Venous Window Needle Guide for deep vessels and difficult arteriovenous fistula cannulation

Venous Window Needle Guide for deep vessels and difficult arteriovenous fistula cannulation

Giacomo Forneris[1], Marco Trogolo[2], Pasqualina Cecere[1], Daniele Savio[3], Dario Roccatello[1]

Abstract

The Venous Window Needle Guide (VWINGTM) has recently been proposed for patients with difficult arteriovenous fistula (AVF) access for hemodialysis due to deep vessels or other cannulation-related problems. This totally subcutaneous titanium device is sutured onto the upper wall of the matured fistula and may facilitate cannulation by the button-hole technique. We describe our initial experience with nine implants in six patients with a cumulative followup of 83 months, and make some experience-based technical suggestions for implant and surveillance radiological imaging. The indication for implantation was deep vessel, previous failure of cannulation or unsuitable site for direct cannulation. No infectious complications were observed during follow-up and proper blood flow was constantly achieved. Some difficulties were occasionally encountered with regard to cannulation; nonetheless, patient satisfaction was not significantly affected. VWING seems to be an interesting option in some patients provided that surgical implantation is carefully carried out and preventive measures against infections are strictly observed.

Keywords Venous Window Needle Guide, VWING, Cannulation, Deep fistula, Artero-venous fistula

Introduction

Since its introduction in clinical practice, native arteriovenous fistula (AVF) has proven to be the safest and most durable vascular access for hemodialysis and, accordingly, it is recommended by international guidelines as the vascular access of choice in most patients with end-stage renal disease (ESRD) who are candidates for hemodialysis [1–3]. The absence or relative impoverishment of superficial vessels is frequently the main barrier to achieving this target in patients, who are increasingly of older age and affected by comorbidities. In other cases, despite the existence of a suitable vein, the course and/or relative depth after AVF construction and maturation can hamper fistula cannulation and compromise the subsequent use. This condition is often encountered in the presence of obesity, a worldwide epidemic comorbidity affecting the general population [4] including hemodialysis patients, thus resulting in a lower probability of achieving a native vascular access [5, 6]. When difficult cannulation of the AVF is anticipated or established, various surgical strategies may be considered based on the patient's medical history, vascular state and more often the surgeon's experience and preference. Among these, superficialization/transposition of the arterialized vein or arteriovenous graft (AVG) represent the most common strategies, although surgical lipectomy [7] or liposuction [8] may also, though less frequently, be adopted. A recent review on this issue has been published including the presentation of a new, totally implantable device, i.e., the Venous Window Needle Guide (VWINGTM, Vital Access, Salt Lake City, UT, USA) which is especially designed for deep vessels, and is target-oriented to facilitate cannulation of the AVF by the so-called button-hole (BH) technique [9]. Clinical experience with the new device is represented by a few implants [10, 11], whereas no European study or survey has been published. In Italy, a pilot experience was initiated in 2012 at our Institution, and since then nine VWINGs have been implanted in six patients. The aim of this brief report is to describe our preliminary results providing never-before published radiological pictures.

Materials and methods

VWING is a small, totally subcutaneous funnel-shaped implantable titanium device equipped with a single fenestration for needle insertion (Fig. 1). The purpose is to assist the operator as a palpable target located on the superior wall of the AVF, hence facilitating cannulation by the constant site method, the so-called BH cannulation. VWING is available in different configurations (width 7–9 mm, height 4–10 mm) depending on the vessel target size and depth. The surgical implant should be carried out after complete fistula maturation (minimum caliber = 5 mm) as a primary indication or as a delayed rescue

bid intervention in the case of established cannulation difficulties. All devices (n = 9) were implanted in local anesthesia (surgery time about 30 min per device), either by the interventional nephrologist (n = 5) or vascular surgeon (n = 4), both of whom work in close cooperation at our Institution. The VWING is sutured to the upper wall of the fistula by means of a surgical cut-down technique. An ultrasound evaluation is essential to map and determine the VWING location(s) when implanted, to take into account the future position of the arm during cannulation. Following the manufacturer's earlier suggestions (sincer modified) we created a 4 cm arch incision for each device, 2 cm to either side of the fistula. Then 1/3 of the superior wall was exposed avoiding vessel mobilization, the correct height confirmed, and, without interruption of the circuit, two orientation sutures were applied with non-resorbable PTFE CV7 threads. Finally a continuous suture to either side of the device was made. After checking palpability, the skin was closed in the usual manner with silk. The device remained in the extra-vascular space in a palpable, subcutaneous position. This made it easy to identify the device by touching it. Cannulation was initially done with 16G sharp needles and then 16G blunt needles (1.6 9 300 mm) were utilized. The indications to implant the device included: vessel too deep for standard cannulation ([7 mm), repeated-failure of needle insertion, and the anatomical path of the arterialized vein unsuitable for direct cannulation (basilic vein in the upper arm). Patient comorbidities, indication for use of the device, and outcomes are reported in Table 1. Formal consent was obtained from patients for image publication.

Case 1

A 49-year-old diabetic male was a late referral to the nephrologist. A right jugular tunneled central venous catheter (tCVC) was inserted in order to start dialysis in emergency (August 2012) and 3 weeks later he was referred to surgery for a left radio-cephalic fistula at the wrist. After maturation, depth of the vessel at the venous site (7–8 mm) and poor palpability led to a single VWING implant (October 2012). The device was used 4 weeks after surgery with minor difficulties in the very first cannulations which, however, were rapidly resolved (learning curve). A month later, acute thrombosis occurred due to a hematoma after needle insertion at the arterial site (not the VWING site); the access was rescued by thrombectomy and a new anastomosis was constructed a few centimeters proximally with immediate reutilization of the device. During followup, post anastomotic stenoses developed after 12, 18, and 24 months. These events were successfully treated by percutaneous transluminal angioplasty (PTA) in all cases, and a stent-graft was inserted during the last procedure. The patient finally underwent kidney transplant 28 months after the initial use of the AVF. No local or systemic infectious episodes were recorded during follow-up. Angiography was performed after 12 months and showed no signs of compression or stenosis at the VWING implant site (Fig. 2).

Case 2

A 78-year-old woman started hemodialysis (April 2012) with a well-functioning access (right radio-cephalic AVF at wrist) made 6 months earlier. Difficulty with cannulation at the venous site and repeated hematomas and infiltration occurred resulting in complaints, missed dialysis and frequently needed use of the single-needle technique. VWING implant (October 2012) allowed regular use of the AVF afterwards until the patient's death due to an unrelated cause (March 2015) without insertion of any CVC. Computed tomography (CT) angiography with 3D reconstruction imaging after 18 months of use to evaluate the state of the vessel on which the VWING was sutured (March 2014) showed correct positioning of the device and absence of stenosis (Fig. 3). No infectious episodes were recorded during follow-up.

Case 3

A radio-cephalic AVF at the wrist was first made in an obese [body mass index (BMI) 34.8] 67-year-old woman early in the pre-dialytic stage (June 2011), attaining regular maturation. However, excessive depth of the entire arterialized vessel ([9 mm) with very scarce palpability was observed. Two VWING devices for arterial and venous cannulation in the forearm were scheduled in February 2012 prior to

starting dialysis in March 2014. Both devices are currently still being used (as at February 2016) with no complications. The skin above the devices is undamaged and the patient reports a high degree of satisfaction. No mechanical complications related to the device have been observed and the prescribed target blood flow (300 ml/min) is consistently achieved. Also in this case, angiography performed 21 months after surgery showed no underlying stenosis (Fig. 4).

Case 4

A 68-year-old man with a history of severe heart disease and chronic obstructive pulmonary disease (COPD) began hemodialysis by means of a tCVC (October 2012). A right brachio-basilic AVF without transposition was carried out and two VWINGs were implanted after maturation; the first use, after 4 weeks, employing sharp needles was performed with ultrasound assistance because of the closeness of the brachial artery. Unfortunately, the patient died after 3 months of use due to a sudden cardiovascular event.

Case 5

A 65-year-old man with a deep arterialized vein in the upper arm received two devices on a non superficialized, brachio-basilic AVF (Fig. 5). He had started using the device at another dialysis facility. Due to the depth of the devices below the subcutaneous tissue, a cannulation expert was required prior to routine use.

Case 6

An obese (BMI 41.6) 67-year-old male was judged eligible for a single VWING at the venous site on the brachiobasilic AVF while awaiting initiation of dialysis. A freehand cannulation at the arterial site and the use of VWING at the venous site was scheduled. A small hematoma occurred after surgery, but it rapidly resolved.

Discussion

Vascular access complications have been a challenge for nephrologists since the beginning of hemodialysis despite remarkable improvements in this field. Thanks to its wellestablished advantages, after more than 40 years since the revolutionary idea was proposed by Cimino and Brescia, AVF continues to be the gold standard for most dialysis patients. However, substantial changes in the dialysis population over the last two decades now make it difficult to preserve AVF for a long time in the majority of patients. As a consequence, a widespread increase in the use of tCVC is reported in many countries, also reflecting demographic changes. Several factors, including comorbidities, aging and logistic aspects, may impact the choice of the vascular access. Furthermore, optimal maturation of a functioning AVF may not always be followed by its easy use. Excessive depth, tortuosity, a usable tract that is too short, and access mobility or frailty may hinder cannulation early or later during its use. Infiltration, hematoma, aneurysm and pseudo aneurysm make using an AVF on a regular basis frequently difficult and sometimes impossible. That may require the use of single-needle hemodialysis, which sometimes leads to complete thrombosis of the vascular access. The cost of major AVF problems in the USA (5 % yearly rate) has been estimated to be up to 5 billion dollars, including complications related to the substitutive use of tCVC [12]. In this setting, VWING may represent a novelty [13]. Its use is inevitably associated to the constant site cannulation method, although it differs from the free-hand BH cannulation, which was developed in 1979 [14], but has recently gained renewed interest and diffusion [15]. However, several studies have reported medium–high risks of local and systemic infection, sometimes with serious complications, occurring at times because of the lack of appropriate disinfection protocols and preventive measures [16, 17]. Although BH cannulation offers wellknown advantages such as low infiltration rate, fewer hematomas and less aneurysm formation [18], it still remains of difficult access in the presence of deep vessels, and non-feasible in specific anatomic sites (i.e., arterialized upper arm basilic vein). Only two reports have been published on VWING use. The first experience [10], in New Zealand, regards nine single VWINGs implanted in nine patients who had

a 9-month follow-up with a cumulative period of 1367 days and 387 cannulations. The device was successfully used in 94 % of cases vs. a success rate of 77 % in the other site of free-hand cannulation that served as the internal control in the same patient. More recently, Jennings et al. [11] reported the SAVE study results, a multi-center trial in the USA designed to evaluate the efficacy and safety of VWING (82 implanted devices in 54 patients) to salvage non cannulatable, though still functional, AVFs. Over a 6-month observation period, the success rate was 96 % and the frequency of complications was 0.31/patient/years. The very-low infectious complication rate of 0.04 spoke in favor of the safety of VWING. The cumulative and assisted patency for AVF was 100 % at 6 months. The same patients who had been enrolled in the SAVE study were subsequently retrospectively re-evaluated after an 18-month follow-up period by reviewing their medical records. There was no contact between clinicians and the patients in the period between the 6- and 18-month followup visits, consonantly with the real-life experience. Fistula survival was 91 %, VWING 76 %—considerably better than the expected results of AVF superficialization [19]. The rate of sepsis further decreased to 0.018 because no episodes were recorded between 6 and 18 months. Interestingly, more than 900 implants have been carried out in the USA and have shown results that are comparable to those of the SAVE follow-up study (data from the manufacturer). In Italy, the first VWING implants were performed at our Institution in 2012. For the time being, our experience has been limited to only a few patients since we are dealing with an innovative device that is applicable as a life-saving measure (i.e., vascular access). In this setting, we must carefully weigh up the reasonable spirit of novelty against the requisite of safety before planning any extensive use. Nevertheless, despite the limited number of cases, the cumulative follow-up of 83 months and the not previously reported radiological images are worthy of note and add some information to the issue. From a surgical point of view, some fundamental aspects should be underscored, to ward against possible failure with the use. It is a relatively simple type of vascular surgery requiring accurate ultrasound pre-evaluation to identify the exact implant site. Skin incisions must be avoided at the site of future cannulations, and the vessel must be exposed only in the upper one-third of the vein avoiding mobilization. There is no need to interrupt circulation with clamps because no bleeding usually occurs when suturing the device onto the AVF. It is essential to correctly match the VWING caliber to the depth of the vessel and to carefully align it along the major axis while avoiding any possible rotation source that could lead to difficulties in the following cannulations. From this point of view, all the devices we implanted were carried out without any significant complications; however, one lymphedema developed in patient #5 which resolved after 2 weeks by aspiration and compression, while a small hematoma appeared in patient #6. The use of VWING in the first four patients started after a variable period, depending on the individual case, and involved shifting from sharp to blunt needles after 2–3 weeks based on the BH universal protocol. During follow-up, the use of sharp needles was temporarily resumed in two patients, as may occur with free-hand BH. Some further remarks may be made regarding specific cases. Early acute thrombosis of the AVF occurred in patient #1, who had been implanted with a single VWING for venous cannulation, because of a hematoma at the arterial cannulation site (not the VWING site). That was likely favored by underlying, post-anastomotic stenosis. This occurrence emphasized the potential harm of any cannulation in the early phases of AVF use. In this case, the presence of the device at the venous site did not hamper the surgical thrombectomy of the access. In patient #2, the initial choice of inserting a tCVC was overcome by the VWING implant. On occasion during follow-up, sharp needle use was re-scheduled in this patient as is sometimes required in the free-hand BH technique. Case #3 may be paradigmatic for the obese patient with a deep cephalic vein beneath subcutaneous fat tissue. Device implantation, which was planned early in the predialytic stage allowed for regular use of the AVF without any complications from the very beginning. Skin integrity over the cannulation site, absence of aneurysms and a high degree of satisfaction testify to the potential advantage of the device. Furthermore, it did not preclude referring the patient to other dialysis facilities during the holidays provided that appropriate instructions for cannulation were observed. A current image of the skin, before scab removal, is presented (Fig. 6). Further considerations can be drawn from case #4 even if the premature death of this patient for unrelated reasons limited a prolonged experience. Implanting two VWINGs onto the basilic vein in the upper arm, as in this case,

would represent a real alternative to more invasive surgical solutions like superficialization/transposition or prosthetic implant. Moreover, despite the closeness of the brachial artery, the guided cannulation avoided any arterial injury. Nevertheless, for the earliest needle insertions ultrasound assistance was used to assure being on the safe side of the vessels. With regard to the potential risk of infection, it is noteworthy that there was a complete absence of local or systemic infections. A strict asepsis protocol represents a procedural cornerstone, although encapsulation by granulation tissue around the device would probably facilitate the formation of a substantial tissue path between the skin and the vessel and provide separation between skin and vessel entry points, thus constituting a potential infection barrier. The device would also standardize a free-hand cannulation and guide the needle to a single entry point. Even if we do not have a formal cannulation team, our center routinely works under strict protocol and with well trained nurses in the field of vascular access. Nevertheless, we restricted the early phase of use of the device to more experienced nurses, gradually expanding the practice over time to a larger group. AVF remains the gold standard for vascular access. Thanks to these new devices, the possibility of rescuing or optimizing its use, although for a minority of patients, could be critical in the economy of AVF. We need to be cautious about the potential long-term advantages of VWING. However, we should not miss the opportunities offered by these new devices. Although our current experience is limited, based on this preliminary report, our experience is sufficiently positive to enable us to consider this option for future implants.

References

References

1. Renal Association Guidelines: Vascular Access for Hemodialysis (2015) http://www.renal.org/guidelines/modules/vascular-accessfor-haemodialysis#sthash.BBYFFliX.3wAczg1H.dpbs. Accessed 31 May 2015

2. Clinical Practice Guidelines for Vascular Access (2006) AJKD 48(Suppl 1):S178–S179

3. Tordoir J, Canaud B, Haage P et al (2007) EBPG on vascular access. Nephrol Dial Transplant 22(Suppl 2):ii88–ii117

4. Caballero B (2007) The global epidemic of obesity. An overview. Epidemiol Rev 29:1–5

5. Allon M, Ornt DB, Schwab SJ, Rasmussen C, Delmez JA, Greeen T, Kusek JW, Martin A, Minda S, for the Hemodialysis (HEMO) Study Group (2000) Factors associated with the prevalence of arteriovenous fistulas in hemodialysis patients in the HEMO study. Kidney Int 58:2178–2185

6. Pisoni R, Young E, Dykstra D, Greenwood R, Heckling E, Gillespie B, Wolfe R, Goodking DA, Held PJ (2002) Vascular access use in Europe and the United States: results from the DOPPS. Kidney Int 61:305–316

7. Bourquelot P, Tawakol JB, Gaudric J, Nata´rio A, Franco G, Turmel-Rodrigues L, Van Laere O, Raynaud A (2009) Lipectomy as a new approach to secondary procedure superficialization of direct autogenous forearm radial-cephalic arteriovenous accesses for hemodialysis. J Vasc Surg 50:369–374

8. Ochoa DA, Mitchell RE, Jennings WC (2010) Liposuction over a shielded arteriovenous fistula for hemodialysis access maturation. J Vasc Access Jan-Mar 11(1):69–71

9. Bourquelot P, Lamisse RE, Pirozzi N (2015) Transposition, elevation, lipectomy and V-Wing for easy needling. J Vasc Access 16(Suppl. 9):108–113

10. Hill A, Vasudevan T, Young NP, Crawford M, Blatter DD, Marsh E et al (2013) Use of an implantable needle guide to access difficult or impossible to cannulate arteriovenous fistulae using the buttonhole technique. J Vasc Access 14:164–169

11. Jennings WC, Galt SW, Shenoy S, Wang S, Ladenheim ED, Glickman MH, Kathuria P, Browne BJ (2014) The Venous Window Needle Guide, a hemodialysis cannulation device for salvage of uncannulatable arteriovenous fistula. J Vasc Surg 60:1024–1032
12. Lee T, Barker J, Allon M (2006) Needle infiltration of arteriovenous fistulae: risk factors and consequences. AJKD 47(6):1020–1026

13. Tordoir JHM, van Loon MM, Peppelenbosch N, Bode AS, Poeze M, van der Sande FM (2012) Surgical techniques to improve cannulation of hemodialysis vascular access. Eur J Vasc Endovasc Surg 39:333–339

14. Twardowski Z (1979) Different sites versus constant sites of needle insertion into arteriovenous fistulas for treatment of repeated dialysis. Dial Transplant 8:978–980 15. Atkar RK, MacRae JM (2013) The buttonhole technique for fistula cannulation: pros and cons. Curr Opin Nephrol Hypertens 22(6):629–636

16. Nesrallah GE, Cuerden M, Wong J, Pierratos A (2010) Staphylococcus aureus bacteremia and buttonhole cannulation: longterm safety and efficacy of mupirocin prophylaxis. Clin J Am Soc Nephrol 5:1047–1053

17. O'Brien FJ, Kok HJ et al (2012) Arterio-venous fistula buttonhole cannulation technique: a retrospective analysis of infectious complications. Clin Kidney J 5:526–529

18. Grudzinski A, Mendelssohn D, Pierratos A, Nesrallah G (2013) A systematic review of buttonhole cannulation practices and outcomes. Semin Dial Jul-Aug 26(4):465–475

19. Bronder C, Cull D, Kuper S, Carsten C, Kalbaugh C, Cass A, Taylor S (2008) Fistula elevation procedure: experience with 295 consecutive cases during a 7-years period. J Am Coll Surg 206(5):1076–1081

Fig. 1 The Venous Window Needle Guide device

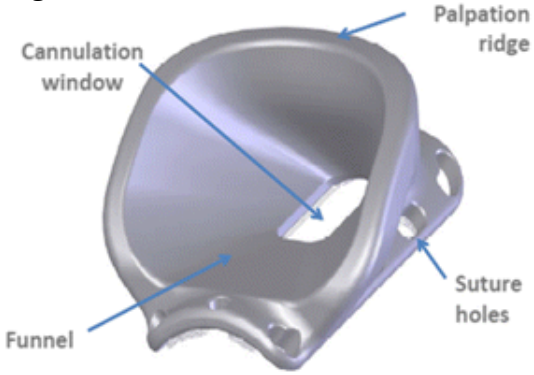


Fig. 2
Angiography of pt 1 after 12 months of use

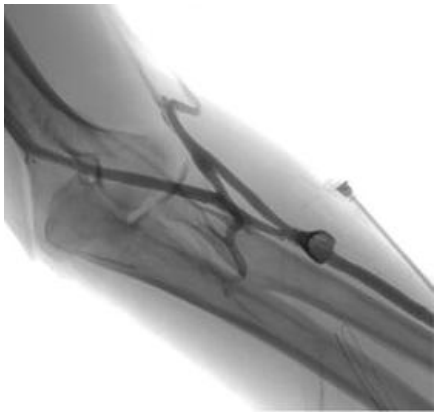


Fig. 3
CT Angiography with 3D reconstruction after 18 months of use

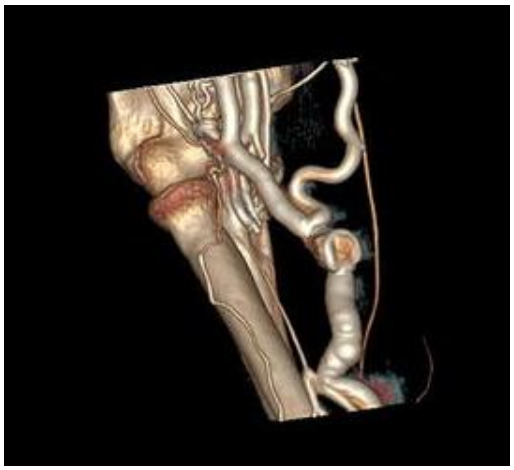


Fig. 4
Angiography after 21 months after surgery

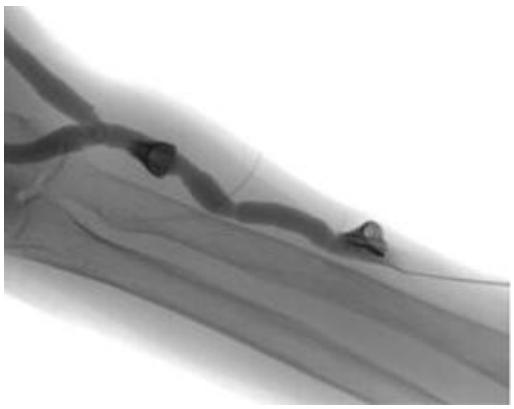


Fig. 5
Implant of two devices onto basilic arterialized vein

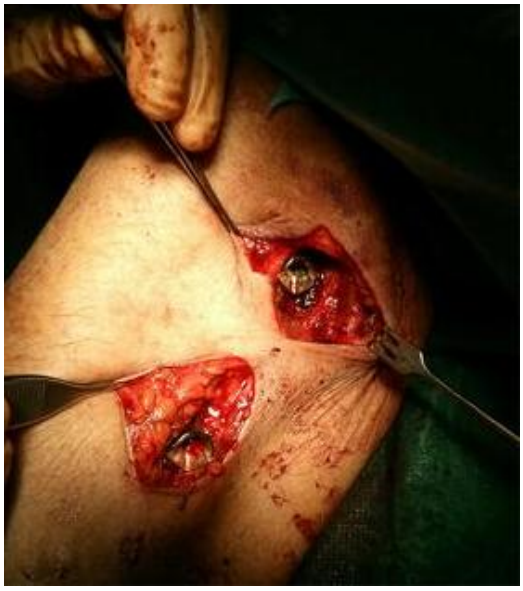
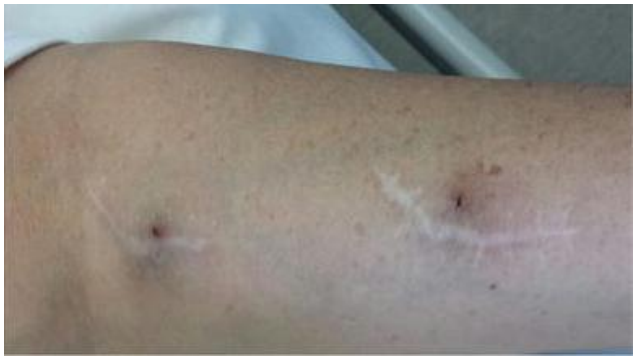


Fig. 6
Site of cannulation after 2 years of use



Patients	Comorbidity	N. VWING devices/site	Indication	Outcome
1	Diabetes, hypertension	1/Forearm	Deep vessel at venous site	Utilized until kidney transplantation; no major complications
2	Valvular heart disease	1/Forearm	Repetitive cannulation failures	Utilized until patient's death (unrelated cause); no major complications
3	Obesity, hypertension	2/Forearm	Deep vessel	In use; no complications
4	Ischemic heart disease, severe obstructive lung disease	2/Upper arm	Site not suitable for direct cannulation	Short use due to patient's death for unrelated cause
5	Obesity	2/Upper arm	Deep vessel, site not suitable for direct cannulation	In use; mild lymphedema after surgery
6	Obesity, diabetes	1/Upper arm	Deep vessel, site not suitable for direct cannulation	Awaiting use

Table 1
Patient's comorbidities, site of implant, indications and outcome of VWING