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Foreword

Welcome to the second edition of the CASE REPORT booklet.

Together with some of the leading physicians in the field, we have selected a number of case studies that illustrate the use of Bentley stents in various everyday clinical settings, involving a range of lesion types.

These Bentley stents were the add-on intervention of choice, providing patients with optimal outcomes both clinically and in terms of quality of life.

Since its foundation in 2009, Bentley has shown marked and sustained growth. The portfolio currently comprises six products, which are used across a broad spectrum of vascular disease, and all of which are manufactured in Hechingen, Germany. Over the relatively short period of its existence, this family owned company has provided covered stents for the treatment of thousands of patients in over 80 countries worldwide. A key strength of Bentley lies in the commitment shown by its employees who strive to develop and manufacture products of superior quality, inspiring confidence that your chosen stent is reliable and will perform to the highest expectations of you and your patients. Against this history of successful product development and reliable customer service, Bentley is now working on the next generation of stents to establish another round of innovative benchmarks in the treatment of vascular diseases around the world.

When you would like to submit one of your cases for this CASE REPORT booklet or when you want to have more information on our product portfolio, please send us an email to m.lux@bentley.global.

With best regards,

Marius Lux
Product Manager

*Products used only within indication!
High-grade renal stenosis after open aortic surgery

Patient history
In February 2020, a 61 year old male patient presented himself in the emergency department of a regional hospital with right sided flank pain. He was an active smoker, but healthy with no regular medication.

Initial situation
A CT scan showed a covered ruptured infrarenal aortic aneurysm with maximum diameter of 11 cm. All the main visceral arteries, including the left renal artery (LRA), were fully contrasted at a preoperative CT scan. He was immediately transmitted to the vascular center of the university hospital in Basel.

Endovascular treatment was no option, because of the unfavorable anatomy with distinct kinking of the abdominal aorta. The open surgery was performed with infrarenal clamping of the abdominal aorta and the implantation of a bifurcated graft.

After the open surgery, a postoperative duplex ultrasound showed lowered perfusion of the left renal kidney. The creatinine blood level raised to pathologic values of 192 mol/l (preoperative 69 mol/l; normal range 49-97 mol/l). A CT scan showed a nearly occluded LRA with thromboembolic contrast sparing in the proximal vessel and signs of malperfusion of the parenchyma. The left kidney showed lowered contrasted areas.

Procedural course
The patient agreed to an interventional procedure to maintain the left remaining kidney parenchyma. He was fully awake during the intervention. The approach was executed over the right groin, establishing a 6Fr cobra-angled 45 cm sheath under ultrasound guidance in local anesthesia. An angled sheath was advanced into the LRA. The initial angiogram confirmed the CT findings with thromboembolic material in the proximal LRA. Aspiration over the sheath did not improve the angiographic result. In the next step, a 7 mm SpiderFX filter wire was placed distal to the thrombus over a 4 Fr catheter and pulled back in open configuration through the stenosis, like a fishnet. Some of the thromboembolic material could be aspirated, but the angiographic result was still unsatisfying.

To protect the distal renal artery from embolic material, the residual stenosis was stented with a 5x18 mm balloon expandable stent (BeSmooth peripheral, Bentley InnoMed GmbH)
over an Amplatz extra stiff wire. The stent was adapted with a 6x20 mm
PTA balloon catheter. The final angiography showed a fully patent LRA
and a good perfusion of the left kidney parenchyma. The patient recovered very well from both, surgery and intervention.
Post-interventional duplex ultrasound acknowledged the good results.
The patient was discharged to a rehabilitation hospital 9 days postop-
erative. The blood creatinine level sank to an almost normal level at
the day of discharge (highest value first postoperative day 192 mol/l,
level at discharge six days postoperative 117 mol/l.

Conclusion
Recent studies showed no benefit in balloon angioplasty or stenting
of renal arteries in atherosclerotic stenosis. (1) (2) However, in this
scenario an iatrogenic acute high-grade stenosis threatened the left
kidney, which could not slowly adapt to this malperfusion like in chron-
ic stenosis. With the described procedure, it was possible to save the
remaining kidney parenchyma.
In this specific situation, we favored the abilities of the very flexible,
balloon expandable BeSmooth peripheral stent. It was safely advanced
through the high-grade stenosis and placed precisely. In our depart-
ment the BeSmooth peripheral is our workhorse as we do also appre-
ciate the fully 6 Fr compatibility up to 10 mm in diameter and its radial
force.

References
(1) Astral Investigators. "Revascularization versus medical therapy for renal-artery steno-
(2) Cooper, Christopher J., et al. "Stenting and medical therapy for atherosclerotic re-
Iliac stent occlusion

Patient history
A 50 year old male patient with a cardiac history and blood hypertension came to our clinic with symptoms of CLI (Fontaine III). In 2012 the patient already received self-expanding covered stent grafts bilaterally to treat stenosis at the level of the aortic bifurcation.

Initial situation
A CT scan revealed an in-stent occlusion in the left iliac artery at the level of the bifurcation and a stenosis of the common femoral and partly in the external artery.

Procedural course
We started with a 6 Fr sheath in the left common femoral artery (CFA) and a 5 Fr sheath in the right CFA. We managed recanalization of the left CFA with a 0.035” Terumo guidewire and 5 Fr vertebral diagnostic catheter.

For restoring and improving blood flow into the left leg, we used one BeGraft peripheral 6x58 mm to open the occlusion at the bifurcation and one BeGraft peripheral 6x58 mm to treat the distal stenosis in the external iliac artery. As a result, the left hypogastric artery was overstented, but it was already occluded before.

Comments and conclusion
One third of the patients with peripheral aortic occlusive disease (PAOD) present pathologies of the iliac artery. (1) Risk factors of this pathology include high blood pressure, diabetes and coronary atherosclerosis. (2)

In our clinic we treat approximately 40 patients with iliac occlusive diseases per year whereof 75 % are stenosis and 25 % complete occlusions or in-stent occlusions. There is no consensus relating to the choice of stent type in treatment of iliac artery disease. In our clinic, we usually treat iliac stenosis by performing a PTA and treatment with bare metal stents afterwards.

For complete occlusions and re-occlusions, we most commonly use covered stents to reduce the risk of complications like ruptures or distal embolization and to improve the long-term patency.

In aorto-iliac occlusions, we use the endovascular approach as first choice according to the guidelines. (3) According the COBEST trial, we prefer the use of balloon expandable stents such as the BeGraft peripheral instead of bare metal stents to treat especially TASC II C and D lesions. Balloon expandable covered stents show less complications and better middle and long term results with lower re-interventions rate in these kind of lesions. (4)
In our opinion, the BeGraft peripheral has a better delivery system that allows easier and more accurate deployment, provides a higher visibility and a more solid adherence of the stent on the balloon compared to other similar stent grafts.

Regarding the pros and cons of self-expanding vs. balloon expandable stents in iliacs we like the adaptability of self-expanding stents to the vessel. However, they do not permit for the same precision of balloon expandable stents and have less radial force, which is preferred in case of obstruction or calcified stenosis. (5) (6)

References
Treatment of renal in-stent restenosis

**Patient history**
A 75 year-old female patient presented with uncontrolled renovascular hypertension despite optimal medical therapy. Her patient history included resistant hypertension, diabetes mellitus, permanent atrial fibrillation, ischemic heart disease, chronic obstructive pulmonary disease and chronic renal failure. In August 2017, a bare-metal-stent was implanted (Biotronik Dynamic, 5 x 19 mm) due to uncontrollable hypertension. Later, plain balloon angioplasties were performed due to restenosis in November 2017 and September 2018. A CT angiography was performed in June 2019 that showed a significant in-stent restenosis of the right renal artery.

**Initial situation**
Percutaneous access was established through the right brachial artery. 2500 IU heparin was administered intraarterially to prevent catheter thrombosis. A selective diagnostic angiography of the right renal artery was performed, which confirmed high grade in-stent restenosis.

**Procedural course**
After successfully crossing the lesion with a hydrophilic guidewire (Terumo Glidewire, 260 cm), a balloon predilatation (Biotronik Passéo-35, 5 x 40 mm) was performed. As the lesion was a restenosis, we decided to treat it with a covered stent (Bentley BeGraft peripheral, 5 x 28 mm). No procedural complication occurred, completion angiog-
During the follow-up CT angiography, there was a good result. The patient’s blood pressure improved remarkably. She was discharged on the following day after an uneventful postoperative period. The patient was put on dual antiplatelet and anticoagulant therapy for three months. Follow-up CT angiography was performed three months later, showing the fully patent BeGraft.

Comments

Percutaneous transluminal renal angioplasty has already had a role in the treatment of renovascular hypertension in the end of the 20th century. [1] Later, large randomized trials proclaimed optimal medical therapy noninferior to renal intervention. [2-4] However, concerns were raised against the conclusions of these trials, e.g. regarding the examined patient population and therefore the generalizability and validity of their findings. [5-7] Clinical practice and novel data suggest, that selected patients may benefit from renal artery revascularisation despite current guidelines [6, 8, 9], whereas we believed the use of a covered stent in the renal arteries in this patient to be more beneficial long term.

Using a covered stent in the renal arteries, the expanded polytetrafluoroethylene layer of these devices prevents neointimal hyperplasia ingrowth through the stent struts, resulting in lower restenosis and thus better patency rate compared to bare metal stents. [10] The 6F compatibility and the high flexibility of the BeGraft stent graft makes upper extremity access really comfortable, which is mandatory to treat lesions in the hostile anatomy of some visceral and renal arteries. The cobalt-chromium stent material paired with the platinum/iridium markers of the balloon results in excellent visibility on fluoroscopy during positioning and less blooming artefacts on follow-up CT imaging.

References

Less trauma, faster procedures through low profile
(6F compatibility up to Ø 8 mm)

Outstanding lesion access through exceptional flexibility

Predictable stent behaviour through low foreshortening & high radial force
Treatment of renal malperfusion due to acute type B dissection

Patient history & initial situation
A 61 year old man with hypertension presented to our emergency department with chest and right back pain. The patient was followed-up for an existing abdominal aortic aneurysm. An enhanced CT scan revealed an acute type B dissection with right kidney malperfusion due to an entry tear in front of the renal artery ostium. The entry tear was 5 cm distal to the left subclavian artery with a thrombosed proximal part of the dissection. Celiac trunc, superior mesenteric artery and the left renal artery were perfused by the true lumen, we could restabilize the affected aortic segment. The dissection ended at the aortic bifurcation, also involving the aneurysmal infrarenal aorta. The right renal artery was only partially perfused.

Procedural course
We started with a cutdown of the right femoral artery and closed the proximal entry tear with a Zenith® Z-Trak dissection device (ZDEG30 x 202, Cook® Medical). Through this, the true lumen expanded, but the right renal entry tear was still persistent causing a malperfusion of the kidney. We catheterized the entry tear with a C2 catheter (Cordis®) and navigated through the false lumen into the right renal artery. We used a stiff guidewire (Rosen wire, Cook® Medical) to introduce a 6 Fr glide sheath into the right renal artery (Flexor®, Cook® Medical). To revascularize the renal artery we implanted a Bentley BeGraft 6 x 27 mm and created a bridge like passage from the right lumen into the right renal artery.

The final angiography showed a fully patent BeGraft stent graft and a good perfusion of both renal arteries. Through this maneuver, the entry tear and the false lumen was excluded. Chest and back pain disappeared immediately after the procedure. A post-operative enhanced CT scan showed a total thrombosis of the false lumen from the left subclavian artery to the aortic bifurcation. The right renal artery was fully perfused.

Comments
Malperfusion of target arteries because of an aortic dissection is a major complication. Most of the times it is sufficient to close the proximal entry tear to decrease the pressure in the false lumen and to achieve reperfusion of all target arteries.

We considered the STABILIZE technique for this indication which has been described extensively in the literature so far. However, this technique was not applicable because of the rather small but progressing abdominal aortic aneurysm. That is why we decided to place the Cook® dissection device into the descending thoracic aorta. Celiac trunc, superior mesenteric artery and left renal artery regained perfusion but the right renal artery was still malperfused. Due to its low profile and placement accuracy, in this case the BeGraft was an ideal stent for restoring the patency of the right renal artery. The BeGraft closed the distal entry tear and the false lumen thrombosed. Successfully treated, the patient was discharged from the clinic.
Iliac-enteric fistula

Patient history
A 65-year-old female patient with hematemesis, nausea and vomiting, and acute onset of lower abdominal pain associated with bloody stools was admitted to Emergency Department in October 2017. On examination, the patient was alert, but pale. The blood pressure recorded non-invasively was 90/60 mmHg, and pulse was 86 beats per minute with a capillary refill time of less than 2 seconds. Oxygen saturation was 95% on room air. On physical examination, the patient’s abdomen was soft with tenderness in the epigastric region. No rebound and no guarding was present when the abdomen was palpated. Urgent laboratory investigations showed a hemoglobin of 10 g/dL with a mean cell volume of 102 fL. Serum creatinine of 0.99 mg/dL and urea was 40 mg/dL. Coagulation was normal (International Normalized Ratio: 1.09) and blood gases showed a pH of 7.39 and a lactate of 0.5 mmol/L. Past medical history included renal cancer with bone, pulmonary and encephalic metastases. Patient was assuming oxycodone naloxone, lansoprazole and sorafenib as antitumoral therapy.

Initial situation
The patient underwent an emergency oesophagogastroduodenoscopy (OGD) which showed absence of bleeding. Since the patient remained hypotensive, she underwent computed tomography (CT) scan that showed a small tumoral mass close to the left common iliac artery; indissociably from a jejunal loop; the CT scan showed also an endoluminal defect at the third medium of left common iliac artery without evidence of dye leakage. The patient was admitted to our department to undergo iliac arteries angiography and treatment.

Procedural course
We crossed the lesion with a 0.035 guidewire (Radifocus® Guidewire M Standard type, Terumo). To cover the arterial lesion we placed a 10 x 37 mm Bentley BeGraft Peripheral covered stent inflated at nominal pressure with good result at the completion angiography, without any residual leakage. The post-procedural CT scan at 24 hours confirmed the exclusion of the lesion with good stent adaptation.
Isolated iliaco-enteric fistula, is a very rare diagnosis with unclear pathogenesis. The majority of reported cases of iliaco-enteric fistulas have not been associated with prior vascular surgery. Predisposing factors include male gender, pelvic surgery, malignancy and infection (1). Fistula to the colon is most common followed by small bowel and rectum. The common iliac artery (CIA) is the most frequently involved iliac vessel.

As with most surgical emergencies, prompt diagnosis is key in determining outcome. Around one third of patients will die in the first 6–12 hours of symptom onset (2).

The options for vascular repair of iliaco-enteric fistula included open, definitive repair of the iliac lesion using a venous conduit or endovascular repair with a stent graft. The latter can be considered either a bridging procedure or definite repair with the advantage of maintaining distal perfusion while allowing for thorough debridement to avoid exposing vascular anastomoses to an infected surgical field.

Endovascular aortic repair (EVAR) is a rapid, minimally invasive technique that can be employed in the unstable patient. Duvnjak et al, used coil embolization to successfully treat a bleeding fistula between the left internal iliac artery and sigmoid colon in a patient who received radiotherapy for prostate and caecal cancer. There were no adverse events during the relatively short 5-months follow-up (3). Leonhardt et al studied the outcome over a 3-year period of five patients with abdominal AEF (four primary, one secondary) who underwent balloon occlusion and endovascular repair. The immediate success rate at stopping bleeding was 80% using stent grafts. Despite the initial success, 80% re-bled after 2 weeks or longer. 30-day mortality was 40%, which doubled at 6 months. This supports the conclusion that EVAR should be considered only as bridging measure prior to definitive surgical repair (4). An exception could be in the palliative setting where endovascular repair can be the only definite procedure (5). As the risk of infection is high, patients require antibiotic cover following EVAR (4).

Considering endovascular therapy with covered stent either as a bridging measure or a definite procedure, endovascular sealing of iliaco-enteric fistula with Bentley BeGraft Peripheral balloon-expandable stent graft is a reliable technique providing time to treat shock, local and systemic infection and comorbidity. This can lead to a better situation to perform open repair, when needed, with possible better outcome. Due to the predictable behavior of the BeGraft Peripheral stent graft, through its low foreshortening and high radial force, it can seal the arterial lesion with high accuracy. Thus, it is a new low-profile balloon-expandable covered stent, 6 F compatible up to 8 mm diameter, CE mark approved for renal and iliac stenting and with a better trackability than conventional covered balloon-expandable stents.

References
Difficult anatomy in young patient with juxtaductal coarctation

Patient history
A 12 year-old boy was presented to the clinic with a complex native aortic coarctation. He was asymptomatic, exercising twice a week with no headache. Clinical examination revealed weak femoral pulses. Systolic blood pressure in the right arm was 135 mmHg and in the right leg 100 mmHg. A 24-hour BP measurement demonstrated systolic blood pressures above 99th percentile. The ECG demonstrated mild left ventricular hypertrophy. Echocardiography demonstrated normal LV function with mild hypertrophy. Doppler in the arch demonstrated a classic double envelope coarctation signal with a Vmax >3.6 m/sec, peak systolic Doppler gradient of 60 mmHg and a diastolic tail with a damped tracing in the abdominal aorta. His exercise test was normal with normal exercise capacity. His weight at the time of intervention was 46 kg.

Initial situation
The CT demonstrated a complex coarctation with pseudocoarctation-like appearance and a juxtaductal coarctation with poststenotic dilatation.

Procedural course
The planned intervention was to place a single covered stent to straighten out the pseudocoarctation covering both the proximal and distal narrowing with the stent extending well below the distal narrowing into the poststenotic dilation. The Hemodynamic evaluation demonstrated a peak-to-peak gradient of 28 mmHg across the aortic arch. An angiography demonstrated a bi-level coarctation with the pseudocoarctation-like appearance seen on CT scan, as well as a juxtaductal coarctation with posterior fold and poststenotic dilatation.
The minimal diameter was between 9 - 10 mm with an overall required length of 38 mm.

An 11 Fr, 75 cm Mullins sheath (Cook® Medical) was advanced over a 0.035” Rosen wire (Cook® Medical) that had been previously advanced to the distal right subclavian artery. An oesophageal temperature probe was placed as an additional landmark to mark the level of the take-off of the left subclavian artery.

We advanced a 14 x 39 mm Bentley BeGraft aortic covered stent through the sheath so that the upper edge of the stent was at the level of the lower edge of the transverse arch opposite to the origin of the left subclavian artery so that it would be stable and not slipping down and angulate into the ductal diverticulum. With the tip of the oesophageal probe we have marked the upper position of the stent so that it won’t protrude into the transverse arch. The sheath was withdrawn to below the stent which was then slowly inflated until there was a dumbbell shape “dogbone” appearance of the balloon. The sheath was then moved forward to under the distal end of the balloon to maintain the balloon’s position at the lower edge of the transverse arch until inflation was complete. Stent positioning was optimal with no residual waist noted and good flow to the left subclavian artery. Hemodynamic evaluation demonstrated a peak-to-peak gradient of 20 mmHg with good upstroke in the descending aorta. A pullback was performed with an end-hole catheter which demonstrated the 20 mmHg gradient to be at the entrance in to the stent.

The Rosen wire was dropped into the ascending aorta and a 16 x 40 mm Maxi LD balloon (Cordis®) was inflated in the proximal part of the stent for flaring it flush with the inner curvature of the transverse arch in order that the balloon can lie more horizontal.

The pullback was repeated with zero gradient post redilation. Angiography demonstrated a significantly improved diameter with rapid flow through the stent with no signs of dissection or aneurysm formation and good flow to the left subclavian artery. On 6 months follow up there are no complications.

Comments
The intervention for this complex coarctation was challenging due to the narrowing at 2 levels with a high risk of the stent slipping into the ductal diverticulum if placed too low and then being angulated and partially obstructing the flow. If placed too high the stent could cause a coarctation by sticking up in to the lumen of the transverse arch. Implantation of a covered stent was chosen due to the long segment of abnormal aortic wall. The 14 x 39 mm Bentley BeGraft aortic stent was used due to its strong radial force, expandability to 20 mm and having a low profile delivery system. Re-evaluation by CT and cath are planned with the possibility of future post-dilation.
Treatment of aortic coarctation in patient with small access arteries

Introduction
Nowadays, balloon expandable covered stents are widely used to treat aortic coarctation in children and adults. Due to the risk of aortic rupture, their use is safer in particular in patients with near-atretic, atretic or complex aortic coarctation (CoA). The main disadvantage can be the need of large sheaths. The BeGraft aortic stent has a lower profile among all officially large diameter stent grafts available, which extends the indications for its use.

Patient history
A thirteen-year-old female patient presented to our clinic with re-coarctation. She had a history of left atrial isomerism, levocardia, aortic coarctation and a Ventricle Septum Defect (VSD) treated at 10 days of life with VSD patch closure and correction of the aortic coarctation by the use of an ePTFE patch. Post-operative course was characterized by significant residual VSD, with a need for a redo operation and neurological injuries.

Further follow-up was then characterized by significant aortic re-coarctation with systemic arterial hypertension (140 / 80 mmHg) and a systolic gradient between upper and lower limbs of 40 mmHg. She was receiving beta-blocker. Her height was 150 cm at a weight of 35 kg.

Procedural course
After informed and signed consent by her parents the procedure was undertaken under general anesthesia and orotracheal intubation. Access was obtained through the right femoral artery and an angiography of the ilio-femoral arteries was performed showing a small arterial axis. The femoral arteries measured not more than 3 mm, which limited the treatment options. After placement of an 8 Fr introducer, the femoral artery was almost completely occluded by it. An Aortography showed a long re-coarctation segment with a minimal diameter of 7 mm. At the level of the horizontal aorta. At diaphragm the aortic arch was almost 13 mm, the invasive gradient was 35 mmHg.

Due to the presence of a patch at the level of the CoA, a higher risk of injury was anticipated by the use of balloon angioplasty alone. In this setting, the use of covered stents is the ideal choice. We managed to place a 9 Fr Mullins sheath (Cook® Medical) into this small access artery for a safe delivery of the Bentley BeGraft aortic (12 mm x 29 mm). We advanced the BeGraft aortic over a 0.035” Amplatz Extra Stiff guide wire (Cook® Medical) and inflated it to the indicated diameter. The stent positioning and expansion was optimal. A moderate waist was still present but there was no residual gradient invasively measured. No interference of the flow in the head and neck vessels was shown. A final angiography of the femoral and iliac vessels did not show signs of injuries.

At 20 months follow-up, the result is stable with no residual gradient, normal systemic arterial pressure and no need for anti-hypertensive agents.

Comments
Use of covered stents in CoA is a major step forward in the treatment of those diseases. The COAST II trial (Coarctation of the Aorta Stent Trial) showed the effectiveness and safety of using covered Cheatham-Platinum stents to treat CoA and to prevent aortic wall injury (1). However, significant complications associated with access site were reported in 3 % of patients. This was mainly due to the need for large sheaths required to implant Cheatham-Platinum stents. In fact, large introducers of 11 Fr - 16 Fr are needed depending on the size of the stent and balloon assembly. For our patient, this would have required at least an 11 Fr sheath and clearly, the femoral artery would have not accommodated it without injury.

In the literature, the initial data about the use of the BeGraft aortic stent in CoA are very promising. Promphan et al. successfully treated 12 patients with different aortic coarctation anatomies (2). End of 2020, we reported on a series of 5 patients with a median age of 15 years (range 8 - 30 years) with near atretic or very severe CoA (3).
All patients had small femoral arteries ranging between 3 mm and 6 mm. Long sheaths between 9 Fr and 11 Fr were used to implant stents, which were dilated from 12 mm to 16 mm. None of the patients had residual coarctation (gradient > 20 mmHg) after stenting. Furthermore, we fully inflated the stents in all patients avoiding the need for a second procedure. Finally, stent foreshortening was ~25 %, which is in line with other stent grafts indicated for CoA.

None of the patients developed acute vascular injuries or local access related complications at the end of the procedure or during follow-up of up to 12 months.

Conclusions
Bentley BeGraft aortic stents provide a significant advantage of having lower profile delivery sheaths, while treating successfully the disease even when femoral artery access is small. These stents widen the spectrum of CoA that can be treated with a percutaneous approach even in very young patients.

References
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