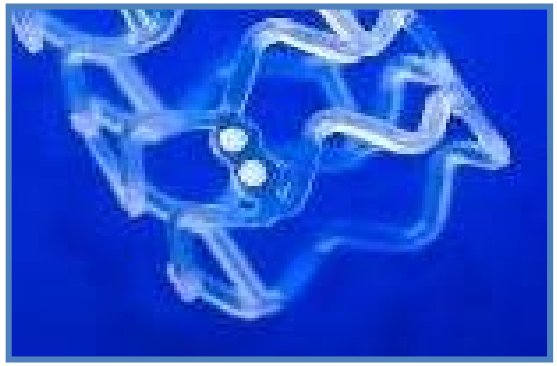
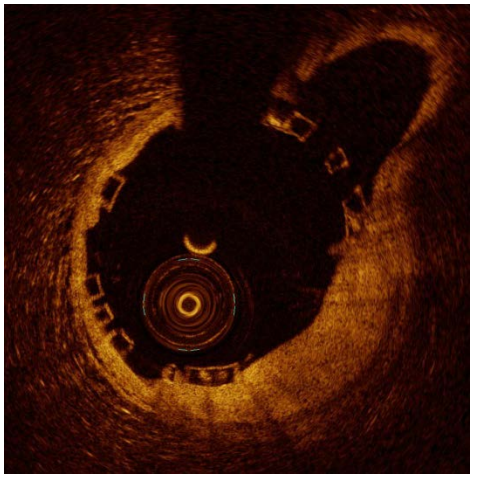
KTO' DA BİYOEMİLEBİLİR VASKÜLER İSKELE KULLANIMININ AVANTAJI VARMI?





Dr. Aylin Hatice Yamaç
Kardiyoloji Kliniği
BezmiÂlem Vakıf Üniversitesi Tıp Fakültesi

KTO Revaskülarizasyon Zorluklar

- Uzun, fibrokalsifik lezyonlar; yoğun plak yükü
- Revaskülarize damarın gerçek çapını belirlemek zor
- Distal damar yatağı takipte genişleyebilir
- Çok sayıda ve uzun stent ihtiyacı (Full metal jacket)
- Daha sonra CABG ?
- Yüksek restenoz riski
- Çok geç stent trombozu

Bardají A, et al. Chronic total occlusion: To treat or not to treat. World J Cardiol. 2014; 6(7):621-9.

Biyoemilebilir Vasküler İskele Avantajlar

- Normal vasküler fizyolojinin restorasyonu
- Vasküler remodeling imkanı/ Geç dönemde lümenin genişlemesi
- Jail yan dalları serbest bırakır
- Cerrahi revask. engel değil
- Non-invaziv görüntüleme mümkün

Medda M, et al. Bioresorbable vascular scaffold (BVS) for in-stent chronic total occlusion: Antegrade recanalization and IVUS-guided BVS implantation by radial access. Cardiovasc Revasc Med. 2016; 17(1):63-5.

PCI sırasında nelere dikkat etmeli?

- BVS'in taşınması ve tam ekspansiyonu için lezyonun hazırlanması çok önemli
- Uzun, kalsifik lezyonlarda;
- predilatasyon ekipman seçimi,
- Damarın gerçek çapının ve BVS ebadinin değerlendirilmesi (IVUS)
- BVS ekspansiyonunu belirlemek için IVUS yada OCT
- Önemli SB korunmalı
- >1 BVS kullanılacak ise minimal overlap (1-2 mm)
- + 0.5 mm NC balon ile postdilatasyon

Vaquerizo B, et al. One-Year Results of Bioresorbable Vascular Scaffolds for Coronary Chronic Total Occlusions. Am J Cardiol. 2016; 117(6):906-17.

Çalışmalar

- CTO-Absorb Registry 12/2014
- Wiebe et al. 01/2015
- Ojeda et al. 06/2015
- Göktekin et al. 10/2015
- Lesiak et al. 06/2016
- Azzalini et al. 09/2016 (DES vs BVS)
- Yamac et al. Ahead of print 12/2016
- Vaka takdimleri

CLINICAL RESEARCH
CORONARY INTERVENTIONS

EuroIntervention 2015;11:555-563 published online ahead of print December 2014

Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study

Beatriz Vaquerizo[1]*, MD; Antonio Barros[1], MD; Sandra Pujadas[1], MD; Ester Bajo[1], NP; Darlene Estrada[1], MD; F. Miranda-Guardiola[2], MD; Juan Rigla[3], MD, PhD; Marcelo Jiménez[1], MD; Juan Cinca[1], MD; Antonio Serra[1], MD

1. Cardiology Department, Hospital Sant Pau, Barcelona, Spain; 2. Interventional Cardiology Unit, Hospital del Mar, Barcelona, Spain; 3. Perceptual Computing Lab, Faculty of Mathematics, University of Barcelona, Barcelona, Spain

Vaquerizo B, et al. Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study. EuroIntervention. 2014; 11(5):555-63

CTO-ABSORB pilot study

- Prospektif, tek merkez (Barselona)
- Güvenlik, etkinlik
- 2013-2014, ardışık 67 hasta

- **Major dışlama kriterleri**

- **LMCA**
- **Greft (arteriyel ya da venöz)**
- **ISR**
- **SB ≥ 2.5 mm bifurk (Medina 1:1:1)**
- **Referans damar çapı <2.5 mm, >4.0 mm**
- **Şiddetli kalsifik/tortüöz damar**
- **Bail-out DES/BMS**

Vaquerizo B, et al. Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study. EuroIntervention. 2015; 11(5):555-63

Hasta Popülasyonu

67 CTO hastası (telle başarılı geçilen)
(2013-2014; 12 ay)

Klinik kriterleri sağlamayan (n=18)

12 hasta:
Hasta/operatör tercih etmedi

6 hasta:
DES kullanıldı

49 kliniği uygun hasta

Anjiyografik kriterleri uymayan (n=11)

5 hasta:
Kalsifik/tortüöz damar

4 hasta:
SB ≥ 2.5mm bifürkasyon

2 hasta:
Referans damar çapı < 2.5 (n=1) ya da ≥ 4mm (n=1)

38 Absorb CTO hastası

Bail-out stent (DES) kullanılan (n=3)

(1) Balon sonrası perforasyona greft stent

(1) Rotasyonel aterektomi sonrası aorto-osteal diseksiyona 4mm DES

(1) BVS sonrası distal koroner diseksiyona 2.25mm DES

35 Absorb CTO hastası

Vaquerizo B, et al. Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study. EuroIntervention. 2015; 11(5):555-63

Prosedürel Akış Şeması

Kılavuz telin lezyonu geçmesi

1.5- 2.0mm balon ile ilk predilatasyon

NTG 400 mcgr (1-2 doz)

IVUS analizi

NC /Cutting balon/ Rotablatör ile ek predilatasyon

IVUS analizi

BFT,
CK, MB, Troponin:
- pre-, 6,12, 24. saat post-PCI

BVS implantasyonu

OCT analizi >%20 rezidüel darlık

Gerekirse NC ile postdilatasyon

Vaquerizo B, et al. Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study. EuroIntervention. 2015; 11(5):555-63

Takip

1. ay telefonla arama

Klinik vizit & MSCT: 6. ay

Anjiyografi & OCT: 12. ay

Klinik vizit & MSCT: 18. ay

Telefonla görüşme:
2, 3, 4, ve 5. yıllarda

Vaquerizo B, et al. Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study. EuroIntervention. 2015; 11(5):555-63

Angiographic Characteristics (N=35)	
Target Vessel : RCA	48 %
LAD	40 %
LCx-OM	12 %
Severe calcification at CTO	34%
Occlusion length (mm)	18.6 ± 12.5
Target lesion length (mm)	35.9 ± 15.8

CTO Complexity (J-CTO Score)	
Easy (Score 0)	25%
Intermediate (Score = 1)	48%
Difficult / Very difficult (Score ≥ 2)	27%

EuroIntervention 2015;11:555-563 published online ahead of print December 2014

Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study

EuroIntervention

Table 6. Short and midterm outcomes.

	In-hospital	6-month follow-up
Overall death	0 (0)	0 (0)
Cardiac death	0 (0)	0 (0)
Q- or non-Q-wave MI	0 (0)/0 (0)	0 (0)/0 (0)
Target lesion revascularisation	0 (0)	0 (0)
MACE	0 (0)	0 (0)
Scaffold thrombosis	0 (0)	0 (0)
In-scaffold reocclusion*	0 (0)	2 (5.7)

Values are number (%) of patients. *6 months of multislice computed tomography follow-up (100% completed). MACE: major adverse cardiac events; MI: myocardial infarction

EuroIntervention 2015;11:555-563 published online ahead of print December 2014
Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study

One-Year Results of Bioresorbable Vascular Scaffolds for Coronary Chronic Total Occlusions

Beatriz Vaquerizo, MD, PhD[a,b,*], Antonio Barros, MD[a], Sandra Pujadas, MD[a], Ester Bajo, MD[a], Marcelo Jiménez, MD[a], José Gomez-Lara, MD[c], Francisco Jacobi, MD[c], Neus Salvatella, MD[b], Guillem Pons, MD[a], Juan Cinca, MD[a], and Antonio Serra, MD, PhD[a]

Vaquerizo B, et al. One-Year Results of Bioresorbable Vascular Scaffolds for Coronary Chronic Total Occlusions. Am J Cardiol. 2016; 117(6):906-17.

CTO-ABSORB Takip

BEZMİÂLEM VAKIF ÜNİVERSİTESİ

Clinical follow-up at 2 yrs

Events	In-hospital	6-month FU	1-year FU	2-year FU
Overall death	0	0	0	0
Cardiac death	0	0	0	0
Q / non Q MI	0	0	0	0
TLR	0	0	0	1 (2.8%)
MACE	0	0	0	1 (2.8%)
Scaffold thrombosis *	0	0	0	1 (2.8%)
In-scaffold reocclusion	0	2 (5.7%)	2 (5.7%)	3 (8.6%)

Vaquerizo B, et al. One-Year Results of Bioresorbable Vascular Scaffolds for Coronary Chronic Total Occlusions. Am J Cardiol. 2016; 117(6):906-17.

CTO-ABSORB Takip QCA

Lezyonlar	İşlem sonrası	1 y Takip
İskele içi		
İskele uzunluğu (mm)	43.90 ± 18.07	44.13 ± 18.47
Referans damar çapı (mm)	2.45 ± 0.46	2.41 ± 0.31
Minimal lümen çapı (mm)	2.18 ± 0.39	1.90 ± 0.35
Geç lümen kaybı (mm)	—	- 0.28 ± 0.31
Rezidüel darlık oranı (%)	9.23 ± 17.31	20.77 ± 12.16
Maksimal lümen çapı (mm)	3.63 ± 0.41	3.47 ± 0.60
Ortalama lümen çapı (mm)	2.89 ± 0.30	2.66 ± 0.35
Segment içi		
Minimal lümen çapı (mm)	1.71 ± 0.46	1.83 ± 0.32
Geç lümen kaybı (mm)	—	0.11 ± 0.41
Rezidüel darlık oranı (%)	24.16 ± 15.09	23.55 ± 8.42

Vaquerizo B, et al. One-Year Results of Bioresorbable Vascular Scaffolds for Coronary Chronic Total Occlusions. Am J Cardiol. 2016; 117(6):906-17.

CTO-ABSORB 1 y Takip OCT

n = 24 lesions	Baseline	Follow-up	Difference (%)	P value
Scaffold length (mm)	48.69 ± 18.39	49.37 ± 19.42	0.68 (1%)	0.188
Mean lumen area (mm^2)	7.59 ± 1.27	6.78 ± 1.68	- 0.82 (-11%)	0.001
Minimal lumen area (mm^2)	5.23 ± 1.29	3.95 ± 1.46	- 1.23 (-24%)	<0.001
Maximal lumen area (mm^2)	10.68 ± 2.57	11.37 ± 4.07	0.70 (7%)	0.308
Mean scaffold area (mm^2)	6.57 ± 1.22	7.28 ± 1.37	0.71 (11%)	<0.001
Minimal scaffold area (mm^2)	4.49 ± 1.20	4.56 ± 1.33	0.08 (2%)	0.553
Maximal scaffold area (mm^2)	8.72 ± 1.49	11.18 ± 3.07	2.47 (28%)	<0.001
Mean ISA area (mm^2)	0.83 ± 2.07	0.90 ± 1.79	0.07 (8%)	0.842
Mean neointimal area (mm^2)	NA	0.67 ± 0.41	NA	NA
Mean neointimal area stenosis (%)	NA	5.10 ± 5.70	NA	NA
Maximal neointimal area stenosis (%)	NA	27.92 ± 35.10	NA	NA

Vaquerizo B, et al. One-Year Results of Bioresorbable Vascular Scaffolds for Coronary Chronic Total Occlusions. Am J Cardiol. 2016; 117(6):906-17.

BEZMİÂLEM VAKIF ÜNİVERSİTESİ

ORIGINAL CONTRIBUTION

Evaluation of the Safety of Everolimus-Eluting Bioresorbable Vascular Scaffold (BVS) Implantation in Patients With Chronic Total Coronary Occlusions: Acute Procedural and Short-Term Clinical Results

Omer Goktekin, MD[1]; Aylin Hatice Yamac, MD[1]; Azeem Latib; MD [2,3]; Ahmet Tastan, MD[4]; Vasileios F. Panoulas, MD[2,3]; Katsumasa Sato, MD[2,3]; Ercan Erdogan, MD[1]; Huseyin Uyarel, MD[1]; Ibrahim Shah, MD[1]; Antonio Colombo, MD[2,3]

Goktekin O, et al. Evaluation of the Safety of Everolimus-Eluting Bioresorbable Vascular Scaffold (BVS) Implantation in Patients With Chronic Total Coronary Occlusions: Acute Procedural and Short-Term Clinical Results. J Invasive Cardiol. 2015; 27(10):461-6.

BEZMİÂLEM VAKIF ÜNİVERSİTESİ

Table 1. Patient demographics and clinical characteristics.	
Age (years)	56.9 ± 9.4
Male	63 (90.0%)
Cardiovascular risk factors	
Hypertension	55 (78.6%)
Hypercholesterolemia	37 (52.9%)
Diabetes mellitus	15 (21.4%)
Smoking, current	12 (17.1%)
Smoking, former	25 (35.7
Family history for coronary artery disease	23 (32.9%
Cardiac history	
Previous myocardial infarction	6 (8.6%)
Previous percutaneous coronary intervention	12 (17.1%)
Previous coronary artery bypass grafting	7 (10.0%)
Number of diseased vessels	
1	15 (21.4%)
2	26 (37.1%)
3	22 (31.4%)
Left ventricular ejection fraction (%)	51.7 ± 6.7
Comorbidities	
Chronic renal failure	2
Chronic obstructive lung disease	6
Prior stroke	0
Data given as mean ± standard deviation or number (percentage).	

70 hasta
76 CTO

Table 2. Angiographic lesion characteristics	
Target vessel	
Left anterior descending	36 (51.4%)
Left circumflex	17 (24.3%)
Right coronary artery	23 (32.9%)
Lesion location	
Ostial	6 (85.7%)
Proximal	36 (51.4%)
Mid portion	27 (38.6%)
Distal	7 (10.0%)
Side branch at occlusion	22
Provisional stenting	17
Double stenting	5
Mini-crush	3
T-stenting	2
Bridging collateral vessels	28
Tapered stump	52
Moderate to severe calcification	28
Data given as number (percentage) or number.	

Table 3. Procedural variables.	
Bilateral injection	53
Approach type	
Antegrade	70
Retrograde	6
Mean balloon diameter at predilation (mm)	2.4 ± 0.6
Inflation pressure (atm)	13.4 ± 2.3
Number of total Absorb BVSs	145
Number of Absorb BVS/CTO (n)	2.01 ± 1.0
Mean scaffold length (mm)	36.5 ± 19.5
Mean scaffold diameter (mm)	3.0 ± 0.4
Mean balloon diameter at postdilation (mm)	3.5 ± 0.4
Inflation pressure (atm)	17.1 ± 3.9
Concomitant PCI of a second vessel	14
Microcatheter	46
Stiff guidewires	52
Special technique	
Parallel wire	8
Reverse CART	3

Data given as mean ± standard deviation or number (percentage).
BVS = bioresorbable vascular scaffold; CTO = chronic total occlusion; PCI = percutaneous coronary intervention.

Table 4. Clinical events and MACE after 12 months follow-up.	
Variable	
Observation duration	11 months
Composite endpoint*	0
MACE	2
Death	0
Ischemia-driven TLR	2 (at 6 months and 9 months)
Myocardial infarction	0
Variable	
1-month symptom evaluation	
Angina pectoris > CCSII before PCI	67 (95.7%)
Angina pectoris > CCSII after PCI	10 (14.2%)

Data given as number (percentage).
*Composite endpoint = death + non-fatal myocardial infarction.
MACE = major adverse coronary events; TLR = target lesion revascularization; PCI = percutaneous coronary intervention; CCS = Canadian Cardiovascular Society classification of Angina pectoris.

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Clinical and angiographic outcomes at more than 1 year after treatment of chronic total occlusions with the everolimus-eluting bioresorbable vascular scaffold

Aylin Hatice Yamac[1], Abdulkadir Yıldız[1], Meherrem Nasifov[1], Ahmet Tastan[2], Nemat Bashirov[1], Omer Goktekin[1]

[1]Bezmialem Foundation University, Department Of Cardiology

[2]Şifa Hospital

OBJECTIVE

Treatment of chronic total occlusions (CTOs) with the everolimus-eluting bioresorbable scaffold (BVS) is safe and effective at short term follow up. The current study aims to investigate the clinical and angiographic outcomes at > 1 year after treatment of CTOs with BVS.

30 hasta, 35 CTO

Median time until Angiography 402 days.

Baseline QCA	
Proximal reference diameter (mm)	3.02 ± 0.39
Distal reference diameter (mm)	2.13 ± 0.54
Lesion length (mm)	40.07 ± 17.52
Post-procedural QCA	
In-scaffold minimal lumen diameter (mm)	2.51 ± 0.51
In-scaffold minimal diameter stenosis (%)	13.19 ± 5.88
In-scaffold minimal area stenosis (%)	22.07 ± 5.33
FU QCA	
In-scaffold minimal lumen diameter (mm)	2.14 ± 0.50
In-scaffold minimal diameter stenosis (%)	20.69 ± 13.04
In-scaffold minimal area stenosis (%)	36.73 ± 16.69
Late lumen loss (mm)	0.38 ± 0.54

Median time of clinical FU 542 days. IQR 366 (Range 175-961 days)

	In hospital	Total FU
Overall death (%)	0	1 (3.0)
Cardiac death (%)	0	1 (3.0)
Target vessel MI (%)	0	0
TVR (%)	0	2 (6.1)
TLR (%)	0	3 (9.1)
BVS thrombosis (%)	0	0

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Percutaneous coronary intervention for chronic total occlusion of the coronary artery with the implantation of bioresorbable everolimus-eluting scaffolds. Poznan CTO-Absorb Pilot Registry

Maciej Lesiak*, MD, PhD; Magdalena Łanocha, MD, PhD; Aleksander Araszkiewicz, MD, PhD; Andrzej Siniawski, MD; Marek Grygier, MD, PhD; Małgorzata Pyda, MD, PhD;

Variable	Lesion-based
Target vessel	
LAD	23 (57.5%)
LCX	3 (7.5%)
RCA	14 (35.0%)
Calcification (moderate/heavy)	12 (30.0%)
Lesion length >2 cm	15 (37.5%)
Vessel tortuosity	7 (17.5%)
Bifurcation lesion	11 (27.5%)
Ambiguous proximal cap (no stump)	12 (30.0%)
Blunt stump type	8 (20.0%)
Second attempt	7 (17.5%)
Mean J-CTO score (points)	1.6±1.16
J-CTO score 0-1	18 (45.0%)
J-CTO score 2	13 (32.5%)
J-CTO score >2	9 (22.5%)
Baseline QCA	
Reference vessel diameter (mm)	2.48±0.33
Occlusion length (mm)	18.81±11.50
Dmax (mm)	2.95±0.34
Post-procedure QCA	
In-scaffold minimal luminal diameter (mm)	2.13±0.31
In-scaffold minimal diameter stenosis (%)	13.90±7.59
In-scaffold minimal area stenosis (%)	20.64±12.25

40 hasta

Variable	Patient-based
Radial approach	7 (17.5%)
Guiding catheter 6 Fr	21 (52.5%)
Guiding catheter 7 Fr	19 (47.5%)
PCI technique	
Antegrade wire escalation	34 (85.0%)
Antegrade dissection re-entry (wire-based)	4 (10.0%)
Retrograde wire escalation	2 (5.0%)
Mean scaffold diameter (mm)	2.90±0.32
Total scaffold length per lesion (mm)	42.4±21.5
Mean scaffold implantation pressure (atm)	15.3±1.5
No. of scaffolds/lesion	1.6 (1–4)
High-pressure post-dilatation	38 (95.0%)
Post-dilatation balloon diameter (mm)	3.15±0.35
Post-dilatation pressure (atm)	20.5±1.4
IVUS/OCT	2 (5.0%)/10 (25.0%)
Scaffold success (device-based)	63 (100%)
Procedure success (patient-based)	40 (100%)
Fluoroscopy time (minutes)	17.3±12.2
Contrast medium use (ml)	196.0±90.4
ASA/clopidogrel/ticagrelor post procedure	40/26/14

IVUS: intravascular ultrasound; OCT: optical coherence tomography

BVS çapı online QCA ile belirlenmiş.

median time of 329 days (57-680 days, IQR 172-415 days)

Table 6. Quantitative coronary analysis at follow-up (27 patients).

Variable	
Baseline, post procedure	
Reference vessel diameter (mm)	2.46±0.37
In-scaffold minimal luminal diameter (mm)	2.11±0.36
In-scaffold minimal diameter stenosis (%)	13.67±7.61
In-scaffold minimal area stenosis (%)	18.81±12.99
Follow-up	
Reference vessel diameter (mm)	2.43±0.44
In-scaffold minimal luminal diameter (mm)	1.91±0.51
In-scaffold minimal diameter stenosis (%)	23.85±14.25
In-scaffold minimal area stenosis (%)	26.35±20.81
Late lumen loss	0.22±0.51

Median of 556 days (274-932, IQR 374-706)

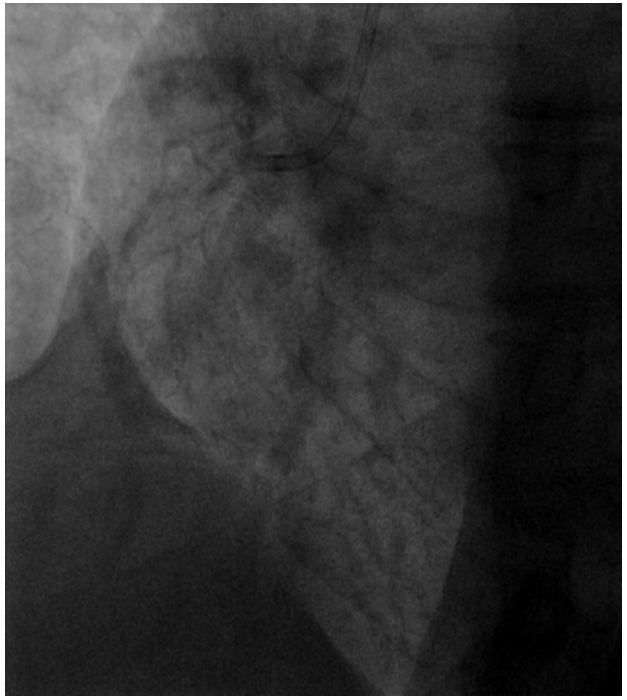
Table 5. Clinical outcomes.

Variable	30 days	9 months
Death	0 (0.0%)	0 (0.0%)
Any MI	1 (2.5%)	2 (5.0%)
Target vessel MI	1 (2.5%)	2 (5.0%)
TVR	1 (2.5%)	3 (7.5%)
TVF	1 (2.5%)	3 (7.5%)
Any scaffold thrombosis	1 (2.5%)	2 (5.0%)

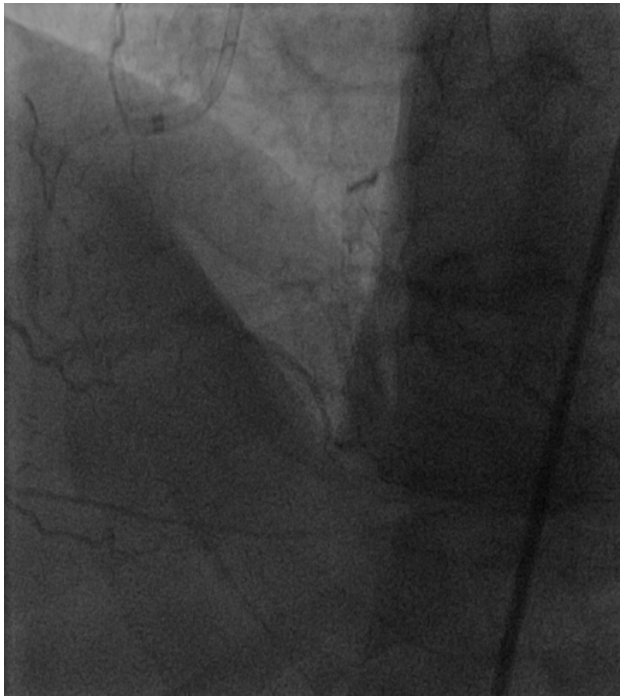
MI: myocardial infarction; TVF: target vessel failure; TVR: target vessel revascularisation

Aynı hasta 2x ST geçirmiş

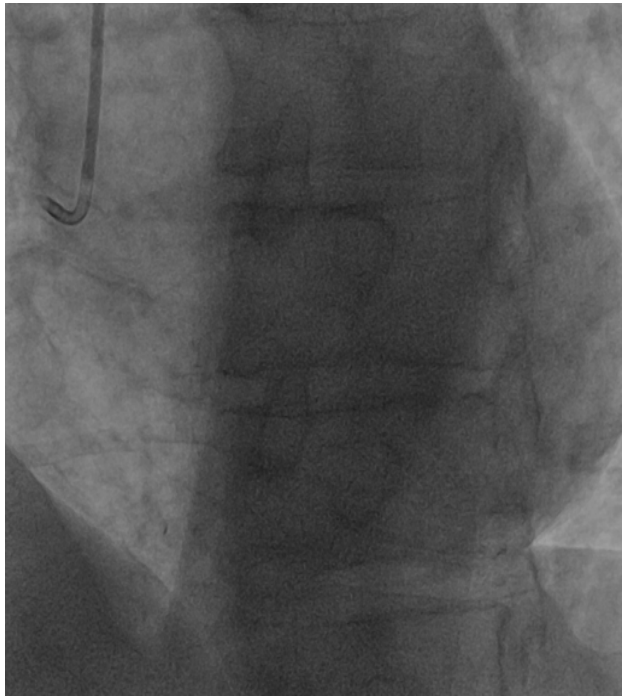
Pre Procedure

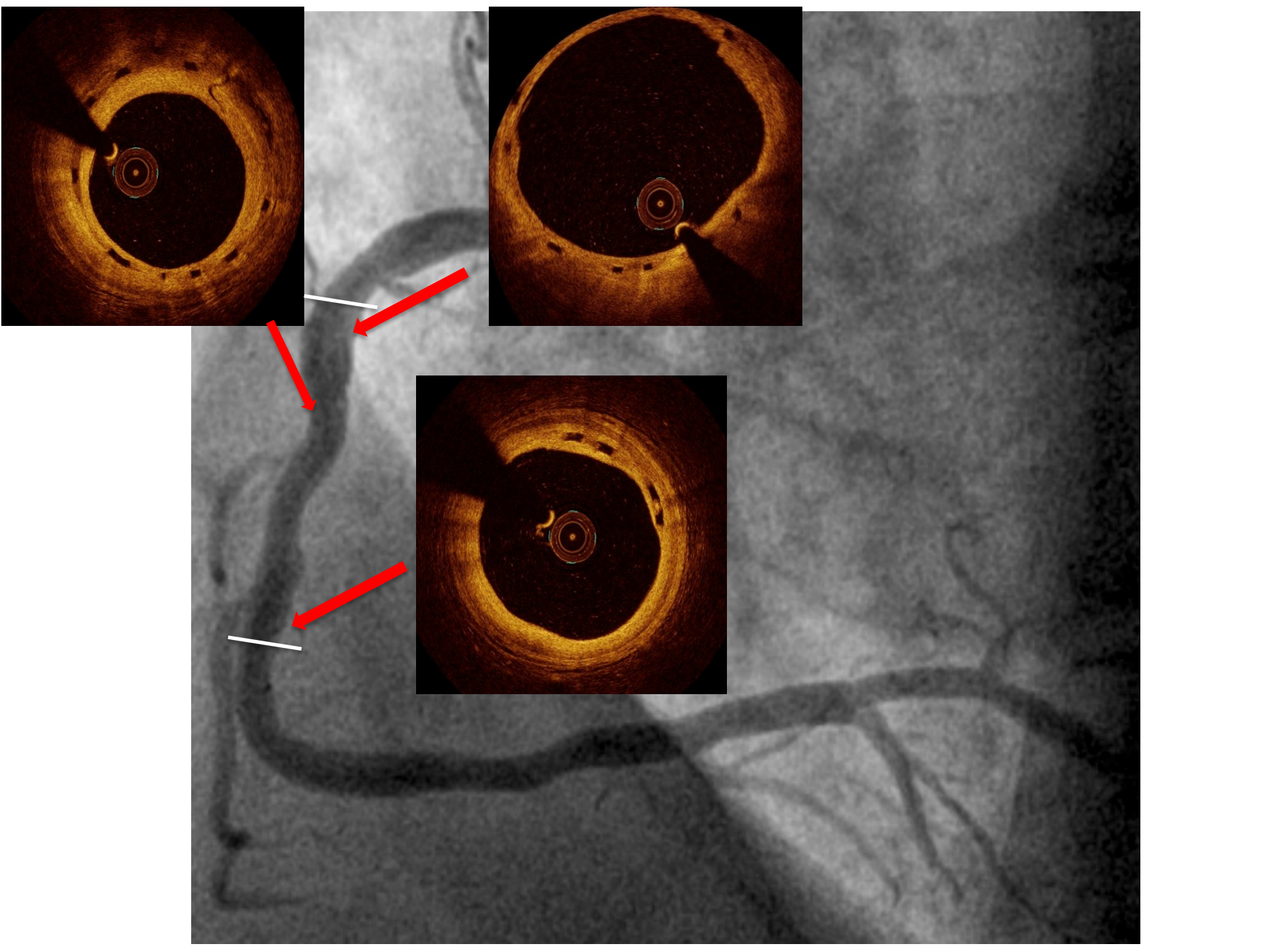


Post Procedure



1y FU





CTO'da 2. nesil DES ve BVS Çalışmaları

Çalışma	n	Yaş	Stent tipi	Stent uzunluğu (mm)	Takip (yıl)	MACE
Almalla et al.	97	—	SES vs EES	—	2	%17.4 vs %15.7
CATOS trial	160	63±12	SES vs ZES	45±20 vs 43±21	1	%10 vs %17.5
Wöhrle et al.	53	62±10	EES	79±36	1	%6
CIBELES study	207	63±11 vs 65±10	SES vs EES	47±25 vs 50±23	1	%15.8 vs %11.3
TWENTE trial	59	63±10	ZES ve EES	66±35	3	%15.3
Wiebe et al.	23	60±9	BVS	65±24	108 gün	%4.3
CTO-ABSORB	35	61±10	BVS	52±23	2 yıl	%2.8
Ojeda et al.	42	58±9	BVS	43±21	1	%4.8

Ojeda S, et al. Outcomes and computed tomography scan follow-up of bioresorbable vascular scaffold for the percutaneous treatment of chronic total coronary artery occlusion. Am J Cardiol. 2015; 115(11):1487-93.

Procedural and Long-Term Outcomes of Bioresorbable Scaffolds Versus Drug-Eluting Stents in Chronic Total Occlusions

The BONITO Registry (Bioresorbable Scaffolds Versus Drug-Eluting Stents in Chronic Total Occlusions)

Lorenzo Azzalini, MD, PhD, MSc; Gennaro Giustino, MD; Soledad Ojeda, MD, PhD; Antonio Serra, MD, PhD; Alessio La Manna, MD; Hung Q. Ly, MD, SM; Barbara Bellini, MD; Susanna Benincasa, MD; Jorge Chavarría, MD; Livia L. Gheorghe, MD; Giovanni Longo, MD; Eligio Miccichè, MD; Guido D'Agosta, MD; Fabien Picard, MD, MSc; Manuel Pan, MD, PhD; Corrado Tamburino, MD, PhD; Azeem Latib, MD; Mauro Carlino, MD; Alaide Chieffo, MD; Antonio Colombo, MD

Procedural and Long-Term Outcomes of Bioresorbable Scaffolds Versus Drug-Eluting Stents in Chronic Total Occlusions: The BONITO Registry (Bioresorbable Scaffolds Versus Drug-Eluting Stents in Chronic Total Occlusions).
Azzalini L, Giustino G, Ojeda S, Serra A, La Manna A, Ly HQ, Bellini B, Benincasa S, Chavarría J, Gheorghe LL, Longo G, Miccichè E, D'Agosta G, Picard F, Pan M, Tamburino C, Latib A, Carlino M, Chieffo A, Colombo A.
Circ Cardiovasc Interv. 2016 Oct;9(10).

Table 2. Baseline Angiographic Characteristics 537 patients (n=153 BRS; n=384 DES)

Variable	Overall (n=537)	BRS (n=153)	DES (n=384)	*P* Value
Three-vessel disease	104 (19.4%)	24 (15.7%)	80 (20.9%)	0.17
SYNTAX score	18.6±8.8	19.0±8.6	18.5±8.9	0.57
Target-vessel CTO				0.01
Left anterior descending artery	198 (36.9%)	71 (46.4%)	127 (33.1%)	
Right coronary artery	110 (20.5%)	29 (19.0%)	81 (21.1%)	
Left circumflex artery	229 (42.6%)	53 (34.6%)	176 (45.8%)	
In-stent CTO	58 (10.8%)	10 (6.5%)	48 (12.5%)	0.04
Blunt stump	165 (31.2%)	46 (31.7%)	119 (31.0%)	0.87
Moderate or severe calcifications	218 (40.6%)	70 (45.8%)	148 (38.5%)	0.13
>45° bending	78 (14.5%)	17 (11.1%)	61 (15.9%)	0.16
Lesion length >20 mm	229 (42.7%)	66 (43.4%)	163 (42.4%)	0.84
Retry	80 (14.9%)	19 (12.4%)	61 (15.9%)	0.31
J-CTO score	1.43±1.16	1.42±1.07	1.44±1.20	0.91
J-CTO score ≥2	233 (43.4%)	65 (42.5%)	168 (43.8%)	0.79
Reference vessel diameter, mm	2.88±0.52	2.96±0.39	2.84±0.56	0.007
Reference vessel diameter <2.5 mm	93 (18.6%)	14 (9.9%)	79 (22.0%)	0.002
CTO length, mm	23.6±16.6	21.6±13.0	24.3±17.7	0.055
Total lesion length, mm	41.6±23.1	36.6±16.6	43.2±24.7	0.003

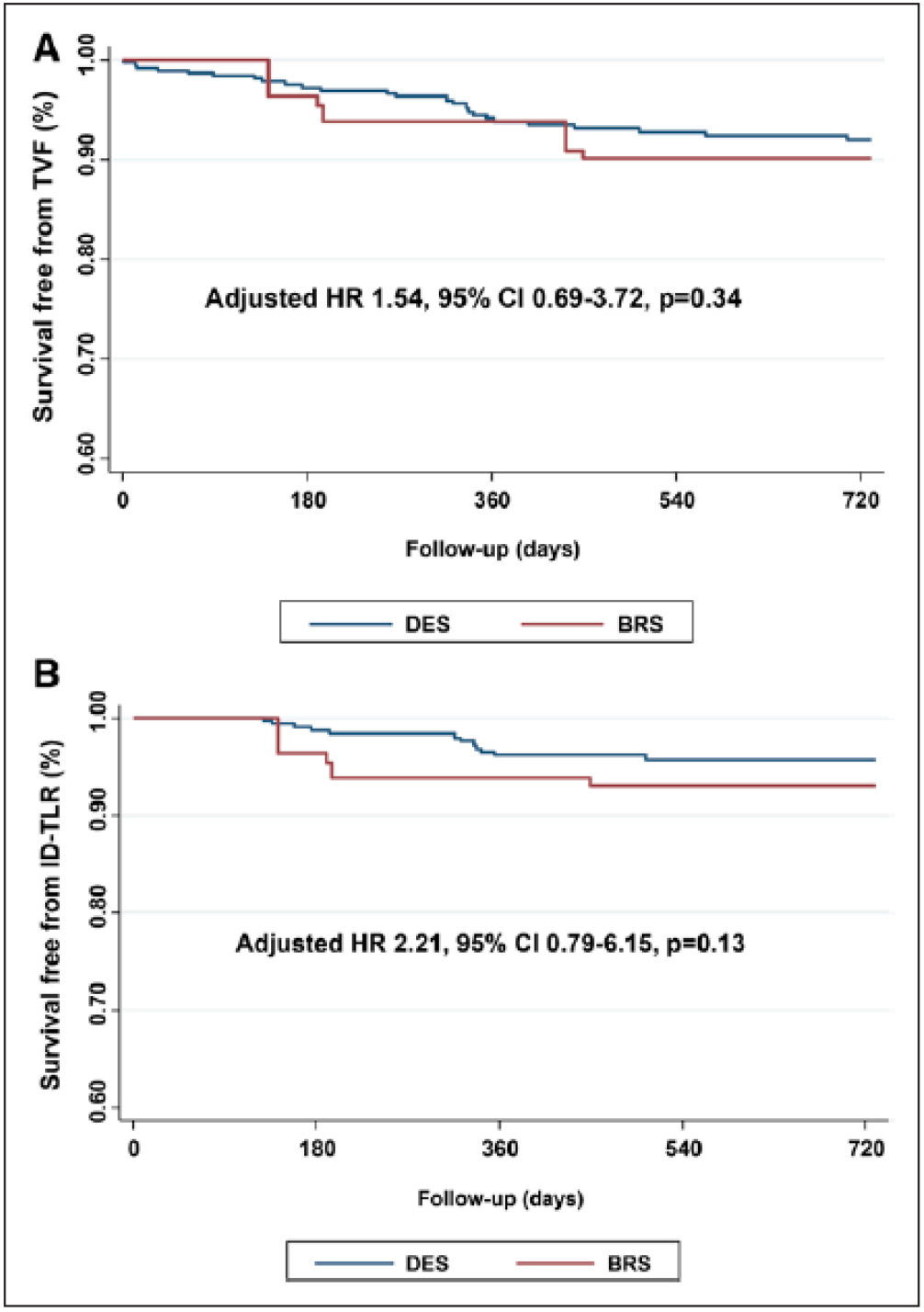
Table 3. Procedural Characteristics

Variable	Overall (n=537)	BRS (n=153)	DES (n=384)	*P* Value
Radial access*	114 (21.3%)	34 (22.2%)	80 (20.9%)	0.73
Contralateral injection	302 (57.2%)	80 (55.2%)	222 (58.0%)	0.56
Successful crossing technique				0.004
Antegrade wire escalation	375 (70.9%)	119 (82.1%)	256 (66.7%)	
Antegrade dissection/reentry	70 (13.2%)	13 (9.0%)	57 (14.8%)	
Retrograde wire escalation	38 (7.2%)	8 (5.5%)	30 (7.8%)	
Retrograde dissection/reentry	46 (8.7%)	5 (3.4%)	41 (10.7%)	
Successful crossing technique: retrograde approach	84 (15.9%)	13 (9.0%)	71 (18.5%)	0.008
Successful crossing technique: dissection/reentry	116 (21.9%)	18 (12.4%)	98 (25.5%)	0.001
Number of stents/scaffolds implanted	2.1±1.0	2.2±1.1	2.1±1.0	0.27
Diameter of largest stent/scaffold, mm	3.14±0.43	3.20±0.36	3.12±0.45	0.02
Total stent/scaffold length, mm	53.4±27.4	51.3±24.1	54.2±28.6	0.24
Total stent/scaffold length >30 mm	405 (75.4%)	109 (71.2%)	296 (77.1%)	0.16
Postdilatation	440 (82.1%)	139 (90.8%)	301 (78.6%)	0.001
Diameter of largest balloon used for postdilatation, mm	3.22±0.48	3.28±0.41	3.20±0.51	0.07
IVUS/OCT	185 (34.5%)	105 (68.6%)	80 (20.8%)	<0.0001
Minimal luminal diameter post-PCI, mm	2.61±0.48	2.61±0.45	2.60±0.49	0.90
Diameter stenosis post-PCI, %	10±8	8±5	10±8	0.03
Contrast volume, mL	349±136	341±129	352±139	0.47
Fluoroscopy time (min)	49±31	50±27	48±32	0.65
Total procedure time (min)	133±70	152±62	126±72	0.001
Procedural complications	10 (1.9%)	1 (0.7%)	9 (2.3%)	0.21
Technical success	525 (97.8%)	152 (99.3%)	373 (97.1%)	0.12
Procedural success	523 (97.4%)	152 (99.3%)	371 (96.6%)	0.07

Median follow-up was 703 (interquartile range 426–989) days.

Table 4. Unadjusted and Adjusted Risk of Clinical Outcomes on Follow-Up

	Overall (n=514)	BRS (n=151)	DES (n=363)	Unadjusted HR (95% CI)*	*P* Value	IPTW-Adjusted HR (95% CI)†	*P* Value
Target-vessel failure	35 (6.8%)	7 (4.6%)	28 (7.7%)	0.59 (0.26–1.35)	0.21	1.54 (0.69–3.72)	0.34
Cardiac death	13 (2.5%)	2 (1.3%)	11 (3.0%)	0.44 (0.10–1.98)	0.27	1.06 (0.23–4.93)	0.94
Target-vessel myocardial infarction	6 (1.2%)	1 (0.7%)	5 (1.4%)	0.48 (0.06–4.11)	0.49	1.57 (0.22–11.37)	0.65
Ischemia-driven target-lesion revascularization	21 (4.1%)	6 (4.0%)	15 (4.1%)	0.95 (0.37–2.45)	0.92	2.21 (0.79–6.15)	0.13
Definite or probable stent/scaffold thrombosis	3 (0.6%)	1 (0.7%)	2 (0.6%)	1.24 (0.11–13.74)	0.86	3.28 (0.37–29.14)	0.29

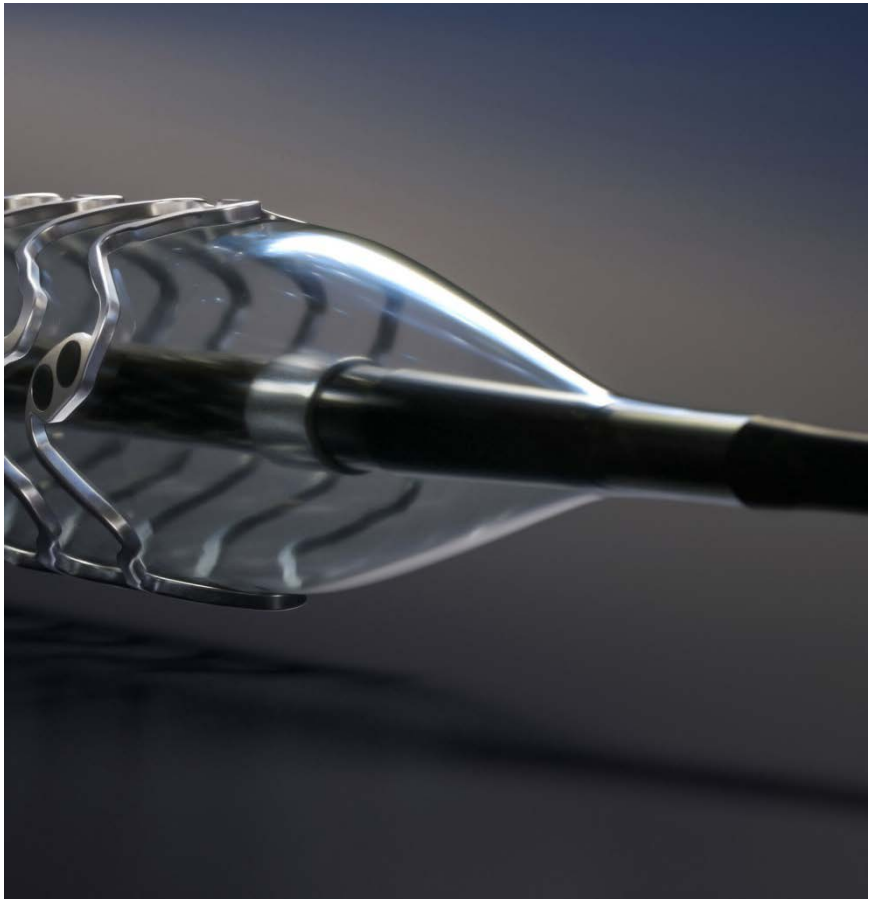

A
Survival free from TVF (%)
1.00
0.90
0.80
0.70
0.60
Adjusted HR 1.54, 95% CI 0.69-3.72, p=0.34
0
180
360
540
720
Follow-up (days)
DES
BRS
B
Survival free from ID-TLR (%)
1.00
0.90
0.80
0.70
0.60
Adjusted HR 2.21, 95% CI 0.79-6.15, p=0.13
0
180
360
540
720
Follow-up (days)
DES
BRS

Sonuç

- BVS'in taşınmasının ve ekspansiyonunun mümkün olmadığı şiddetli kalsifik ve/veya tortüöz damarlar hariç, KTO` da BVS güvenli ve etkin.
- Kısa ve orta dönem sonuçları, 2. jenerasyon DES'lerle benzer (yüksek prosedürel başarı, kabul edilebilir MACE).
- Uzun dönem (>5 yıl) sonuçlar ve RCT bekleniyor.

Magmaris - Sirolimus-Eluting Resorbable Coronary Magnesium Scaffold System

- First clinically proven resorbable Magnesium scaffold
- Compelling safety data[1]
- Better deliverability[2]
- ~95 % of Magnesium resorbed at 12 months[3]



1 BIOSOLVE-II; 2 IIB, BIOTRONIK data on file, 3 Preclinical test, BIOTRONIK data on file

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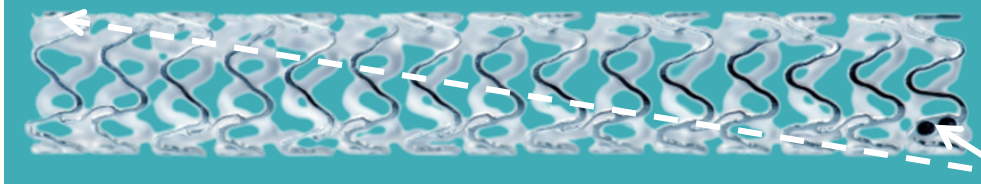
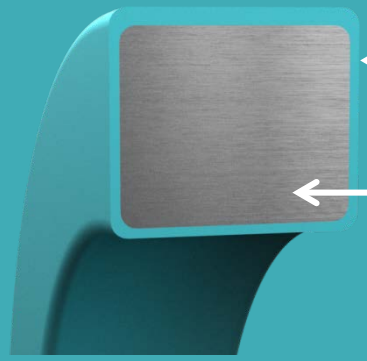
Magmaris description



Backbone — *resorbable*

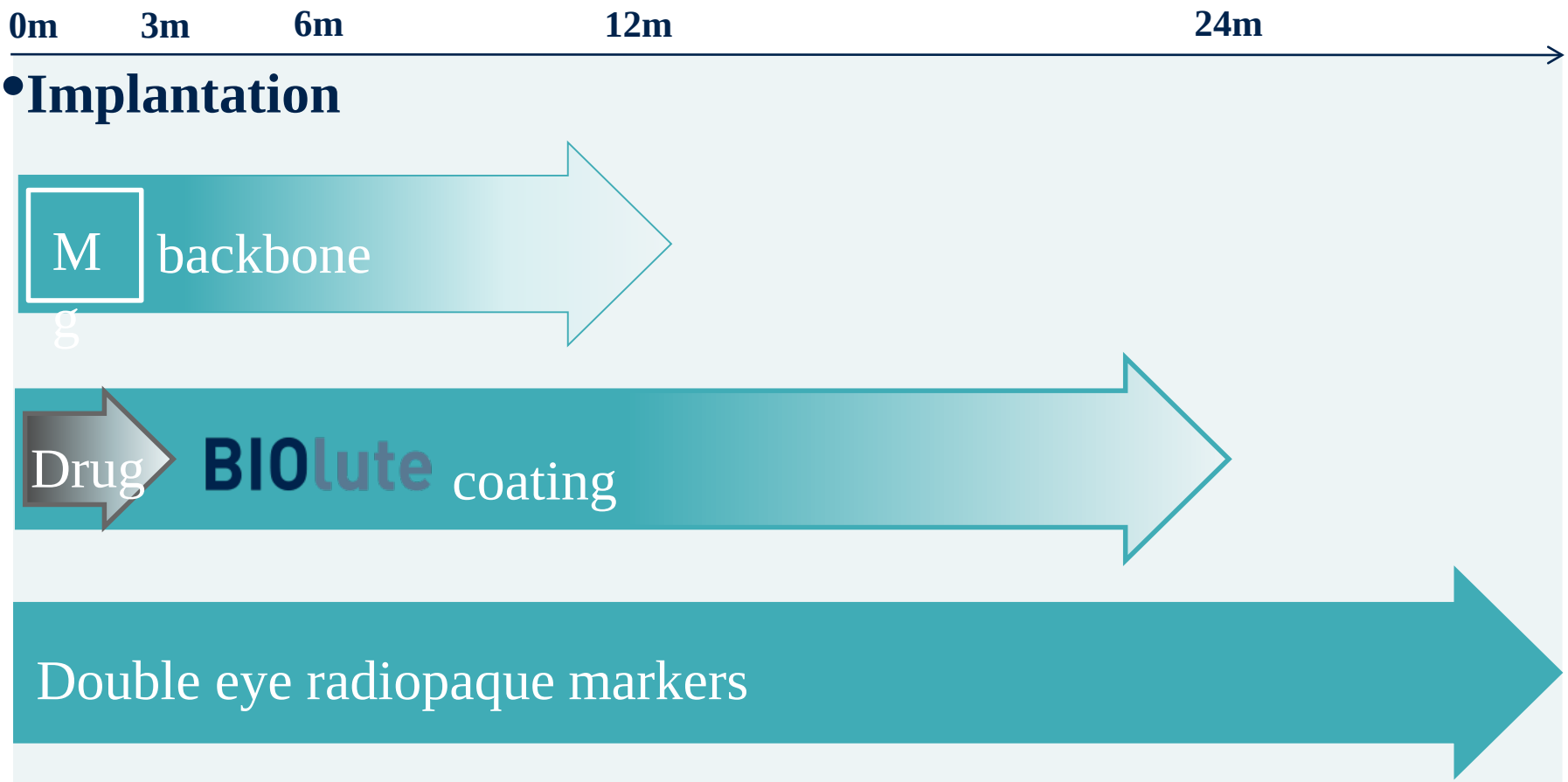
Double eye radiopaque markers (Tantalum) — *permanent*



BIOlute Coating — *resorbable*

Backbone — *resorbable*

Magmaris resorption process over time



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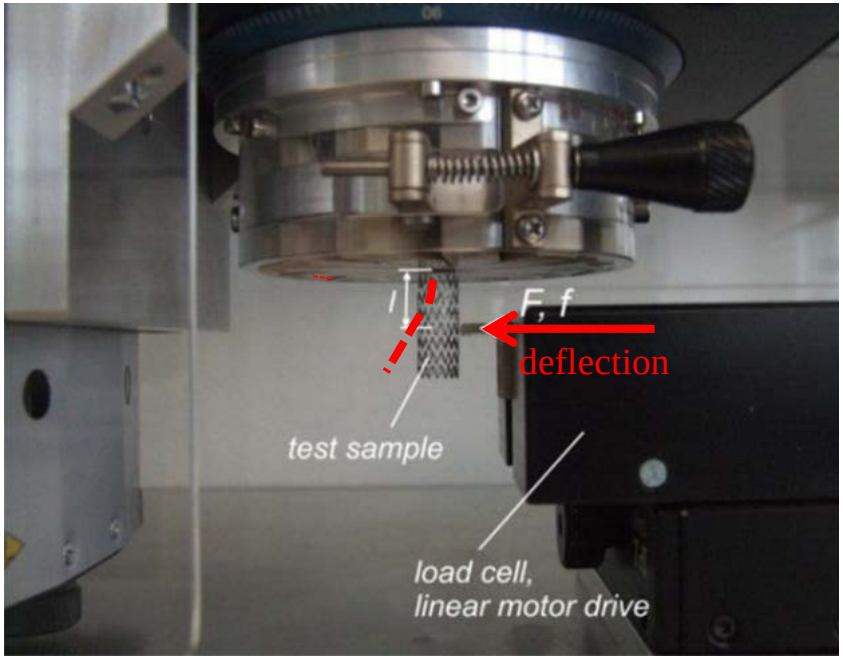
Magmaris backbone flexibility

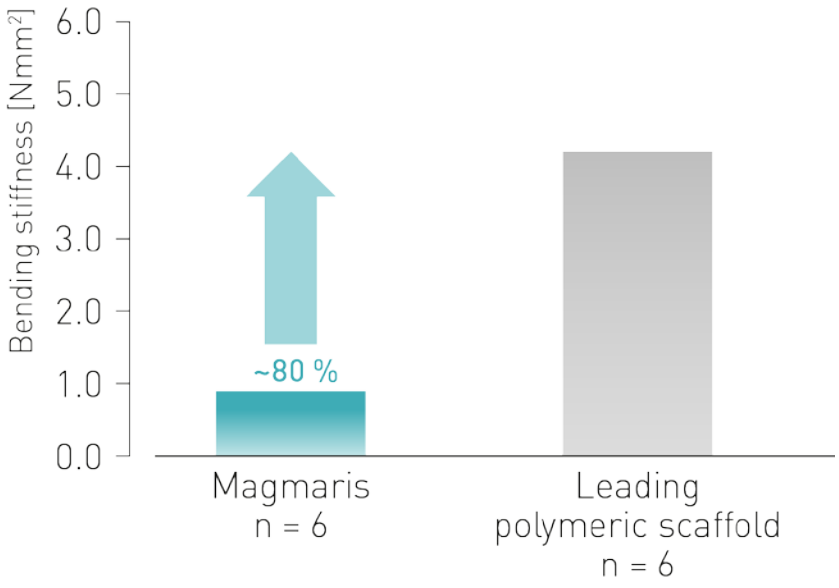
Simulation



The Magmaris backbone is exposed to constant deflection and the reaction force of the scaffold backbone is measured.

Bending flexibility

The Magmaris backbone is up to 80% more flexible compared to a leading polymeric scaffold.



Test set up by IIB; BIOTRONIK data on file

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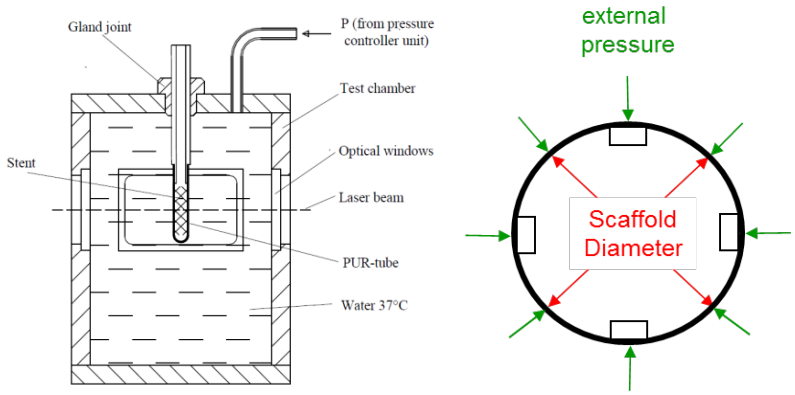
Magmaris backbone is robust: Radial resistance

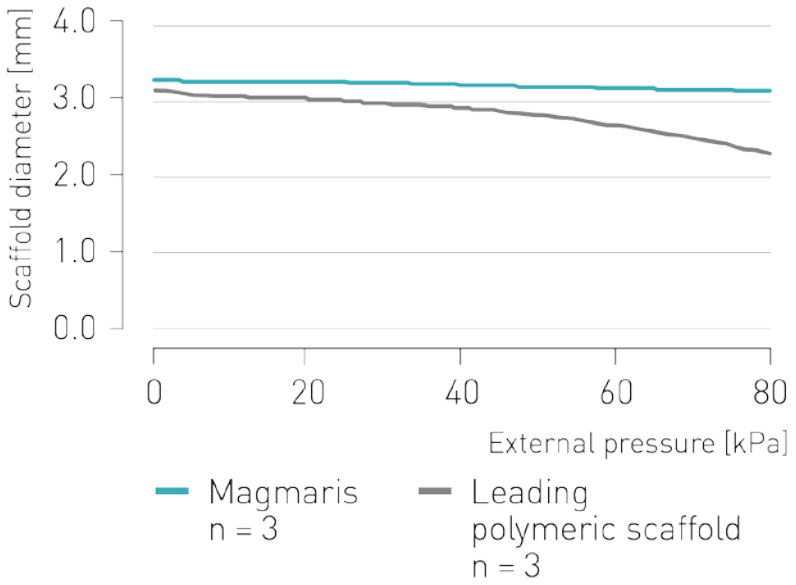
Simulation



The scaffold is implanted into a thin walled tube and exposed to external pressure.
The diameter change of the scaffold is measured.

Radial resistance

Strong radial resistance: Magmaris has no significant diameter change under increasing physiological pressure, whereas leading polymeric scaffold* diameter is decreasing under increasing pressure



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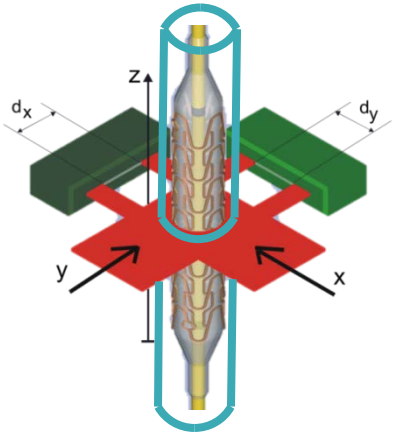
Magmaris backbone is robust: Acute recoil

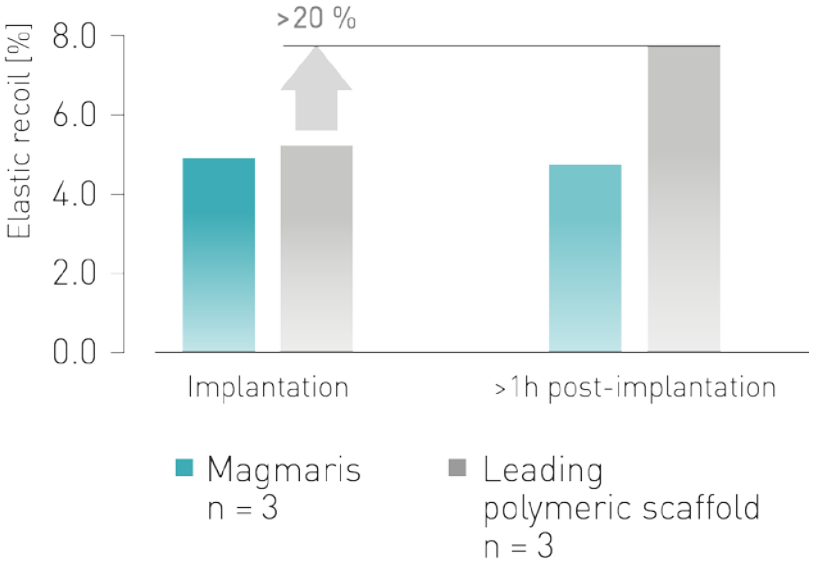
Simulation



The scaffold is implanted into a mock vessel.
The scaffold is 10% oversized.
The recoil measured is impacted by the intrinsic recoil and the force from oversizing.

Acute recoil

No recoil increase: Conventional leading polymeric scaffold diameter decrease >20% within 1st hour .



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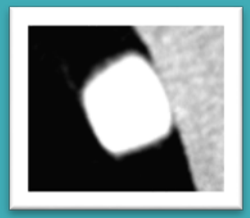
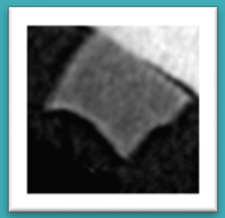
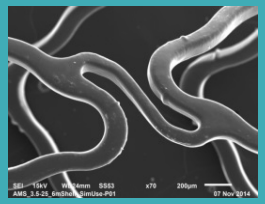
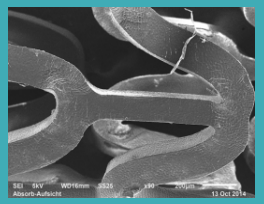
Magnesium allows for electropolishing

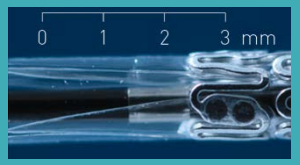
Magmaris	Leading polymeric scaffold	Magmaris	Leading polymeric scaffold	Magmaris	Leading Polymeric scaffold

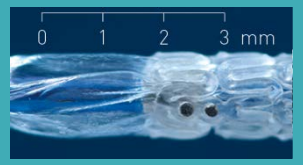


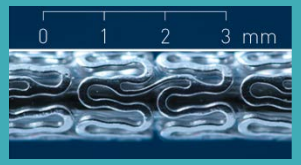


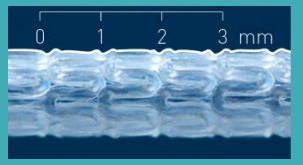












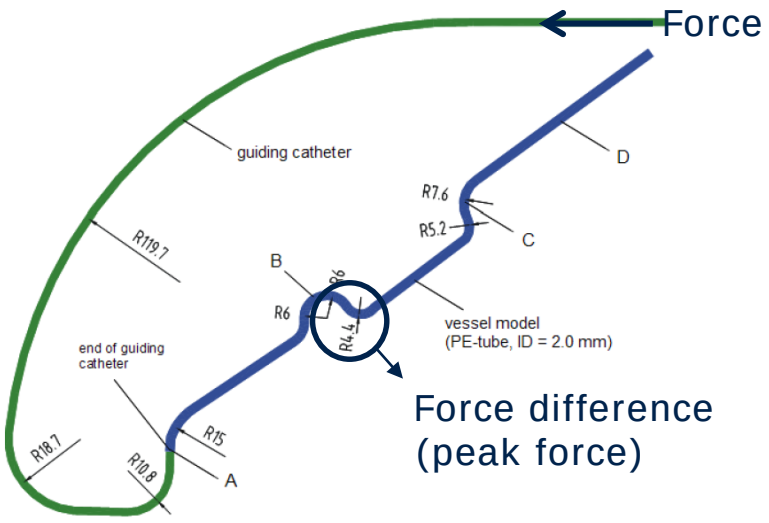
Magmaris: Squared shape with rounded edges

Leading polymeric scaffold: Rectangular shape with sharp edges

Test set up by IIB; BIOTRONIK data on file

Deliverability: Trackability

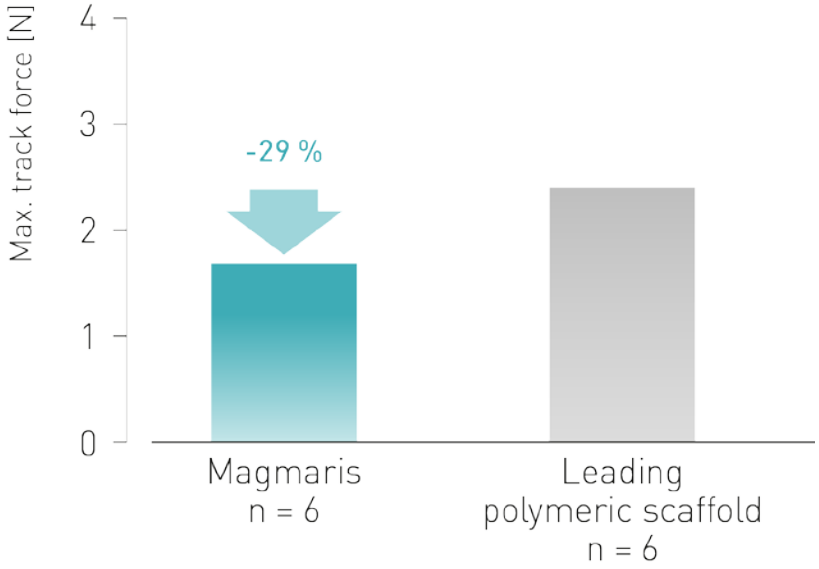
Simulation of a tortuous path



- Advance reference catheter
- Retreat reference catheter to 220mm
- Fix this as starting position
- Start measurement

Trackability

Better trackability in tortuous anatomy: Magmaris has 29% less peak force compared to the leading polymeric scaffold



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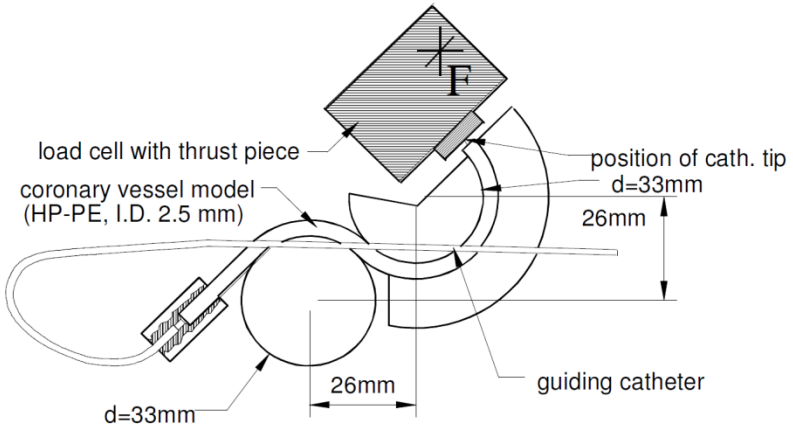
Deliverability: Pushability

Simulation

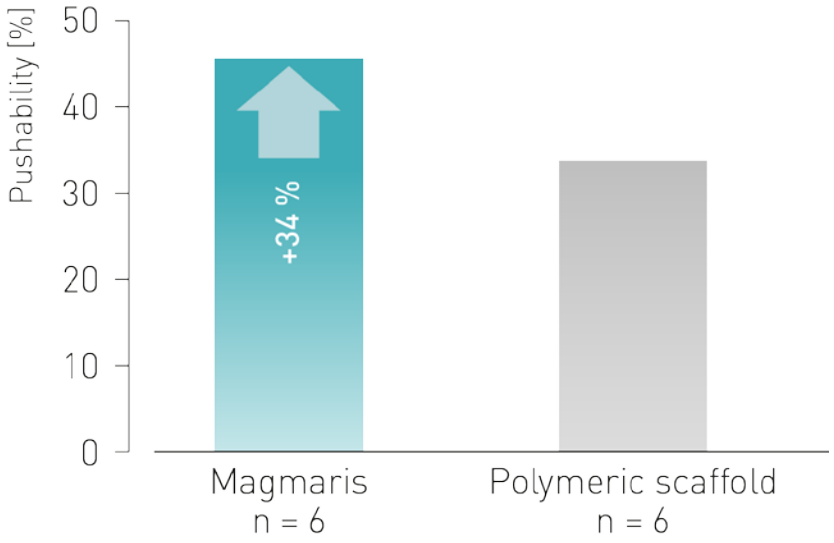


The catheter is pushed against a wall (simulating a total occlusion).
The force is measured at the proximal and distal end (wall) and were expressed as a percentage by each other.

Graph: W. Schmidt et.al. “A comparison of the mechanical performance characteristics of seven drug-eluting stent systems”, Catheterization and Cardiovascular Intervention, 73 (2009), 350-360

Pushability

Better pushability: Magmaris has 34% more force transmitted from hub to tip compared to the leading polymeric scaffold



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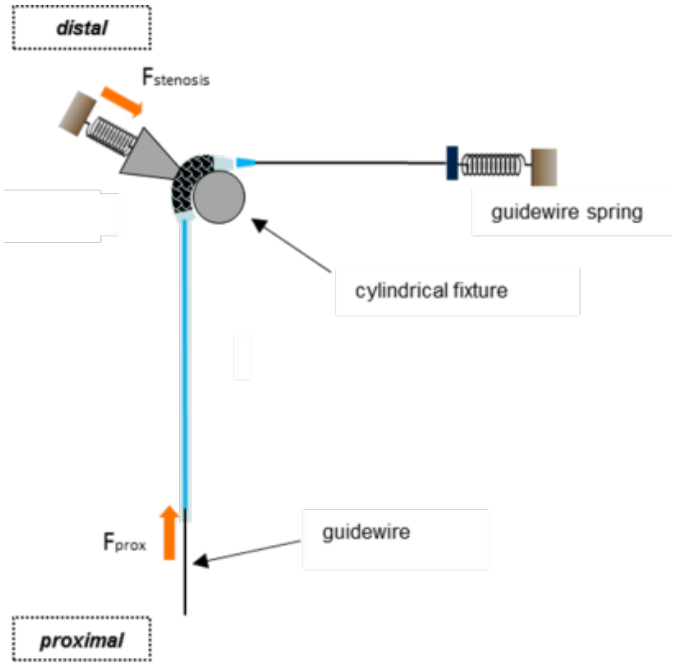
Deliverability: Crossability

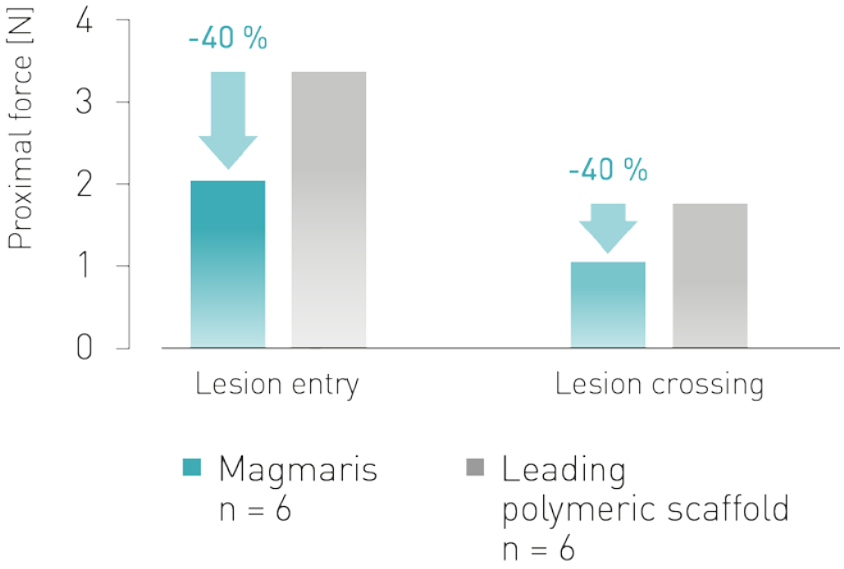
Simulation



The delivery system is crossing a narrow lesion while the force is measured

Crossability

Better lesion crossing: Magmaris needs up to 40% lower lesion entry and crossing force compared to the leading polymeric scaffold



BIOTRONIK data on file

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Magmaris allows single step inflation

Magmaris

Single step inflation of the balloon

"Inflate the dilatation balloon slowly to expand the scaffold to the diameter in accordance with the compliance chart on the label. Maintain inflation pressure for at least 15-30 seconds for full expansion of the scaffold."[2]

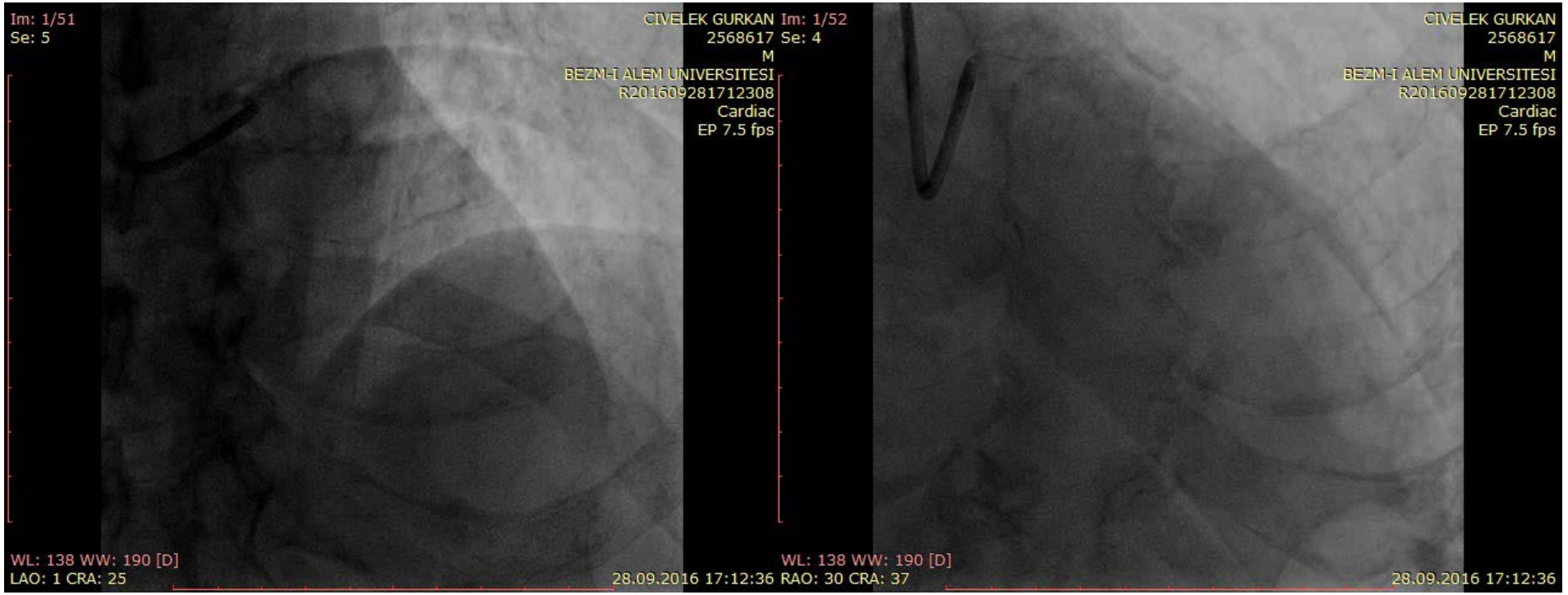
Absorb

Stepwise inflation of the balloon

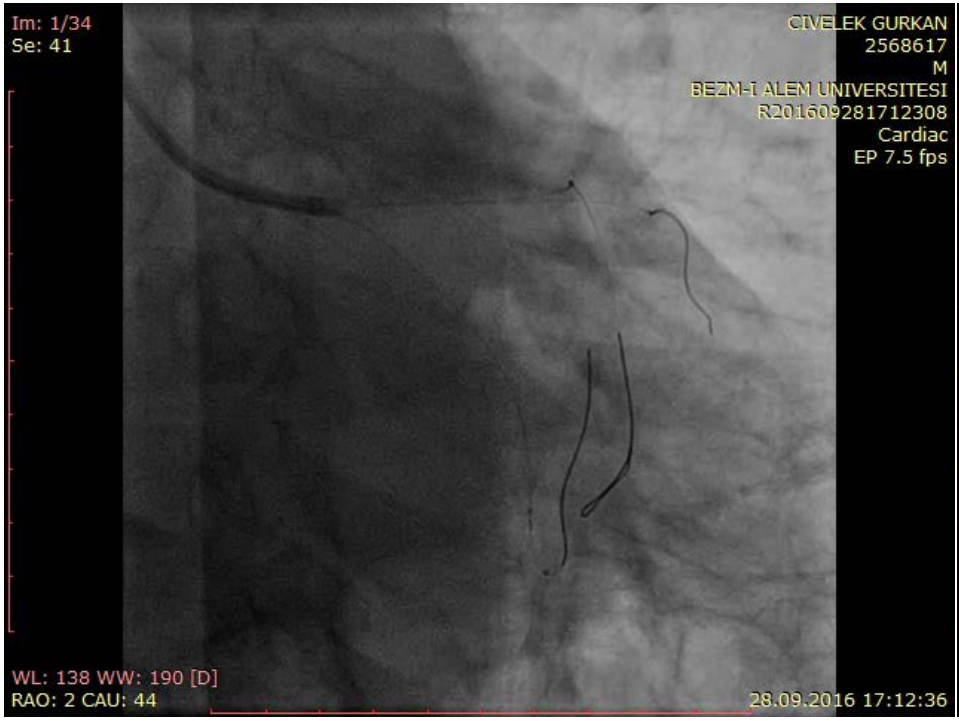
"Deploy the scaffold slowly, by pressu-rizing delivery system in 2atm increase-ments, every 5 seconds, until scaffold is completely expanded. Maintain pressure for 30 seconds."[1]

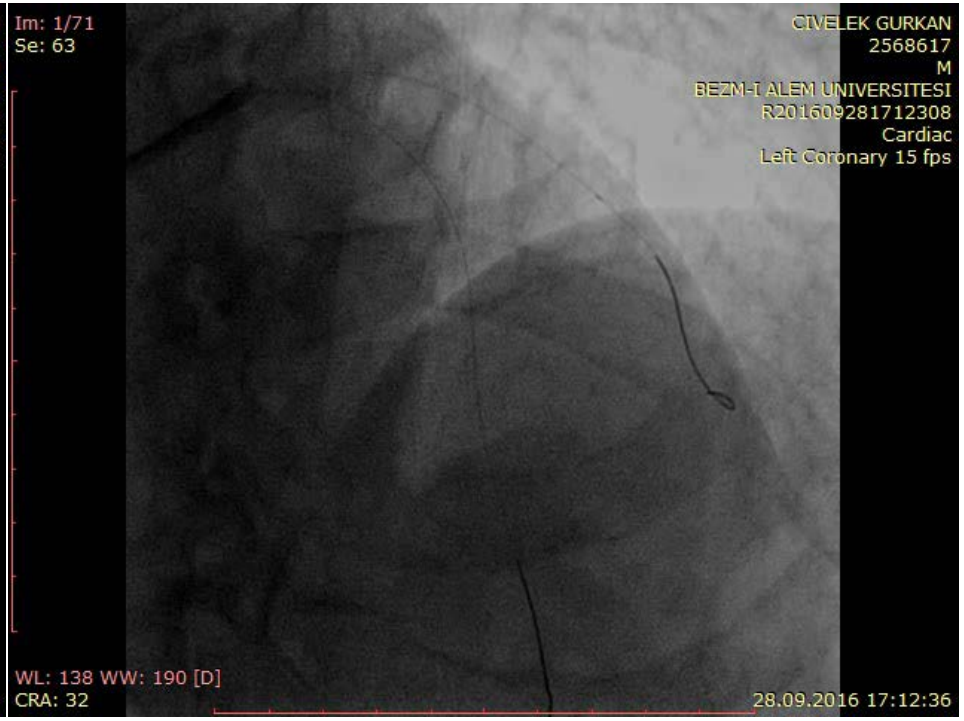
[1] ABSORB IFU 2013
[2] Magmaris IFU 2016

VAKA SUNUMU



VAKA SUNUMU





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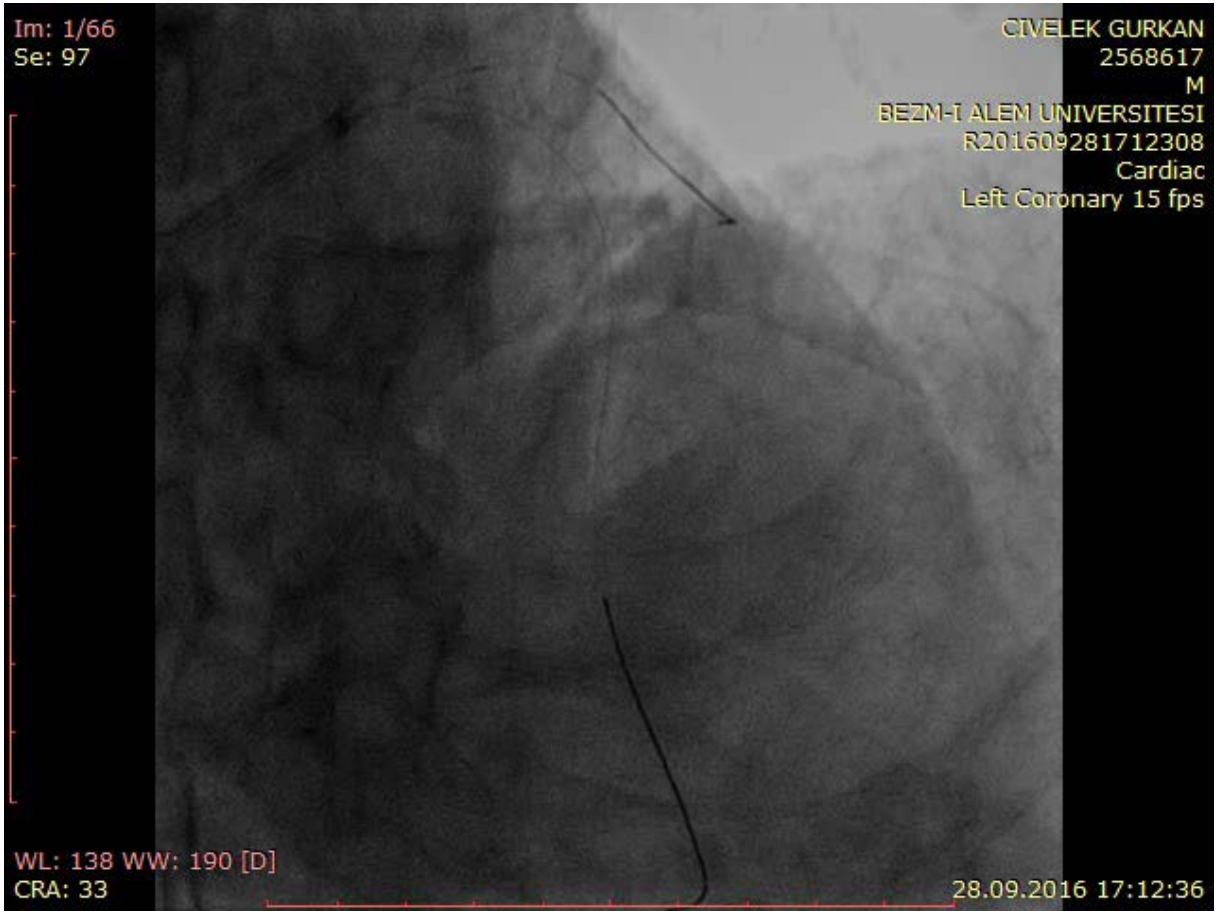

Magmaris stentler prox.-dist. 3.5x25 mm 3.5x15 mm 3.0x20 mm

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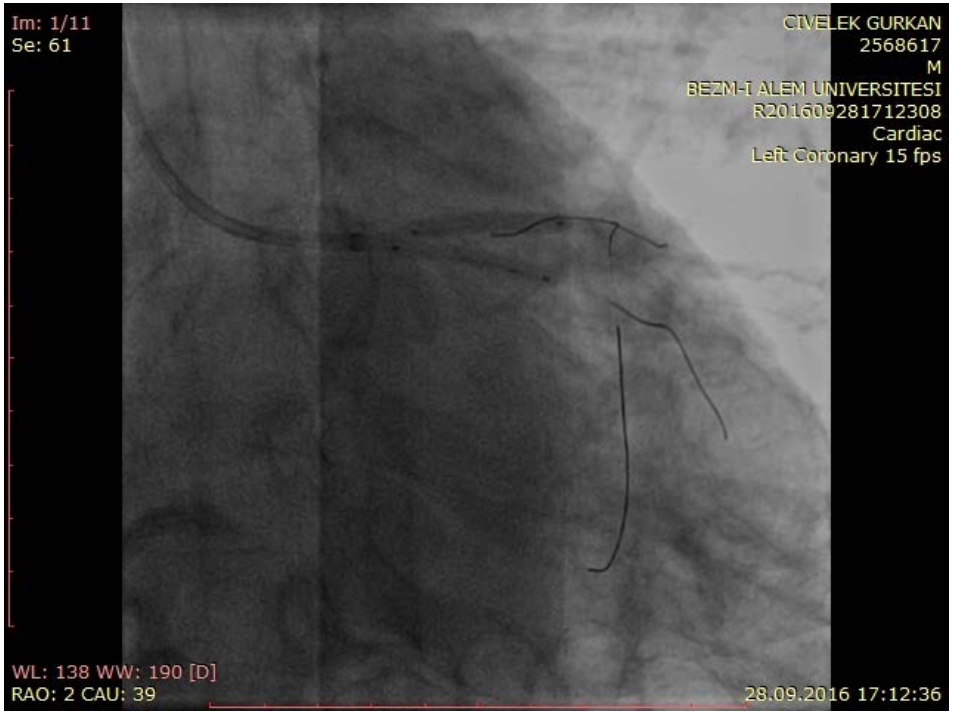

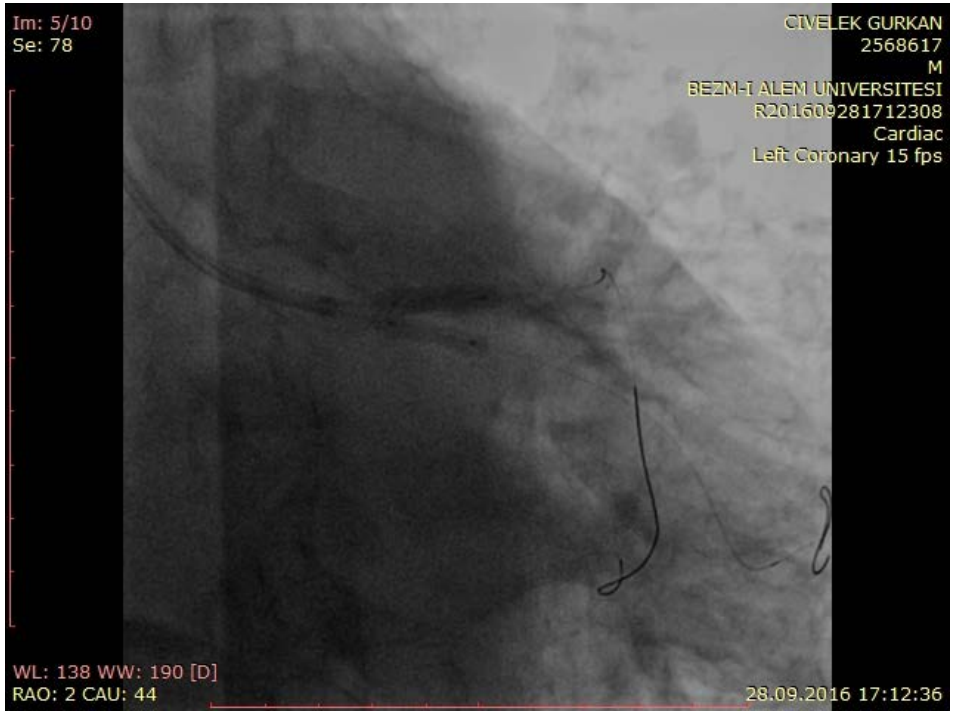

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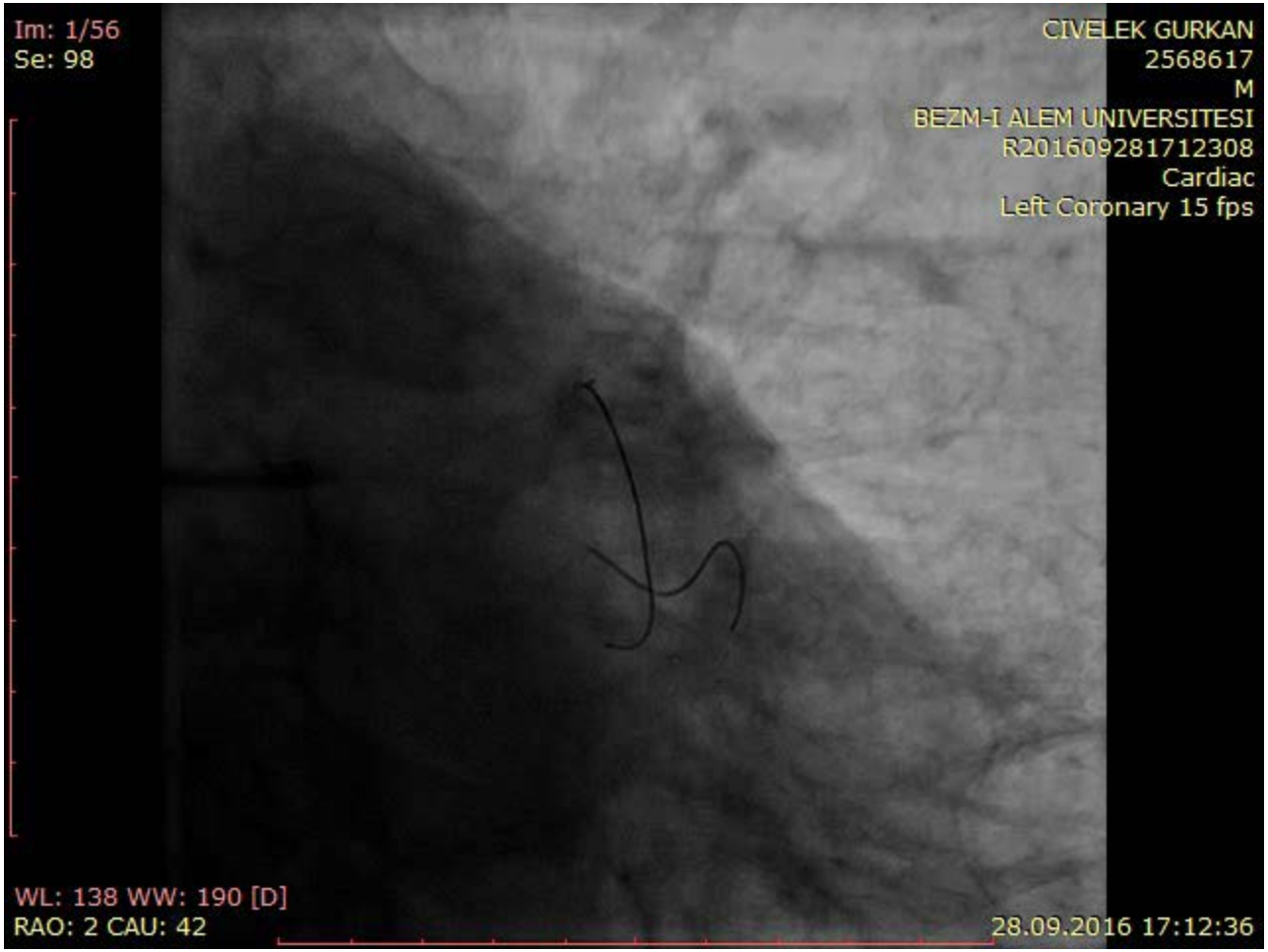

TEŞEKKÜR EDERİM...

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