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# One Year Outcomes of 101 BeGraft Stent Grafts used as Bridging Stents in Fenestrated Endovascular Repairs

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**WHAT THIS PAPER ADDS**

This study evaluates the outcomes of BeGraft stents used as bridging stents during fenestrated endovascular aortic aneurysms repair. To date, none of the balloon expandable covered stents which are currently commercially available in Europe have been specifically designed and evaluated for that purpose.

**Objectives:** To evaluate the outcomes of the second generation BeGraft balloon expandable covered stent Graft System (Bentley InnoMed, Hechingen, Germany) implanted as bridging stent grafts during fenestrated endovascular aortic repair (FEVAR) of complex aneurysms.

**Design:** This was a single centre prospective study including all consecutive patients treated by FEVAR performed with second generation BeGraft stent grafts as bridging stents.

**Methods:** Demographics of patients, diameter and length of the bridging stent grafts, technical success, re-interventions, occlusions, post-operative events, and imaging (Cone Beam CT and/or CT scan, and contrast enhanced ultrasound) were prospectively collected in an electronic database. Duplex ultrasound was performed before discharge and at 6 month follow-up. At 1 year, patients were evaluated clinically and by imaging (CT and ultrasound).

**Results:** Between November 2015 and September 2016, 39 consecutive patients (one woman) were treated with custom made fenestrated endografts (2–5 fenestrations) for complex aneurysms or type 1 endoleak after EVAR, using a variety of bridging stents including the BeGraft. All 101 BeGraft stent grafts were successfully delivered and deployed. There was no in hospital mortality. Early fenestration patency rate was 99% (96/97); the sole target vessel post-operative occlusion was secondary to a dissection of the renal artery distal to the stent. Complementary stenting was unsuccessful in recovering renal artery patency; bilateral renal stent occlusion was observed in the same patient on a CT scan performed 2 months after the procedure. He required post-operative dialysis. No additional renal impairment was observed. During follow-up (median 13 months [11–15]), all fenestrations stented with BeGraft stent grafts remained patent (95/97, 98%). One type 1b endoleak was detected and treated (2.6%).

**Conclusions:** BeGraft stent grafts used as bridging stents during FEVAR are associated with favourable outcomes at 1 year follow-up. Long-term follow-up is required to confirm these promising results.



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## INTRODUCTION

Fenestrated endovascular aortic repair (FEVAR) is a validated option for treating complex aortic aneurysms.[1,2] This challenging endovascular procedure may be associated with early or late complications such as target vessel occlusion.[3] Target vessels patency rates at 1 year follow-up of 92%–98% have been reported in the literature.[4–7] Re-interventions after FEVAR are frequent, ranging from 7.6% to 26.2%; they are often performed to treat bridging stent related type 3 endoleaks.[8–11]

Bridging stents are associated with specific complications such as fracture, occlusion and type 3 endoleaks during follow-up. Choosing the adequate bridging stent is therefore of paramount importance to ensure the technical success and durability of FEVAR. Clinical studies have evaluated covered and uncovered stents[4,12] implanted during FEVAR; however, there is currently a general consensus in favour of the liberal use of covered stents, which are associated with a 2.5% occlusion rate compared with the

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occlusion rate of 10% for uncovered stents described by Mohabbat et al.[13] None of the balloon expandable covered stents which are currently commercially available have been specifically designed and tested as bridging stents for FEVAR. To date, the following covered stents have been used as bridging stents during FEVAR: JOSTENT (Abbott Laboratories, Abbott Park, Illinois, USA), Advanta V12 (Atrium Medical, Hudson, New Hampshire, USA), Lifestream (Bard, Tempe, Arizona, USA), and BeGraft (BentleyInnoMed, Hechingen, Germany).[14,15] All these stents are manufactured with expanded polytetrafluoroethylene (ePTFE) fabric and a stainless steel stent, except the BeGraft, which is based on a cobalt chromium stent. Compared with the first generation of the BeGraft, the second generation was modified (among other changes) by increasing the thickness of the ePTFE covering (from 100 μm to 200 μm) and the width of the stent connectors (by approx. 20%). The bench test results provided by the manufacturer revealed significantly improved sealing properties and radial force; it was considered that these new features made this new platform suitable for use as a bridging stent during FEVAR. This is an off label use of this stent. This second generation has the same profile characteristics as the first (6Fr compatibility up to 8 mm in diameter) and is therefore still compatible with preloaded delivery systems to the renal arteries. In addition, it is the only available stent manufactured in large diameters (8–10 mm) and short lengths (27 or 28 mm). For these reasons, this second generation stent graft was used routinely during FEVAR when renal arteries required bridging stents $>$ 6 mm in diameter or $>$ 22 mm in length, or when visceral arteries required bridging stents $>$ 7 mm in diameter and $<$ 38 mm in length.

In this prospective study, the outcomes of the first consecutive 101 BeGraft stent grafts used as bridging stents during FEVAR for complex aneurysm repairs were evaluated.

## MATERIAL AND METHODS

### Study population

During the study period, all consecutive patients treated at the study centre with second generation BeGraft stent grafts during fenestrated endograft repair (FEVAR) for complex aneurysm were prospectively included. Indication for repair was maximum aortic diameter $>$ 55 mm or rapid growth ($>$10 mm in 12 months). BeGraft stent grafts were used as bridging stents to connect fenestrations to target vessels (renal and visceral arteries) when renal arteries required bridging stents $>$ 6 mm in diameter or $>$ 22 mm in length, or when visceral arteries required bridging stents $>$ 7 mm in diameter and $<$ 38 mm in length (inclusion criteria). Standard bridging stents were used in target vessels with anatomies outside the inclusion criteria. These second generation BeGraft stent grafts became available at the study centre in October 2015, which is the starting date for enrolment in the study. The goal was to evaluate the 1 year outcomes of the first 100 BeGraft stent grafts implanted. Patients undergoing FEVAR without BeGraft stent grafts during the study period were not included.

Pre-operative demographics collected included age, gender, body mass index (BMI), American Society of Anaesthesiologists (ASA) score, cardiovascular risk factors, estimated glomerular rate filtration (GFR) by Modification of Diet in Renal Disease (MDRD), prior aortic surgery differentiating thoracic and abdominal repair and endovascular and open repair. Pre-operative anatomical characteristics included diameter and extent of the aneurysm (Crawford modified classification for thoraco-abdominal aneurysms[16]). FEVAR was also performed for type 1 endoleak repair following EVAR. Diameter and length of BeGraft stent grafts implanted were recorded. Intra-operative data such as procedure length, fluoroscopy time, dose area product (DAP, Gray-centimetres squared [Gycm$^2$]), volume of contrast agent injected, and all stent related events and additional procedures were prospectively collected.

During follow-up, adverse events were collected according to reporting standards.[17] Renal insufficiency was defined as a GFR estimated with MDRD $\leq$ 60 mL/min and renal impairment as a post-operative decrease in GFR of more than 20% compared with the pre-operative GFR. Computed tomography (CT) scans were performed during the first post-operative month and at 1 year. Doppler ultrasound was performed before discharge (mostly contrast enhanced exams), at 6 months, and at 1 year.

Follow-up was defined as early during the first 30 post-operative days, and late thereafter.

The study was approved by the research ethics committee and signed informed consent was obtained from all patients.

### Fenestrated endografts

All fenestrated endografts were custom made and manufactured by Cook Medical (Bloomington, IN, USA). They were delivered through 20 to 22Fr delivery sheaths. Most renal fenestrations were preloaded with a catheter. Technical details of the deployment sequence have been described previously.[18] The procedures were always performed under fusion imaging guidance (Innova Vision, GE Healthcare, Chalfont St Giles, UK). At the end of the procedure, a completion cone beam CT (CBCT) was always performed (with contrast when eGFR was $>$ 60 mL/min). Procedures were all performed under general anaesthesia in a hybrid room (Discovery IGS 730, GE Healthcare, Chalfont, UK). Patients with type 1, 2, or 3 TAAA underwent a standardised protocol for spinal cord ischaemia prevention.[19] Single antiplatelet therapy was started before the procedure, was not discontinued at the time of the procedure, and continued thereafter. During the procedure, to obtain a target ACT $>$ 250 s, 100 units/kg of heparin were injected intravenously.

### Pre-operative planning of bridging stents

All target arteries were analysed on the pre-operative CT scan using a 3D workstation. A centreline was generated for each target artery and corrected manually when required. The curved planar reconstruction allowed analysis of the

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