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ABSTRACT

INTRODUCTION: endovascular repair of thoracoabdominal and juxtarenal aortic aneurysm has recently become a valuable alternative to open surgery especially in high-risk patients. Progressive improvements in graft materials and low-profile devices allow treatment of complex aneurysms even in adverse anatomical settings. However, all published experiences report risks of occlusion and reinterventions due to visceral stent-graft failures in the long term. The purpose of this systematic review is to analyze the results of currently used balloon expandable bridging stent-grafts and to evaluate the newest developments for FEVAR in juxtarenal endovascular repair.

EVIDENCE ACQUISITION: data were retrieved from retrospective analyses, case series and case reports conducted from 2000 to September 2019.

EVIDENCE SYNTHESIS: the literature analysis provided a list of the most commonly used balloon-expandable bridging stent-grafts for FEVAR. For each stent-graft a brief summary of structural characteristics and performances have been described. No Randomised Controlled Trials (RCTs) or comparative data between the stent-grafts are available for this specific topic.

CONCLUSIONS: so far, several balloon-expandable stent-grafts have been used as bridging stents during FEVAR but the ideal bridging stent-graft is far to be designed. The better understanding of the system FEVAR-native aorta and the strict collaboration and exchange of expertise between physicians and engineers are mandatory in order to increase the performances of these important components and to reduce re-interventions and complications in FEVAR.

Key words: FEVAR, bridging stent, stent patency, covered stent, stent-graft, reinterventions

TEXT

INTRODUCTION

In the last decade, endovascular repair of thoracoabdominal (TAAA) and pararenal aortic aneurysms (pAAA) has become a valuable alternative to open surgery in particular for the subgroup of patients with high-risk cardiovascular and pulmonary comorbidities.[1,2] This result has been achieved through a combination of factors: improvement in graft materials (i.e. more flexible and low-profile stent grafts) and implementation of imaging techniques (i.e. fusion imaging technique) with a common result of increased performances and precision in deployment.[3-5] However, many Authors agree considering the bridging stent components as the Achilles' heel of this technique: in fact, the updated results available in literature show a lower target vessel patency and a higher reintervention rate compared to open repair.[6] Bare metal stents and covered stents have been implanted in fenestrated (FEVAR) and branched endografts (BEVAR). In early experience bare metal stents were employed if a good apposition was expected between the aortic body stent graft fabric and the para-ostial aortic wall. When there was poor apposition or a gap between the endograft and the aortic wall, covered stents were required to prevent para-ostial endoleak.[7] In the modern series, due to reported lesser risks of in-stent restenosis, easier access in case of need for re-intervention and more stable sealing, stent-grafts have been preferred as the sole option at least for standard indications.

So far, several several balloon-expandable stent-grafts have been used as bridging stents during FEVAR: Jostent (Abbott Laboratories, Abbott Park, Illinois, USA), iCAST/Advanta V12 (Getinge, Goteborg, Sweden), Lifestream (BD, Franklin Lakes, New Jersey, USA), BeGraft Peripheral and BeGraft Peripheral Plus (Bentley InnoMed GmbH, Hechingen, Germany), E-ventus BX (CryoLife/Jotec, Hechingen, Germany), Viabahn VBX (W.L. Gore & Associates, Flagstaff, Arizona). (Table I) [8,9]

All these covered stents currently available on the market have not been designed and tested for this specific purpose. In fact, manufactures extended the indications of their current ranges of covered stents, rather than to introduce dedicated products for FEVAR, making their use off-label as part of clinical studies or investigational device exemption protocols. The purpose of this systematic review is to picture the state of art of the bridging stent-grafts and to evaluate the newest developments for FEVAR in pAAA endovascular repair.

EVIDENCE ACQUISITION

The area of interest of the bibliographic search was defined as *fenestrated endovascular procedures- f-evar - bridging stents – stent-graft materials – target vessels*

Data were retrieved from retrospective analyses, case series and case reports conducted from 2000 to September 2019. No Randomised Controlled Trials (RCTs) are available for this specific topic. Articles were searched on PUBMED and MEDLINE. Different search strings were employed for each area of interest, using a combination of relevant terms to obtain optimal sensitivity. Studies not written in English or published before 2000 were excluded. In case of multiple publications of a single study, only one presenting most updated data was included.

The specific technical characteristics of each device have been acquired through their producer instruction for use.

ENDOGRAFT CHARACTERISTICS

Jostent

The JOSTENT stent-graft (Abbott Laboratories, Abbott Park, Illinois, USA) consists of a distensible polytetrafluoro-ethylene (PTFE) membrane sandwiched between 2 316L stainless steel slotted tube, balloon-expandable stents. Scurr JHR et al. demonstrated in a testing rig that Jostent, compared to Advanta V12 and Palmaz stent, is the most resistant to crushing when used in FEVAR.[7] These stent-grafts are no longer implanted in FEVAR procedures.

iCAST/Advanta V12

iCAST/Advanta V12 (Getinge, Goteborg, Sweden) is a 0.035 compatible balloon-expandable stent-graft. Its design consists of a stainless-steel stent encapsulated in expanded-PTFE fabric (film-encapsulated technology). The device is 6F compatible for 5/6x16mm and 5/6x22mm stents while all other sizes need a 7F introducer sheath. Available sizes and compatibility of the device are reported in Table II.

In the early phase of FEVAR experience, this stent-graft was the only one balloon expandable covered stent available on the market, and for this reason it was the most widely used as bridging covered stent and therefore many publications with long-term follow up are now available.

Long-term outcomes of iCAST/Advanta V12 as branches in B/FEVAR were reported by Mastracci T et al. in 2013.[10] Between 2001 and 2010, 650 patients underwent endovascular aortic repair with branched or fenestrated devices for a total of 1679 branches, in most of the cases iCAST/Advanta V12 were chosen as bridging components. A primary end point indicative of branch instability was created using a composite of data, including branch occlusion, device migration effecting a branch, branch-related growth, or the need for any secondary intervention. The 30-day, 1-year, and 5-year freedom from branch intervention was 98%, 94%, and 84% respectively. After 9 years of follow-up, secondary procedures were performed for 0.6% of celiac trunk (CT), 4% of superior mesenteric artery (SMA), 6% of right renal artery (RRA), and 5% of left renal artery (LRA) stents. Bridging stent related death occurred in three patients, 2 as a consequence of SMA thrombosis and one due to an unstented SMA scallop. Multivariate analysis revealed no factors as independent predictors of need for branch reintervention. Unfortunately, from the data reported it was not possible to make a distinction between outcomes of FEVAR and BEVAR procedures and the type of implanted bridging stents.

In 2015 Panuccio et al. assessed the performance of bridging stent-grafts on patients treated from 2010 with F/BEVAR.[11] One hundred and fifty consecutive patients underwent F/BEVAR, and 523 target vessels were involved. These included 104 CT, 140 SMA, 275 renal arteries, and four other arteries. Balloon expandable stent-grafts (BSGs) were mainly used (n = 494; 95%), and in 336 (65%) relining stents were combined. Among BSGs, 468 (89.8%) were iCAST/Advanta V12, 24 (4.6%) were BeGraft, 2 (0.4%) were E-ventus stent-grafts. The technical success rate was 99% (520/523 target vessels). The renal artery as the target vessel showed a statistically significant association with peri-operative vessel related events (9 of 266 [3%]; p= .02). The 30-day mortality was 3%. With the exception of one patient with an unknown cause of death, there was no relationship between 30-day mortality and BSG related events.

The patency and freedom-from-re-intervention rates at 3 years resulted 85% and 91%, respectively. The 4-year freedom from secondary intervention and composite event was 91% and 79%, respectively. In 9 (1.7%) vessels, a crimping or collapse of the BSG was observed, leading to 5 type 1b endoleaks, 2 stenoses and 2 vessel occlusions. In 2 patients a disconnection of the BSG from the fenestration led to a type 3 endoleak. Only one fracture

of BSG was identified 21 months post-procedure leading to a type 3 endoleak. This stent was deployed in a caudally directed cuff with adjunctive lining stent. The use of a branched main body was the only independent risk factor for re-intervention. The use of relining stents seemed not to prevent BSG related complications. Unfortunately, in this manuscript Authors did not report which type of stent graft presented these complications.

Khoury et al. in a recent publication evaluated branch-related outcomes of FEVAR using iCAST/Advanta V12 covered stents alone or associated with bare metal stent extension on 142 patients undergoing FEVAR.[12] A total of 442 target vessels were incorporated (49 scallops and 393 fenestrations). Uncovered stents were used in 38 (9.6%) visceral vessels. Median follow-up time was 11 months. Overall, visceral vessel primary patency was 91% at 12 and 24 months. The overall primary patency rate was 86% in the distal extension group vs 93% when only covered stents were used at 12 and 24 months (P = .8). Similarly, the rate of branch-related reinterventions at 12 months was 9% and 15% for each group, respectively, and 22% vs 32% at 24 months, respectively (P = .5). Overall, freedom from branch instability was 87% at 12 months and 81% at 24 months. Freedom from branch instability in the distal extension group was stable at 82% at 12 and 24 months vs 89% at 12 months and 81% at 24 months when only covered stents were used (P =.08). The 2-year mortality rate was 15% for the bare-metal stent extension group vs 14% for the covered stent only group (P = .4). iCAST/Advanta V12 stentgrafts confirmed their good outcomes at mid-term follow up and the use of distal uncovered stents to prevent kinks was not associated with a decrease in early branch patency.

Lifestream

Lifestream (BD, Franklin Lakes, New Jersey, USA) stentgraft is a 0.035 compatible balloon-expandable covered stent. Its design consists of a stainless-steel stent between two layers of ePTFE fabric. The device is 6 F compatible up to 7x37 mm, 7 F compatible up to 9x58 mm, and 8 F compatible for all the remaining sizes. Stentgraft from 5 to 8 mm can be post-dilated up to 10 mm, while 9 mm and 10 mm up to 12 mm. Available sizes and compatibility of the device are reported in Table III.

The 1-year outcomes of this device in F/B-EVAR were reported by Bertoglio L et al.[13] Eighteen patients received 43 Lifestream BSGs in conjunction with Zenith Cook F/BEVAR device for a total of 32 fenestrations and 11 branches. While stent delivery and deployment

were successful in all cases, at 30 days, 5 patients presented with peri-fenestration endoleaks (type III C) due to inadequate sealing of the stent in 7 (22%) of 32 fenestrations, an unexpectedly high rate. Secondary procedure by means of a bare BSG at the peri-fenestration transition area was successfully performed in 4 cases (1 patient refused the intervention). The excessive tendency to recoil after dilatation with the flaring balloon at peri-fenestration level was a complication not always clearly noted at the completion angiography through the sheath placed inside the stent graft itself. Because of this preliminary experience, the Lifestream covered stent is no longer used by the cited Authors for fenestrations in their practice.

BeGraft Peripheral and BeGraft Peripheral Plus

The BeGraft Peripheral Stent Graft (Bentley InnoMed, GmbH, Hechingen, Germany) is a BSG composed of cobalt-chromium and expanded polytetrafluoroethylene (ePTFE). The first generation of BeGraft Peripheral has been associated with a high risk of stent fracture, especially in branches.[14] Stent-graft fractures were also often associated with graft tears leading to a type IIId endoleak. The BeGraft Peripheral has been redesigned in October 2015 with a double thickness (200-micron) of the ePTFE layer clamped at the stent ends and an integrated stent scaffold with widener stent connectors. Available sizes and compatibility of the device are reported in Table IV. The diameters range between 5 and 10 mm and the lengths between 18 and 58 mm. The system has some unique features including 6F sheath compatibility up to 8 mm diameter in diameter (all lengths), while the 9- and the 10-mm-diameter devices are delivered in 7F sheaths. This characteristic makes it especially useful in Cook preloaded devices where the maximum sheath size is 6F. Available lengths also include 28 mm (5 and 6 mm in diameter) and 27 mm (7-10 mm) which sometimes make positioning easier than with the 22 mm stent-grafts (i.e. to avoid too short intra-aortic or target vessel landing zones). Moreover, the improved radiopacity, increases the accuracy of deployment under fluoroscopy.

In early 2019, Bentley introduced a new generation BeGraft Peripheral Plus, with as unique feature a double layer of graft material alternating with two stents. This configuration increases kink resistance. The diameter ranges between 5 and 10 mm and the length between 18 and 58 mm. The system is 7F compatible up to 8 mm diameter, while the 9- and the 10-mm-diameter devices are delivered in 8F sheaths. Available sizes and compatibility of the

device are reported in Table V. Its use has been reported also in retrograde approach to the Zenith t-Branch thoracoabdominal Endovascular Graft (Cook Meidcal, Bjaeverskov, Denmark) in the acute setting.[15]

The performance of BeGraft Peripheral and BeGraft Peripheral Plus as a bridging stent for FEVAR was evaluated by Torsello et al. in an in-vitro study.[3] No fabric or metal changes, fabric tears or metal fractures, or direct exposure of the stent struts were detected in any of the tested stent-grafts. A significant structural difference was found in the flared zones between the two stents. In fact, the stent architecture of the BeGraft Peripheral specimen showed an increased space between the stent rows and the stretching of the connector struts compared to the BeGraft Peripheral Plus group where a more uniform configuration was maintained even in the area of maximal stress under the condition of flaring. In this experience, the BeGraft Peripheral exhibited different failure modes in terms of pullout testing and separation of the stent scaffold from the graft, while the BeGraft Peripheral Plus device failed exclusively after deformation and consequently slipping. The different behavior of the two devices suggests that the material and engineering ameliorations made for the newer device design increase material stability. Nevertheless, when compared with pullout testing in branched graft, both devices show superior results to other bridging stents.[16]

One-year outcomes of BeGraft Peripheral stent-graft used as bridging stents in FEVAR has been recently reported by Spear et al.[17] Thirty-nine consecutive patients were enrolled. Among the 150 fenestrations, 97 (97/150, 64.7%) were bridged with BeGraft for a total of 101 stents successfully deployed. Delivery systems with preloaded renal catheters were used in 37/39 patients (92.3%). Technical success was achieved in all cases. One BeGraft was kinked in the intra-aortic portion of the bridging stent. The kink was probably secondary to damage of the bridging stent caused by the delivery system of the bifurcated component inserted after bridging stent deployment, as stated by the Authors. The BeGraft was successfully catheterized and an additional covered stent (BeGraft) was deployed to treat the kink. At early follow up, BeGraft patency was 99% (100/101). One renal stent occluded immediately post-operatively due to a dissection of the renal artery distal to the stent-graft, but supplementary stenting was unsuccessful to recover patency of the renal artery. An acute angulation distal to the contralateral artery stent required additional preventive nitinol stenting. Median follow-up was 13 months. One endoleak from the distal end of a BeGraft (type Ib) was reported. BeGraft stent-graft patency during follow-up was 98%. The patient

with a post-operative renal occlusion had a contralateral renal BeGraft stent-graft occlusion on CT scan 2 months after the procedure. All other BeGraft stent-grafts (99/101, 98%) remained patent. These results compare favorably with the patency rates for other stent-graft reported in literature. The renal occlusion rate observed in this study was similar to the one reported in the multicenter study on F/BEVAR published by Martin Gonzalez et al.[18] Author remarked the added value of BeGraft stents when performing FEVAR with delivery systems with preloaded renal catheters, which allows for renal access and stenting through 6F sheaths from the same side as the endograft delivery. Since the device is 6F compatible up to 8 mm in diameter, stenting of the renal arteries can be easily performed with preloaded renal delivery also in case of renal arteries requiring a stent-graft >6 mm. Authors conclude that BeGraft can safely be used in FEVAR with favorable outcomes at one year follow up.

E-ventus BX

E-ventus BX (CryoLife/Jotec, Hechingen, Germany) is a 0.035 guidewire compatible cobalt-chromium BSG with an ePTFE sleeve clamped at the stent ends. The diameter ranges between 5 and 10 mm and the length between 18 and 58 mm. The device is 6F compatible up to 6x58 mm and 7F compatible for all the other sizes. Available sizes and compatibility of the device are reported in Table VI.

The outcomes of the E-ventus BX stent-graft as a bridging stent in FEVAR have been reported by Sayed TS and al. in a recent single center study including all consecutive patients implanted with this device.[19] They performed 32 FEVAR procedures with Cook device for branches in single fenestration in 4 patients, two fenestrations in 8 patients, and three fenestrations in 18 patients, for a total of 74 fenestrations. There was a 2.4% early renal occlusion rate, similar to the multicenter study published by Martin-Gonzalez, et al.[18] Two patients had an early stent occlusion with failure of adjunctive relining procedures. The first case was in patient who developed an anastomotic juxta-renal aneurysm after open repair of the AAA with the single left renal artery. The renal artery was 4.3 mm and was coming out at an angulated angle. The second patient had a small diameter right renal artery (4.2 mm) with a short main stem and was angulated starting from the aorta. Late complications included two further renal stent occlusions due to kink. One needed re-intervention for a declined kidney function which was done successfully as day case under local anesthesia, and the other one was managed conservatively as there was no significant deterioration of

renal function. Secondary intervention for renal artery were needed in 3 patients (3.6%) and only 1 was successful. A total of 7 patients (8.5%) experienced a renal function derangement. One patient (1.2%) needed permanent dialysis and another one (1.2%) temporary dialysis.

Viabahn VBX

The balloon expandable Viabahn VBX endoprosthesis (W.L. Gore & Associates, Flagstaff, Arizona) consists of a stainless-steel balloon-expandable stent and a fluoropolymer graft. The stent is fully encapsulated in the fluoropolymer and the endoprosthesis is coated with the Carmeda BioActive Heparin Surface designed to resist thrombus formation. The stent is constructed with individual stainless-steel rings interconnected with the help of a fluoropolymer graft. The endoprosthesis is preloaded on a delivery system equipped with a semi-compliant balloon. The delivery system is compatible with 0.035 guidewire. Six mm and 7 mm diameter all lengths, and 8 mm diameter: 29 mm, 39 mm and 59 mm lengths are 7 F compatible, while all the other sizes are 8 F compatible. This stent-graft is the only one available in 79 mm length. The sizes include short large-diameter grafts that can be post-dilated up to 16 mm that also makes them suitable for arch branches and fenestrations.

Available sizes and compatibility of the device are reported in Table VII.

The performance of this device as a bridging stent was first evaluated by Torsello and al. in an in vitro study.[20] The VBX showed material resistance to fracture after implantation and flaring in the FEVAR model. The stent-graft also demonstrated markedly higher pullout force resistance when compared to other devices.

Mafeld et al. reported in a recent paper their initial clinical experience with VBX as bridging stent-graft in juxta-renal and thoracoabdominal aneurysm repair demonstrates excellent short-term patency without stent compression/occlusion.[21] A total of 41 VBX were implanted in 13 patients, 7 of those with fenestrated endografts. The Viabahn VBX as a BSG was technically successful in 40 (98%) of 41 of cases. One technical failure occurred due to maldeployment into the aneurysm sac due to the stent being too short. No specific device-related complications occurred in this study. At median follow-up of 223 days (range: 2-462), there was a (40/40) 100% Viabahn VBX patency rate with no significant in-stent stenosis identified. Two intraprocedural complications occurred where the wrong target vessel was selected resulting in non-target BSG deployment. Seven endoleaks were identified intra- or post procedurally in 6 (46%) of 13 cases. This study presents data up to

15 months supporting the safety and feasibility of the Viabahn VBX as a BSG. The target vessel patency of 100% mirrors or exceeds what has been published in the existing literature. Of particular interest is the renal branch patency rate of 100% which is slightly higher when compared with large data analyses which estimate a 6% renal occlusion rate. Authors advocated also how the Viabahn VBX independent stainless-steel ring design allows for greater flexibility while maintaining high radial force due to 316L surgical grade stainless steel, allowing the device to conform to the target artery anatomy. Secondary to this flexibility, placement of a self-expandable stent inside the VBX to the native artery is not needed, unlike with the iCAST/Advanta V12. Despite a theoretically promising design, the Viabahn VBX also has certain pitfalls. The most significant limitation is the flaring property of the 5 to 6 mm diameter stent-graft limited to 8 mm as recommended by the manufacturer, while iCAST/Advanta V12 5 mm and 6 mm, length 32mm, 38 mm and 39 mm, can be flared up to 10 mm (for 16 mm and 22 mm maximum post-dilation is 7 mm also for iCAST/Advanta V12). This can be problematic if the graft fenestration is 8 mm and the target vessel is 6 mm. A further disadvantage is that the Viabahn VBX typically requires larger sheath sizes (7F and 8F) for insertion while other comparable BSGs can pass through 6F and 7F sheaths. Another concern regarding the independent stainless-steel ring design of the VBX is that in the event of abdominal aortic graft migration, the resultant misalignment could cause a shutter effect within the BSG. The reason of this problem is thought to be related to the lack of stent-graft support in between the individual stent rings. Then, the VBX use in FEVAR may lead to the eventuality that the unsupported segment of the stent is deployed exactly within a fenestration which may result in kinking of the stent graft fabric. In a series of 95 Viabahn VBX implantations there was a 5% stenosis or occlusion rate already after 4 months.[22] Yi JA et al. reported a case of near-occlusion of a VBX targeting the CT due to narrowing of this interspace identified 3 months after FEVAR.[23] Computed tomography imaging demonstrated a dramatic change in celiac branch configuration of the 8- 29-mm Viabahn VBX, flared proximally to 10 mm between stent rings at the transition point between the fenestration and the celiac artery orifice. To prevent subsequent occlusion of the stent, the patient was scheduled for relining using 2 iCAST/Advanta V12 7- 22-mm stents, over-dilated to 8 mm and flared proximally to 10 mm. Development of late branch kinking was not predictable from early postoperative imaging. This modality of kinking, is unique to this device and its modular stent structure. Although the VBX offers several potential advantages over other available stents for use as a branch endoprosthesis, the risk

of unpredictable, delayed-onset kinking between stent rings should be strictly monitored when it is used in this application.

To prevent this from occurring, efforts have been made to place the VBX so that a metal supported part of the stent is placed right at the level of fenestration. The relative improved radiopacity of the stent makes this easier to do under fluoroscopy. Gallitto and al. reported their preliminary outcomes of the VBX as bridging stent for F/BEVAR in 15 patients for a total of 60 target vessels, 51 accommodated by fenestrations.[24] A renal artery dissection was successfully managed by a self-expandable bare metal stent. Overall, relining of a bridging stent-graft was required in 2 target visceral vessels revascularized by fenestrations (1 SMA, 1 RA). One intraoperative type III endoleak from renal fenestration was detected and successfully sealed by an adjunctive flaring maneuver. Technical success was achieved in all cases. At 5-day, 1 VBX (2.5%) lost its sealing in a renal artery revascularized by a branch (type II thoracoabdominal aortic aneurysm) and required reintervention and relining with a self-expandable stent-graft. No target visceral vessel occlusion or reintervention occurred. Author concluded that the Gore Viabahn VBX balloon-expandable endoprosthesis can be safely used as bridging stent-graft for fenestrated or branched endografts.

DISCUSSION

Reinterventions after FEVAR range from 7.6% to 26.2% and in most of cases they are performed for stent related occlusion, separation or migration and device integrity issue.[25-26] These complex endovascular repairs are subjected to hemodynamic forces that can result in migration of the endograft and loss of alignment between the fenestrations and the target vessel ostia. Migration of the abdominal component has been observed for Zenith endograft, up to 3 to 4 mm of caudal displacement, which may threaten target vessel patency. This finding lead to the consequence that resistance to crushing (as shown by Jostent and iCAST/Advanta stent-grafts due to their intrinsic design) is not the only desirable attribute of a stent in FEVAR, but it must be flexible enough to accommodate the movements of the graft and the first tract of the target vessel. Despite the extensive use of relining stents, plastic deformation remained the main reason for distal type 1 endoleak and restenosis of the BSGs. To face this issue, in recent years companies have focused they effort to create new stent-graft designs with more flexibility. The increase of stent flexibility comes from lowering the connectivity of the stent design to an open cell format (as BeGraft) or single

stent rings (as for Viabahn VBX), which reduces the number of connections between struts and lowers the metal content overall. However, this type design is less resistant to crushing and it is not ideal in FEVAR since the edge of the fenestration may be able sit between adjacent struts, favoring collapse of the lumen. The use of distal uncovered stents to prevent kinks could be considered in complex and tortuous anatomy without important drawbacks in terms of short and mid-term patency.[12] This result, however must be confirmed in long term follow-up.

Overall, renal arteries have an higher occlusion rate compared to the celiac trunk and superior mesenteric artery, this result could be partially explained with some characteristics of these specific target vessels: a variable point of origin from the aorta, variable direction, and a higher excursion during the respiratory cycles.[10, 27-30] Martin-Gonzalez et al evaluated the outcomes on 427 renal target vessels and concluded that a fenestrated configuration demonstrated a higher patency rate compared to branches.[17] The same result was confirmed by Katsargyris et al. on 347 patients.[31] The bridging stent-graft must be also resistant to "fatigue stress" due to these repetitive low amplitude movements.

Several studies in recent literature reported the outcomes of different stent-grafts used as bridging components for FEVAR (Table VIII), however an effective comparison among the performance of all the stent-grafts available is difficult to be done, especially due to the impossibility to differentiate FEVAR BEVAR bridging stents results in the vast majority of the studies. Many efforts have been recently made to understand the complexity of these junctions in terms of mechanical and dynamical forces in order to create a more resistant and durable connection between the graft main body and the target vessels. Despite being far from designing the perfect stent-graft, many improvements have been made to increase the performances of these components which heavily affect long-term durability of such complex procedures. For this reason, first generation bridging stents (conceived for different purposes and then adapted to F/BEVAR), are now slowly been replaced by a second-generation bridging stent-grafts designed and tested specifically to increase resistance to kinking, fracture and pull-out forces. The characteristics of an ideal bridging stent should have a composite design: relative rigidity within the fenestration, but increasing flexibility

within the target vessels. The better understanding of the system FEVAR-native aorta, the strict collaboration and exchange of expertise between physicians and engineers and the consequent improvement of graft flexibility and resistance could really increase the performances of the bridging stent-graft and reduce re-interventions and complications in FEVAR.

REFERENCES

1. Verhoeven ELG, Katsargyris A, Bekkema F, Oikonomou K, Zeebregts CJAM, Ritter W, et al. Editor's Choice - Ten-year Experience with Endovascular Repair of Thoracoabdominal Aortic Aneurysms: Results from 166 Consecutive Patients. Eur J Vasc Endovasc Surg 2015;49(5):524–31.

2. Kanaoka Y, Ohki T. Midterm Results of Endovascular Treatment for the Patients with Thoracoabdominal Aortic Aneurysms. Ann Vasc Dis 2019;12:163-170.

3. Torsello GF, Herten M, Frank A, Müller M, Jung S, Torsello GB, et al. Performance of BeGraft and BeGraft+ Stent-Grafts as Bridging Devices for Fenestrated Endovascular Aneurysm Repair: An In Vitro Study. J Endovasc Ther. 2019;60:152660281986643–8 [Epub ahead of print].

4. Tenorio ER, Oderich G, Sandri G, Ozbek P, Karkkainen JM, Macedo TA, et al. Impact of onlay fusion and cone beam computed tomography on radiation exposure and technical assessment of fenestrated-branched endovascular aortic repair. J Vasc Surg. 2019;69(4):1045–1058.e3.

5. Hertault A, Sobocinski J, Spear R, Azzaoui R, Delloye M, Fabre D, et al. What should we expect from the hybrid room? J Cardiovasc Surg. 2017;58:264-9

6. Fiorucci B, Speziale F, Kölbel T, Tsilimparis N, Sirignano P, Capoccia L, et al. Short- and Midterm Outcomes of Open Repair and Fenestrated Endografting of Pararenal Aortic Aneurysms in a Concurrent Propensity-Adjusted Comparison. J Endovasc Ther. 2018;26(1):105–12.

7. Scurr JRH, How TV, McWilliams RG, Lane S, Gilling-Smith GL. Fenetrated stent-graft repair: which stent should be used to secure target vessel fenestration? J Endovasc Ther 2008; 15:344-348

8. Kalder J, Keschenau P, Tamm M, Jalaie H, Jacobs MJ, Greiner A. Anatomic changes of target vessels after fenestrated and branched aortic aneurysm repair. J Cardiovasc Surg (Torino)2014;55:115-21

9. Mastracci TM, Carrel T, Constantinou J, Dias N, Martin-Gonzalez T, Katsargyris A, et al. Editor's choice – effect of branch stent choice on branch-related outcomes in complex aortic repair. Eur J Vasc Endovasc Surg 2016;51:536-542

10. Mastracci TM, Greenberg RK, Eagleton MJ, Hernandez AV. Durability of branches in branched and fenestrated endografts. J Vasc Surg. 2013;57(4):926–33

11. Panuccio G, Bisdas T, Berekoven B, Torsello G, Austermann M. Performance of Bridging Stent Grafts in Fenestrated and Branched Aortic Endografting. Eur J Vasc Endovasc Surg. 2015;50(1):60–70

12. Khoury MK, Timaran DE, Knowles M, Timaran CH. Visceral stent patency after fenestrated endovascular aneurysm repair using bare metal stent extensions versus covered stents only. J Vasc Surg 2019;[Epub ahead of print]

13. Bertoglio L, Loschi D, Cambiaghi T, Mascia D, Kahlberg A, Melissano G, et al. Preliminary outcomes of the Lifestream balloon-expandable covered stent in fenestrated and branched thoracoabdominal endovascular repair. J Endovasc Ther 2018;25(2):230-236

14. Lindstrom D, Mani K, Lundberg G, Wanhainen A. Bridging stent grafts in fenestrated and branched endovascular aortic repair: current practice and possible complications. J Cardiovasc Surg 2019(4):476-484

15. Watkins AC, Avramenko A, Soler R, Fabre D, Haulon S. A novel all-retrograde approach for t-Branch implantation in ruptured thoracoabdominal aneurysm. J Vasc Surg Cases Innov Tech 2018;4:301-4

16. Jones SM, Poole RJ, How TV, Williams RL, McWilliams RG, Brennan JA, et al. Computational fluid dynamic analysis of the effect of morphologic features on distraction forces in fenestrated stent grafts. J Vasc Surg 2014. 60:1648-1656

17. Spear R, Sobocinski J, Hertault A, Delloye M, Azzauiu R, Fabre D, et al. One Year Outcomes of 101 BeGraft Stent Grafts used as Bridging Stents in Fenestrated Endovascular Repairs. Eur J Vasc Endovasc Surg. 2018;55:504-510

18. Martin-Gonzalez T, Mastracci T, Carrell T, Constantinou J, Dias N, Katsargyris A, et al. Mid-term Outcomes of Renal Branches Versus Renal Fenestrations for Thoraco-abdominal Aneurysm Repair. Eur J Vasc Endovasc Surg. Elsevier 2016;52(2):141–8.

19. Sayed T, Ahmed I, Rodway A, El Sakka K, Yusuf SW. Jotec E-ventus BX stent graft deployment in FEVAR and iliac branch device: single centre experience. Ann VAsc Dis. 2019;12(2):171-175

20. Torsello GF, Herten M, Muller MM, Frank A, Torsello GB, Austermann M. In vitro evaluation of the Gore Viabahn balloon-expandable stent-graft for fenestrated endovascular aortic repair. J Endovasc Ther. 2019;26(3):361-368

21. Mafeld S, Annamalai G, Lindsay TF, Zhong I, Taulli E, Mironov O, et al. Initial experience with Viabahn VBX as the bridging stent graft for branched and fenestrated endovascular Aneurysm repair. Vasc Endovascular Surg. 2019;53(5):395-400

22. Rao A, Beckerman W, Tadros RO, McKinsey J. Use of a novel flexible covered stent (GORE VIABAHN VBX) in fenestrated and parallel grafts during endovascular treatment of complex perivisceral aortic aneurysms: acute results. Abstracts J Vasc Surg 2018;67(6):e175-176

23. Yi JA, Kuwayama DP. Fenestrated aortic endograft branching with Gore VBX poses failure risk from delayed-onset branch kinking. J Vasc Surg Cases and Innovative techniques. 2019;5:18-21

24. Gallitto E, Faggioli G, Pini R, Mascoli C, Sonetto A, Abualhin M, et al. First/Preliminary Experience of Gore Viabahn Balloon-Expandable Endoprosthesis as Bridging Stent in Fenestrated and Branched Endovascular Aortic Repair. Ann Vasc Surg 2019;S0890-5096(19)30505-9 [epub ahead of print]

25. Budtz-Lilly J, Wanhainen A, Eriksson J, Mani K. Adapting to a total endovascular approach for complex aortic aneurysm repair: Outcomes after fenestrated and branched endovascular aortic repair. J Vasc Surg. 2017;66(5):1349–56.

26. Troisi N, Donas KP, Austermann M, Tessarek J, Umsheid T, Torsello G. Secondary procedures after aortic aneurysm repair with fenestrated and branched endografts. J Endovasc Ther 2011;18:146-53

27. Ou J, Chan Y-C, Chan CY-T, Cheng SWK. Geometric Alteration of Renal Arteries After Fenestrated Grafting and the Impact on Renal Function. Ann Vasc Surg. 2017;41:89–95.

28. Ullery B, Suh G-Y, Lee J T, Liu B, Stineman R, Dalman RL, et al. Geometry and respiratory-induced deformation of abdominal branch vessels and stents after complex endovascular aneurysm repair. J Vasc Surg 2015;61(4):875–85.

29. Gallitto E, Faggioli G, Pini R, Mascoli C, Ancetti S, Abualhin M, et al. Renal Artery Orientation Influences the Renal Outcome in Endovascular Thoraco-abdominal Aortic Aneurysm Repair. Eur J Vasc Endovasc Surg. 2018;56(3):382–90.

30. Reilly LM, Rapp JH, Grenon SM, Hiramoto JS, Sobel J, Chuter TA. Efficacy and durability of endovascular thoracoabdominal aortic aneurysm repair using the caudally directed cuff technique. J Vasc Surg 2012;56:53e63

31. Katsargyris A, Marques de Marino P, Verhoeven EL. Graft design and selection of fenestrations vs. branches for renal and mesenteric incorporation in endovascular treatment of pararenal and thoracoabdominal aortic aneurysms. J Cardiovasc Surg. 2019;60:35-40

NOTES

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TABLES

Table I. Characteristics of commercially available 0.035-inch-compatible balloon-expandable covered stents

Name	Stent	Fabric	Sheath compatibility (F)	Diameters (mm)	Lengths (mm)	Delivery system lengths (mm)
iCAST/Advanta V12 [a]	Stainless steel	Encapsuled in 1 layer of ePTFE	6,7	5-10	16-59	80/120
LifeStream [b]	Stainless steel	2 layers of ePTFE	6,7,8	5-12	16-58	80/135
BeGraft Peripheral [c]	Cobalt chromium	1 layer of 200-micron ePTFE	6,7	5-10	18-58	75/120
BeGraft Peripheral Plus [d]	2 Cobalt chromium stents	2 layers of 200-micron ePTFE	7,8	5-10	18-58	75/120
E-ventus BX [e]	Cobalt chromium	1 layer of ePTFE	6,7	5-10	18-57	120
Viabahn VBX [f]	Stainless steel	1 layer PTFE coated with the CBAHS*	7,8	5-16	15-79	80/135

Table notes:
[a] iCAST/Advanta V12 (Getinge, Goteborg, Sweden)
[b] Lifestream (BD, Franklin Lakes, New Jersey, USA)
[c] BeGraft Peripheral Stent Graft (Bentley InnoMed, GmbH, Hechingen, Germany)
[d] BeGraft Peripheral Plus Stent Graft (Bentley InnoMed, GmbH, Hechingen, Germany)
[e] E-ventus BX (CryoLife/Jotec, Hechingen, Germany)
[f] Viabahn VBX (W.L. Gore & Associates, Flagstaff, Arizona)

* Carmeda BioActive Heparin Surface

Table II. Available size and characteristics of ***iCAST/Advanta V12***. °Technical limit of the device. Expansion beyond the nominal diameter is outside of indication.

Diameter (mm)	°Max post-dilated stent diameter (mm)	Length (mm)	Required introducer sheath (F)	Working catheter length (cm)	Guidewire (inch)
5	7.3	16	6	80/120	0.035
5	7.3	22	6	80/120	0.035
5	9.3	32	7	80/120	0.035
5	9.8	38	7	80/120	0.035
5	9.8	59	7	80/120	0.035
6	7.3	16	6	80/120	0.035
6	7.3	22	6	80/120	0.035
6	9.3	32	7	80/120	0.035
6	10	38	7	80/120	0.035
6	10	59	7	80/120	0.035
7	7.3	16	7	80/120	0.035
7	7.3	22	7	80/120	0.035
7	9.3	32	7	80/120	0.035
7	10.1	38	7	80/120	0.035
7	10.1	59	7	80/120	0.035
8	9.3	32	7	80/120	0.035
8	10.2	38	7	80/120	0.035
8	10.2	59	7	80/120	0.035
9	9.3	32	7	80/120	0.035
9	10.4	38	7	80/120	0.035
9	10.4	59	7	80/120	0.035
10	10.6	38	7	80/120	0.035
10	10.6	59	7	80/120	0.035

Table III. Available size and characteristics of ***Lifestream.*** °Technical limit of the device. Expansion beyond the nominal diameter is outside of indication.

Diameter (mm)	°Max post-dilated stent diameter (mm)	Length (mm)	Required introducer sheath (F)	Working catheter length (cm)	Guidewire (inch)
5	10	16	6	80/135	0.035
5	10	26	6	80/135	0.035
5	10	37	6	80/135	0.035
6	10	16	6	80/135	0.035
6	10	26	6	80/135	0.035
6	10	37	6	80/135	0.035
6	10	58	7	80/135	0.035
7	10	16	6	80/135	0.035
7	10	26	6	80/135	0.035
7	10	37	6	80/135	0.035
7	10	58	6	80/135	0.035
8	10	16	7	80/135	0.035
8	10	26	7	80/135	0.035
8	10	37	7	80/135	0.035
8	10	58	7	80/135	0.035
9	12	38	7	80/135	0.035
9	12	58	7	80/135	0.035
10	12	38	8	80/135	0.035
10	12	58	8	80/135	0.035

Table IV. Available size and characteristics of ***BeGraft Peripheral***. °Technical limit of the device. Expansion beyond the nominal diameter is outside of indication.

Diameter (mm)	°Max post-dilated stent diameter (mm)	Length (mm)	Required introducer sheath (F)	Working catheter length (cm)	Guidewire (inch)
5	8.5	18	6	75/120	0.035
5	8.5	22	6	75/120	0.035
5	8.5	28	6	75/120	0.035
5	8.5	38	6	75/120	0.035
5	8.5	58	6	75/120	0.035

6	8.5	18	6	75/120	0.035
6	8.5	22	6	75/120	0.035
6	8.5	28	6	75/120	0.035
6	8.5	38	6	75/120	0.035
6	8.5	58	6	75/120	0.035
7	10.5	18	7	75/120	0.035
7	10.5	23	7	75/120	0.035
7	10.5	27	7	75/120	0.035
7	10.5	37	7	75/120	0.035
7	10.5	57	7	75/120	0.035
8	10.5	27	7	75/120	0.035
8	10.5	37	7	75/120	0.035
8	10.5	57	7	75/120	0.035
9	11.8	27	7	75/120	0.035
9	11.8	37	7	75/120	0.035
9	11.8	57	7	75/120	0.035
10	11.8	27	7	75/120	0.035
10	11.8	37	7	75/120	0.035
10	11.8	57	7	75/120	0.035

Table V. Available size and characteristics of ***BeGraft Peripheral Plus***. °Technical limit of the device. Expansion beyond the nominal diameter is outside of indication.

Diameter (mm)	°Max post-dilated stent diameter (mm)	Length (mm)	Required introducer sheath (F)	Working catheter length (cm)	Guidewire (inch)
5	8.5	28	7	75/120	0.035
5	8.5	38	7	75/120	0.035
5	8.5	58	7	75/120	0.035
6	8.5	28	7	75/120	0.035
6	8.5	38	7	75/120	0.035
6	8.5	58	7	75/120	0.035
7	10.5	27	7	75/120	0.035
7	10.5	37	7	75/120	0.035
7	10.5	57	7	75/120	0.035
8	10.5	27	7	75/120	0.035
8	10.5	37	7	75/120	0.035
8	10.5	57	7	75/120	0.035

9	11.8	27	8	75/120	0.035
9	11.8	37	8	75/120	0.035
9	11.8	57	8	75/120	0.035
10	11.8	27	8	75/120	0.035
10	11.8	37	8	75/120	0.035
10	11.8	57	8	75/120	0.035

Table VI. Available size and characteristics of ***E-ventus***. °Technical limit of the device. Expansion beyond the nominal diameter is outside of indication.

Diameter (mm)	°Max post-dilated stent diameter (mm)	Length (mm)	Required introducer sheath (F)	Working catheter length (cm)	Guidewire (inch)
5	8.5	18	6	120	0.035
5	8.5	22	6	120	0.035
5	8.5	28	6	120	0.035
5	8.5	38	6	120	0.035
5	8.5	58	6	120	0.035
6	8.5	18	6	120	0.035
6	8.5	22	6	120	0.035
6	8.5	28	6	120	0.035
6	8.5	38	6	120	0.035
6	8.5	58	6	120	0.035
7	10.5	18	7	120	0.035
7	10.5	23	7	120	0.035
7	10.5	27	7	120	0.035
7	10.5	37	7	120	0.035
7	10.5	57	7	120	0.035
8	10.5	27	7	120	0.035
8	10.5	37	7	120	0.035
8	10.5	57	7	120	0.035
9	11.8	27	7	120	0.035
9	11.8	37	7	120	0.035
9	11.8	57	7	120	0.035
10	11.8	27	7	120	0.035
10	11.8	37	7	120	0.035
10	11.8	57	7	120	0.035

Table VII. Available size and characteristics of ***Viabahn VBX***. *Technical limit of the device. Expansion beyond 13 mm is outside of the indication

Diameter (mm)	Max post-dilated stent diameter (mm)	Length (mm)	Required introducer sheath (F)	Working catheter length (cm)	Guidewire (inch)
5	8	15	7	80/135	0.035
5	8	19	7	80/135	0.035
5	8	29	7	80/135	0.035
5	8	39	7	80/135	0.035
5	8	59	7	80/135	0.035
5	8	79	7	80/135	0.035
6	8	15	7	80/135	0.035
6	8	19	7	80/135	0.035
6	8	29	7	80/135	0.035
6	8	39	7	80/135	0.035
6	8	59	7	80/135	0.035
6	8	79	7	80/135	0.035
7	11	15	7	80/135	0.035
7	11	19	7	80/135	0.035
7	11	29	7	80/135	0.035
7	11	39	7	80/135	0.035
7	11	59	7	80/135	0.035
7	11	79	7	80/135	0.035
8	11	29	7	80/135	0.035
8	11	39	7	80/135	0.035
8	11	59	7	80/135	0.035
8	11	79	7	80/135	0.035
9	13	29	8	80/135	0.035
9	13	39	8	80/135	0.035
9	13	59	8	80/135	0.035
9	13	79	8	80/135	0.035
10	13	29	8	80/135	0.035
10	13	39	8	80/135	0.035
10	13	59	8	80/135	0.035
10	13	79	8	80/135	0.035
11	16*	29	8	80/135	0.035
11	16*	39	8	80/135	0.035
11	16*	59	8	80/135	0.035
11	16*	79	8	80/135	0.035

Table VIII. summary of data retrieved from the literature analysis

Author	Year	Type of study	N° of patients	N target vessels	Stent used	Type of procedure	Tech success	Mean follow-up (months)	30 day patency	1 year patency	Long term patency	Branch related reintervention rate
Mastracci [10]	2013	Retrospective	650	1679	-	F/BEVAR	-	36	-	98.3%		15.6% (9 yrs)
Panuccio [11]	2015	Prospective	150	523	95% balloon expandable, 5% self expandable	F/BEVAR	99%	15	99.2%	97.5%	85% (36 months)	9% (4 yrs)
Khoury [12]	2019	Retrospective	142	393	iCAST/Advanta	FEVAR	99%	11	-	91%	91% (24 months)	11% (2 yrs)
Bertoglio [13]	2018	Retrospective	18	43	Lifestream	F/BEVAR	83%	14	97.6%	88.3%	-	-
Spear [17]	2019	Prospective	39	101	BeGraft Peripheral	FEVAR	100%	13	99%	98%	-	5% (1 yr)
Martin-Gonzalez [18]	2016	Retrospective	449	856	-	FEVAR	99%	24	99%	-	97.1 (24 months)	5% (2 yrs)
Sayed [19]	2019	Retrospective	32	74	Jotec E-ventus BX	F/BEVAR	97.6%	18	97.6%	97.6%	95.1 (36 months)	-
Mafeld [21]	2019	Prospective	13	41	Gore VBX	F/BEVAR	98%	7	100	-	-	-
Rao [22]	2018	Prospective	102	76	Gore VBX	F/BEVAR	98.7%	3.6	93.4	-	-	-

Gallitto [24]	2019	Retrospective	15	40	Gore VBX	F/BEVAR	97,5%	6	100	-	-	-
Katsargyris[31]	2019	Prospective	347	1263	-	F/BEVAR	-	-	-	-	98.2% for FEVAR 92.2% for BEVAR (36 months)	-