Safety and pitfalls in frozen elephant trunk implantation

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The frozen elephant trunk (FET) procedure, or open stent grafting, is a tool for the combined open and endovascular treatment via a median sternotomy of extensive aortic disease involving both aortic arch and descending thoracic aorta. The technique aims to stabilize the maximum extent of the thoracic aorta in one step, with the goal of either rendering a secondary intervention to the downstream aorta unnecessary or producing an easy landing zone for secondary thoracic endovascular aortic repair (TEVAR) or open surgery. Even though large case series have reported good results, we still have no conclusive evidence as to which patients and what kind of pathologies benefit from this technique. The surgical sequences described for total arch replacement with the FET procedure are just as varied as the associated devices and indications. This article focuses on important perioperative and surgical aspects, as well as potential complications during FET procedures.

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Introduction

The frozen elephant trunk (FET) procedure, or open stent grafting, is a tool for the combined open and endovascular treatment of extensive aortic disease involving both the aortic arch and descending thoracic aorta. This technique aims to stabilize the maximum extent of the thoracic aorta in one step, with the goal of either rendering a secondary intervention to the downstream aorta unnecessary or producing an easy landing zone for secondary thoracic endovascular aortic repair (TEVAR) or open surgery.

Since its first description, a variety of commercially available and homemade FETs have been inserted in a broad set of pathologies. Even though large case series have reported favorable results, it should be kept in mind that we still have no definitive evidence as what kind of patient and pathology would most benefit from this technique.

The surgical sequences described for total arch replacement with the FET procedure are just as varied as the associated devices and indications.

Indications and devices

While indications for the FET technique are not yet well defined, the procedure has been described in atherosclerotic aneurysms and both chronic and acute type A and type B dissections (1-7).

At our center, open stent grafting is the standard of care for acute type A dissection involving the descending thoracic aorta. We also employ the technique for aortic arch and descending aortic aneurysms with a suitable landing zone in the descending thoracic aorta, but not routinely in chronic dissections.

Although stent grafting has been advised against in patients with connective tissue disorders several groups have since published case series with Marfan patients demonstrating good results (8).

Open stent grafting can be performed with home-made devices as well as commercially available devices such as the E-vita Open Plus (Jotec GmbH, Hechingen, Germany), the Chavan Haverich Prosthesis (Curative GmbH, Dresden, Germany) or the Thoraflex Hybrid Prosthesis (Vascutek, Terumo, Inchinnan, Scotland, UK), which consists of different graft and stent graft types.

Ius *et al.* (5) recently published their experience with all three commercially available devices and did not find any significant differences in their performance. Other comparative studies concerning the devices or the stent graft they incorporate are still awaited. Until then, surgeons should choose the device they feel most comfortable with.

General surgical considerations

Even though the implantation procedure for the FET is the same, surgical technique as well as sizing of the stent graft should be adapted to the aortic pathology.

For arterial cannulation, both axillary artery cannulation and direct aortic cannulation are not only suitable but are the preferred techniques. Femoral artery cannulation has been reported to be associated with a poorer outcome because of mortality and stroke (9). While we routinely use axillary artery cannulation, which is comfortable and facilitates antegrade cerebral perfusion if desired, it is advisable to have alternative cannulation techniques available.

In order to enhance organ protection during circulatory arrest, a variety of techniques have been proposed. These include deep hypothermic circulatory arrest (DHCA) alone, retrograde cerebral perfusion and uni- or bilateral antegrade cerebral perfusion at varying flow rates and degrees of hypothermia. Additionally, antegrade left subclavian artery (LSA) and distal body perfusion have been introduced for spinal cord and distal organ protection (10-12). In general, possible advantages of antegrade perfusion compensates for a more crowded field and less surgical comfort.

Another strategy to reduce cardiac, cerebral and lower body ischemia during aortic arch replacement with supraaortic debranching is to suture the distal and left common carotid artery anastomosis before completing the proximal aortic anastomosis and to start reperfusion before connecting the innominate artery and the LSA, as proposed by Sun *et al.* (2).

Even though an increasing number of studies point towards the superiority of antegrade cerebral perfusion in reducing the rate of postoperative stroke, there is no definite evidence yet as to which technique is the best (10,13).

Near-infrared spectroscopy (NIRS) is a useful adjunct, especially in cases of aortic dissection or if unilateral antegrade cerebral perfusion is used. If the aorta is cross-clamped during a case of aortic dissection, false lumen pressurization could possibly lead to insufficient cerebral perfusion that may be detected by NIRS. A significant reduction in regional cerebral oxygen saturation of one hemisphere indicates an insufficient cerebral cross-perfusion during unilateral antegrade cerebral perfusion (14).

Regarding the choice of temperature during circulatory arrest, favorable results have been reported with total arch replacement using mild or moderate hypothermia and antegrade cerebral perfusion. However, in the setting of FET implantation, spinal cord ischemia rather than cerebral ischemia during circulatory arrest seems to be the limiting factor. Moreover, hypothermia is an important tool to increase spinal cord ischemic tolerance, and a temperature of more than 28 ℃ during circulatory arrest has been identified as a risk factor for spinal cord ischemia during FET implantation (4,15). This is especially the case if a large portion of the thoracic aorta is going to be covered, the expected duration of lower body ischemia is long or the patient has additional risk factors. Therefore we strongly advise against excessive high temperatures during circulatory arrest.

Over the past few years a strategy using straight hypothermic circulatory arrest at 18 ℃ alone led to favorable surgical results in our institution, aided by the clear, comfortable surgical field and improved outcome. However, we look forward to the results of the "ARCH Project" initiated by Yan and co-workers to answer the question of which cerebral protection strategy is the best (16).

Insertion and positioning

After the resection of the aortic arch, the FET is manually and smoothly inserted into the descending aorta, positioned and deployed. Though rare, distal perforation of the descending aorta or of the dissection membrane is a potentially serious intraoperative complication of open stent grafting. In patients with a kinked or tortuous aorta, insertion can be difficult or even impossible. If any resistance is felt during the insertion process we strongly advise either retrying with a shorter device or changing the strategy to a conventional elephant trunk implantation.

In patients with aortic dissection the challenge is to insert the stent graft into the true lumen throughout its whole length. Even though the true lumen can usually be easily identified when opening the aortic arch, it is possible that the stent graft, though inserted into the true lumen proximally, can slide into the false lumen distally via a second entry tear or perforate the dissection membrane and enter the false lumen.

The stent graft can be inserted without any additional guidance or with an antegrade guidewire, but additional techniques have been proposed to prevent stenting of the false lumen, especially in patients with aortic dissection.

The most widespread technique is the insertion of a femoral guidewire into the true lumen. A femoral guidewire is a useful tool, but it should be kept in mind that identifying the guidewire in the true lumen when transecting the arch, or in the true lumen on transoesophageal echocardiography (TEE), does not necessarily mean that the guidewire lies in the true lumen for its full length. It could have entered and left the false lumen via distal entry tears. If angiography is available, the best check would be to confirm the position of the wire in the true lumen for its full length by contrast angiography.

Another helpful technique is the use of a camera (e.g., a bronchoscope) to screen the aorta for distal entry tears. The camera can be inserted in parallel with the stent graft to ensure correct positioning, and must be removed before deploying the stent graft.

The depth of implantation depends on the level of the targeted landing zone as well as the desired position of the proximal suture line. We usually aim for a deep implantation to stabilize a maximum length of the descending aorta, but the first priority should be a location where the aortic tissue allows a safe anastomosis, i.e. the tissue is not too calcified.

Some surgeons prefer to ligate the LSA and to implant the FET proximal to the LSA, which may reduce the risk of recurrent laryngeal nerve damage. This technique is easier for the surgeon, but shortens the segment of the aorta that is stabilized by the procedure. Though deliberate covering of the LSA without revascularization has been described for TEVAR, we recommend bypassing the LSA in this setting in order prevent compromising spinal cord perfusion (17).

After insertion and deployment of the stent graft, the prosthesis is sutured to the proximal end of the descending thoracic aorta. This anastomosis should be done very accurately, since the arch can be difficult to reach once it has been replaced. We used a 4.0 Prolene suture with a small, but strong needle. Teflon felt reinforcement of the suture line can also be used, but is not necessary.

If a device has a non-stented portion which can be crimped into the stented part (e.g., E-vita open plus) then there are some advantages to suturing this anastomosis while the non-stented prosthesis is still invaginated into the stent. Once the non-stented part is pulled out and the lumen is pressurized after arch replacement, the suture line tightens itself. After pulling out the non-stented part, it should be checked to see if the anastomosis is constricting the stent graft itself.

Alternatively, the non-stented part can be pulled out first and be sutured to the aorta afterwards. A sewing collar that can be used for the anastomosis is an integral part of some devices.

Subsequently, the supra-aortic branches can either be implanted into the arch prosthesis as an island or as individual branches. If an island reimplantation is performed, sufficient prosthesis should be left between the island and the distal anastomosis in order to prevent strain being placed on the suture lines once the lumen is pressurized. The Thoraflex Hybrid Prosthesis features a non-stented part with four branches for supraaortic debranching and lower body reperfusion via the fourth branch.

Acute aortic dissection

At our center, the FET procedure has been the standard of care for patients with acute type A dissection involving the descending thoracic aorta over the last five years, irrespective of the site of the entry tear. It allows extensive stabilization of the dissected aorta and immediate closure of the false lumen in the descending aorta around the stent graft. Several other groups have reported excellent results with open stent grafting in acute dissection (1-3).

Sizing of the stent graft

The goals of open stent grafting in acute dissection are the stabilization of the descending thoracic aorta, the closure of entry tears in this area and the obliteration of the false lumen. Most authors recommend choosing the stent diameter according to the diameter of the true lumen because of the fear of stent perforation (11,18). Although this concept predisposes to distal endoleakage and false lumen patency, it is hoped that the false lumen might thrombose during follow-up (19,20).

In contrast, in our experience with acute dissection, the membrane is usually elastic and can easily be realigned with the adventitia. Consequently, we have adopted the concept of sizing the stent graft according to the total aortic diameter, diameter. Indeed, in a recently published case series we found immediate false lumen closure around the stent graft in all patients, and no endoleak or aortic wall damage related to the stent graft (21). Recently, an undersized stent was implanted in one patient because the appropriate size was not available. This patient developed a type Ib endoleak that required endovascular repair. In acute aortic dissections, we advocate choosing the stent graft size according to the total diameter of the aorta at the level of the left atrium. The optimal imaging method for stent graft sizing is a curved multiplanar reconstruction around the vessel's centreline from ECG gated CT angiography. If detailed imaging is not available in the emergency setting, an additional measurement by TEE is performed intraoperatively, and the measurements from CT angiography and TEE are combined.

Length and depth of stent graft implantation

The choice of the distal landing zone for the FET in acute dissection is a controversial issue. Extensive stent grafting of the thoracic aorta carries the risk of spinal cord injury (17). On the other hand, if the stent graft is implanted deeper and for longer the greater segment of the descending aorta will be stabilized by the procedure.

Flores *et al.* (22) found a significantly higher incidence of spinal cord injury if the distal landing zone was lower than T7. Therefore most surgeons have refrained from aiming towards a deeper landing zone than T7 (11). However, several retrospective studies on FET implantation did not find a correlation between landing zone and the incidence of spinal cord injury (4,6). In our case series mentioned above, we aimed for a landing zone at T10-T12 and none of the patients presented with new postoperative spinal cord injury. We suppose that this discrepancy is most likely due to differences in perioperative management, which play a crucial role in spinal cord protection.

A limited choice of stent graft lengths is available when a commercially available device for the FET procedure is used. For acute type A dissections we usually choose the longest stent available (150-160 mm). Particularly in short patients, it should be confirmed on preoperative CT angiography that a stent graft of the desired size does not exceed a distal landing zone of T10-12 and does not cover the celiac trunk. Furthermore, in patients with a severely kinked aorta the choice of a shorter stent might be reasonable.

Technical aspects

The FET is implanted during a period of circulatory arrest with or without antegrade cerebral perfusion. Firstly, when transecting the aortic arch, the true and false lumina of the dissected aorta as well as the layers of the aorta have to be identified. In all anastomoses, both the dissection membranes as well as the adventitial layer have to be included. Additionally, before further trimming the supraaortic island or individual branches, the number of supraaortic vessels should be noted in order not to overlook a left vertebral artery arising directly from the aortic arch.

The proximal descending aorta should be carefully mobilized to prepare for the distal anastomosis. Around the whole circumference, the dissection membrane and adventitia have to be realigned and included in the anastomosis. Since the aortic tissue can be very fragile, it is useful not to dissect the aorta too closely as the surrounding connective tissue can help to buttress the anastomosis.

After insertion and deployment of the stented graft, it should be confirmed that all layers of the aorta and the stent graft are well aligned and that the dissection membrane has not been invaginated into the descending aorta.

One of the major advantages of open stent grafting in acute aortic dissection is that, once the stent is appropriately sized, it occludes the false lumen and secures the suture line. With regard to the hemostasis of the distal anastomosis, open stent grafting is therefore an easier approach than conventional total arch replacement.

Arteriosclerotic aneurysm

Chronic degenerative aneurysms of the aortic arch and thoracic aorta were the primary indications for FET procedure. If the FET has a suitable landing zone in the descending thoracic aorta the pathology can be treated using a single-stage procedure.

If the patient presents with an extended thoracic or thoraco-abdominal aneurysm without a suitable landing zone, a type Ib endoleak will most likely result. In these cases, further treatment of the downstream aorta should be discussed beforehand since the FET, being a single stage procedure, may not offer much advantage in comparison to a conventional elephant trunk.

Sizing of the stent graft

In degenerative aneurysms, the diameter and depth of the landing zone are essential information for the selection of the stent graft, and particular care should be taken to ensure that the stent graft is long enough to reach the desired landing zone. As discussed in the setting of acute aortic dissection above, targeting a distal landing zone lower than T7 is not recommended in order to protect spinal cord perfusion (11,22). In contrast, our experience does not confirm this assumption, and recent case series have supported this argument (4,6).

The diameter of the stent graft should be chosen according to the diameter of the aorta at the level of the distal landing zone with a 10-20% oversizing to reduce the risk of type Ib endoleak.

Technical aspects

The surgical challenge when implanting a FET in a patient with an arteriosclerotic aneurysm is that the aortic wall can be heavily calcified, rendering a tight suture line difficult.

When anastomosing the graft to the proximal descending aorta, the adaptation of the sclerotic, dilated aortic wall to a potentially smaller graft may be a challenge. It is advisable to check the degree of calcification of the proximal descending aorta on the preoperative CT scan, and to note at which level of the aortic arch or descending aorta a safe alternative suture line might be feasible. When opening the aortic arch, we recommend assessing again the quality of the aortic wall before resecting the arch. If the aortic wall is too calcified, choosing a hemiarch replacement might be the safer option. Otherwise, replacement of the proximal descending aorta via a clamshell incision is an alternative.

Chronic aortic dissection

Pacini *et al.* (6), as well as other authors (4,5,23), have reported respectable results with FET procedure in chronic aortic dissection. Though we have implanted FET in selected patients with chronic aortic dissection, our standard procedure in these cases would be to resect the proximal dissection membrane and implant a conventional elephant trunk.

Open stent grafting can help to secure the true lumen in chronic aortic dissection, but since the dissection membrane is usually not elastic in these cases and distal re-entries are frequent, false lumen thrombosis can be delayed and unpredictable (4-6,19,20,23). On the other hand, false lumen thrombosis might not even be desirable. In the chronic setting, intercostal, renal and visceral arteries might fully depend on false lumen perfusion. Consequently, we are not convinced that FET procedure is justified and beneficial in chronic aortic dissection.

If a FET procedure is considered in a patient with chronic aortic dissection, the origin of the visceral and renal arteries—either from the true or from the false lumen and the presence of potential distal re-entries—should be assessed preoperatively. If not done, open stent grafting could jeopardize distal organs perfusion and should not be performed.

Most surgeons performing FET in chronic dissection recommend sizing the stent graft according to the diameter of the true lumen because of the quality of the membrane. The difficulty of the distal anastomosis in chronic dissections is that the usually sclerotic, or even calcified, aortic wall has to be adapted to the smaller diameter stent graft or graft. Both the dissection membrane and the adventitial layer of the dissected aorta should be included in the suture line. If the dissection membrane is too fragile, its proximal part can be resected, and the graft can be attached to the adventitial layer only. Any thrombus in the false lumen should be extracted before creating the anastomosis.

Hemostasis

The crucial aspects for hemostasis in FET procedure are, as in any aortic procedure, surgical technique and coagulation management.

Any part of the suture line that will probably be difficult to reach later on, such as the distal anastomosis of the arch or the dorsal part of a supraaortic island, should be sutured very tightly and carefully.

Before the procedure, the quality of the tissue should be assessed when planning the extent of the surgery. In acute aortic dissection, we recommend a FET procedure with a stent sized to the total aortic diameter since the stent tightens the distal anastomosis and prevents back bleeding from the false lumen. A small but strong needle to reduce bleeding from the suture line is favored. The surrounding connective tissue is helpful in stabilizing and tightening the anastomosis.

Avoiding the opening the left pleura is advantageous when dissecting the proximal end of the descending aorta to prepare for the distal anastomosis. It can subsequently be opened just below the sternum at the end of the procedure. If blood is found in the left pleural space at this moment, there is either bleeding from the distal anastomosis, or, in the worst case, the aorta has been perforated by the stent graft in the descending thoracic aorta. If bleeding from the distal anastomosis or descending aorta is suspected, the pleura should be fully opened to identify the source of bleeding, with one option being a clamshell incision of the left thorax to reach the descending thoracic aorta if necessary.

Once the procedure is finished and the patient is weaned from cardiopulmonary bypass (CPB), profuse diffuse bleeding often occurs. The crucial decision at this point is to conclude if the bleeding is merely coagulopathic or if there is a major surgical source of bleeding. We advise against any unnecessary manipulation of the aorta to prevent tears forming in the possibly fragile aortic tissue. If there are no signs of active bleeding, CPB is terminated and protamine is administered. The diffuse bleeding should improve over the next few minutes even though the bleeding can be worryingly high at this point. A cell saver should be used, and adequate volume administration is necessary to compensate for the blood loss. There may be some surgical bleeding detectable apart from the diffuse bleeding that can now be treated. If at this point there is still no major bleeding source that requires resumption of CPB, we rapidly and aggressively administer coagulation products (platelets, fibrinogen, prothrombin concentrate) guided by thrombelastometry. Following this, the volume of hemorrhage usually dramatically decreases within a few minutes. However, if a hemorrhagic diathesis persists after the initial coagulation products are given we again use thromboelastometry to further guide the coagulation management. We also recommend postoperative coagulation studies and subsequent substitution of coagulation products immediately and 6 hours postoperatively, even if the patient does not show signs of bleeding, to prevent late coagulopathic bleeding.

Stent graft complications

A few serious intraoperative surgical complications from open stent grafting should be kept in mind.

A possible complication of aortic dissection is distal malperfusion; in acute dissection it can occur preoperatively and may be resolved by the stabilization of the true lumen by stent grafting. However, in any patient, with acute or chronic aortic dissection, malperfusion can persist or newly occur after open stent grafting. This can for example, be the case if a vessel depends on false lumen perfusion is occluded by a dynamic flap, or, in the worst case, if the stent graft enters into the false lumen distally.

Stenting of the false lumen and the potential occlusion of the false lumen is a rare but serious complication. In these cases, the stent graft is inserted into the correctly identified true lumen proximally, but may slide through a distal entry tear or perforate the dissection membrane distally and subsequently enter the false lumen. Measures to prevent this complication have been discussed above.

Signs of distal malperfusion after open stent grafting include rising or persistently high lactate levels, anuria, a difference in aortic, radial and femoral mean arterial pressures or missing peripheral pulses. If preoperative signs of abdominal malperfusion were present in acute aortic dissection, or if there is any suspicion of malperfusion after stent graft deployment, we strongly recommend performing a diagnostic laparotomy intraoperatively. This is a fast, easy and sensitive way of excluding visceral ischemia. If readily available, such as in a hybrid operation room setting, angiography is another option. CT angiography can be inconclusive at a very early stage of mesenteric ischemia, and might delay treatment if transport is necessary (24).

Stent graft perforation and rupture of the descending thoracic aorta have been reported, particularly in a kinked or tortuous descending aorta (5). This complication should present itself as bleeding in the left pleural space. Depending on the extent of the damage and the available resources, an over stenting of the damaged aorta may be feasible. Otherwise, a descending aortic replacement might be the sole option.

Another complication to be considered is incomplete deployment or kinking of the distal stent graft (25). If a hemodynamically relevant stenosis is present, balloon dilatation or the deployment of a second stent graft may be performed in order to dilate or realign the FET.

If postoperative endoleakage occurs and is relevant, endovascular repair should be feasible in the majority of cases. We recommend a postoperative CT or MR angiogram in all patients before discharge to check for endoleakage or any other procedure-related complication.

Spinal cord protection

Ischemic spinal cord injury is one of the most feared and major complications of the FET procedure.

Its prevalence is reported to be higher with open stent grafting as compared to the conventional elephant trunk repair (4,11), ranging from 0% to 24% (1,7,21-24), with patients with extensive thoracoabdominal aortic pathology as well as patients with previous aortic surgery or TEVAR seem to be at a special risk (17). Numerous factors have been suggested to influence the risk of spinal cord ischemia. As previously mentioned, a distal landing zone lower than T7 has been suggested as a risk factor for spinal cord ischemia (22), but this was not supported by recent findings (4,6).

We could not confirm the high rate of postoperative spinal cord injury described in our own series, even though we aimed for a distal landing zone of Th10-12 (21). Hence, we assumed that the perioperative management and patient-related factors are more relevant determinants of spinal cord injury than the procedure itself and depth of the distal landing zone.

Though favorable results regarding cerebral protection have been published in aortic arch surgery with moderate and mild hypothermic circulatory arrest with antegrade cerebral perfusion, hypothermia is an important means of increasing spinal cord ischemic tolerance. Etz *et al.* (15) reported in experimental studies that the ischemic tolerance of the spinal cord is limited during mild hypothermia and antegrade selective cerebral perfusion, and Leontyev *et al.* (4) recently published a single center study on frozen and conventional elephant trunk technique and reported a body core temperature of 28 ℃ and higher to be an independent predictor of paraplegia if distal body arrest exceeded 40 minutes (4). In accordance with these findings, we recommend at least moderate hypothermia for FET procedures, especially if the expected lower body arrest time is long or if additional risk factors are present.

A prolonged lower body arrest time may increase the risk of spinal cord injury, especially if moderate or mild hypothermia are used (12,15). To reduce the period of spinal cord and distal organs ischemia, additional antegrade perfusion of the LSA as well as the insertion of a perfusion cannula into the descending aorta after stent deployment have been proposed (12). The clinical significance of these adjuncts has not yet been studied in detail.

In order to ensure adequate spinal cord perfusion pressure, stable hemodynamics with a mean arterial pressure of at least 80 mmHg should be targeted after stent graft deployment, and combined with a central venous pressure (CVP) below 10 mmHg (16,26) if possible. An increased mean arterial pressure may render hemostasis more difficult, but lowering the blood pressure should not be a means of achieving hemostasis. Therefore, diligent surgical technique and adequate administration of coagulation products is important in these patients.

For neuropharmacological protection, we administer steroids and thiopental to reduce cerebrospinal oxygen demand. Even though experimental studies have shown a benefit with these adjuncts, clear clinical evidence is still missing (26).

Cerebrospinal fluid (CSF) drainage and pressure monitoring is another useful tool to prevent spinal cord injury. Its benefit has been extensively reported in open thoracoabdominal surgery (26). We recommend preoperative CSF drainage in all patients undergoing elective FET procedure. CSF pressure should be maintained at a pressure below 10-12 mmHg. We leave the CSF drainage for 3-5 days postoperatively because the development of late paraplegia has been described. In emergent cases such as acute aortic dissection, early extubation and close postoperative monitoring of the neurologic status should be performed, and a CSF drain can be inserted if there is any sign of postoperative neurologic deficit.

Conclusions

The FET procedure is a surgical technique developed for patients with aortic pathologies involving both the arch as well as the thoracic descending aorta. Though we do not have concrete data as to which patients benefit from FET implantation, clinical experience suggests that the procedure facilitates the repair of extensive thoracic aortic pathologies via a median sternotomy with favorable results.

There is a variety of devices and surgical strategies, particularly cerebrospinal protection, which have been proposed but there is no clear evidence yet which approach is most beneficial. Until this is available, it seems that favorable results can be achieved with different strategies and we can only recommend using the strategy the surgeon feels most comfortable with. Besides the surgical approach, the perioperative management is crucial for the safety of the procedure.

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