Surfacer® Inside-Out® Catheter Access System Literature Summary

As of September 2022 there have been 13 peer-reviewed publications reporting on the use of the Surfacer System to gain central venous access in patients with thoracic central venous obstructions (TCVOs).[1-13] These publications include the results of prospective, multicenter single-arm studies, case series, case reports and a comprehensive review associated with the use of the device.

Below is table which reports the results from three multicenter studies published to date which report on the use of the Surfacer System. This is followed by a summary of each publication.

Full copies of each publication can be found at:
https://drive.google.com/drive/folders/1idGlLKntAzAzr8dVu2U7znWMonLNasl3?usp=sharing

References:

1. Razavi MK, Peden EK, Sorial E, Ross JR, Aruny JE, Pflederer TA, et al. Efficacy and safety associated with the use of the Surfacer® Inside-Out® Access Catheter System: Results from a prospective, multicenter Food and Drug Administration-approved Investigational Device Exemption study. J Vasc Access. 2021 Jan;22(1):141-146. doi: 10.1177/1129729820937121.

2. Gallieni M, Matoussevitch V, Steinke T, Ebner A, Brunkwall S, Cariati M, et al. Multicenter Experience with the Surfacer Inside-Out Access Catheter System in Patients with Thoracic Venous Obstruction: Results from the SAVE Registry. J Vasc Interv Radiol. 2020 Oct;31(10):1654-1660.e1. doi: 10.1016/j.jvir.2020.06.020.

3. Reindl-Schwaighofer R, Matoussevitch V, Winnicki W, Kalmykov E, Gilbert J, Matzek W, Sengölge G. A Novel Inside-out Access Approach for Hemodialysis Catheter Placement in Patients With Thoracic Central Venous Occlusion. Am J Kidney Dis. 2020 Apr;75(4):480-487. doi: 10.1053/j.ajkd.2019.08.024.

4. Galas N, Shahverdyan R. Use of the Surfacer® Inside-Out® Catheter Access System to Obtain Central Venous Access in Dialysis Patients With Thoracic Venous Obstructions: Single-Center Series. Vasc Endovascular Surg. 2021 Apr;55(3):228-233. doi: 10.1177/1538574420980604.

5. Hentschel DM, Minarsch L, Vega F, Ebner A. The Surfacer® Inside-Out® Access System for right-sided catheter placement in dialysis patients with thoracic venous obstruction. J Vasc Access. 2020 Jul;21(4):411-418. doi: 10.1177/1129729819867547.

6. Azoulay A, Gaudin A, Mallios A. Extra-anatomical endo-bypass between left arm vascular access and superior vena cava. J Vasc Surg. 2022 Jun;75(6):2072-2073. doi: 10.1016/j.jvs.2021.10.004.

7. Huang C, Smeds MR. Use of the Surfacer® Inside-Out® access catheter system to place permanent dialysis access via hemodialysis reliable outflow (HeRO) graft. Ann Vasc Surg – Brief Reports and Innovations. 2021; 1(2). https://doi.org/10.1016/j.avsurg.2021.100026

8. Qi Tian T, Hao Yun Y, Jia Sheng T, Tjun Yip T, Tieng Chek EC. Use of Surfacer, an inside-out device, in tandem with HeRO graft for creation of vascular access: Case report of three patients with 18-months follow up. J Vasc Access. 2021 Aug 31:11297298211041434. doi: 10.1177/11297298211041434.

9. Tonko JB, Black SA, Rinaldi CA. "Inside-Out" Central Venous Access approach with infraclavicular exit for right-sided CRT-D Implantation in bilateral brachiocephalic and superior vena cava occlusion. Clin Case Rep. 2021 Apr 4;9(6):10.1002/ccr3.3980. doi: 10.1002/ccr3.3980.

10. Baetens TR, Rotmans JI, van der Meer RW, van Rijswijk CS. A novel technique to restore access in patients with central venous occlusion using the Surfacer® Inside-Out® Access Catheter System. J Vasc Access. 2020 Sep;21(5):778-782. doi: 10.1177/1129729820909730.

11. Quek LHH, Tan TSM, Tan GWL, Pua U. Salvage of exhausted neck access using a novel inside-out device in dialysis-dependent patients. Hemodial Int. 2019 Oct;23(4):E111-E114. doi: 10.1111/hdi.12770.

12. Klepanec A, Hoferica M, Harsany J, Sengölge G. Dialysis vascular access restoration by a transcollateral approach using the Surfacer® Inside-Out® Access Catheter System. J Vasc Access. 2022 Apr 8:11297298221085457. doi: 10.1177/11297298221085457. Epub ahead of print. PMID: 35394391.

13. Razavi MK. Overview of the safety and efficacy of the Surfacer® Inside-Out® Access Catheter System for obtaining central venous access in patients with thoracic central venous obstructions. Expert Rev Med Devices. 2020 Sep;17(9):937-944. doi: 10.1080/17434440.2020.1825938.

	U.S. IDE Study [1]	International Registry [2]	Independent Multicenter Study [3]
Trial design	Prospective, single-arm, multicenter study	Prospective, single-arm, multicenter study	Retrospective, single-arm, multicenter study
Evidence level	IV	IV	IV
Year(s) performed	2017-2019	2017-2018	2016-2018
Main inclusion criteria	Patients referred for placement of CVC with limited or diminishing upper body venous access or pathology impeding standard access methods	Patients referred for placement of a CVC with limited or diminishing upper body venous access pathology	Patients with bilateral TCVO requiring urgent vascular access and patients with right-sided TCVO requiring a CVC
Number of study sites	7	5	3
Site locations	USA	Austria, Germany, Italy and Uruguay	Austria, Germany United Kingdom
Number of patients	30	30	32[*]
Mean age, years ±SD, (range)	55.5 ± 12.9 (30-79)	60.1 ± 12.8 (38-80)	59 [d] (20-82)
Gender (males/females)	15/15	18/12	6/26
% requiring venous access for hemodialysis	28 (93.3%)	29 (96.7%)	100%
TVCO type, number of patients (%)			
Type 1	7 (23.3%)	8 (26.7%)	3 (8%)
Type 2	6 (20.0%)	5 (16.7%)	27 (75%)
Type 3	16 (53.3%)	8 (26.7%)	3 (8%)
Type 4	1 (3.3%)	9 (30.0%)	3 (8%)
Number of patients obtaining successful catheter placement (%)	27/30 (90%)	29 (96.7%)	38 (97.4%)
Mean procedure time, minutes ±SD (range)	44.1 ± 30.6 [a] (10-130)	24 ± 14.9 [b] (6-70)	43 [c,d] (25 to 80)
Mean fluoroscopy time, minutes ±SD (range)	11.2 ± 9.72 (2.5-49.4)	6.8 ± 4.5 (2.2-25.5)	6 [d] (2-14)
Mean contrast used, mL ±SD (range)	95.4 ± 107.3 (5-360)	29.7 ± 22.2 (6-100)	15 [d] (0-90)
Device-related complications	None	None	None

CVC = Central venous catheter, SD = Standard deviation, TCVO = Thoracic central venous obstruction

[*] 7 patients repeated the procedure during the study period but more than 3 months following initial procedure in order to replace a malfunctioning catheter

[a] from initial femoral access through skin closure

[b] from initial device insertion to removal of the workstation sheath

[c] initial femoral access to end of central venous catheter implantation

[d] Standard deviation not reported

Prospective, multicenter, single-arm studies

1. Razavi MK, Peden EK, Sorial E, Ross JR, Aruny JE, Pflederer TA, Wasse H, Haskal ZJ. Efficacy and safety associated with the use of the Surfacer® Inside-Out® Access Catheter System: Results from a prospective, multicenter Food and Drug Administration-approved Investigational Device Exemption study. J Vasc Access. 2021 Jan;22(1):141-146. doi: 10.1177/1129729820937121.

   ClinicalTrials.gov Identifier NCT03209050.

   SYNOPSIS:

   - Prospective, single-arm, multi-center FDA Investigational Device Exemption (IDE) study to demonstrate the safety and efficacy of the Surfacer System
   - 30 patients enrolled at 7 US centers (50%/50% male/female, mean age 55.5+/-12.9
   - 90% Success Rate in Achieving Central Venous Access (27/30); three conversions/incomplete procedure due to tortuous anatomy
   - No device related adverse events/complications, procedure related complications (13%), none considered "device related"

   ABSTRACT

   Purpose: Thoracic central venous obstruction is commonly associated with the use of central venous catheters. The *Surfacer System to Facilitate Access in Venous Occlusions* Study was an Food and Drug Administration-approved US Investigational Device Exemption study designed to evaluate the performance and safety of the Surfacer System when used to facilitate central venous access in patients with thoracic central venous obstruction.

   Methods: Thirty patients were enrolled in this prospective, multicenter, single-arm study between December 2017 and May 2019. Device performance and adverse events were collected peri-procedurally and at discharge. Enrollment included 15 female and 15 male subjects with a mean age of 55.5 ± 12.9 (range: 30-79) years. Twenty-eight patients (93.3%) required central venous access for hemodialysis access. Locations of thoracic central venous obstruction were graded from 1 to 4 based on severity and extension of venous occlusions. Seven patients (23.3%) had type 1, 6 (20.0%) type 2, 16 (53.3%) type 3, and 1 (3.3%) type 4 obstruction.

   Results: Successful central venous catheter placement was achieved in 27 of 30 patients (90.0%). The procedure was discontinued in three (10.0%) due to tortuous anatomy discovered intraprocedurally. All 27 patients with successful CVC placement achieved adequate catheter patency and tip positioning with a mean overall procedural time and time to achieve central venous access with the Surfacer System being 44.1 ± 30.6 and 19.1 ± 25.1 min, respectively. There were no device-related adverse events or catheter malposition.

Conclusion: The results of the SAVEUS Study confirm the safety and efficacy of the Surfacer System and the Inside-Out procedure when used for the placement of right-sided central venous access in patients with thoracic central venous obstruction.

2. Gallieni M, Matoussevitch V, Steinke T, Ebner A, Brunkwall S, Cariati M, Gallo S, Reindl-Schwaighofer R, Sengölge G. Multicenter Experience with the Surfacer Inside-Out Access Catheter System in Patients with Thoracic Venous Obstruction: Results from the SAVE Registry. J Vasc Interv Radiol. 2020 Oct;31(10):1654-1660.e1. doi: 10.1016/j.jvir.2020.06.020.

   ClinicalTrials.gov Identifier NCT02875899

   SYNOPSIS:

   - prospective, single arm, multicenter international post-market registry study
   - 30 patients enrolled, 60% male/40% female, with mean age 60.1 ± 12.8 (38-80)
   - 97% technique success rate (29/30), one case discontinued due to vascular anatomical tortuosity
   - No complications or "device related" adverse events

   ABSTRACT

   Purpose: To report the device performance and safety for the Surfacer Inside-Out access catheter system in patients with thoracic central venous obstruction (TCVO) requiring central venous access (CVA).

   Materials and methods: Five sites prospectively enrolled 30 patients requiring a tunneled dialysis catheter between February 2017 and September 2018 in the SAVE (Surfacer System to Facilitate Access in Venous Obstructions) registry. Patient demographics, medical history, and type of TCVO were documented at enrollment. Device performance and adverse events were collected during the procedure and upon hospital discharge. Twenty-nine of the 30 patients enrolled required CVA for hemodialysis. Retrospective classification of TCVOs according to SIR reporting standards showed 9 patients (30%) had Type 4 obstructions, 8 (26.7%) had Type 3, 5 (16.7%) had Type 2, and 8 (26.7%) had Type 1 obstruction.

   Results: Central venous catheters (CVCs) were successfully placed in 29 of 30 patients (96.7%). The procedure was discontinued in 1 patient due to vascular anatomical tortuosity. All 29 patients with successful CVC placement achieved adequate catheter patency and tip positioning. There were no device-related adverse events, catheter malposition, or intra- or postprocedural complications. Mean time from device insertion to removal for the 29 patients who successfully completed the procedure was 24 ± 14.9 (range, 6-70) minutes. Mean fluoroscopy time was 6.8 ± 4.5 (range, 2.2-25.5) minutes.

   Conclusions: The Surfacer Inside-Out procedure provided an alternative option to restore right-sided CVA in patients with TCVO.

3. Reindl-Schwaighofer R, Matoussevitch V, Winnicki W, Kalmykov E, Gilbert J, Matzek W, Sengölge G. A Novel Inside-out Access Approach for Hemodialysis Catheter Placement in

Patients With Thoracic Central Venous Occlusion. Am J Kidney Dis. 2020 Apr;75(4):480-487. doi: 10.1053/j.ajkd.2019.08.024.

ClinicalTrials.gov Identifier NCT03766828.

SYNOPSIS:

- Retrospective, independent study at three centers in Europe (2016-2018)
- 32 (89%) patients were eligible and 39 procedures were performed (7 patients undergoing the procedure a second time more than 3 months after initial CVC placement). Patient aged 59 (20-82), 26 female, 6 male
- Success rate: 97% (38); no procedure-related complications
- Patency of access at 3 month was 100%

ABSTRACT

Rationale & objective: Left-sided internal jugular and all subclavian central venous catheters (CVCs) cause thoracic central vein occlusions (TCVOs) more often than right-sided internal jugular catheters. To enable right-sided CVC placement in patients with TCVO, an inside-out access (IOA) approach was established at 3 vascular access centers in Europe involving use of a novel IOA device advanced from the right femoral vein. In the current analysis, we assessed the eligibility and success rate of this IOA approach in a cohort of patients with TCVO requiring a tunneled dialysis catheter.

Study design: Retrospective multicenter observational study.

Setting & participants: 36 patients with TCVO treated in Vienna, Austria; Oxford, England; or Cologne, Germany, who required hemodialysis access between July 2016 and June 2018.

Exposure: Application of the IOA approach to gain vascular access.

Outcome: The primary end point was the success rate of passing the TCVO to gain dialysis access using the IOA approach. Secondary end points were catheter patency at 3 months and procedure-related complications (early infections, bleeding, hematoma, and pericardial effusions).

Analytical approach: Descriptive statistics to characterize eligibility, success rate, and complications of the IOA approach.

Results: 36 patients with TCVO and history of multiple CVCs and arteriovenous fistulas were referred to the participating centers for vascular access. 32 (89%) patients were eligible for the IOA approach. 39 treatments were performed, with 7 patients undergoing the IOA procedure a second time more than 3 months after initial CVC placement. Dialysis access was established successfully in 38 of 39 (97%) implementations of the IOA procedure. Median intervention time was 43 minutes. No complications occurred.

Limitations: No comparison to other methods to place CVCs and the observational study design.

Conclusions: The IOA approach is a promising method to enable rapid access to the right jugular vein in the setting of pre-existing TCVO. Additional experience is needed to understand the generalizability of these observations.

Case Series

4. Galas N, Shahverdyan R. Use of the Surfacer® Inside-Out® catheter access system to obtain central venous access in dialysis patients with thoracic venous obstructions: single-center series. Vasc Endovascular Surg. 2021 Apr;55(3):228-233. doi: 10.1177/1538574420980604.

   SYNOPSIS:

   - Retrospective Surfacer System case series with 10 patients
   - Patients (70% male/30% female, with a mean patient age of 62.4 ± 19.6 years
   - 100% Surfacer technique success, no "device related" complications and no adverse events associated with the use of Surfacer device were encountered.

   ABSTRACT

   Background: Thoracic central venous obstruction (TCVO) is a common condition which can impact the ability to achieve central venous access (CVA) in patients on hemodialysis. The Surfacer® Inside-Out® Catheter Access System is designed to enable repeated right-side central venous access in patients with TCVO.

   Methods: We retrospectively analyzed medical records of 10 dialysis patients who presented with TCVO and underwent the Inside-Out procedure with the Surfacer System to obtain CVA between 2017 and 2020. Patient demographics, hemodialysis vascular access history, and procedural data were identified and analyzed. The mean patient age was 62.4 ± 19.6 years (25.9-89.1 years) with 7 of the 10 patients being male. Eight patients (80.0%) were diagnosed with chronic kidney disease with time on hemodialysis ranging from 3 to 13 years. The remaining 2 required CVA to treat acute-on-chronic kidney injury due to septic shock. Patients in our series had a mean of 2.8 ± 1.6 previous catheters placed prior to the Surfacer procedure.

   Results: CVA was achieved in all 10 patients with 1 patient requiring a second attempt to achieve access due to the inability to initially traverse the iliac vein with the device, possibly due to a history of kidney transplantation. One multimorbid patient died shortly after the successful procedure, possibly due to cardiac decompensation. Mean total procedure time for the 7 patients having only dialysis catheter placement using the Surfacer device was 67.2 ± 19.1 minutes (49-103 minutes). The remaining 3 patients received a Hemodialysis Reliable Outflow (HeRO) graft in conjunction with the Inside-Out procedure. All vascular accesses functioned properly during the immediate time period following placement. No adverse events associated with the use of Surfacer device were encountered.

   Conclusions: Data presented from our patient series confirms the effectiveness of the Surfacer System to safely achieve CVA in dialysis patients with TCVOs with a history of multiple catheter placements

5. Hentschel DM, Minarsch L, Vega F, Ebner A. The Surfacer® Inside-Out® Access System for right-sided catheter placement in dialysis patients with thoracic venous obstruction. J Vasc Access. 2020 Jul;21(4):411-418. doi: 10.1177/1129729819867547.

   SYNOPSIS:

   - Case series with 9 patients (4 female, 5 male), mean age 57.6 (24-85)
   - Success rate of 88.9% (8); in one patient, significant venous tortuosity resulted in the inability to achieve venous access.
   - No complications were reported.

   ABSTRACT

   Purpose: Thoracic central venous obstruction is a common clinical complication in dialysis patients utilizing hemodialysis catheters. Thoracic central venous obstruction can lead to inability to utilize affected veins for catheter placement and sequential use of less preferred alternative venous access sites. The latter can affect the ability to create and/or mature permanent arteriovenous access and contribute to the future loss of thoracic veins for venous access. While alternative procedures exist for gaining venous access in patients who have exhausted routine venous access options, these procedures are complex, time-consuming, and associated with high patient risk. The Surfacer System provides a new approach in patients with right-sided thoracic central venous obstruction, enabling the ability to establish repeated access from the right side of the neck to the right atrium.

   Methods: We describe the use of the Surfacer System to facilitate placement of hemodialysis catheters in a series of nine patients with thoracic central venous obstruction involving one or more central veins. Patient characteristics and procedure-related outcomes were recorded for all patients.

   Results: Central venous access was successfully achieved in eight of nine patients using the Surfacer System. Significant venous tortuosity resulted in the inability to achieve venous access in one patient and prolonged procedural time to achieve access in another patient. The mean time required for Surfacer-related procedural steps and associated fluoroscopy time in the remaining seven patients was 13.3 and 3.7 min, respectively.

   Conclusion: The Surfacer System provides an efficient low-complexity alternative for gaining repeated right-sided central venous access in hemodialysis patients with obstructed thoracic veins.

Case Reports

6. Azoulay A, Gaudin A, Mallios A. Extra-anatomical endo-bypass between left arm vascular access and superior vena cava. J Vasc Surg. 2022 Jun;75(6):2072-2073. doi: 10.1016/j.jvs.2021.10.004.

   SYNOPSIS:

   - Patient case report, 57yo male with left arm axillary loop graft.

- Patient developed severely symptomatic superior vena cava (SVC) syndrome with bilateral innominate vein and SVC occlusion, and voluminous pseudoaneurysm at the level of the graft-vein anastomosis.
- Previous attempts at recanalization of the central vein occlusion were unsuccessful.
- The Surfacer System was utilized to successfully obtain central venous access through the occlusion and enabled extra-anatomical bridging of the graft to the SVC.

SUMMARY

The patient had a history of previous hemodialysis access-induced distal ischemia and known bilateral chronic venous outflow problems that was successfully used for a couple of months with minor-to moderate left arm swelling. Patient subsequently presented worsening swelling and eventually severely symptomatic superior vena cava (SVC) syndrome with bilateral innominate vein and SVC occlusion, and voluminous pseudoaneurysm at the level of the graft-vein anastomosis. Recanalization of the central vein occlusion through the left arm and right femoral vein was attempted but was unsuccessful. The Surfacer System was utilized to successfully obtain central venous access through the occlusion. The graft was then bridged to the SVC with the placement of four overlapping self-expandable covered stents. The trajectory of the conduit over the clavicle and into the thorax allowed avoidance of areas of potential compression and kinking at the level of the thoracic outlet. The patient reported immediate improvement of his symptoms and had a considerable reduction of swelling on day 1 and complete recovery in the following weeks. Dialysis continued without interruption through his graft and no catheter placement was required. This was the first report of a fully extra-anatomical minimally invasive approach, bridging a functioning upper extremity access and the SVC.

7. Huang C, Smeds MR. Use of the Surfacer® Inside-Out® access catheter system to place permanent dialysis access via hemodialysis reliable outflow (HeRO) graft. Ann Vasc Surg – Brief Reports and Innovations. 2021; 1(2). https://doi.org/10.1016/j.avsurg.2021.100026

SYNOPSIS:

- One patient case report, 55yo with femoral catheter
- Central venous access via Surfacer System was gained and HeRO graft implanted
- 100% technique success, no adverse events or complications, good flow post-op

ABSTRACT

Central venous occlusion (CVO) poses a great challenge to maintain dialysis access for end-stage renal disease patients. In patients with exhausted peripheral vascular access from central venous occlusion, currently available solutions such as central venous catheters, angioplasty, and lower extremity access provide limited benefits. This paper describes the use of the Surfacer® Inside-Out® Access Catheter System from right femoral vein to cross a central venous occlusion (CVO) that had failed crossing from the internal jugular vein. The needlewire of the Surfacer system was retrieved extravascularly at the base of the neck.

Instead of a central venous catheter, a Hemodialysis Reliable Outflow (HeRO) Graft was placed in the right atrium and joined with right brachial artery at the same setting. A technique is described for placing upper extremity Hemodialysis Reliable Outflow (HeRO) grafts in patients with severe superior vena cava occlusion via Surfacer® Inside-Out® Access Catheter System. The procedure was technically successful, and on postoperative day 1, the patient had flow volumes greater than 1000 cc/min in the HeRO graft. In conclusion, using the Surfacer® Inside-Out® Access Catheter System to cross central venous occlusion to place Hemodialysis Reliable Outflow (HeRO) grafts rather than tunneled dialysis catheters is safe and technically feasible.

8. Qi Tian T, Hao Yun Y, Jia Sheng T, Tjun Yip T, Tieng Chek EC. Use of Surfacer, an inside-out device, in tandem with HeRO graft for creation of vascular access: Case report of three patients with 18-months follow up. J Vasc Access. 2021 Aug 31:11297298211041434. doi: 10.1177/11297298211041434.

SYNOPSIS

- Three patient case series, restore access in total central vein occlusion
- 18 months follow-up, patients were treated with HeRO graft after Surfacer use
- 100% technique success, no adverse events or complications, able to cannulate 3 day post-op

ABSTRACT

The Surfacer Inside-Out Access Catheter System (Surfacer) is a novel approach to restore access in total central vein occlusion (TCVO). We report a series of three cases, with mean 18-months follow up, in our institution where this technique was safely and effectively used in tandem with Hemodialysis Reliable Outflow (HeRO) graft for creation of upper limb vascular access in patients with TCVO. Although there have been reports describing the simultaneous combination of Surfacer and HeRO graft, to our knowledge, this is the first time where the outcomes with 18-months mean follow-up are reported. All three patients had failed prior conventional attempts at TCVO crossing and had exhausted most conventional upper limb vascular access methods. The above technique yielded a 100% technical success rate with mean operative time of 140 min. Cannulation rate was 100% with all undergoing successful early cannulation by post-operative day 3. Mean primary patency of 199 days was achieved. Average intervention rate of 1.2 a year was required to maintain patency. The Surfacer device used together with HeRO graft is a feasible technique to avoid femoral catheter in patients where conventional attempts to cross the TCVO have failed.

Conclusions: In all three patients, salvage of vascular access was achieved with long term assisted primary patency without significant complications or adverse events from the procedure.

9. Tonko JB, Black SA, Rinaldi CA. "Inside-Out" Central Venous Access approach with infraclavicular exit for right-sided CRT-D Implantation in bilateral brachiocephalic and superior

vena cava occlusion. Clin Case Rep. 2021 Apr 4;9(6):10.1002/ccr3.3980. doi: 10.1002/ccr3.3980.

SYNOPSIS:

- Single patient/center, 77-year-old man with superior vena cava syndrome
- CRT- D Implantation completed with “inside- out” central venous access approach
- Technique was successful with no adverse events or complications

ABSTRACT

Background: The use of the “inside- out” approach with an infraclavicular exit site with a dedicated system in the presence of complex central venous occlusion is feasible and safe for the implantation of complex cardiac devices.

Methods: Subsequently, a Surfacer Device ® (Merit Medical) (consisting of a needle guide, needle wire, and a handle) was introduced over the work- sheath to the occluded segment. A radiopaque marker was placed on the skin in the infraclavicular region to indicate the target exit area for the needle wire. The needle guide was then advanced through the obstruction segment of the SVC and the right brachiocephalic vein under fluoroscopic guidance. The fluoroscopy system was then rotated and adjusted in a RAO/cranial projection until the tip of the device was visible in the exit target. The device tip was rotated so the opening of the tip aligned with the externally placed exit target circle. The needle wire was then advanced anteriorly through the soft tissue with the indicator on the handle matching the degree of the cranial angulation of the fluoroscopy system. Puncture through the skin with the needle wire was performed at the center of the exit target with externalization and fixation of the needle wire. An introducer sheath was inserted over the externalized wire and pulled through the skin and soft tissue into the vein until the tip passed the occlusion. Following this, the Surfacer® Device was withdrawn and three Terumo wires inserted through the sheath. Implantation of a CRT- D device was then performed in standard fashion using a single- coil RV lead and positioning the LV lead in a posterolateral vein.

Results: Overall, procedure time was 102 minutes and screening time 24.7 minutes (DAP 1774cGycm2). In view of excellent lead measurements after insertion and fluoroscopically well- sited high voltage lead in a standard RV apical position as well as the increased risk for refractory arrhythmias or thromboembolic events (nonrevascularized coronary artery disease, aortic stenosis, impaired LV function, paroxysmal atrial fibrillation with withhold anticoagulation for 48 hours prior to procedure), a DFT test was not performed. The routine next- day chest X- Ray showed unchanged lead positions and no evidence of pneumothorax and the CRT- D interrogation confirmed stable lead measurements and 100% biventricular pacing with no intrinsic AV conduction. The Micra device (Medtronic) was turned off. The patient was discharged and remains symptomatically well. A follow- up six months after the procedure showed a mildly improved LV function of 45%, good device function with 99% biventricular pacing and no ventricular arrhythmias. No adverse events associated with the use of Surfacer device were reported.

Conclusions: This case report demonstrates the use of the "inside- out" with a dedicated system with an infraclavicular exit site in the presence of complex central venous occlusion is feasible and safe for the implantation of complex cardiac devices.

10. Baetens TR, Rotmans JI, van der Meer RW, van Rijswijk CS. A novel technique to restore access in patients with central venous occlusion using the Surfacer® Inside-Out® Access Catheter System. J Vasc Access. 2020 Sep;21(5):778-782. doi: 10.1177/1129729820909730.

    SYNOPSIS:

    - 2 patient Surfacer System case series in Netherlands reporting long term results
    - 70 y/o female and 36 y/o male
    - 100% success with no complications, with catheter patency up to 25 months

    ABSTRACT

    Exhausted central venous access is a potentially life-threatening situation for patients dependent on haemodialysis. If standard guidewire recanalisation fails, unconventional venous access or central venous needle recanalisation can be considered but are often associated with higher rates of complications and/or dysfunction. Here, we report about two patients treated successfully with the Surfacer® Inside-Out® Access Catheter System (Bluegrass Vascular Technologies, San Antonio, TX, USA) to achieve transmediastinal central venous access.

11. Quek LHH, Tan TSM, Tan GWL, Pua U. Salvage of exhausted neck access using a novel inside-out device in dialysis-dependent patients. Hemodial Int. 2019 Oct;23(4):E111-E114. doi: 10.1111/hdi.12770.

    SYNOPSIS:

    - 4 patient case series
    - No failures (100%) success rate
    - Longest catheter dwell time of 164 days
    - No complications, one patient encountered sepsis on Day 70 and underwent successful tunneled catheter exchange, event was unrelated to Surfacer System

    ABSTRACT

    Purpose: This is a report of retrospective series of four cases in which the Surfacer System is used to gain upper body venous access from a single center in Singapore. This report seeks to integrate the understanding of the technical aspects of a new inside-out device and its utility in recanalization of occluded right-sided neck veins as it relates to Asian patients.

    Patients and Methods: Four patients of Asian descent, were included in this review. These patients had catheter inserted via the femoral vein due to occluded right neck veins, and left-sided internal jugular access was not possible due to planned fistula creation for three patients, and one patient had a non-maturing left brachiocephalic fistula.

Results: In all four cases, central venous anatomy was first delineated using a pigtail catheter introduced via the right femoral vein for suitability. All procedures were performed under conscious sedation and dialysis catheter was successfully inserted without complications with a mean procedure time of 41 minutes and mean fluoroscopy time of 10 minutes. All four patients underwent same-day dialysis through the newly implanted catheters, which remained usable up to the time of writing—the longest dwell time to date is 164 days. No complications were observed in all the four patients with the Surfacer technique.

12. Klepanec A, Hoferica M, Harsany J, Sengölge G. Dialysis vascular access restoration by a transcollateral approach using the Surfacer® Inside-Out® Access Catheter System. J Vasc Access. 2022 Apr 8:11297298221085457. doi: 10.1177/11297298221085457. Epub ahead of print. PMID: 35394391.

ABSTRACT

Chronic thoracic venous occlusion (CTVO) as a result of repeated or prolonged central venous catheter insertion represents a significant problem in catheter-dependent patients. Different endovascular techniques techniques have been utilised for CTVO recanalization. The Surfacer® Inside-out® system represents a new approach to restore right-sided central venous access in CTVO by the inside-out recanalization technique. Standard approach for device implantation is through right femoral vein. In this case report, we report the first case to our knowledge of dialysis access restoration with Surfacer® system implantation via an unconventional and non-standard route by a transcollateral approach in a patient with exhausted vascular access options.

Review Papers

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SYNOPSIS

Invited review article to summarize clinical studies conducted with Surfacer System

ABSTRACT

Introduction: The development of thoracic central venous obstruction (TCVO) leads to narrowing of the vessel lumen which impacts blood flow and the placement of central venous access. The most common cause of TCVO is central venous catheters (CVCs) which can induce intravascular scarring or endoluminal obstruction via thrombus formation.

Areas covered: The Surfacer® System is used to obtain central venous access (CVA) in patients with TCVO by facilitating catheter insertion via the novel Inside-Out® approach. This review summarizes the results of clinical studies to date with the Surfacer System, focusing on the how the procedure is performed, clinical efficacy and safety of the device and patient populations where the device offers substantial clinical benefit.

Expert opinion: The Surfacer System offers a safe and effective approach to reliably preserve and restore critical upper body vascular access sites. For dialysis patients, the device offers an alternative which avoids placement of dialysis catheters in veins which may impact the ability to achieve maturation of hemodialysis vascular access or in locations which have an increased risk of insertion-related complications or are associated with higher morbidity.