

Endovascular Repair of Diffuse Atherosclerotic Occlusive Disease Using Stented Grafts

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Abstract

Minimally invasive techniques have greatly influenced the practice of surgery in the past two decades, especially the vascular surgical specialty. Current technological advances and refinements have allowed for the application of less invasive or percutaneous endovascular techniques to the treatment of arterial aneurysms and peripheral vascular occlusive disease. While balloon angioplasty and stenting for occlusive disease have proven successful in certain vascular beds (such as common iliac arteries), infrainguinal results are generally less impressive.

This paper reviews the results of the application of covered stent-grafts to peripheral arterial occlusive disease, both at the aortoiliac and infrainguinal anatomical levels. The review includes the results of iliac artery stented graft placement utilizing a combined open surgical and endovascular technique at Mount Sinai Medical Center.

Key Words: Endovascular, stent-graft, iliac artery, superficial femoral artery, minimally invasive, peripheral vascular disease.

Introduction

THE APPLICATION of endovascular techniques to the treatment of arterial occlusive disease has become a focus of much interest among physicians treating patients with peripheral vascular disease. Initially, endovascular therapy was seen as an attractive alternative to traditional open surgical management for patients with multiple medical comorbidities placing them in high or prohibitive surgical risk categories. More recently, with the improvement of biomedical devices and techniques, many more specialists who treat vascular diseases have proposed the use of minimally invasive treatment.

Completely percutaneous, as well as combined endovascular approaches coupled with limited open surgical exposures, have been described for recanalization of arterial occlusive disease.

Although the accumulated experience and reports of endovascular stented-graft treatment of arterial occlusive disease are relatively limited, the allure of less-invasive treatment has led to new strategies and device designs. Currently available devices and applied techniques are highlighted in this paper, especially the use of endografts in atherosclerotic arterial occlusive disease of the iliac arteries and lower extremities.

Development and General Techniques

Reports by Dotter (1) in 1983, on a transluminally expanded nitinol-coiled (nickel-titanium polymer) stented graft, and Volodos (2) in 1986, on a Dacron-covered Z-stent for recanalization of an iliac artery occlusion, provided the first descriptions of endovascular stent-grafting for treatment of arterial occlusive disease. Early percutaneous treatment for superficial femoral artery (SFA) and popliteal artery occlusive disease, utilizing the Cragg Endopro Stentgraft (Mintec Corp, Grand Bahamas) was subsequently described. It was theorized that stented grafts might decrease recurrence of some of the early lesions following SFA balloon angioplasty, with or without adjuvant stenting (3, 4). At present, several devices have been developed and applied to endoluminal treatment of

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arterial occlusive disease. They range from homemade devices, utilizing hand-sewn Palmaz (Cordis, Miami, FL) stents to polytetrafluoroethylene (PTFE) grafts, to industry-made stent-grafts, including the Passager (Boston Scientific, Natick, MA) (formerly, the Cragg Endopro), the Jostent (Jomed, Atlanta, GA), and the Viabahn (latest update of the Hemo-bahn, WL Gore, Flagstaff, AZ) (Fig 1).

General technical considerations for use of these devices include the need to first recanalize the severely stenosed or occluded arterial segment, often by use of a hydrophilic guidewire, and ensuring re-entry into the true lumen either proximal or distal to the lesion. Balloon dilation is then often used to re-establish luminal diameter, after which the stented graft is deployed and secured proximally and distally by stents, if not already fully supported throughout its length. Subsequent post-deployment balloon angioplasty can be employed to achieve full graft expansion and wall apposition.

Aortoiliac Level Disease

In the iliac artery, recanalization of occlusions can be performed percutaneously by both the ipsilateral (retrograde) and contralateral (“up-and-over” or anterograde) approaches. Percutaneous transluminal angioplasty (PTA) and stenting have been shown to have both high technical success rates and durability approaching that of the traditionally preferred open-surgical aorto-bi-femoral bypass grafting, with 5-year patency rates greater than 90% (5). Shortcomings include higher rates of restenosis and failure in total occlusions and long-segment

disease, and limitations in the simultaneous management of femoral and outflow disease. Indications for endoluminal stented graft use in iliac disease range from claudication to acute limb ischemia. Use of a stent-graft for prevention of embolization by covering a large iliac thrombus has also been reported (6).

The technique utilized at Mount Sinai Medical Center for management of long-segment iliac artery occlusion is based on the potential benefit of using covered stents in combination with surgical femoral artery exposure and arteriotomy. With this combined surgical and endovascular strategy, external iliac and femoral artery disease can be addressed, thus expanding the application of endoluminal techniques to those patients who would not be candidates for a purely percutaneous approach. The procedures are performed in the operating room, preferably under spinal/epidural anesthesia. Following femoral artery cutdown, angiographic sheaths are placed to allow guidewire and directional catheter recanalization of the occluded iliac artery from either an anterograde or retrograde approach (Fig. 2A, B). Balloon dilation of the artery is then performed with an 8 mm angioplasty balloon (Fig. 2C). With vessel-loop control of the artery, the sheath is removed, an arteriotomy is made, and insertion of the fabricated delivery system is performed under fluoroscopic guidance over the guidewire (Fig. 2D). The stent graft is fashioned by suturing a Palmaz stent to a PTFE graft, crimping the stent over a balloon catheter, and furling the assembled graft within a long sheath equipped with hemostatic valves and a leading balloon forming a proximal tapering (Fig. 3). When the device is properly positioned in the proximal iliac artery, the sheath is withdrawn, the leading balloon is deflated and withdrawn, and the Palmaz stent and attached stent-graft are deployed. The distal end of the PTFE graft is brought down through the arteriotomy, and further balloon inflation of the length of the graft is carried out along with angiography via an attached large French angiographic sheath. The distal graft anastomosis is then created surgically according to the pattern of outflow disease (Fig. 4). The following example case report serves to illustrate the technique.

Illustrative Case

A 76-year-old woman with severe coronary artery disease, untreated critical 90% left carotid stenosis, emphysema, and known pe-

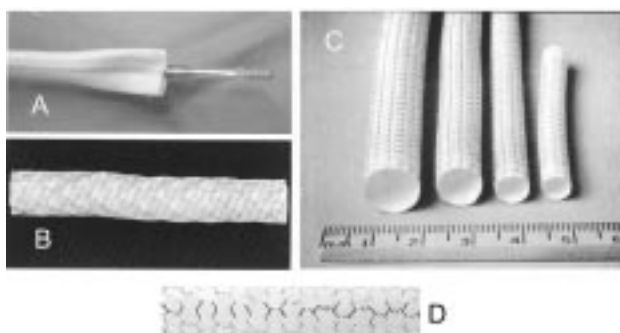


Fig. 1. (A) Homemade endovascular stent-graft: Palmaz stent sutured to polytetrafluoroethylene (PTFE) graft. (B) Cragg Endopro: a nitinol self-expanding stent is covered by a polyester fabric material. (C) Viabahn: an exoskeleton of self-expanding nitinol coils supports an expanded PTFE lining. (D) Jostent: an ultrathin layer of ePTFE between two stainless steel stents.

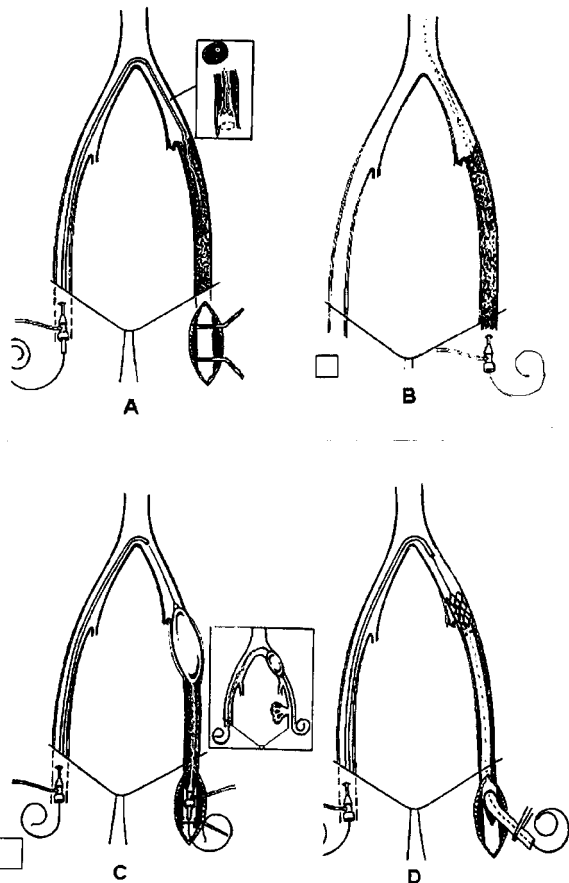


Fig. 2. (A) Anterograde directional catheter and wire recanalization of iliac occlusion. (B) Retrograde recanalization. (C) Balloon dilation of recanalized iliac segment. (D) Deployed homemade stent-graft. A Palmaz stent sutured to the PTFE graft secures the proximal graft. The distal graft is brought out through the arteriotomy.

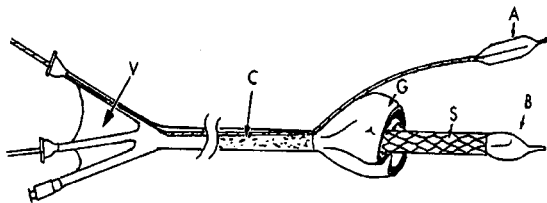


Fig. 3. Delivery system fashioned for aortoiliac endograft insertion and deployment. The lead balloon (A) forms a tapered tip for the delivery sheath (C). The stent-graft is contained within the delivery sheath, with the graft (G) sutured to the Palmaz stent (S). With inflation of the lead balloon (A) and closure of the hemostatic valves (V), fluid pressurization of the sheath provides rigidity to facilitate insertion up the iliac artery over a guidewire. With the outer sheath retracted, inflation of the second balloon (B) deploys the Palmaz stent and the graft.

ripheral vascular disease (prior left and right iliac PTA and stenting) underwent an outpatient angiogram via a right femoral approach during

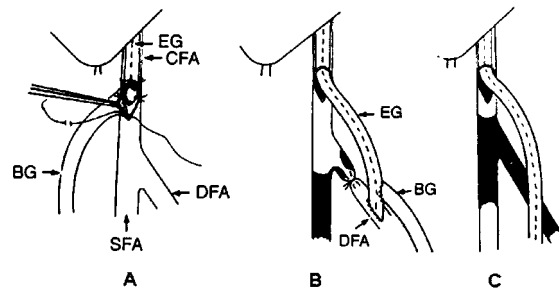


Fig. 4. Options (A, B, C) for creating distal anastomoses at the femoral arteriotomy with distal limb bypass extension. EG = endograft; CFA = common femoral artery; DFA = deep (profunda) femoral artery; SFA = superficial femoral artery; BG = bypass graft.

work-up for chronic mesenteric ischemic symptoms. Recurrent stenosis of her right external iliac artery (EIA) stents was noted. Twelve hours after the angiogram, she presented to the emergency room with acute right leg ischemia, manifested by a cold, pulseless foot with mild sensory deficit. Urgent repeat angiogram revealed occluded right EIA and common femoral artery (CFA) with reconstituted profunda femoral artery and occluded superficial femoral artery (SFA) (Fig. 5). She was immediately brought to the operating room and was given spinal anesthesia; right SFA exposure was performed, a 5F sheath was placed, and a hydrophilic guidewire was maneuvered across the occlusion. Systemic heparin was administered and balloon angioplasty of the right iliac system was performed with an 8 mm balloon (Fig. 6). The stent-graft device was created on a sterile back-table and inserted over the guidewire after femoral arteriotomy was created. Under fluoroscopic guidance, the insertion sheath device

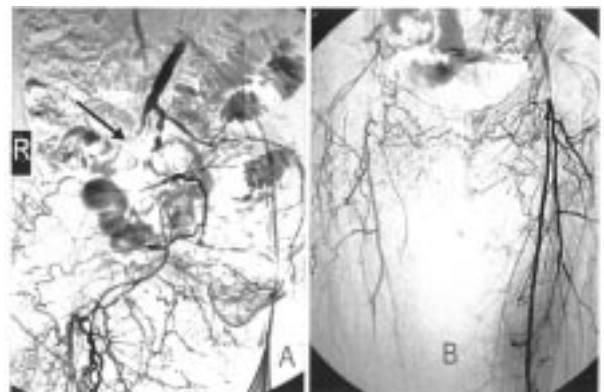


Fig. 5 (A) Preoperative selective right iliac angiogram showing external iliac artery occlusion within remotely placed stent (arrow). (B) Iliofemoral angiogram showing occluded right external iliac, common femoral, and superficial femoral arteries.

was positioned, the outer sheath withdrawn, and the stent-graft deployed (Fig. 7). The distal end of the PTFE graft is shown emerging from the common femoral arteriotomy. A shortened angiographic sheath was attached to the distal end of the PTFE graft for postdeployment balloon dilation of the graft (Fig. 8). Completion retrograde angiogram showed a widely patent result (Fig. 9). The distal graft end was then anastomosed to the right profunda femoral artery (PFA) (Fig. 10). The patient had restoration of pedal Doppler signals with alleviation of her symptoms. She was discharged on postoperative day two.

Utilization of the above technique was initially reported by Marin in 1995 (7). Wain et al. (8) reported further data on 52 high-morbidity patients who underwent this technique for critical limb ischemia, with half requiring concomitant adjunctive infrainguinal bypass. These patients were prohibitive surgical risks for open aortoiliac bypass. Initial procedural success was 93%. The respective 5-year primary and secondary patency rates were 66% and 77%, with a limb-salvage rate of 88%.

Infrainguinal Arterial Level

For arterial occlusive disease of the femoropopliteal region, consistently inferior patency has been seen for endoluminal stent-grafting when compared to both endovascular techniques applied to iliac occlusive disease and to open infrainguinal bypass surgery. However, the allure of minimally invasive treatment for the femoral artery has resulted in the trial of several devices and techniques.

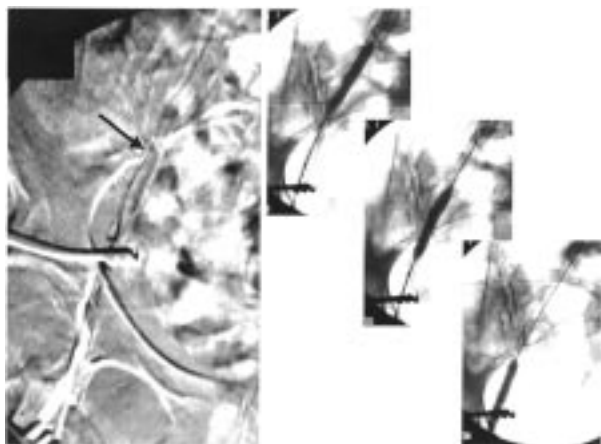


Fig. 6. **Left panel:** Retrograde hydrophilic guidewire recanalization (arrow) of iliac occlusion. **Right panel:** Sequential balloon dilation of iliac artery.

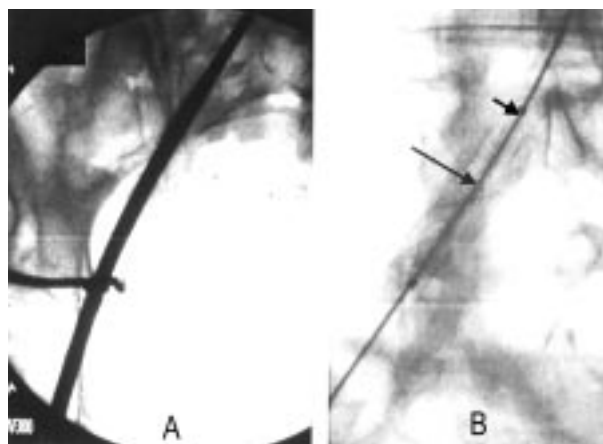


Fig. 7 (A) Insertion of deployment sheath containing stent-graft. (B) Outer sheath withdrawn and proximal stent-graft is positioned. Long arrow denotes proximal edge of undeployed Palmaz stent premounted on deployment balloon; short arrow identifies balloon proximal marker.



Fig. 8. Distal PTFE graft emerging from SFA, with shortened angiographic sheath attached to allow postdeployment balloon angioplasty and angiography.

Generally poor outcomes for percutaneous transluminal angioplasty (PTA), with or without stenting, of long-segment SFA stenosis or occlusion have led to attempts to reline the SFA with an endoluminal bypass following recanalization. The endoluminal graft can be fully supported by stents along its length, or it can utilize a PTFE graft anchored by stents at one or both ends. Theoretical benefits for this approach include a potentially less invasive procedure, an in-line “end-to-end” reconstruction with resultant hemodynamic improvements compared to an end-to-side surgical bypass, and the possibility of future surgical revascularization, should the procedure fail. A potential neg-

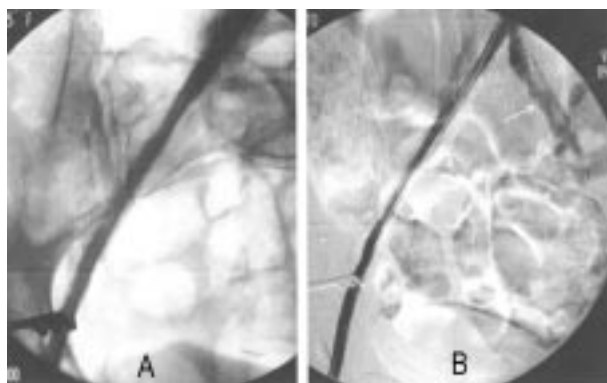


Fig. 9. Completion angiography (retrograde) of stent-grafted right iliac artery. (A) shows a magnified view of the stent-graft repair of the right iliac system. (B) shows the wider view of the retrograde contrast injection opacifying the aortic bifurcation and proximal left iliac artery (arrow).

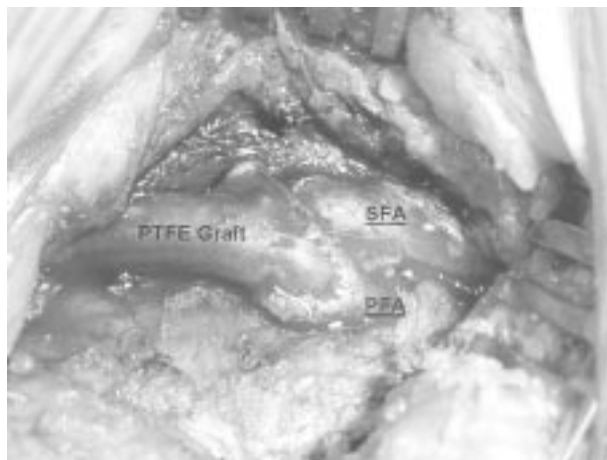


Fig. 10. PTFE graft surgical anastomosis to profunda femoral artery (PFA). Superficial femoral artery (SFA) is occluded.

ative effect, however, is the covering of any collateral side branches, something avoided by use of uncovered stents.

Disputed issues include whether or not the SFA requires debulking of the lesion prior to endoluminal graft deployment. Several techniques have utilized percutaneous recanalization with PTA without debulking the lesion. Results of nondebulking trials have been variable, and most reports have been of immediate and short-term follow-up, with little long-term data. The initial report of the use of the Cragg Endopro (now the Passager) graft demonstrated immediate procedural success in the eight treated patients, with primary patency in six of these cases during early follow-up (3). Later follow-up, however, showed all grafts to be occluded at

2 years (9). Henry's data on the Passager graft demonstrate 94% procedural success, with 75% secondary patency at 8-month follow-up (4). Another report utilizing this stent-graft had 45% and 56% primary and secondary patency rates, respectively, for ten patients at 17 months (10).

Diethrich utilized a PTFE/Palmaz stent combination delivered via percutaneous access in 50 patients; he reported primary patency of 65% and secondary patency of 85% at 8 months, with six acute postoperative occlusions (11). Longer follow-up exhibited primary patency of 46% and secondary patency of 68% at 2 years (12). Salvage procedures included use of thrombolysis and surgical thrombectomy. Seven patients required surgical femoral-popliteal bypass after occlusion of their endografts.

Other authors have advocated intra-operative endograft deployment via surgical femoral artery exposure and arteriotomy. After balloon angioplasty of the SFA, Marin created a sutured proximal anastomosis of the proximal end of an unsupported PTFE graft to the native femoral artery, and then fixed the distal graft end to the distal vessel with a Palmaz stent. At 18 months, only one graft remained patent in the seven patients on whom the procedure was performed (13). Spoelstra reported one-year follow-up for 55 patients, utilizing the same technique described above, with overdilation of the SFA with a 9 mm angioplasty balloon. Early primary patency was 73% and secondary patency 86%. Long-term follow-up was not reported (14).

With early experience using the percutaneously deployed Hemobahn device in the SFA after PTA, Bleyne showed 6-month primary patency of 83%, with 86% secondary patency (15). Two-year follow-up data on the Hemobahn device, as reported by Dake, revealed 65% and 90% primary and secondary patency, respectively (16). More recent reports have revealed a high rate of technical success in deployment and early angiographic result, but mixed results regarding patency. Bauermeister recanalized long-segment occlusions in 35 patients and successfully deployed Hemobahn stent-grafts. Adjuvant thrombectomy techniques were employed in the majority (ring cutter, balloon thrombectomy, thrombolysis), and 16 required adjuvant surgical procedures (femoral bifurcation patch angioplasty). One-year primary and secondary patency were 73% and 82%, respectively, by life-table analysis (17). Deutschmann and colleagues successfully placed Hemobahn stent-grafts in 17 of 18 pa-

tients. Primary patency at 3 months was 61%, dropping to 49% at 6-month follow-up. Secondary patency improved 6-month patency results to 61%. Patency was seen to be decreased for stented segments longer than 10 cm and intimal hyperplasia was observed in 39%, at either the proximal or distal ends of the stent-graft (18). Ahmadi reported a 17% rate of early occlusion (within 24 hours) in a series of 30 patients who underwent PTA of SFA with placement of a Dacron-covered stent-graft. Restenosis was observed in 83% of patients at mean follow-up of 5 years, with primary patency rates of 23%, 17%, and 17%, respectively, at 1, 3, and 5 years. Secondary patency rates were 60%, 34%, and 34%, respectively. Patients were maintained on warfarin and aspirin (19).

As previously mentioned, the second technique of stent-grafting for SFA disease employs surgical debulking of plaque prior to relining the lumen with a PTFE graft. Bergeron and Ho described SFA endarterectomy with the Mollring Cutter (Fig. 7), followed by endovascular placement of the PTFE graft (20, 21). Ho and associates' technique evolved from initial Mollring SFA endarterectomy alone with stenting for fixation of the distal endarterectomy flap, to relining the endarterectomized SFA with PTFE. Of Bergeron's 17 patients treated with semi-closed Mollring endarterectomy and PTFE relining, three experienced early re-occlusion, requiring surgical bypass, and two others needed interventional adjunctive stent placement to maintain patency (22). Ho's results exhibited one-year primary and secondary patency rates of 76% and 78%, with two-year primary and secondary patency rates of 61% and 70% (23). At the 2000 VEITH symposium, Moll presented data on 40 patients treated as described above, with 6-month follow-up having an 81% secondary patency rate (24).

Morris (25) has employed wire-guided rotational and nonrotational remote endarterectomy devices (EVI, Vancouver, Canada) to clear the SFA of plaque, sequentially upsizing the size of the endarterectomy catheter, followed by PTA. He then uses endoluminal forceps to pass the PTFE graft through the newly cleared lumen. He creates a surgically sutured proximal anastomosis at the arteriotomy site, while the distal end of the PTFE graft is left unanchored (without stent fixation), hoping to decrease neointimal hyperplasia at this site. Morris reports that 12 of 14 patients had successful treatment with the EVI endarterectomy and PTFE relining. Three had immediate failures (all cleared with

thrombolysis), two additional failures at 2 months, and two-year primary and secondary patencies of 61% and 70%, respectively (25). Bergeron also reported on the use of the EVI device, with his eight patients having 100% patency six months after the procedure (26).

Summary

The past decade has witnessed an acceleration in the interest in minimally invasive treatment of peripheral vascular disease. As described in the above overview, the application of endovascular techniques using stented grafts has brought success in the treatment of arterial occlusive disease, particularly in the aortoiliac arterial bed. For the femoropopliteal arterial location, novel strategies involving both percutaneous and combined open and catheter-based techniques have shown promising results in the short-to-intermediate term, particularly for those patients at high risk for conventional surgery. Careful patient selection and diligent long-term follow-up is mandatory. Continuing application of technical advances and a targeting of the causes of failure, such as graft stenosis, kinking, and intimal hyperplasia, await long-term outcome studies.

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