—**Original**—

Peripheral Directional Atherectomy Evaluated with a Rotational Digital Angiography System

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Abstract

Background: One of the factors that affect the recurrence rate after peripheral directional atherectomy (DA) is the degree of residual stenosis. A new method of peripheral DA to reduce residual stenoses was evaluated with a rotational digital angiography (RDA) system that provides both angiography and fluoroscopy at multiple projections within 360 degrees.

Patients and methods: Between March 1995 and July 1999, severe short segmental stenoses of six iliac arteries and two superficial femoral arteries (SFA) in eight patients were treated with the Simpson DA catheter under RDA system guidance. After pre-procedural RDA evaluation, the first series of DA were performed under ordinary PA fluoroscopic guidance. The residual stenoses were evaluated with RDA. If the residual stenoses exceeded 30%, a second series of DA were performed covering the residual plaque with the cutter window of the DA catheter. To this purpose the fluoroscopy of the RDA system was fixed in the direction in which the residual stenoses were largest and most eccentric. The end point was defined to be a residual stenosis of less than 30% evaluated with the RDA system, and the procedures were repeated until the end point was achieved.

Results: Five of six iliac artery lesions were curved at the pre-procedural RDA evaluation. After the first series of DA, only two of six iliac lesions but all SFA lesions achieved the end point. Among the four other iliac lesions, three achieved the end point with one or two additional series of DA using the RDA system guidance to control the selective cuts of the residual plaques. One patient had a residual stenosis of 50% because the procedure could not be completed by balloon rupture of the DA catheter. In the patients with iliac stenoses, there was no final residual stenosis in one, and the range was from 20% to 25% in the four patients. The residual stenoses were located on the greater curvature side of the curved artery in three of these four patients.

Conclusion: The RDA system is a valuable tool in aiding reduction of the residual stenoses during peripheral DA. Minimal stenoses often remain on the greater curvature side of the wall because the rigid and straight metallic capsule (cylindrical housing) of the Simpson DA catheter does not completely fit the curved wall. This phenomenon was thought to be a mechanical limitation of this device. (J Nippon Med Sch 2000; 67: 335—341)

Key words: atherosclerosis, peripheral vascular disease, atherectomy, angiography

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Introduction

The rotational digital angiography system[1], SF-VA 100 (Hitachi Medico, Tokyo, Japan), was developed in cooperation with our department and has been used for both diagnostic angiography and vascular interventions since July 1993. The X-ray tube and the image intensifier (I. I.) are disposed in a straight line inside the gantry of the system, and rotate 360 degrees around the patient's body axis while the X-ray pulse exposures are carried out every 1.25 degree. In this way, this system is capable of performing 360 degree angiograms composed of 288 images in different directions in just 4.8 seconds with a single injection of contrast medium. It provides continuous three-dimensional rotating cine-display of the angiogram. The X-ray tube and I. I. can be fixed in any direction during the procedure.

The Simpson directional atherectomy catheter for the peripheral artery is a valuable device for the treatment of arterial occlusive disease caused by atherosclerosis. It removes atheromatous plaque from the vessel wall, resulting in an increased luminal diameter with a relatively smooth channel. One of the factors that affect the recurrence rate after peripheral directional atherectomy is the degree of residual stenosis[2].

To achieve maximum removal of the plaques, we evaluated a new method of peripheral directional atherectomy using the rotational digital angiography system. We would like to report the advantage of this new method in performing a precise and safe atherectomy and report some limitations of the Simpson peripheral directional atherectomy device for use in iliac lesions.

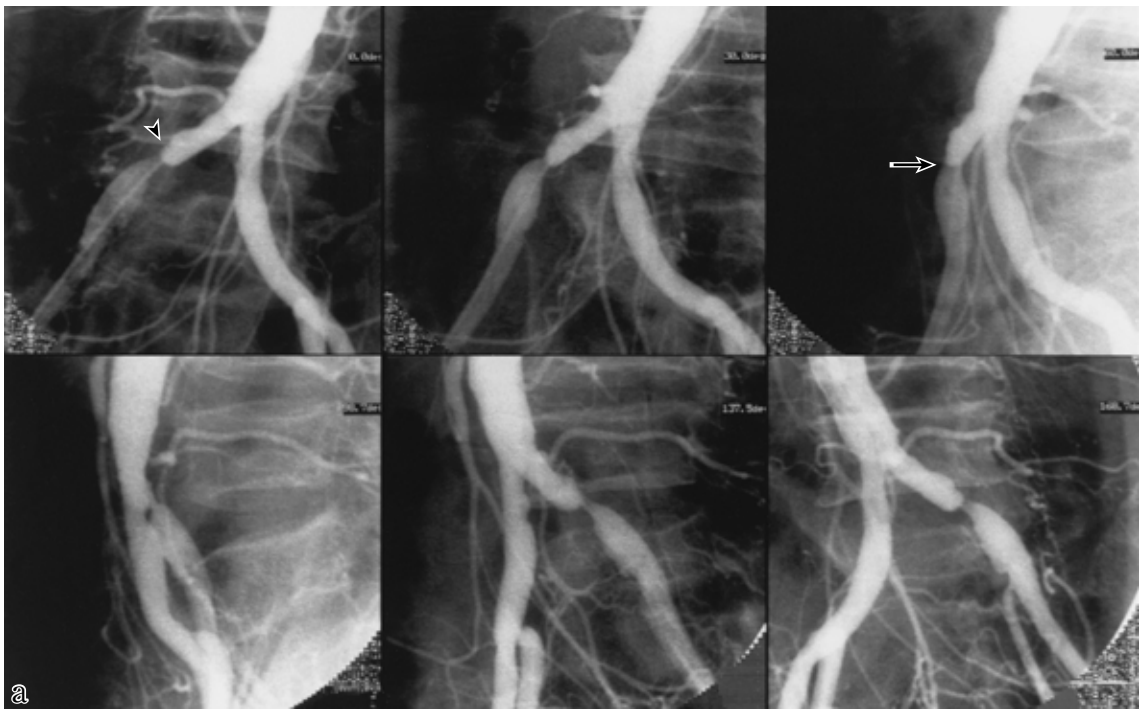
Patients and Methods

Between March 1995 and July 1999, eight male patients, ranging in age from 51 to 76 years (mean 65.8 years) presented at our department with claudication. Six patients had single severe stenoses of the iliac arteries and two patients single severe stenoses of the superficial femoral arteries caused by atherosclerosis; all patients had good distal run-off arteries. The patients were treated by peripheral directional atherectomy (DA) evaluated by the rotational digital angiography (RDA) system.

Peripheral DA catheters (Simpson Athero Track, DVI, Redwood City, CA, USA) were used for all procedures. The size of the DA catheter was chosen so that the working diameter was equal to or slightly greater than the diameter of an ajacent normal portion of the artery measured by RDA. The technique of DA has been fully described elsewhere[2-5]. A retrograde approach from the ipsilateral common femoral artery was chosen for the treatment of iliac lesions and an antegrade femoral approach for the superficial femoral lesions.

All procedures were evaluated by the rotational digital angiography (RDA) system with the following protocol. A rotational digital angiogram was performed to evaluate the lesion precisely from all direction before the procedure (**Fig. 1 a**). Then the first series of atherectomies, including up to more than 12 cuttings of the atheromatous plaque in a 360 degree circuit, were performed under ordinary posterior-anterior (PA) fluoroscopic guidance. After this first series of atherectomies, another rotational digital angiogram of the lesion was obtained. If the residual stenosis was more than 30%, the I.I. of the RDA system was fixed in the direction in which the stenosis

Fig. 1 (a) Demonstrating six directions from 288 of pre-procedural RDA. A 90% concentric stenosis is seen at the right common iliac artery. The vessel at the lesion is tortuous (arrow) in the lateral view, although it looks rather straight in the PA view (arrowhead). (b) The RDA after the first series of DA, upper three, reveals a residual stenosis on the anterior wall (arrowhead) and a small intimal flap (arrow). The two pictures below show the 2nd series of DA. Positioning both the residual stenoses and the cutter window eccentrically, the controled cuts of the residual stenosis of the anterior wall and of the intimal flap are performed. (c) The RDA after the 2nd series of DA. Both the residual stenosis and the intimal flap are reduced and the final residual stenosis is measured to be 20% luminal diameter. The minimal intimal flap is remaining on the greater curvature side of the wall (arrow).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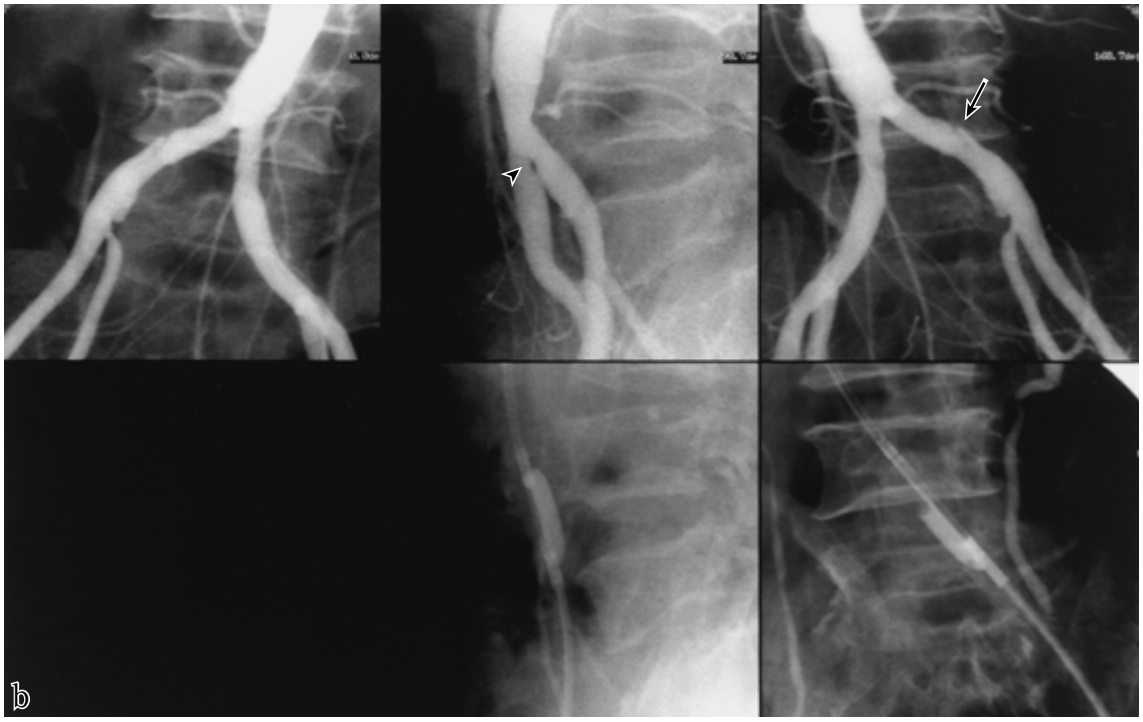
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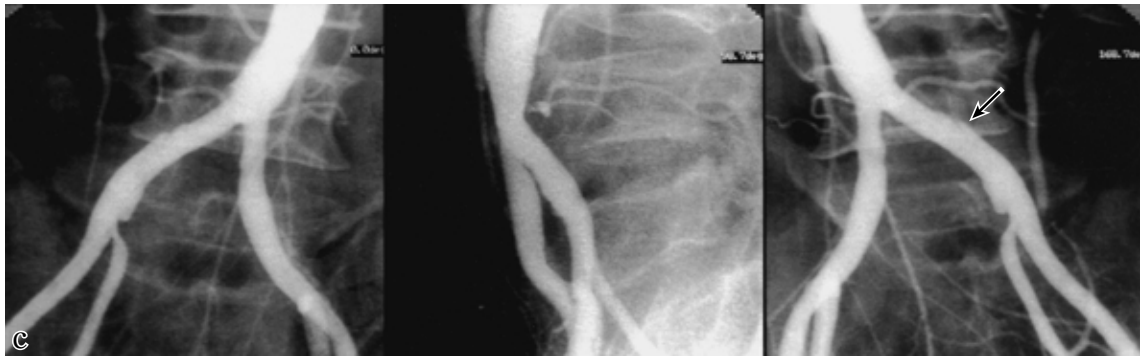
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Table 1 Pre-procedural RDA evaluation

Case No.	Age/sex	Site of stenosis	Length of lesion (cm)	Structure of stenosis	% stenosis (%)	Tortuosity of the vessel
1	66/M	EIA	1.0	Eccentric	80	+
2	76/M	CIA	1.5	Eccentric	75	+
3	73/M	CIA	1.5	Eccentric	90	−
4	70/M	CIA	1.5	Concentric	80	+
5	62/M	CIA	2.0	Concentric	80	+
6	61/M	CIA	2.0	Concentric	90	+
7	51/M	SFA	2.0	Eccentric	75	−
8	62/M	SFA	1.5	Eccentric	80	−

Note.: EIA; external iliac artery, CIA; common iliac artery, SFA; superficial femoral artery,
+: The vessel at the lesion was curved. −: The vessel at the lesion was straight.

was visualized most eccentrically and the vessel lumen narrowest. In that fluoroscopic position, the window of the atherectomy catheter was positioned to cover the atheromatous plaque and the second series of atherectomies was performed (**Fig. 1 b**). The catheter window was placed adjacent to the atheromatous plaque under road mapping guidance or bony structures were used as reference. Another rotational digital angiogram of the lesion was obtained after this manipulation. The end point of the procedure was defined as a reduction of the stenosis to less than 30% luminal diameter as evaluated by RDA (**Fig. 1 c**). If necessary, a third or further series of atherectomies would be performed in the same way until the residual stenosis became less than 30%.

The structural characteristics of the lesions and arteries before and after the DA were evaluated in all patients and the number of DA series needed to achieve the end point was analyzed.

Results

Pre-procedural RDA evaluation of the lesions is summarized in **Table 1**. All lesions were stenoses of at least 75% in luminal diameter with a length not exceeding 2 cm. Evaluating the lesions with 360 degree angiograms of RDA, there were some curves in five of six iliac vessels at the lesions even if the vessels looked straight in the ordinary PA view (**Fig. 1 a, 2 b**).

The processes to achieve the end point and the morphologic feature of the lesions after completion of the DA series are summarized in **Table 2**. After the first series of DA under PA fluoroscopic guidance, only two iliac stenoses were less than 30% in luminal diameter. On the other hand, all superficial femoral lesions achieved the end point after the first DA.

In the completion RDA, all but one achieved the end point and the residual stenosis became equal to or less than 25%. The treated vessel walls were visualized as smooth in six patients but minimal dissected intimal flaps were demonstrated in two patients. Among the five iliac lesions that achieved the end point, the residual stenosis was 0% in one and ranged from 20% to 25% in four patients. In three of these four iliac patients, the residual stenoses were located on the greater curvature side of the curved vessel walls (**Fig. 1 c, 2 d**). In one patient with an iliac lesion (case No. 4), a balloon rupture of the DA catheter occurred during the procedure after 50% luminal diameter was gained and the procedure was terminated at that time.

All patients had complete relief of symptoms at discharge. There were no complications during the hospitalization periods (up to one month) after the procedure.

Discussion

The RDA system allows both fluoroscopy and angiography at 288 different projections within 360 degrees. Thus a precise evaluation of the stenotic degree, structural characteristics of the lesions, vessel tortuosity, and the position of plaques in the curved vessels' walls with only one injection of the contrast

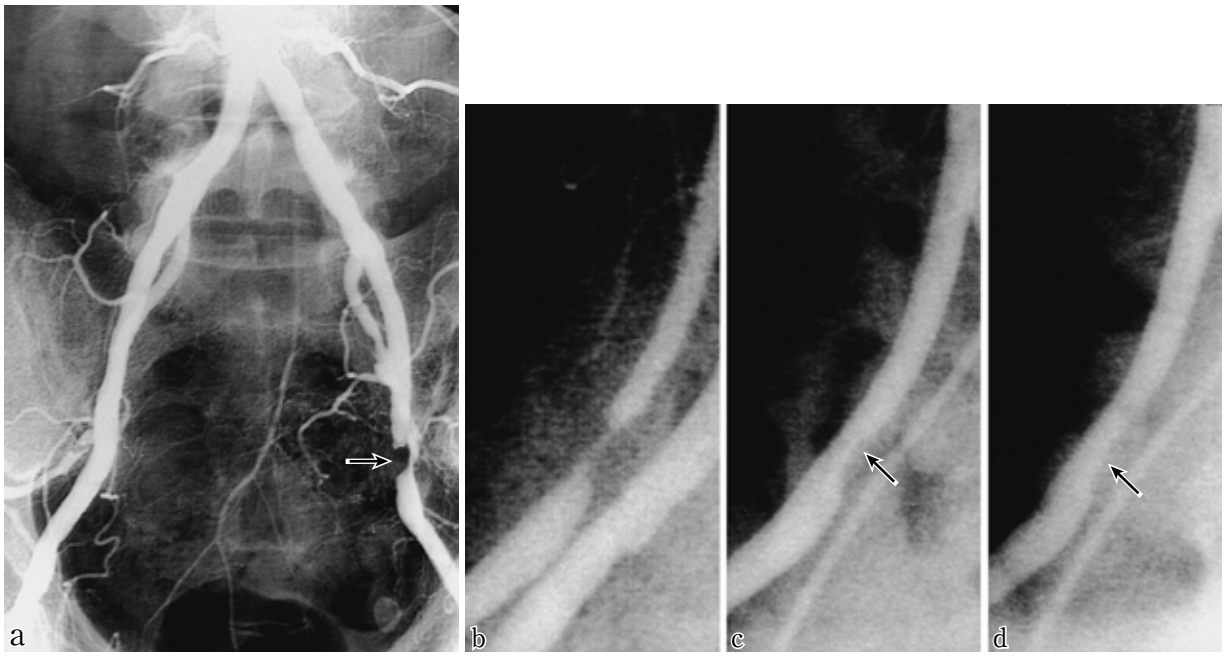

Fig. 2 (a) Pre-procedural evaluation of RDA (RAO 7.5°) shows 80% eccentric stenosis at the left external iliac artery (arrow). (b) A magnified picture of the pre-procedural RDA in the same direction as (c) and (d). (c) After the first series of DA under PA fluoroscopic guidance, RDA at LAO 95° reveals 40% residual stenosis on the greater curvature side of the wall (arrow). (d) After the 2nd series of DA of controlled cutting of the residual plaque, RDA at LAO 95°shows a 25% residual stenosis (arrow). Further cuts were of no effect in reducing the residual stenosis. The procedure was considered to be successful and conclusive.

Table 2 The process to achieve the end point and the final RDA evaluation

Case No.	Residual stenosis after the 1st series of DA (%)	Added series of DA	Residual stenosis at completion RDA (%)	Final structural characteristic
1	40	2nd	25	Smooth
2	20	None	20	Minimal intimal flap
3	0	None	0	Smooth
4	50	−	50	Smooth
5	40	2nd	25	Smooth
6	60	2nd, 3nd	20	Minimal intimal flap
7	0	None	0	Smooth
8	0	None	0	Smooth

medium are possible. Furthermore, controlled and selective cuts of the atheromatous plaques are possible during the procedure (**Fig. 1 b**). Therefore, using the RDA system in peripheral DA, a more precise yet safe removal of the atheromatous plaques can be achieved. The usefulness of intravascular ultrasound (IVUS) or angioscopy to assess the degree of lumen reconstruction has been reported[5-8]. However, the vessel tortuosity and the precise position of the atheroma in the arteries are impossible to evaluate with these devices. Controlled and selective cuts of residual atheromatous plaque during the procedure are impossible with any commercially available devices other than an RDA system that allows the angiographer to direct the cuts. Thus the RDA system is superior to any other device to control lumen reconstruction during the peripheral DA procedure and a more complete artheroma removal can be obtained by RDA than by ordinary PA angiography.

The degree of the residual stenoses after DA affects the recurrence rate of the stenoses. Simpson et al.[2] reported that residual stenoses larger than 30%

are associated with a 52% recurrence rate at 6 months, in comparison with residual stenoses of less than 30%, which have an 18% recurrence rate. For the purpose of achieving residual stenoses less than 30%, the method of DA taking advantage of the RDA system was developed.

Four of six iliac stenoses were larger than 30% after one series of DA under the ordinary PA fluoroscopic guidance. On the other hand, all superficial femoral lesions achieved less than 30% residual stenosis after the first series of DA. The main reason for this is thought to be the rigidity of the DA catheter that can not be adapted to the vessel's curve and tortuosity. Five of six iliac vessels were curved with RDA evaluation, whereas all the superficial femoral arteries at the lesion were running straight. Because of the rigid peripheral DA catheter, holding the catheter to fix the cutter window in all directions inside a curved or tortuous vessel is difficult. Thus residual stenoses larger than 30% remained in four of six iliac stenoses after one series of DA. Using our method, selective cuts of these residual plaques were possible. However residual stenoses equal to or less than 25% remained in four patients with iliac lesions, and three of these four residual stenoses were observed on the greater curvature side of the vessel. This is caused by the rigid and straight metallic capsule (cylindrical housing) of the DA catheter containing the cutter and storage area, that does not completely fit to the curved vessel wall. This means that a risk of cutting too deep on the opposite lesser curvature side of the wall also exists. This phenomenon was thought to be a mechanical limitation of the DA system in the iliac arteries, although the achievement of residual stenoses of less than 25% is considered to be a satisfactory result. Nevertheless residual stenoses in the iliac arteries are prone to be larger than the residual stenoses of the femoral arteries and remain on the greater curvature side of the vessel.

While early studies have shown favorable follow-up results of Simpson DA in the femoropopliteal arteries with good long-term patency[9-12], more recent studies have reported not encouraging data about the long-term outcome of DA in comparison with balloon angioplasty[12-15]. The stent treatment for the occlusive disease of the iliac arteries has a good long-term patency[16-18]. (All our patients with iliac lesions were treated while no stent for peripheral arteries was commercially available in Japan.). Furthermore, there are some drawbacks to the Simpson DA[9,12,13]. Besides the fact that the procedure is complicated and time-consuming, the device is relatively expensive. Although the reported overall complication rates vary from 2% to 43%[15], some authors have reported an increased number of minor complications like hematoma in the groin caused by the rather big required introducer sheaths[14]. In these circumstances, the initial enthusiasm for atherectomy of lower-extremity atherosclerotic lesions seems to have vanished. However, the DA has a higher initial success rate than balloon angioplasty because acute occlusions caused by dissection or recoil are rare[2,9,12]. Therefore it is useful for short and markedly eccentric lesions, for situations in which the dissected flap obstructs the lumen after balloon angioplasty[19] of the femoropopliteal arteries, or for the removal of intimal hyperplasia occurring in grafts to native arteries[20]. The DA is also a useful method combined with balloon PTA in the treatment of restenoses or occlusion after iliac stent placement[21]. In the present study, two patients with iliac lesions were treated shortly before planned coronary artery angioplasty that required the bilateral iliac arteries to be fully open for the angioplasty catheter and intraarterial balloon pumping catheter from the bilateral common femoral arteries. In such cases, the stent placement in iliac arteries may obstruct the passage of big catheters and a risk of stents migration due to catheter manipulation exists. In these selected patients, the role of DA is still important, and the RDA system allows achievement of an effective, precise and safe peripheral DA procedure.

The present study reports a new method using an RDA system to enhance the initial success of peripheral DA. No previous study has evaluated all patients' final degree of luminal reconstruction by three-dimensional RDA.

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