



Case reports

Volume 1



Content

- 3** Foreword
- 4** Fast growing coronary aneurysm
Dr. Javier Coggiola, Dr. Esteban De Giovanni
- 5** Coronary aneurysm & stenotic lesion
Dr. Gerardo Nau
- 8** High grade stenosis in left common iliac artery
Dr. Kim Taeymans
- 9** Iliac recanalisation in young patient
Dr. Ramita Dey
- 11** Bilateral common iliac artery stenosis
Dr. Antonella Ruffino
- 12** Pediatric coarctation (CoA)
Dr. Stephan Schubert

Disclaimer

The opinions or views expressed in these case reports are those of the authors, and do not necessarily reflect the opinions or recommendations of Bentley InnoMed GmbH.

Foreword

Welcome to the first edition of Bentley's 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 covered stents in various everyday clinical settings, involving a range of lesion types.

In these case studies, covered stents were the intervention of choice, providing patients with optimal outcomes both clinically and in terms of quality of life. All of the featured stents were made by Bentley.

This family owned company has shown marked and sustained growth since its foundation in 2009. The portfolio currently comprises five products, which are used for a broad spectrum of vascular disease, and all of which are developed and manufactured in Hechingen, Germany.

Over the relatively short period of its existence, Bentley has provided covered stents for the treatment of thousands of patients in over 75 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.

With this history of successful product development and reliable customer service, Bentley is now working on the next generation of stents to establish yet additional innovative benchmarks in the treatment of vascular diseases.

If you would like to submit one of your cases for this CASE REPORT booklet*, or if you would like to receive more information on our product portfolio, please send us an email at info@bentley.global.

With best regards,

Marius Lux
Product Manager

*Products used only within indication!



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Fast growing coronary aneurysm

Patient history

A 70 year-old male with hypertension and a history of coronary pre-diseases presented to our clinic. In May 2013 he got a conventional stent placed in the middle segment of the anterior descending artery, with subsequent in-stent restenosis, and thus placing of a DES in June 2016.

He returned in our clinic in September 2017 due to acute coronary syndrome without ST segment elevation. We performed a coronary angiography where aneurysmal dilatation was observed in the proximal anterior descending artery, prior to the stent. Due to personal reasons of the patient immediate treatment was postponed.

Angiographic findings

In November 2017 the patient came to the clinic due to a new acute coronary syndrome without ST elevation. Echocardiography was normal. It is studied again by cinecoronariography, confirming a 70 % ostial lesion of the anterior descending artery and an increase in the size of the aneurysm detected in September 2017.

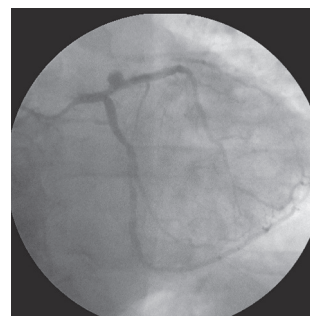
Procedural course

Percutaneous access was established through the right femoral artery with a 6 Fr introducer sheath. Selective catheterization of the left coronary artery is performed with XB 3.5 catheter. The angiographic control showed an increase in the size of the aneurysm (within 10 days). A passage of two 0.014" guides was made to the distal circumflex artery and the anterior descending artery. Pre-dilation of the left coronary artery was made with a balloon 2.0 x 15 mm at 12 atm at the level of ostial stenosis. For exclusion of the aneurysm we placed a BeGraft coronary 3.5 x 18 mm at 12 atm. The subsequent angiographic control confirmed the complete exclusion of the aneurysm and a complete resolution of the stenosis in the ostial segment. The patient evolved favorably, without complications. He was discharged 48 hours post-procedure.

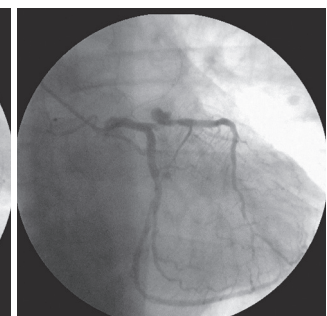
Comments and conclusion

The decision to choose a covered stent was based on the rapid growth of the aneurysm within a short time. The BeGraft coronary is indicated for the treatment of coronary aneurysms and provides the smallest profile available in conjunction with an excellent trackability and navigability. It has a great flexibility and a low profile and allows the use of a 5 Fr guiding catheter. For eventual complications in this procedure we have chosen a 6 Fr catheter for access as the patient had an ostial disease of the anterior descending artery.

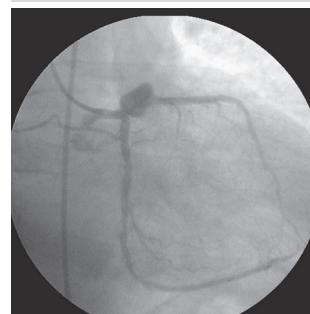
From its handling the system provides a very pleasant feeling at the touch and the manipulation of the system (stent and shaft). It is very comfortable and agile.



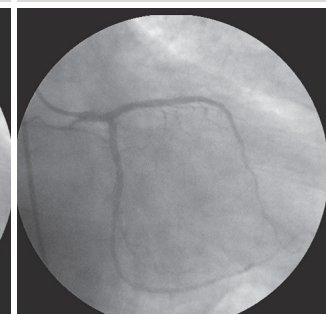
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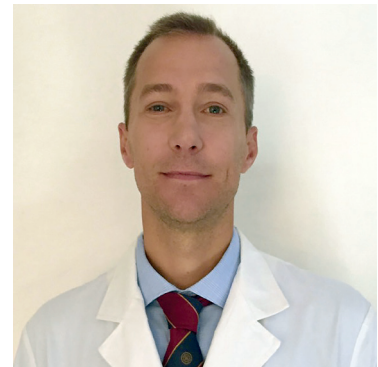


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28-Nov-2017

Coronary aneurysm & stenotic lesion



Dr. Gerardo Nau

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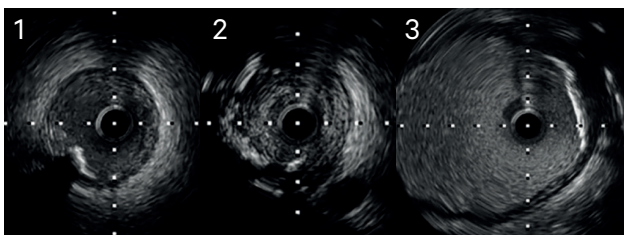
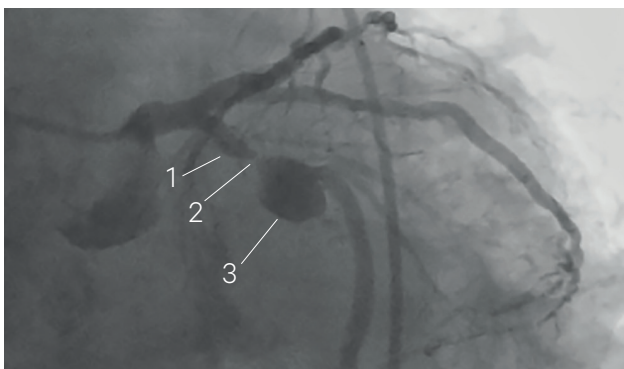
Patient history

A 59 year-old male patient with a history of hypertension and chronic renal failure, presented at the emergency department due to chest pain lasting 30 minutes. An ECG was performed in triage, T-wave inversion V4 to V6 were observed. The patient was admitted, initiating medical therapy with 300 mg of acetyl salicylic acid, low molecular weight heparin, intravenous vasodilators, statins and beta-blocker. After this first approach, he evolved asymptotically, without hemodynamic alterations.

Initial situation

The laboratory result showed a positive ultrasensitive troponin of 126 ng/l. The condition was interpreted as non ST elevation myocardial infarction. Ticagrelor loading dose was administered and a coronary angiography performed on the same day.

After establishing access through the femoral artery with a 6 Fr sheath, we performed a diagnostic angiography, showing a chronic occlusion at the mid-level of the right coronary artery. Severe lesion on the diagonal branch without compromising the bifurcation. The proximal circumflex artery showed a severe lesion with a stenosis of nearly 90 % and a subsequent saccular aneurysmal dilation. From inside this latter, two small branches appear irrigating the lateral region without further significant lesions.



Procedural course

We continued with coronary angioplasty, placing a XB 3.5 guide catheter. The diagonal branch was treated first. We implanted a direct drug eluting stent, without ostium involvement.

Afterwards we advanced a 0.014" Balanced Middle Weight (BMW) guide wire through the circumflex coronary (CX) artery. With a 2.5 x 12 mm balloon we pre-dilated the stenotic lesion at 16 atm. After this, IVUS was done in order to assure the pre-, intra- and post-aneurysm diameters and length. It is of vital importance to recognize the vessel diameters, since the covered stents require the complete apposition to avoid leaks and at the same time avoid undersizing, since they present a higher risk of thrombosis.

Before implanting the covered stent, we prefer to dilate the lesion with a high pressure balloon 3.0 x 12 mm at 22 atm due to heavy calcification.

To cover the stenotic lesion and aneurysm we placed a 3.5 x 24 mm Bentley BeGraft coronary covered stent at 14 atm.



Contrast stentboost and IVUS showed a nice stent adaptation and freedom from leakage. Nonetheless, signs of stent under-expansion appeared, and we decided to post-dilate with high pressure balloon 3.5 x 15 mm. It is suggested not to oversize covered ePTFE stents due to the risk of material damage.



Comments

The diagnosis of coronary artery aneurysm (CAA) is described as a condition where the artery is 1.5 times larger than the adjacent arterial segment. The incidence of coronary aneurysms varies from 0.3 % to 5.3 %. (1) They can be saccular like in our presentation or fusiform. Up to 70 % of aneurysms appear within the right coronary artery whereby ca. 23 % occur in the circumflex artery.

The physio-pathological mechanism continues to be controversial, being half in adults associated with atherosclerotic disease. Chronic inflammation results in the weakening of the arterial wall, destruction of the muscular elastic layer, fibrosis and calcification. Moreover, the vast majority of aneurysms reveal an association with coronary stenosis as exemplified in our case. (3, 4, 5)

In most cases CAA evolve asymptotically. In the case of manifesting symptoms, they are in greater proportion ischemic due to the formation of internal thrombus and embolization and/or alteration of the blood flow. Even more acute coronary syndromes can be caused due to their association with stenotic lesions. In our case it is showing different patterns of the same disease.

There is no consensus on the proper management of CAAs, since the natural history of the disease is based on multiple factors which make it necessary to customize the treatment according to the patient. For that reason, before taking an interventional decision, we must consider the clinical presentation, possible etiology (infectious, atherosclerosis, connective tissue disorders, vasculitis, etc.), aneurysm size and expansion on follow up.

Today percutaneous treatment is a less invasive option than open surgery, however scarce data is obtained. One of the largest studies retrospectively compared outcomes in a series of patients treated with either surgery (n = 18) or covered stents (n = 24). Patients treated with covered stents tended to be older (60.5 vs. 47.7 years old) and to have smaller aneurysms (9.8 vs. 35.1 mm). No deaths were reported in either group. Only 5 of the 24 patients who received stents were found to have restenosis on follow-up angiography. (6)

Due to the new technological developments such as the Bentley BeGraft coronary a much better trackability and long-term safety has been obtained. These two missing qualities diminished the percutaneous choice in the past.

Percutaneous treatment and the decision for exclusion should be considered in anatomies that do not exclude important branches. Also, we strongly suggest angiography-supported images in order to reduce the risks of thrombosis and restenosis in follow-up. The use

of IVUS is extremely helpful. Since suitable lengths and diameters are available it is becoming more and more the gold standard for the evaluation of the vessel wall and aneurysmal diameters. IVUS variables are described as anatomic risk factors for rupture, encourage us to take an invasive stand.

In our case the percutaneous treatment of the aneurysm was due to main findings in IVUS and the unstable stenotic disease. Our knowledge of coronary artery aneurysms is limited, and management is still a challenge. New tools to recognize high risk patterns and devices to deal with these complex anatomies make us a great progress. Through its excellent performance the BeGraft coronary is a very helpful device which we are using regularly for such challenging cases.

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BeGraft

coronary

Coronary Stent Graft System

High flexibility and low crimped profile

(5F guiding catheter) for outstanding lesion access

Large size matrix

- Ø 2.5 - 5.0 mm
- Length 8 - 24 mm

3 years shelf life



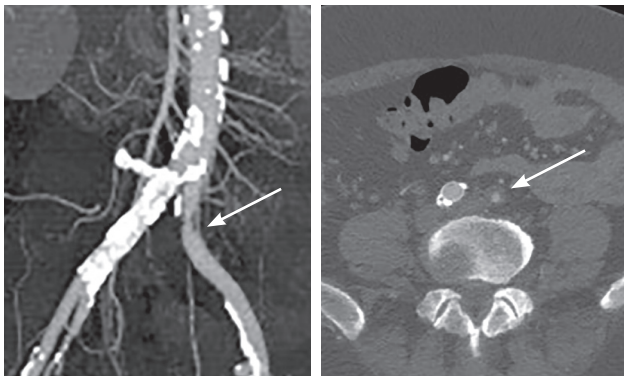


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High grade stenosis in left common iliac artery

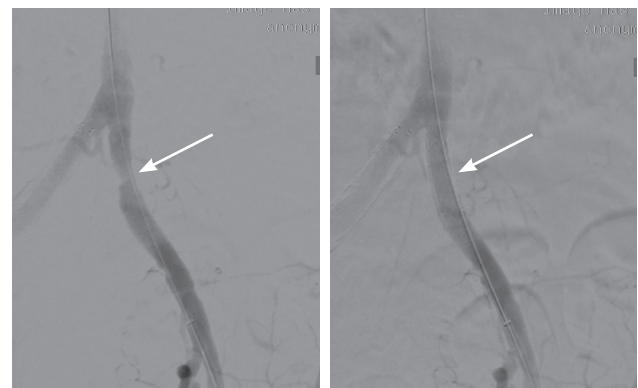
Patient history

A 58 year-old female patient presented with Rutherford III claudication in the left leg. She had a history of an acute occlusion of the right superficial femoral artery treated with thrombolysis and PTA and stenting of the right common iliac artery. Duplex ultrasound showed monophasic signals in the left common femoral artery. CT angiogram was performed and showed a high grade stenosis in the common iliac artery on the left side. Percutaneous transluminal angioplasty was planned.



Procedural course

The procedure was performed under general anesthesia. A 6 Fr sheath (23 cm) was placed in the left common femoral artery. Angiography showed the high grade stenosis. The lesion was crossed with a 0.035" stiff Terumo™ guide-wire. We decided to primarily stent the lesion with a Bentley BeGraft 8 x 37 mm stent. Angiography after stent placement showed absence of residual stenosis and very good flow. A StarClose SE (Abbott) closure device was used to close the puncture site. There were no peri- or post-operative complications and the patient was completely asymptomatic after the procedure.



Comments and conclusion

We decided to primary stent this lesion with a balloon expandable covered stent. We chose the Bentley BeGraft peripheral balloon expandable covered stent, because it is compatible with a 6 Fr sheath up to 8 x 57 mm in stent size, this in comparison to his competitors which require larger sheath sizes. This stent also has an optimal radial force to overcome high grade stenosis.

The benefit of using covered stents in the treatment of iliac lesions is the ability to immediately solve intra procedural complications like flow limiting dissection and perforation. Another benefit is the trapping of possible thrombus between the stent and the vessel wall caused by the dog-bone inflation of the stent and thereby preventing or minimizing distal embolization. Using a stent covered with expanded polytetrafluoroethylene could also reduce restenosis and improve patency rates by introducing a mechanical barrier between intimal hyperplasia and the arterial lumen.

We believe that, due to the aforementioned benefits, the balloon expandable BeGraft peripheral is an added value in the treatment of high grade iliac stenosis or iliac occlusions.



Dr. Ramita Dey

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Iliac recanalisation in young patient

Patient history

A 55 year-old gentleman presented with short distance claudication at 25 yards. He was a smoker, non-diabetic, non-hypertensive. An MR angiogram, showed an occlusion of the left common and internal iliac arteries. ❶

Procedural course

Bilateral groin access was obtained under local anaesthesia and a pigtail run performed from the right side, showing full length chronic occlusion of the left common and external iliac arteries. ❷ An initial attempt was made to cross the occlusion retrograde from the left side, but luminal re-entry into the aorta could not be obtained. Hence, the occlusion was crossed from the right side, over the aortic bifurcation, using a SIM 1 catheter and standard 0.035" Terumo™ Glidewire. ❸ The wire was snared out through the left groin (Ensnare™), and a retrograde wire established on the left. The occlusion was primarily stented with two 8 x 57 and one 6 x 57 Bentley BeGrafts overlapping each other, from the level of the aortic bifurcation up to the CFA origin.

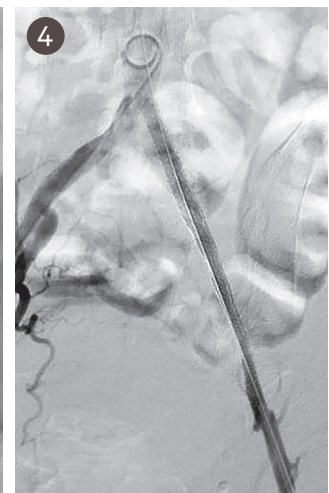
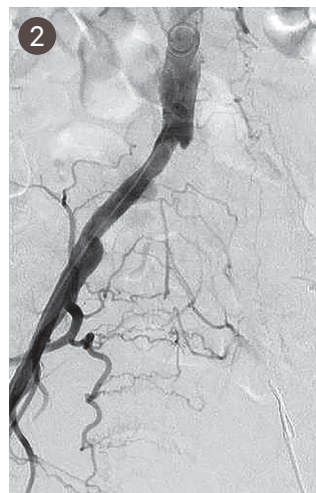
Excellent flow was present at the end, with a strong groin pulse and the patient was discharged the same day. ❹

He was put on life-long dual antiplatelet therapy and strongly advised to stop smoking.

The patient has been seen in follow-up 6 weeks after the procedure and his claudication has completely resolved, and he is able to walk unlimited distances and has stopped smoking.

Discussion and conclusion

The patient was relatively young and led an active lifestyle. The aim was to maximise the long-term outcome of the procedure. Hence the BeGraft was chosen over a bare metal stent, due to better patency for covered grafts compared to bare metal stents. On the other hand, given the long occlusion we expected extensive underlying disease and hence the cobalt-chromium platform was chosen for its radial force to ensure long-term patency as well.



BeGraft

peripheral

Peripheral Stent Graft System

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



Bilateral common iliac artery stenosis



Dr. Maria Antonella Ruffino

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Patient history

A 68 year-old male diabetic, with hypertension and bilateral buttock claudication, walking distance < 100 m (Rutherford class 3) came to our attention in October 2018. The Duplex ultrasound (DUS) showed a severe bilateral common iliac artery stenosis located at the ostium of the vessel. Femoral-popliteal axes were patent and the distal run-off was sustained by peroneal and tibial arteries bilaterally, with a slow post-stenotic flow. CT angiography confirmed the DUS findings. The aortic diameter above the junction was 18 mm, while both common iliac artery diameter were > 10 mm. According to TASC II classification the lesion was classified as a TASC A lesion. (1)

Initial situation

The patient was admitted to our department to undergo an angiography of the iliac arteries and subsequent treatment. Through the right common femoral artery, we performed an iliac angiography with a 5 Fr x 11 cm sheath (Radifocus® Introducer II Standard Kit, Terumo™) and a 4 Fr UF catheter (Cordis®, Tempo™ Aqua). Preliminary angiography showed stenosed, very calcified common iliac arteries. ❶ On the left side the stenoses were located at the junction of the bifurcation and at the middle third of the common iliac of the right side.

Procedural course

Through the right and left common femoral artery we used a 9 Fr sheath (Flexor® Introducer, Cook® Medical) and crossed the lesion with a 0.035" guidewire (Radifocus® Guidewire M Standard type, Terumo™). A pre-dilation to 6 mm was needed to cross the stenosis of the left common iliac artery. On the right side we placed a 12 x 29 mm, on the left side a 12 x 39 mm BeGraft aortic at nominal pressure and with good results. ❷ The completion angiography showed a residual stenosis of < 30 % on the left and good patency on the right CIA. At the post-procedural DUS no flow impairment could be detected. ❸ The 6-months DUS showed good patency of the stents with direct flow through both of the common femoral arteries.

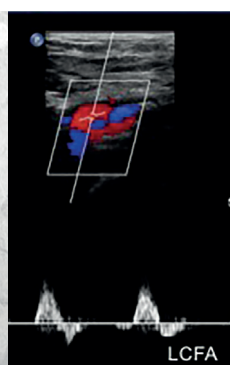
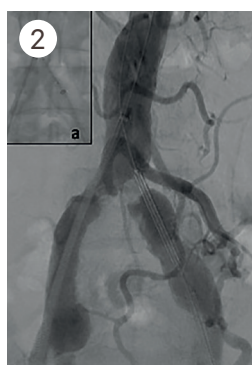
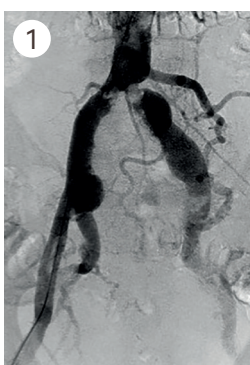
Comments

The endovascular treatment of obstructive lesions involving the origin of both, common iliac arteries, in particular when the aortic bifurcation is involved by the disease, can be really challenging. Surgery is still considered the treatment of choice but the 30-day mortality rate for an aorto-bifemoral bypass is 4 %, with a systemic morbidity rate of 16 %. (2) Endovascular kissing stenting (KS) has frequently been used to reconstruct the aortic bifurcation with a 1-year primary patency ranging from 70 % to 100 %, with a morbidity rate up to 24 % and a rate of distal embolization up to 8 %. (3) Covered stents seem to improve the patency rates, but, as reported by Jebbink et al. different stent configurations may affect patency rates, including the patency of the stents and the discrepancy between the stented lumen and the aortic lumen, the so-called radial mismatch. (4) This causes flow turbulence and thrombus apposition decreasing stent patency.

In our case, due to the discrepancy between the aortic diameter and the diameters of the common iliac arteries, we decided not to perform the kissing stent technique. According to the large diameters of both common iliac arteries, we decided to place two BeGraft aortic stent grafts to achieve the best wall apposition. The BeGraft aortic is CE marked for restoring and improving the patency of iliac arteries and seemed to be the best choice for us in this case.

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Pediatric coarctation (CoA)

Patient history

An eleven year-old patient presented to our clinic with re-CoA after external and prior surgical treatment with end to end anastomosis during the first weeks of life, which was followed by two balloon dilations of the re-CoA in childhood (7 and 22 months). Both were complicated by a femoral artery occlusion. The patient has intermittent tiredness and reduced exercise tolerance, if compared with children at the same age. The patient weight: 33 kg and height: 152 cm. Blood pressure gradient (arm to leg) was measured with 20 mmHg and NYHA status: I-II; no medication.

Initial situation

The angiography showed a circumscriptive re-CoA with a minimal diameter of 6.5 mm and a proximal and distal diameter of 9 - 10 mm, which is small for age. The invasive gradient was 15 - 20 mmHg during sedation. ① ②

Procedural course

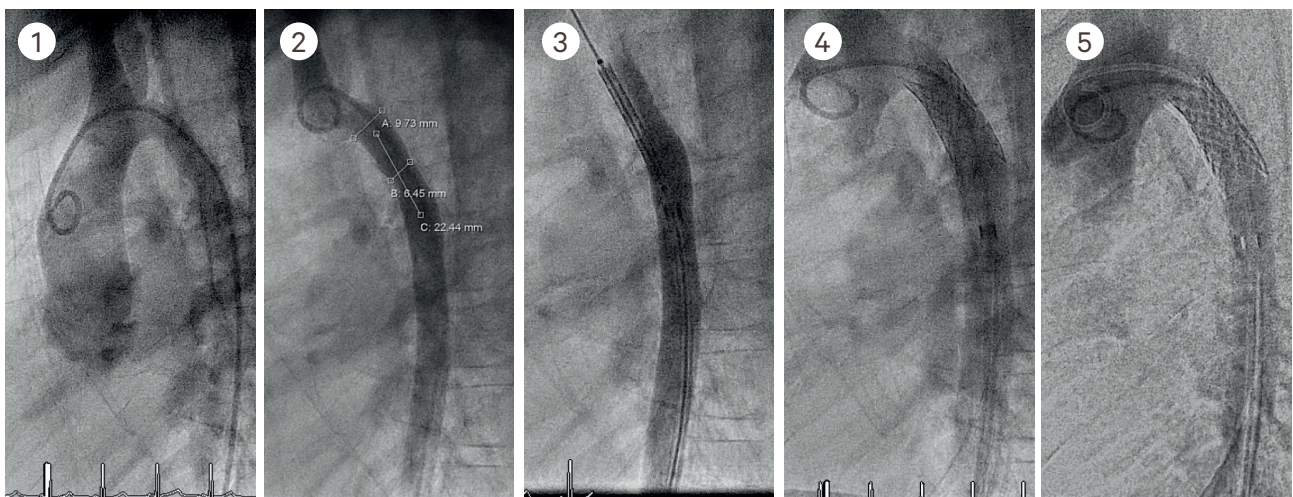
Balloon dilatation was performed with the use of a 12 mm Powerflex-balloon (Cordis®) at 8 atm. The balloon dilatation alone was not effectively reducing the gradient and was showing a residual intention

during inflation. Therefore stenting was preferred, as the residual CoA showed a restrictive pattern and was dilated three times in the past. Covered stenting was the preferred method, as expansion of this segment in the future will be necessary.

For treatment a BeGraft aortic (12 x 29 mm) was implanted through a 9 Fr Mullins sheath (Cook® Medical) and via a 0.035" Amplatz Extra Stiff wire (Cook® Medical). The stent positioning and expansion was optimal. There was no residual gradient invasively measured. Head and neck vessels were freely perfused. ③ ④ ⑤

Comments and conclusion

The re-intervention was needed in this child after prior external surgical and two times interventional treatment of a CoA. Overall aortic diameters were small; therefore a covered stent implantation was chosen after failure to relieve the residual gradient by balloon dilatation with moderate pressure application only. Stent-placement with the use of a Bentley BeGraft aortic was performed due to its pre-mounted availability and low profile (1 - 2 Fr smaller profile than a covered CP-Stent (NuMed)). Furthermore future post-dilatation can be performed without risk of aneurysm.



BeGraft

aortic

Aortic Stent Graft System

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pre-mounted on balloon

Low Profile

9F for diameter of 12 mm

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through a wide range of diameters (12 - 24 mm)



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