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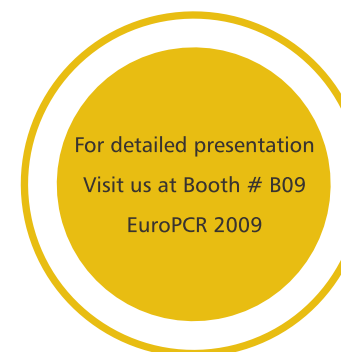
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ABSTRACT_EUROPCR/001/MLS/20090327/IND



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IMPACT OF NOVEL PLATFORM DESIGNS ON THE IN-VIVO BIOCOMPATIBILITY OF BARE-METAL STENTS IN PORCINE CORONARY ARTERIES

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BACKGROUND:

Coronary stenting is an essential component of percutaneous coronary intervention (PCI). Despite the several advantages of drug-eluting stents in terms of lower restenosis, bare-metal stents still maintain an important role given their overall safer profile.

Yet there has been little research on improvements in bare-metal stent design platforms and their impact on biocompatibility.

We thus aimed to compare in a porcine coronary model the biocompatibility of different bare-metal stents, including *a novel cobalt chromium stent with transitioning design*.

METHODS:

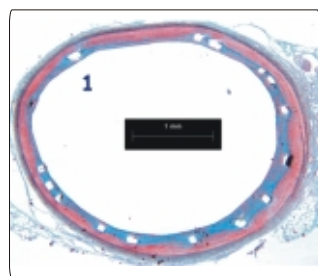
Thirty-three piglets underwent coronary stenting in at least 2 coronary segments each with the following devices:

- ❖ Thinner strut cobalt chromium stents (NexGen™ or Osum™, Meril Life Sciences; group A)
- ❖ Thicker strut cobalt chromium stents (Driver, Medtronic; group B) or
- ❖ Thicker strut stainless steel stents (Duraflex, Avante; group C)

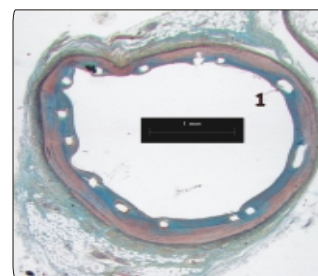
Pigs were then sacrificed at 28 and 90 days to appraise biocompatibility.

The primary end-point was mid in-stent neointimal thickness.

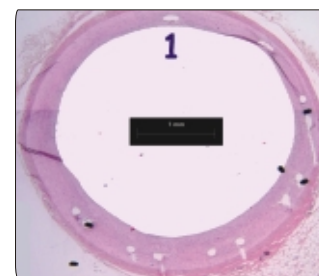
28-day histopathology slides



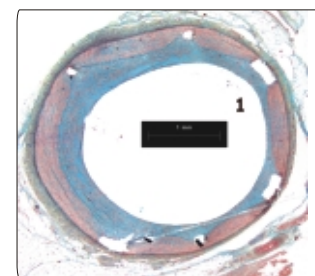
NexGen™



Osum™



Driver



Duraflex

RESULTS:

Angiographic and procedural success was obtained in all cases. No untoward effects were found in any of the animals.

Histomorphometric analysis at 28 days after sacrifice showed significant differences in mid stent neointimal thickness (0.18 ± 0.08 mm for group A vs 0.33 ± 0.13 mm for group B and C, $p=0.03$), favoring thinner strut cobalt chromium stents.

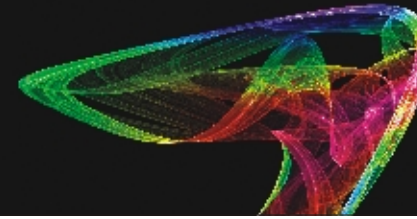
This difference was maintained when comparison was focused only at cobalt chromium stents, showing significant differences in terms of mid stent neointimal thickness (0.18 ± 0.08 mm for group A vs 0.30 ± 0.41 mm for group B, $p=0.02$) favoring stents with thinner strut designs.

Similarly beneficial results for thinner strut cobalt chromium stents on mid stent neointimal hyperplasia were also found at 90 days (0.09 ± 0.04 mm for group A vs 0.26 ± 0.04 mm for group B and C, $p=0.02$), with thinner strut designs proving superior even when the comparison was focused only on cobalt chromium stents (0.09 ± 0.04 for group A vs 0.25 ± 0.03 for group B, $p=0.05$).

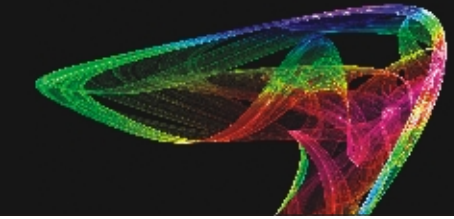
CONCLUSION:

This study provides in vivo demonstration of the different bare-metal stents can offer different degrees of biocompatibility, and also that thinner strut cobalt chromium stents can reduce neointimal hyperplasia, warranting further research on drug-eluting stents based on thinner strut cobalt chromium stent platforms.

NEXGEN™
Cobalt Chromium Coronary Stent System



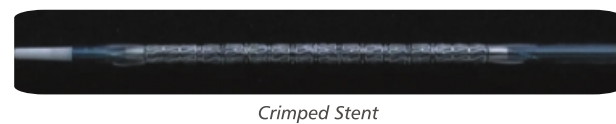
NEXGEN™
Cobalt Chromium Coronary Stent System



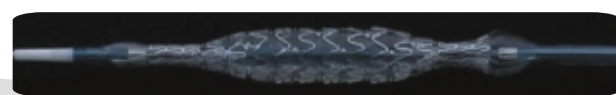
Delightful performance. Delivered.

Design premise & philosophy

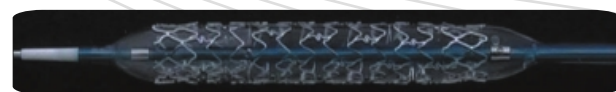
- ❖ Stenting induced arterial injury is an important determinant of restenosis and the amount of vascular injury inflicted during a stenting procedure is a function of stent-balloon complex.
- ❖ NexGen™ design is based on low-injury stent-balloon complex minimizing injury and thus restenosis.



Crimped Stent



Morphology Mediated Expansion™



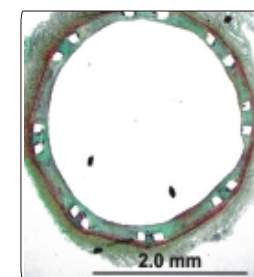
Fully Expanded Stent

Delightful low injury stent – NexGen™

- ❖ NexGen™'s 65µm ultra-low strut thickness, novel hybrid design comprises of an intelligent mix of open & closed cell design configuration which ensures a delightful Morphology Mediated Expansion™ and minimized vascular injury.

Highly competitive bio-mechanical features

- ❖ On bench tests, NexGen™ has competitive radial strength(>1bar) and zero recoil and foreshortening.
- ❖ The 6, 8 and 10 crown configurations ensure that there is optimal scaffolding and conformability, while maintaining a metal to artery ratio of ~14%.
- ❖ The special polishing process ensures that there is a mirror finish on the surface without any residual surface metal oxides.



NexGen™ Histopathology
Porcine Coronary artery 28-Days

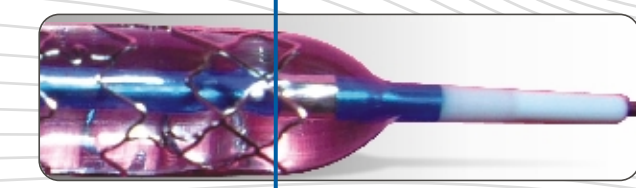
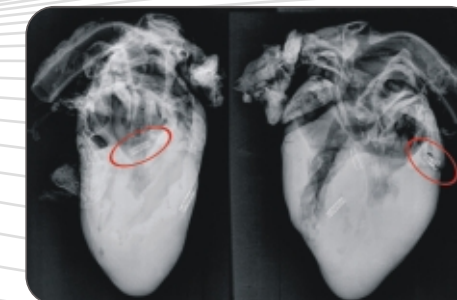
Data on file

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Delightful performance. Delivered.

Highly competitive bio-mechanical features

- ❖ The stent is pre-mounted on a semi-compliant balloon catheter and demonstrates excellent trackability and pushability.
- ❖ The balloon has short abrupt shoulders thus minimizing any chance for an edge injury.
- ❖ Our crimping process results in high stent dislodgement forces which ensure safe navigation through tortuosity and during direct stenting.
- ❖ Uncompromised radiopacity in this cobalt-chromium stent system.

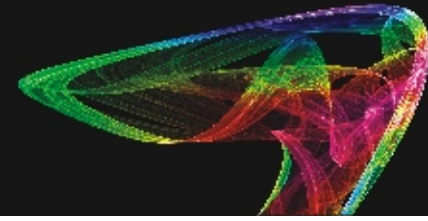


Stent & delivery system details

- ❖ Stent Material : Cobalt Chromium L605
- ❖ Strut Thickness : 65 µm (0.065mm or 0.0026") for all diameters
- ❖ Stent Diameters (mm) : 2.50, 2.75, 3.00, 3.50, 4.0, 4.50
- ❖ Stent Lengths (mm) : 8, 13, 16, 19, 24, 29, 32, 37, 40
- ❖ Mean Foreshortening : 0.29%
- ❖ Mean Recoil : <3%
- ❖ Delivery System : Rapid Exchange
- ❖ Nominal Pressure : 9 ATM
- ❖ Rated Burst Pressure : 16 ATM (for 4.5mm dia. 14 ATM)
- ❖ Balloon Overhang : <0.5 mm

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NEXGEN™ Cobalt Chromium Coronary Stent System



Delightful performance. Delivered.

Delivery system details contd.

❖ Stent Diameter	: Crossing Profile
mm	mm / inch
2.50	0.90mm / 0.035"
2.75	0.95mm / 0.037"
3.00	1.00mm / 0.039"
3.50	1.04mm / 0.041"
4.00	1.12mm / 0.044"
4.50	1.20mm / 0.047"
❖ Shaft Outer Diameter	: Proximal 1.9F / Distal 2.7F
❖ Radiopaque Markers	: 2-Platinum / Iridium
❖ Min. Guide Cath I.D.	: 5Fr
❖ Max. Guide Wire	: 0.014" (0.36mm)

Ordering Information-54 SKUs to choose from!

Dia / Length	8mm	13mm	16mm	19mm	24mm
2.50mm	NXG25008	NXG25013	NXG25016	NXG25019	NXG25025
2.75mm	NXG27508	NXG27513	NXG27516	NXG27519	NXG27524
3.00mm	NXG30008	NXG30013	NXG30016	NXG30019	NXG30024
3.50mm	NXG35008	NXG35013	NXG35016	NXG35019	NXG35024
4.00mm	NXG40008	NXG40013	NXG40016	NXG40019	NXG40024
4.50mm	NXG45008	NXG45013	NXG45016	NXG45019	NXG45024

Dia / Length	29mm	32mm	37mm	40mm
2.50mm	NXG25029	NXG25032	NXG25037	NXG25040
2.75mm	NXG27529	NXG27532	NXG27537	NXG27540
3.00mm	NXG30029	NXG30032	NXG30037	NXG30040
3.50mm	NXG35029	NXG35032	NXG35037	NXG35040
4.00mm	NXG40029	NXG40032	NXG40037	NXG40040
4.50mm	NXG45029	NXG45032	NXG45037	NXG45040

Nexgen™ & Osum™ are registered trademarks of Meril Life Sciences and both are CE marked & Indian FDA approved

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Launched in 2007, Meril's core objective is to design, manufacture and distribute clinically relevant, 'State-of-the-art' and 'Best-in-class' medical devices to alleviate human suffering and improve Quality of Life. We thus have a strong commitment towards R & D and adherence to best quality standards in manufacturing, scientific communication and distribution known to science today.

Meril's Infrastructure

- ❖ 40,000 sq. ft. of ultra-modern manufacturing facility.
- ❖ 8,000 sq. ft. of Class 10,000 clean rooms (all key activities under Class 100 LAF).
- ❖ Extremely sophisticated man-material movement via dynamic pass-boxes to eliminate production errors.
- ❖ Highly trained & motivated production team with an average age of 27 years.
- ❖ All manufacturing processes for vascular stents and balloon catheters.
- ❖ ISO 13485 & cGMP certified.
- ❖ In-house EtO sterilization with all analytical and microbiological QA tests.
- ❖ Experienced team of design, engineering, QA, regulatory, clinical & marketing.
- ❖ We are poised to undertake OEM assignments for vascular stents & balloon catheters and welcome enquiries for site inspection.

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