ADULT CARDIAC

# Physician-Modified Thoracic Stent Grafts for the Arch After Surgical Treatment of Type A Dissection

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*Background.* This study evaluated the outcome of physician-modified thoracic stent grafts for the treatment of dissecting aortic arch aneurysms after surgical treatment of acute type A dissection.

*Methods.* From August 2016 through February 2018, 13 patients (8 men and 5 women) underwent thoracic endovascular aortic repair in which physician-modified thoracic stent grafts were used to treat dissecting aortic arch aneurysms after surgical treatment of acute type A dissection. Patients were a mean age of  $70.7 \pm 10$  years (range, 43 to 82 years). Four patients were treated in an emergent setting for a symptomatic aortic arch aneurysm. The aneurysmal disease involved zone 0 in 10 patients and zone 2 in 3. Seven patients (48%) were treated using an aortic arch stent graft with a single fenestration, combined with cervical debranching in 4 patients. Six patients underwent total endovascular aortic arch repair using a double-fenestrated stent graft. Additional

C urrently, open surgery is the gold standard for Stanford type A acute aortic dissection, the primary goal being to save the patient while minimizing surgical risk. The conventional approach is conservative, typically limiting replacement to include the ascending and hemiarch. In patients with intimal tear of the arch, with a known connective tissue disorder or with an arch rupture, the whole aortic arch is replaced. Small, localized tears in a nonaneurysmal arch can be repaired directly [1, 2]. Therefore, extensive replacement of the aortic arch is limited to a minority of patients.

Routine extension of replacement to completely include the aortic arch in the initial operation has been propagated by some [3, 4], a strategy that adds risk to an already complex procedure with a high mortality rate. Persistent perfusion of the distal false lumen has been repeatedly associated with dilatation of the downstream aorta. There remains therefore a frequent need for late reoperation. In addition, longevity after the primary procedure with an aging population has contributed to planned endovascular procedures were performed in 3 patients.

*Results.* Median time for stent graft modifications was 18 minutes (range, 14 to 21 minutes). All the proximal entry tears in the arch were successfully excluded. The 30-day mortality rate was 0%. One patient (7.6%) had a stroke without permanent sequelae. The median length of stay was 5 days (range, 1 to 17 days). During follow up of  $8 \pm 6$  months, there were no conversions to open repair, aortic rupture, paraplegia, or retrograde dissection.

*Conclusions.* The use of physician-modified thoracic stent grafts for the treatment of dissecting aortic arch aneurysm after surgical treatment of acute type A dissection is feasible and effective. Durability concerns will need to be assessed in future studies.

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increased frequency of surgery for the arch after ascending aortic surgery [5].

Although acceptable results have been achieved with reoperation, repair of residual Stanford type A dissections with involvement of the aortic arch and descending aorta, in which hypothermic circulatory arrest and redo sternotomy are sometimes associated with concomitant thoracotomy, continues to be a formidable challenge [4]. We have previously reported our experience using a hybrid approach requiring supraaortic trunk (SAT) debranching and revascularization, followed by stent graft deployment covering the entire arch, with encouraging results [6]. But redo sternotomy is required for both techniques.

An alternative option is a physician-modified thoracic stent graft. This involves deploying a conventional stent graft device [7], fashioning customized fenestrations, and reconstraining the device into the delivery system. This study evaluated the outcomes of physician-modified thoracic stent grafts for the treatment of postdissection aortic arch aneurysms after surgical treatment of acute type A dissection. We started our experience with singlefenestration devices combined, if required, with cervical debranching [8]. Since then, our technique has been refined to allow a complete endovascular approach, even

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when zone 0 landing is required, by using a double-fenestrated stent graft.

#### Material and Methods

The study protocol and informed consent were approved by the Arnaud de Villeneuve Hospital Institutional Review Board.

## Patients

Patients treated using physician-modified thoracic stent grafts for aortic arch lesions in our tertiary referral center (Arnaud de Villeneuve Hospital, Montpellier, France) were included. Owing to serious comorbidities, all patients were at high surgical risk (American Society of Anesthesiologists Physical Status Classification  $\geq$ III or emergent repair).

The stent graft modifications were planned and performed at our institution to conform to the aortic configuration of each patient. The Valiant device (Medtronic, Santa Rosa, CA) was used in all of the cases. This experience with physician-modified thoracic stent grafts started in August 2016 with single-fenestration devices. Since June 2017, our technique in patients who require landing in zone 0 has been refined to allow a complete endovascular approach using double-fenestrated stent grafts.

The aneurysmal disease involved zone 0 in 10 patients and zone 2 in 3 patients. For zone 0, 4 patients were treated using an aortic arch stent graft with a single fenestration combined with cervical debranching, and 6 underwent total endovascular aortic arch repair using a double-fenestrated stent graft. This latter group therefore avoided surgical SAT revascularization. One proximal large fenestration for the brachiocephalic trunk (BT) and the left common carotid artery (LCCA) and 1 distal fenestration for the left subclavian artery (LSA) were fashioned for this group.

Patients were suitable for this approach if the proximal and distal landing zone were longer than 20 mm and with a maximal aortic diameter of between 20 mm and 40 mm. Expansion of the true lumen in the arch of more than 45 mm and the combination of a short surgical graft (smaller than 4 cm) and a mechanical aortic valve determined ineligibility for the procedure. During the same period, 2 conventional aortic arch replacements and 2 hybrid approaches of SAT debranching, followed by stent graft implantation, were performed for the same indication.

All patients underwent high-resolution computed tomography angiography preoperatively. Demographic, morphologic, intraoperative, and postoperative data were recorded in a prospectively maintained database. Followup computed tomography angiography was performed at 1 week, 3 and 6 months, and annually thereafter.

## Planning, Sizing, and Device Preparation

Procedure planning and device sizing were performed using a dedicated three-dimensional vascular imaging workstation (Endosize [Therenva, Renne, France] or OsiriX Imaging Software [Pixmeo, Bernex, Switzerland]) with centerline luminal reconstructions. Stent graft diameters in the proximal and distal sealing zones were oversized by 10% to 15%.

Centerline luminal reconstruction is used to measure the distance between the BT and the LCCA and between the LCCA and the LSA, as well as the diameters of the BT, LCCA, and LSA. Centerline luminal reconstruction is also used to locate the origin of each vessel from the aorta in relation to its clock position. Volume rendering is used to determine the optimal position of the C-arm and to evaluate tortuosity of the aortic arch.

Modification of the stent graft is performed on a back table in the operating theater, commencing before the start of anesthesia. The proximal portion of the device is unsheathed deploying the area to be modified plus 1 additional stent. Fenestrations are premarked in the main stent graft according to the measurements obtained from centerline analysis.

## Single Fenestration Modifications

A single fenestration for the SAT target vessel of appropriate size and location is made between the struts of the stent graft. Fenestrations are circular, do not have stent struts going across them, and are 1 mm smaller than the target vessel. A sterile marking pen is used to mark the location of the fenestration based on the length and clock face measurements obtained from the reconstructed images. Minor adjustments in the placement site are permitted to facilitate construction of strut-free fenestrations. A cautery device is used to carefully burn the Dacron (DuPont, Wilmington, DE) fabric to create the fenestration. Thereafter, a radiopaque nitinol wire is sutured to the edge of the fenestration.

## Double Fenestration Modification

The LSA fenestration is constructed as described for the single-fenestration device. The small fenestration for the LSA is fashioned first, with no struts crossing, again 1 mm smaller than the size of the native vessel origin. A radiopaque nitinol wire is sewn onto the margins of the fenestration. Clock position is used to determine the position of the BT and LCCA island relative to the LSA using the reconstructed images. The large fenestration for the BT and the LCCA of appropriate size (5 mm larger laterally than that of the BT and LCCA orifices) is made without removing the crossing stent graft struts. The distance between the LSA and the LCCA ranges from 5 mm to 18 mm (Fig 1).

## Technique

All procedures are performed with the patient under general anesthesia in an operating room equipped with a mobile C-arm or in a hybrid theater with a fixed C-arm. If performed, the LCCA or LSA revascularization through a cervical approach precedes the thoracic endovascular aortic repair. Heparin (5,000 IU) is administered as the thoracic stent graft is introduced over an ultrastiff guidewire through femoral access. Angiographic runs are performed through a pigtail catheter introduced percutaneously through the left brachial artery. Because the branch vessels originate from the superior aspect of the arch, it is necessary to position the delivery system such that the stent graft fenestration(s) are oriented superiorly on entering the arch. The stent graft fenestration marker is therefore positioned on the outer curve of the thoracic aorta. It is important to ascertain that the fenestration is oriented toward the target vessel by aligning the radiopaque marker with the target vessel. If not aligned, the stent graft is pulled back in the descending thoracic aorta, and the stent graft is rotated to the correct position and reintroduced into the aortic arch.

With the C-arm in the optimal left anterior oblique position, based on the preoperative reconstruction, an angiogram is performed to localize the target vessel origin. The arch angiogram is used to align the radiopaque marker with the target vessel. After ascertaining that the fenestration is oriented toward the SAT target vessel, the mean blood pressure is lowered to approximately 80 mm Hg to optimize accuracy, and the stent graft is partially deployed. Minor rotational adjustments to the stent graft to align fenestrations are possible after the first stents are deployed.

A 7F brachial sheath is introduced over a 0.035-inch guidewire, using SAT access, through the fenestration into the stent graft lumen. The thoracic stent graft is fully deployed. An 8-mm to 10-mm balloon-expandable iCAST (38-mm or 59-mm-long) covered stent (Atrium, Hudson, NH) is deployed approximately one-quarter into the stent graft lumen and three-quarters into the branch vessel. The portion protruding into the thoracic stent graft is flared using a 14-mm to 20-mm balloon. Completion angiography is performed.

For double-fenestration devices, the LSA fenestration is used for orientation and positioning in all cases. The operator relies on accurate positioning of the BT/LCCA fenestration relative to both the LSA fenestration and vessel origins, based on preoperative imaging, careful planning, and stent graft modification.

### Postoperative Follow-Up

Demographic, morphologic, intraoperative, and postoperative data were recorded in a prospectively maintained database. Follow-up surveillance was performed with serial CT scans at 1 week, at 3, 6, and 12 months, and annually thereafter. A duplex scan was performed ad hoc for clinical concerns or abnormalities on CT.

## Results

From August 2016 through February 2018, 13 patients (8 men and 5 women) underwent thoracic endovascular aortic repair with homemade fenestrated stent grafts for the treatment of dissecting aortic arch aneurysm after surgical treatment of acute type A dissection. Patients were a mean age of  $70.7 \pm 10$  years (range, 43 to 82 years). All patients underwent previous replacement of the ascending aorta for a type A aortic dissection. A Bentall procedure was performed in 4 patients and supracoronary ascending aortic replacement in 9.

Aneurysm formation requiring treatment in these aortic arches was observed from 3 months to 11 years after the initial aortic dissection repair. Four patients were treated in an emergent setting for a symptomatic aneurysm (2 ruptured and 2 symptomatic aneurysms; Table 1). The Valiant device was used in all procedures. An average of 1.8 stent grafts (range, 1 to 2) was deployed. The proximal landing was in zone 0 in 10 patients and in zone 2 in 3 patients.

Median duration for stent graft modifications was 18 minutes (range, 14 to 21 minutes). Four patients



Fig 1. (A) Centerline luminal reconstruction is used to (C) measure the length of the brachiocephalic trunk (BT) and left common carotid artery (LCCA) island corresponding to the large fenestration. (B) Clock position is used to determine the position of the BT and LCCA island relative to the position of the left subclavian artery (LSA) using the reconstructed images. (D) A radiopaque nitinol wire is sutured to the edge of the fenestration for the LSA. (E) Reloading of the stent graft.

Table 1. Patient Demographics

Variables	(n = 13)			
Age, years	70.7 (43-82)			
Male sex	8 (61.5)			
Previous aortic repair	13 (100)			
Bentall procedure	4 (30.8)			
Supracoronary aortic replacement	9 (69.2)			
Time to aortic arch aneurysmal degeneration	5 years (3 months–12 years)			
Emergent setting	4 (30.8)			
Indication				
Ruptured aneurysm	2 (15.4)			
Symptomatic aneurysm (chest pain)	2 (15.4)			
Distal anastomosis pseudoaneurysm	1 (7.7)			
Aneurysm enlargement	8 (61.5)			
Extent of the dissection				
Aortic arch	10 (76.9)			
Thoracic aorta	12 (92.3)			
Abdominal aorta	9 (69.2)			

Values are mean (range) or n (%).

underwent combined cervical debranching and stent grafting with a single fenestration, 3 single fenestrations, and 6 total endovascular aortic arch repairs using a double-fenestrated stent graft (Table 2).

An additional 3 patients underwent planned endovascular procedures. Transcatheter aortic valve replacement through the LCCA approach was performed in 1 patient, and SAT reentry tear closures using covered stent grafts were performed in 2 patients (Fig 2).

#### Outcomes at 30 Days

Endovascular exclusion of the aortic arch was achieved in all patients. A stroke, without permanent sequelae, occurred in 1 patient (7.6%) in the territory of the posterior cerebral artery, probably related to the LCCA-LSA bypass. The overall mortality was 0%. All remaining SATs were patent. No endoleaks were identified. There were no cases of spinal cord ischemia. The median length of stay was 5 days (range, 1 to 17 days).

#### Follow-Up

During a mean follow-up of  $8 \pm 6$  months, there were no open surgical repair reinterventions, aortic ruptures, paraplegias, or retrograde dissections. One patient died of myocardial infarction unrelated to the aortic repair. In all patients, complete thrombosis and stabilization or shrinkage of the false lumen of the arch and thoracic aorta were observed. All remaining SATs were patent (Figs 3, 4).

#### Comment

This retrospective analysis reports our experience of homemade fenestrated stent grafts for endovascular aortic arch repair of chronic type A dissection. With no aortic-related death, type I endoleak, or spinal cord ischemia and patency of all the revascularized arteries, we demonstrate the feasibility of this approach and encouraging short-term results.

Acceptable results with open reoperative strategies, after acute Stanford type A dissection repair, have been achieved. Nevertheless, repair of residual Stanford type A dissections involving the arch and descending aorta, requiring hypothermic circulatory arrest and redo sternotomy, sometimes with concomitant thoracotomy, continues to be a formidable challenge [4]. Although a few centers of excellence are reporting excellent outcomes for repair of the arch in patients with a history of thoracic aortic surgery, these results are challenging to reproduce in other units. In four recently reported large series of elephant trunk procedures, the cumulative mortality for the two procedures and from deaths in the interval between the two procedures (commonly from aortic rupture) exceeded 20% [9–12].

To simplify the distal anastomosis and to simultaneously treat the dissecting thoracic aorta, the frozen elephant trunk technique has been introduced. Jakob and colleagues [13] lately reported their experience treating dissecting aortic arch aneurysm after surgical treatment of acute type A dissection using the frozen elephant trunk in a cohort of young patients (mean age,  $56 \pm 13$  years). The 30-day mortality was 7%, the rate of perioperative stroke was of 12%, and the rate of spinal injury was of 12%. Reconstruction of the aortic arch remains demanding, particularly in elderly patients and in those requiring an emergency repair or with major preexisting comorbidities.

The hybrid approach of supraaortic debranching and revascularization, followed by stent graft deployment, is a valuable alternate, avoiding circulatory arrest and cardiopulmonary bypass, but remains major operations associated with significant perioperative mortality and mandatory redo sternotomy [6]. Hence, total endovascular approach in this specific indication of chronic type A dissection has two major advantages: no risk of retrograde dissection and the avoidance of redo sternotomy.

One such approach is the chimney technique; however, there are concerns about type I gutter endoleaks in the gaps between the chimney graft and the main graft. Furthermore, in practice, most cases using the chimney technique only treat 1 branch. Typically when 2 or 3 supraaortic branches are to be preserved, additional extraanatomic bypasses have to be performed [14].

Custom-made branched devices are available. The global experience with 38 branched arch devices was first reported as a multicenter study by Haulon and colleagues [15] in 2014. A 13% mortality rate, 16% stroke rate, 15.8% technical failure rate, and 19.6% secondary procedure rate was reported. This approach is unsuitable for emergent cases. There is an inherently high risk of cerebral embolism with this approach owing to the technically demanding nature of catheterization of side branches.

Incorporating larger fenestrations into custom-made arch endografts increases the margin of safety of the procedure, with centers in Japan reporting extensive experience with this approach. In a recent study [16], this

#### Table 2. Procedure Characteristics

			Aortic Arch Zone 1	Aortic Arch Zone 2	Thoracic Aorta Zone 3		Double Fenestration				Stent Graft Diameter
No.	Proximal tear location	PLZ Diam (mm)	D/TLd/TOTd (mm)	D/TLd/TOTd (mm)	D/TLd/TOTd (mm)	Single Fenestration	Large	Small	Cervical Bypass	Retrograde Stenting	Prox/Distal/Nb (mm)
1	Z3: descending aorta	Zone 2/32	-/38/38	-/32/32	+/32/60	LSA				LSA	38/38/1
2	Z3: descending aorta	Zone 2/36	-/38/38	-/36/36	+/32/48	LSA				LSA	42/38/1
3	Z3: descending aorta	Zone 2/30	-/33/33	-/30/30	+/35/60	LSA				LSA	34/34/1
4	Z3: descending aorta	Zone 0/32	+/35/42	+/35/42	+/37/100	BT			RCA-LCA-LSA		38/38/2
5	Z2: LSA	Zone 0/32	+/35/38	+/35/38	+/38/55	BT + LCA			LCA-LSA		38/38/2
6	Z2: LSA	Zone 0/30	+/28/35	+/28/35	+/30/55	BT + LCA			LCA-LSA		34/34/2
7	Z2: LSA + descending aorta	Zone 0/30	+/36/42	+/42/55	+/42/55		BT + LCA	LSA		LSA	38/42/2
8	Z0: distal anastomosis	Zone 0/28	+/34/42	+/30/90	+/33/80	LCA			RCA-LCA-LSA		34/34/2
9	Z0: distal anastomosis	Zone 0/32	-/37/37	-/31/31	-/33/33		BT + LCA	LSA		LSA	38/38/1
10	Z0: distal anastomosis	Zone 0/30	+/32/55	+/27/40	+/27/38		BT + LCA	LSA		LSA	40/38/2
11	Z0: distal anastomosis + RSA	Zone 0/28	+/28/42	+/29/42	+33/57		BT + LCA	LSA		RSA/RCA+ LSA	36/37/2
12	Z0: distal anastomosis + BT	Zone 0/34	+/40/46	+/45/56	+/44/48		BT + LCA	LSA		LSA	42/46/2
13	Z0: distal anastomosis $+$ RCA	Zone 0/28	+/25/42	+/32/44	+/27/66		BT + LCA	LSA		BT/RCA + LSA	34/34/1

BT = brachiocephalic trunk; D = presence of dissection; diam = diameter; LCA = left common carotid artery; LCA-LSA = left common carotid artery-left subclavian artery bypass; Nb = number of stent grafts implanted; No. = number; PLZ = proximal landing zone; RCA = right common carotid artery; RCA-LCA-LSA = right common carotid artery-left common carotid artery-left subclavian artery bypass; RSA = right subclavian artery; TLd = true lumen diameter; TOTd = total diameter; Z0 = zone 0; Z2 = zone 2.

Fig 2. (A) The Valiant Thoracic stent graft (Medtronic, Santa Rosa, CA) is partially unsheathed. The double fenestration is fashioned. (B) With the C-arm in the optimal left anterior oblique position, based on preoperative reconstruction, an angiogram is performed to localize the left subclavian artery. The arch angiogram is used to align the radiopaque marker (blue arrows) with the target vessel. (C) The stent graft is partially deployed. A 7F brachial sheath is introduced over a 0.035-inch guidewire through the fenestration into the stent graft lumen. (D) Completion angiography after implantation of the double-fenestrated stent graft in zone 0 demonstrates exclusion of the arch aneurysm and patency of the supraaortic trunks.



technique was used in patients with a short seal zone distal to the LCCA (mean length, 11 mm; range, 5 to 15 mm). The authors report a 32.4% type IA endoleak rate at discharge and 16.2% aneurysm enlargement at follow-up.

The Valiant Mona LSA (Medtronic) and Gore singleside branch (W.L. Gore & Associates, Inc., Flagstaff, AZ) off-the-shelf branch devices consist of a main stent graft and a branch stent graft designed to maintain patency of one of the SATs while diverting circulation away from the encroaching aneurysm [17]. This approach allows preservation of patency for only one of the SATs during emergent thoracic endovascular aortic repair. These devices are not currently available on the market.

Even today, patients with rapidly expanding, symptomatic, or ruptured arch aneurysms who are poor candidates for open surgical repair have limited options other than immediate physician modification.

In situ retrograde laser fenestration is a type of physician modification that is feasible and effective for LSA revascularization. Redlinger and colleagues [18] reported 22 patients with a technical success of 100%. For total endovascular arch repair, the use of in situ fenestration requires more complex procedures using transient cardiopulmonary bypass between femoral and cerebral vessels to avoid cerebral ischemia [19]. Furthermore, the angle of SAT takeoff from the aortic arch considerably influences the technical ease and outcome of laser fenestration.

In our series, although minor adjustments are possible, ascertaining that the single fenestration or the small fenestration of the double fenestrated stent graft is well oriented toward the SAT target vessel is crucial before starting stent graft deployment. The specific feature of the double-fenestrated device is simple handling during the operation. The large fenestration is directed to the target vessel automatically when the small fenestration is catheterized and secured by covered stent placement. Furthermore, because the large fenestration is large enough to accommodate the branches with low risk of branch occlusion, neither bare-metal nor covered stents necessarily need to be placed into the branches.

A major advantage is the simplicity and rapidity of the procedure compared with branched stent grafts, decreasing the need for manipulation in the arch and the associated risk of microembolic strokes. In our series, only 1 patient had a stroke, without permanent sequelae, in the territory of the posterior cerebral artery, probably related to the LCCA-LSA bypass. In addition, stent graft landing proximally in the Dacron prosthesis prevents proximal endoleak. It is important that the diameter of the true lumen in zone 1 does not exceed 45 mm. This ensures a good seal between the aortic graft around the



Fig 3. (A) Patient presenting with an aortic arch aneurysm after surgery for type A dissection. The black arrows indicate 2 residual tears originating from the left subclavian artery and from the descending aorta. After implantation of a double-fenestrated stent graft, (B) control computed tomography scan and (C) volumerendered image reveal complete thrombosis of the false lumen and patency of the supraaortic trunks.

large fenestration and the aortic wall around the BT-LCA island.

In this study, the complete closure of the proximal tear permitted thrombosis of the false lumen of the arch and thoracic aorta, but an infradiaphragmatic aorta will need ongoing careful follow-up. If the endograft fails during follow-up, surgical strategy will depend on the origin of the endoleak as well as the comorbidities of the patient. It should be noted that for higher-risk patients, redo sternotomy and SAT debranching, followed by stent graft coverage of the arch, would still be possible for patients requiring it after the approach presented in this series.

We used the Medtronic stent graft because we have extensive experience with this device. The tip capture facilitates accurate deployment. Other devices could eventually be used for the same approach, namely, the



Fig 4. (A, B) This patient presented with an aortic arch aneurysm after surgery for type A dissection. The black arrows indicate 2 residual tears originating from the distal anastomosis and from the brachiocephalic trunk (BT). (C) A double-fenestrated stent graft was implanted, and additional planned endovascular procedures were performed corresponding to stenting of the BT and the right common carotid artery. A control computed tomography scan reveals complete thrombosis of the false lumen and patency of the supraaortic trunks.

Bolton (Bolton Medical, Sunrise, FL) and the Cook Alpha (Cook Medical, Bloomington, IN). The deployment system of the Gore device prevents reloading of the stent graft into the sheath

The disadvantages are the necessity for the physician to spend time modifying the endograft, lack of industrial quality control after device modification, and lack of a sizeable body of evidence supporting its use. Modification of commercially available devices by physicians may void any guarantee of safety by the manufacturer, and systematic evaluation of such devices is best done within a protocol approved at the institutional or regulatory level, or both. The long-term interactions between the stent graft and the covered stent will need to be monitored closely over time because of the potential for stent collapse or stent breakage and the development of late type III endoleak between the components. Because the durability of these devices is unknown, careful long-term monitoring of patients is required to minimize major complications.

#### Conclusion

The use of physician-modified thoracic stent grafts for the treatment of chronic type A dissection is both feasible and effective for coverage of the arch entry tear while maintaining the patency of the SATs. With experience, complete endovascular repair can be performed using a double-fenestrated stent graft. Durability concerns will need to be assessed in additional studies with longer follow-up.

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