Novel "Inside Out" Approach to Central Venous Access in Patients with Occlusive Disease Requiring Hemodialysis

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PURPOSE

Central venous access (CVA) becomes increasingly complex in patients with recurrent central venous catheters, venous thromboemboli, or malignancy. Typically, occluded central veins necessitate an experienced surgeon to intervene. The inability to gain durable CVA may preclude treatment of many chronic, life threatening conditions. The feasibility and safety of a novel "inside out system" (IOS) designed to achieve CVA in such patients is described here in a 20-patient case series (IOS; Bluegrass Vascular Technologies, Lexington, KY).

MATERIAL

The IOS is catheter-based with fluoroscopic guidance used to direct a sheath/dilator via the femoral vein over a .035 standard J wire. An 8F delivery instrument with steerable needle guide is advanced to the occluded CVA site where the needle wire is stiff enough to exit through the occlusion and puncture the skin from the inside out (Figure 1). Once exit is achieved, a 16F introducer is tracked back into the body over the needle wire (Figure 2). A CVA catheter is tunneled through the new access and sutured into place (Figure 3). The delivery instrument is retracted and manual pressure applied to the groin.

FIGURE 1

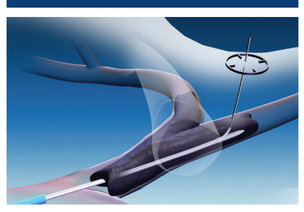


FIGURE 2

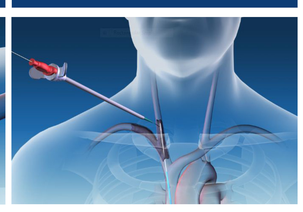
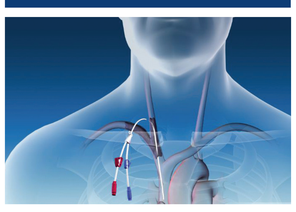


FIGURE 3



METHODS

The case series includes patients with severe renal dysfunction and upper extremity venous occlusive disease who require hemodialysis (Table 1). All patients are prepped for routine percutaneous femoral venous access and subclavicular exits with the IOS, and sedated with intravenous midazolam plus fentanyl. All patients receive a patent access catheter which is left in place for 14 days to assess patency, infection, and efficacy.

TABLE 1: Total Number of Occlusions*

Occlusion Location	N	%
Internal Jugular	10	83.3
Subclavian	10	83.3
Brachiocephalic	1	8.3
Superior Vena Cava	5	41.7
Total # Occlusions	**26**	**100**

*Data reported from first six and additional six patients completed post abstract submission (n=12).

RESULTS

A total of six (6) subjects (mean age 41.1 yrs; 5 female) have been enrolled to date at one center. All six subjects (100%) had severe renal dysfunction; three (50%) also had hypertension. All patients had creatinine levels averaging 10.0. Procedure time ranged from 24-70 min (Table 2). Total contrast ranged 10-25cc. All six patients successfully received an access catheter which remained in place and was functional for 14 days.

TABLE 2: Procedural Results – First Six Patients

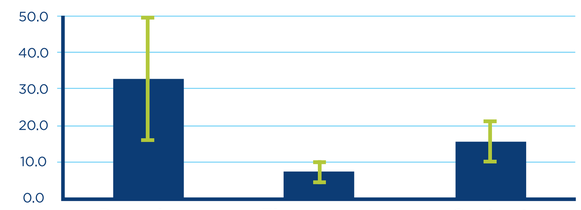
Subject ID	Procedure Time (min)	Fluoroscopy Time (min)	Contrast Volume (cc)
01-01	31	10.4	20
01-02	34	10.5	20
01-03	24	10.3	20
01-04	36	9.3	20
01-05	70	10.4	25
01-06	60	9.5	10

TABLE 3: Procedural Results – Additional Six Patients*

Subject ID	Procedure Time (min)	Fluoroscopy Time (min)	Contrast Volume (cc)
01-07	29	4.0	10
01-08	19	4.6	10
01-09	25	5.3	20
01-10	35	4.8	10
01-11	17	4.4	15
01-12	13	5.7	10

* Data from additional six patients completed post abstract submission and not included in discussion.

FIGURE 4: Procedural Results (N=12)



	Procedure Time (min)	Fluoroscopy Time (min)	Contrast Volume (cc)
AVG	32.8	7.4	15.8

FIGURE 5: Procedure Time

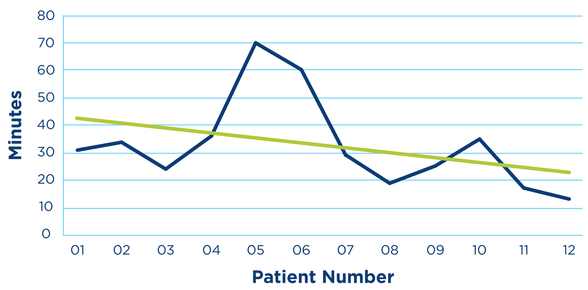


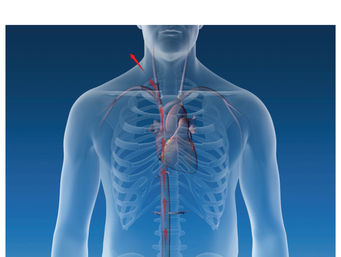
TABLE 4: Clinical Endpoints

Endpoint	Short Term (48-hours Post-procedure)	Long Term (14-day)
Technical Success	100%	
Safety	100%	100%
Patency	100%	100%

Technical Success Ability to successfully place the IOS into the femoral vein and vena cava, in the absence of system failures or unintended vessel trauma requiring surgery due to device delivery.

Safety Absence of adverse events within 48 hours post-procedure and at 14 days post-procedure.

Patency Presence of a patent central venous access as of procedure completion and at the 14-day follow-up visit.



CONCLUSION

Our series of 6 patients, with 14 subsequent patients to be treated, demonstrates safety, performance, and efficacy with the IOS. The implications of such a device are significant for patients with loss of CVA.