Development of four different devices to turn over introducer sheaths

Jan Borggrefe, MD, Helmuth Knabe, MD, Beata Hoffmann, Martin Heller, MD, and **Jost Philipp Schäfer, MD,** *Kiel, Germany*

Introduction: **We developed four prototype sheath-turning auxiliary devices (STADs) and evaluated them in an in vitro study setup designed to enable the change of catheter direction in endovascular interventions.**

Methods: **Four different prototypes, A through D, of STADs were designed and created by modifying commercially available dilators and catheters. All STADs work with different anchor-like tips to ensure fixation inside the vessel at the puncture site. The STAD is loaded into the introducer sheath, retracted with the introducer sheath, and turned at the puncture site. The STADs were tested in an in vitro vascular study setup using bovine veins. Success rates and procedure times were calculated, and the handling, reliability, and overall performance were evaluated. The maximum soft tissue thickness (STTmax) applicable was tested using bovine vessels with 7-mm thickness surrounded by a soft tissue phantom consisting of chicken breast. A retrospective cross-sectional observation in 108 patients from our center was performed to provide mean STTmax at the common femoral artery in patients for comparison.**

Results: **The success rate ranged between 75% for prototype D and 90% for prototypes A and C. The procedure time averaged 60 seconds (range, 25-165 seconds). The mean handling was rated 2.4 (good) for prototype A, 2.0 (good) for prototype B, 2.6 (satisfactory) for prototype C, and 3.5 (poor) for prototype D. Mean reliability was rated 3.4 (satisfactory) for prototype A, 2.0 (good) for prototype B, 1.6 (good) for prototype C, and 2.4 (good) for prototype D. Mean overall performance was rated 2.0 (good) for prototype C, 2.6 (satisfactory) for prototype B, 3.3 (poor) for prototype D, and 3.4 (poor) for prototype A. In the cross-sectional patient observation, the mean STTmax was 3.3 cm (range, 0,5-13 cm) with a 95% confidence interval of the distribution including an STTmax of up to 8 cm. The STTmax was ≤5 cm in 100 of 108 patients (93%). The applicable STTmax for prototype A was 1 cm (8 of 10 successful cases), 3 cm for prototype B (9 of 10 successful cases), 5 cm for prototype C (8 of 10 successful cases), and 3 cm for prototype D (7 of 10 successful cases).**

Conclusions: **All four STAD prototypes offered the ability of turning the sheaths at the puncture site in an in vitro vascular study setup. In the future, this concept may allow routine clinical performance of turning maneuvers at the groin vascular access site. (J Vasc Surg 2013;58:194-200.)**

Clinical Relevance: **We developed and tested four different turning devices that are loaded into an introducer sheath in interventions and that enable the introducer sheath to be turned in a blood vessel. There is no standard procedure or dedicated device on the market that allows such a function in interventional procedures, such as at the groin vascular access site or on venous shunts. The idea is to offer a safe method to perform such procedures to facilitate angiographic diagnostics and to improve the safety of interventions by means of reducing the number of punctures that are being performed as well as the time of the intervention.**

Peripheral arterial occlusive disease (PAOD) is a common disease associated with nicotine abuse, hypertension, and diabetes that concerns >5% of the population aged ≥70 years.[1-3] Because PAOD is a systemic disease, treatment by endovascular intervention is often indicated in the arteries of both legs at the same time.[2,3] The intended use of regular sheaths commercially available for percutaneous vascular access is to operate in one direction only, retrograde or antegrade. If it is necessary to treat additional lesions located in the opposite direction of the chosen access path, a secondary puncture, usually in another session, is performed. Complications are thus more likely to occur because the chance of incidental complications increases with the number of puncture sites and interventional approaches.[4,5] To minimize the procedural risk and cost, the number of interventions should be minimized.

In special indications, several catheter maneuvers have been reported of conversion of a retrograde access to an antegrade access by use of commercially available materials.[3,6-10] The off-label use of catheters for turning maneuvers is limited due to the high risk of losing the vascular access. Further, the catheters, which are not designed for the maneuver, may compromise patient safety because they can lead to severe vessel damage at the puncture site. To improve safety and implement a standard for

From the Klinik für Diagnostische Radiologie, Universitätsklinikum Schleswig-Holstein, Campus Kiel.

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Reprint requests: Jan Borggrefe, MD, Arnold-Heller-Str 3, 24118 Kiel, Germany (e-mail: jan.borggrefe@rad.uni-kiel.de).

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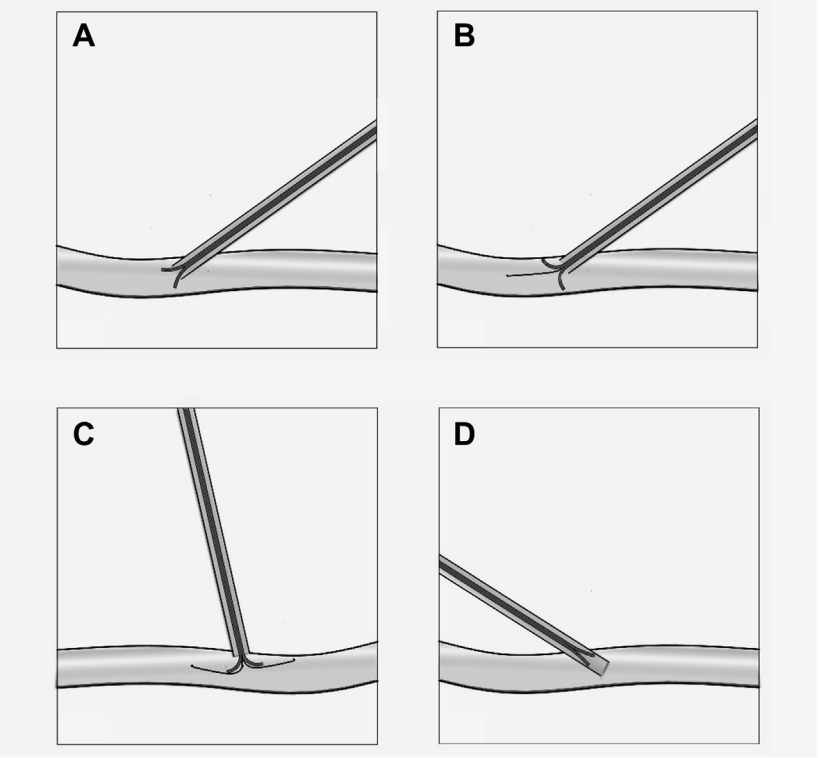

Fig 1. Turning maneuver with prototype A. **A,** A sheath is placed in a blood vessel. The sheath-turning auxiliary device (STAD) is loaded in the sheath while a guidewire can be kept in place. The split tip of the STAD spreads apart when reaching the endovascular position. **B,** The STAD with the sheath is retracted. When the split tip reaches the puncture site, the STAD and the sheath are flipped as shown. **C,** The wire is guided into the opposite direction. **D,** The STAD is pulled out.

turning maneuvers at the puncture site, we developed sheath turning auxiliary devices (STADs) enabling the conversion of a retrograde access to an antegrade access in the common femoral artery (CFA).

This report describes the four prototypes of these STADs and presents experimental results of the clinical applicability to define the clinical opportunities connected with their development. For this purpose, we examined the performance of preliminary handmade prototypes in an experimental study setup. The four major end points were to investigate the approximate success rate, the clinical acceptance by a group of testing radiologists, an approximate time range that is necessary for the procedure, and the maximum applicable soft tissue thickness (STTmax) between the cutis and the targeted vessel because the common finding of patient adiposity might limit the success of the procedures.

METHODS

We developed four different STAD prototypes by modifying commercially available dilators and catheters. These STADs have anchor-like tips that can be deployed and removed by different mechanisms. The STADs are loaded into the introducer sheath. When the device is in place, the anchor can be released, and the device with the introducer sheath can be pulled back until the anchor reaches the inner vessel wall at the puncture site. In that position, the anchor hooks in and ensures the introducer sheath with the STAD will remain inside the vessel lumen. Now, the introducer sheath with the STAD can be flipped and inserted into the vessel pointing in the opposite direction. The anchor is retracted, and the STAD is pulled out. The STAD prototypes work in detail as follows:

STAD prototype A. The tip of a dilator was truncated and split into half for a length of 3 mm and shaped and tempered by heating in a water quench to ensure that both parts stayed in shape apart from each other, creating a bird's wing-like tip (Fig 1). The new tips are semirigid to maintain flexibility, can be pressed together in a closed position, and can thus be loaded into the introducer sheath. When the split tip leaves the end of the introducer sheath, the two parts will spread apart again in an open position. A guidewire can be kept in place. The STAD with the sheath is retracted, and the bird's wing-like tip ensures fixation inside the vessel at the puncture site by gentle resistance. After guiding the wire into the opposite direction, the STAD is exchanged for a regular dilator to reinsert the sheath.

STAD prototype B. An incision was made at the tip of a dilator with a reverse angle of 30° at a distance from