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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

# Starclose SE® hemostasis after 6F direct antegrade superficial femoral artery access distal to the femoral head for peripheral endovascular procedures in obese patients

Stavros Spiliopoulos
Panagiotis Kitrou
Nikolaos Christeas
Dimitris Karnabatidis

**PURPOSE**
Direct superficial femoral artery (SFA) antegrade puncture is a valid alternative to common femoral artery (CFA) access for peripheral vascular interventions. Data investigating vascular closure device (VCD) hemostasis of distant SFA 6F access are limited. We aimed to investigate the safety and effectiveness of the Starclose SE® VCD for hemostasis, following direct 6F antegrade SFA access distal to the femoral head.

**METHODS**
This prospective, single-center study included patients who were not suitable for CFA puncture and were scheduled to undergo peripheral endovascular interventions using direct antegrade SFA 6F access, at least 2 cm below the inferior edge of femoral head. Hemostasis was obtained with the Starclose SE® VCD (Abbott Laboratories). Primary endpoints were successful hemostasis rate and periprocedural (30-day) major complication rate. Secondary endpoint was the rate of minor complications. Clinical and Doppler ultrasound follow-up was performed at discharge and at one month.

**RESULTS**
Between September 2014 and August 2015, a total of 30 patients (21 male; 70.0%) with a mean body mass index of 41.2 kg/m$^2$ were enrolled. Mean age was 72±9 years (range, 67–88 years). Most patients suffered from critical limb ischemia (87.1%) and diabetes (61.3%). Calcifications were present in eight cases (26.6%). Reason for direct SFA puncture was obesity (100%). Successful hemostasis was achieved in 100% of the cases. No major complications were noted after one-month follow-up. Minor complications included two <5 cm hematomas (6.6%) not necessitating treatment.

**CONCLUSION**
In this prospective study, Starclose SE® VCD was safe and effective for hemostasis of antegrade direct SFA puncture. Uncomplicated hemostasis was achieved even in cases of puncturing 2 to 7 cm below the inferior edge of the femoral head.

Percutaneous endovascular interventions have become a standard method of treatment of peripheral arterial disease (PAD), demonstrating satisfactory clinical outcomes with excellent safety profile (1, 2). Arterial access is the first and one of the most important stages of lower limb interventions. Ideal arterial access for peripheral endovascular procedures is conventionally obtained by puncturing the mid segment of the common femoral artery (CFA). The main reasons for this approach are puncture ease, because CFA is adequately sized, palpable and therefore easily accessible in most cases, as well as safety because the artery can be compressed against the underlying femoral head to achieve hemostasis. Caudal punctures, below the femoral head at the level of the superficial femoral artery (SFA) have been associated with increased bleeding related complications, such as pseudoaneurysms and large hematomas, due to the lack of underlying bony structure and support by the femoral sheath (3–5).

In peripheral interventions, antegrade CFA provides a shorter distance to access lesion and is mainly recommended in cases in which no iliac inflow disease is present, where pushability and torcability is required to recanalize distal complex lesions such as infrapopliteal or long SFA calcified occlusions. Nevertheless in cases of aortobifemoral surgical bypass, iliac artery occlusion or marked aortoiliac angulation and tortuosity not permitting the "up and over" technique using retrograde contralateral CFA puncture, ipsilateral antegrade puncture is mandatory. Antegrade puncture is technically more demanding com-

From the Department of Interventional Radiology (S.S ✉ *stavspiliop@upatras.gr*), Patras University Hospital, Rio, Greece.

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pared with the retrograde approach and has also been related with increased bleeding complication rates (6). Among the main reasons to avoid or fail to obtain ipsilateral antegrade access is the presence of a "hostile" abdomen, in obese patients (5).

Growing experience with ultrasonography (US)-guided arterial puncture allowed physicians to obtain accurate, fast, safe, and nearly painless antegrade access even in not easily palpable arteries such as the SFA (7). Moreover, using vascular closure devices (VCD) provides hemostasis, minimizing the risk of bleeding even after low SFA puncture (8). Using VCD following percutaneous access for percutaneous peripheral interventions has been widely accepted in every day clinical practice, as according to randomized trials it reduces time to hemostasis and ambulation; VCD has also been reported to demonstrate a superior safety profile compared with manual compression (9, 10).

The safety and efficacy of Starclose SE® extraluminal VCD in obtaining hemostasis following antegrade CFA access for peripheral arterial interventions has been widely reported (11, 12). However, data regarding its use in antegrade direct SFA access remain limited (8). The aim of this study was to investigate the safety and feasibility of the off-label Starclose SE® VCD use in achieving hemostasis following direct superficial femoral artery 6F access, far below the level of the femoral head, in patients undergoing peripheral endovascular interventions, in cases not suitable for contralateral retrograde or ipsilateral antegrade CFA access.

**Main points**

- Direct antegrade puncture of the superficial femoral artery (SFA) below the femoral head may be required for infrainguinal endovascular procedures in obese patients but entail increased bleeding risk, due to the lack of underlying bony structure and support by the femoral sheath.
- In this prospective trial, which included 30 obese patients (mean body mass index 41.2 kg/m$^2$), direct antegrade SFA punctures were performed followed by 6F sheath positioning, 2 to 7 cm below the inferior edge of the femoral head, for the endovascular treatment of infrainguinal arterial disease.
- Hemostasis using the Starclose SE® arterial closure device was 100% successful with no major complications occurring after one month of follow-up.
- Two small <5 cm hematomas (6.6%) were noted but did not require further treatment.

**Table 1.** Inclusion and exclusion criteria of the study

| |
|---|
| Inclusion criteria |
| Age ≥18 years |
| US-guided, direct, antegrade SFA puncture ≥2 cm below the inferior edge of the femoral head, confirmed with fluoroscopy |
| Contralateral retrograde not possible or not preferred by performing physician |
| CFA access deemed not possible due to large abdomen confirmed with Doppler US |
| 6F sheath for arterial access |
| Starclose SE® device used to obtain hemostasis |
| No restriction in arterial calcification grade |
| Patients suffering from either IC or CLI |
| Exclusion criteria |
| Inflow iliac artery or CFA significant stenosis |
| Proximal SFA significant >50% stenosis requiring treatment |
| SFA diameter at puncture site ≤4 mm |
| Direct SFA puncture at the level of the femoral head due to cranial CFA bifurcation |
| Uncorrectable coagulopathy (INR >1.5, PLT <50.000) |
| Acute limb ischemia |
| History of severe allergy to contrast media |

US, ultrasonography; SFA, superficial femoral artery; CFA, common femoral artery; IC, intermittent claudication; CLI, critical limb ischemia; INR, international normalized ratio; PLT, platelet count.

## Methods

### Study design

This was a prospective, single-center, single-arm study approved by the Hospital's Scientific and Ethics Committee. Written informed consent regarding the risk and benefits of the procedure was obtained from all participating patients. The study included patients in which the Starclose SE® VCD (Abbott Laboratories) was used for hemostasis following direct antegrade SFA access for peripheral arterial endovascular interventions. The study included patients undergoing direct SFA access performed in cases of inability to gain antegrade CFA access and in cases were contralateral retrograde CFA access was deemed unfavorable or impossible, due to specific anatomical and/or procedural details such as unfavorable iliac anatomy for "up and over" technique or treatment of distal crural disease. The exact puncture site was confirmed with fluoroscopy, measured with a radiopaque ruler, and recorded. SFA access at the level of the femoral head (due to more cranial location of the CFA bifurcation) or <2 cm distal to the lower limit of the femoral head were excluded from the analysis. Cases in which a 4F sheath was used were also excluded. The study's inclusion and exclusion criteria are reported in Table 1. In total 30 patients (21 male; 70.0%; mean age, 72±9 years; range, 67–88 years) were enrolled between September 2014 and August 2015. Patients' demographics and access variables are reported in Table 2. Reference vessel diameter was measured using CTA imaging during preprocedural planning or using US just prior puncture, while arterial calcifications at the puncture site were graded using fluoroscopy as: 0, no calcifications; 1, mild calcifications; 2, moderate; and 3, severe calcifications, as reported before (8).

Study's primary endpoints were: 1. Successful hemostasis rate defined as the achievement of complete hemostasis following VCD deployment including additional 2–3 minutes prophylactic manual compression, without any signs of major acute bleeding or ischemic complications. 2. Periprocedural (30-day) major complications rate. Secondary endpoint was the rate of puncture site-related minor complications. Major and minor complications were defined according to the SIR reporting standards (13).

| **Table 2.** Demographics and procedural details | |
|---|---|
| Patients (n) | 30 |
| Age, years | 72±9 (67–88) |
| Starclose SE® VCD deployments, n | 30 |
| Diabetes mellitus | 19/30 (63.3) |
| Coronary disease | 22/30 (73.3) |
| Dialysis | 2/30 (6.6) |
| Smoking | 6/30 (20) |
| Hyperlipidemia | 26/30 (86.6) |
| Hypertension | 29/30 (96.6) |
| Body mass index, kg/m$^2$ | 41.2±4.3 (37–60.1) |
| Intermittent claudication | 3/30 (10) |
| Critical limb ischemia | 27/30 (90) |
| SFA diameter, mm | 5.8±0.8 (4.6–6.7) |
| Calcifications at access site | |
| None | 22/30 (73.3) |
| Mild | 5/30 (16.6) |
| Moderate | 1/30 (3.3) |
| Severe | 2/30 (6.6) |
| Distance from femoral head, cm | |
| ≥2 to ≤4 cm | 20/30 (66.6) |
| >4 to ≤7 cm | 10/30 (33.3) |

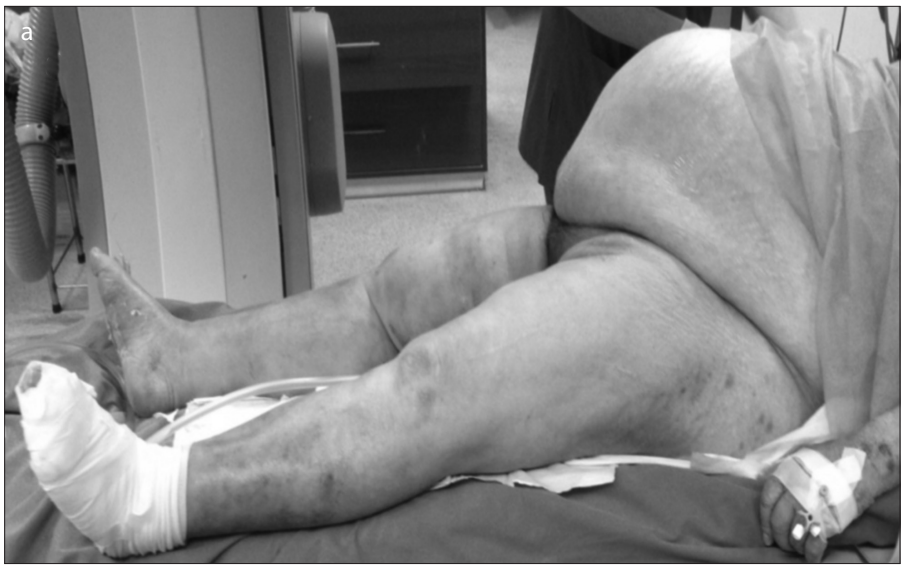
Continuous data are presented as mean±standard deviation (range); categorical data are presented as n (%).
VCD, vascular closure device; SFA, superficial femoral artery.

### Intervention

Patients were scheduled to undergo infrainguinal endovascular revascularization due to severe, life-style limiting, intermittent claudication (IC) or critical limb ischemia (CLI), diagnosed during preprocedural clinical and imaging assessment. Preprocedural imaging included Doppler US (DUS), computed tomography angiography (CTA), or intra-arterial digital subtracted angiography (DSA) in selected cases. Patients were prescribed dual antiplatelet therapy at least seven days prior to the procedure. Patients receiving oral anticoagulants (warfarin) were put on a bridge therapy and were advised to commence anticoagulation the day following the procedure. Preprocedural clinical and imaging assessment as well as all procedures in this study were performed by four interventional radiologists with more than 10-year experience in peripheral interventions, US-guided puncture and the use of the specific VCD under investigation. Preprocedural imaging assessment included review of the available imaging (CTA/DUS), while prior to the puncture, dual image-guidance with DUS using a 10 MHz probe and fluoroscopy was used in order to confirm the study's inclusion criteria such as inability to puncture the CFA due to a large abdomen, SFA puncture site ≥2 cm below the inferior edge of the femoral head, patency of the proximal segment of the artery, and diameter of the vessel ≥4 mm. US-guided local lidocaine infusion and arterial puncture was performed to reduce pain and achieve safe and rapid access with a single, anterior wall puncture, as described before (7). Arterial puncture was performed using a 21G, 4F micropuncture set (S-MAK™ Coaxial Mini Access Kit, Merit Medical™) to further reduce the risk of complications. The micropuncture introducer was then exchanged over a 0.035-inch stiff guidewire (Amplatz Super Stiff™, Boston Scientific; Radiofocus® Terumo) with a standard 6F arterial sheath. Following sheath positioning a bolus dose of 50 IU/kg of unfractioned heparin was administrated according to international guidelines (14, 15). Following completion of endovascular revascularization, hemostasis was achieved with the nitinol clip-based, StarClose SE® extraluminal VCD, as previously described for antegrade access, after meticulously creating a subcutaneous canal for clip deployment using mosquito forceps for bland dissection and exchanging the arterial sheath with the sheath of the VCD over a nonhydrophilic stiff guidewire (Amplatz Super stiff ™ guidewire, Boston Scientific) (11). For safety reasons, 2–3 minutes of manual compression was also applied. When hemostasis was confirmed patients were advised to lay flat for five hours and remained in the ward for surveillance. If no complications occurred, patients were discharged after clinical and DUS assessment of the groin by a member of the investigational team. Follow-up visit was scheduled at one month and included both clinical (clinical history, pulses check, risk factor modification, ankle brachial index, Rutherford classification) and DUS examination of puncture site. Patients were prescribed antiplatelet therapy based on the site and complexity of the revascularization and severity of the disease, for at least six months following the procedure.

## Results

In all patients, the reason for direct SFA puncture was the necessity of an ipsilateral antegrade access because CFA puncture was deemed technically improbable or impossible due to a hostile large abdomen (Fig. a). Mean body mass index was 41.2±4.3 kg/m$^2$ (range, 37–60.1 kg/m$^2$). Majority of the patients were suffering from CLI (90.0%; 27/30 patients) and diabetes (63.3%; 19/30 patients) and were on antihypertensive therapy (96.6%; 29/30 patients). Patients included in the study had preprocedural INR <1.5 and platelet count >150.000 cells per microliter. All punctures were performed in proximal SFA segments without stenosis, according to preprocedural imaging verified by preprocedural DUS just prior to puncture. In all cases, SFA puncture site was situated within ≥2 to ≤7 cm distance from the inferior edge of the femoral head (Fig. b). Mean arterial diameter was 5.8±0.8 mm (range, 4.6–6.7 mm). Calcifications were present in 26.6% (8/30 cases) and were graded as severe in 6.6% (2/30 cases). Successful hemostasis was obtained in all 30 cases (100%). Clinical and DUS assessment of the groin prior to discharge was performed in all patients, and no major complications were noted. Minor complications included two small <5 cm soft hematomas detected prior to discharge that did not ne-



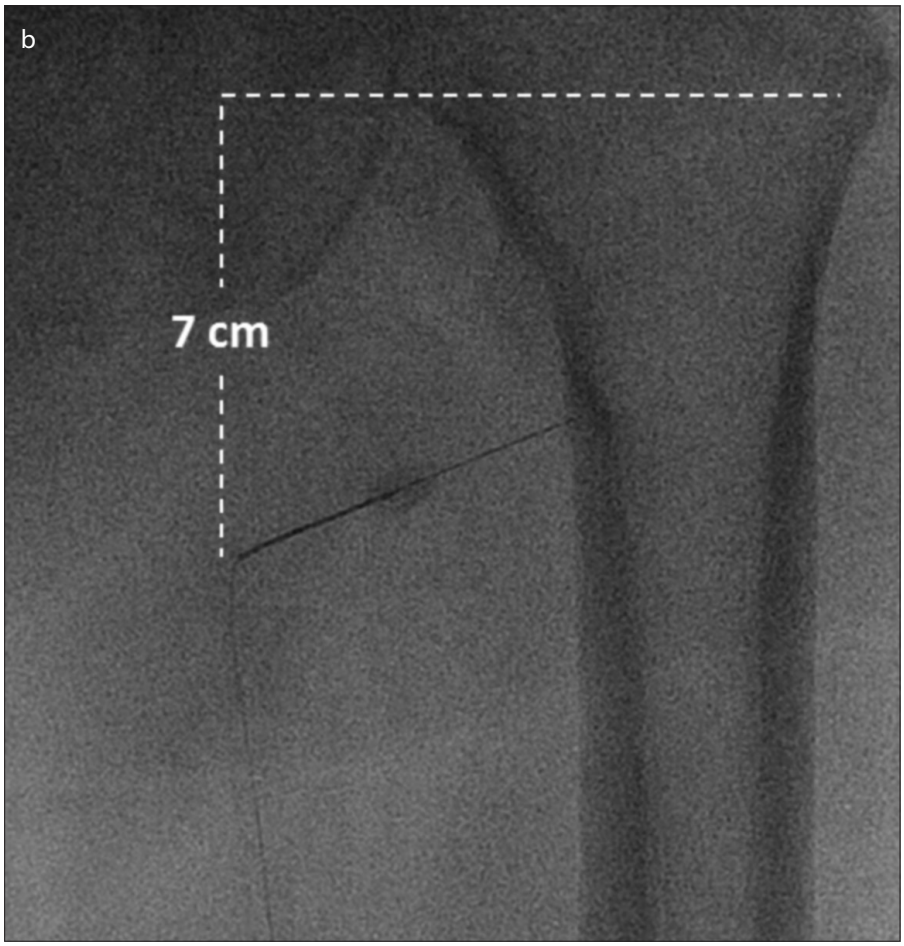




**Figure a, b.** Panel **(a)** shows a 71-year old female diabetic patient with critical limb ischemia in the left limb, having a body mass index of 60.1 kg/m$^2$. Panel **(b)** shows antegrade direct superficial femoral artery puncture 7 cm below the inferior edge of the femoral head.

cessitate any further treatment and self-resolved within 30 days. One-month follow-up was available in all patients and no major complications were noted. Patients remained asymptomatic and DUS scan did not detect any signs of pseudoaneurysm.

## Discussion

In this prospective study, using the Starclose SE® VCD, hemostasis was achieved in 100% of the cases, following direct antegrade SFA puncture and 6F sheath positioning 2 to 7 cm below the lower edge of the femoral head, without occurrence of any major complication at 30 days follow-up. The main advantage of using the Starclose SE® VCD is its extraluminal mechanism of hemostasis. Therefore, permanent intraluminal components are not present, and a very small percentage of vascular occlusion has been reported. Other advantages include the relative ease of deployment, the widely reported safety and efficacy in both antegrade and retrograde CFA punctures, and safety in several cases of direct SFA puncture. Usually bleeding complications occur due to suboptimal clip sealing or early patient mobilization, which are amenable to manual compression. The main disadvantages of this specific VCD include the possibility of delayed oozing or bleeding mainly in cases of hypertension and increased technical difficulty in clip deployment in obese patients, attributed to nonadequate aligning of the device as to successfully deliver the nitinol clip to the adventitia (11). Perhaps this technical detail is one of the main reasons for 100% of hemostasis achieved in this series, since in low SFA access there is no steep angulation between the artery and the device created by large abdomen, leading to easier clip deployment. Other reasons contributing to successful hemostasis could be the use of all devices in adequately sized arterial segments without stenosis, as well as the meticulous postprocedural care protocol involving interventional radiology or vascular surgery nurse and medical staff, familiar with endovascular procedures and their complications.

Interestingly, in this study nearly one-third of the arteries punctured were calcified, and in two cases severe calcifications were present. Although according to the manufacturing company, Starclose SE® VCD deployment in calcified arteries is contraindicated, calcifications did not influence the hemostasis or complication rates. Notably, its successful antegrade use in calcified vessels has been previously reported (11). Consequently, we believe that hemostasis can be achieved with this VCD in antegrade punctures of calcified below the femoral head SFA segments; however, it should be cautioned that technical failure is more possible because the device's hemostatic mechanism is based on constricting the outer arterial wall.

Data investigating the use of Starclose SE® VCD in direct antegrade SFA puncture

remain limited. In a prospective study investigating direct antegrade SFA puncture and hemostasis using US-guided compression proximal to SFA puncture against the femoral head, lower complication rates were reported. Specifically, Marcus, et al. (16) investigated 30 patients with a hostile groin that underwent direct SFA puncture and reported two access site complications. However, 4F sheaths were also used, and although the distance of puncture from the femoral head was not reported, retrograde punctures and high CFA bifurcation cases were included, indicating that these were punctures close to the femoral head. In another prospective trial, Gutzeit, et al. (17) investigated 100 US-guided direct antegrade SFA accesses, reporting a 15.7% complication rate, including 10.2% pseudoaneurysm formation, which is exceedingly higher than the reported 0.2% incidence of pseudoaneurysm formation during US-guided CFA punctures, as well as results herein presented (6, 16, 18). Still, hemostasis was again obtained mainly by manual compression (84 cases resulting in 9 pseudoaneurysms), while the Starclose SE® VCD was used in only 14 cases resulting in one pseudoaneurysm formation (17). In a subsequent retrospective study, the same group investigated the safety and efficacy of the Starclose SE® and Proglide Perclose© VCDs for achieving hemostasis after a direct SFA puncture. Devices performed similarly, resulting in low complication rates. All complications occurred in the Starclose SE® group (four pseudoaneurysms, one occlusion, and four hematomas) (19). In another retrospective analysis, Kweon, et al. (20) reported results from 28 planned SFA punctures. A VCD was deployed after two SFA punctures (7%), but Starclose SE® was not used. There was one minor groin hematoma in the SFA puncture group not requiring further treatment compared with six bleeding complications noted in the CFA puncture group (3.5%), two of which required urgent surgical operations (20). Finally, the ExoSeal VCD was also retrospectively analyzed in 110 SFA accesses using 5F to 7F sheaths, resulting in a 3.6% complication rate, including three pseudoaneurysms treated with thrombin injection and one large hematoma requiring blood transfusion (8).

According to the abovementioned data, an interesting detail of the present prospective study is that successful and uncomplicated hemostasis was achieved following distant SFA punctures performed even 4 to 7 cm below the inferior edge of the femoral head. Hemostasis at this particular anatomical location, far below the femoral head, in which SFA lays within thigh's musculature and not in proximity to bony structures, manual compression is much less effective than in cases of SFA puncture in proximity to the femoral head, where compression of the CFA suffices to attain hemostasis of proximal SFA puncture site. This has not been reported before, although a case report of safe hemostasis following popliteal artery puncture has been reported (21). Technical failure of VCD in such cases of low SFA access could be of increased risk of bleeding complications and therefore this particular approach should be undertaken in selected cases, such as CLI patients with no other endovascular or surgical options. In patients included in this study the indication for treatment was limb-threatening CLI, and alternative access or surgical management was not feasible. Nonetheless, it should be highlighted that the only major complication reported following direct SFA access is pseudoaneurysm formation, which usually can be easily treated using US-guided percutaneous thrombin injection, whereas complication following CFA punctures include life-threatening retroperitoneal hematomas necessitating surgical repair (19). Notably, all patients were receiving dual antiplatelet prior to and at the time of the procedure, as well as during the one-month follow-up period, without any bleeding complications.

Limitations of this study include the relatively small number of patients investigated, which is a significant bias for complication rates. If a considerably larger number of patients had been investigated, complications would have possibly been encountered. Moreover, single-center design does not allow generalized conclusions to be drawn regarding wider use of this strategy in every day clinical practice. Nevertheless, the quality of data and the prospective design of this study can support the safety of the method.

In conclusion, in this prospective single-center trial, hemostasis using the Starclose SE® extraluminal VCD was safe and effective, following US-guided, direct SFA antegrade 6F access for peripheral endovascular interventions in obese patients with a hostile groin. Uncomplicated hemostasis was achieved in all cases of puncture 2 to 7 cm below the inferior edge of the femoral head.

## Conflict of interest disclosure

The authors declared no conflicts of interest.

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