



Transfemoral implantation of the ACURATE *neo* prosthesis using a low-profile expandable introducer system: A multicenter registry



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ABSTRACT

Background: The ACURATE *neo* prosthesis is commonly implanted using introducer sheaths with inner diameters of up to 20 French. The use of only the expandable mesh component of the transGlide introducer system (Mesh_{only}) would substantially decrease the inner diameter to 13 French.

We sought to assess the feasibility and safety of using Mesh_{only} for femoral access of the ACURATE *neo* device and to compare outcomes with patients in whom standard sheaths were used.

Methods and results: We retrospectively analyzed a total of 551 patients with severe aortic stenosis from 4 high volume centers in Germany and Switzerland undergoing transfemoral TAVI between February 2016 and February 2018 with implantation of the ACURATE *neo* device.

The median age was 81.7 [78.3–85.2], 67.0% were female, the STS score was 4.2% [2.8–6.5]. The use of the Mesh_{only} was feasible in all attempted cases ($n = 272$); in all other patients, a standard sheath was used. Major vascular complications at the main access-site (VARC-2) were less frequent in the Mesh_{only} group than in the standard sheath group (1.5% vs. 7.9%; $p < 0.001$). In the multivariable analysis, the use of Mesh_{only} was independently associated with less major vascular complications (odds ratio 0.10 [95% CI 0.02–0.48]; $p = 0.004$). **Conclusions:** Transfemoral implantation of the ACURATE *neo* device using the Mesh_{only} was associated with a lower rate of major access-related complications when compared to the standard of care.

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Abbreviations: ID, inner diameter; MajorVasc_{main}, major vascular complication at the main access site; Mesh_{only}, mesh assembly of the transGlide® expandable introducer; OD, outer diameter; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve.

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1. Introduction

In the past decade, tremendous advances have been achieved in the field of transcatheter aortic valve implantation (TAVI) [1–4]. Apart from optimized patient selection, sophisticated imaging, and novel devices, the continually decreasing diameter of the access for the transvascular approach has contributed to this progress [5,6]. Particularly with regard to the most commonly used transfemoral access, there is evidence that smaller sheath diameters imply a lower rate of vascular complications [6,7]. Thus, there are ongoing efforts to further reduce the dimensions of delivery systems and to minimize the diameter of the applied sheath system. The ACURATE *neo*TM (Symetis SA/Boston Scientific, Ecublens, Switzerland) is a self-expanding transcatheter heart valve (THV) that is increasingly implanted [8]. The delivery system has a diameter of 18

French and is compatible with a variety of different sheaths, of which the most commonly used have inner diameters (ID) up to 20 French.

The transGlide® expandable introducer (TransAortic Medical, Morgan Hill, CA, USA) consists of an expandable mesh assembly with an ID of 13 French composed of a polymer braid with an outer hydrophilic coating and an elastomer seal covering the proximal part, and a sheath with an ID of 20 French (Fig. 1). The sheath is advanced over a 0.035" guidewire through the mesh assembly, which due to its elastic properties can adapt to the larger sheath size and protects the vessel wall from longitudinal friction. The use of the transGlide® mesh (Mesh_{only}) without the sheath for delivery of the ACURATE *neo* would decrease the size of the arteriotomy to the lowest currently possible with an ID of 4.3 mm, an outer diameter (OD) of 5.0 mm, and an insertion profile of 6.7 mm.

The aim of this study was to assess the feasibility and safety of using Mesh_{only} for femoral access of the ACURATE *neo*™ THV and to compare outcomes with patients in whom standard sheaths were used.

2. Methods

2.1. Study population

We retrospectively analyzed patients with severe aortic stenosis undergoing transfemoral TAVI with implantation of the ACURATE *neo*™ device from 4 high volume centers. We included only patients in whom femoral access was obtained percutaneously using the Perclose-Proglide (referred to as Proglide, Abbott Vascular, CA, USA) preclosure system. The indication for TAVI was based on current guidelines, and each case was discussed within the institutional heart team [9].

All patients underwent a diagnostic workup including transthoracic echocardiography and multidetector computed tomography of the aortic valve, the complete aorta and the femoro-iliac vessels. The evaluation of the femoral vessels included measurement of the minimum diameter, semiquantitative classification of tortuosity and calcification at the puncture site (none, mild, moderate, severe). The sheath-to-femoral artery-ratio (SFAR) was calculated by dividing the sheath size by the access diameter.

2.2. Procedure and vascular access

Procedures were performed as previously described [8] according to in-house standards, either under general anesthesia, conscious sedation, or with local anesthesia. For femoral access, at first an angiography of the common femoral artery was performed, either via a 4-French sheath in the ipsilateral superficial femoral artery or from the

contralateral side using a 6-French catheter. The common femoral artery was then punctured under fluoroscopic control and a 6-French sheath was inserted. Subsequently, the Proglide closure device was placed into the femoral artery and exchanged for an 11-French sheath. Heparin was administered intravenously in a dose of 100 units/kg and the activated clotting time was kept between 250 and 300 s. The aortic valve was crossed and a stiff guidewire was placed into the left ventricle. The 11-French sheath was removed and the large bore sheath was inserted into the vessel. Pre-dilatation was performed at the discretion of the operator under rapid pacing, thereafter the prosthesis was implanted. The delivery system was withdrawn and the procedural result was verified with an aortogram and hemodynamic measurements. At the end of the procedure, the large bore sheath was removed and the prepared sutures were tied. In the event of an immediate failure of the closure device, commonly another Proglide or an 8-French Angioseal (Abbott, USA) was applied. A final angiography was performed to assess vascular integrity at the main access site. Finally, a pressure bandage was applied in the groin for 12 h. Patients were referred to the intensive care unit for close inspection of the groin, check of the pulse status and hemodynamic monitoring for at least 24 h. After removal of the bandage, the access site and peripheral pulse status were examined by a physician. In the event of clinical signs suggestive of vascular complications, various imaging modalities were applied according to hemodynamic status and severity of symptoms, including duplex ultrasound, computed tomography, or intraarterial angiography.

2.3. Management of vascular complications

Depending on the type and severity of the vascular complication, a stepwise approach was pursued. In the case of pseudoaneurysms, either an ultrasound-guided compression or ultrasound-guided percutaneous injection of thrombin was carried out. Persistent bleedings at the main access site or vessel obstructions were either treated with percutaneous balloon angioplasty or with the implantation of a (covered) stent. If these measures failed, or in severe cases, a surgical therapy was implemented, regardless of the etiology.

2.4. Endpoint definitions

The primary endpoint was the in-hospital rate of major vascular complications at the main access site (MajorVasc_{main}) according to Valve Academic Research Consortium (VARC)-2 criteria [10]. Secondary endpoints were the in-hospital rate of any major or life-threatening bleedings (VARC-2), bail-out measures which were classified into non-surgical (conservative or endovascular) and surgical vascular repair, and 30-day mortality.

2.5. Statistical analysis

Continuous variables are expressed as median and interquartile range (IQR), and categorical data are given as numbers and percentages. Continuous variables were compared with the Wilcoxon test, and categorical data were analyzed with the Fisher's exact or Chi-

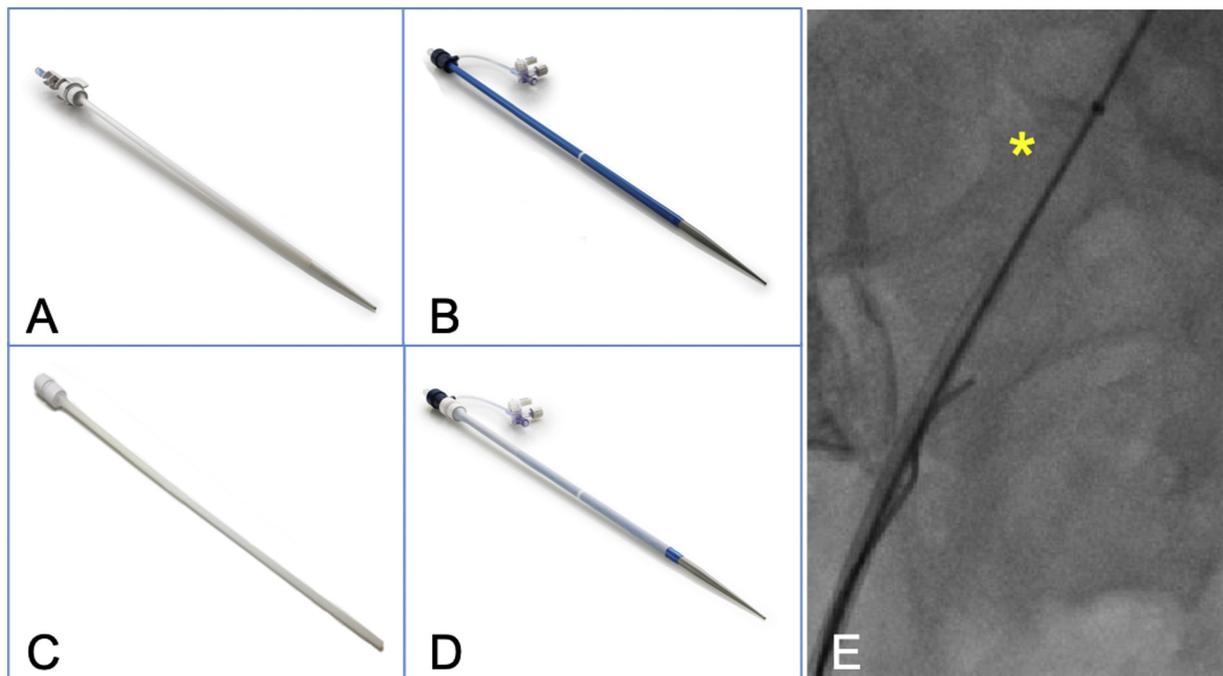


Fig. 1. TransGlide® expandable introducer. In the first step, the expandable 13 French mesh assembly is introduced into the vessel with the indwelling dilator (A). Sheath assembly (B). Mesh assembly after removal of the dilator (C). (D) depicts the system in its originally intended fashion: the sheath assembly is introduced into the vessel via the mesh assembly. (E) The yellow asterisk indicates the useable end of the mesh assembly in the right external iliac artery, which is faintly visible under fluoroscopy.

square test as appropriate. Logistic multistep regression analysis was performed to identify independent predictors of major complications at the main access site. All variables that showed a p -value ≤ 0.1 in the univariable analysis or showing an imbalance between the groups in the baseline analysis were included. A two-sided p -value < 0.05 was considered significant. All statistical data were calculated with SPSS (IBM SPSS, Armonk, NY, USA) version 22.

3. Results

3.1. Patients and procedure

The total study population consisted of 551 patients from 4 centers (Kerckhoff Heart Center, Bad Nauheim, Germany; $n = 386$; Luzerner Kantonsspital, Lucerne, Switzerland, $n = 96$; University of Leipzig-Heart Center, Leipzig, Germany, $n = 61$; Völklingen Heart Center, Völklingen, Germany, $n = 8$) undergoing transfemoral TAVI with the ACURATE *neo*TM prosthesis between February 2016 and February 2018. The median age was 81.7 years [78.3–85.2], 67.0% were female, and the Society Thoracic Surgeons (STS) score was 4.2% [2.8–6.5]. Baseline characteristics, procedural details, and complications are provided in Table 1.

3.2. Vascular access and complications

The use of the Mesh_{only} was feasible in all attempted cases ($n = 272$); minor side-bleedings at the hemostatic valve could be managed by additional insertion of a 6-French sheath. The radiopacity was rather poor, but this fact did not impair the general applicability (Fig. 1). In 2 cases the distal part of the mesh partially collapsed during the retrieval of the valvuloplasty balloon catheter, which was resolved upon complete deflation of the balloon. This observation was not made during the withdrawal of the delivery system. In all other patients, a variety of different commercially available sheaths was used as specified in Fig. 2. Major vascular complications were noted in 38 (6.9%) cases, of which 24 (4.4%) were related to the main access (MajorVasc_{main}), whereas 17 (3.1%) occurred at other access sites (there were 3 patients with major vascular complications at the main access and concomitantly at other access sites). With respect to the main access, a non-surgical (conservative and endovascular) treatment was employed in 18 (3.3%) cases, and a surgical revision became necessary in 23 (4.2%) cases.

The incidence of MajorVasc_{main} was significantly associated with left sided access (odds ratio 3.11 [95% confidence interval (CI) 1.18–8.19]; $p = 0.02$) and the use of Mesh_{only} (odds ratio 0.19 [95% CI 0.07–0.57]; $p = 0.003$), whereas SFAR (odds ratio 4.09 [95% CI 0.80–20.85]; $p = 0.09$) was non-significantly associated with MajorVasc_{main} (Table 2).

In the multivariable analysis, the use of Mesh_{only} was independently associated with MajorVasc_{main}, showing a protective effect (odds ratio 0.10 [95% CI 0.02–0.48]; $p = 0.004$).

Thirty-day all-cause mortality was significantly increased in patients with any vascular complication (7.1% vs. 1.6%; $p = 0.002$) as well as in patients with major vascular complications (16.2% vs. 1.4%; $p < 0.001$).

3.3. Comparison of Mesh_{only} versus standard sheaths

Comparison of baseline characteristics showed significant differences between the Mesh_{only} and the standard group with respect to body surface, height, estimated glomerular filtration rate, the rate of hypertension, coronary artery disease, and patients with access diameter ≤ 6 mm. Of note, the median diameter of the main-access vessel (8.0 mm [7.0–8.9] vs. 8.0 mm [7.0–9.0]; $p = 0.51$), and the proportion of patients with moderate to severe calcification and with moderate to severe tortuosity at the main access-site were similar.

Patients in the Mesh_{only} group had significantly less frequent MajorVasc_{main} than the group with standard sheaths (1.5% vs. 7.9%; $p < 0.001$), whereas the rate of major vascular complications at other access sites was similar (2.9% vs. 3.2%; $p = 0.85$). Surgical vascular treatment

was less frequent in the Mesh_{only} group than in the standard group (2.2% vs. 6.1%; $p = 0.02$), but the rate of non-surgical vascular repair did not differ (3.3% vs. 3.3%; $p = 0.96$). Thirty-day mortality was similar (2.3% vs. 2.5%; $p = 0.92$).

4. Discussion

The following main findings of this multicenter registry should be emphasized:

- 1) For the first time, we demonstrate the feasibility and safety of using solely the mesh of the transGlide® expandable introducer for transfemoral access with the ACURATE *neo*TM prosthesis.
- 2) The rate of major vascular complications at the main access-site was significantly lower when using the Mesh_{only}.

In view of the lowest insertion profile that can be achieved for transfemoral implantation of the ACURATE *neo*TM prosthesis when using the Mesh_{only}, the results confirm previous studies in which smaller sheath diameters have been related to a reduction of vascular complications [6,11]. Both systems, which originally were not designed to match one another were well compatible in this off-label use.

4.1. Sheath dimensions

By default, the ACURATE *neo*TM can be used with either 15 French balloon-expandable or 20 French rigid sheaths. Fig. 2 provides an overview of commercially available introducer sheaths that were used with the ACURATE *neo*TM prosthesis in this study. It becomes clear that apart from the discrepancy between the specified ID and OD, in expandable sheaths the OD may further increase during the insertion of the delivery system. Since the relation between the OD of the sheath to the minimal diameter of the artery (SFAR) is a strong predictor of vascular complications [7], it is crucial to specify the effective outer diameter of the sheath also during the passage of the delivery system. In this context, the incorporation of the Mesh_{only} brings about a nominal downsizing of the ID to 4.3 mm with only a minimal increase of the OD to 5.0 mm. Due to the low profile, the insertion and retrieval of the sheath is facilitated and the risk of vessel injury can be reduced. Importantly, during insertion of the mounted prosthesis the OD of the mesh would only become marginally larger (6.7 mm) than the delivery system itself (6.0 mm), hence coming close to a sheathless approach. The latter, however, is not feasible with the ACURATE *neo*TM device since there is an uncovered portion of the loaded prosthesis.

The reduced effective outer sheath diameter of the Mesh_{only} may not only translate into less vascular complications, but would expand the spectrum of patients who can be treated with the ACURATE *neo*TM device via transfemoral access. Even though median diameters of the femoral artery were similar, the proportion of patients with vessel sizes < 6 mm was significantly higher in the Mesh_{only} group. The fact that the use of the Mesh_{only} was the only independent predictor of MajorVasc_{main} in this specific population underlines the clinical relevance of the decrease in diameter.

4.2. Vascular repair

There is a wide range of therapeutic options for vascular complications, including conservative strategies (mechanical compression), percutaneous injection of fibrin, interventional and surgical repair.

Overall, treatment for vascular damage was necessary in 40 (7.3%) cases, but the rate of endovascular repair was identical between Mesh_{only} and the standard sheath group (3.3% vs. 3.3%; $p = 0.96$), whereas there was a higher need for surgical vascular repair in the group with the standard sheaths (6.1% vs. 2.2%; $p = 0.02$). The latter may not necessarily indicate more severe vascular complications due to the use of standard sheaths, but may be a consequence of operator

Table 1
Baseline characteristics and outcome.

	Total cohort (n = 551)	Mesh _{only} (n = 272)	Standard (n = 279)	p
Baseline values				
Age, years	81.7 [78.3–85.2]	81.5 [78.0–84.9]	82.0 [78.8–85.6]	0.22
Female gender	369 (67.0%)	172 (63.2%)	197 (70.6%)	0.07
Body mass index, kg/m ²	27.0 [24.1–30.1]	27.0 [24.3–30.1]	26.9 [23.8–30.4]	0.56
Body surface area, m ²	1.83 [1.69–1.97]	1.85 [1.72–1.97]	1.82 [1.67–1.96]	0.04
Weight, kg	73.0 [65.0–83.0]	74.0 [66.0–83.8]	72.0 [63.0–81.0]	0.07
Height, cm	164 [158–170]	165 [160–170]	164 [157–170]	0.04
Logistic Euroscore, %	18.3 [11.6–26.3]	18.7 [12.4–28.4]	17.7 [11.4–25.1]	0.23
STS PROM, %	4.2 [2.8–6.5]	3.9 [2.7–6.2]	4.4 [2.9–6.6]	0.09
eGFR, ml/min	63.0 [44.0–81.0]	67.9 [48.0–85.8]	58.9 [41.0–76.0]	0.001
Hypertension	497 (90.2%)	237 (87.1%)	260 (93.2%)	0.02
Diabetes	184 (33.4%)	91 (33.5%)	93 (33.3%)	0.98
COPD	94 (17.1%)	44 (16.2%)	50 (17.9%)	0.59
Coronary artery disease	315 (57.2%)	175 (64.3%)	140 (50.2%)	0.001
Peripheral vascular disease	45 (8.2%)	27 (9.9%)	18 (6.5%)	0.14
EF baseline, %	64.0 [55.0–65.0]	65.0 [55.0–65.0]	64.0 [55.0–65.0]	0.58
Pmean baseline, mm Hg	43.0 [33.0–53.0]	43.0 [34.0–55.0]	43.0 [32.0–52.0]	0.47
AVA baseline, cm ²	0.7 [0.6–0.8]	0.7 [0.5–0.8]	0.7 [0.6–0.8]	0.06
Access				
Moderate and severe calcification	75 (13.9%)	38 (14.2%)	37 (13.6%)	0.85
Moderate and severe tortuosity	151 (27.5%)	71 (26.3%)	80 (28.7%)	0.53
Diameter, mm	8.0 [7.0–9.0]	8.0 [7.0–8.9]	8.0 [7.0–9.0]	0.51
Diameter ≤6 mm	64 (11.7%)	42 (15.6%)	22 (7.9%)	0.005
Sheath ID, mm	4.7 [4.3–6.7]	4.3 [4.3–4.3]	6.7 [6.7–6.7]	<0.001
Sheath OD, mm	6.0 [5.0–7.5]	5.0 [5.0–5.0]	7.5 [7.5–8.0]	<0.001
Sheath insertion profile, mm	7.5 [6.7–7.5]	6.7 [6.7–6.7]	7.5 [7.5–8.0]	<0.001
SFAR	0.83 [0.63–0.95]	0.63 [0.56–0.71]	0.94 [0.83–1.07]	<0.001
SFAR insertion profile	0.94 [0.83–1.07]	0.84 [0.75–0.96]	0.95 [0.87–1.09]	<0.001
Procedural data				
Procedural duration, min	38.0 [30.0–48.0]	36.0 [29.0–46.0]	38.0 [31.5–47.0]	0.02
Fluoroscopy time, min	9.2 [6.9–12.6]	9.0 [6.9–12.6]	9.7 [6.9–12.6]	0.50
Contrast agent, ml	90.0 [70.0–110.0]	90.0 [70.0–115.0]	83.0 [66.0–104.3]	0.006
Predilatation	405 (73.5%)	207 (76.1%)	198 (71.0%)	0.17
Post-dilatation	225 (40.8%)	113 (41.5%)	112 (40.1%)	0.74
EF at discharge, %	65.0 [58.0–65.0]	65.0 [57.0–65.0]	65.0 [59.0–65.0]	0.87
Pmean at discharge, mm Hg	8.0 [6.0–11.0]	8.0 [6.0–12.0]	7.0 [5.0–10.0]	0.003
AVA at discharge, cm ²	1.7 [1.4–1.9]	1.6 [1.4–1.8]	1.8 [1.5–2.0]	0.001
Complications				
30-day mortality	13/531 (2.4%)	6/252 (2.3%)	7/279 (2.5%)	0.92
Major bleeding	42 (7.6%)	17 (6.3%)	25 (9.0%)	0.23
Major vascular complications ^a	38 (6.9%)	13 (4.8%)	25 (9.0%)	0.05
Main access-site complications^b				
Major	24 (4.4%)	4 (1.5%)	20 (7.2%)	0.001
Major and minor	64 (11.6%)	22 (8.1%)	42 (15.1%)	0.01
Additional closure device	42 (7.6%)	22 (8.1%)	20 (7.2%)	0.68
Non-surgical repair ^c	18 (3.3%)	9 (3.3%)	9 (3.3%)	0.96
Surgical repair	23 (4.2%)	6 (2.2%)	17 (6.1%)	0.02
Other access-site complications^b				
Major	17 (3.1%)	8 (2.9%)	9 (3.2%)	0.85
Major and minor	27 (4.9%)	14 (5.1%)	13 (4.7%)	0.79
PVR ≥2° (echo)	17/531 (3.2%)	7/257 (2.7%)	10/274 (3.6%)	0.55
Conversion to surgery	6 (1.1%)	3 (1.1%)	3 (1.1%)	0.98
Major stroke	12 (2.2%)	6 (2.2%)	6 (2.2%)	0.97
Pacemaker implantation	56 (10.2%)	34 (12.5%)	22 (7.9%)	0.07
Acute kidney injury St 2 and 3	14 (2.5%)	8 (2.9%)	6 (2.2%)	0.56
Device success (VARC-2)	516 (93.6%)	254 (93.4%)	262 (93.9%)	0.80

Data are displayed as median [interquartile range] and n (%).

Abbreviations: CABG = coronary artery bypass graft, COPD = chronic obstructive pulmonary disease, eGFR = estimated glomerular filtration rate, EF = ejection fraction, Log. EuroSCORE I = logistic EuroSCORE I, Pmean = mean transaortic gradient, PVR = paravalvular regurgitation, SFAR = sheath-to-femoral-artery ratio, STS PROM = Society of Thoracic Surgeons Score for Prediction of Mortality. Significant p-values are in bold.

^a Per patient.

^b Per access site.

^c One patient was treated with both endovascular and surgical repair.

preference and local expertise. Even if all vascular complications in the standard sheath group had been resolved with an interventional approach instead of surgical repair, this would not change the fact, that in the standard sheath group the rate of vascular complications requiring further treatment was significantly higher. Importantly, according to VARC-2 criteria, even surgical repair in the absence of major bleeding, death, or other severe circumstances is not rated as major vascular

complication. Hence, the transition from surgical to endovascular repair would not primarily impact the rate of major vascular complications.

4.3. Prognostic impact

Vascular complications have been identified as predictors of 30-day mortality [11]. In the present analysis, even though the rates of

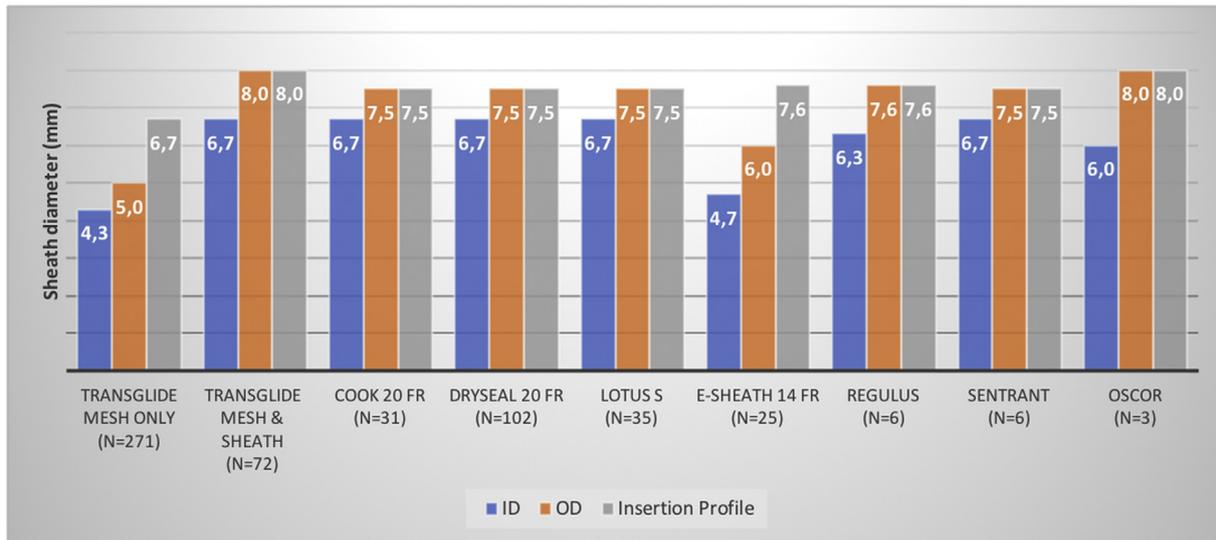


Fig. 2. Sheath dimensions. Overview of the sheaths that were used with the ID, OD, and insertion profile of each sheath. Abbreviations: ID = inner diameter, OD = outer diameter, FR = French.

MajorVasc_{main} significantly differed between the Mesh_{only} group and controls, 30-day all-cause mortality was not affected. This may be explained by the fact that the rate of vascular complications occurring at other sites than the main access was similar between the groups.

4.4. Limitations

Major limitations relate to the retrospective character of the present study with potential selection bias. Importantly, vascular adverse events were site-reported and hence, not adjudicated independently. Due to close site monitoring of the access site, however, the probability of overlooking or misjudging a vascular complication is low. Additional imaging with duplex ultrasound before and after the procedure would have been desirable, but is not the standard of care in clinical routine; at least, almost all patients had a pre-procedural computed tomography angiography of the femoro-iliac arteries, and at the end of the procedure, the access site was assessed by angiography. Even though there were some

baseline differences between the Mesh_{only} and standard sheath group, it is unlikely that these specific differences had relevant impact on vascular complications, as these imbalances were adjusted for in the multivariable analysis, and the characteristics regarding the access-site were similar. There was a high diversity of sheaths in the standard sheath group with various IDs and ODs, but the insertion profiles were homogeneous with values between 7.5 and 8.0 mm, and hence clearly differed from that of the Mesh_{only} with only 6.7 mm.

5. Conclusions

The application of the transGlide® mesh represents the approach with the currently lowest insertion profile for transfemoral implantation of the ACURATE neo™ device and comes close to a sheathless approach. This translates into a reduction of major vascular complications at the main access-site in comparison to the use of standard sheaths. Hence, it may be a viable option that could facilitate transfemoral TAVI even in suboptimal and smaller vascular anatomy and thereby expand the spectrum of patients who can be treated with this device.

Conflicts of interest statement

WK: proctor for Symetis SA/Boston Scientific and St. Jude Medical/Abbott, received speaker fees from Symetis SA, St. Jude Medical, and Edwards Lifesciences. NM: received speaker fees from Symetis SA/Boston Scientific, Edwards Lifesciences and Medtronic, received consultant fees from Biotronik. FG: proctor for Symetis SA/Boston Scientific. OH: proctor for Symetis SA/Boston Scientific. MR: received speaker fees from St. Jude Medical. CL: received speaker fees from Abbott, Astra Zeneca, Bayer, Berlin-Chemie, Boehringer Ingelheim, Daiichi Sankyo, Elixir, and Pfizer. MD: proctor for Symetis SA/Boston Scientific and St. Jude Medical/Abbott. CH: Advisory board Medtronic. AL: received speaker's fees from or served as a consultant for Medtronic, St. Jude Medical, Claret Medical Inc., Boston Scientific, Edwards Lifesciences, Symetis and Bard, and owns stock options from Claret Medical Inc. ST: Proctor and consultant for Symetis SA, Research Grant from Boston Scientific, Proctor and Consultant for nvt GmbH, speaker fees from Edwards Lifesciences and Medtronic Inc. HM: Proctor for Medtronic, St. Jude Medical, Symetis SA; speaker fees from Abbott, Edwards Lifesciences, Medtronic, St. Jude Medical, Symetis SA. All other authors state that they have no financial disclosures to declare.

Table 2
Predictors of major vascular complications.

	Univariable analysis Odds ratio (95% CI)	<i>p</i>	Multivariable analysis Odds ratio (95% CI)	<i>p</i>
Age, years	1.05 [0.97–1.13]	0.26		
Female gender	1.92 [0.71–5.23]	0.20		
Body surface area, m ²	0.24 [0.03–1.91]	0.18		
STS PROM, %	1.06 [0.99–1.15]	0.09		
eGFR, ml/min	0.99 [0.98–1.01]	0.42		
Hypertension	0.39 [0.05–2.94]	0.36		
Diabetes	1.96 [0.72–5.32]	0.19		
Peripheral vascular disease	1.02 [0.23–4.49]	0.98		
Coronary artery disease	0.66 [0.28–1.56]	0.34		
Experienced operator	0.32 [0.27–1.53]	0.32		
Access side left	3.11 [1.18–8.19]	0.02		
Access diameter < 6 mm	1.19 [0.88–1.63]	0.25		
Severe tortuosity	1.09 [0.44–2.68]	0.85		
Severe calcification	1.25 [0.42–3.78]	0.69		
SFAR	4.09 [0.80–20.85]	0.09		
TransGlide mesh only	0.19 [0.07–0.57]	0.003	0.10 [0.02–0.48]	0.004

Abbreviations: eGFR = estimated glomerular filtration rate, SFAR = sheath-to-femoral artery-ratio, STS PROM = Society of Thoracic Surgeons Score for Prediction of Mortality. Significant *p*-values are in bold.

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