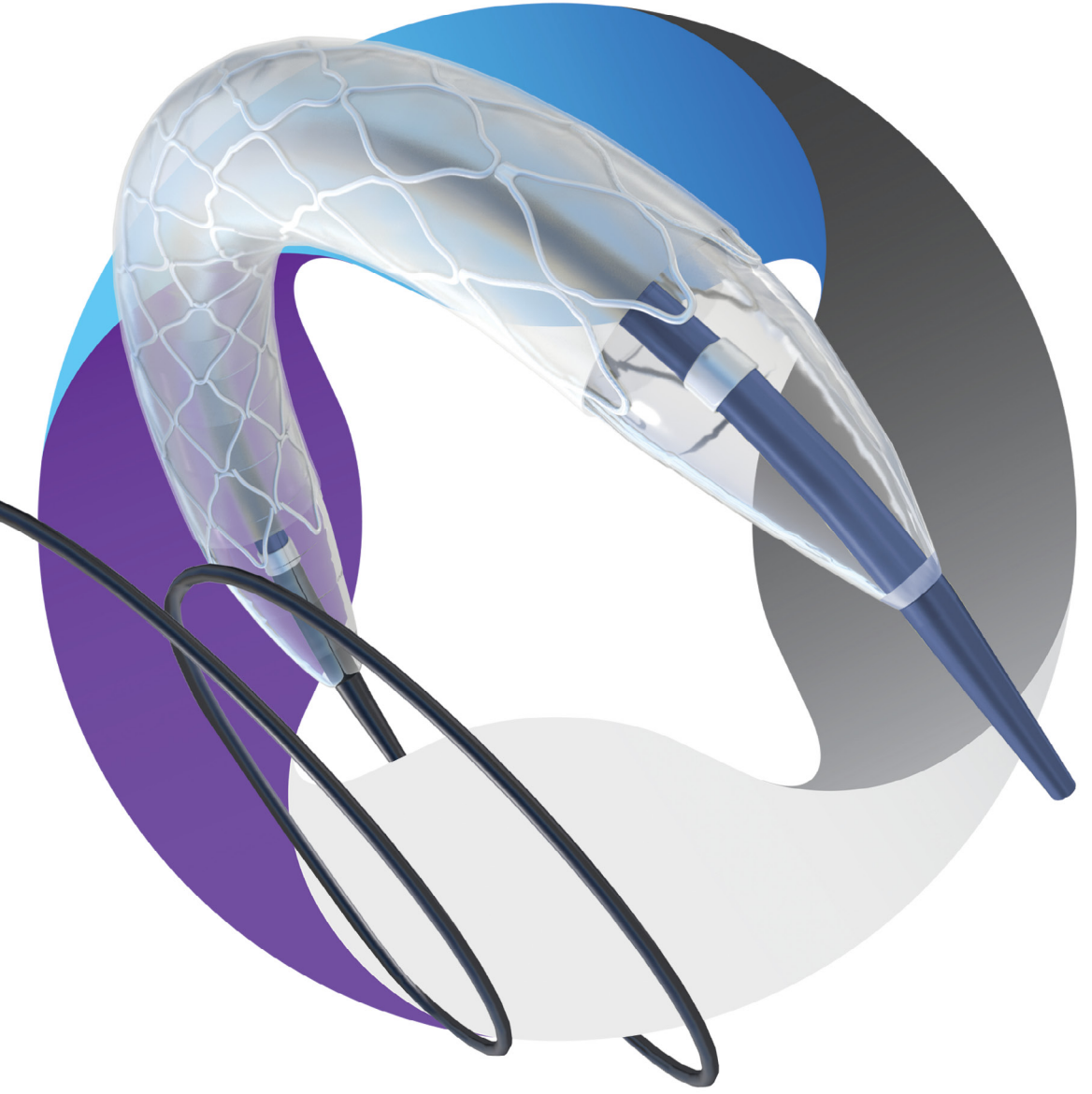

Celosia™ Covered Stent

InSitu Technologies® Inc.
Extending Life and Improving Health™

The most deliverable covered stent

Perforation?
Aneurysm?
Rupture?
Dissection?
Fistula?

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Indications

When emergency situations arise, surgical backup is not always an option. Minimize your risk and equip your cath lab with the Celosia™ Covered Stent today.

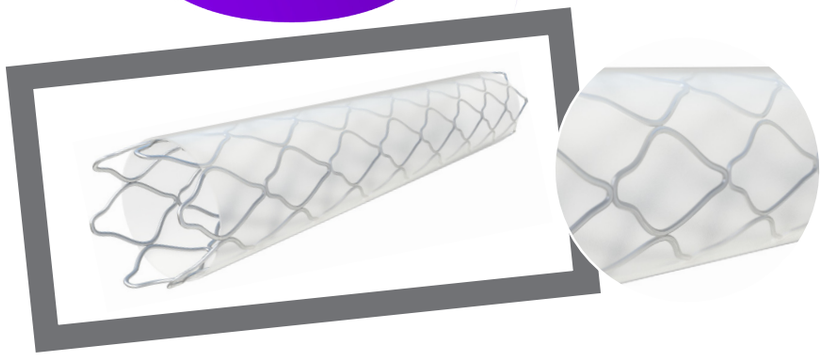
Indications For Use:
The Celosia™ Covered Stent is indicated for use in the treatment of free perforations, defined as free contrast extravasation into the coronary vasculature, in native coronary vessels >2.0mm in diameter.

The Celosia™ Covered Stent has also been used to treat the following conditions:

Hematoma
Ruptures
Dissections
Fistulas
Aneurysms:
- Pseudo Aneurysms
- Excluded Aneurysms
- Fenestrated Aneurysms

Saphenous Vein Grafts
Muscle Branching
Carotid Blowouts
Degenerated Vein Grafts

Celosia™ Covered Stent



Manufactured in the USA

FEATURES

US Patented and Proven Direct-Stent® Platform
- Hybrid stent cell design for optimum radial strength
- Variable width struts for superior flexibility

Patented Micro-porous ePTFE Polymer
- Enhances hemocompatibility
- Promotes endothelialization

Proprietary Manufacturing Technology
- Ensuring high crimp retention
- Excellent navigability due to a unique balloon pillowing technology and the stent design
- Optimum trackability and deliverability in tortuous anatomy

Case I

CASE SUMMARY:
Patient with severe 88% stenotic occlusion in the right coronary artery. Stenting was performed using a Celosia™ Covered Stent without previous dilation using balloon angioplasty. Post-procedural vessel patency confirmed.

CASE DETAILS:
55 years of age male patient with family history of CAD and hypertension. Previous documented myocardial infarction. No surgical, interventional, or endovascular procedures performed prior to the study. Diagnostic QCA revealed severe stenotic lesion in the right coronary artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:
Weight: 93kg, Height: 160cm, Blood pressure: 140/80, HR: 61/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):
BUN: 32mg/dl, Sodium NA: 147mEq/L, Potassium K: 4.2mEq/L, Chloride CL: 103mEq/L, Calcium CA: 1.21mmol/L, Creatinine: 0.97 mg/dl, Glucose GL: 75mg/dl.

Hemoglobin HGB: 14.2g%, Hematocrit: 43%, Platelets: 182,000/mm^3, Part Thrombin Time PPT: 33.9s, Thrombin TTIME: 77.5%, Fibrinogen FBGN: 306mg/dl.

PHARMACOLOGICAL TREATMENT:
ASA 125mg, Carvedilol 6.25mg bid, Iopamidol (contrast agent): 150cc.

DIAGNOSIS CATHETERIZATION:

Patient presented severe 88% lesion in the right coronary artery (Figure 1). QCA of the left main coronary artery showed no occlusions. Left anterior descending was of medium caliber with no significant stenotic lesions; diagonal branches with no lesions. Circumflex artery of medium caliber, non-dominant with ostium lesion of 50% with good distal patency; marginal arteries of good caliber and with no lesions. Dominant right coronary artery of good caliber with 89% stenotic lesion in the third segment with good patency in the distal section. Occlusion was ø1.0mm with length of 12.7mm.

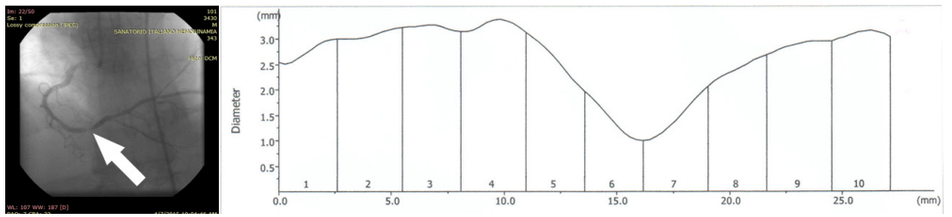


Figure 1: Severe 88% lesion in the third segment of the right coronary.

INTERVENTIONAL STRATEGY:

Puncture of the right common femoral artery with a 6F introducer. Using a JR3 guide catheter (6F) and a 0.014" guidewire, stenting with no pre-dilation was performed with a 3.0 x 13mm Celosia™ Covered Stent in the distal right coronary artery. Stent delivery system tracked with ease into the lesion site and expanded at 14atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection.

FINAL RESULTS:

Lesion in target vessel was able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Stent adequately and successfully deployed at target location; retraction of delivery system confirmed. QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter was 2.57mm with a stenotic percent improvement of 64%.

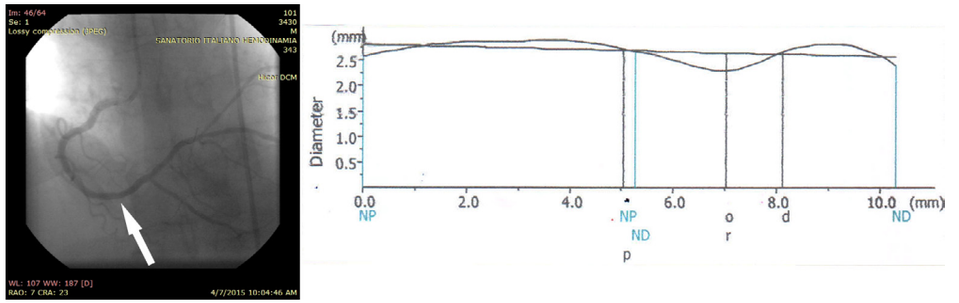


Figure 2: 64% stenotic improvement post-implantation of the Celosia™ Covered stent in the right coronary artery.

CONCLUSION:

Device was able to cross the stenotic lesion site without the need to predilate. Ischemic cardiopathy with severe lesion in the third segment of the right coronary successfully treated with Celosia™ Covered Stent.

Case II

CASE SUMMARY:
Patient with severe 63% stenotic occlusion in the proximal segment of the first marginal branch of the circumflex coronary artery; first stent implanted missed the lesion proximally, so a second stent was successfully deployed overlapping the first to relieve the stenotic obstruction. Left anterior descending artery presented 98% severe proximal lesion. Stenting was performed using Celosia™ Covered Stents without previous dilation using balloon angioplasty in both cases. Post-procedural vessel patency confirmed.

CASE DETAILS:
61 years of age male patient with hypertension and diabetes, as well as family history of CAD. No surgical, interventional, or endovascular procedures performed prior to the study. Diagnostic QCA revealed severe stenotic lesion in the first marginal branch of the circumflex artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:
Weight: 79kg, Height: 160cm, Blood pressure: 128/58, HR: 89/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TESTS (METABOLIC AND CHEMISTRY/HEMATOLOGY)
BUN: 41mg/dl, Sodium NA: 147mEq/L, Potassium K: 5.6mEq/L, Chloride CL: 103mEq/L, Calcium CA: 1.20mmol/L, Creatinine: 1.15 mg/dl, Glucose GL: 71mg/dl.

Hemoglobin HGB: 14.2g%, Hematocrit: 43%, Platelets: 286,000/mm³, Part Thrombin Time PPT: 33.7s, Thrombin TTIME: 89.2%, Fibrinogen FBGN: 306mg/dl.

PHARMACOLOGICAL TREATMENT
ASA 125mg, Clopidogrel 75mg, Iopamidol (contrast agent): 150cc.

DIAGNOSIS CHARACTERIZATION
Patient presented no lesions in neither the right coronary artery nor the left main coronary artery. Left anterior descending of medium caliber with 98% severe proximal lesion of length 6.78mm and ø0.32mm with good distal patency; diagonal branches showed no significant stenotic lesions. Dominant circumflex artery of medium caliber, with no significant stenotic lesions; first marginal branch of good caliber with 63% stenotic lesion of 3.28mm in length and ø0.78mm in the proximal segment; good distal patency.

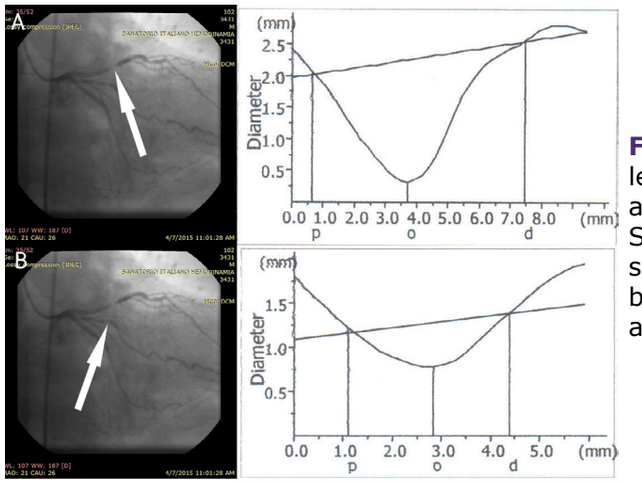


Figure 1: (A) Severe 98% lesion in the proximal left anterior descending. (B) Severe 63% stenotic lesion in the first marginal branch of the circumflex artery.

INTERVENTIONAL STRATEGY
Puncture of the right common femoral artery with a 6F introducer. Using an Extraback guide catheter (6F) and a 0.014" guidewire, stenting with no predilation of the proximal LAD with a 3.0 x 13mm Celosia™ Covered Stent was successfully performed. Stent delivery system tracked with ease into the lesion site and expanded at 14atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection.
Stenting of the first marginal LCX was performed with a 2.5 x 13 Celosia™ Covered Stent. At the moment of balloon inflation implant missed the bulk of the stenotic lesion proximally. A second Celosia™ Covered Stent (2.5 x 16mm) was then tracked past the distal end of the implanted stent and deployed at 14atm for 30 seconds to overlap 2mm inside the first stent. Successful implant was confirmed by QCA with no angiographic evidence of overlapping stents migration or vessel dissection.

FINAL RESULTS

Lesions in target vessel were able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Implant in the proximal LAD adequately and successfully deployed at target location; retraction of delivery system confirmed. Successful implant of 2 overlapping stents in the marginal branch of the LCX confirmed in angiography. In both cases, QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter was 1.80mm with a stenotic percent improvement of 51% in the proximal LAD, and 1.97mm with a stenotic percent improvement of 42% in the marginal LCX (Figure 2).

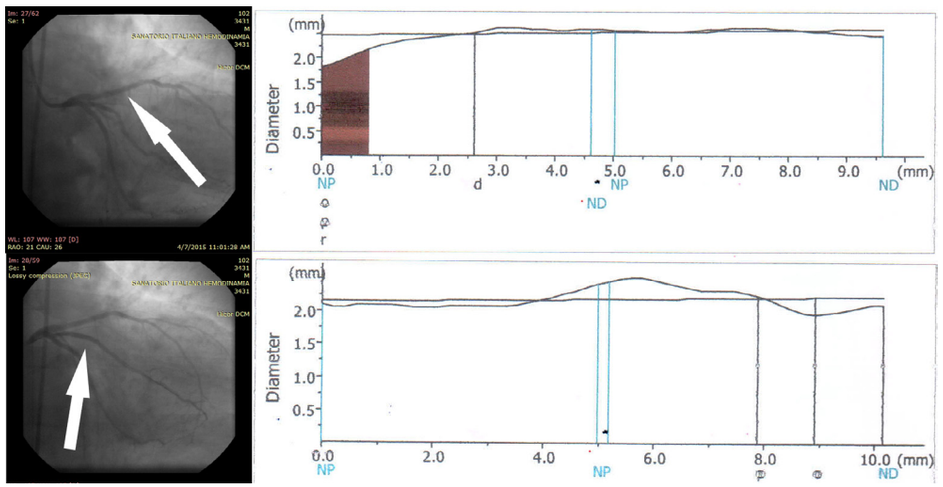


Figure 2: (A) Post-procedure 51% stenotic improvement with the Celosia™ Covered Stent in the proximal LAD. (B) Post-procedure 42% stenotic improvement in the first marginal branch of the LCX with 2 overlapping Celosia™ Covered Stents.

CONCLUSIONS

In both cases, device was able to cross stenotic lesion sites without the need to pre-dilate. Ischemic cardiopathy with severe lesion in the proximal LAD and first marginal LCX were successfully treated with Celosia™ Covered Stents. Stents proved to be able to deploy overlapping without the risk of stent migration or vessel dissection.

Case III

CASE SUMMARY:

Patient with severe 74% stenotic occlusion in the medial left anterior descending coronary artery; challenging case because of patient's tortuous vasculature. Stenting was performed using a Celosia™ Covered Stent without previous dilation using balloon angioplasty. Post-procedural vessel patency confirmed.

CASE DETAILS:

72 years of age female patient with hypertension; no family history of CAD. No surgical, interventional, or endovascular procedures performed prior to the study. Patient presented a severe case of kyphoscoliosis and spondylosis which made the tracking in the descending aorta challenging. Diagnostic QCA revealed severe stenotic lesion in the mid-section of the left anterior descending coronary artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:

Weight: 75kg, Height: 150cm, Blood pressure: 160/80, HR: 55/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):

BUN: 36mg/dl, Sodium NA: 146mEq/L, Potassium K: 5.2mEq/L, Chloride CL: 102mEq/L, Calcium CA: 1.19mmol/L, Creatinine: 0.81 mg/dl, Glucose GL: 80mg/dl.

Hemoglobin HGB: 12.4g%, Hematocrit: 37%, Platelets: 261,000/mm^3, Part Thrombin Time PPT: 33.1s, Thrombin TTIME: 90%, Fibrinogen FBGN: 301mg/dl.

PHARMACOLOGICAL TREATMENT:

ASA 125mg, Carvedilol 25mg bid, Clopidogrel 75mg, Iopamidol (contrast agent): 150cc.

DIAGNOSIS CATHETERIZATION:

Patient presented no lesions in neither the right coronary artery nor the main left coronary artery. The left anterior descending artery was of good caliber with a 74% stenotic lesion with length of 7.90mm and ø0.72mm in the medial section; no lesions in the diagonal branches (Figure 1). The circumflex artery was dominant of good caliber with no lesions; the second marginal branch was thin with 95% distal stenotic lesion.

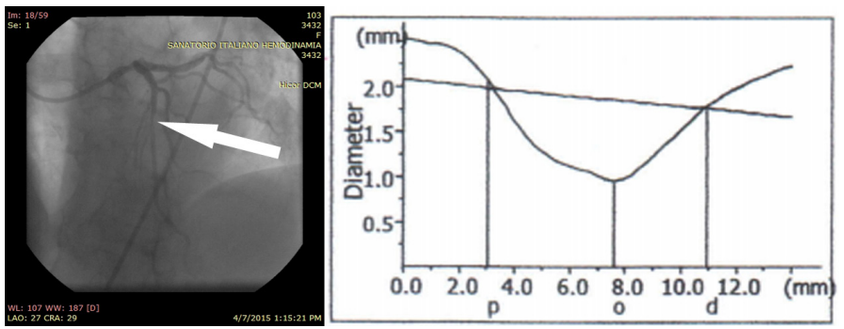


Figure 1: Severe 74% lesion in the mid-section of the LAD.

INTERVENTIONAL STRATEGY:

Puncture of the right common femoral artery with a 6F introducer. Using an Extraback guide catheter (6F) and a 0.014" guidewire, stenting with no pre-dilation was performed with a 2.5 x 16mm Celosia™ Covered Stent in the medial LAD. Stent delivery system tracked with ease up the descending aorta despite tortuous vasculature and into the lesion site. Stent expanded at 14atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection.

FINAL RESULTS:

Lesion in target vessel was able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Stent adequately and successfully deployed at target location; retraction of delivery system confirmed. QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter of the medial LAD was 3.15mm with a stenotic percent improvement of 57.26% (Figure 2).

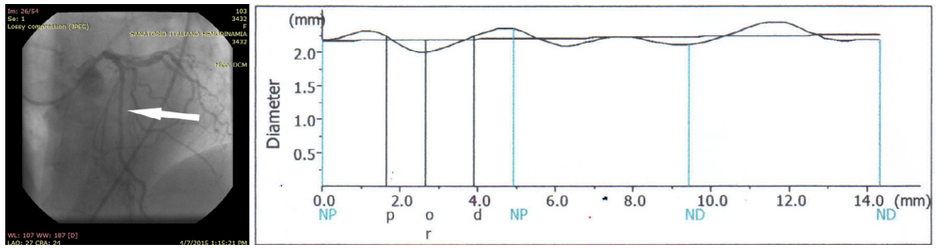


Figure 2: 57% stenotic improvement post-implantation of the Celosia™ Covered stent in the medial LAD.

CONCLUSION:

Device was able to track past the tortuous descending aorta and across the stenotic lesion site without the need to pre-dilate. Ischemic cardiopathy with severe lesion in the medial left anterior descending artery successfully treated with Celosia™ Covered Stent.

Case IV

CASE SUMMARY:
Patient with severe 86% and 78% thrombous occlusions in the distal and medial segments of the right coronary artery respectively. Stenting was performed using Celosia™ Covered Stents in both segments without previous dilation using balloon angioplasty. Post-procedural vessel patency confirmed.

CASE DETAILS:
51 years of age male patient with hypertension, and well as family history of CAD; previously documented myocardial infarction. No surgical, interventional, or endovascular procedures performed prior to the study. Diagnostic QCA revealed severe thrombous occlusions lesion in the distal and mid segments of the right coronary artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:
Weight: 71kg, Height: 164cm, Blood pressure: 110/70, HR: 78/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):
BUN: 29mg/dl, Sodium NA: 145mEq/L, Potassium K: 4.6mEq/L, Chloride CL: 102mEq/L, Calcium CA: 1.25mmol/L, Creatinine: 0.90 mg/dl, Glucose GL: 74mg/dl.

Hemoglobin HGB: 16.5g%, Hematocrit: 50%, Platelets: 250,000/mm³, Part Thrombin Time PPT: 33.8s, Thrombin TTIME: 78.7%, Fibrinogen FBGN: 303mg/dl.

PHARMACOLOGICAL TREATMENT:
ASA 125mg, Clopidogrel 75mg, Iopamidol (contrast agent): 150cc.

DIAGNOSIS CATHETERIZATION:
Patient presented no lesions in neither the left main coronary artery nor the left anterior descending. Circumflex artery and its marginal branches showed no significant lesions. Right coronary artery is non-dominant and of good caliber. It presents severe thrombous occlusions in both the distal (85.7% occlusion with length of 7.14mm and ø0.85mm) and medial (77.38% occlusion with length of 6.98mm and ø1.18mm) sections (Figure 1).

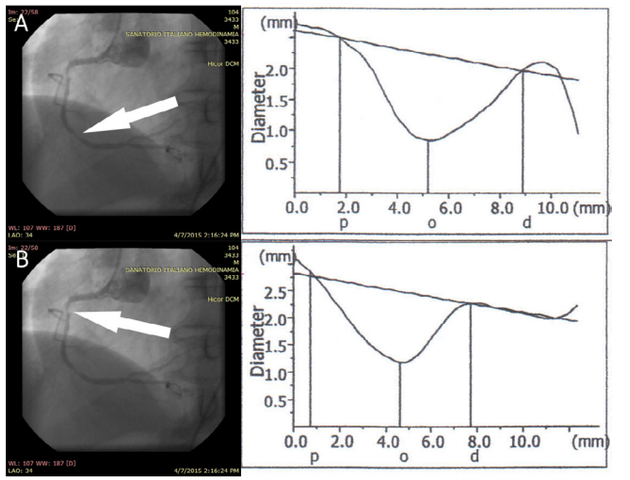


Figure 1: (A) Severe 86% thrombous occlusion in the distal RCA. (B) Severe 77% stenotic thrombous occlusion in the medial RCA.

INTERVENTIONAL STRATEGY:
Puncture of the right common femoral artery with a 6F introducer. Using a JR guide catheter (6F) and a 0.014" guidewire, stenting with no pre-dilation of the distal RCA with a 3.0 x 19mm Celosia™ Covered Stent was successfully performed. Stent delivery system tracked with ease into the lesion site, past the occlusion in the medial section of the artery, and expanded at 14atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection. Stenting of the medial RCA was performed using a 3.0 x 13mm Celosia™ Covered Stent with no pre-dilation expanded at 13am for 30 seconds. Device was able to track easily through the vasculature and into the lesion site. Successful implant was confirmed by QCA with no angiographic evidence of overlapping stents migration or vessel dissection.

FINAL RESULTS:

Lesions in target vessel were able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Implants in both the distal and medial RCA adequately and successfully deployed at target location; retraction of delivery system confirmed. In both cases, QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter in the distal RCA was 2.23mm with a thrombous percent improvement of 62.8%, and 2.57mm with a thrombous percent improvement of 62.12% in the medial RCA (Figure 2).

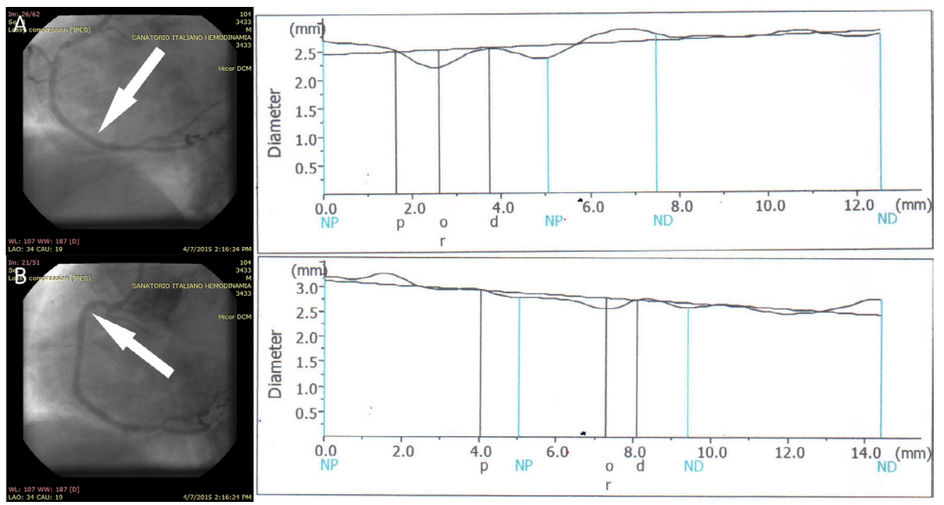


Figure 2: (A) Post-procedure 62% occlusion improvement with the Celosia™ Covered Stent in the distal RCA. (B) Post-procedure 62% occlusion improvement in the medial RCA with Celosia™ Covered Stents.

CONCLUSION:

In both cases, device was able to cross thrombous lesion sites without the need to pre-dilate. Ischemic cardiopathy with severe lesion in the distal and medial RCA were successfully treated with Celosia™ Covered Stents.

Case V

CASE SUMMARY:

Patient with severe 95% stenotic lesion in the medial circumflex coronary artery and 99% stenotic lesion in the medial right coronary artery. Patient presented severely tortuous anatomy caused by hardened stenotic plaque in both the proximal LCX and the medial RCA. Stenting was performed using Celosia™ Covered Stents in both arteries with previous dilation using balloon angioplasty. Post-procedural vessel patency confirmed in both cases.

CASE DETAILS:

46 years of age male patient with hypertension, and well as family history of CAD; previously documented myocardial infarction. No surgical, interventional, or endovascular procedures performed prior to the study. Diagnostic QCA revealed severe thrombous occlusions lesion in mid segments of the right coronary artery and the proximal circumflex artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:

Weight: 70kg, Height: 158cm, Blood pressure: 120/80, HR: 80/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):

BUN: 35mg/dl, Sodium NA: 147mEq/L, Potassium K: 4.8mEq/L, Chloride CL: 103mEq/L, Calcium CA: 1.22mmol/L, Creatinine: 1.26 mg/dl, Glucose GL: 94mg/dl.

Hemoglobin HGB: 15.1g%, Hematocrit: 45%, Platelets: 329,000/mm^3, Part Thrombin Time PPT: 33.6s, Thrombin TTIME: 92.5%, Fibrinogen FBGN: 300mg/dl.

PHARMACOLOGICAL TREATMENT:

ASA 125mg, Clopidogrel 75mg, Iopamidol (contrast agent): 150cc.

DIAGNOSIS CATHETERIZATION:

Patient presented no lesions in the left main coronary artery. Left anterior descending was dominant and of good caliber; atheromatous plaque present but with no significant stenotic lesions; diagonal branches were thin and without lesions. Circumflex artery was dominant with 95% (length of 7.87mm, ø0.81mm) severe lesion at the medial segment, distal segment was clear; marginal branches showed no stenotic lesions. Right coronary artery was non-dominant with a 99% (length of 5.74mm, ø0.46mm) severe lesion at the medial segment (Figure 1).

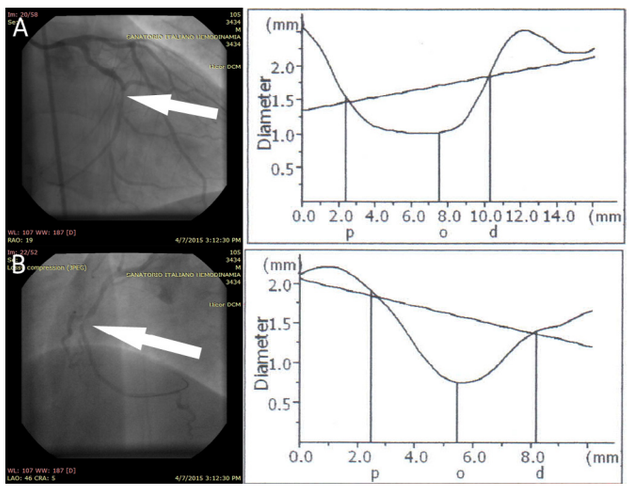


Figure 1: (A) Severe 95% stenotic lesion at the medial segment of the LCX. (B) Severe 99% stenotic occlusion at the medial RCA.

INTERVENTIONAL STRATEGY:

Puncture of the right common femoral artery with a 6F introducer. Pre-dilation was performed because of the severity of the stenotic plaque profile in both LCX and RCA. Using an Extraback guide catheter (6F) and a 0.014" guidewire, pre-dilation of the medial LCX was performed using a 3.0 x 20mm PTCA balloon catheter. Stent delivery system tracked with ease into the pre-dilated lesion site, past the occlusion in the medial section of the artery, and expanded to successfully deploy a 3.0 x 16mm Celosia™ Covered Stent at 14atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection. Stenting of the pre-dilated (3.0 x 16mm PTCA balloon) medial RCA was performed using a 3.0 x 19mm Celosia™ Covered Stent at 18atm for 30 seconds. Device was able to track easily through the vasculature and into the lesion site. Successful implant was confirmed by QCA with no angiographic evidence of stent migration or vessel dissection.

FINAL RESULTS:

Lesions in target vessel were able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Implants in both the medial LCX and RCA adequately and successfully deployed at target location; retraction of delivery system confirmed. In both cases, QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter in the medial LCX was 3.05mm with a stenotic percent improvement of 70%, and 2.42mm with a thrombous percent improvement of 79% in the medial RCA (Figure 2).

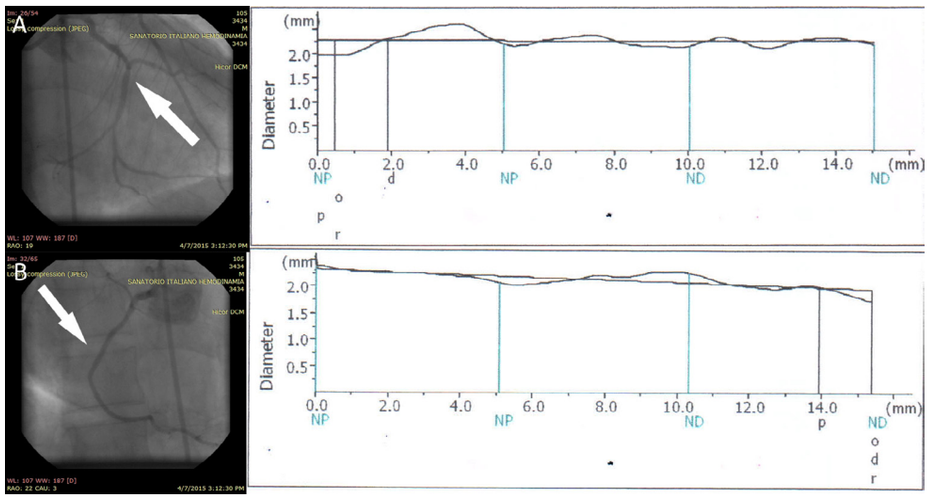


Figure 2: (A) Post-procedure 70% occlusion improvement with the Celosia™ Covered Stent in the medial LCX. (B) Post-procedure 79% occlusion improvement in the medial RCA with Celosia™ Covered Stent.

CONCLUSION:

In both cases, device was able to cross thrombous lesion sites. Ischemic cardiopathy with severe lesion in the medial LCX and RCA were successfully treated with Celosia™ Covered Stents.

Case VI

CASE SUMMARY:
Patient with severe 99% stenotic occlusion in the proximal left anterior descending coronary artery; challenging case because of patient's tortuous vasculature and severe atheromatous occlusion. Stenting was performed using a Celosia™ Covered Stent with previous dilation using balloon angioplasty. Post-procedural vessel patency confirmed.

CASE DETAILS:
46 years of age male patient with hypertension and family history of CAD. Previous documented myocardial infarction. No surgical, interventional, or endovascular procedures performed prior to the study. Patient presented a severe case of atheromatous plaque occlusion in the proximal left anterior descending artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:
Weight: 95kg, Height: 165cm, Blood pressure: 130/70, HR: 71/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):
BUN: 45mg/dl, Sodium NA: 143mEq/L, Potassium K: 4.5mEq/L, Chloride CL: 100mEq/L, Calcium CA: 1.17mmol/L, Creatinine: 1.12 mg/dl, Glucose GL: 145mg/dl.

Hemoglobin HGB: 16.3g%, Hematocrit: 49%, Platelets: 182,000/mm³, Part Thrombin Time PPT: 33.7s, Thrombin TTIME: 82.6%, Fibrinogen FBGN: 303mg/dl.

PHARMACOLOGICAL TREATMENT:
ASA 125mg, Clopidogrel 75mg, Iopamidol (contrast agent): 100cc.

DIAGNOSIS CATHETERIZATION:
Patient presented no lesions in neither the right coronary artery nor the main left coronary artery. The left anterior descending artery was dominant and of good caliber with a severe 99% stenotic lesion with length of 7.70mm and ø0.53mm in the proximal segment; no lesions were found in the diagonal branches (Figure 1). The circumflex artery was non-dominant and of good caliber with neither lesions in the main vessel nor in the marginal branches.

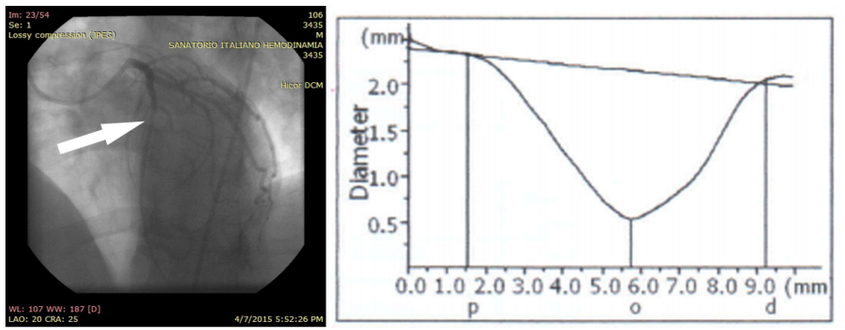


Figure 1: Severe 99% stenotic lesion in the proximal LAD.

INTERVENTIONAL STRATEGY:
Puncture of the right common femoral artery with a 6F introducer. Using an Extraback guide catheter (6F) and a 0.014" guidewire, stenting with no predilation was attempted using a 2.5 x 16mm Celosia™ Covered Stent in the proximal LAD. Stenotic plaque was too occlusive for the stent to track past the lesion (ø<0.6mm). Furthermore, the occlusion was significantly hardened and could not be removed by means of pushing the stent catheter. Device was successfully retracted into the guide catheter without experiencing stent dislodgement. A 3.0 x 16mm PTCA balloon catheter was used to relieve the occlusion by pre-dilating the vessel. The 2.5 x 16mm Celosia™ Covered stent was re-inserted and tracked past the stenotic lesion, where it expanded at 14atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection.

FINAL RESULTS:
Lesion in target vessel was able to be accessed with stent delivery system after pre-dilation; balloon marker bands confirmed to be visible under fluoroscopy. Stent successfully retracted and then re-inserted to fully deploy and the target location; retraction of delivery system confirmed. QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter of the proximal LAD was 1.77mm with a stenotic percent improvement of 81.23% (Figure 2).

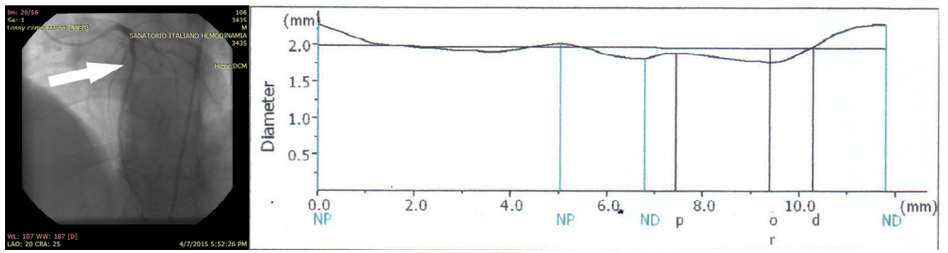


Figure 2: 81% stenotic improvement post-implantation of the Celosia™ Covered stent in the proximal LAD.

CONCLUSION: Device was able to track past the tortuous descending aorta and across the stenotic lesion site without the need to pre-dilate. Ischemic cardiopathy with severe lesion in the proximal left anterior descending artery successfully treated with Celosia™ Covered Stent.

Case VII

CASE SUMMARY:
Patient with severe 92% stenotic occlusion in the proximal right coronary artery. Stenting was performed using a Celosia™ Covered Stent without previous dilation using balloon angioplasty. Post-procedural vessel patency confirmed.

CASE DETAILS:
56 years of age male patient with hypertension and diabetes, in addition to documented family history of CAD. Previous documented myocardial infarction. No surgical, interventional, or endovascular procedures performed prior to the study. Diagnostic QCA revealed severe stenotic lesion in the proximal right coronary artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:
Weight: 94kg, Height: 171cm, Blood pressure: 160/100, HR: 72/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):
BUN: 67mg/dl, Sodium NA: 144mEq/L, Potassium K: 5.2mEq/L, Chloride CL: 101mEq/L, Calcium CA: 1.20mmol/L, Creatinine: 1.33 mg/dl, Glucose GL: 76mg/dl.

Hemoglobin HGB: 16.5g%, Hematocrit: 50%, Platelets: 306,000/mm^3, Part Thrombin Time PPT: 33.0s, Thrombin TTIME: 91.7%, Fibrinogen FBGN: 303mg/dl.

PHARMACOLOGICAL TREATMENT:

ASA 125mg, Carvedilol 6.25mg bid, Metformin 800mg, Insulin NPH, Iopamidol (contrast agent): 150cc.

DIAGNOSIS CATHETERIZATION:

Patient presented severe lesion in the proximal right coronary artery (Figure 1). QCA of the left main coronary artery showed no occlusions. Left anterior descending was of medium caliber with no significant stenotic lesions; diagonal branches with no lesions. Circumflex artery of medium caliber, non-dominant with mild proximal lesion with good distal patency; marginal arteries of good caliber and with no lesions. Dominant right coronary artery of good caliber with 92% stenotic lesion in the first segment with good patency in the distal section. Occlusion was ø0.85mm with length of 8.31mm.

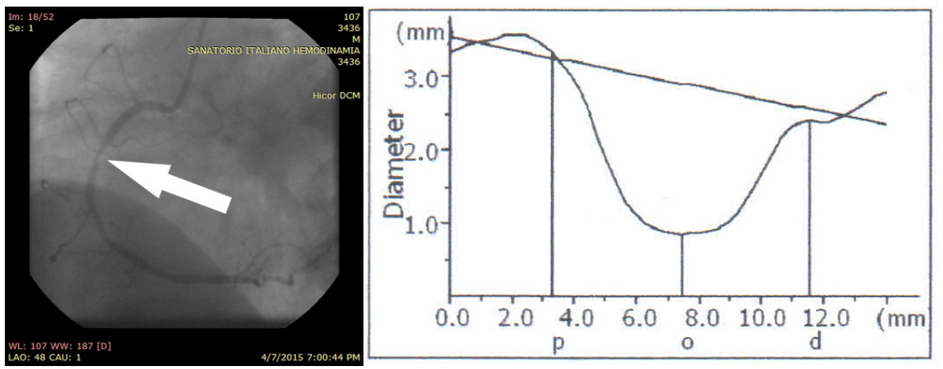


Figure 1: Severe 92% lesion in the proximal RCA.

INTERVENTIONAL STRATEGY:

Puncture of the right common femoral artery with a 6F introducer. Using a JR3 guide catheter (6F) and a 0.014" guidewire, stenting with no predilation was performed with a 3.0 x 16mm Celosia™ Covered Stent in the proximal right coronary artery. Stent delivery system tracked with ease into the lesion site and expanded at 14atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection.

FINAL RESULTS:

Lesion in target vessel was able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Stent adequately and successfully deployed at target location; retraction of delivery system confirmed. QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter of the proximal RCA was 2.39mm with a stenotic percent improvement of 69.8%.

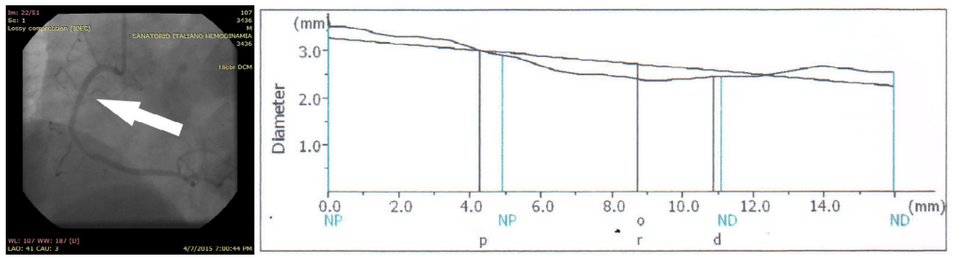


Figure 2: 69.8% stenotic improvement post-implantation of the Celosia™ Covered stent in the proximal right coronary artery

CONCLUSION:

Device was able to cross the stenotic lesion site without the need to predilate. Ischemic cardiopathy with severe lesion in the first segment of the right coronary successfully treated with Celosia™ Covered Stent.

Case VIII

CASE SUMMARY:
Patient with 2 severe stenotic lesions in the left anterior descending coronary artery. Patient presented severely tortuous anatomy caused by hardened stenotic plaque at the proximal and distal LAD. Stenting was performed using Celosia™ Covered Stents in both arteries with previous dilation using balloon angioplasty on the proximal lesion only. Post-procedural vessel patency confirmed in both cases.

CASE DETAILS:
68 years of age female patient with hypertension, and well as family history of CAD. No surgical, interventional, or endovascular procedures performed prior to the study. Diagnostic QCA revealed severe stenotic occlusion lesions in the distal and mid segments of the right coronary artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:
Weight: 49kg, Height: 158cm, Blood pressure: 110/70, HR: 83/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):

BUN: 101mg/dl, Sodium NA: 144mEq/L, Potassium K: 5.5mEq/L, Chloride CL: 101mEq/L, Calcium CA: 1.21mmol/L, Creatinine: 2.79 mg/dl, Glucose GL: 80mg/dl.

Hemoglobin HGB: 9.8g%, Hematocrit: 30%, Platelets: 216,000/mm³, Part Thrombin Time PPT: 33.9s, Thrombin TTIME: 79.3%, Fibrinogen FBGN: 313mg/dl.

PHARMACOLOGICAL TREATMENT:
ASA 125mg, Clopidogrel 75mg, Iopamidol (contrast agent): 150cc.

DIAGNOSIS CATHETERIZATION:
Patient presented no lesions in neither the left main coronary artery nor the right coronary artery. Left anterior descending was dominant with tortuous anatomy and of good caliber; atheromatous plaque in the distal (63% occlusion, length of 7.12mm and ø0.78mm) and proximal section (96% occlusion, length of 8.98mm and ø0.50mm) caused severe stenotic lesions (Figure 1); diagonal branches were thin and without lesions. Circumflex artery was non-dominant of medium caliber with no significant lesions; distal segment was clear; marginal branches showed no stenotic lesions.

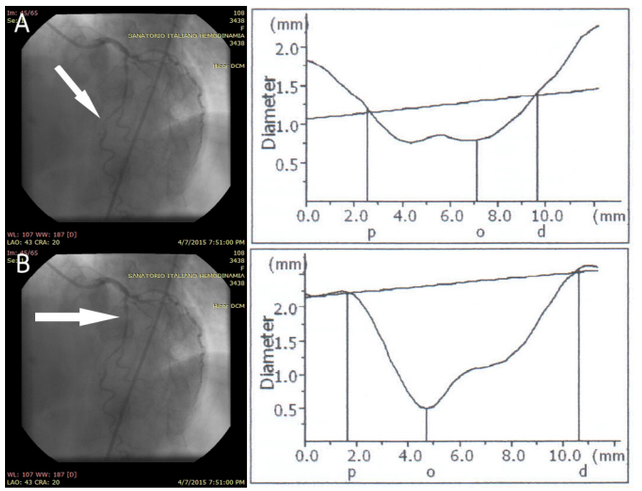


Figure 1: (A) Severe 63% stenotic lesion at the distal segment of the LAD. (B) Severe 96% stenotic occlusion at the medial LAD.

INTERVENTIONAL STRATEGY:
Puncture of the right common femoral artery with a 6F introducer. Even though stenotic occlusion made anatomy of the vessel exceedingly tortuous a 2.5 x 16mm Celosia™ Covered Stent was able to track past the proximal and distal lesions with no significant resistance. Stenting was performed at 14atm for 30 seconds on the distal LAD. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection; device retracted successfully.

A 3.0 x 16mm Celosia™ Covered Stent was used to dilate the proximal lesion. However, stenotic hardened calcification prevent the stent to get past the lesion. Device was successfully retracted into the guide catheter and a 3.0 x 23mm PTCA balloon was inserted to pre-dilate the vessel. The Celosia™ Covered stent was then re-inserted and expanded at 16atm for 30 seconds to successfully alleviate the stenotic occlusion. Device was able to track easily through the vasculature and into the lesion site. Successful implant was confirmed by QCA with no angiographic evidence of stent migration or vessel dissection in the proximal and medial LAD.

FINAL RESULTS:

Lesions in target vessel were able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Implants in both the distal and proximal LAD adequately and successfully deployed at target location; retraction of delivery system confirmed. In both cases, QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter in the distal LAD was 1.64mm with a stenotic percent improvement of 36%, and 2.35mm with a stenotic percent improvement of 85% in the proximal LAD (Figure 2).

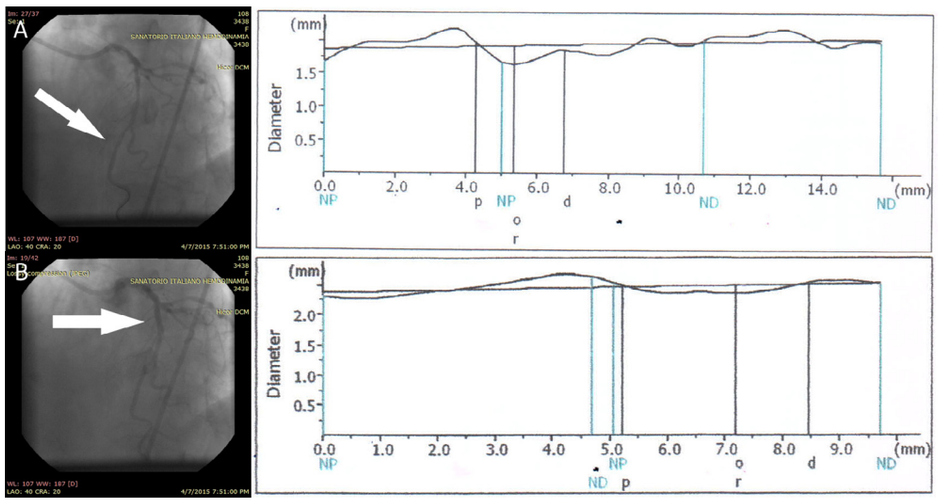


Figure 2: (A) Post-procedure 36% occlusion improvement with the Celosia™ Covered Stent in the distal LAD. (B) Post-procedure 85% occlusion improvement in the proximal LAD with Celosia™ Covered Stent.

CONCLUSION:

In both cases, device was able to cross thrombous lesion sites. Ischemic cardiopathy with severe lesion in the distal and proximal LAD were successfully treated with Celosia™ Covered Stents.

Case IX

CASE SUMMARY:

Patient with 2 in tandem 99% severe stenotic lesions in the distal right coronary artery. Severe stenotic 60% lesion in the proximal left descending artery. Patient presented severely tortuous anatomy caused by hardened stenotic plaque at the proximal and distal LAD. Stenting was performed using Celosia™ Covered Stents in both arteries with previous dilation using balloon angioplasty on the proximal lesion only. Post-procedural vessel patency confirmed in both cases.

CASE DETAILS:

56 years of age female patient with hypertension, and well as family history of CAD. No surgical, interventional, or endovascular procedures performed prior to the study. Diagnostic QCA revealed severe stenotic occlusion lesions in the distal and mid segments of the right coronary artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:

Weight: 49kg, Height: 158cm, Blood pressure: 110/70, HR: 83/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):

BUN: 101mg/dl, Sodium NA: 144mEq/L, Potassium K: 5.5mEq/L, Chloride CL: 101mEq/L, Calcium CA: 1.21mmol/L, Creatinine: 2.79 mg/dl, Glucose GL: 80mg/dl.

Hemoglobin HGB: 9.8g%, Hematocrit: 30%, Platelets: 216,000/mm^3, Part Thrombin Time PPT: 33.9s, Thrombin TTIME: 79.3%, Fibrinogen FBGN: 313mg/dl.

PHARMACOLOGICAL TREATMENT:

ASA 125mg, Clopidogrel 75mg, Iopamidol (contrast agent): 150cc.

DIAGNOSIS CATHETERIZATION:

Patient presented a clean left main coronary artery with no lesions. The left anterior descending presented a 90% eccentric proximal stenotic lesion with a second lesion of 60% with clear distal segment. The first diagonal branch is a medium caliber vessel with presence of atheromatous plaque but no significant lesions. The circumflex artery is medium-sized with presence of atheromatous plaque but no significant lesions. The right coronary artery is dominant of medium caliber with 2 99% lesions in tandem at the distal segment.

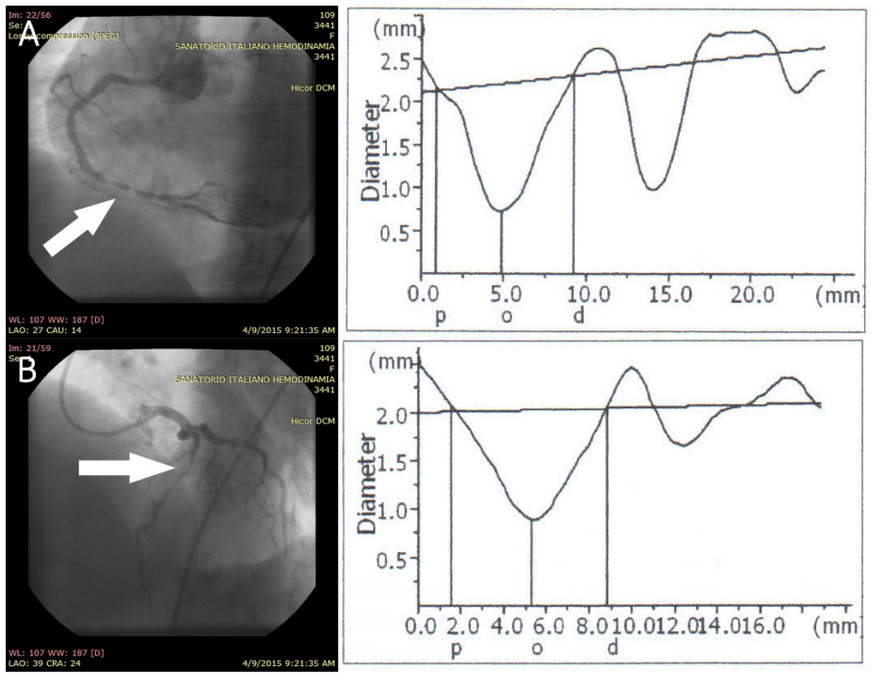


Figure 1: (A) Severe 99% stenotic lesions in tandem at the distal segment of the RCA. (B) Severe 60% stenotic occlusion at the proxima LAD.

INTERVENTIONAL STRATEGY:

Puncture of the right common femoral artery with a 6F introducer. With a 6F JR3 guide catheter and a 0.014" guidewire, pre-dilation of the distal section of the RCA was performed using a 2.5 x 16mm balloon. Stenting was then performed with a single 2.5 x 26mm Celosia™ Covered Stent at 12atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection; device retracted successfully.

With a 6F Extraback guide catheter and 0.014" guidewire the lesion in the proximal LAD was pre-dilated with a 2.5 x 16mm PTCA balloon. Stenting was performed using a 3.0 x 26mm Celosia™ Covered Stent at 12atm for 30 seconds to successfully alleviate the stenotic occlusion. Device was able to track easily through the vasculature and into the lesion site. In both cases, successful implant was confirmed by QCA with no angiographic evidence of stent migration or vessel dissection in neither the distal RCA nor the proximal LAD.

FINAL RESULTS:

Lesions in target vessel were able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Implants in both the distal RAC and the proximal LAD adequately and successfully deployed at target location; retraction of delivery system confirmed. In both cases, QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter in the distal RCA was 2.53mm with a stenotic percent improvement of 80%, and 1.97mm with a stenotic percent improvement of 65% in the proximal LAD (Figure 2).

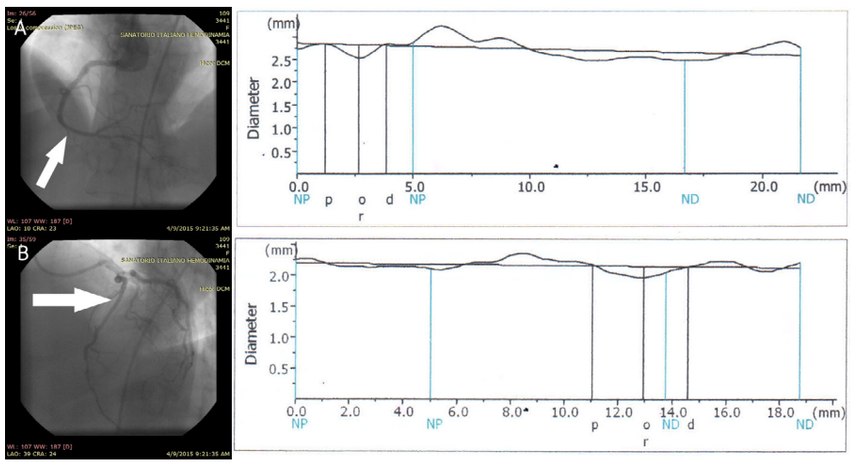


Figure 2: (A) Post-procedure 80% occlusion improvement with the Celosia™ Covered Stent in the distal RCA. (B) Post-procedure 65% occlusion improvement in the proximal LAD with Celosia™ Covered Stent.

CONCLUSION:

In both cases, device was able to cross thrombous lesion sites. Ischemic cardiopathy with severe lesion in the distal RCA and proximal LAD were successfully treated with Celosia™ Covered Stents.

Case X

CASE SUMMARY:
Patient with severe 81% stenotic occlusion in the medial left anterior descending artery. Stenting was performed using a Celosia™ Covered Stent without previous dilation using balloon angioplasty. Post-procedural vessel patency confirmed.

CASE DETAILS:
48 years of age male patient with hypertension and family history of CAD. No previous documented myocardial infarction. No surgical, interventional, or endovascular procedures performed prior to the study. Diagnostic QCA revealed severe stenotic lesion in the medial LAD. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:
Weight: 89kg, Height: 160cm, Blood pressure: 135/80, HR: 72/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):

BUN: 135mg/dl, Sodium NA: 142mEq/L, Potassium K: 5.9mEq/L, Chloride CL: 100mEq/L, Calcium CA: 8.8mmol/L, Creatinine: 10.2 mg/dl, Glucose GL: 86mg/dl.

Hemoglobin HGB: 11.0g%, Hematocrit: 33%, Platelets: 170,000/mm³, Part Thrombin Time PPT: 33.7s, Thrombin TTIME: 83.3%, Fibrinogen FBGN: 304mg/dl.

PHARMACOLOGICAL TREATMENT:
ASA 125mg, Iopamidol (contrast agent): 100cc.

DIAGNOSIS CATHETERIZATION:
Patient presented severe 81% lesion in the mid LAD (Figure 1). QCA of the left main coronary artery showed no occlusions. Diagonal branches of the LAD presented no lesions. Circumflex artery of medium caliber, non-dominant with no lesion and good distal patency; marginal arteries of good caliber and with no lesions. Dominant right coronary artery of good caliber with no significant occlusions and good patency in the distal section. Occlusion was ø0.47mm with length of 4.83mm.

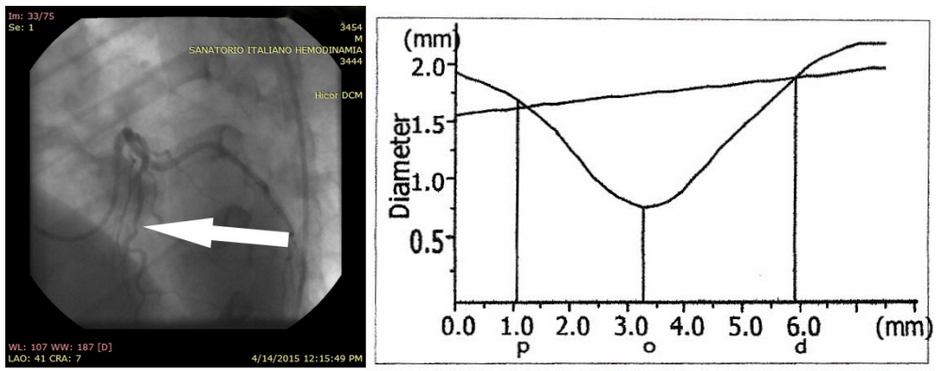


Figure 1: Severe 81% lesion in the second segment of the left anterior descending coronary artery.

INTERVENTIONAL STRATEGY:
Puncture of the right common femoral artery with a 6F introducer. Using a JR3 guide catheter (6F) and a 0.014" guidewire, stenting with no predilation was performed with a 2.5 x 13mm Celosia™ Covered Stent in the medial LAD. Stent delivery system tracked with ease into the lesion site and expanded at 11atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection.

FINAL RESULTS:
Lesion in target vessel was able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Stent adequately and successfully deployed at target location; retraction of delivery system confirmed. QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter was 1.64mm with a stenotic percent improvement of 56%.

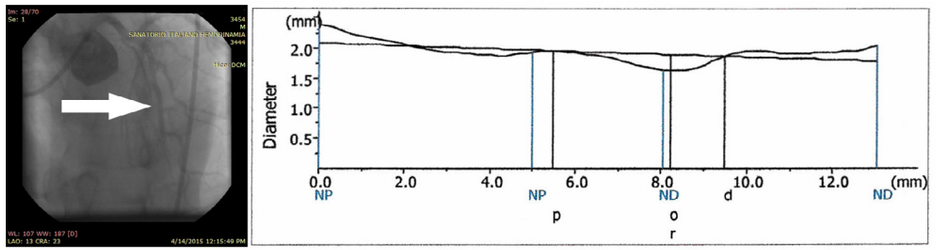


Figure 2: 56% stenotic improvement post-implantation of the Celosia™ Covered stent in the mid LAD.

CONCLUSION:

Device was able to cross the stenotic lesion site without the need to pre-dilate. Ischemic cardiopathy with severe lesion in the second segment of the left anterior descending coronary artery successfully treated with Celosia™ Covered Stent.

Case XI

CASE SUMMARY:

Patient with severe 91% stenotic occlusion in the proximal left anterior descending coronary artery. Stenting was performed using a Celosia™ Covered Stent without previous dilation using balloon angioplasty. Post-procedural vessel patency confirmed.

CASE DETAILS:

69 years of age male patient with hypertension in addition to documented family history of CAD. Previous documented myocardial infarction. No surgical, interventional, or endovascular procedures performed prior to the study. Diagnostic QCA revealed severe stenotic lesion in the proximal left anterior coronary artery. Patient admitted the same day of the procedure with previous signed consent of the trial.

Principal Investigator: Dr. Adrian Ebner. Study Coordinator: Dr. Santiago Gallo. Hospital Name: Sanatorio Italiano. Asuncion, Paraguay.

PHYSICAL EXAMINATION:

Weight: 56kg, Height: 159cm, Blood pressure: 110/60, HR: 62/min. Normal chest auscultation: no murmurs, sinus rhythm, normal lungs auscultation.

RELEVANT TESTS AND TREATMENT PRIOR TO CATHETERIZATION

LABORATORY TEST (METABOLIC AND CHEMISTRY/HEMATOLOGY):

BUN: 41mg/dl, Sodium NA: 148mEq/L, Potassium K: 4.6mEq/L, Chloride CL: 108mEq/L, Calcium CA: 0.84mmol/L, Creatinine: 0.84 mg/dl, Glucose GL: 89mg/dl.

Hemoglobin HGB: 15.6g%, Hematocrit: 41.2%, Part Thrombin Time PPT: 37.2, Thrombin TTIME: 12.7%, Fibrinogen FBGN: 234mg/dl.

PHARMACOLOGICAL TREATMENT:

ASA 125mg, Clopidogrel 75mg, Iopamidol (contrast agent): 150cc.

DIAGNOSIS CATHETERIZATION:

Patient presented severe 91% lesion in the proximal LAD (Figure 1). QCA of the dominant left main coronary artery showed no occlusions. Left anterior descending was of medium caliber with no significant stenotic lesions in the second and third segments; diagonal branches with no lesions. Circumflex artery of medium caliber, non-dominant with good distal patency; marginal arteries of good caliber and with no lesions. Non-dominant right coronary artery of good caliber with no significant stenotic lesions and good patency in the distal section. Occlusion was ø0.80mm with length of 6.09mm.

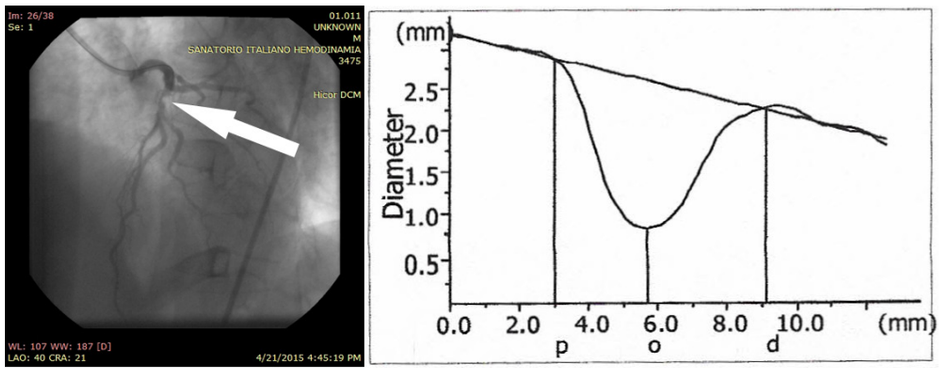


Figure 1: Severe 91% lesion in the proximal LAD.

INTERVENTIONAL STRATEGY:

Puncture of the right common femoral artery with a 6F introducer. Using a JR3 guide catheter (6F) and a 0.014” guidewire, stenting with no pre-dilation was performed with a 2.5 x 19mm Celosia™ Covered Stent in the proximal LAD. Stent delivery system tracked with ease into the lesion site and expanded at 14atm for 30 seconds. Post-dilation performed to ensure stent securement onto the lumen of the vessel with no angiographic evidence of balloon rupture or vessel dissection.

FINAL RESULTS:

Lesion in target vessel was able to be accessed with stent delivery system; balloon marker bands confirmed to be visible under fluoroscopy. Stent adequately and successfully deployed at target location; retraction of delivery system confirmed. QCA shows no lesion residual and TIMI flow evaluation is normal. Post-procedure diameter of the proximal LAD was 1.94mm with a stenotic percent improvement of 57%.

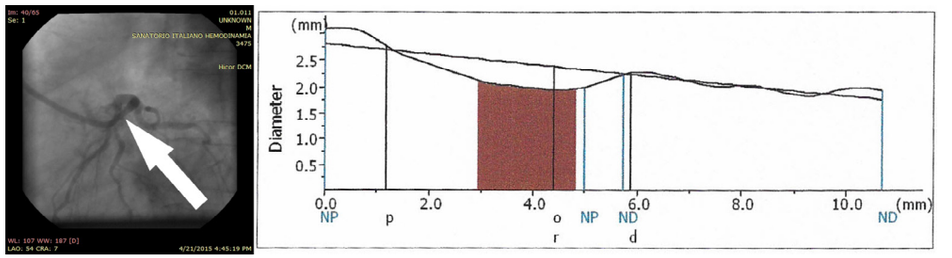
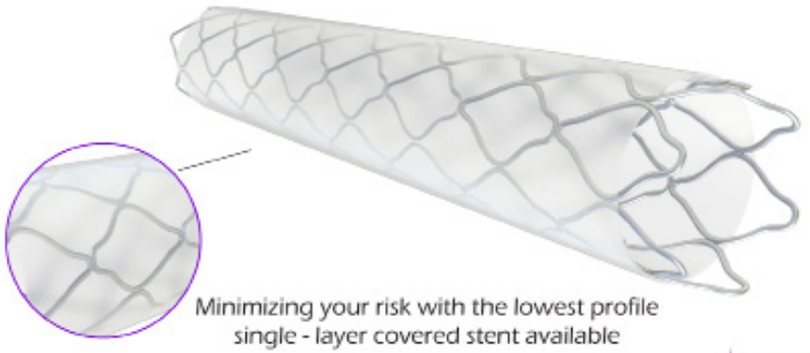


Figure 2: 57.18% stenotic improvement post-implantation of the Celosia™ Covered stent in the proximal LAD.

CONCLUSION:

Device was able to cross the stenotic lesion site without the need to pre-dilate. Ischemic cardiopathy with severe lesion in the first segment of the LAD successfully treated with Celosia™ Covered Stent.

Device Information



Minimizing your risk with the lowest profile single - layer covered stent available

Celosia™ Covered Stent

Features

Stent Design:	Direct-Stent® U.S. Patented Hybrid Cell Design
Stent Material:	Cobalt Chromium
Stent Covering Polymer:	ePTFE
Wall Thickness:	0.076mm / 0.003"
Variable Strut Width:	0.046mm - 0.127mm / 0.0018 - 0.005"
Delivery System:	Rapid Exchange (RX)
Balloon Material:	Semi-Compliant, Nylon Blend
Optimal Deployment Pressure:	6 ATM
Rated Burst Pressure:	16 ATM
Shaft Size (Proximal -Distal):	1.9 - 2.7F
Premounted Profiles:	0.94 - 1.4mm
Tip Entry Profile:	0.017"
Recommended Guidewire:	0.014"
Minimum Guiding Catheter:	5 - 6F
Working Length:	142cm
Stent Diameter:	2.0 - 7.0mm
Stent Length:	5 - 40mm

Comparative Information

General Comparison

Characteristics	InSitu	Bently Innomed	Biotronic
Design	Single Layer Design	Single Stent - Single Layer	Encapsulated Design
Covering	Thin ePTFE Aids in Tracking Highly Biocompatible	Relatively Thick Tubing	Relatively Bulky Polyurethane
Flexibility	Optimal Flexibility	Relatively Stiff	Relatively Flexible
Porosity	Optimal Porosity	Less Porous	Least Porous
Deployment Pressure	Easy to Deploy	Requires High Pressure	Relatively Easy to Deploy
Stent Platform	Flexible Hybrid Open-Closed Cell Design	Closed Cell Design	Open Cell Design
Size Offerings	Most Available	Relatively Less	Least

Technical Comparison

Characteristics	InSitu	Bently Innomed
Size Range (Ø,Length)	2.0 - 7.0mm, 5 - 40mm	2.5 - 5.0mm, 8 - 24mm
Deployment Pressure	6 ATM	11 ATM
Rated Burst Pressure	16 ATM	16 ATM
Covering	ePTFE Film	ePTFE Sleeve
Thickness (ePTFE)	60µm	89µm
Guide Cath Comp.	5F (Ø 2.0 - 7.0mm) 6F (Ø 2.0 - 7.0mm)	5F (Ø 2.5 - 5.0mm)
Crossing Profile	0.9mm	1.1mm
Stent Material	Cobalt Chromium	Cobalt Chromium

Technical Comparison

Characteristics	InSitu	Biotronic
Size Range (Ø,Length)	2.0- 7.0mm, 5 - 40mm	2.5 - 5.0mm, 15 - 26mm
Deployment Pressure	6 ATM	8 ATM
Rated Burst Pressure	16 ATM	16 ATM
Covering	ePTFE Film	Electro Spun polyurethane
Thickness (ePTFE)	60µm	90µm
Guide Cath Comp.	5F (Ø 2.0 - 7.0mm) 6F (Ø 2.0 - 7.0mm)	5F (Ø 2.5 - 4.0mm) 6F (Ø 4.5 - 5.0mm)
Crossing Profile	0.9mm	0.9mm
Stent Material	Cobalt Chromium	Cobalt Chromium

With a nominal deployment pressure of 6 ATM and crossing profile of 0.9mm

The Celosia™ Covered Stent is the most deliverable covered stent available

A Perfect Balance of Flexibility & Radial Strength

- Dr. Adrian Ebner

The Director of the Catheterization Lab and Endovascular Procedures at Sanatorio Italiano Hospital in Asuncion, Paraguay

Why Choose InSitu?

Easy to deploy

InSitu?

- **Best Design**
  - Single-Layer Hybrid Design
  - Cells Expand Independently
  - LOW Profile
  - U.S. Patented
- **Excellent Stent Trackability**
  - HIGH Crimp Retention Force
  - Balloon Pillowing Technology
- **Largest Range of Sizes Available**
- **Made with Patented ePTFE Polymer ensuring HIGHEST Biocompatibility**
  - Ideal Porosity

Greater than 40% availability in the variety and range of stent lengths

Find out more...

To speak with an InSitu team member about the Celosia™ Covered Stent or other devices from our portfolio of Coronary and Peripheral Devices...

Contact sales@insitu-tech.com
or visit us at www.insitu-tech.com

InSitu Technologies® Inc.
Extending Life and Improving Health™

Caution: Federal USA law restricts these devices to sale, distribution and use by or on the order of a physician.

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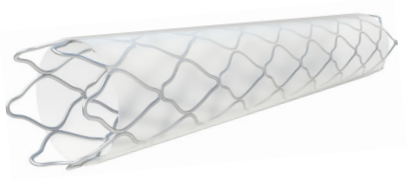

Not only do we offer a one-of-a-kind Covered Stent,
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