



## The combined use of multilayer flow modulator stent and conventional stent grafts in complex thoracoabdominal aortic aneurysms and Type 3 dissections accompanying aneurysms

*Kompleks torakoabdominal aort anevrizmalarında ve anevrizmaya eşlik eden tip 3 diseksiyonlarda çok katmanlı akım çevirici stent ve konvansiyonel stent greftlerin birlikte kullanımı*

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### ABSTRACT

**Background:** In this study, we present early and mid-term results of the combined use of multilayer flow modulator stent and conventional stent grafts in aortic aneurysms and Type B aortic dissections.

**Methods:** The files and computerized data of 78 patients who underwent endovascular stent graft implantation due to an aortic aneurysm and dissection in our clinic between January 2015 and December 2016 were retrospectively analyzed. Among these patients, six male patients (mean age 69.5 years; range 63 to 77 years) who were treated with multilayer flow modulator stents in combination with conventional stent grafts were included. A successful intervention was defined as the placement of the stents into the aneurysmatic region without any complications. The patients were followed for the development of any clinical events during 12 months.

**Results:** The common symptoms observed in the half of the patients were abdominal pain and back pain. One patient had claudication during walking. In all patients, the interventions were successfully completed and no mortality was observed in any patient. One of the patients developed Type I endoleak during the procedure; however, it was completely corrected using the aortic stent graft extension. Creatinine levels were elevated (2.1 mg/dL) in one patient on the second day of the operation. The patient did not require dialysis and the kidney functions completely returned to normal on the seventh day. No intra- or postoperative complications developed.

**Conclusion:** Multilayer flow modulator stents seem to be effective and safe in the treatment of aortic aneurysms with major side branches. The combined use of stents with different stent-graft devices increase the success rate and reduce the complication rate in complex aortic aneurysms.

**Keywords:** Multilayer flow modulator stent; thoracoabdominal aortic aneurysm; type B aortic dissection.

### ÖZ

**Amaç:** Bu çalışmada aort anevrizmaları ve tip B aort diseksiyonlarda çok katmanlı akım çevirici stent ve konvansiyonel stent greftlerin birlikte kullanımının erken ve orta dönem sonuçları sunuldu.

**Çalışma planı:** Ocak 2014 - Aralık 2016 tarihleri arasında kliniğimizde aort anevrizması ve diseksiyon nedeniyle endovasküler stent greft implantasyonu yapılan 78 hastanın dosyaları ve bilgisayar verileri retrospektif olarak incelendi. Bu hastalardan çok katmanlı akım çevirici stent ve konvansiyonel stent greftlerin birlikte kullanıldığı altı erkek hasta (ort. yaş 69.5 yıl; dağılım 63-77 yıl) çalışmaya alındı. Stentlerin komplikasyon olmaksızın anevrizmalı bölgeye yerleştirilmesi başarılı girişim olarak tanımlandı. Klinik olay gelişimi açısından hastalar 12 ay boyunca takip edildi.

**Bulgular:** Hastaların yarısında görülen ortak semptom karın ve sırt ağrısı idi. Bir hastada ise, yürüyüş sırasında kladikasyon vardı. Hastaların tamamında işlem başarıyla tamamlandı ve hiçbir hastada mortalite gözlenmedi. Bir hastada işlem esnasında tip I kaçak oluştu; ancak oluşan kaçak aortik stent greft uzatma ile tamamen düzeltildi. Bir hastanın işlem sonrası ikinci gün kreatinin düzeyinde (2.1 mg/dL) artış izlendi. Hastada diyaliz ihtiyacı olmadı ve böbrek fonksiyonları yedinci gün tamamen normale döndü. İşlem sırasında ya da sonrasında herhangi bir komplikasyon gelişmedi.

**Sonuç:** Önemli yan dalların çıktığı aort anevrizmalarının tedavisinde çok katmanlı akım çevirici stentler etkili ve güvenli görünmektedir. Kompleks aort anevrizmalarında farklı yapı ve özelliklerdeki stentlerin birlikte kullanılması başarı oranını artırırken, komplikasyon oranını da azaltır.

**Anahtar sözcükler:** Çok katmanlı akım çevirici stent; torakoabdominal aort anevrizması; tip B aort diseksiyonu.

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Aneurysms of the aorta and peripheral arteries are uncommon clinical conditions. When not treated, they can grow in size and cause death due to rupture.<sup>[1]</sup> The treatment of aneurysms has been done by the open surgical approach since the early 1950s.<sup>[2]</sup> With developments in endovascular techniques for the past 20 years, percutaneous treatment methods have become an alternative to the surgery. Its areas of use are on the increase due to its contribution in shortened duration of intensive care and hospital stay, reduced blood loss and transfusion requirement, its application in patients with other system problems, and because it has a lower mortality and morbidity rate.<sup>[2,3]</sup>

Some special endovascular devices have been developed which can be used in the presence of complex aneurysms of major side branches within or near the aneurysmal sac. The best known of these are chimney stent grafts, fenestrated stent grafts,<sup>[3,4]</sup> and multilayer flow modulator (MFM) stents.<sup>[5,6]</sup> Unlike aneurysms, there are insufficient studies on the use of MFM stents in dissections. The use of stent grafts (coated stents) instead of MFM stents in the presence of dissection would be more appropriate.

Multilayer flow modulator stents are self-expanding, three-layered, high-radial strength and elastic, chrome-cobalt alloy containing, and bare structured stents which are not coated with any material. They have been developed for the treatment of aneurysms of the aorta and peripheral arteries. These multilayered stents change the flow dynamics along the vessel, converting the turbulent flow in the aneurysm sac into a laminar flow, and at the same time acting as a passive barrier by significantly reducing the flow (>90%). They provide thrombus formation in the aneurysmal sac and the size of the aneurysm shrinks with time. The laminar flow does not cause any deterioration in the continuity of flow in the lateral branches.<sup>[7]</sup>

In this study, early and midterm results of six patients who underwent conventional endovascular stent-grafts in combination with MFM stents were presented.

## PATIENTS AND METHODS

The patient files and computer data of 78 patients who underwent endovascular stent graft implantation for an aortic aneurysm and dissection in our clinic between January 2014 and December 2016 were retrospectively reviewed, after obtaining approval from the Ethics Committee. The study was carried out in accordance with the principles of the Declaration of Helsinki. The study inclusion criteria were a diameter of the aneurysm of at least 55 mm or an aneurysm accompanied by

dissection, and the MFM stent and other conventional stents being used in the same patient. Six male patients (mean age 69.5 years; range 63 to 77 years) from the 78 patients who met these criteria were included in the study. Placement of the stent-grafts into the aneurysm region without complications was defined as a successful intervention.

The common symptom in half of the patients was abdominal pain and back pain. Claudication on walking was also reported in one patient. The other two patients were asymptomatic. Evaluation of the patients according to etiology demonstrated that there was at least one disease associated with a non-specific degenerative aneurysm and aortic pathology in all of the patients. Two patients had Type B dissection according to Stanford classification, hypertension in four patients, diabetes mellitus in two patients, coronary artery disease and hyperlipidemia in two patients, while there were chronic obstructive pulmonary disease and peripheral atherosclerotic disease in one patient. The basic characteristics of the patient are shown in Table 1.

All patients who were scheduled to undergo endovascular stent graft implantation in our clinic were subjected to contrast-enhanced computed tomography (CT) angiography with 1.5 cm section as a standard procedure. Detailed evaluation of the structure of the aneurysm and the state of the major lateral branches from the aneurysm were made on CT angiography. Aortic diameter, wall calcification, the presence of

**Table 1. Basic characteristics of the patients**

Basic characteristics of patients	n	Median	Range
Age (year)		69.5	63-77
Gender			
Male	6		
Female	0		
Thoracoabdominal aortic aneurysm	6		
Type 3 aortic dissection	2		
Iliac aneurysm	3		
Severe stenosis in the iliac artery	1		
Symptoms			
Back and abdominal pain	3		
Claudication	1		
Asymptomatic	3		
Hypertension	4		
Diabetes mellitus	2		
Coronary artery disease	2		
Hyperlipidemia	2		
Chronic obstructive pulmonary disease	1		
Peripheral artery disease	1		
Malignancy	1		

thrombus in the vascular lumen, the length and angulation of the aneurysm neck where the stent was to be placed were calculated. Examination of the iliac and femoral arteries was also performed with regards to the type and size of the graft according to the state of entry suitability. The healthy vessel placement site proximal and distal to the grafts were measured and graft diameter was determined as more than 20% of the diameter.

Complex thoracoabdominal aortic aneurysm with major lateral branch involvement was reported in all of six patients in this study. Four of the patients were identified as Type 2 according to Crawford calcification, and two as Type 4. Furthermore, two patients had Type B dissection according to Stanford classification, while biiliac artery aneurysm in two patients, left iliac artery aneurysm in one patient, and severe stenosis in the right iliac artery in one patient was reported. All of the aneurysms were fusiform. An endovascular intervention was scheduled because of the high mortality and morbidity rate associated with the surgery to be performed. Conventional stent grafts were preferred in aneurysms with no major lateral branch involvement and in the presence of dissection, while multilayer flow modulator stents were preferred for patients with major lateral branches within or near the aneurysmal sac. Cardiatis MFM stents (Cardiatis, Isnes, Belgium) were used in all patients while Endologix AFX abdominal bifurcated stent graft (Endologix, Inc., Irvine, CA, USA) were used in five

patients. On the other hand, two patients were treated with Endologix AFX proximal-distal extension tube stent graft, one patient with Jotec E-vita thoracic tube stent graft (Jotec AG, Hechingen, Germany) and two patients with Bolton relay thoracic tube stent graft (Bolton Medical Inc. Sunrise, FL, USA) (Table 2).

After informing the patients about the procedures to be performed and obtaining written consents, the surgical operation was carried out after providing the necessary sterilization and operating environment in the angiography unit. All procedures were performed under local anesthesia and sedation via the femoral arteries.

Postoperative follow-ups of the patients were performed at 1, 3, 6 and 12 months. By the third month, endovascular stents were also evaluated by CT angiography.

#### Patients treated with combined procedures:

##### *Patient 1*

*Angiographic diagnosis:* Type 2 aneurysm extending to a diameter of 65 mm at its widest point + biiliac aneurysm + Type B dissection extending from the left subclavian artery to about 2 cm proximal to the celiac artery (CA).

*Procedure performed:* Jotec E-Vita Thoracic, a 38 mm in diameter and 23 cm long thoracic graft-coated stent (1 piece) from the left main femoral artery, was positioned and opened at the level of the left subclavian

**Table 2. Diagnosis of patients, stents and the grafts used**

Patient no	Age/Gender	Diagnosis (*)	Stent-grafts used
1	67/M	Type 2 aortic aneurysm Biiliac aneurysm Type B dissection	Tube stent graft Bifurcated stent graft + aortic extension + left iliac extension Multilayer flow modulator stent
2	69/M	Type 2 aortic aneurysm Severe stenosis in the right common iliac artery	Bifurcated stent graft Tube stent graft Multilayer flow modulator stent
3	67/M	Type 2 aortic aneurysm Type B dissection	Tube stent graft Multilayer flow modulator stent
4	74/M	Type 4 aortic aneurysm Left iliac aneurysm	Bifurcated stent graft Multilayer flow modulator stent
5	63/M	Type 2 aortic aneurysm	Bifurcated stent graft + aortic extension Tube stent graft Multilayer flow modulator stent
6	77/M	Type 4 aortic aneurysm Biiliac aneurysm	Bifurcated stent graft Multilayer flow modulator stent

\* The Crawford classification was used for thoracoabdominal aortic aneurysms, while the Stanford classification was used for dissections.

artery. An Endologix graft-coated bifurcated stent with code number BA25-60/I16-40 (abdominal diameter 25 mm, iliac diameter 16 mm, abdominal length 60 mm, iliac length 40 mm) (1 piece) was positioned. Aortic extension (1 piece) with code number Endologix A25-25/C95-O20 (25 mm in diameter, 95 mm in length and proximal 20 mm bare metal) was placed through the implanted main trunk to the level of the renal arteries. Cardiatis thoracoabdominal MFM (35 mm x 100 mm, 1 piece) stent with code number CTMS35100, including CA, superior mesenteric artery (SMA) and bilateral renal arteries, between the abdominal and thoracic stent grafts (including the two grafts) placement was made. An Endologix graft-coated stent with code number I20-13/C88F SA (total length 88 mm, proximal diameter 20 mm, distal diameter 13 mm) and iliac extension were placed in the left iliac artery (Figure 1a, b).

### Patient 2

**Angiographic diagnosis:** Type 2 aneurysm extending a diameter of 56 mm at its widest point + severe stenosis in the right common iliac artery.

**Procedure performed:** Bolton 36-32 mm, in a tapered structure, a 15 cm long (1 piece) thoracic graft-coated stent was positioned about 4-5 cm distal to the left subclavian artery. Endologix graft-coated bifurcated stent (1 piece) was placed with code number BA28-100/I20-40 (abdominal diameter 28 mm, iliac diameter 20 mm, abdominal length 100 mm,

iliac length 40 mm). A cardiatis thoracoabdominal 35x200 mm stent (1 piece) with code number MFM CTMS35200, which included CA, SMA and bilateral renal arteries was placed between the thoracic and abdominal stent grafts (including these two grafts). The right common iliac bifurcation level was dilated with an 8x40 mm balloon.

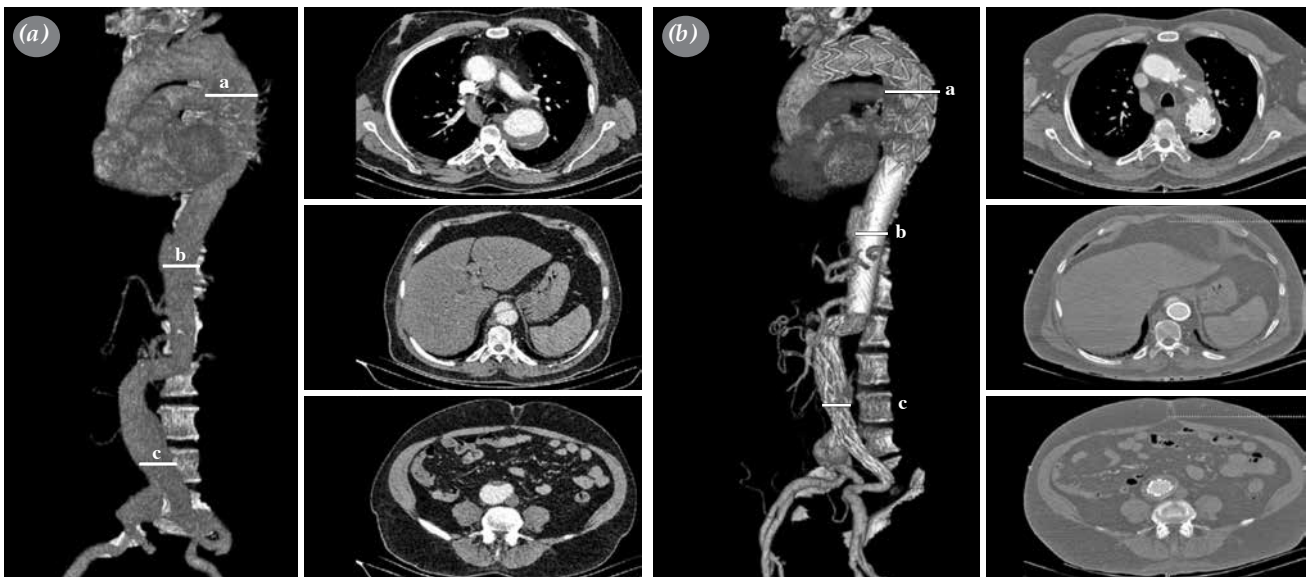
### Patient 3

**Angiographic diagnosis:** Type 2 aneurysm extending a diameter of 55 mm at its widest point + Type B dissection.

**Procedure performed:** A Bolton 15 cm in long thoracic graft-coated tube stent (1 piece) (the widest area of the aneurysm and including the location of the tear in the intima of the dissection) with 32 mm diameter and 100 mm long tube graft structure, was opened by positioning a tube stent approximately 10 cm distal to the left subclavian artery. A cardiatis thoracoabdominal 40x150 mm stent (1 piece) with code number MFM CTMS40150, was placed 5 cm proximal to the bifurcation level including CA, SMA, and bilateral renal arteries to oversize the inserted thoracic tube stent graft 2 cm distal to graft (Figure 2a, b).

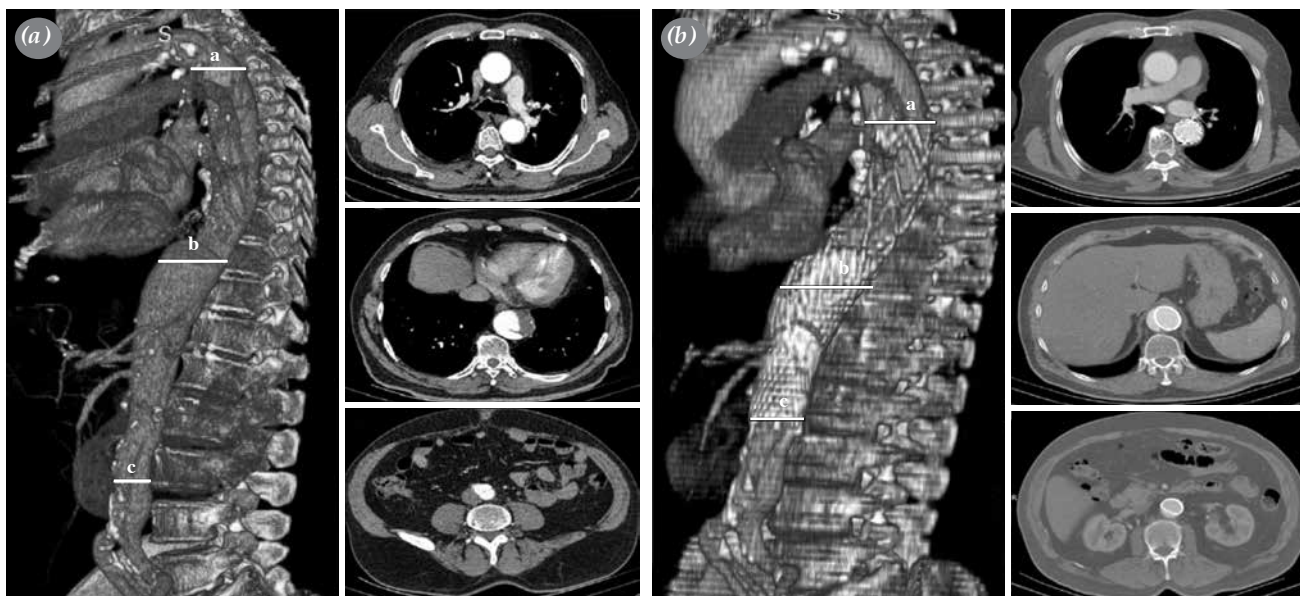
### Patient 4

**Angiographic diagnosis:** Type 4 aneurysm extending a diameter of 78 mm at its widest point + left iliac aneurysm.



**Figure 1.** Computed tomography angiography images of patient number one (a) before surgery, and (b) after surgery. Axial section aortic diameter.

Level a: 65 mm; Level b: 42 mm; Level c: 55 mm.



**Figure 2.** Computed tomography angiography images of patient number three (a) before surgery, and (b) after surgery. Axial section aortic diameter.

Level a: 38 mm; Level b: 55 mm; Level c: 27 mm.

*Procedure performed:* An Endologix graft-coated bifurcated stent (1 piece) was placed with code number BA25-80/I16-55 (abdominal diameter 25 mm, iliac diameter 16 mm, abdominal length 80 mm, iliac length 55 mm).

A Cardiatis thoracoabdominal 35×100 mm stent (1 piece) with code number MFM CTMS35100 was placed from the point of the main trunk extending proximally from CT to the aortic bifurcation level, and including the CA, SMA, and bilateral renal arteries.

#### **Patient 5**

*Angiographic diagnosis:* Type 2 aneurysm extending a diameter of 58 mm at its widest point.

*Procedure performed:* A Bolton Relay tube stent graft (1 piece) 38 mm in diameter and 150 mm in length was positioned at the level of the left subclavian artery. An Endologix graft-coated bifurcated stent (1 piece) was placed with code number BA28-80/I20-40 (abdominal diameter 28 mm iliac diameter 20 mm abdominal length 80 mm iliac length 40 mm). An aortic extension (1 piece) with code number Endologix A34-34/C80-020V (diameter 34 mm, length 80 mm, and a 20 mm bare metal proximal portion) was placed through the main trunk to the level of the renal arteries. Cardiatis thoracoabdominal MFM (40 mm diameter and 150 mm long, 1 piece) stent with code number CTMS40150, was placed between the abdominal and thoracic stent grafts (including CA-SMA-Renal arteries).

#### **Patient 6**

*Angiographic diagnosis:* Type 4 aneurysm extending a diameter of 78 mm at its widest point + a biiliac aneurysm.

*Procedure performed:* An Endologix graft-coated bifurcated stent (1 piece) was placed with code number BA28-80/I20-40 (abdominal diameter 28 mm, iliac diameter 20 mm, abdominal length 80 mm, iliac length 40 mm). A cardiatis thoracoabdominal MFM 35×150 mm stent (1 piece) with code number CTMS35150, was placed from the point of the main trunk extending proximally from CA to the aortic bifurcation level (including CA-SMA-Renal arteries).

## **RESULTS**

Procedures were successfully completed in all six male patients. The mean duration of the procedure was 85 minutes, while the mean hospital stay was 6.5 days. Patients were followed-up for an average of 12 months (range 6-18 months) with regards to clinical event development. No case of mortality was reported during this period (Table 3).

A Type 1 leak occurred during operation in one patient. The bifurcated stent which was placed on the abdominal aorta was the proximal end of the graft. Placement of an aortic stent graft extension was made during the procedure, and the leak was observed to be completely corrected during follow-up.

**Table 3. Procedure-related results (n=6)**

	n	%	Mean±SD	Min-Max
The success of procedure	6	100		
Complication of procedure				
Leakage	1			
Femoral hematoma	0			
Stent migration	0			
Aneurysmal rupture	0			
Type of anesthesia				
Local	6			
General	0			
Duration of procedure (minutes)			85±25	53-122
Duration of hospitalization (days)			6.5±2.1	4-10
The 12-month mortality rate	0	0		

SD: Standard deviation; Min: Minimum; Max: Maximum.

One patient was reported to have an elevated creatinine level (2.1 mg/dL) on the second day after the procedure. There was no need for dialysis, and renal functions were completely normal by the seventh day. No complications were reported in the other patients during or after the procedure. All of the patients were discharged with 100 mg aspirin/day and 75 mg clopidogrel/day therapy.

No complications were reported during follow-ups conducted on postoperative 1<sup>st</sup>, 3<sup>rd</sup>, 6<sup>th</sup> and 12<sup>th</sup> month and on the CT angiography performed in the third month.

## DISCUSSION

Multilayer flow modulator stents are a new technology-type of stents used in the treatment of thoracoabdominal aortic aneurysms. Although there are publications in the literature on the mid- and short-term outcomes of these stents, only a few publications have been reported on their use together with other conventional stent grafts.<sup>[6,7]</sup>

Surgical treatment of thoracoabdominal aortic aneurysms and Type B aortic dissections is a high intervention even in experienced centers, and the mean intraoperative mortality rate is reported at 5% and can rise up to 50% in the presence of a rupture.<sup>[8,9]</sup> Although surgical procedures are the gold standard in the treatment of these diseases, endovascular methods have become the first choice in recent years.<sup>[10-12]</sup> With the development of new technologies, complex aneurysms have become endovascularly treatable, with increasing rates of complications and technical failure.<sup>[13,14]</sup>

Current treatment of thoracoabdominal aortic aneurysms is associated with a reduced mortality and

morbidity rate. The most dangerous complications include rupture of the aneurysm, paraplegia and organ failure which may be associated with blockage of major branches. Flow in the major lateral branches is mechanically sustained when the aneurysm is isolated with Chimney and fenestrated stent grafts developed to provide reduced states of these conditions. However, the application of these stents is very difficult and the clinical results are not satisfactory.<sup>[5,15]</sup> On the other hand, MFM stents, which have recently been developed and introduced into clinical practice, are easier to apply and do not require patient-specific preliminary preparations. The short and mid-term clinical results are also encouraging.<sup>[5,6]</sup>

Three studies using different types of stent grafts for thoracic aortic pathologies demonstrated that the 30 days mortality rate was 3.8 to 12.3%, while the rate of paraparesis/paraplegia was 2.5 to 5.5%, stroke: 2.8 to 8% and leakage: 11 to 12%.<sup>[16-18]</sup> In our study, no mortality was reported and the most important complications including paraplegia, stroke and major lateral branch blockage, did not develop. We attribute this to the fact that we used MFM stents in the region of the aneurysm with major lateral branches; however, our study sample was relatively small and we emphasize that this should be supported by more extensive studies.

The most common reported complication of endovascular treatment is leakage and varies between 10% and 50% in various studies. In the treatment of Type 1 and Type 3 leakages, a new graft should immediately be applied during the procedure. Type 2 leakage should be treated in cases where they the last for six months since they may cause dilation and rupture of the aneurysm. Type 4 leakage is occasionally



caused by new generation stents.<sup>[19,20]</sup> In our study, Type 1 leakage was reported only in one patient and was corrected by the additional tube graft placed during the procedure.

Endovascular treatment has become the preferred method of treatment for complicated Type B aortic dissections due to the high morbidity and mortality risks observed with conventional open surgery. The main objective is to cover the primary tear site with the stent-graft to direct blood flow into the real lumen and to reduce compression of the false lumen to the real lumen in order to provide antegrade flow to the main branch.<sup>[21,22]</sup> Evaluation of the early stage results of endovascular stent graft application in the study published by Dias et al.<sup>[23]</sup> on acute complicated Type B aortic dissection, demonstrated a mortality rate of 16%. Stent-graft-related was reported in two patients within the first 30 days, whereas four patients were reported to have died due to cardiac causes. Paraplegia was also reported in one patient, stroke in four patients while the neurologic complication rate was reported as 22.7% (n=5). Sajid et al.,<sup>[10]</sup> in their study reported that the primary tear site was successfully closed in 97.1% of patients using conventional stent grafts, with a one-month mortality rate of 2.8%. Furthermore, a 2.8% stroke, 2.8% permanent renal failure and 2.8% spinal cord ischemia rates were reported.<sup>[24]</sup>

Stent grafts are widely used in Type B dissections, whereas there is very limited data in the literature on the use of MFM stents. In one of these studies which were published in 2011, Chocron et al.<sup>[25]</sup> successfully applied MFM stent on Type B dissection. The authors suggested that in the treatment of thoracoabdominal aortic aneurysms, MFM stents translate turbulent flow in the aneurysm into laminar flow, cause thrombosis in the aneurysm and that this may also be applicable to chronic aortic dissections. The authors also commented that if in the presence of multiple re-entries during chronic dissections, there would be turbulent blood flow due to the small nature of these re-entries, and that MFM stents could, therefore, be used.

In our study, the aneurysm was accompanied by Type B dissection in two patients. The main site of the tear in the intima of the dissection was distal to the left subclavian artery in both patients. We used tube stent grafts to cover this area and false lumen from the true lumen of the site. We do not prefer multilayer flow modulator stents because of the possibility of providing continuous flow into the false lumen and because there was not enough data on

this subject in the literature. Complete recovery was achieved in both of our patients after the procedure and there were no reported complications.

Another reason for the use of multilayer flow modulator stents in combination with other stent grafts is the fact that the cost of MFM stents is significantly higher in Turkey than the other stent grafts, and the cost of combined use is low. Despite the cost, the MFM stents were preferred because flow in the major branches persisted, from within or near the aneurysm at the exit of the major branches, and especially at the levels of the aneurysms into the CA, SMA, and renal arteries.

Our study has some limitations, which include a relatively few patient groups, such as of six patients, and the 12-month mid-term results devoid of any long-term results. Although we did not have any mortality or serious complications in any of our patients, we suggest that careful patient selection is necessary when using MFM stents.

In conclusion, we think that the combined use of different structural features and stents increases the chances of success and decreases the complication rates in complex aortic aneurysms, depending on the type of stent selected according to characteristics of the aneurysm.

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