

Klinický profil a osud nemocných s bioresorbovatelným hořčíkovým stentem

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Revoluce v intervenční kardiologii

- 1977 Andreas Gruntzig (první angioplastika)
- 1986 Sigwart and Puel (první implantace stentu)
- 1999 Eduardo Sousa (první implantace drug eluting stentu)
- 2011 Schválení Absorb BVS (bioresorbable vascular scaffold) v Evropě
fourth revolution in interventional cardiology

Proč implantovat BVS?

Possible advantages of transient BRS vs. permanent DES

Restoration of vessel anatomy

Vessel angulation and curvature are anticipated to be **restored by the time the scaffold loses its integrity.**

Restoration of vessel functionality

Liberation from the permanent metal cage will facilitate **restoration of vessel pulsatility and vasomotion.** Compensatory expansive remodeling and/or lumen enlargement will not be restricted.

Restoration of low thrombogenic milieu

The risk of late or very late scaffold thrombosis will be eliminated as **the foreign material (platform & coating) will be resorbed.**

Potential elimination of neoatherosclerosis

Complete scaffold resorption, intact endothelium with restored vasomotion will potentially eliminate the risk of in-scaffold neoatherosclerosis.

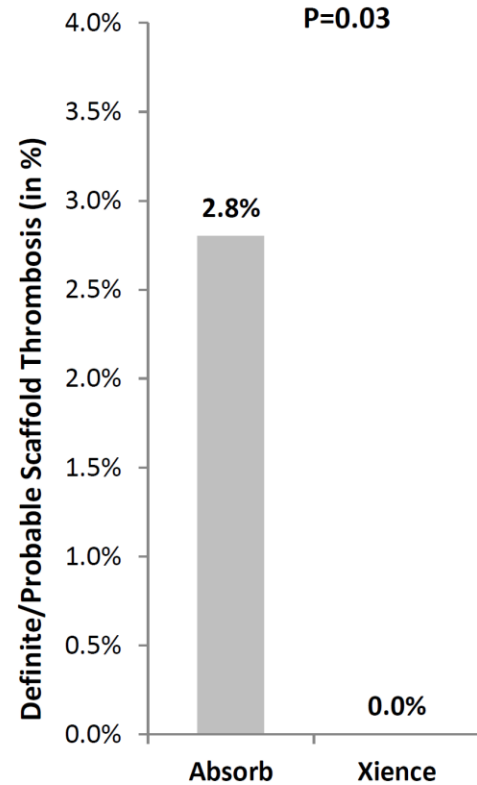
Vascular Restoration Therapy

Absorb BVS

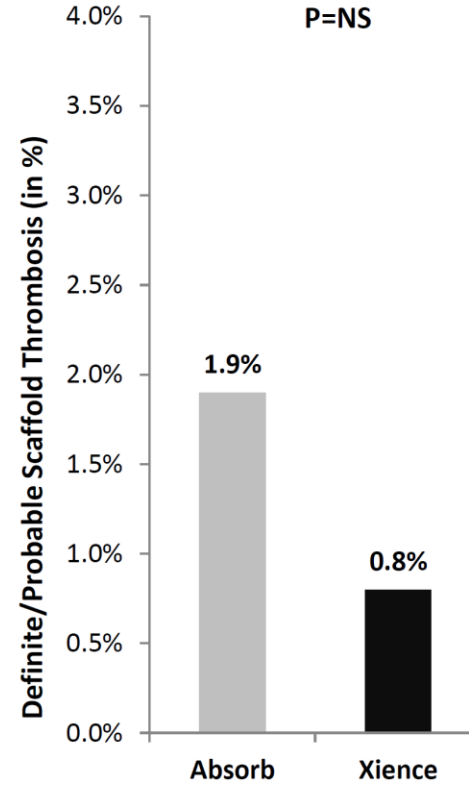
Recent studies show increased thrombosis tendency in BVS vs DES.

Thrombosis in general however has multifactorial causes, thick strut design being one of them

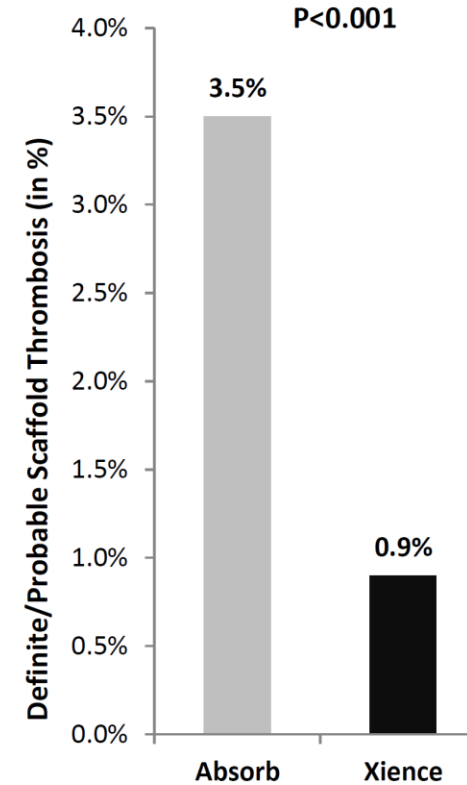
ABSORB II – 3-year data¹



ABSORB III – 2-year data²



AIDA – 2-year data³



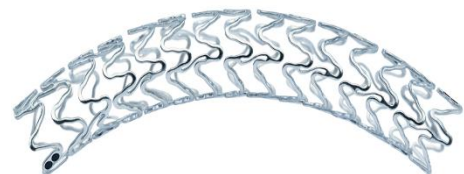
1) Adapted from Serruys P. et al., The Lancet 2016; 388(10059):2479-2491

2) Adapted from Ellis S.G. oral abstract presentation at ACC 2017

3) Adapted from Wykrzykowska J.J. et al., New England Journal of Medicine 2017, published online ahead of print

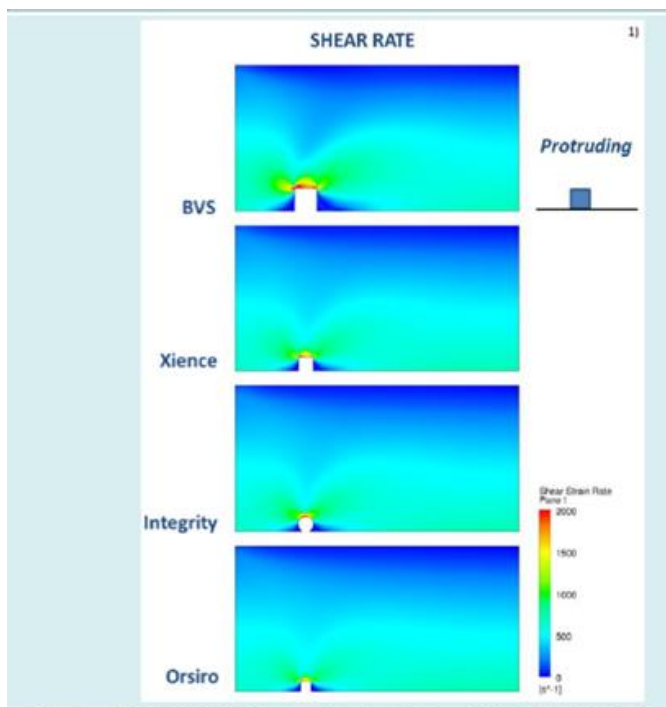
Magmaris vs Absorb (GT1)

Product	Magmaris	Absorb (GT1)
Availability	2016: CE	2012;(2015): CE 2017: Withdrawn from market in Europe and Australia
Material	Magnesium	PLLA
Scaffolding time	Up to 3m	6-12m
Resorption time	1y	3-4y
Number of sizes	6	14
Diameter [mm]	3.0; 3.5	2.5; 3.0; 3.5
Length [mm]	15; 20; 25	8; 12; 18; 23; 28
Marker	Tantalum	Platinum
Struts thickness/width [μm]	150/150	150/180
Crossing profile [mm]	1.5	1.45
Drug	Sirolimus	Everolimus
Nb of implantations	> 1500 232 in studies	> 150'000 > 30'000 in studies



Stent struts

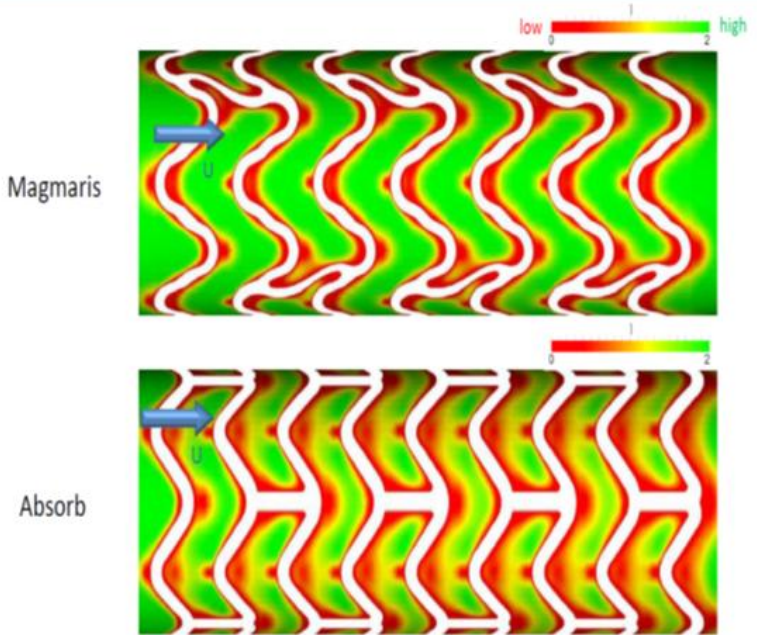
Velikost strutu



1) Foin, N., et al. IJCA . 2014;143 (09), 2) Tolentino, A. Cardio Nurse/Tech. Symp. 2016, 3) Koskinas K., J Am Coll Cardiol

Strut design

The Magmaris backbone design was found to optimize the wall shear stress compared to the Absorb design. High WSS in between strut crowns (green areas) is physiologic and is associated with accelerated endothelialization.

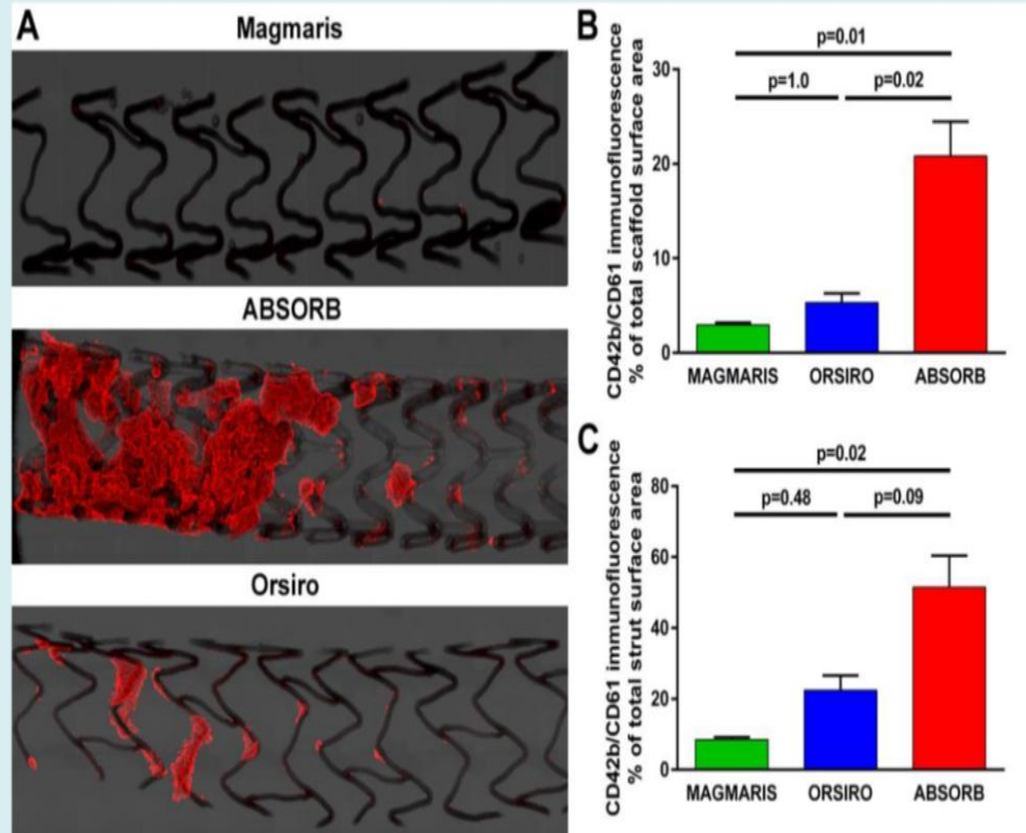


Stent (kostra)

Platform

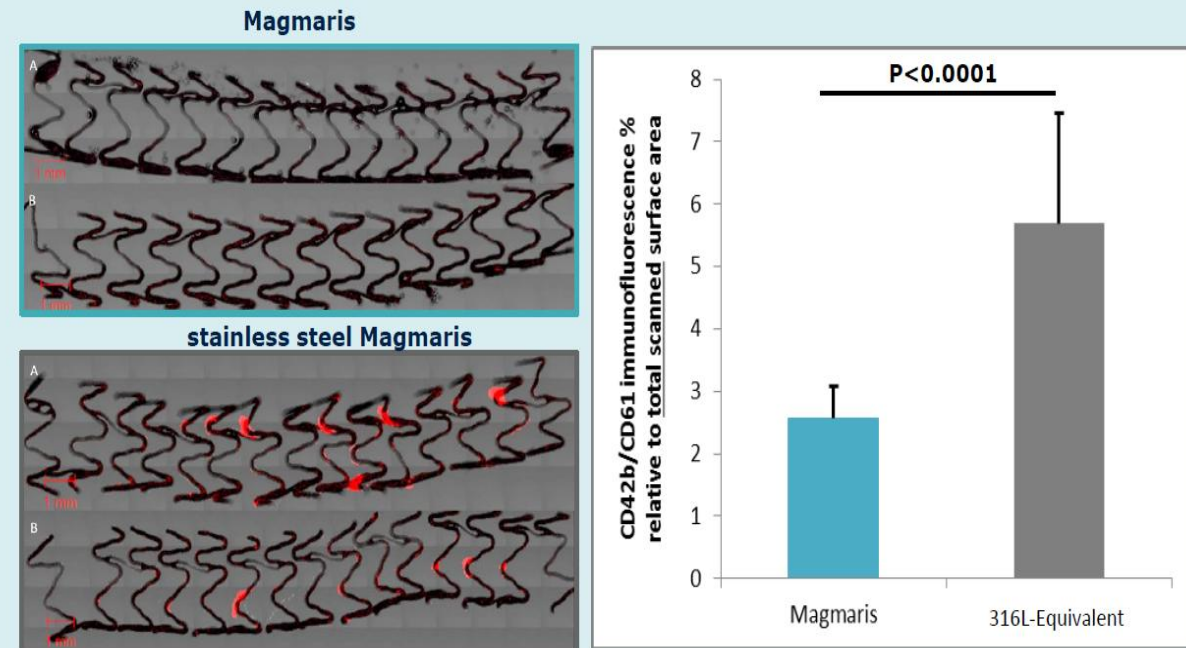
Mg, PPLA, Co-cr

- Significantly less platelet coverage in Magmaris and Orsiro compared to Absorb



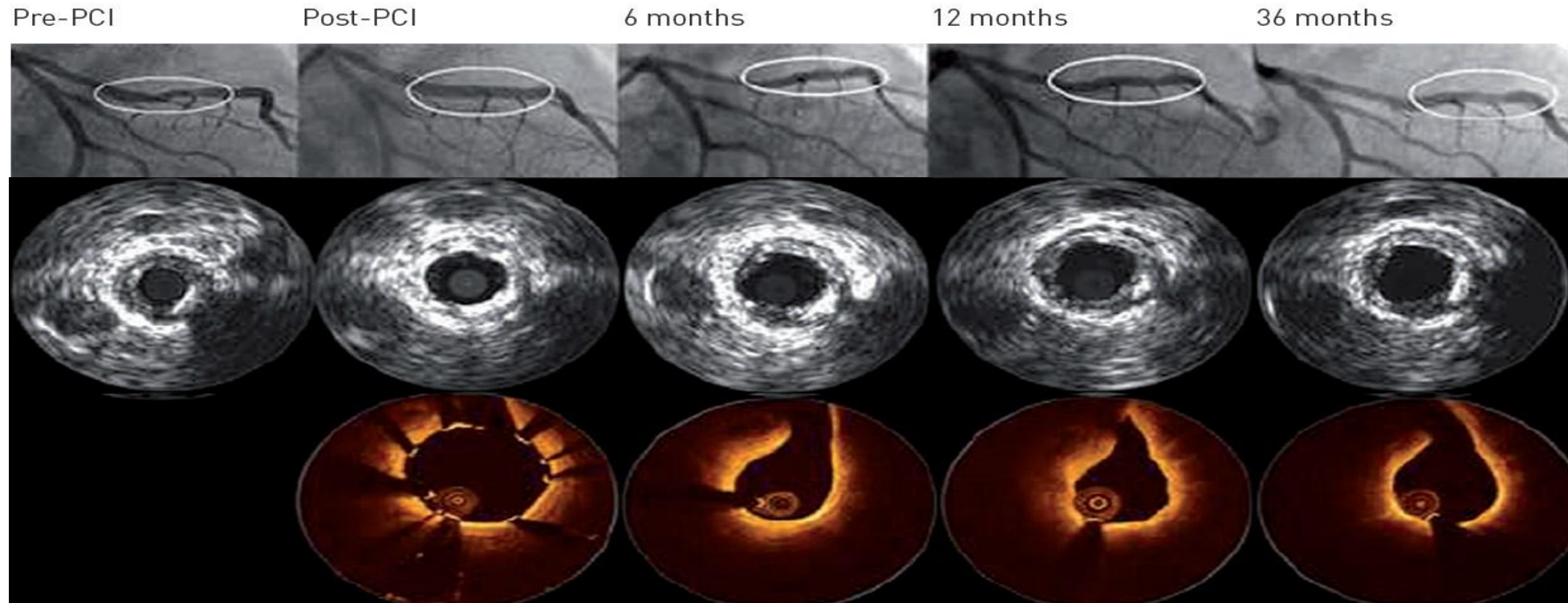
Mg kostra

- Significantly less platelet coverage in Magmaris compared to stainless steel Magmaris



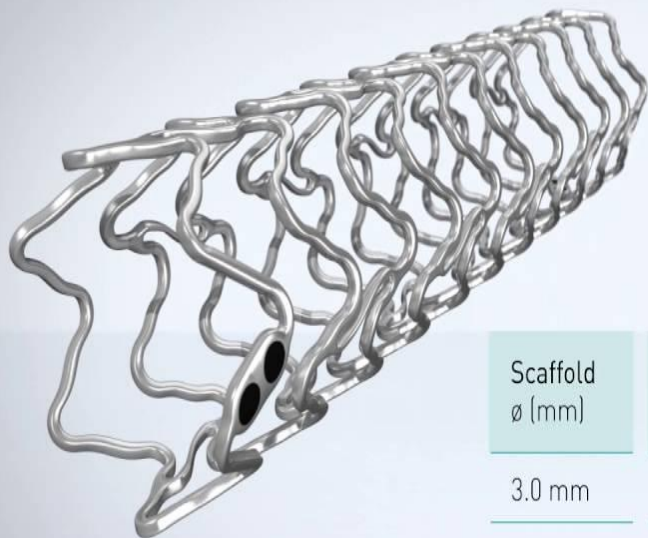
Vascular restoration therapy

Serial angiographic, IVUS and OCT of a patient implanted with Magmaris at 3-year follow-up



Magmaris

Product portfolio



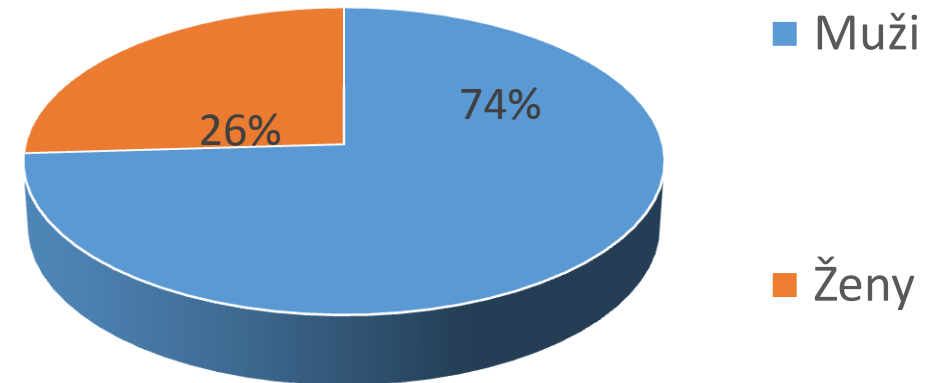
Scaffold ø (mm)	Scaffold length (mm)		
3.0 mm	15 mm	20 mm	25 mm
3.5 mm	15 mm	20 mm	25 mm

- bioresorbovatelný kovový stent
- sirolimus eluting (90 dní)
- 150 ug struts
- 12 měsíců 95 % resorbováno

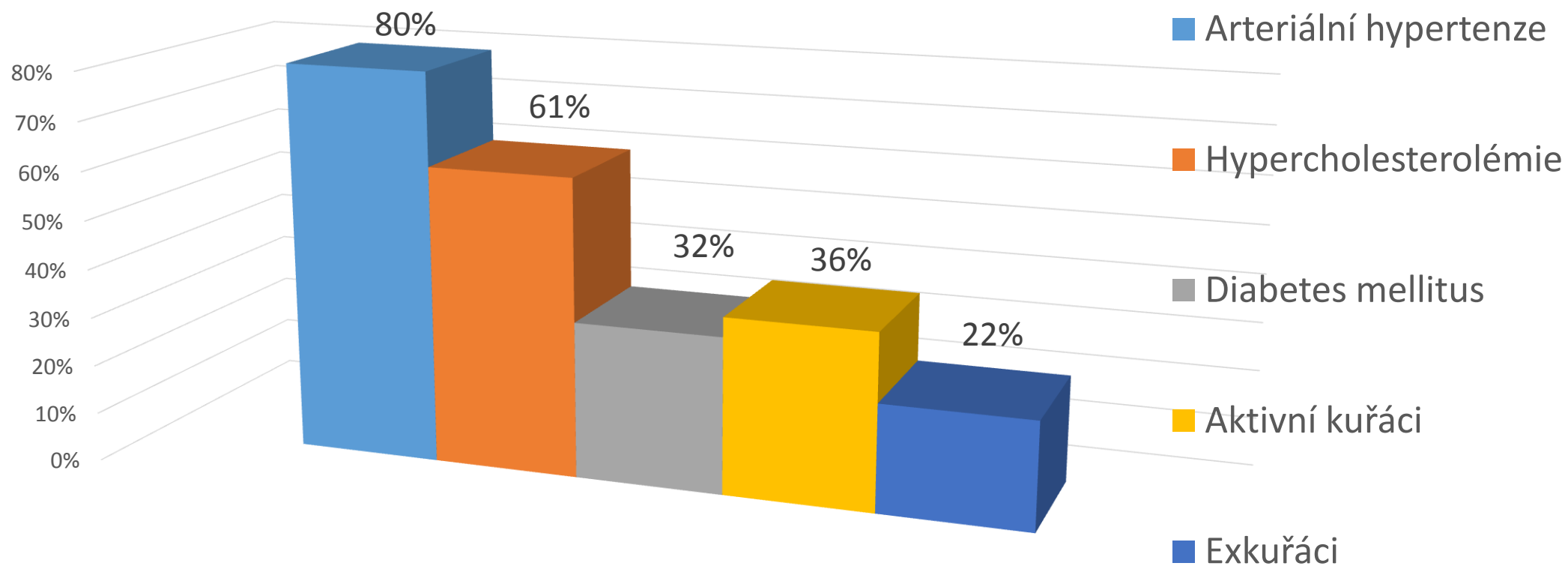
Soubor pacientů

- v období 10 měsíců (3-12/2017) implantováno 87 stentů Magmaris u 81 pacientů
- průměrný věk 62 let (33 let – 87 let)
- prospektivní sledování pacientů

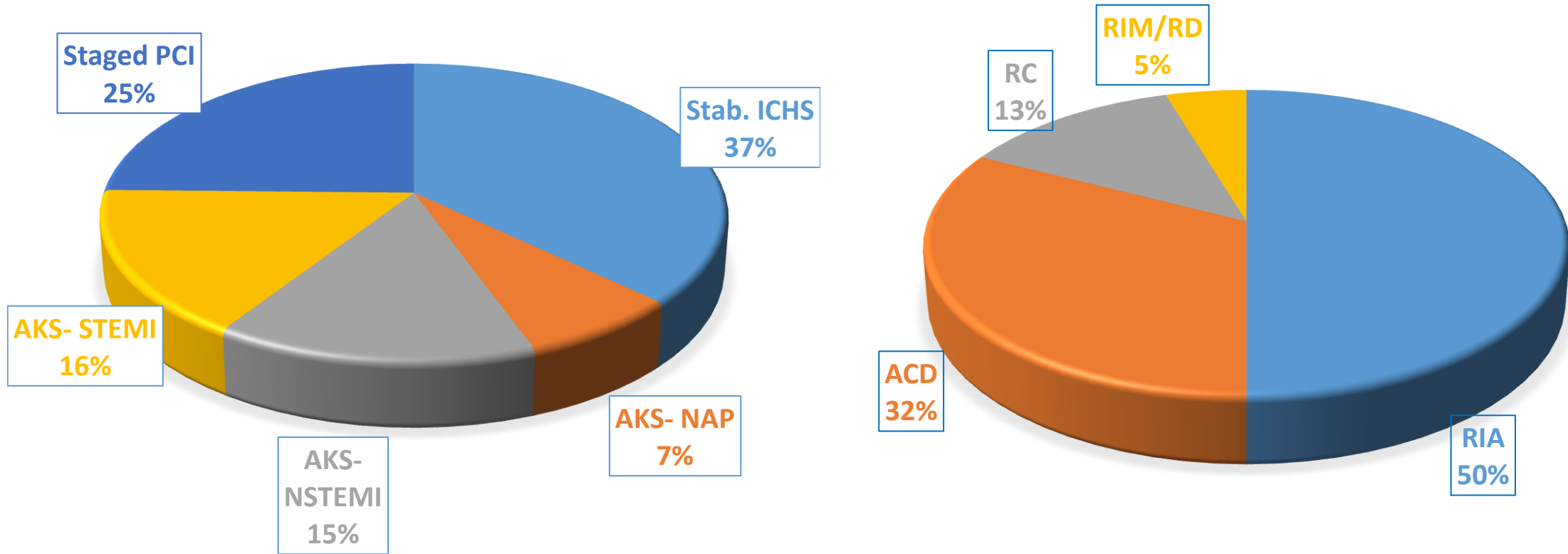
Pohlaví



Rizikový profil pacientů



Indikace a intervenovaná tepna



Perioperační zobrazovací metody

euro
PCR

The 4Ps: Patient Selection, Proper Sizing, Pre-Dilatation, Post-Dilatation



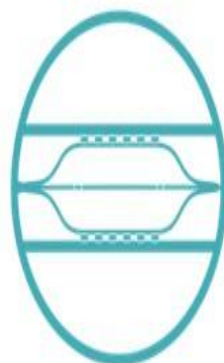
Patient Selection



Proper Sizing

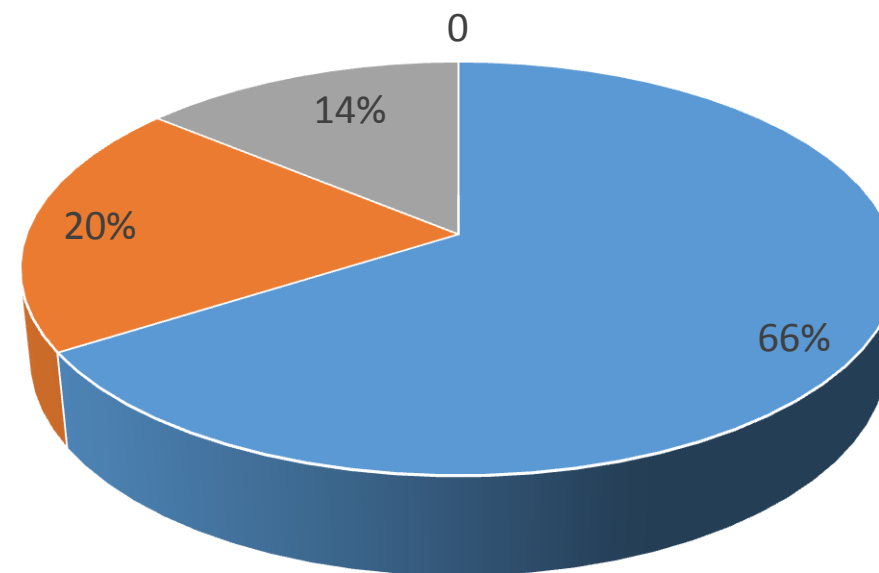


Pre-Dilatation



Post-Dilatation

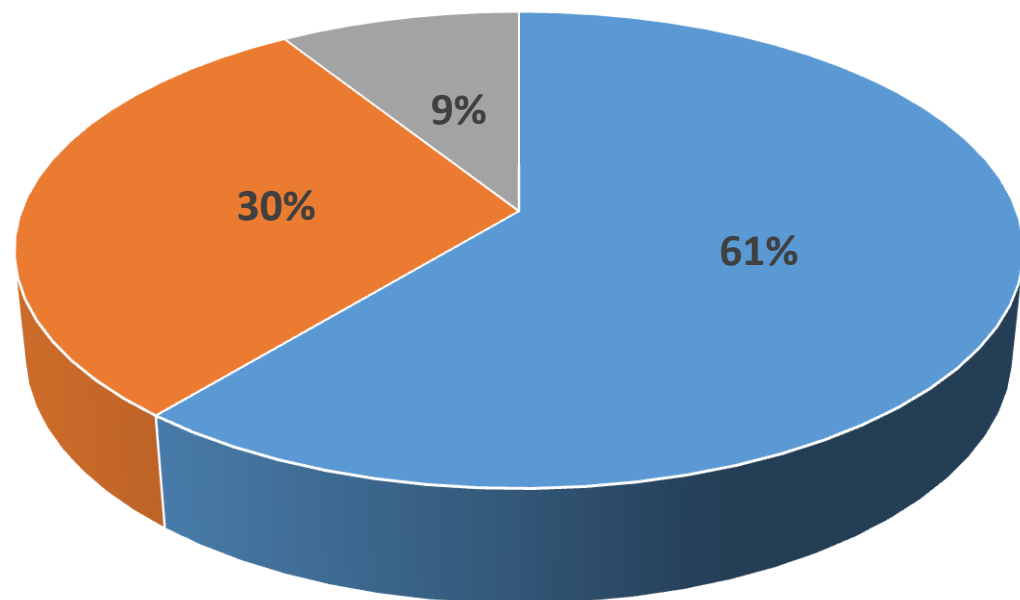
Metoda



■ Angiografie ■ OCT ■ IVUS

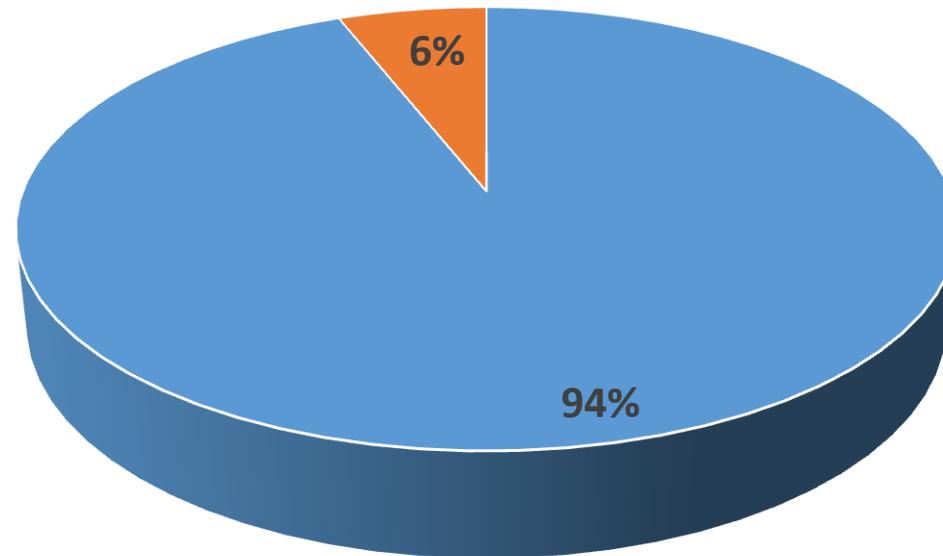
Periprocedurální aspekty

Predilatace



■ Balon ■ Scoring balon ■ Cutting balon

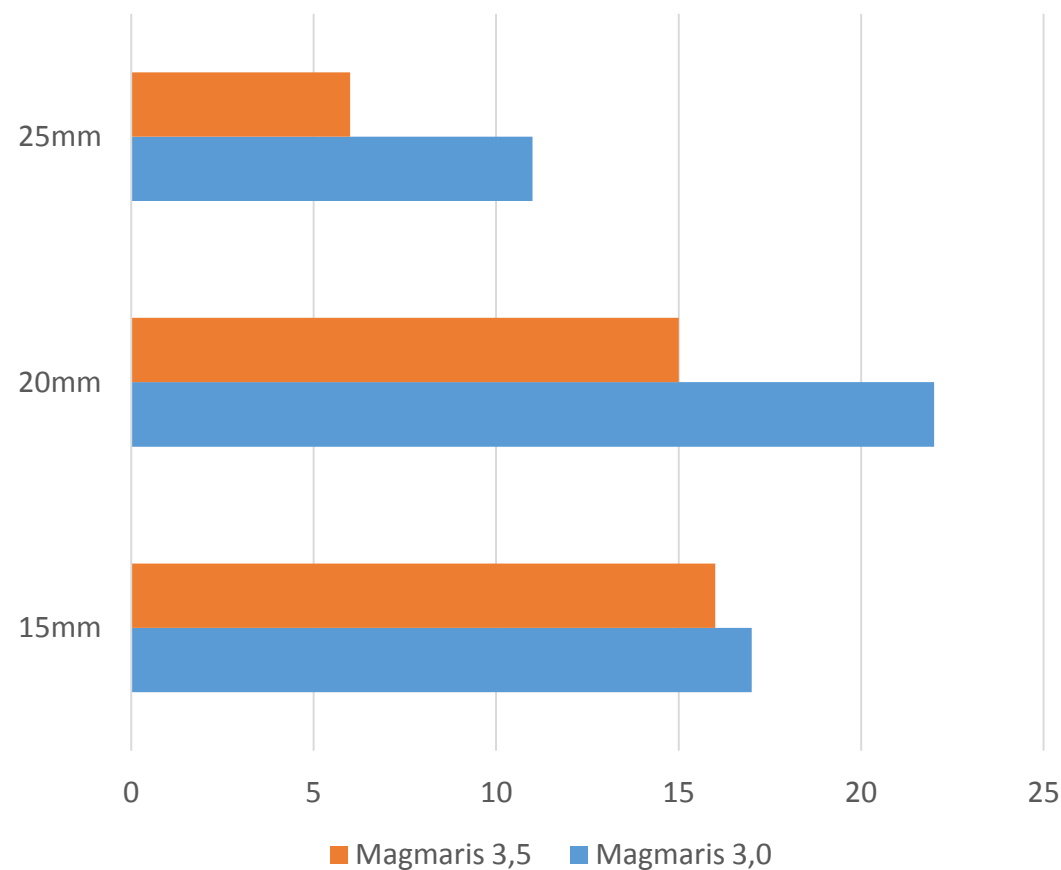
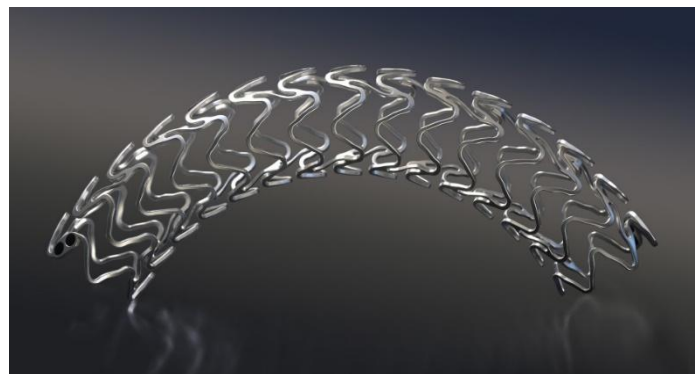
Postdilatace



■ ano NC balonkem ■ ne

Rozměry implantovaných stentů

- periprocedurální úspěch 100 %
- komplikace: 3 pacienti
edge disekce s nutností
implantace dalšího stentu
(1 pacient periprocedurální IM)



08.09.2017
13:07:46
7 Sn 7

RAO 20.0
CRAN 21.7
kV 79
mA 677
ms 7

08.09.2017
13:34:12
23 Sn 23

RAO 17.6
CRAN 16.0
kV 75
mA 677
ms 6

Kardiocentrum Pardubice
AlluraXper

um Pardubice
AlluraXper

W 189
C 128

Sledování (3-12 měsíců)

- prospektivní klinické a telefonické
- 50 % pacientů 12 měsíční sledování , 85 % 6 měsíční
- žádná akutní či subakutní trombóza stentu
- 4 pacienti s vynucenou revaskularizací

Target lesion/vessel failure

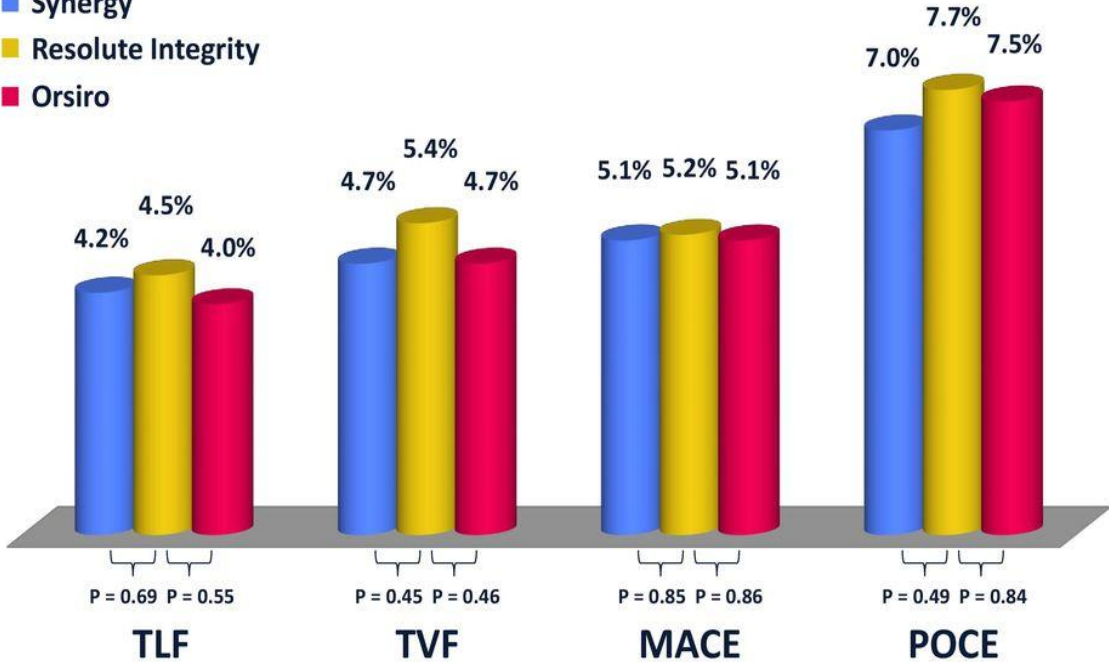
- 2 pacienti target lesion revascularization – ve stentu
(underexpanze stentu, recoil)
- 2 pacienti target vessel revascularization – mimo stent
(mismatch, IM při vysazení DAPT)

Srovnání s DES

Composite Clinical Endpoints

At 1-Year Follow-Up

- Synergy
- Resolute Integrity
- Orsiro



- Target lesion revascularization

2,45 %

- Target vessel revascularization

4,9%

Take home message

- správná indikace a výběr pacienta (life expectancy, inserce bypassu)
- důraz na optimální přípravu léze
- nízký prah pro zobrazovací metody (OCT , IVUS)
- mandatorní postdilatace vysokotlakým balonem
- DAPT 12 měsíců (6 měsíců minimum)