

Fracking Technique: The Novel Approach To Crack Deep Calcified Plaque In Common Femoral Artery With Hydraulic Pressure.

Takuya Haraguchi (✉ t.haraguchi@scvc.jp)

Sapporo Heart Center <https://orcid.org/0000-0002-2116-2178>

Tsutomu Fujita

Sapporo Heart Center

Yoshifumi Kashima

Sapporo Heart Center

Masanaga Tsujimoto

Sapporo Heart Center

Tsuyoshi Takeuchi

Sapporo Heart Center

Yutaka Tadano

Sapporo Heart Center

Daisuke Hachinohe

Sapporo Heart Center

Umihiko Kaneko

Sapporo Heart Center

Ken Kobayashi

Sapporo Heart Center

Daitaro Kanno

Sapporo Heart Center

Katsuhiko Sato

Sapporo Heart Center

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Abstract

Background:

The patency of conventional peripheral intervention for atherosclerotic lesions in common femoral artery (CFA), called “no stenting zone”, are not superior to surgical endarterectomy due to calcified plaque occupying the area. Plaque modification strategies to obtain acute gain in CFA provide the better clinical outcome compared to standard balloon angioplasty. Atherectomy devices, which focus on modification of superficial calcification, contribute to the improvement of clinical outcomes. However, deep calcium resists vessel expansion so that luminal gain is not easily achieved.

Main text:

We propose a novel calcified plaque modification technique, named the “Fracking technique”. The term fracking refers to how a rock is fractured apart by the high hydraulic pressure. This technique is to crack deep calcification with hydraulic pressure with a balloon deflator through 18-gauge needle, which punctures into calcification in order to obtain larger acute luminal gain. Case 1 involved an 81-year-old male with eccentric calcified plaque in right CFA. Conventional balloon angioplasty for the lesion provided the suboptimal minimal lumen area (MLA) from 6.2 to 10.7mm² with intravascular ultrasound (IVUS) measurement. Fracking technique was implemented to obtain the larger MLA. After fracking was repeated three times until there were no more Fracking points, a much larger MLA of 27.1mm² was achieved without complications. Case 2 involved a 72-year-old male undergoing hemodialysis presented with ischemic rest pain of his right limbs due to severe stenosis with eccentric calcification in distal CFA to proximal superficial femoral artery. MLAs with IVUS before and after ballooning were 10.0mm², 13.1mm², respectively. None of the results of MLA lived up to our expectation. Fracking technique was attempted, and MLA of 28.9mm² was successfully obtained after this technique. No complications observed.

Conclusions:

Fracking technique was effective for severe calcified lesion in CFA to obtain significantly larger lumen area which will lead to long-term patency superior to conventional peripheral intervention.

Background

Surgical treatment for atherosclerotic lesions involving common femoral artery (CFA) is still considered the gold standard treatment because of excellent long-term patency and limb salvage, while the surgical complications were unexpectedly high (B.N. Nguyen. 2015).

Peripheral intervention has become more common. Conventional balloon angioplasty for CFA lesions has failed to show promising results due to calcification (R.F. Bonvini. 2011). Balloon and atherectomy target superficial calcium. However, these devices cannot affect deep calcium which resists vessel expansion

and luminal gain (Dini CS. 2019). The problem is that atherectomy devices increased complications. (M.T. Finn. 2020).

Main Text

This paper is the first time to disclose our novel technique, named the “Fracking technique (FT)”, to crack deep calcium with hydraulic pressure through 18-gauge needle which punctures into calcification, so as to obtain larger luminal gain, increase vessel compliance, then provide new versatile treatment options for patients.

The process of FT is described as below. Balloon dilatation with a precisely sized balloon for calcified CFA lesions is performed. If minimal lumen area (MLA) by intravascular ultrasound (IVUS) is suboptimal, FT is indicated. 18-gauge needle (Terumo, Japan) with plastic outer sheath removed is optimal tip size and strength chosen to insert into a part of calcification which is not expanded adequately by angiography and/or IVUS. Any larger needle is not recommended because of hydraulic pressure leakage. The reason for keeping the balloon dilation during implementing FT is to compress the lesion to make it denser and prevent dissection which might unexpectedly spread with FT. After needle insertion, 3.0-ml lock syringe is sequentially attached to the back end of needle to check the location of needle tip with injecting saline from the syringe. As the needle tip reaches dense calcification, and plunger of syringe cannot be pushed further, the location of “fracking point” is determined. A balloon indeflator with a half concentration of contrast agent is connected to the back end of needle, and the pressure of indeflator is gradually applied for the dense calcification under angiography till sudden drop in the pressure which means cracks of calcification occurred. This process is “fracking”. During fracking, the needle and the indeflator must be kept connected by hand so that they are not dislodged by the force of pressure. Fracking is repeatedly performed in several fracking points in calcification until the fracking point cannot be detected anymore or sufficient MLA is obtained. The contrast agent in the indeflator sometimes flows from fracking point into the vessel lumen, which means that deep calcification is cracked and connects to the lumen. Most calcifications are cracked by less than 10 atmosphere (atm), a few severe calcium acquire up to 30 atm. After fracking, the dilatation using the previous balloon is performed to compress the calcification which has the network of grains, pores, and cracks due to fracking, and this ballooning also serves to stop bleeding via fracking points. Most of hemostasis takes less than five minutes. Finally, when IVUS demonstrates the larger or targeted MLA, then the procedure finished. The typical process of FT is in the additional file (Supplementary Movie 1).

In terms of limitations, FT can be performed with only CFA or lower arteries. Calcification on the dorsal side of artery is also difficult to be punctured with needle. The effect of FT depends on the volume and density of calcification. FT may be more effective for eccentric calcified lesions than for concentric calcification. Also, there is a learning curve to puncture the calcification being compressed with balloon without puncturing the balloon or damaging the artery.

Here are two cases treated with FT. Case 1 involved an 81-year-old female with diabetes mellitus presented with claudication in her right calf. A 6-Fr sheath was inserted into left CFA as contralateral approach. Quantitative vessel analysis (QVA) demonstrated 94% stenosis with the eccentric calcification which occupied the middle to distal part of right CFA. A 0.014-in. guidewire passed the lesion, and IVUS revealed the eccentric calcification with MLA (6.2mm^2 ; $3.9 \times 2.2\text{mm}$) (Fig. 1A). After dilation with 6.0x20-mm balloon with blades, QVA showed 24% residual stenosis. However, MLA (10.7mm^2 ; $6.3 \times 2.1\text{mm}$) was not acceptable (Fig. 1B). Percutaneous direct needle puncture of calcified plaque (PIERCE) technique was attempted to modify the calcification (S. Ichihashi. 2014), and 7.0x40-mm non-compliant balloon at highest pressure dilated the lesion. IVUS showed the unsatisfactory MLA (17.1mm^2 ; 6.8×2.9) (Fig. 1C), therefore, FT was implemented to modify the eccentric calcification which could not be satisfactorily compressed with conventional intervention. After fracking was repeated three locations, with up to 8 atm, QVA and MLA improved significantly to 16%, 27.1mm^2 (Fig. 1D), respectively. Finally, the satisfied result was obtained with no complications.

Case 2 involved a 72-year-old male undergoing hemodialysis presented with ischemic rest pain on his right limbs. Angiogram revealed the severe stenosis with eccentric calcification in distal CFA to proximal superficial femoral artery. MLA-IVUS before, after dilation with 7.0x40-mm non-compliant balloon, and after PIERCE technique resulted with 10.0mm^2 , 13.1mm^2 , and 15.9mm^2 , respectively (Fig. 2A, 2B, 2C). None of the results lived up to our expectation. Therefore, FT was attempted and cracked this lesion at 5 atm. A larger MLA of 28.9mm^2 was achieved without complications (Fig. 2D). Notable point in our cases was that larger MLA was obtained even though IVUS demonstrated the shape of superficial calcification did not change (Fig. 2A-D). From these IVUS images, we assumed a low probability of distal embolization. These cases have no clinical events two years after FT.

The concept of FT which targets deep calcified plaque is the same as intravascular lithoplasty (IVL) (M. Brodmann. 2019). IVL uses pulsatile sonic pressure waves to modify from intimal till medial calcium. Conversely, FT cracks the calcification from outer parts into the middle. FT might have the potential to achieve larger MLA and provide clinical outcomes similar to IVL. Therefore, long-term comparison studies between two methods are necessary.

Conclusions

Fracking technique was effective for calcified CFA lesion to obtain significantly larger MLA which leads to long-term patency superior to conventional intervention. Investigation of long-term clinical outcomes is necessary.

Abbreviations

Common femoral artery (CFA)

Fracking technique (FT)

Minimal lumen area (MLA)

Intravascular ultrasound (IVUS)

Atmosphere (atm)

Quantitative vessel analysis (QVA)

Percutaneous direct needle puncture of calcified plaque (PIERCE)

Intravascular lithoplasty (IVL)

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

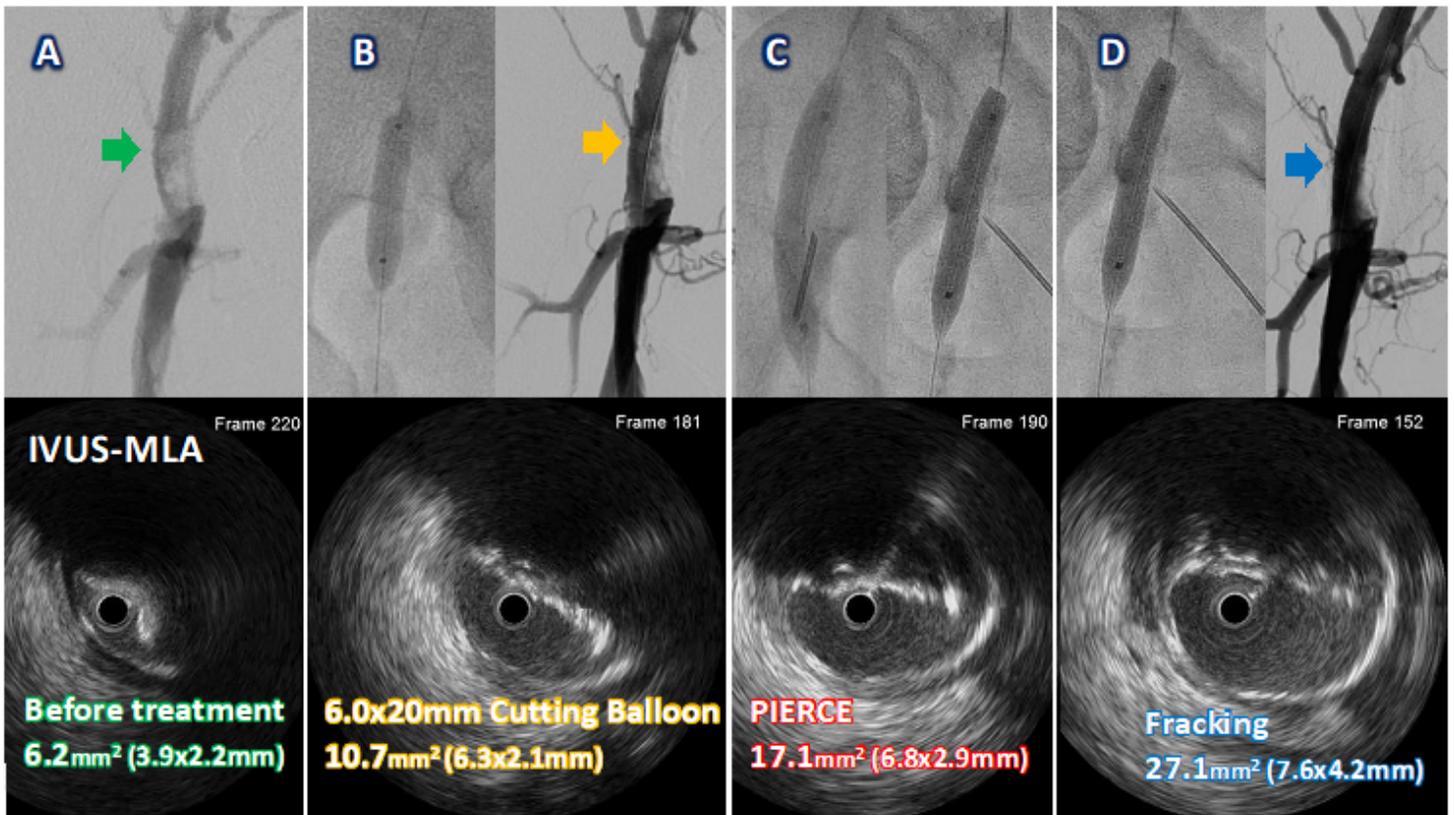


Figure 1

Representative case 1 of the treatment with Fracking technique. A. Control angiography showed quantitative vessel analysis (QVA) of 94% (green arrow) with the eccentric calcification which occupied the middle to distal part of right common femoral artery. Minimal lumen area (MLA) by IVUS after guidewire crossing was 6.2mm². B. After dilatation with 6.0x20-mm balloon with blades, QVA showed 24% residual stenosis (yellow arrow). However, MLA (10.7mm²) was not acceptable. C. Percutaneous direct needle puncture of calcified plaque technique was attempted to modify the calcification (S. Ichihashi, et al. 2014), and 7.0x40-mm non-compliant balloon at highest pressure dilated the lesion. IVUS showed the unsatisfactory MLA (17.1mm²). D. After fracking was repeated three times, with up to 8 atmosphere, QVA and MLA improved significantly to 16%, 27.1mm², respectively. Finally, the satisfied result was obtained with no complications.

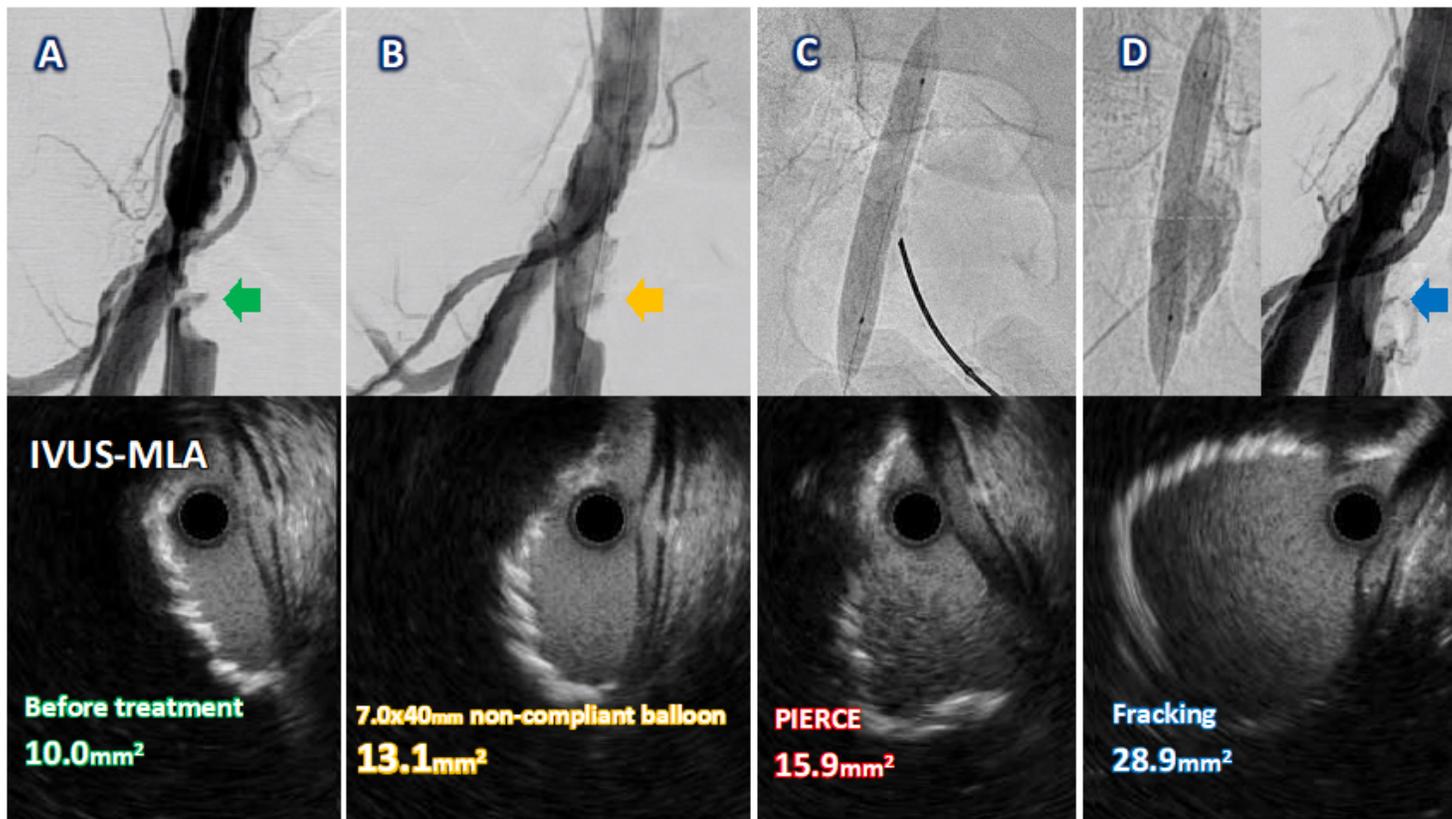


Figure 2

Representative case 2 of the treatment with Fracking technique. A. Control angiogram revealed the quantitative vessel analysis (QVA) of 96% stenosis with eccentric calcification in distal common femoral artery to superficial femoral artery (green arrow). Minimal lumen area (MLA) by intravascular ultrasound (IVUS) before treatment after guidewire crossing was 10.0mm². B. After dilatation with 7.0x40-mm non-compliant balloon, QVA showed 42% residual stenosis (yellow arrow), and MLA (13.1mm²) was not acceptable. C. After 7.0x40-mm non-compliant balloon dilatation and percutaneous direct needle puncture of calcified plaque technique (S. Ichihashi, et al. 2014), IVUS showed the unsatisfactory MLA (15.9mm²). D. After fracking technique cracked the calcified plaque at 5 atmospheres, QVA improved significantly to 26% (blue arrow), and a much larger MLA of 27.1mm² was achieved without complications.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [FrackingCIVRsupplementalmaterial.mp4](#)