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Original Article

Endarterectomy Using the Lateral Approach with an Ultrasonic Surgical Aspirator Device for Heavily Calcified Peripheral Arterial Occlusive Disease

Takashi Shibuya, MD, PhD,[1,2] Ken-ichi Watanabe, MD, PhD,[1,2] Takashi Nakamura, MD, PhD,[3] Hironobu Fujimura, MD, PhD,[4] Takashi Shintani, MD,[5] and Yoshiki Sawa, MD, PhD[1]

Objective: To present a new and easy technique for performing endarterectomy in patients with peripheral arterial occlusive disease (PAD) having dollop calcification at the common femoral artery (CFA).

Materials and Methods: We developed a procedure for angioplasty for PAD using a supersonic surgical suction device, based on the new concept of "to create a new lumen to dig tunnel in calcification." Ultrasonic surgical aspiration device was inserted into the intravascular space from outside the area of the target lesion and only internal calcification was removed.

Results: We performed this technique in three patients who had PAD with dollop calcification at CFA. We succeeded in performing endarterectomy easily and safely. This method does not require vascular wall closure suture at calcified lesion or intimal fixation suture of dollop calcification.

Conclusion: We address the technical difficulty in treating highly calcified lesions that could not be dealt with conventional endarterectomy. Our new method is one of the options for revascularization of heavily calcified lesions.

[1] *Department of Cardiovascular Surgery, Osaka University Graduate School of Medicine, Suita, Osaka, Japan*
[2] *Department of Cardiovascular Surgery, Suita Tokushukai Hospital, Suita, Osaka, Japan*
[3] *Department of Vascular Surgery, Osaka Rosai Hospital, Sakai, Osaka, Japan*
[4] *Department of Cardiovascular Surgery, Toyonaka Municipal Hospital, Toyonaka, Osaka, Japan*
[5] *Department of Cardiovascular Surgery, Nippon Life Hospital, Osaka, Osaka, Japan*

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Corresponding author: Takashi Shibuya, MD, PhD. Department of Cardiovascular Surgery, Osaka University Graduate School of Medicine, 2-2 Yamadaoka, Suita, Osaka 565-0871, Japan
Tel: +81-6-6879-3154, Fax: +81-6-6879-3163
E-mail: t-shibuya@surg1.med.osaka-u.ac.jp

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Introduction

Atherosclerotic changes in the blood vessel wall are the main pathological factor for peripheral arterial occlusive disease (PAD).

In recent years, with the change in the disease structure, the number of patients with complications of diabetes, chronic renal dysfunction, and maintenance dialysis has been increasing.[1,2] The common characteristic of the vascular pathology of these patients is heavy arterial wall calcification. In the classical arteriosclerotic pathology, calcification occurs in the medial smooth muscle layer of the arterial wall, but in Mönckeburg-type calcification, which is common in patients with diabetes, chronic renal dysfunction, and maintenance dialysis, wall structure destruction and calcification commonly occurs.[3] The common femoral artery (CFA) is the most common site for such calcified lesions,[4] which is unsuitable for endovascular treatment (EVT); thus, surgical endarterectomy is the first choice of treatment for such lesions.

In current endarterectomy, the basic procedure is to peel off the lesion at the boundary of the three-layered structure of the wall or to scrape off the lesion that protrudes into the inner lumen.[5] However, this is difficult to perform, especially in the presence of heavy calcification. Thus, surgeons are required to have advanced skills, such as forming a blood vessel wall, fixing the intima, and closing the blood vessel wall in the calcified portion, when performing endarterectomy for heavily calcified PAD.

Thus, we aimed to present our newly developed angioplasty technique based on the new concept "to create a new lumen by digging a tunnel into the dollop calcification." We performed the endarterectomy using a surgical ultrasonic aspiration device that could reach the intravascular space from outside the area of heavily calcified lesions and remove only the calcification of the lumina.

Method and Cases

Indications for the new technique

In all cases, computed tomography (CT) was performed before surgery.

① Cases with heavy calcification, such as that occupying the lumen of the CFA, in which reconstruction was difficult using the standard procedure.
② Cases in which during the operation, the calcification could be seen through the vessel wall, and in which it was expected that almost no adventitia will remain after the calcification is peeled off.
③ There were parts of the vessel wall that could be incised/sutured on the distal side of the calcification.
④ The CFA has no curve and could be linearized.

Even if there is an indication for the new method before surgery, if the standard procedure can be performed during the operation, the standard procedure must be followed.

Method

In the outline image, a surgical ultrasonic aspiration device ‘SONOPET’ (Japan Stryker, Tokyo, Japan) (**Fig. 1**) was inserted into the intravascular space from a good portion of the vessel wall characteristics diagnosed by palpation of the wall away from the lesion, and the calcified part was shaved “by digging a tunnel” from the inside to create a new lumen (**Fig. 2**).

The CFA, deep femoral artery (DFA), and superficial femoral artery (SFA) were exposed in the usual manner with an inguinal longitudinal incision. The exposed area was the length of the clamping forceps that entered the proximal side of the lesion, whereas the distal side was the size of the SONOPET insertion site (about 1–1.5 cm), plus the length that the clamping forceps entered. After systemic heparinization, the proximal and distal sides were clamped with the forceps. At the distal side of the lesion, a 1-cm incision was made in the previously identified part with a good wall property, and SONOPET was inserted toward the proximal side. The machine settings were as follows: frequency, 25 kHz; vibration mode, LT vibration (longitudinal vibration + torsional vibration); amplitude, 300 µm; tip shape, drum type; and suction function, provided (**Fig. 1**).

The SONOPET has a filing function at its tip. It also has the functions of longitudinal vibration (also in other ul-

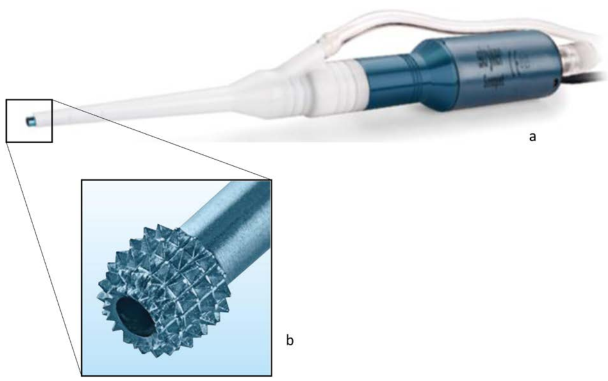


Fig. 1 (**a**) Ultrasonic surgical aspiration device ‘SONOPET’ system and hand piece. (**b**) A surgical tip is shown, blade outer diameter is 3.12 mm and blade length is 2.7 mm.

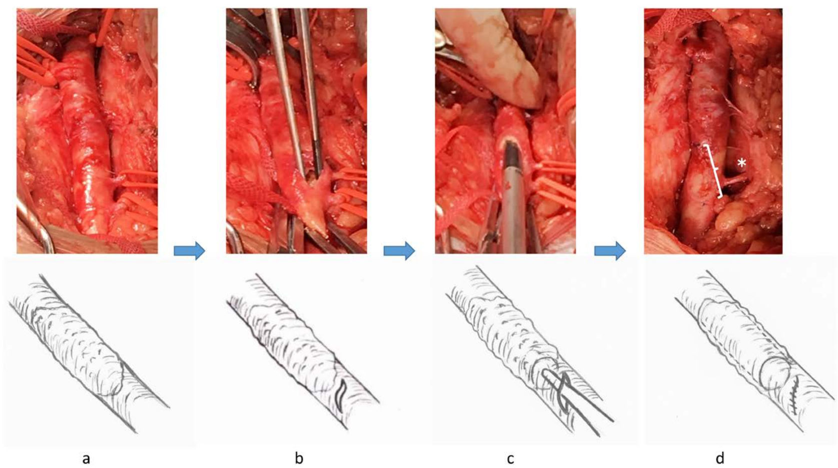


Fig. 2 Technical image schema and illustration of the endarterectomy using the lateral approach.
(**a**) In addition to the usual distance, separation of blood vessels requires a distance necessary for device insertion. (**b**) For insertion of the device, an incision of about 1–1.5 cm is made in a blood vessel wall with a good condition. (**c**) SONOPET is inserted and endarterectomy is performed. (**d**) Suturing of the vascular incision site (*) is performed easy.

Table 1 Patient characteristics

Case	Age	F/M	Rutherford category	DM	HD	HT	HL	Smoking	PH	ABI		Dollop calcification (length, mm)	Tunneling time (min.)
										pre	post		
1	70	M	5	+	+	+	+	Previous	CABG	UM	UM	46.6	10
2	82	F	3	+	—	+	+	—	PCI	0.69	0.93	17.2	13
3	70	F	3	+	—	+	+	Current	FF	0.68	0.94	30.1	15

DM: diabetes mellitus; HD: maintenance dialysis; HT: hypertension; HL: hyperlipidemia; PH: past history; ABI: ankle brachial pressure index; CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention; FF: femoro–femoral bypass for PAD; UM: unmeasurable

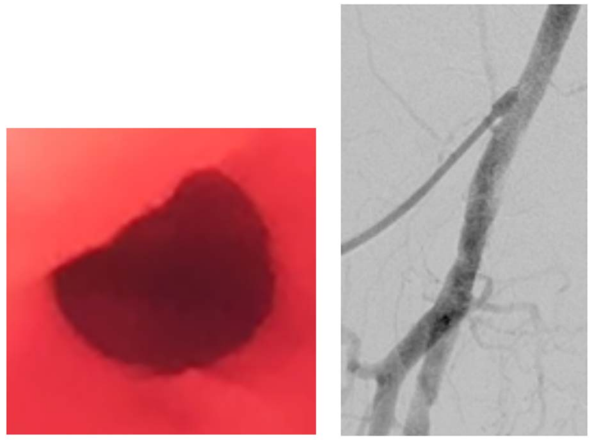
trasonic aspiration devices) and torsional motion (unique to SONOPET). With these two additional functions, it is possible to bring the tip end into contact and press it off.

To create a cavity, the calcified lesion was crushed by mechanical vibration, and the tip of the SONOPET was guided by using the vibration transmitted to the finger as a guide, and thickness of the blood vessel wall to be formed (thickness of the retained wall) was adjusted. After applying vibration to the proximal side and creating the lumen, the area should be washed thoroughly to prevent crushed pieces left behind. Due to the nature of the machine (at this frequency), the calcification will break up, but in the unlikely event of it coming in contact with soft tissue, it will not destroy the soft tissue. However, unlike other ultrasonic aspiration devices, the SONOPET also has a filing function, and with long-time filing soft tissue may be damaged. We targeted a part that can be linearized so that the tip does not hit the adventitia at an acute angle. Furthermore, by moving the device only in parallel with the vessel wall, the distal end portion did not exceed calcification and careful attention was paid to the damage of the adventitia. This means that other ultrasonic aspiration devices crush only the hard tissue corresponding to the frequency and do not damage the other tissues; however, since the SONOPET has a physical scraping function, that can cause non-frequency damage to the contact tissues. This function has great advantages, as well as some disadvantages to be cautious about.

The equipment was then withdrawn and an endoscope was inserted to check the formed lumen. After confirming the presence of reverse blood flow, the wound was closed. Since only the part of the vessel with a good wall property was selected for vessel incision for inserting the device, the suture could be closed easily. Then, after allowing for blood flow, the new lumen formed was checked using angiography and the procedure was completed.

Patients gave informed consent prior to participation in the study.

Three patients (intermittent claudication and critical limb ischemia) who underwent the procedure using this technique were included in the analysis. The patients' background information is shown in **Table 1**. To determine the effectiveness of the technique, intraoperative endoscopy, angiography, and postoperative CT were performed.



a b

Fig. 3 Confirmation of the created intraoperative lumen. (**a**) Confirmation of lumen by endoscope (before release of blood flow). The cutting part is smooth. (**b**) Angiography after de-clump is shown.

Results

The handling of the device in surgery was good. There was no damage to the vessel wall that was to be preserved. Since we examined a minor part of calcification beforehand, incision and suture closure were performed easily (**Fig. 2d**). The newly created lumen was able to secure a sufficient space. The luminal surface was macroscopically smooth (**Fig. 3a**). The transition to the intima on the distal side was smooth without a step (There is no level difference and the transition to the host intima is smooth.) and did not require intimal fixation (**Fig. 3b**). The surgical time required for cutting the calcification was 10–15 min. **Figure 4** shows a CT image taken before the operation and at 6 months postoperatively, which revealed that the lumen was in good condition even 6 months after the operation. In addition, the ankle brachial pressure index and clinical symptoms were also maintained in an improved condition.

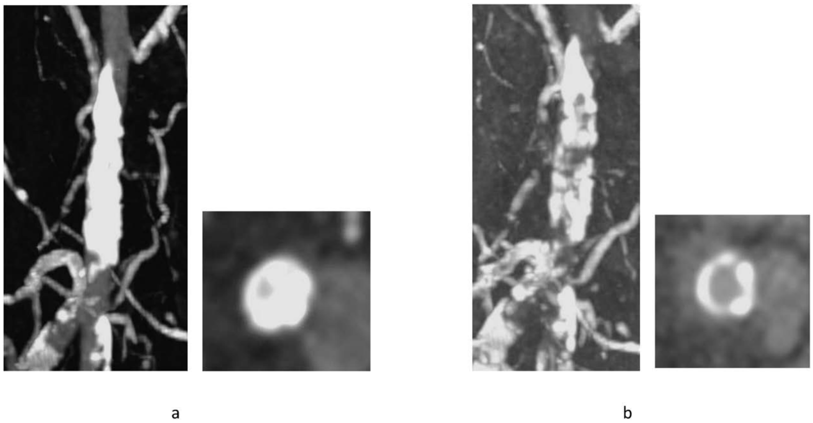


Fig. 4 Preoperative and 6-month postoperative computed tomography (CT).
(**a**) CT image preoperatively showing the common femoral artery is occluded by a dollop calcification. (**b**) A sufficient lumen was formed while leaving the vessel wall with calcification with average thickness, and the lumen is in good condition even after 6 months.

Discussion

Endarterectomy is widely performed to treat lesions in the iliac artery, CFA, DFA, and SFA region and has obtained good therapeutic outcomes.[6–8] Currently, for lesions in the iliac artery areas requiring major surgical invasion and extensive SFA lesions, equivalent outcomes can be expected from minimally invasive EVT, which is the first choice of treatment. However, EVT is difficult to perform in areas with deep/superficial bifurcation of the CFA; thus, endarterectomy is regarded as the first choice of treatment.[9,10]

Basically, to date, endarterectomy for lesions in the femoral artery region has been performed as a direct surgery and has the following steps: the blood vessel wall with the lesion is incised, a layer suitable for peeling under direct view is found, a thickened part (calcified intima and media) of the outer elastic layer is identified, and the blood vessel wall with the adventitia outside the remaining outer elastic plate is closed and sutured. In this case, it is assumed that the following conditions are present: the adventitia has little calcification, the wall is resilient, functions of the blood vessel wall to resist blood pressure are preserved, and the three-layered structure originally possessed by the blood vessel wall remains.[5]

In recent years, PAD cases with heavy calcification have been rapidly increasing due to an increase in the number of patients with complications of diabetes and maintenance dialysis.[1,2] The common characteristic of the lesions in these patients is the Mönckeburg-type calcification, in which the destruction of wall structure and calcification are common. In cases with heavy calcification, if the calcified part is completely removed, the remaining adventitia is very thin, fragile, and unable to withstand the blood pressure. If only the thin adventitia remains, performing the closed suturing technique is difficult, because the needle hole easily breaks and repair becomes difficult, resulting in difficulty in restoration. Moreover, even if a lumen structure is made, it is difficult to use this as a blood vessel wall that could withstand blood pressure. Sometimes this may cause an aneurysm in the long term. However, for the adventitia to be stronger as a vessel wall, we need to maintain a balance between the removal volume and preservation area of the calcified mass, which requires the use of advanced technology. Furthermore, vessel walls where calcification remains are very difficult to suture for closure or intimal fixation, and the operation is very difficult. These issues are the same whether it is a direct closure of a vessel wall, or a vein patch formation, or a similar operation.

In semi-closed endarterectomy, the thickened intimal hyperplasia is excised from the luminal side. First, the layer that leaves the adventitia under direct vision is found, and peeling along this layer is performed in the same manner as in endarterectomy under direct view.[11–13] Therefore, in the case of calcification in which the layer structure of the blood vessel wall is destroyed and forms into a mass, it is difficult to identify the peeling layer; hence, endarterectomy becomes difficult to perform. Sometimes, endarterectomy is not performed at all.

A method of crushing the heavily calcified portion under direct view with a surgical ultrasonic aspiration device has been developed so far.[14–16] This device brings the tip of an ultrasonic vibration probe, which is capable of adjusting its frequency, in contact with a lesion site and crushes liver tissues and hard tissues, such as calcifications and bone tissues. It has been used in orthopedic and liver surgeries before and has also been applied to treat aortic valve calcification.[17,18] However, calcification remains when using this method and in order to solve the problem of closing the blood vessel wall, decalcification at the suture line is necessary. Because the incision is made right above the lesion it only exposes the blood vessel incision at the lesion site and crushes the calcification under direct vision.[14–16]

The novel method we proposed will solve the above-mentioned problems. Our concept "to create a new lumen by digging a tunnel into the dollop calcification" allows the formation of a new lumen, independent of the strata, in a massive calcification. The SONOPET is similar to a surgical ultrasonic aspiration device, which enables surgeons to perform a push cutting operation by attaching a filiform shape to the tip portion and adding a twist to the direction of vibration. This enables angioplasty through our new concept of "creating lumens by digging a tunnel." Since cutting is done from the luminal side, it is not necessary to incise the vessel wall at the calcified part (lesion site) or close the incision for direct viewing.

The size of the severable cavity can be as large as the diameter of the front and rear blood vessel lumen. Unlike the case of direct suturing, there is no need for a suturing space (stitching space) for closing, and there is no worry of stenosis. A cross-sectional area equivalent to EVT can be secured. Normally, when coral calcification is resected under direct vision, intimal fixation on the distal side is not required.[14)] This was not performed in our cases for the same reason. There was no adverse effect detected in postoperative angiography. Regarding the long-term outcome of leaving the calcified part, it is reported that the mid-term results of calcification removal by a surgical ultrasonic aspiration device under direct vision against the CFA are good.[14–16)] In this method, as well as in direct surgery, the incised section of the calcified surface is in contact with the blood flow, but the results are expected to be equivalent.

The thickness of the wall to be left was checked by confirming the vibration of the tip of the SONOPET with a sense transmitted through palpation from the outside of the calcified lesion blood vessel. In this way, it was possible to prevent any damage to the blood vessel wall; however, for that reason, it was necessary to sufficiently separate the vessel, so that it could be palpated all around in the operative area.

The indication for this method is heavy calcifications limited to the CFA, which is difficult to operate under direct vision endarterectomy in order to preserve the blood vessel wall that could withstand incisions and sutures at the peripheral lesion. Although the range of application of this novel technique is limited to the CFA, many of the current endarterectomys are targeted to lesions confined to CFA. So the indication of the new technique is not significantly inferior to the current endarterectomy. However, the limitation of this method is that it is not suitable for bent lesions or lesions in small-diameter vessels, because the device cannot be inserted.

In this study, since the safety against fragmentation to the distal side at the time of penetration could not be confirmed, the retrograde approach was adopted. Regarding the antegrade approach, due to the nature of the equipment, all fragments will be aspirated, unlike in EVT, because they clump in the proximal side of blood flow, and they will be extruded with the backflow of the blood from the distal side after penetration. It seems that this approach can be enforced. In the future, we would like to consider this approach for treating deep femoral arteries.

The strength of the newly formed blood vessel wall is unknown. However, since the wall thickness is about the same as that formed by using the surgical ultrasonic aspiration device under direct vision, the strength is presumed to be equivalent. Future follow-up observation is necessary. In addition, as compared with the case where lesions are subjected to conventional endarterectomy, the remaining wall constituting components are left thicker; thus, the strength is considered not to be inferior.

Using this method, the problems with calcified lesions due to direct visual endarterectomy will be avoided, such as the adventitia becoming thinner, the needle hole breaking the blood vessel wall being unable to withstand blood pressure, an inability to form a lumen when the calcification is removed, the suture needle being unable to pass, and intimal fixation being difficult when the calcification is retained.

It was shown that this method allows removal of heavy calcified lesions that had formed clumps. This widens the options of considering revascularization.

Study limitations

This study was a single-arm analysis, included a small number of cases, and the strategy of treatment was operator-dependent.

Conclusion

Endarterectomy using the lateral approach with the SONOPET is a quick and easy method for treating heavily calcified vessels of patients with PAD. It is a suitable technique to be used especially for vascular surgeons.

Disclosure Statement

The authors have no conflicts of interest to disclose.

Author Contributions

Study conception: TS

Data collection: TS, KW
Writing: TS
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

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