Use of an implantable needle guide to access difficult or impossible to cannulate arteriovenous fistulæ using the buttonhole technique

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ABSTRACT
Purpose: The aim of this work was to assess the safety and efficacy of the VWING Vascular Needle Guide to assist in cannulation of difficult or impossible to access fistulæ using the buttonhole cannulation technique.

Methods: VWING devices were surgically implanted into patients with difficult to access fistulæ. A nondevice site and a device site were used to access the fistula and perform dialysis over a six month period. The device site utilized the buttonhole cannulation technique. The performance of each access site was recorded.

Results: VWING devices were implanted in nine patients. A total of 387 cannulations took place over 1367 study days. The device site was successfully used 94% of the time compared to 77% for the nondevice site. Cannulation success was comparable between the device and nondevice sites. Ease of insertion, pain during insertion and complication rates were also comparable. No interventions were required at the device site to maintain access compared with four interventions for the nondevice access site.

Conclusions: The VWING performed as intended by facilitating required repeated access to the vascular system and access for hemodialysis treatment. The study has demonstrated that the VWING is a potential solution for access to difficult to cannulate fistulæ.

Key words: Buttonhole, Hemodialysis, Needle guide, Vascular access

INTRODUCTION

Vascular access is the lifeline for patients receiving hemodialysis treatments. The arteriovenous fistula (AVF) is the gold standard for hemodialysis vascular access because of lower complication rates and lower maintenance costs, compared with prosthetic and central venous line access.

Many AV fistulæ have poor functional patency because of poor blood flow in the vessel or the inability to cannulate due to depth or size of the vessel. Patency can be improved with superficialization, elevation or transposition procedures. These require a longer skin incision with mobilization of the vessel from its native position. A primary patency rate for elevation procedures of 60% at one year has been reported in the literature with a period when the fistula cannot be used (1). Many patients and clinicians avoid this more significant procedure (2).

Other fistulæ lose their functionality because of damage from repeated needle access (area puncture technique) which can result in the formation of aneurysms in the fistula. One of the methods to extend fistula life is to utilize the buttonhole technique or single cannulation site (3). This was pioneered over 30 years ago by Twardowski et al (4) and approaches the fistula damage challenge by accessing the fistula as a single cannulation location. Eventually a tract is formed from the skin to the vessel wall enabling a blunt needle to pass into the vessel without causing further damage to the vessel. The KDOQI Standards recommend that all fistula patients be assessed for a buttonhole access to help preserve the fistula and extend the fistula’s useable life. Resistance to implementation of the buttonhole cannulation technique exists because of the perceived difficulty in creating a buttonhole and the potential risk of infection.
The purpose of this study was to assess the feasibility and safety of an implantable needle guide as a device to promote the buttonhole cannulation technique in these difficult to cannulate native A-V fistulae for hemodialysis access.

MATERIALS AND METHODS

The VWING Vascular Needle Guide was developed to create a palpable target for repeated single site cannulation. It is an extravascular, subcutaneous titanium implant (Fig. 1) surgically attached to the outside of the target fistula through a small incision without mobilizing the vessel. It is implanted subcutaneously and sutured to the fistula wall utilizing a surgical cut-down technique. Once healed the VWING is palpable and is then used as a target to guide needle access to the fistula, which is now fixed to the base of the device.

The vessel interfacing surface comprised of titanium beads promotes ingrowth of tissue, resulting in fixation and sealing of the implant to the fistula. There is no artificial septum. Instead, the implant relies upon the sealing and healing of the fistula wall to create hemostasis in the same way as any conventional fistula puncture. The upper surface is designed to be a needle target and guide. A broad funnel opening provides a wide needle target and directs the needle tip into a needle channel. The top surface around the funnel opening is a palpation ridge that facilitates location of the device during the cannulation process. The needle channel exits the VWING at the bottom surface of the device that has been securely attached to the fistula wall. Suture slots or holes are located on the periphery of the device. The suture slots or holes are used to secure the Needle Guide to the exterior of the fistula wall. The VWING is approximately 13 mm wide and 18 mm long. The device is offered in multiple heights ranging from 4 mm to 10 mm. The device weights 1 g – 3 g, depending on the size.

The VWING is designed to facilitate access where there are cannulation problems. These could be a short available length of fistula (of the fistula itself or because of proximity to joint flexures or aneurysm), a fistula that is too deep or too tortuous or mobile.

The study was designed as a first-in-man, prospective, non-randomized, single arm trial. The trial was performed in Auckland and Hamilton, New Zealand and was approved by the Northern X Regional Ethics Board. The aim was to assess the functionality and safety of the VWING device in patients who have an existing upper extremity A-V fistula which is difficult to cannulate. Patients who received hemodialysis treatments at least two times per week and had a fistula considered difficult to cannulate because of short length, being non-palpable or too deep were considered for enrollment into the clinical trial. The difficult to cannulate determination was made by the principal investigator and the dialysis staff based on the patient’s access history and anatomy. Additional inclusion criteria included: fistula diameter of 5 mm or greater at the site of device attachment, buttonhole cannulation technique was appropriate and the fistula had adequate flow to perform dialysis as determined by the principal investigator. Exclusion criteria included: skin infection at implant sites, active systemic infection, known bleeding disorders, uncontrolled major symptomatic medical problem or the likelihood of poor compliance. Enrollment occurred when the VWING entered the body.

The study included nine subjects with study devices implanted from two investigative sites in New Zealand; Auckland City Hospital in Auckland, NZ and Waikato Hospital in Hamilton, NZ. Patients enrolled in the study had an arterial cannulation site deemed cannulatable and a venous site deemed uncannulatable in a standard fashion during a physician’s assessment. Allowing implantation at only one puncture site allowed direct comparison, in the same patient as a form of internal control, between cannulation variables. Two study devices were implanted at the uncannulatable venous cannulation site as determined by the surgeon and as permitted by the protocol. Two devices were placed in the event that the implantation procedure was not successful for one of the devices. For the first eight subjects, the protocol stated that one VWING site and one non VWING site were to be used for access. The protocol was modified during treatment of the final patient to allow both VWINGs sites to be used for access. This change was made because access to the non-device site could not be established and the patient was relying on the catheter for fluid uptake while returning through the VWING. The surgeon implanted the VWING and followed the patient for six months, including follow-up visits at three weeks, three and six months to monitor the cannulation site, adverse events, and fistula viability. In addition to follow-up visits by the implanting surgeon, the cannulation and treatment parameters for each dialysis session were recorded.

After a brief three to five week healing period, the VWING sites were assessed for approval to cannulate. Prior to this assessment, subjects continued to receive dialysis either through a catheter or a short segment of fistula where needle spacing or site rotation was not adequate for long term access. Palpability of the VWING, healing of
the wound and fistula patency were assessed to determine whether the chosen VWING was ready for use. Once the VWING was approved for cannulation, the patients received dialysis, as clinically indicated and prescribed by their nephrologist, utilizing a non VWING location for the one access needle and the approved VWING for the second access needle. In one patient the VWING devices were used for both access needles after three months of failed access to the non VWING location. Conversion to blunt needles was attempted when the dialysis staff believed the access site was ready for conversion. The following dialysis data were kept: date of first hemodialysis visit using the VWING, total number of hemodialysis visits, cannulation success (ability to be used for hemodialysis), needle type used, time to hemostasis, complications (hematoma, infiltration, bleeding around the needle, aneurysm) and other VWING functionality assessments (e.g., blood flow rates, venous line pressures, cannulator's name), as documented at the dialysis unit. Safety data was also collected and included dialysis complications, interventions, and adverse events.

A Clinical Events Committee (CEC), composed of three independent clinicians was in place throughout the study and reviewed and classified all site-reported device or procedure-related adverse events, all events leading to death and all cases of device abandonment.

RESULTS

The subject population consisted of two men and seven women. The mean age of the subjects was 60 with a range of 45 to 69. The ethnicity of the subjects included two European New Zealanders, two Maori and five Pacific Islanders. Subject comorbidities included diabetes mellitus (9/9), hypertension (4/9), obesity (2/9), ischemic heart disease (2/9) and peripheral vascular disease (1/9). The AV fistula types included three radio-cephalic, four brachio-cephalic and two transposed brachio-basilic. The mean age of the fistulae was 14 months at the time of enrollment with a range of three to 30 months. Central venous catheters were being used by four patients at the time of the index procedure. The reasons for inclusion for difficult cannulation included five short segment fistulae with proximal segment being deep, three deep fistulae and one mobile fistula. See Table I for additional characteristics of patients undergoing VWING implantation.

At the time of the index procedure the study subjects presented a mean fistula depth at the VWING implantation site of 8.2 mm (SD 4.1 mm), a mean diameter of 7.2 mm (SD 1.6) and a mean flow rate of 789 mL/min (SD 555). Nine subjects received 18 VWING devices (two devices per patient). All nine surgical procedures were performed without complications. In nearly all the procedures, one incision accommodated the implantation of two VWINGS, except for the last procedure where each VWING was implanted through different incisions. All implants were oriented to facilitate antegrade cannulation. The implants were positioned on the vessels with good orientation relative to the skin surface and the vessel. Fatty tissue was removed from over the implants as determined necessary by the surgeon to position the implants an average of approximately 3 mm below the skin surface and to facilitate easy (66%) or moderate (34%) palpability. In most surgeries, the fistula was not mobilized from its native position. During two procedures, mobilization was performed to gain better access of the fistula. Bleeding was minor and controlled by pressure. Two subjects required superficialization of the fistula at the non-implant cannulation site at the time of the index procedure to improve cannulation. There were no observations of stenosis, thrombosis, infection or aneurysm at the implant site throughout the study.

Post-procedurally, one patient experienced a hematoma at the surgical site, observed six days following the index procedure. The hematoma resolved without intervention. Another patient had small fluid pockets, assumed to be hematomas, at each VWING three weeks post-procedure. These resolved without intervention.

At the time of the three week follow-up visit, eight out of nine subjects were assessed to determine whether the VWINGs were ready for cannulation. One patient was withdrawn from the study prior to the three week visit.

| Characteristics | Values |
|-----------------|--------|
| **N** | 9 |
| **Mean Age (y)** | 60 |
| **Sex** | Male 2, Female 7 |
| **Ethnicity** | European/NZ 2, Maori 2, Pacific Islander 5 |
| **Fistula Type** | Radio-cephalic 3, Brachio-cephalic 4, Transposed Brachio-basilic 2 |
| **Mean Fistula Age (m)** | 14 |
| **Reason for Inclusion** | Short Segment 5, Deep 3, Mobile 1 |
| **Catheter Dependent** | 4 |

m = months; y = years.

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**TABLE I - CHARACTERISTICS OF PATIENTS UNDERGOING VWING IMPLANTATION**
because of unexpected death unrelated to the study. All patients assessed had a fistula with good bruit and thrill. There were no signs of infection, bleeding, arm edema or vessel stenosis at the implant site. Six of the eight subjects assessed were considered qualified for cannulation. Two patients had residual swelling from the implant procedure. They were reassessed and approved for cannulation after five weeks. The VWINGS were generally palpable with 56% being easy and the remainder being moderately palpable. Thirteen of the 16 (81%) VWING’s assessed were considered acceptably aligned, being oriented with less than 15 degrees tilt relative to the skin. Three of the 16 (19%) VWINGS were considered to be not optimally aligned with the skin surface, being up to 30 degrees off of the skin. Two of these VWING’s were in patients whose vessel had been completely mobilized at the time of implantation.

Six of the nine subjects enrolled participated in the three and six month follow-up visits. Two subjects were withdrawn from the study because of unexpected death unrelated to the study. A third subject was withdrawn because of recurrence of a previous neoplasm. All patients assessed had a fistula with good bruit and thrill. Only one VWING was not easily palpable at three months and all VWINGS were easily palpable by the six month point of the study. Five of 12 (42%) VWINGs assessed were observed to be rotated relative to the skin (20-40 degrees). Consistent blunt needle access and prescribed dialysis was achieved on all six patients prior to the three month follow up. One patient experienced difficulty with access at the time of the six month implant and was not being accessed through the VWING. After a protocol modification, one patient was having both VWINGs accessed at six months because the non VWING access site could not be successfully cannulated. Six out of seven VWINGs in five out of six patients were being successfully used at the time of the six month follow up.

Cannulation data were collected at every dialysis session from the first VWING access attempt through to the six month follow up. First cannulation with a sharp needle was achieved a mean of 36 days after implant (range 25 days to 55 days). Cannulation through the VWING and subsequent dialysis utilizing the VWING was successful in all seven patients where access was attempted. Successful cannulation of the VWING and adequate dialysis on the first day of access was achieved in five out of seven subjects. All patients had successful VWING cannulation by the third access.

Initial use of a blunt needle for cannulation was successful for six subjects following a mean of six sharp needle cannulations (range 1-14). One subject was withdrawn from the study following successful sharp needle cannulations but prior to a blunt needle attempt. Blunt needles were used for 71% of the cannulations of the VWING site. The VWING was used for both arterial (13%) and venous (87%) access.

During the 1367 study days, cannulation through the VWING was attempted 387 times with a mean of 55 times per patient (range 4 to 74). Successful use of the VWING was achieved 94% (365 of 387 accesses) of the time. This compares with a use rate of 77% (272 of 355 dialysis sessions) for the nonimplant cannulation site. The nonimplant cannulation site failed cannulation or was not attempted for 23% of the dialysis sessions and a central venous catheter was used instead of fistula access. When cannulation of the cannulatable nonimplant site was attempted, fistula access was achieved 96% (272 of 282 access attempts) of the time. This compares with the 94% access success rate of the VWING site, which was previously uncannulatable.

Other factors analyzed and compared between the VWING and non VWING site include single stick success (access on the first attempt), ease of cannulation, pain, hemostasis time and cannulation complications. Table II outlines the results from these observations. The number of cannulators used to create the buttonhole ranged from one to four cannulators and the total number of cannulators that accessed a device ranged from one to 19.

No interventions were performed at the implant sites to maintain fistula viability and assessment of the fistula by fistulogram was not a routine part of the study protocol. Nevertheless, fistulograms were performed in three patients in order to assess the cause of cannulation difficulty at the non VWING site. Figure 2 demonstrates a fistulogram of a patient with repeated cannulation failures at the arterial cannulation segment. An aneurysm is observed at the arterial cannulation segment. The VWING site in this patient is normal.

**TABLE II - CANNULATION OBSERVATIONS**

|                      | VWING Site | Non-Implant Site |
|----------------------|------------|-----------------|
| Total Access Procedures | 387        | 355             |
| Successful Site Use (%) | 94        | 77              |
| Successful Cannulation (%) | 94        | 96              |
| Single Stick Success (%) | 90        | 94              |
| Insertion Ease (1: Easy, 10: Impossible) | 1.52 | 1.67 |
| Insertion Pain (1: none, 10: extreme) | 0.46 | 0.382 |
| Time to Hemostasis (min.) | 8.99 | 7.95 |
| Backwall Puncture (%) | 0.6       | 1.0             |
| Bleeding Around Needle (%) | 2.7      | 4.6             |
| Hematoma (%) | 0.6       | 0               |
| Infiltration (%) | 1.2       | 0               |
| Overall Complications (%) | 4.8    | 4.3             |
| Interventions | 0         | 4               |

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One patient required three interventions (superficialization, fistuloplasty, arterial end revision) and one patient had one intervention (fistulaplosty) before the non VWING site could be used. One patient remained on a catheter because of continued difficulty at the arterial site (non VWING). A final patient was never able to use the non VWING site and eventually got approval to use the second VWING. In these patients, it is estimated that a mean of 77 catheter days would have been avoided if two VWINGs had been used from the outset of the study.

**DISCUSSION**

Consistent, reliable and safe access to fistulae will always be a challenge in dialysis access. A first-in-man VWING study was undertaken to assess initial device functional feasibility and safety in human subjects with difficult to cannulate fistulae.

Final study results indicate that the VWING functions as a reliable fistula access guide for difficult fistula access sites with a 94% cannulation success rate. The implantation procedures were performed without complications. Fistula access was achieved through the VWING for all seven subjects where cannulation was attempted. Successful achievement of the study's primary endpoint of cannulation using the buttonhole cannulation technique with a blunt needle was attained by seven VWINGs of six subjects. In total, there were 1367 study days. Cannulation parameters through the VWING were demonstrated to be clinically comparable to a cannulatable, non-implant site.

There were no device or procedure-related serious adverse events, including infection. There were no incidences of vessel stenosis, aneurysm or thrombosis related to the device. Fistula interventions at the VWING site were not required to maintain fistula viability; however, four interventions at the non VWING sites were required. This suggests there are no adverse effects on the fistula from the VWING attachment.

By facilitating buttonhole cannulation of the fistula, the VWING may reduce trauma and damage to the fistula. An example of this is a comparison of the non-implant and VWING cannulation sites of one subject observed in Figure 2. This shows the fistula at the VWING site is non-dilated, non-stenotic and there is no indication of thrombosis or aneurysm. The non-implant cannulation site shows unobstructed flow; however, dilation of the fistula indicating an aneurysm can be observed at the non-implant cannulation site. This is likely a result of area puncture of the fistula because only a short segment of the fistula was cannulatable.

The most significant possible adverse event was infection. Several authors have reported infection associated with AVF cannulation. Most of these report an incidence of between 0.16/1000 days and 0.32/1000 days (5, 6). In the current study there were no reported device-related infections during 1367 subject days. While this remains a small sample size, these preliminary results are promising. The low infection rate observed in the study may be attributable to the design and material of the VWING. Titanium has been revealed to have a reduced bacteria adhesion rate (7). Unlike other subcutaneously implanted devices used for access to the bloodstream such as ports, the VWING does not require interaction of the needle and the implant. There is no septum that must be traversed or valve that must be opened. The cannulators that gained experience with the VWING reported that after achieving blunt needle access, they did not usually perceive contact between the metal of the implant and the needle as it entered the vessel. In addition, the buttonhole cannulation technique used in the study utilized a double prep technique where the site was prepped with an antiseptic solution, the scab from the cannulation site was removed and the site was prepped again with a second antiseptic solution. Use of a topical antibacterial ointment following needle removal may have also contributed to the low infection rate for the study. The infection rates observed in the study were also lower than what is reported in the literature for buttonhole access. A recent study showed local infections occurred twice as often in buttonhole patients than traditional rope ladder and the only episode of bacteremia was in the buttonhole patient (8). However, cannulation of the buttonhole sites were nearly 10 times as difficult once blunt needles were used starting in the fourth week. This suggests that an adequate buttonhole was not created. In this study, the difficulty of access of
the nondevice site and the VWING site was comparable. The inadequate creation of the buttonhole may hinder the ability for the cannulation site to heal, resulting in an increased susceptibility to infection.

Conversion to blunt needles occurred following a mean of six sharp needle cannulations (range 1-14). When early conversion to blunt needles was attempted, blunt needle access was possible. Additional observations included an increased flexibility in the number of cannulators that utilized the VWING buttonhole. For one patient, four different cannulators helped establish the buttonhole and up to 19 different cannulators accessed the VWINGs during the six month study. Typically, buttonhole cannulation is performed by only a few cannulators, and the initial creation is performed by one cannulator. The VWING device may help alleviate the obstacles associated with buttonhole access.

The use of ultrasound has been discussed in the literature as another method of accessing difficult to cannulate fistulae (9). In dialysis centers that have access to ultrasound, an ultrasound assessment can be performed prior to cannulation. Depth of the vessel, location of the vessel and course can be determined and marked on the patient’s skin to determine the ideal cannulation location. However, this requires training, equipment and additional time. The VWING device is a one time implant that enabled dialysis to be performed without adjustments. It is not practical to use ultrasound at every dialysis access session and this will not enable creation of a buttonhole access. Furthermore, many dialysis centers are moving towards home hemodialysis and self care, where access and use of an ultrasound for dialysis access is not feasible. The VWING enables use of a segment of vein which would not have otherwise been able to be used, without the requirement of changing current practice within the dialysis service.

The VWING performed as intended by facilitating repeated access to the vascular system allowing for the prescribed hemodialysis treatment. The study has demonstrated that the VWING is a potential solution for access to difficult to cannulate fistulae. Additional studies are being performed to further demonstrate the safety and efficacy of the vascular needle guide.

Informed consent: Institutional Review Board (IRB)/Ethics Committee approval was obtained. Informed consent was obtained from each study subject.

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Conflict of interest statement: Nathaniel P. Young, Mark Crawford, Duane D. Blatter, Trent Perry, Doug Smith, and Chris Phillips have proprietary interest in the VWING.

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REFERENCES

1. Bronder CM, Cull DL, Kuper SG, et al. Fistula elevation procedure: experience with 295 consecutive cases during a 7-year period. J Am Coll Surg. 2008;206(5):1076-1081, discussion 1081-1082.

2. Singh P, Robbin ML, Lockhart ME, Allon M. Clinically immature arteriovenous hemodialysis fistulas: effect of US on salvage. Radiology. 2008;246(1):299-305.

3. Marticorena RM, Hunter J, Macleod S, et al. He salvage of aneurysmal fistulae utilizing a modified buttonhole cannulation technique and multiple cannulators. Hemodial Int. 2006;10(2):193-200.

4. Twardowski Z, Lebek R, Kubara H. Different sites versus constant sites of needle insertion into arteriovenous fistulas for treatment by repeated hemodialysis. Dial Transplant. 1979;8:978-980.

5. Nesrallah GE, Cuerden M, Wong JH, Pierratos A. Staphylococcus aureus bacteremia and buttonhole cannulation: long-term safety and efficacy of mupirocin prophylaxis. Clin J Am Soc Nephrol. 2010;5(6):1047-1053.

6. Hussain N, Salama M, Aly NY, Al-Mousa H, Abdel-Ghani A, Alhilali N. Infection related processes during haemodialysis: A study in General Hospital Haemodialysis unit. Reviews in Infection. 2010;1(1):1-6.

7. Schildhauer TA, Robie B, Muhr G, Köller M. Bacterial adherence to tantalum versus commonly used orthopedic metallic implant materials. J Orthop Trauma. 2006;20(7):476-484.

8. MacRae JM, Ahmed SB, Atkar R, Hemmelgarn BR. A randomized trial comparing buttonhole with rope ladder needling in conventional hemodialysis patients. Clin J Am Soc Nephrol. 2012;7(10):1632-1638.

9. van Hooland S, Donck J, Ameye F, Aerden D. Duplex ultrasonography and haemodialysis vascular access: A practical review. Int J Nephrol Urol. 2010;2(2):283-293.