European Post-Market Clinical Experience with the Surfacer® Inside-Out® Access Catheter System

INTRODUCTION

The Surfacer® Inside-Out® Access Catheter System is uniquely designed to facilitate entry and placement of central venous access catheters in patients with venous obstruction. The Surfacer Device received a CE Mark and has been commercially available in Europe since mid-2016. Following the launch of the Surfacer System in the European Union (EU), Bluegrass Vascular has conducted post-market surveillance to gain insight on the use of the Surfacer System and to assess product performance.

BACKGROUND

Central venous access (CVA) is vital for the management of many chronic medical conditions. Access is typically obtained via one of four large upper body veins; the right (RIJ) or left (LIJ) internal jugular veins, or the right or left subclavian vein. Unfortunately, repeated access in these veins can lead to the development of thoracic central venous obstruction (TCVO) that can limit the ability to place catheters in patients. Studies have reported that TCVO occurs in 25% to 40% of patients with hemodialysis catheters.[1,2] Over time, the need to place catheters across all of a patient's central veins due to occlusions can result in the depletion of CVA sites.

The development of TCVO leads to the inability to utilize the affected veins for catheter placement and the sequential use of alternative venous access sites. TCVO often occurs first in the right internal jugular (RIJ) vein since this is the preferred anatomical location for catheter placement due to its ease of identification, large diameter, direct path to the right atrium and reduced risk of insertion-related and long-term complications.[3] While the left internal jugular vein (LIJ) is commonly utilized in patients whose RIJ is occluded, this placement location can be associated with reduced blood flow rates as well as greater risk of thrombosis or stenosis resulting from the tortuous route required for catheter placement and associated increased trauma to vessel walls.[4,5] This can affect the maturation of permanent access placed on the ipsilateral side.[6]

The development of bilateral obstruction of the thoracic veins is especially problematic since alternative catheter placement approaches using femoral, lumbar, or hepatic veins or obtaining access through the obstruction via sharp recanalization are technically difficult, poorly tolerated, and prone to higher risk of complications.[7,8]

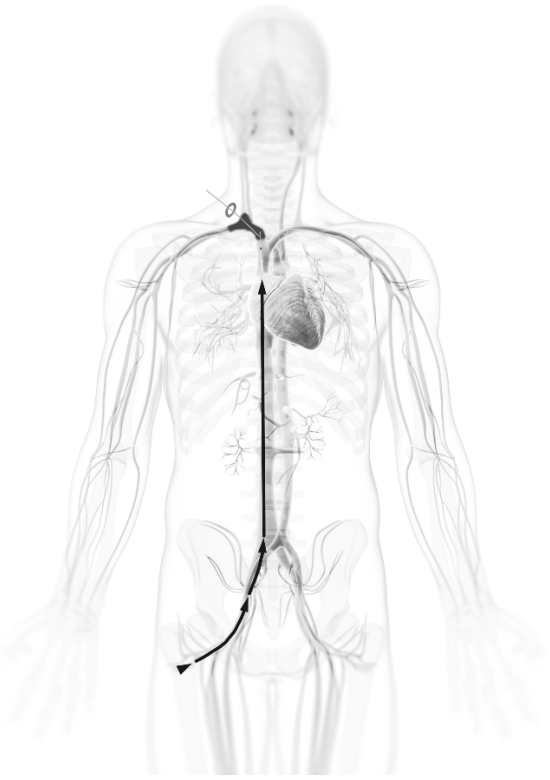
There are currently no effective low risk procedures which address this clinical issue. Femoral, translumbar and transhepatic approaches may provide short-term solutions but are time consuming and undesirable for obtaining long-term access due to invasiveness and serious risks associated with these procedures.

THE SURFACER® SYSTEM

While the Surfacer System uses the same basic technique as conventional CVA procedures, it accomplishes venous access in a reverse direction from the inside of the vasculature to the outside.[9] This "inside-out" approach enables the device to tunnel through or bypass the occlusion. The device is designed to enable repeated right-sided access for CVA in patients with obstructed thoracic veins.

The Surfacer Device is percutaneously introduced into the right femoral vein through the Workstation Sheath and then advanced upwards through the inferior vena cava and the superior vena cava (SVC) to the location of the occlusion (Fig. 1). After advancement of the device tip to the supraclavicular area and visualization via fluoroscopy, the Needle Guide is oriented to exit to a pre-determined external target and the Needle Wire is advanced externally. Once the Needle Wire exits the skin, the Peelable Introducer is loaded onto the wire and pulled into the vascular system below the site of the occlusion. A central venous catheter is then inserted into the vasculature through the Peelable Introducer.

Fig. 1. Anatomical path for the Surfacer® Inside-Out® access procedure

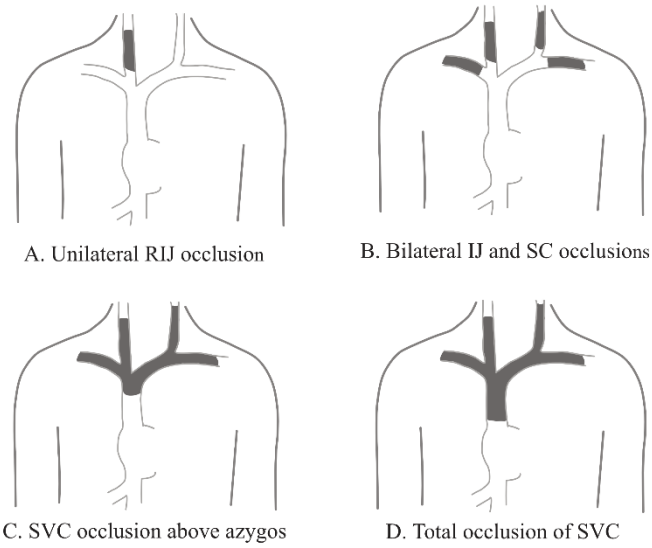


The use of the Surfacer System provides potential clinical benefits which cannot be achieved with alternative approaches currently being utilized in patients with TCVO. For hemodialysis patients, the ability to avoid the placement of catheters via the more tortuous approach associated with left-sided thoracic veins also has the potential to improve the ability to create or mature permanent arteriovenous (AV) access on the contralateral side, since catheter placement on the ipsilateral sides has been demonstrated to have a negative impact on fistula outcomes.[6,10] Achieving the ability to utilize an AV fistula as opposed to the prolonged use of a catheter for hemodialysis access has clear clinical and economic benefits.[11,12]

Prior to commercialization in the European Union, the Surfacer System was utilized for 12 patients with TCVOs in an IRB approved clinical investigational study.[9] Subsequent to receiving CE Mark, the Surfacer Device has now been utilized to enable catheter placement in over 250 patients with TCVOs worldwide.

The present analysis reports on post-commercialization experience with the Surfacer System in patients from over 30 hospitals and clinics, primarily in Europe. The information below is based on data obtained via device evaluation forms completed for patients at these sites. This form was designed to enable the identification of the clinical condition that necessitated central venous access, the type of occlusion (Fig. 2), procedural times, and the assessment of product performance. Specific patient demographic information was not collected for privacy reasons.

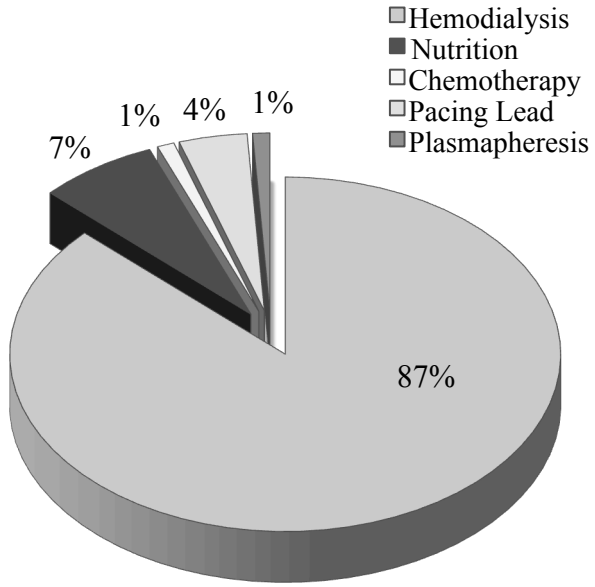
Fig. 2. Categories of thoracic central venous occlusions (TCVOs)



RESULTS

Evaluation forms were completed for a total of 95 patients undergoing the Surfacer procedure between July 2016 and March 2019. As shown in Figure 3, 87% of patients in this series required central venous access for delivery of hemodialysis. Table 1 summarizes the locations for venous occlusions in this patient population. This included 21.7% of patients with an occlusion of the RIJ alone, 25.3% of patients with bilateral occlusions of their IJs and subclavian veins, and 38.6% of patients with occlusions of the superior vena cava above the azygos vein, 9.6% with total occlusion of the superior vena cave (SVC) and 2.4% with unilateral left or right IJ with subclavian vein occlusions.

Fig. 3. Clinical reason why central venous access was required



The median total cumulative procedure time for this patient series was 50.0 minutes (range 9 to 175 minutes). The median time required for the Surfacer procedure, Workstation Sheath insertion to Surfacer Device removal, was 18.0 minutes (range 3 to 125 minutes). Figure 4 summarizes the range of Surfacer procedure times for the present patient series.

One Surfacer procedure had to be terminated due to abnormal anatomy of the patient due to Kleinfelder's syndrome. Central venous access was successfully obtained for all remaining patients. Physicians performing the procedure reported they were very satisfied with the handling of the Surfacer Workstation Sheath and the ability to visualize the obstruction and device during the procedure.

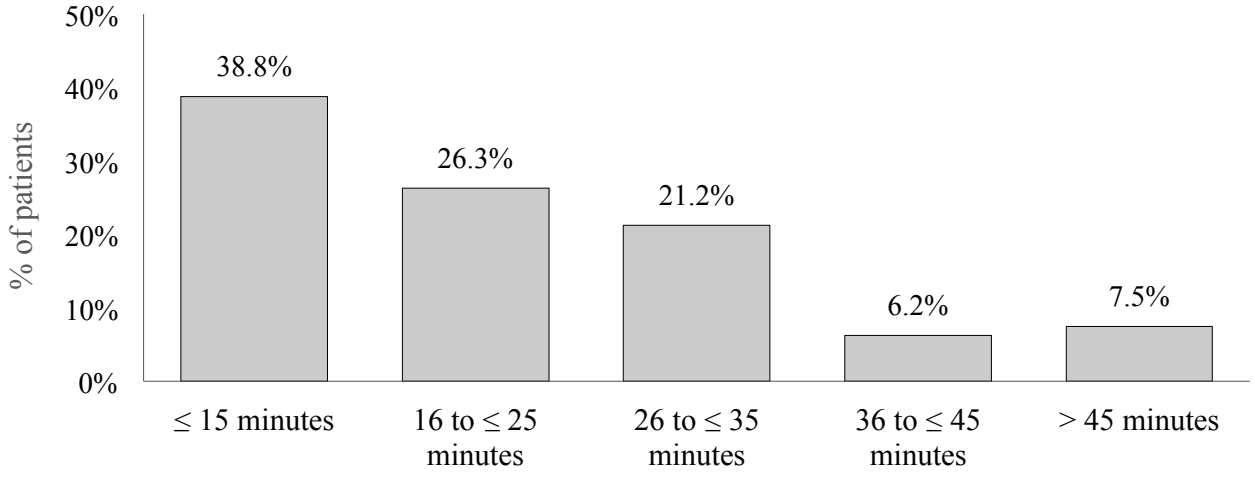
While the desired access was obtained for all patients, some resistance of the Surfacer Device advancing through the Workstation Sheath was reported for 10.4% of the procedures. Physicians reported that for 98.8% of the procedures, they were easily able to visualize the external Exit Target and advance the Needle Wire externally to this target.

Table 1. Summary of anatomical location for venous obstructions

Location of venous obstruction	% of patients
Unilateral RIJ occlusion	21.7%
Bilateral IJ and SC occlusions	25.3%
SVC occlusions above azygos	38.6%
Total occlusion of the SVC	9.6%
Right IJ and SC occlusions	1.2%
Left IJ and SC occlusions	1.2%
Other	2.4%

The Surfacer System was used a second time to obtain right-sided access in five patients. Three patients required catheter replacement for medical reasons following initial successful catheter placement with the Surfacer System. Two additional patients achieved subsequent successful catheter replacement with the Surfacer System following the development of catheter infections which required catheter removal. These infections were unrelated to the use of the Surfacer System.

Fig. 4. Time required for Surfacer Procedure



From a device safety perspective, no device-related adverse events or complications were reported for any of the patients in the present series. One procedure-associated patient death was reported, however, the cause of death for this patient was associated with a subsequent adjunctive procedure that was performed following the use of the Surfacer System. The death was determined to be unrelated to the use of the Surfacer Device.

CONCLUSION

This summary provides an updated clinical summary associated with the commercial use of the novel Surfacer System. The Surfacer Device enabled the right-sided placement of central venous catheters in patients with thoracic central venous occlusions requiring dialysis or other catheter-based therapies. Clinical experience with the Surfacer System to date supports that the Inside-Out endovascular procedure can be performed efficiently and safely using a standard fluoroscopy with no need for a specialized angiography room. For patients with catheter dysfunction, the Surfacer System is a viable option to achieve reliable and repeatable right-sided central venous access, preserving the viability of secondary central veins (Don't Go Left™).

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BLUEGRASS VASCULAR

12500 Network Boulevard, Suite 308
San Antonio, TX 78249 USA
Phone: +1 210.558.0819

bluegrassvascular.com

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