascular complications such as leakage, dissection, stricture/narrowing, or occlusion. Standardized protamine reversal was done according to final ACT.

## 2.3. Description of techniques AS + PP for hemostasis

The actual execution sequence of AS+PP for femoral access haemostasis is illustrated in Fig. 1. One PP is deployed in the conventional manner [6] before procedure (Fig. 1A). After the conclusion of the TAVR, the large-bore TAVR delivery sheath is removed. The PP suture is then tightened around an 8 Fr sheath, inserted over the guidewire (Fig. 1B). If significant oozing noted at this stage, another bail-out PP still could be deployed after removing 8 Fr sheath, although none of case needed adjunctive PP device in our practice. Once confirming no excessive oozing around it, the 8 Fr sheath was then removed and replaced with an 8 Fr AS device. The AS device was then deployed in the conventional manner [12] (Fig. 1C), to seal the remaining arteriotomy space after the first PP suture. Finally the PP knot is locked and cut, to complete the hemostatic procedure (Fig. 1D & 1E).

## 2.4. Definition and management of complications

Arterial stricture was defined as >50% diameter stenosis at the access site immediately after conclusion of closure procedures. Balloon angioplasty will be performed if pressure gradient across the stricture was higher than 20 mm Hg. Flow-limiting iliofemoral dissections were treated with balloon angioplasty or, if necessary, self-expanding stents. Ilio-femoral perforation/extravasation after conclusion of closure procedures will first be

managed with 15–20 min manual compression, with or without cross-over internal balloon tamponade. If failed, further treatment with covered stents or open surgical repair will be done accordingly. Closure-device failure was defined as insufficient or absence of haemostasis at the arteriotomy site requiring alternative treatment (other than manual compression or adjunctive endovascular ballooning) during the index procedure. Vascular complications and bleeding were defined using the Valvular Academic Research Consortium-2 (VARC-2) consensus criteria [13].

## 2.5. Statistical analysis

Continuous variables are expressed as mean ± standard deviation. Categorical data are expressed as numbers and percentages. The Student's *t*-test or Mann-Whitney *U* test was used to compare continuous variables. Categorical data were compared with the Pearson's chi-square test or Fisher exact test. Normality of distribution was tested by means of the Kolmogorov-Smirnov test. Statistical significance was defined as  $p < 0.05$ .

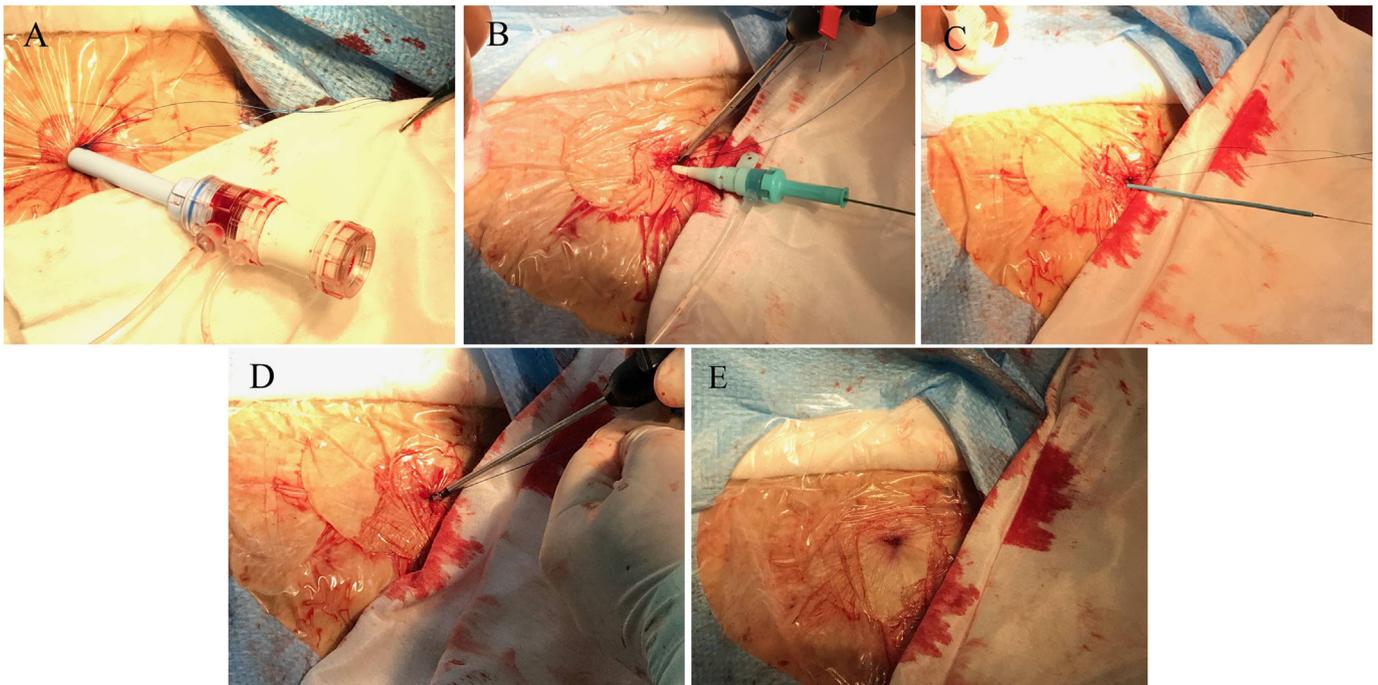
## 3. Results

### 3.1. Study population

The baseline characteristics of 151 patients are summarized in Table 1. More chronic pulmonary disease was seen in dual PP group (21.6% vs. 7.0%,  $p = 0.009$ ), but others were similar between 2 groups. No difference in left ventricular ejection fraction ( $67.4 \pm 11.7\%$  vs  $65.1 \pm 13.1\%$ ,  $P = 0.288$ ), aortic valve area ( $0.71 \pm 0.19 \text{ cm}^2$  vs  $0.75 \pm 0.18 \text{ cm}^2$ ,  $P = 0.144$ ), maximal femoral artery diameter ( $7.3 \pm 1.1 \text{ mm}$  vs  $7.6 \pm 1.2 \text{ mm}$ ,  $P = 0.202$ ), and minimal femoral artery diameter ( $6.8 \pm 1.2 \text{ mm}$  vs  $7.3 \pm 1.2 \text{ mm}$ ,  $P = 0.173$ ) was seen between 2 groups.

### 3.2. Procedural variables and clinical outcomes

The procedural variables and complications in both groups are presented in Table 2. The dual PP group showed a significantly higher incidence of arterial stricture (21.6% vs 8.0%,  $P = 0.017$ ), arterial dissection (13.7% vs 4.0%,  $P = 0.030$ ), and need of endovascular intervention (21.6% vs 9.0%,  $P = 0.031$ ) at access site. There was no statistically significant difference between the groups in the in-hospital VARC-2 major vascular complications (2.0% vs. 2.0%,  $p = 0.987$ ), minor vascular



**Fig. 1.** Illustration of combining one Angio-Seal (AS) with one PercloseProglide (PP) for femoral access haemostasis. (A) One PP pre-suture is placed. (B) PP suture is tightened around an 8 Fr sheath after removing 18 Fr sheath. (C) AS deployed after removing 8 Fr sheath. (D) PP suture knot is locked. (E) Complete haemostasis.

complications (15.6% vs. 10.0%,  $p = 0.308$ ), major bleeding (2.0% vs. 1.0%,  $p = 0.625$ ), minor bleeding (7.8% vs. 7.0%,  $p = 0.850$ ), nor closure device failure (2.0% vs 3.0%,  $P = 0.707$ ). However, the procedure time was longer ( $139.8 \pm 36.9$  min vs  $97.9 \pm 31.4$  min,  $P < 0.0001$ ) and contrast medium consumption was more ( $223.9 \pm 88.3$  ml vs  $174.1 \pm 49.7$  ml,  $P < 0.0001$ ) in the dual PP group, while fluoroscopy time was similar ( $24.5 \pm 12.2$  min vs  $24.3 \pm 9.2$  min,  $P = 0.949$ ) between 2 groups.

#### 4. Discussion

This retrospective study showed that the rates of arterial injury and need of endovascular intervention were lower in AS + PP group, compared to those in dual PP group. There was no significant difference between two groups in regard of closure device failure, vascular and bleeding complications using the VARC II criteria. The results demonstrated that intentional combination of one AS and one PP to achieve haemostasis after patients receiving TF-TAVR is feasible, safe, and efficacious. To our best knowledge, the intentional utilization of this hybrid technique for vascular access closure following TF-TAVR has not been previously described in the literature.

In previous literature, the failure rates of Prostar and dual PP devices have been reported at 4–19%, with sheath sizes ranging from 18 to 24Fr [1,7,8,14,15]. The rationale of the present hybrid technique is to first shrink the large-bore puncture hole to 8Fr in diameter by the PP suture, and then utilize the re-absorbable collagen plug and the footplate (composed of polylactide and polyglycolide polymer) of AS device to achieve complete haemostasis. There have been reports of off-label use of the AS device to close 9–12Fr arteriotomy after balloon aortic valvuloplasty and endovascular aneurysm repair procedures [16,17]. We believe the 8Fr AS safely and efficiently. This is demonstrated well by the similarly low device failure rate in the AS+PP group, compared to that of the standard dual PP groups.

Theoretically, our hybrid technique leaves less cinching and strain on the arterial wall at the end of the procedure, as only 1 suture is applied. The resulting advantage is reduction of immediate local kinking/stricture, which was clearly demonstrated by our cohort. Kodama et al [18] compared single versus double PP for vascular closure following

**Table 1**  
Baseline characteristics.

	Dual PP (N = 51)	AS + PP (N = 100)	P-value
Age (year)	81.8 ± 6.1	80.6 ± 7.7	0.367
Male	28 (54.9%)	39 (39.0%)	0.053
Body mass index	23.0 ± 3.9	24.3 ± 5.4	0.155
Diabetes Mellitus	17 (33.3%)	43 (43.0%)	0.455
Hypertension	31 (60.8%)	65 (65.0%)	0.611
Hyperlipidemia	15 (29.4%)	30 (30.0%)	0.940
Atrial fibrillation	9 (17.6%)	17 (17.0%)	0.921
Coronary artery disease	24 (47.1%)	37 (37.0%)	0.234
Peripheral vascular disease	9 (17.6%)	14 (14.0%)	0.555
Chronic kidney disease	15 (29.4%)	31 (31.0%)	0.841
Chronic pulmonary disease	11 (21.6%)	7 (7.0%)	0.009
LVEF (%)	67.4 ± 11.7	65.1 ± 13.1	0.288
Ao max PG (mm Hg)	77.9 ± 28.1	72.8 ± 26.5	0.228
Ao mean PG (mm Hg)	44.8 ± 16.5	42.1 ± 18.6	0.390
Aortic valve area (cm <sup>2</sup> )	0.71 ± 0.19	0.75 ± 0.18	0.144
Hemoglobin (g/dl)	11.7 ± 1.9	11.9 ± 0.9	0.457
Platelet count (k/μl)	216.0 ± 86.7	201.1 ± 74.0	0.273
Maximal femoral artery diameter (mm)*	7.3 ± 1.1	7.6 ± 1.2	0.202
Minimal femoral artery diameter (mm)*	6.8 ± 1.2	7.1 ± 1.2	0.173
Femoral artery calcification score	0.51 ± 0.73	0.59 ± 0.79	0.547
Femoral artery tortuosity score	0.31 ± 0.70	0.35 ± 0.77	0.779

Mean ± SD are shown.

LVEF, left ventricular ejection fraction; Ao max PG, aortic valve maximal pressure gradient; Ao mean PG, aortic valve mean pressure gradient; all measured by echocardiography.

\* Measured by multi-detector computed tomography.

**Table 2**  
Procedural and clinical outcomes.

	Dual PP (N = 51)	AS + PP (N = 100)	P-value
Arterial stricture	11 (21.6%)	8(8.0%)	0.017
Arterial dissection at access site	7(13.7%)	4(4.0%)	0.030
Pseudoaneurysm	0(0%)	1(1.0%)	0.474
Endovascular intervention at access site	11(21.6%)	9(9.0%)	0.031
Stent implantation	3(5.9%)	2(2.0%)	0.207
Balloon angioplasty	7(13.7%)	7(7.0%)	0.178
Balloon tamponade for haemostasis	5(9.8%)	4(4.0%)	0.154
Unplanned surgical intervention	1(2.0%)	1(1.0%)	0.625
Closure device failure	1(2.0%)	3(3.0%)	0.707
Major vascular complications	1(2.0%)	2(2.0%)	0.987
Minor vascular complications	8(15.6%)	10(10.0%)	0.308
Major bleeding complications	1(2.0%)	1(1.0%)	0.625
Minor bleeding complications	4 (7.8%)	7 (7.0%)	0.850
Procedural variables			
Procedure time (min)	139.8 ± 36.9	97.9 ± 31.4	<0.001
Fluoroscopy time (min)	24.5 ± 12.2	24.3 ± 9.2	0.949
Contrast medium volume (ml)	223.9 ± 88.3	174.1 ± 49.7	<0.001

PP: Perclose ProGlide.

AS: Angio-Seal.

TF-TAVR in a multi-center registry. The rates of vascular and bleeding complications were similar between the 2 groups, and there was no significant difference in respect of vascular stenosis. Shoeib et al. [19] reported the comparison between pre-procedural and post-procedural femoral angiography obtained during TAVR practice. In a total 124 patients, ProStar (13.5%) and dual PP devices (82.2%) were used as the main hemostatic techniques. The authors found significant shrinkage in common femoral artery after TAVR, with significant reduction in minimal lumen diameter (5.6 mm after TAVR vs. 6.8 mm before,  $P < 0.001$ ) and increase of percentage diameter stenosis (30.3% after vs. 17.0%,  $P < 0.001$ ). Past history of peripheral arterial disease and smaller pre-TAVR common femoral artery diameter were identified as the main predictors for shrinkage. This phenomenon could also be observed in patients without vascular complication (85.5%). It is difficult to ascertain the actual clinical consequence of this subclinical stenosis in a longer follow-up, but they did report one case with late development of symptomatic femoral artery stenosis requiring further endovascular intervention after an early, uncomplicated course. We also have a similar case receiving dual PP haemostasis in the current series. A well-designed study would be mandatory to evaluate the long-term hemodynamic and clinical impact of femoral artery stenosis caused by different vascular closure techniques in TF-TAVR patients.

Kiramijyan et al. [9] reported using AS as an adjunctive device to augment wound closure, when the routine dual PP fails to achieve complete haemostasis after TF-TAVR. In 387 consecutive patients, 208 (55%) needed adjunctive use of AS to stop residual oozing or bleeding after dual PP deployment. Most adjunctive AS achieved immediate complete haemostasis, reduced the time to arousal of the patient, and reduced cathlab turnaround time. However, we have to raise one major concern on this adjunctive practice. Double suturing is known to reduce the minimal vessel diameter by 1 mm on average [19], and AS device is contraindicated in vessels with diameter < 5 mm or luminal compromise of >40% within 5 mm of the puncture site [12]. Therefore, the adjunctive use of AS after dual PP, proposed by Kiramijyan et al., may in fact increase the risk of acute or subacute arterial occlusion, especially in femoral arteries with lumen diameter around 6 mm. Our strategy is different, as AS is used intentionally rather than as a bailout, and only 1 PP is deployed. The advantage of our hybrid technique is less cost, less procedure steps and hence shorter procedure time, and most importantly less cinching and potential damage to the femoral artery.

Several study limitations should be addressed. The current study was a single center experience with relatively small sample size, and was retrospective and not randomized. Multiple confounding factors

may exist, including different skill level and time sequence, and use of new generation devices of lower delivery profile in AS+PP group. The generalizability of this hybrid technique and its clinical benefit needs to be confirmed by further large prospective randomized trial, which is ongoing in our institution. Otherwise, a novel collagen plug-based vascular closure device, the MANTA™ (Essential Medical Inc., Malvern, Pennsylvania), has already been used to achieve haemostasis following TF-TAVR [20,21]. The study comparing this hybrid technique with MANTA device is also warranted.

## 5. Conclusion

The hybrid technique of intentional combination of one AS and one PP device is feasible and safe for percutaneous femoral closure in patients undergoing TF-TAVR, with low rate of vascular and bleeding complications and less vascular injury. It would be an optimal choice of hemostatic procedure for large-bore arterial access closure, especially in patients with relatively small vessel size.

## References

- [1] C. Tamburino, D. Capodanno, A. Ramondo, et al., Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis, *Circulation* 123 (2011) 299–308.
- [2] K. Hayashida, T. Lefevre, B. Chevalier, et al., Transfemoral aortic valve implantation new criteria to predict vascular complications, *JACC Cardiovasc Interv.* 4 (2011) 851–858.
- [3] J. Rodes-Cabau, J.G. Webb, A. Cheung, et al., Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience, *J. Am. Coll. Cardiol.* 55 (2010) 1080–1090.
- [4] G. Ducrocq, F. Francis, J.M. Serfaty, et al., Vascular complications of transfemoral aortic valve implantation with the Edwards SAPIEN prosthesis: incidence and impact on outcome, *EuroIntervention.* 5 (2010) 666–672.
- [5] M. Barbanti, J.G. Webb, Interventions to reduce major vascular complications of TAVR, *Expert. Rev. Cardiovasc. Ther.* 11 (2013) 891–901.
- [6] S. Toggweiler, J. Leipsic, R.K. Binder, et al., Management of vascular access in transcatheter aortic valve replacement: part 1: basic anatomy, imaging, sheaths, wires, and access routes, *JACC Cardiovasc Interv.* 6 (2013) 643–653.
- [7] I.M. Barbash, M. Barbanti, J. Webb, et al., Comparison of vascular closure devices for access site closure after transfemoral aortic valve implantation, *Eur. Heart J.* 36 (2015) 3370–3379.
- [8] M. Barbanti, P. Capranzano, Y. Ohno, et al., Comparison of suture-based vascular closure devices in transfemoral transcatheter aortic valve implantation, *EuroIntervention* 11 (2015) 690–697.
- [9] S. Kiramijyan, M.A. Magalhaes, I. Ben-Dor, et al., The adjunctive use of Angio-Seal in femoral vascular closure following percutaneous transcatheter aortic valve replacement, *EuroIntervention* 12 (2016) 88–93.
- [10] M.K. Amponsah, R. Tayal, Z. Khakwani, M. Sinclair, N. Wasty, Safety and efficacy of a novel “hybrid closure” technique in large-bore arteriotomies, *Int. J. Angiol.* 26 (2017) 116–120.
- [11] B.G. Peterson, J.S. Matsumura, Internal endoconduit: an innovative technique to address unfavorable iliac artery anatomy encountered during thoracic endovascular aortic repair, *J. Vasc. Surg.* 47 (2008) 441–445.
- [12] A. Abando, D. Hood, F. Weaver, S. Katz, The use of the Angioseal device for femoral artery closure, *J. Vasc. Surg.* 40 (2004) 287–290.
- [13] A.P. Kappetein, S.J. Head, P. Genereux, et al., Updated standardized endpoint definitions for transcatheter aortic valve implantation: the valve academic research Consortium-2 consensus document, *J. Am. Coll. Cardiol.* 60 (2012) 1438–1454.
- [14] S. Toggweiler, R. Gurvitch, J. Leipsic, et al., Percutaneous aortic valve replacement: vascular outcomes with a fully percutaneous procedure, *J. Am. Coll. Cardiol.* 59 (2012) 113–118.
- [15] Z. Dimitriadis, W. Scholtz, J. Börgermann, et al., Impact of closure devices on vascular complication and mortality rates in TAVI procedures, *Int. J. Cardiol.* 241 (2017) 133–137.
- [16] Q.T. Bui, D.M. Kolansky, A. Bannan, H.C. Herrmann, “Double wire” angio-seal closure technique after balloon aortic valvuloplasty, *Catheter. Cardiovasc. Interv.* 75 (2010) 488–492.
- [17] A. Fallahi, M. Kim, Initial experience of removal of 10-French sheaths using the 8-French Angio-Seal vascular closure device, *J Invasive Cardiol.* 22 (2010) 130–131.
- [18] A. Kodama, M. Yamamoto, T. Shimura, et al., Comparative data of single versus double proglide vascular preclose technique after percutaneous transfemoral transcatheter aortic valve implantation from the optimized catheter valvular intervention (OCEAN-TAVI) japanese multicenter registry, *Catheter. Cardiovasc. Interv.* 90 (2017) E55–E62.
- [19] O. Shoeib, F. Burzotta, C. Aurigemma, et al., Percutaneous transcatheter aortic valve replacement induces femoral artery shrinkage: angiographic evidence and predictors for a new side effect, *Catheter. Cardiovasc. Interv.* 91 (2018) 938–944.
- [20] N.M. Van Mieghem, A. Latib, J. van der Heyden, et al., Percutaneous plug-based arteriotomy closure device for large-bore access, A Multicenter Prospective Study, *JACC Cardiovasc Interv.* 10 (2017) 613–619.
- [21] F. Biancari, H. Romppanen, M. Savontaus, et al., MANTA versus ProGlide vascular closure devices in transfemoral transcatheter aortic valve implantation, *Int. J. Cardiol.* 263 (2018) 29–31.