

"Needle Bypass" Technique: Percutaneous Anatomical Bypass with Needle Rendezvous for No-Option Peripheral Arterial Disease.

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Abstract

Background:

The complex lesions failed by surgical bypass treatments have yet to be solved even with the latest endovascular devices. We describe a new method of fully percutaneous anatomical bypass, named the "Needle bypass" technique.

Case presentation:

A 68-year-old male patient was suffered from chronic limb-threatening ischemia due to the surgical removal of right distal common femoral artery to proximal superficial femoral artery and two surgical bypasses, axillary-femoral bypass and iliac-femoral bypass, repeated infection 10 years before. He was referred for peripheral intervention by vascular surgeons due to the surgical higher risk background. Conventional peripheral intervention for the removal of common femoral bifurcation failed. "Needle bypass" technique was successfully performed that the tips of the needles which are inserted bi-directionally from outside the body are aligned in the body to perform the guidewire externalization through the needles, "Needle rendezvous", and to deploy scaffolds the complex anatomical lesion including extravascular site. This technique provided the great success with this no-option patient.

Conclusions:

"Needle bypass" technique is a new effective percutaneous treatment option for no-option patient.

Background:

Long segment chronic total occlusion (CTO) in peripheral arterial disease (PAD) is a common finding. Recanalization with endovascular therapy (EVT) for occluded infrainguinal arteries can often be performed successfully with latest devices and techniques. Surgical bypass (SB) for long CTO has proven to be most durable but also has significant mortality due to its complications (J.Q. Zhang, et al. 2014). Some cases after surgical bypass failure are more difficult to treat with EVT due to complexity of anatomy. We propose a new percutaneous anatomical bypass, named the "needle bypass" technique, for the patient with no-option PAD which means higher surgical risk and too complex lesion to treat with conventional peripheral intervention.

Case Presentation:

A 68-year-old male patient with a history of right common femoral artery (CFA), axillary-femoral bypass, and ilio-femoral bypass transection due to recurrent methicillin resistant staphylococcus aureus (MRSA) infection after Miles' operation and lymphadenectomy for anal cancer 10 years ago was suffered from ischemic right foot pain at rest. The ankle brachial index was 0.59 in the right leg. The patient was referred to our hospital to undergo EVT by vascular surgeon due to the high risk of complications from

surgical procedures. Computed tomography angiogram (CTA) showed that there were some skin defects, anastomosis sites, and no arteries from distal CFA to proximal superficial femoral artery (SFA) in his right leg due to frequent surgical treatments. Contrast effect was found from stenotic middle SFA to normal distal vessel.

The lesion was extremely complicated, and bi-directional approach was performed from the beginning. 7-Fr guiding sheath (Destination®, Terumo Co., Japan) as antegrade crossover approach and 6-Fr guiding sheath (Parent Cross®, Medikit Co. Ltd., Japan) as retrograde approach were inserted via left CFA and right popliteal artery, respectively. Angiographical image showed the same overview of lesion as CTA (Fig. 1A). Any hard guidewire including tail of 0.035-in. wire supported with 4-Fr catheter (Tempo®, Cardinal Health Inc., USA) were not able to advance into the lesion and outside the vessel due to the solid tissue hardened from the repeated infections and surgical procedures. Since it was too difficult to treat with conventional intervention, “Needle bypass” technique as a novel percutaneous anatomical bypass was implemented. After the administration of local anesthesia to the puncture spots, 18-gauge needle (Terumo Co., Japan) punctured retrogradely from the proximal thigh into the body below the proximal true lumen (Fig. 1B, 1C) and the other 18-gauge needle punctured antegradely from the right groin via right CFA in front of the proximal CTO orifice, confirming the tip of the needle inside CFA by the sign of blood return, and continued inserting to meet the tip of retrograde needle. 0.014-in. guidewire was manipulated carefully to advance into the hole of the other needle to attempt the guidewire externalization from needle to needle, named the “Needle rendezvous” technique (Fig.1D).

A new 6-Fr Parent Cross® sheath was inserted antegradely over the pull-through guidewire between the puncture sites (Fig. 2A). 4.0x20-mm semi-compliant balloon (Sterling®, Boston Scientific Co., USA) dilated the tissue in front of antegrade guiding sheath to create a space, and 18-gauge needle punctured antegradely from the proximal thigh through the space, which was formed by previous balloon dilatation, to reach the distal true lumen as 4-Fr retrograde catheter was targeted. (Fig. 2B). 0.014-in. guidewire through the needle was advanced antegradely into the retrograde catheter to perform the guidewire externalization. 4-Fr catheter was inserted retrogradely over the pull-through guidewire into the space formed with previous ballooning. 0.035-in. guidewire and 4-Fr catheter as retrograde system were manipulated gently to advance through the 6-Fr antegrade guiding sheath (Fig. 2C) to right CFA. Antegrade 6-Fr guiding sheath was pulled out into right CFA as proximal true lumen. After bi-directional systems were separated from each other within right CFA lumen, 0.014-in. guidewire via 4-Fr retrograde catheter were advanced through the space and into 7-Fr antegrade guiding sheath inserted via left CFA as crossover approach to accomplish the true guidewire externalization between bi-directional guiding sheathes (Fig. 2D).

In order to treat the complex lesions including extravascular route, “Pave-and-Crack” technique which facilitates the safe introduction and effective scaffolding of stent-grafts through the lesion access followed by an aggressive balloon dilatation was intentionally performed (R.J. Hinchliffe, et al. 2007; M. Dias-Neto, et al. 2018). The lesion was aggressively dilated with a 7.0x40-mm non-compliant balloon (SHIDEN HP, Kaneka Co., Japan) and fully covered with a 7.0x250-mm stent graft (Viabahn®, W. L. Gore

& Associated, Inc., USA). In this case, it was mandatory to implant interwoven stent (Supera®, Abbott Vascular, USA) which provides higher radial force to resist recoil and extrinsic compression from the solid tissue in the extravascular site and hip joint motion. After 6.5x150-mm interwoven stent implantation and post-balloon dilation with 7.0-mm non-compliant balloon with highest pressure, angiogram and intravascular ultrasound finally demonstrated the great success of “needle bypass” technique to perform percutaneous anatomical bypass without any complications (Fig. 3A, B, C). His symptom and physiological examinations were completely improved after the procedure, and there have been no events of patency loss, reintervention, and stent thrombosis a year after the treatment (Fig. 3D).

Discussion:

We described the “Needle bypass” technique, which is percutaneous anatomical bypass with needle rendezvous technique, was a novel recanalization procedure in this case report. This crossing technique can revascularize the artery removed by surgery or trauma. Two-stage puncture to shorten lesion length was required for this lesion to be successful because needle directed puncture from CFA to middle SFA is difficult due to the shallow depth between both arteries. The type of scaffold needed to deploy depends on the lesion stiffness and anatomy. We implanted a combination of endovascular stent graft and interwoven stent for this complex anatomy after failed SB. Less complicated lesion would be acceptable to stent graft alone in this technique.

Determining the utility of any treatment for failed SB is made difficult by the variety of treatment options (R.T. Hagino. et al. 2007). There are some reconstruction techniques for no-option patient. As one of the newer therapies, the PQ DETOUR system (PQ Bypass, Inc., Sunnyvale, CA, USA) is also a fully percutaneous bypass technique with TORUS stent graft implantation (D. Krievins. et al. 2018). This unique crossing device is used to cross from the proximal SFA into the deep femoral vein and back into the popliteal artery. The DETOUR1 trial evaluated the 1-year safety and effectiveness outcomes associated with this system. This trial demonstrated the 1-year primary patency, secondary patency, and freedom from stent graft thrombosis rates were $81\pm4\%$, $90\pm3\%$, and $84\pm4\%$. Deep venous thrombosis (DVT) developed in 2 of 79 target limbs (3%) through 1 year (D.K. Krievins. et al. 2020). In Japan, this system has not been approved to use in daily practice. Therefore, we should invent the new treatment method and technique for the complex lesions. Nakama. et al. described the percutaneous endoluminal bypass procedure via vein for iliac artery occlusion which was not candidates for conventional EVT (T. Nakama, et al. 2020). These procedures were arterial reconstruction via vein which have a possibility of the development of DVT. Needle bypass technique connects artery-to-artery directly without venous flow disturbance leading to DVT.

The main limitation of this technique is that it must be performed below the inguinal ligament, not intraperitoneal cavity, in terms of complications. Dedicated devices to standardize this technique need to be produced. Recently, there were three cases performed successfully with this technique without complications.

Conclusions:

“Needle bypass” technique as percutaneous anatomical bypass with needle rendezvous is a safe and new effective percutaneous treatment option for no-option patient. Long-term outcomes using this technique have not yet been fully studied, and careful patient follow-up is mandatory following this procedure.

List Of Abbreviations:

Chronic total occlusion (CTO)

Peripheral arterial disease (PAD)

Endovascular therapy (EVT)

Surgical bypass (SB)

Common femoral artery (CFA)

Methicillin resistant staphylococcus aureus (MRSA)

Computed tomography angiogram (CTA)

Superficial femoral artery (SFA)

Deep venous thrombosis (DVT)

Declarations:

Ethics approval and consent to participate

Informed consent was achieved. The report followed the declaration of Helsinki of 1964.

Consent for publication

Written informed consent was obtained from the patient for publication of this case report and any accompanying images.

Availability of data and material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

All authors contributed to the study conception and design. The first draft of the manuscript was written by Takuya Haraguchi and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Figures

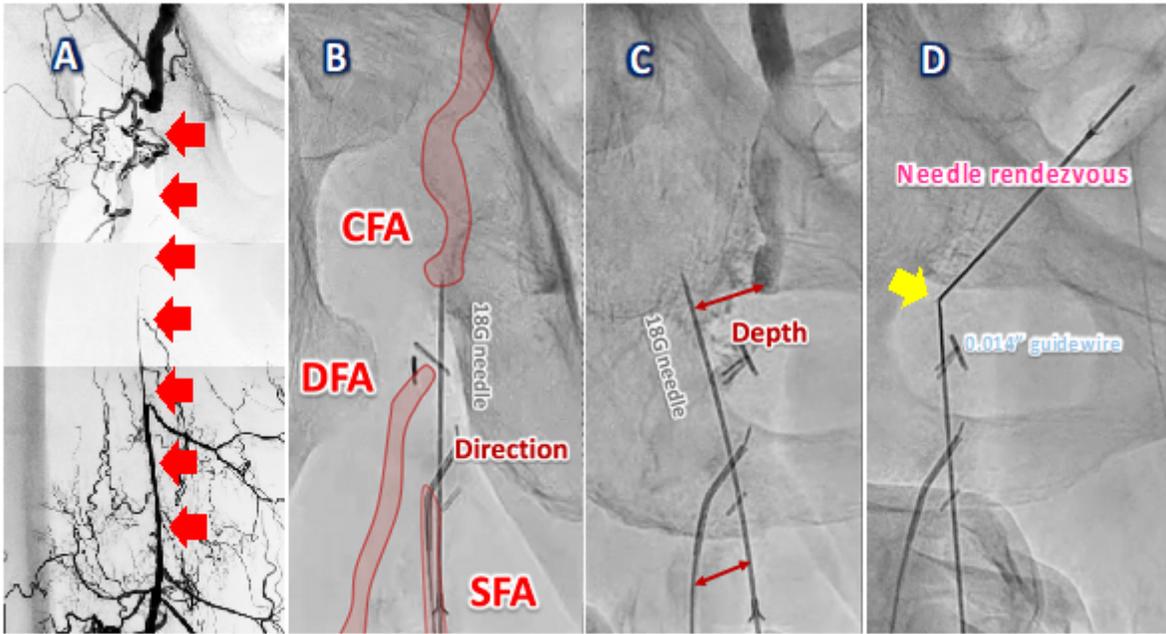


Figure 1

Angiography and Needle rendezvous technique. A. Digital subtraction angiography via bi-directional guiding sheath showed the overall of lesion (red arrows). B and C. Confirming the correct direction and depth in contralateral and ipsilateral view, 18-gauge needle punctured retrogradely from the proximal thigh into the body below the right CFA. D. The other 18-gauge needle punctured antegradely from the right groin via right CFA in front of the proximal CTO orifice, confirming the tip of the needle inside CFA by the sign of blood return, and continued inserting to meet the tip of retrograde needle (yellow arrow). 0.014-in. guidewire was manipulated carefully to advance into the hole of the other needle to attempt the guidewire externalization from needle to needle, named the “Needle rendezvous” technique.

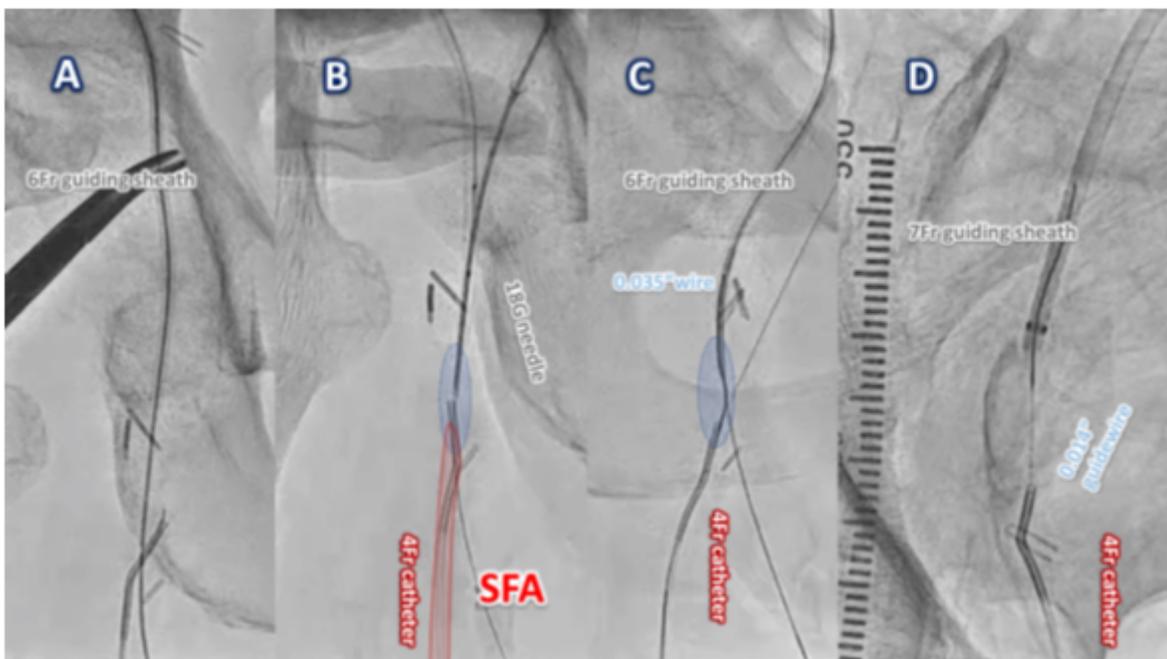


Figure 2

The treatment process of Needle Bypass technique A. 6-Fr guiding sheath was inserted antegradely over the pull-through guidewire into the body between the puncture sites. B. 18-gauge needle punctured antegradely from the proximal thigh through the space (blue frame), which was formed by 4.0x20-mm semi-compliant balloon dilatation, to reach the distal true lumen as 4-Fr retrograde catheter was targeted. C. After the guidewire externalization with 0.014-in. guidewire between the antegrade 18-gauge needle and retrograde 4-Fr catheter, retrograde catheter was advanced retrogradely into the space formed with previous ballooning (blue frame). 0.035-in. guidewire and retrograde catheter were advanced through the 6-Fr antegrade guiding sheath. D. After bi-directional systems were separated from each other within right CFA lumen, 0.014-in. guidewire via 4-Fr retrograde catheter were advanced into 7-Fr antegrade guiding sheath inserted via left CFA as contralateral approach.

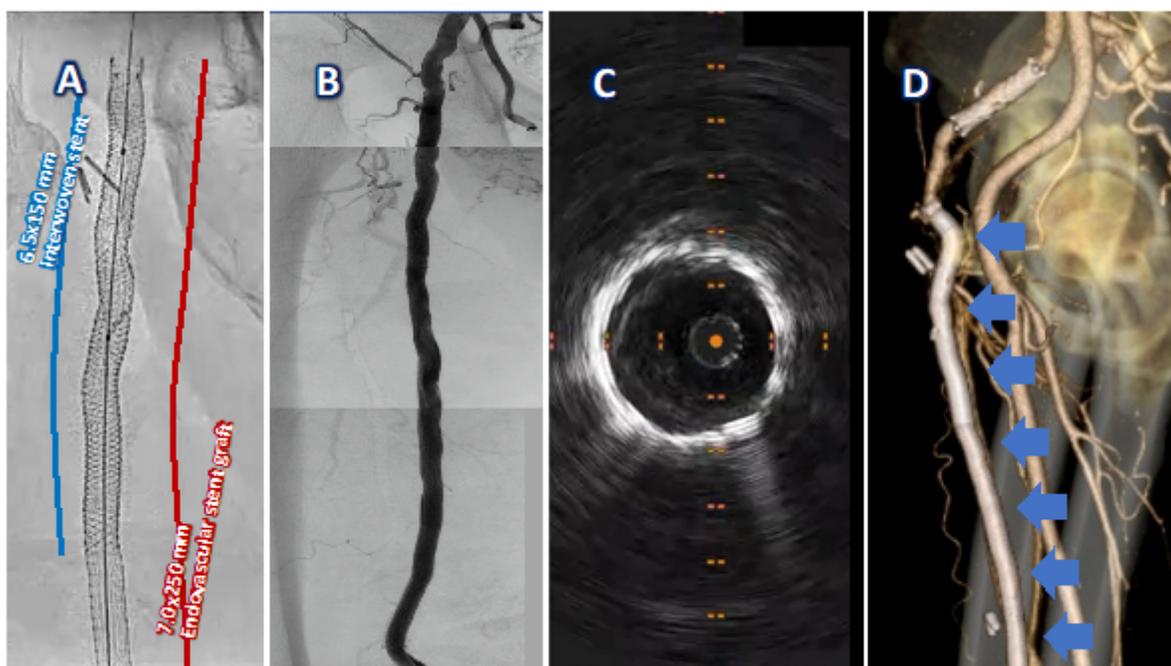


Figure 3

Final results and computed tomography angiogram at 12-month follow-up. A. The lesion was fully covered with 7.0x250-mm endovascular stent graft (red line), and the arterial extraction part of the lesion around right joint was implanted with 6.5-150mm interwoven stent (blue line) to resist recoil and extrinsic compression. B. Final angiogram demonstrated the great blood flow. C. Intravascular ultrasound showed the symmetrically and concentrically expanded scaffolds. D. Computed tomography angiogram and physiological examinations revealed no clinical events (blue arrows) a year after the treatment.