LOTO 25

SCHEDA TECNICA DI PRODOTTO

PRODOTTO: CATETERE A PALLONCINO ANGIOSCULPT® PER IL TRATTAMENTO COMBINATO DI INCISIONE E DILATAZIONE DELLA PLACCA ARTERIOSA

DESCRIZIONE:
Il catetere a palloncino AngioSculpt® è caratterizzato da un palloncino semicompliante rivestito da lame a spirale in nitinolo. Creando una concentrazione focale di forza dilatante, il catetere AngioSculpt® incide le lesioni arteriose quando il palloncino si espande. Può essere utilizzato come trattamento a sé o aggiuntivo prima dello *stenting*.
L'elevata conducibilità comparabile ai tradizionali cateteri a palloncino in combinazione ai benefici dell'incisione della placca e ad elevati livelli della pressione di rottura, fanno sì che il catetere AngioSculpt® sia la prima scelta nel trattamento di lesioni semplici e complesse, sia a livello coronarico che periferico.

SICUREZZA — Gli elementi di incisione semisferici hanno un corpo rettangolare con i bordi smussati:
- sicuro come i cateteri a palloncino più comuni per l'angioplastica
- livelli più bassi di dissezioni incontrollate rispetto ai cateteri a palloncino più comuni per l'angioplastica
- nessun maggior rischio di perforazione
- utilizzabile in lesioni *de novo* o ristenosi intra-*stent* (ISR)

CONDUCIBILITA' — Disegnato per garantire una dilatazione controllata con eccellente conducibilità:
- palloncino semicompliante a basso profilo
- il disegno a spirale delle lame in nitinolo fornisce una flessibilità maggiore
- la punta distale è assottigliata per una maggiore capacità di attraversamento

N.G.C. Medical S.p.A.
22060 Novedrate (CO) – Strada Prov. Novedratese 35 phone +39.031.7941.11 – fax +39.031.792130 www.ngc.it – e-mail ngc@ngc.it

Lotto 25

NCC medical spa

CODICI:

CODICE	Piattaforma	Diametro Palloncino	Lunghezza Palloncino	Lunghezza Catetere	Guida
ANG-2001-2010	RX	2.0 mm	10 mm	137 cm	0.014"
ANG-2001-2015	RX	2.0 mm	15 mm	137 cm	0.014"
ANG-2001-2020	RX	2.0 mm	20 mm	137 cm	0.014"
ANG-2001-2510	RX	2.5 mm	10 mm	137 cm	0.014"
ANG-2001-2515	RX	2.5 mm	15 mm	137 cm	0.014"
ANG-2001-2520	RX	2.5 mm	20 mm	137 cm	0.014"
ANG-2001-3010	RX	3.0 mm	10 mm	137 cm	0.014"
ANG-2001-3015	RX	3.0 mm	15 mm	137 cm	0.014"
ANG-2001-3020	RX	3.0 mm	20 mm	137 cm	0.014"
ANG-2001-3510	RX	3.5 mm	10 mm	137 cm	0.014"
ANG-2001-3515	RX	3.5 mm	15 mm	137 cm	0.014"
ANG-2001-3520	RX	3.5 mm	20 mm	137 cm	0.014"
ANG-2039-2010	OTW	2.0 mm	10 mm	137 cm	0.014"
ANG-2039-2020	OTW	2.0 mm	20 mm	137 cm	0.014"
ANG-2039-2520	OTW	2.5 mm	20 mm	137 cm	0.014"
ANG-2039-3020	OTW	3.0 mm	20 mm	137 cm	0.014"
ANG-2039-3520	OTW	3.5 mm	20 mm	137 cm	0.014"
ANG-2076-4020	OTW	4.0 mm	20 mm	137 cm	0.018"
ANG-2076-4040	OTW	4.0 mm	40 mm	137 cm	0.018"
ANG-2076-5020	OTW	5.0 mm	20 mm	137 cm	0.018"
ANG-2076-5040	OTW	5.0 mm	40 mm	137 cm	0.018"
ANG-2076-6040	OTW	6.0 mm	40 mm	137 cm	0.018"
ANG-2076-6020	OTW	6.0 mm	20 mm	137 cm	0.018"
ANG-2092-4040	OTW	4.0 mm	40 mm	90 cm	0.018"
ANG-2092-5040	OTW	5.0 mm	40 mm	90 cm	0.018"
ANG-2092-6020	OTW	6.0 mm	20 mm	90 cm	0.018"
ANG-2105-6020	OTW	6.0 mm	20 mm	50 cm	0.018"

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Lotto 25

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CARATTERISTICHE

- Piattaforme RX e OTW
- Diametri del palloncino:
  2.0, 2.5, 3.0, 3.5 mm per RX
  2.0, 2.5, 3.0, 3.5, 4.0, 5.0 e 6.0 mm per OTW
- Lunghezze del palloncino: 10, 15, 20 e 40 mm
- Profilo di attraversamento di 2.7Fr
- Compatibilità:
  con guide da 0.014" e cateteri guida 6Fr per diametri da 2.0 a 3.5 mm e
  con guide da 0.018" e cateteri guida 7Fr per diametri 4.0, 5.0 e 6.0 mm
- Conducibilità comparabile ai tradizionali cateteri a palloncino
- Lunghezza catetere 137, 90 e 50 cm

In fase di sviluppo lunghezze maggiori del palloncino nella piattaforma OTW.

PROCESSO DI STERILIZZAZIONE: ossido di etilene.

Confezione monouso sterile.
Confezione da 1 pezzo.

Smaltire secondo le normative vigenti.
Conservare in luogo fresco e asciutto.
Privo di lattice.

Marchio CE 0344

Prodotto da: Angioscore, Inc., USA
Distribuito in Italia da: NGC Medical S.p.A.

Modalità d'uso, controindicazioni, avvertenze e precauzioni sono riportate nelle Istruzioni per l'Uso allegate al prodotto. Le indicazioni contenute in questo documento non sostituiscono la lettura del manuale di Istruzioni per l'Uso.

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Lotto 25

KEMA

CERTIFICATE

Number: **2073439CE01**

CE

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Issued to:

AngioScore, Inc
5055 Brandin Court
Fremont, CA 94538
USA

For the product category:

Coronary and Peripheral Angioplasty Devices and Accessories

KEMA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 2073439CN, initially dated September 16, 2004
Addendum, initially dated September 16, 2004

KEMA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II, section 3 for Class II and Class III products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **July 1, 2010**
Issued for the first time: September 16, 2004
Renewed: July 11, 2007

drs. G.J. Zoetbrood
Managing Director

dr. ir. G.W. Bos
Certification Manager

KEMA Medical
KEMA Quality B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem The Netherlands
T +31 26 3 56 20 00 F +31 26 3 52 58 00 customer@kema.com www.kema.com Registered Arnhem 09085396

Lotto 25

KEMA

ADDENDUM

Belonging to certificate: **2073439CE01**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Coronary and Peripheral Angioplasty Devices and Accessories

Issued to:

AngioScore, Inc
5055 Brandin Court
Fremont, CA 94538
USA

This certificate covers the following product(s):

AngioSculpt Scoring Balloon Catheter (Class III)
Peripheral Scoring Balloon Catheter (Class IIa)
AngioSculpt OTW Scoring Balloon Catheter (Class III)
Peripheral OTW Scoring Balloon Catheter (Class IIa)

Initial date: September 16, 2004
Revision date: July 11, 2007

drs. G.J. Zoetbrood
Managing Director

dr. ir. G.W. Bos
Certification Manager

KEMA Medical
KEMA Quality B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem The Netherlands
T +31 26 3 56 20 00 F +31 26 3 52 58 00 customer@kema.com www.kema.com Registered Arnhem 09085396

LOTO 25

KEMA

CERTIFICATE

CE

Number: **2073439DE01**

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Issued to:

AngioScore, Inc
5055 Brandin Court
Fremont, CA 94538
USA

For the product(s) / product category:

AngioSculpt Scoring Balloon Catheter (Class III)

Documents that form the basis of this certificate:

Certification Notice 2073439CN, initially dated September 16, 2004
CE Marking of Conformity Certificate 2073439CE01

KEMA hereby certifies that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of 14 June 1993 concerning medical devices, including all subsequent amendments, and that the design of the product(s) falling within the product category mentioned above, conforms to the relevant provisions of the Council Directive 93/42/EEC of 14 June 1993, in accordance with Annex II, section 4, of this Directive. The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **July 1, 2010**
Issued for the first time: September 16, 2004
Renewed: July 11, 2007

drs. G.J. Zoetbrood
Managing Director

dr. ir. G.W. Bos
Certification Manager

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Lot 25

DECLARATION OF CONFORMITY

Medical Devices

Manufacturer	**European Authorized Representative**
AngioScore, Inc. 5055 Brandin Court Fremont, CA 94538 Phone: (510) 933-7900 Fax: (510) 933-7901	**Quality First International Limited** Suites 317/318 Burford Business Centre 11 Burford Road Stratford London E15 2ST, UK Tel: +44 (0)208 221 2361 Fax: +44 (0)208 221 1912

We hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by the "CE Marking of Conformity Certificate", reference number: 2073439CE01 issued on September 16, 2004 and delivered by KEMA Quality B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as specified below and falling within Class IIa, meet the applicable provisions of the EC-Directive. The standards used to show compliance with the EC Directive Essential Requirements are identified in the AngioSculpt Essential Requirements checklists (RG-1005 and RG-1013).

This declaration is supported by the Quality System certification based on ISO 13485:2003, Quality System Certificate with reference number 560298.01, issued on July 12, 2004 and delivered by KEMA Registered Quality, Inc.

This declaration is valid for all products described here below, bearing the CE marking and manufactured at the AngioScore facility identified above.

Product Information

Name:	**AngioSculpt® PTA Scoring Balloon Catheter**
Product and Catalog Numbers:	See attached product list
Regulatory Classification:	The AngioSculpt Scoring Balloon Catheter is classified as a Class IIa medical device per Council Directive 93/42/EEC, Annex IX, Section III, Rule 7.
Place and Date of Issue:	Fremont, California July 2008
Signature:	Karin Gastineau, VP, Medical, Regulatory, Quality / 23 July 2008 Date

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QA APPROVED
Signature
Date 7/23/08

PRODUCT LIST
AngioSculpt® PTA Scoring Balloon Catheter

Product Part Number	Product Description	Balloon Diameter	Balloon Length	Catheter Working Length	Catalog Number	Date Added
PN-2038-2010	AngioSculpt PTA, RX, 2.0mm x 10mm	2.0 mm	10 mm	137 cm	2038-2010	May, 2005
PN-2038-2015	AngioSculpt PTA, RX, 2.0mm x 15mm	2.0 mm	15 mm	137 cm	2038-2015	May, 2005
PN-2038-2020	AngioSculpt PTA, RX, 2.0mm x 20mm	2.0 mm	20 mm	137 cm	2038-2020	May, 2005
PN-2038-2510	AngioSculpt PTA, RX, 2.5mm x 10mm	2.5 mm	10 mm	137 cm	2038-2510	May, 2005
PN-2038-2515	AngioSculpt PTA, RX, 2.5mm x 15mm	2.5 mm	15 mm	137 cm	2038-2515	May, 2005
PN-2038-2520	AngioSculpt PTA, RX, 2.5mm x 20mm	2.5 mm	20 mm	137 cm	2038-2520	May, 2005
PN-2038-3010	AngioSculpt PTA, RX, 3.0mm x 10mm	3.0 mm	10 mm	137 cm	2038-3010	May, 2005
PN-2038-3015	AngioSculpt PTA, RX, 3.0mm x 15mm	3.0 mm	15 mm	137 cm	2038-3015	May, 2005
PN-2038-3020	AngioSculpt PTA, RX, 3.0mm x 20mm	3.0 mm	20 mm	137 cm	2038-3020	May, 2005
PN-2038-3510	AngioSculpt PTA, RX, 3.5mm x 10mm	3.5 mm	10 mm	137 cm	2038-3510	May, 2005
PN-2038-3515	AngioSculpt PTA, RX, 3.5mm x 15mm	3.5 mm	15 mm	137 cm	2038-3515	May, 2005
PN-2038-3520	AngioSculpt PTA, RX, 3.5mm x 20mm	3.5 mm	20 mm	137 cm	2038-3520	May, 2005
PN-2039-2010	AngioSculpt PTA, OTW, 2.0mm x 10mm	2.0 mm	10 mm	137 cm	2039-2010	Nov, 2007
PN-2039-2015	AngioSculpt PTA, OTW, 2.0mm x 15mm	2.0 mm	15 mm	137 cm	2039-2015	Nov, 2007
PN-2039-2020	AngioSculpt PTA, OTW, 2.0mm x 20mm	2.0 mm	20 mm	137 cm	2039-2020	Nov, 2007
PN-2039-2510	AngioSculpt PTA, OTW, 2.5mm x 10mm	2.5 mm	10 mm	137 cm	2039-2510	Nov, 2007
PN-2039-2515	AngioSculpt PTA, OTW, 2.5mm x 15mm	2.5 mm	15 mm	137 cm	2039-2515	Nov, 2007
PN-2039-2520	AngioSculpt PTA, OTW, 2.5mm x 20mm	2.5 mm	20 mm	137 cm	2039-2520	Nov, 2007
PN-2039-3010	AngioSculpt PTA, OTW, 3.0mm x 10mm	3.0 mm	10 mm	137 cm	2039-3010	Nov, 2007

PRODUCT LIST
AngioSculpt® PTA Scoring Balloon Catheter

Product Part Number	Product Description	Balloon Diameter	Balloon Length	Catheter Working Length	Catalog Number	Date Added
PN-2039-3015	AngioSculpt PTA, OTW, 3.0mm x 15mm	3.0 mm	15 mm	137 cm	2039-3015	Nov, 2007
PN-2039-3020	AngioSculpt PTA, OTW, 3.0mm x 20mm	3.0 mm	20 mm	137 cm	2039-3020	Nov, 2007
PN-2039-3510	AngioSculpt PTA, OTW, 3.5mm x 10mm	3.5 mm	10 mm	137 cm	2039-3510	Nov, 2007
PN-2039-3515	AngioSculpt PTA, OTW, 3.5mm x 15mm	3.5 mm	15 mm	137 cm	2039-3515	Nov, 2007
PN-2039-3520	AngioSculpt PTA, OTW, 3.5mm x 20mm	3.5 mm	20 mm	137 cm	2039-3520	Nov, 2007
PN-2076-4020	AngioSculpt PTA, OTW .018" Platform, 4.0mm x 20mm	4.0 mm	20 mm	137 cm	2076-4020	Nov, 2007
PN-2076-5020	AngioSculpt PTA, OTW .018" Platform, 5.0mm x 20mm	5.0 mm	20 mm	137 cm	2076-5020	Nov, 2007
PN-2076-4040	AngioSculpt PTA, OTW .018" Platform, 4.0mm x 40mm	4.0 mm	40 mm	137 cm	2076-4040	July, 2008
PN-2092-4040	AngioSculpt PTA, OTW .018" Platform, 4.0mm x 40mm	4.0 mm	40 mm	90 cm	2092-4040	July, 2008
PN-2076-5040	AngioSculpt PTA, OTW .018" Platform, 5.0mm x 40mm	5.0 mm	40 mm	137 cm	2076-5040	June, 2008
PN-2092-5040	AngioSculpt PTA, OTW .018" Platform, 5.0mm x 40mm	5.0 mm	40 mm	90 cm	2092-5040	June, 2008

REVISION HISTORY

Version (Rev)	Effective Date	DCO #	Author	Reason
A	05/24/05	D00316	Brant Gard	Initial release.
B	01/17/06	D00488	C. Kalinowski	Location move
C	02/12/07	D00789	M. Swanson	Updated RX product part number Deletion 1.5 mm diameter balloon Addition of OTW platform
D	03/29/07	D00858	M. Swanson	Include reference to ISO13485 and update per KEMA guidance document. Delete OTW platform until CE Mark received.
E	11/13/07	D01153	K. Kline	Updated the product list to add all OTW catheters (0.014 and 0.018 platforms).
F	5/20/2008	D01421	K. Kline	Added reference to the Essential Requirements Checklist for the 0.018" OTW platform (RG-1013).
G	6/16/2008	D01487	K. Kline	Added 2076-5040 and 2092-5040. Added a column for catheter length.
H	7/23/2008	D01593	K. Kline	Added 2076-4040 and 2092-4040.

Lotto 25

DICHIARAZIONE SOSTITUTIVA DELL'ATTO DI NOTORIETA'
(art.38 del D.P.R. nr.445 del 28/12/2000)

La scrivente N.G.C. Medical S.p.A. con sede legale in Novedrate (CO), Strada Novedratese, 35 codice fiscale 09831040150 e partita IVA 02196770131, nr. iscrizione C.C.I.A.A. Como 234052 e Trib.Como 31669 – Vol.7702, nella persona del Suo Legale Rappresentante nonché Presidente del Consiglio di Amministrazione Dr. Paolo Cremascoli, nato a Milano 03/10/1971 ed ivi residente in Via Larga, 11

DICHIARA

che la documentazione allegata è conforme all'originale.

In fede
N.G.C. Medical S.p.A.
Il Legale Rappresentante
Dr. Paolo Cremascoli

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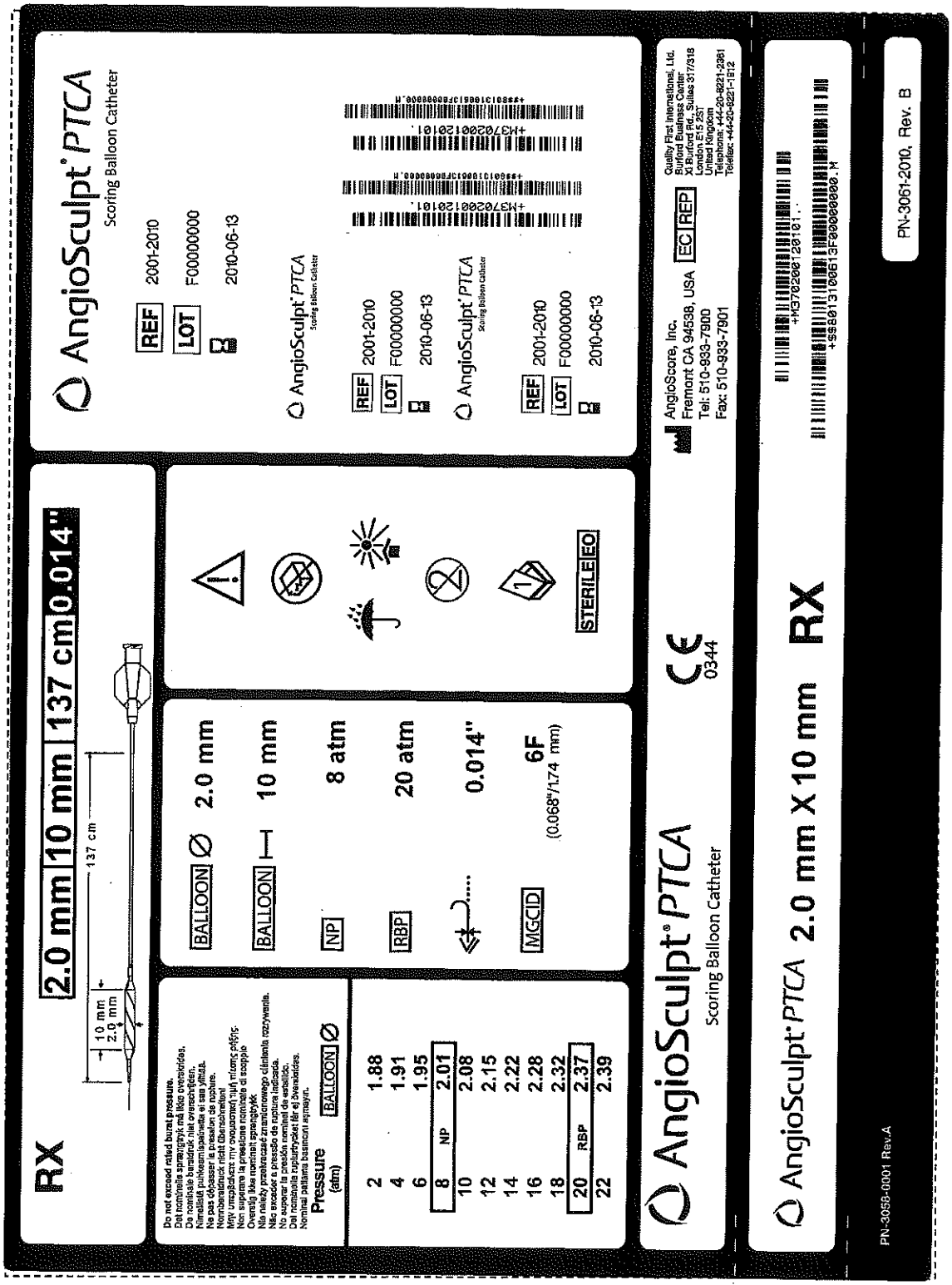
C.C.I.A.A. Como 234052 – Tribunale Como 31669

AngioScore, Inc.	Document No.: **PN-3061**
Specification, Printed Label, AngioSculpt PTCA, RX	Revision No.: **B**
	Effective Date: 6/12/2008



Cognome CREMASCOLI
Nome PAOLO
nato il 03/10/1971
(atto n. 3230 1 s. A) 24
a MILANO ( )
Cittadinanza ITALIANA
Residenza MILANO
Via LARGA N. 11
Stato civile CONIUGATO
Professione IMPRENDITORE

CONNOTATI E CONTRASSEGNI SALIENTI

Statura 1,73
Capelli CASTANI
Occhi CASTANI
Segni particolari

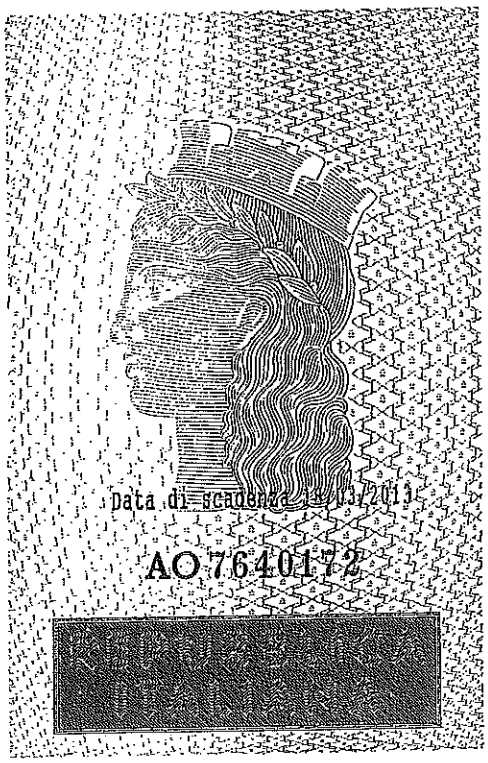
Firma del titolare

Milano li 19/03/2008

IL SINDACO
Santangelo Anna

Impronta del dito indice sinistro

Euro 5,42



Data di scadenza 19/03/2011

AO 7640172

I.P.Z.S. S.p.A. - OFFICINA C.V. - ROMA

REPVBBLICA ITALIANA

COMVNE DI MILANO

CARTA D'IDENTITA

N° AO 7640172

DI

CREMASCOLI

PAOLO

23 MAR. 2010

NGC medical spa

N.G.C. MEDICAL S.p.A.
Strada Novedratese, 35 - 22060 NOVEDRATE (CO)
P. IVA 02196770131 - C.F. 08891040160

Nonrandomized Comparison of Coronary Stenting Under Intravascular Ultrasound Guidance of Direct Stenting Without Predilation Versus Conventional Predilation With a Semi-Compliant Balloon Versus Predilation With a New Scoring Balloon

Jose de Ribamar Costa, Jr., MD, Gary S. Mintz, MD*, Stéphane G. Carlier, MD, PhD, Roxana Mehran, MD, Paul Teirstein, MD, Koichi Sano, MD, Xuebo Liu, MD, Joanna Lui, BA, Yingbo Na, MS, Celia Castellanos, MD, Sinan Biro, BS, Lockeshi Dani, BS, Jason Rinker, BS, Issam Moussa, MD, George Dangas, MD, PhD, Alexandra J. Lansky, MD, Edward M. Kreps, MD, Michael Collins, MD, Gregg W. Stone, MD, Jeffrey W. Moses, MD, and Martin B. Leon, MD

This study was conducted to determine the influence of lesion preparation using the AngioSculpt balloon on final stent expansion. Stent expansion remains an important predictor of restenosis and subacute thrombosis, even in the drug-eluting stent (DES) era. In these patients, the role of different predilation strategies has yet to be established. Two hundred ninety-nine consecutive de novo lesions treated with 1 >2.5-mm DES (Cypher or Taxus) under intravascular ultrasound guidance without postdilation, using 3 implantation strategies, were studied: (1) direct stenting without predilation (n = 145), (2) predilation with a conventional semi-compliant balloon (n = 117), and (3) predilation with the AngioSculpt balloon (n = 37). Stent expansion was defined as the ratio of intravascular ultrasound–measured minimum stent diameter and minimum stent area to the manufacturer's predicted stent diameter and area. These ratios were larger after AngioSculpt predilation, and a greater percentage of stents had final minimum stent areas >5.0 mm^2 (another commonly accepted criterion of adequate DES expansion). Lesion morphology, stent and lesion length, and reference vessel size did not affect DES expansion. In conclusion, in this observational, nonrandomized study, pretreatment with the AngioSculpt balloon enhanced stent expansion and minimized the difference between predicted and achieved stent dimensions. © 2007 Elsevier Inc. All rights reserved. (Am J Cardiol 2007; 100:812–817)

Although the improved designs, profiles, and flexibility of new-generation stents permit direct delivery in >80% of percutaneous coronary interventions,[1,2] we recently demonstrated that (1) directly deployed sirolimus-eluting and paclitaxel-eluting stents achieve on average only 70% of the diameter and area predicted by their compliance charts, and (2) almost 30% of them fail to achieve minimum in-stent final areas ≥5.0 mm^2, a consistent predictor of drug-eluting stent (DES) failure.[3–6] Plaque modification strategies such as rotational atherectomy and cutting balloon angioplasty have been developed to alter lesion compliance and improve stent expansion.[7,8] The newest of these devices is the AngioSculpt Scoring Balloon Catheter (AngioScore, Inc., Fremont, California), consisting of a minimally compliant balloon encircled by a low-profile attached spiral nitinol cage. In a observational, nonrandomized study, we used intravascular ultrasound (IVUS) to compare DES expansion after 3 implantation strategies: direct stenting, predilation with a semi-compliant balloon, and plaque modification using the AngioSculpt Scoring Balloon Catheter before stent implantation.

Methods

Two hundred ninety-nine consecutive patients who underwent elective IVUS-guided DES implantation were prospectively enrolled (in a observational, nonrandomized study) and grouped according to stent delivery technique: (1) direct stenting (145 patients), (2) predilation with a regular semi-compliant balloon catheter (117 patients), and (3) predilation with the AngioSculpt Scoring Balloon Catheter (37 patients). All 3 strategies were used during the time period in which patients were enrolled. Patients were eligible if they had de novo lesions in native coronary arteries ≥2.5 mm in angiographic diameter (visual assessment) treated with a single DES deployed and postdilated using only the stent delivery balloon. Restenosis lesions, stenoses in bypass grafts, stenoses treated with multiple stents, and stents that were postdilated with other balloons were excluded. The final maximal deployment pressure was obtained from the physician's report, and predicted stent diameter and area were derived from the stent manufacturer's compliance charts. The institutional review board approved

Cardiovascular Research Foundation and Columbia University Medical Center, New York, New York. Manuscript received February 20, 2007; revised manuscript received and accepted March 28, 2007.

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0002-9149/07/$ – see front matter
doi:10.1016/j.amjcard.2007.03.100

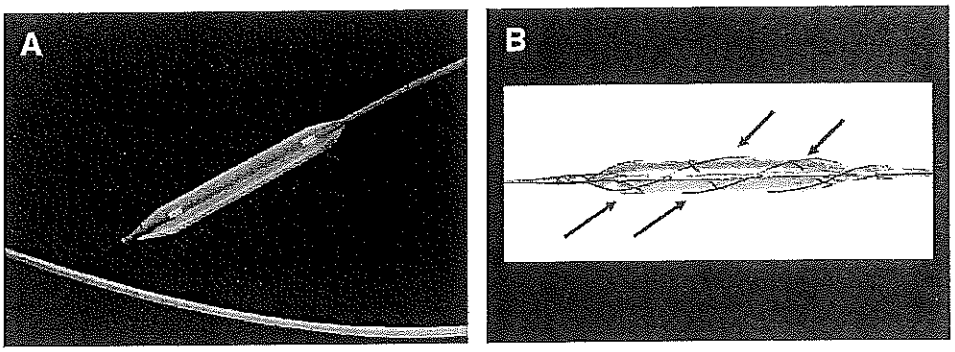

Figure 1. The Maverick over-the-wire balloon catheter *(A)* and the new AngioSculpt Scoring Balloon Catheter *(B)*. The *arrows* point to the low-profile spiral nitinol cage..

Table 1
Patient demographics

Variable	Direct (n = 145)	Predilation (n = 117)	AngioSculpt (n = 37)	p Value
Age (yrs)	65.2 ± 10.7	62.8 ± 11.6	64.1 ± 11.5	0.5
Men/women	92/53	80/37	25/12	0.7
Diabetes mellitus	45 (31%)	38 (33%)	9 (24%)	0.08
Non-insulin-treated	36 (25%)	31 (27%)	6 (16%)	0.2
Insulin-treated	9 (6%)	7 (6%)	3 (8%)	0.2
Hypertension*	116 (80%)	101 (86%)	27 (73%)	0.2
Hypercholesterolemia†	120 (83%)	98 (85%)	30 (81%)	0.1
Clinical presentation				
Silent myocardial ischemia	32 (22%)	27 (23%)	7 (19%)	0.9
Stable angina pectoris	80 (55%)	66 (56%)	23 (62%)	0.7
Unstable angina pectoris	33 (23%)	24 (21%)	7 (19%)	0.8

* Hypertension was defined as systolic blood pressure >140 mm Hg or diastolic blood pressure >90 mm Hg or treatment with medication.

† Hypercholesterolemia was defined as total cholesterol >200 mg/dl or treatment with medication.

Table 2
Angiographic and procedural characteristics

Variable	Direct (n = 145)	Predilation (n = 117)	AngioSculpt (n = 37)	p Value
Coronary artery treated				
Left anterior descending	78 (54%)	62 (53%)	13 (35%)	0.02*
Left circumflex	36 (25%)	21 (18%)	5 (14%)	0.07
Right	31 (21%)	34 (29%)	19 (51%)	0.01*
Lesion complexity				
Type A	30 (21%)	24 (21%)	7 (19%)	0.7
Type B1	40 (28%)	30 (26%)	9 (24%)	0.9
Type B2	53 (36%)	48 (41%)	14 (38)	0.9
Type C	22 (15%)	15 (13%)	7 (19%)	0.4
Reference vessel diameter (mm)	2.8 ± 0.3	2.7 ± 0.3	2.9 ± 0.2	0.7
Diameter stenosis (%)	62 ± 8	64 ± 12	64 ± 10	0.8
Lesion length (mm)	15.6 ± 9.5	15.9 ± 9.1	16.5 ± 9.2	0.7
Predilation balloon length (mm)	N/A	13.5 ± 3.8	15 ± 4.2	0.04
Stent length (mm)	20.2 ± 6.4	21.6 ± 7.5	22.5 ± 6.4	0.1
Stent/lesion length ratio	1.29	1.35	1.36	0.2

* p Value of AngioSculpt compared with the other 2 groups. There were no differences between the direct stenting and balloon predilation groups.
N/A = nonapplicable.

this study. Written informed consent was obtained from all patients.

Two different commercially available DESs were used: sirolimus-eluting stents (Cypher; Cordis Corporation, Miami Lakes, Florida) and paclitaxel-eluting stents (Taxus; Boston Scientific Corporation, Natick, Massachusetts). Sirolimus-eluting stents were available in diameters of 2.5 to 3.5 mm and lengths of 8 to 33 mm. Paclitaxel-eluting stents were available in the same diameters and in 8- to 32-mm lengths. Stent size as well as the final deployment pressure were at the discretion of the operator. The semi-compliant predilation balloon, the Maverick over-the-wire balloon catheter (Boston Scientific Corporation), was available in diameters of 1.5 to 3.5 mm and in lengths of 9, 15, and 20 mm. The AngioSculpt Scoring Balloon Catheter (Figure 1) is a semi-compliant angioplasty balloon surrounded by a nitinol scoring element that works in tandem with the balloon to "score" the target lesion upon balloon inflation. As the balloon inflates, the radial forces are concentrated along the surfaces of the nitinol cage. The hypothesis is that this results in luminal expansion that is predictable and controlled with reduced barotrauma, lower dissection rates, and less device slippage. It is available in lengths of 10, 15, and 20 mm and diameters of 2.0 to 3.5 mm.

IVUS was performed before and after stent implantation using motorized transducer pullback (0.5 mm/s) and a commercial scanner (Boston Scientific Corporation, Minneapolis, Minnesota) consisting of a rotating 40-MHz transducer (AtlantisPro) within a 2.6Fr imaging sheath. Before imaging, intracoronary nitroglycerin 100 to 200 μg was administered. IVUS images were recorded on 0.5-inch, high-resolution S-VHS videotape or digital disc for off-line analysis. Before the intervention, the section with the smallest luminal cross-sectional area (CSA) was identified, and the following measurements made using computerized planimetry (EchoPlaque; INDEC Systems, Inc., Mountain View, California): external elastic membrane, lumen, plaque and media (external elastic membrane − lumen) CSA, and plaque burden (plaque and media/external elastic membrane). Plaque was classified as soft, fibrous, calcific, and mixed according to its echogenicity. The arc of calcium, when present, was measured with a protractor centered in the lumen and is reported in degrees; cal-

Table 3
Number of stents, type, and size

Variable	2.5 mm			3.0 mm			3.5 mm			Total
	Direct	Predilation	AngioSculpt	Direct	Predilation	AngioSculpt	Direct	Predilation	AngioSculpt	
Cypher	14	17	11	41	42	6	59	43	7	240
Taxus	8	4	3	14	2	5	9	9	5	59
Total	22	21	14	55	44	11	68	52	12	299

Table 4
Preintervention intravascular ultrasound lesion morphology

Variable	Direct (n = 145)	Predilation (n = 117)	AngioSculpt (n = 37)	p Value
Plaque morphology				
Soft	46 (32%)	40 (34%)	10 (27%)	0.5
Fibrous	38 (26%)	29 (25%)	9 (24%)	0.3
Calcific	22 (15%)	20 (17%)	6 (16%)	0.9
Mixed	39 (27%)	28 (24%)	12 (33%)	0.4
Superficial lesion calcium	35 (24%)	28 (24%)	10 (27%)	0.9
Calcium length (mm)	3.4 ± 2.5	3.2 ± 2.6	3.6 ± 2.8	0.1
Arc of lesion calcium				
No calcium	82 (56%)	68 (58%)	20 (54%)	0.3
<90°	29 (20%)	20 (17%)	7 (19%)	0.4
90–180°	18 (12%)	14 (12%)	4 (11%)	0.9
180–270°	11 (8%)	4 (3%)	3 (8%)	0.3
>270°	5 (3%)	11 (9%)	3 (8%)	0.1

cium at the lesion site was classified as superficial or deep, and its length was measured. Similar measurements were made at the proximal and distal reference segments (the largest lumen with the least plaque within 10 mm proximal and distal from the minimum lumen CSA but within the same segment) and are reported as means of the 2 measurements. After the intervention, minimum stent CSA and minimal stent diameter were measured. The presence of a residual, untreated dissection was assessed. Stent expansion was defined as minimal stent luminal diameter (or area) divided by the minimum stent diameter (or area) predicted by manufacturers' compliance charts, as has been reported previously.[3,4]

Statistical analysis was performed using SAS version 9.1 (SAS Institute Inc., Cary, North Carolina). Categorical data were compared using Fisher's exact test and are presented as frequencies. Continuous data were compared using the unpaired Student's *t* test, analysis of variance, or regression coefficients and are presented as mean ± SD. A p value <0.05 was considered significant.

Results

Overall, among 299 patients (299 lesions) included in this analysis, 66% were men, 31% had diabetes mellitus, and 56% presented with stable angina. Most lesions were classified as American College of Cardiology/American Heart Association type B2 or C (54.1%). There were no significant differences in the baseline patient demographics (Table 1). The AngioSculpt balloon was used more often in the right coronary artery and less often in the left anterior descending artery; AngioSculpt balloon length was longer than the balloon used in the conventional predilation group (Table 2). Sirolimus-eluting stents were used in most of the cases (80.3%; Table 3). Final deployment pressures were comparable among the 3 groups (p = 0.4) and among the nominal stent sizes (p = 0.3). The median procedure time was shorter with direct stenting (30 minutes), with no significant difference between the 2 other groups (42 minutes for conventional balloon predilation and 44 minutes for predilation with the AngioScuplt balloon, p = 0.02).

Preintervention IVUS lesion characteristics were similar across the 3 groups (Table 4). Quantitatively, lesions treated with the AngioSculpt balloon had smaller preintervention minimum luminal dimensions and larger preintervention plaque burdens (Table 5).

On average, the DES achieved 77 ± 13% of the predicted final diameter and 70 ± 22% of the predicted final stent area (Table 5). However, when analyzed according to predilation strategy, patients pretreated with the AngioSculpt Scoring Balloon Catheter achieved larger percentages of predicted final stent diameter and area compared with those pretreated with the other 2 strategies (p <0.001 for all comparisons; Table 5 and Figure 2). The beneficial effect of this new "scoring" balloon extended to all plaque morphologies (Figure 3). Furthermore, predilation with the AngioSculpt balloon increased the final stent diameter (p = 0.004) and area (p = 0.02). Acute gain (defined as the final stent diameter minus the preintervention minimum luminal diameter) was also larger in the group pretreated with the AngioSculpt balloon (1.17 ± 0.35 mm) compared with the group treated with direct stenting (0.84 ± 0.4 mm) and the conventional predilation group (0.93 ± 0.55 mm) (p = 0.004).

Overall, 26% of direct-deployed stents and 26% of stents implanted after predilation with a semi-compliant balloon failed to achieve final minimum stent areas of 5 mm^2. Conversely, in the group pretreated with the AngioSculpt Scoring Balloon Catheter, only 11% of the final stent areas were <5 mm^2 (p <0.001). Stent expansion (defined as minimum stent area divided by reference luminal area) measured 0.59 ± 0.17 in group 1, 0.61 ± 0.22 in group 2, and 0.67 ± 0.26 in group 3 (p = 0.02).

There were no cases of abrupt vessel closure, distal embolization, and coronary perforation. Major coronary dissections with hematoma formation were observed in 1 patient pretreated with the AngioScupt balloon (2.7%) and in 1 patient pretreated with the ordinary semi-compliant balloon (0.9%) (p = 0.09). In the 2 patients, stents were deployed to successfully seal the dissections.

Table 5
Quantitative intravascular ultrasound assessment

Variable	Direct (n = 145)	Predilation (n = 117)	AngioSculpt (n = 37)	p Value
Reference segment				
External elastic membrane area (mm^2)	10.8 ± 4.4	10.1 ± 4.3	10.6 ± 6.5	0.4
Luminal area (mm^2)	8.5 ± 2.2	8.0 ± 2.3	9.0 ± 2.9	0.1
Luminal diameter (mm)	3.3 ± 0.7	3.2 ± 0.7	3.6 ± 0.9	0.09
Preintervention lesion site				
External elastic membrane area (mm^2)	11.8 ± 4.6	11.7 ± 4.6	11.6 ± 4.7	1.0
Luminal area (mm^2)	3.0 ± 0.9	2.9 ± 1.0	2.5 ± 0.9	0.02
Minimum luminal diameter (mm)	1.7 ± 0.3	1.7 ± 0.6	1.6 ± 0.3	0.2
Plaque and media area (mm^2)	8.9 ± 3.2	8.6 ± 3.4	8.8 ± 3.5	0.6
Plaque burden (%)	72 ± 10	73 ± 10	76 ± 10	0.08
Postintervention lesion site				
Minimal stent diameter (mm)	2.6 ± 0.4	2.5 ± 0.4	2.8 ± 0.4	0.048*
Minimal stent CSA (mm^2)	6.0 ± 1.7	5.9 ± 1.6	6.8 ± 1.5	0.02*
IVUS/manufacturer-predicted stent diameter (%)	76 ± 10	76 ± 13	88 ± 18	<0.001*
IVUS/manufacturer-predicted stent area (%)	67 ± 16	70 ± 23	88 ± 32	<0.001*

* p Value of AngioSculpt compared with the other 2 groups. There were no differences between the direct stenting and balloon predilation groups.

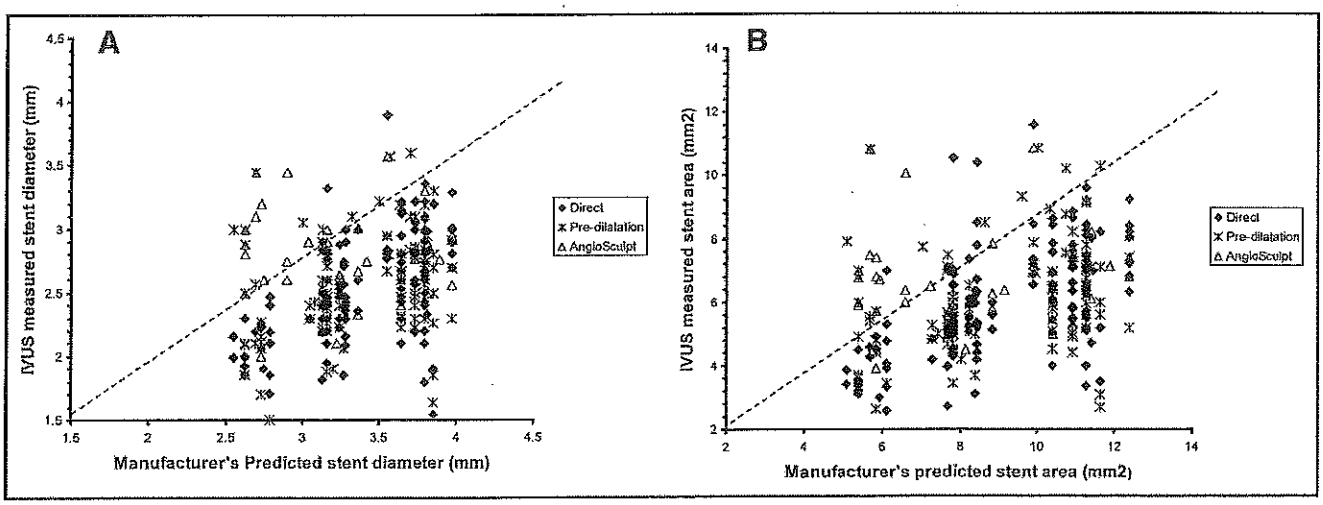

Figure 2. IVUS-measured minimum stent diameter *(A)* and minimum stent area *(B)* versus the predicted measurements from each manufacturer's compliance charts. Overall, most patients in all 3 groups failed to achieve the predicted minimal stent diameter and area. However, this difference was significantly less after pretreatment with the AngioSculpt balloon catheter.

Discussion

In previous DES studies, stent underexpansion has been a consistent predictor of DES failure.[5,6,9] In the present observational, nonrandomized study, predilation with the AngioSculpt balloon resulted in better stent expansion compared with either direct stenting or conventional semi-compliant balloon predilation, regardless of preintervention plaque morphology. Histologic and IVUS observations suggest that plaque burden and lesion calcification interfere with stent expansion.[10] These observations led to the hypothesis that better lesion preparation could improve clinical outcomes. Preliminary single-center experiences with directional or rotational atherectomy showed improved stent expansion.[11,12]

More recently, in an attempt to simplify the procedure and optimize stent expansion, special scoring balloons were developed to predilate complex lesions. The first such device was the cutting balloon, which was shown in CB-BEST to improve bare metal stent expansion.[13] The Restenosis Reduction by Cutting Balloon Evaluation (REDUCE) III randomized trial, comparing cutting balloon to conventional balloon angioplasty, showed the benefit of this device only when the procedure was guided by IVUS.[14] Compared with the cutting balloon, the new AngioSculpt balloon has the potential advantages of a lower profile as well as the ability to produce more scoring marks per millimeter of plaque, allowing an interventionist to safely achieve higher pressures when dealing with severely calcified lesions. In our study, AngioSculpt was inflated on average to 12 ± 2 atm with balloon ruptures.

We used 2 IVUS end points in the present analysis. Absolute minimum stent area has been shown to be a consistent predictor of restenosis in the bare metal stent and DES eras, with a stepwise relation between smaller minimum stent area and increasing restenosis rate. Recent DES reports indicate that a smaller final stent area is acceptable with DES compared with bare metal stents, at least with

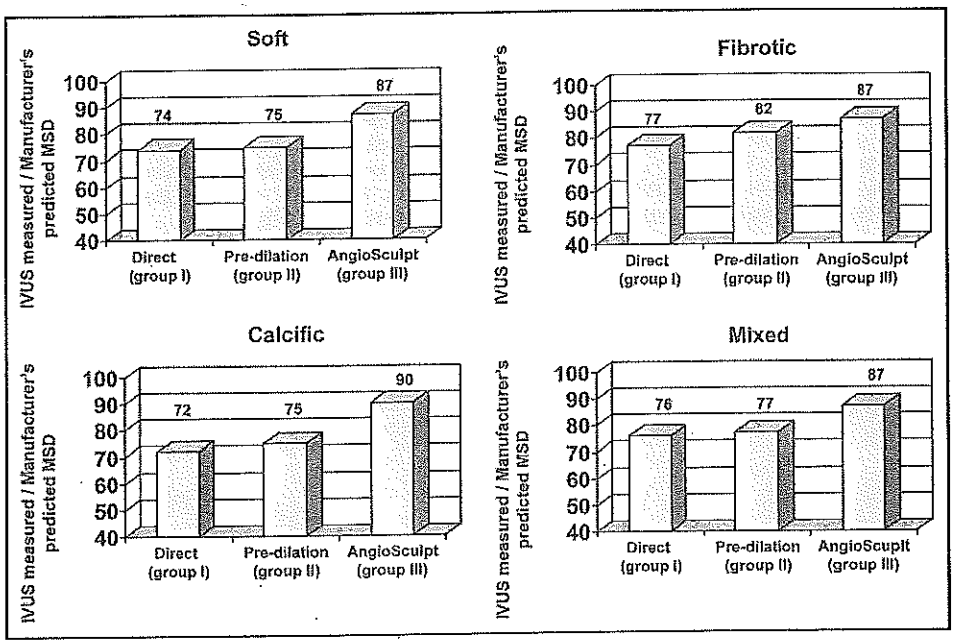

Figure 3. Stent expansion (IVUS-measured minimum stent diameter [MSD] divided by manufacturer's predicted MSD) as a function of IVUS plaque morphology. Noticeably, for all different plaque morphologies, pretreatment with the AngioSculpt balloon significantly improved final stent expansion.

regard to minimizing restenosis. Nevertheless, a minimum DES area of <5.0 to 5.5 mm^2 is still associated with restenosis and acute stent thrombosis.[5,6,9] In the present study, only 11% of patients treated with AngioSculpt predilation had minimum stent areas <5.0 mm^2 compared with (1) 26% of patients in the other 2 groups in the present study, (2) approximately 1/3 of the 72 patients treated with sirolimus-eluting stents in the IVUS substudy of Sirolimus-Eluting Stent in Coronary Lesions (SIRIUS),[5] (3) 34% of 543 lesions in a report by Hong et al,[9] and (4) 26% of patients in a report by de Ribamar Costa et al.[3]

Final stent dimensions are determined by the sizes of the stent and balloon, the size of the vessel, the inflation pressure, and the lesion. Therefore, we propose that the ratio of IVUS-measured stent dimensions to those predicted by manufacturers' compliance curves is a vessel-, stent-, and balloon-size-independent and lesion-dependent predictor of stent expansion.[3,4] This was the second end point in the present analysis. In previous studies, stents achieved approximately 75% of predicted minimum stent diameter and 66% of predicted minimum stent area, similar to the direct stent and conventional balloon dilation groups of the present study and less than after AngioSculpt predilation.

The major limitation of our study is its nonrandomized design. Very complex lesions were not included in our analysis. We did not assess differences in clinical outcomes. Operators and investigators were not blinded to IVUS findings when performing the interventions or when performing quantitative IVUS analysis. IVUS gray-scale analysis has limitations in assessing plaque composition. The subgroup treated with AngioSculpt was relatively small because this new device is still in initial clinical evaluation in the United States. This was a mechanistic study without the clinical follow-up data necessary to prove clinical superiority. Patients whose stents were postdilated with other balloons were excluded, and these 3 predilation strategies were not compared with direct stenting followed by high-pressure postdilation with oversized balloons.

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Intravascular Ultrasound Assessment of the Novel AngioSculpt® Scoring Balloon Catheter for the Treatment of Complex Coronary Lesions

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ABSTRACT: Background. Despite the advances in interventional cardiology, stent expansion remains an important predictor of success, impacting restenosis and thrombosis rates after either bare-metal (BMS) or drug-eluting stent implantation. Especially for the treatment of complex lesions (*e.g.*, calcified lesions, in-stent restenosis, etc.), adequate lesion preparation might help improve procedural results as well as clinical outcomes. We sought to investigate the safety, feasibility and mechanism of action of a new scoring-balloon catheter, the AngioSculpt®, comprised of a semicompliant balloon and a nitinol spiral cage designed to address complex lesions. **Methods.** A total of 60 consecutive patients at two centers were prospectively enrolled in this first-in-man coronary study and divided into two groups according to the type of lesion treated: *Group I:* patients with *de novo* coronary lesions (n = 47) as a pretreatment strategy before BMS implantation, and *Group II:* patients with BMS restenosis (n = 17) as a standalone therapy. A subgroup of patients in each cohort was assigned to intravascular (IVUS) analysis. Patients in Group II were submitted to routine 6-month follow-up angiography. In Group I, angiographic restudy was contingent upon the presence of ischemia. Lesions longer than 20 mm in very tortuous vessels, in arterial or vein grafts, in the setting of acute myocardial infarction or with visible thrombus were excluded from this study. **Results.** Success was achieved in all cases. The mean age of the study populations was 62 ± 11.6 years (Group I) and 53 ± 9.4 years (Group II), with 26% and 18% diabetics, respectively. In Group I, 73% of lesions were diffuse and fibrocalcified, while in Group II, 72% were classified as diffuse. No serious complications were observed in either group. Balloon slippage (or the "watermelon seed" phenomenon) was not observed. Significant acute gain was achieved in both groups (0.7 mm in Group I and 1.64 mm in Group II). A minimum final area (in-stent) ≥ 6.5 mm² was achieved in 85% of the cases in Group I and in 82% of the cases in Group II. **Conclusions.** In this preliminary *in vivo* study, the use AngioSculpt® proved to be feasible and safe for the treatment of complex coronary lesions. Six-month results suggest the use of this novel device as an attractive option for the percutaneous approach of restenotic coronary lesions and should be assessed in a larger, more complex cohort of patients.

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Despite the recent advent of drug-eluting stents (DES), preparation of complex lesions (*e.g.*, ostial, diffuse, fibrocalcified lesions and in-stent restenosis) before stent implantation remains an essential component of percutaneous coronary intervention (PCI).[1,2] Inadequate stent expansion has repeatedly been associated with restenosis and acute/subacute stent thrombosis.[3–7] Pretreatment with ordinary balloon catheters has not been shown to improve immediate- and long-term results of PCI.[8,9] Predilatation with high-pressure balloons may also lead to significant dissection, coronary perforation, more pronounced plaque shift and substantial vessel wall damage, especially when approaching restenotic lesions, where the "watermelon seed" phenomenon has been frequently reported.[10]

In an attempt to modify lesion compliance and improve stent expansion, new dedicated devices for directional and rotational atherectomy, namely the Cutting™ Balloon *(Boston Scientific Corp., Natick, Massachusetts)* and the FX-miniRail™ *(Guidant Corp., Santa Clara, California)* balloon catheters have been developed.[11–15] The latest of these devices is the AngioSculpt® scoring balloon catheter *(AngioScore, Inc., Fremont, California)*, which is comprised of a semicompliant balloon with a nitinol spiral cage specifically designed to address complex lesions.

The aim of this pilot study was to assess the feasibility and the safety of this novel angioplasty catheter as well as to evaluate its efficacy for the treatment of *de novo* and restenotic coronary lesions.

Methods

Study population. Patients in two centers (Brazil and Germany) who underwent percutaneous intervention of native coronary lesions were enrolled in this pilot study and sorted into two groups according to the type of target lesion: Group I was comprised of patients with *de novo* lesions, and Group II included patients with in-stent restenosis (ISR).

In Group I, the AngioSculpt catheter was used only for predilatation, followed by bare-metal stent (BMS) placement and, if deemed appropriate, postdilatation with ordinary semicompliant/noncompliant balloon catheters. In Group II, the AngioSculpt catheter was used as standalone treatment for bare-metal ISR. A subset of patients in each group was submitted for intravascular ultrasound (IVUS). Clinical follow up

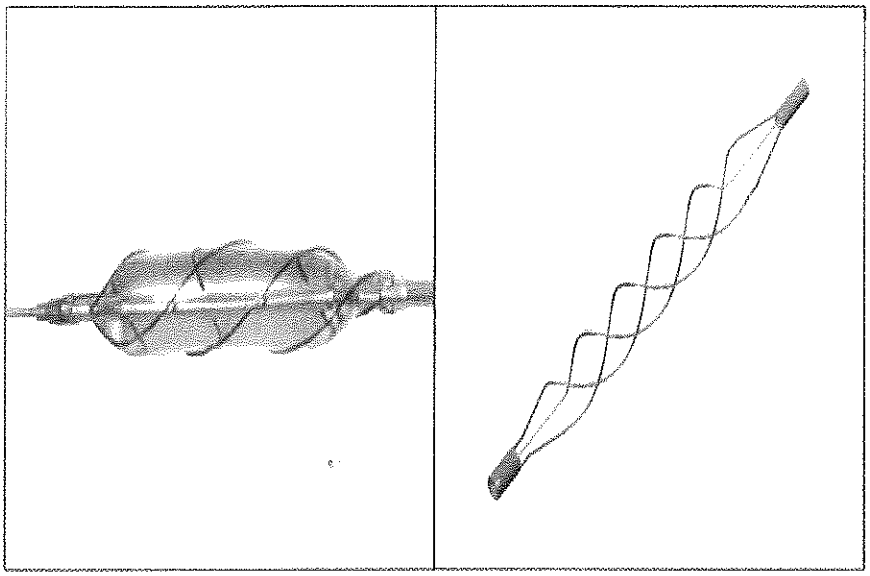

Figure 1. *The AngioSculpt® balloon catheter and its nitinol spiral cage in detail.*

at 1 and 6 months was obtained for all patients. Six-month angiographic and IVUS follow up was performed only in the ISR group.

Patients were excluded if they had an index lesion > 20 mm in length, vessel size < 2.5 mm, left main coronary disease, lesions located at the arterial or venous grafts, angulations ≥ 45 degrees, visible thrombus by angiography, a totally occluded target lesion, myocardial infarction within the last 72 hours of the revascularization procedure and serum creatine ≥ 2.0 mg/dl. Additionally, patients with proliferative restenosis (restenosis extending beyond the stent limits) were treated with additional stent placement and were therefore excluded from Group II.

Investigational device description. The AngioSculpt catheter, as previously mentioned, is a semicompliant balloon catheter incorporating a nitinol spiral cage, as illustrated in Figure 1. The nitinol spiral cage consists of three spiral wires wrapped around the balloon catheter designed to create focal concentrations of dilating force and thereby assisting in the luminal expansion of coronary lesions. When the balloon is inflated, the spiral wires slide and rotate over the balloon to achieve its fully open configuration. The expanded configuration provides a linear cutting surface that efficiently scores the plaque, allowing low-pressure dilatation and avoiding balloon slippage. Once the balloon is deflated, the spiral cage collapses to its original closed configuration. The AngioSculpt has twice the linear blade length of the FX miniRail and the 1.5 the linear blade length of the Cutting Balloon. The catheter was designed to be compatible with standard 0.014 inch coronary guidewires and 6 Fr guiding catheters. In this study, this novel device was available in diameters ranging from 2.5 to 3.5 mm and in lengths of 16, 18 and 20 mm.

As a first-in-man study, the operators were trained to increase the inflation pressure slowly (2 atm every 5 seconds) in order to achieve uniform inflation of the AngioSculpt device. Next, according to the procedure strategy, the balloon was inflated to a balloon/artery ratio of 0.8 in Group I, or a maximum 1.2 ratio in Group II. The inflation was filmed at two intervals: 1) when the device was uniformly inflated, and 2) at its maximum inflation pressure.

Study procedure and follow up. AngioSculpt balloon inflation was performed in all patients in both cohorts. Patients allocated to Group I, as mentioned previously, received a BMS right after predilatation with the investigational device. Patients in Group II underwent the final stages of the procedure after the operator deemed the AngioSculpt balloon inflation had rendered an acceptable result. When used with the sole intention of lesion preparation (predilatation), the AngioSculpt was inflated to a balloon-to-artery ratio of ~0.8. When intended to be the final step of the interventional procedure, the operators attempted to achieve a balloon-to-artery ratio of 1.2. Intracoronary stenting was performed using standard interventional techniques. Patients were premedicated with aspirin (200 mg) and were recommended to continue its use lifelong. Additionally, patients receiving a stent (Group I) were premedicated with clopidogrel (loading dose of 300 mg) initiated 24 hours before the intervention, or ticlopidine (250 mg b.i.d.) administered 72 hours prior to the percutaneous procedure, and were recommended to stay on thienopyridines for 1 month. During the procedure, heparin was administered as a bolus dose of 100 U/kg, with an additional bolus to maintain an activated clotting time > 250 seconds.

A 12-lead electrocardiogram (ECG) was obtained before the procedure, immediately afterward and 24 hours later. Blood sample laboratory analysis included creatine kinase cardiac enzymes (CK and CK-MB) before the procedure (< 24 hours) and 12–18 hours after treatment. This study was approved by the Institutional Ethics Committee, and eligible patients were asked to sign an informed consent.

Endpoints, definitions and clinical follow up. The primary objective of this study was to determine the feasibility and safety of the AngioSculpt balloon catheter during the hospitalization period. All deaths were considered to be cardiac unless a noncardiac origin could be clearly established by clinical and/or pathological study. The diagnosis of MI was based on either the development of new pathological Q-waves in ≥ 2 contiguous ECG leads and/or elevation of CK-MB isoenzyme > 3 times the upper limit of normal postprocedure during the index hospitalization, or cardiac enzyme elevation > 2 times the upper limit of normal thereafter.

Angiographic success was defined as attainment of < 20% residual stenosis by quantitative coronary angiography

(QCA) in the treated segment at the end of the procedure. Procedural success was defined as angiographic success plus the absence of major adverse cardiac events (MACE) during hospitalization. As an additional analysis, we performed QCA and IVUS analysis of the presence and type of coronary dissection and acute results of the procedure, particularly in regard to acute gain and final in-stent dimensions. Clinical follow up by office appointment was obtained for all patients at 1 and 6 months. Angiographic and ultrasonographic 6-month follow up was performed only in the ISR group.

Quantitative coronary analysis. Intracoronary nitroglycerin (0.1–0.2 mg) was administered prior to and after each intervention to achieve maximal vasodilatation. QCA measurements were performed using a computer-assisted automated edge-detection algorithm *(CMS-Medis, Leiden, The Netherlands)*. Minimum lumen diameter (MLD), reference diameter (RD) and percent diameter stenosis (%DS) were measured in two projections. Acute gain was defined as MLD after the AngioSculpt inflation minus baseline MLD. Late luminal loss was calculated as MLD after the AngioSculpt inflation minus follow-up MLD.

Quantitative IVUS analysis. IVUS was performed prior to and following AngioSculpt catheter inflation and, in Group I, was repeated after stent placement. AngioSculpt inflation was filmed in three stages: 1) when the balloon was inflated at 2 atm; 2) at full inflation; and 3) at maximum (final) pressure.

IVUS was performed after intracoronary administration of nitroglycerin (0.1–0.2 mg). The imaging catheter was advanced at least 10 mm beyond the stent/lesion. Images were acquired using a commercially available imaging system with 40 MHz transducers (*Atlantis SR, Boston Scientific*) featuring automated pullback at a constant speed of 0.5 mm/second. All cases were recorded on high-resolution S-VHS videotapes for subsequent analysis.

Quantitative analyses were performed according to the American College of Cardiology/American Heart Association IVUS guidelines.[16] Minimal lumen cross-sectional area (MLA) in lesion segments was measured immediately pre- and post-AngioSculpt inflation and after stent implantation, and was repeated at 6-month follow up in the ISR group. Additionally, IVUS volumetric analysis was performed in the stent segment immediately pre- and post-AngioSculpt inflation and at 6-month follow up in the ISR group with commercially computer-based contour detection software (*EchoPlaque, Indec Systems, Inc., Santa Clara, California*) by Simpson's rule. The following volumetric parameters were calculated for Group II: 1) stent volume; 2) vessel volume; 3) lumen volume; 4) neointimal hyperplasia (NIH) volume (stent volume minus lumen volume); and 5) plaque volume behind stent (vessel volume minus stent volume). The percentage of in-stent NIH volume obstruction was defined as neointimal hyperplasia volume divided by stent volume x 100. The delta (△) of each parameter between pre- and post-AngioSculpt inflation (△ luminal volume, △ NIH volume, △ stent volume, △ plaque behind stent and △ vessel volume) were calculated in an attempt to understand the mechanism responsible for the acute luminal gain.

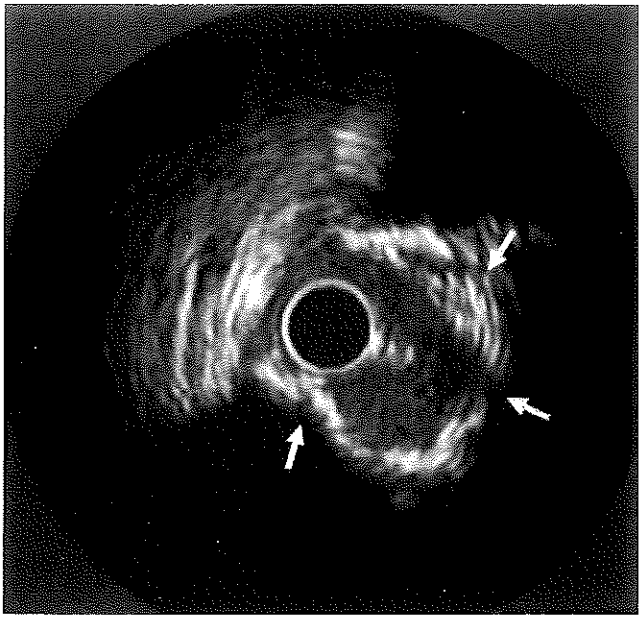

Figure 2. *Example of intravascular cross-sectional image of a plaque post-AngioSculpt® inflation. The arrows are pointing to the "scoring" marks produced by the nitinol spiral cage.*

Table 1. Baseline clinical, angiographic and procedural characteristics of the total population.

Characteristics	Group I (n = 43)	Group II (n = 17)
Age, *years*	62 ± 11.6	53 ± 9.4
Male gender	31 (72%)	12 (71%)
Diabetes mellitus	11 (26%)	3 (18%)
Previous MI	22 (51%)	8 (47%)
Interpolated reference diameter *(mm)*	2.99 ± 0.35	3.04 ± 0.35
Lesion length *(mm)*	15.60 ± 6.11	18.05 ± 6.5
Treated vessel		
LAD	13 (30%)	6 (35%)
LCX	12 (27.9%)	4 (23.5%)
RCA	18 (42.1%)	7 (41.5%)
Presence of calcification at lesion site		
None/mild	25 (58.2%)	11 (64.7%)
Moderate/severe	18 (41.8)	6 (35.3%)
Full inflation pressure *(atm)*'	7.1 ± 3.5	10.4 ± 3.1
Maximum pressure *(atm)*	10.7 ± 2.8	14.3 ± 3.1
Balloon diameter *(mm)*	2.5 ± 0.3	3.0 ± 0.4
Balloon length *(mm)*	17 ± 1.7	18± 1.7

Full inflation pressure = minimum pressure to fully open the AngioSculpt® balloon
MI = myocardial infarction; LAD = left anterior descending artery; LCX = left circumflex artery; RCA = right coronary artery

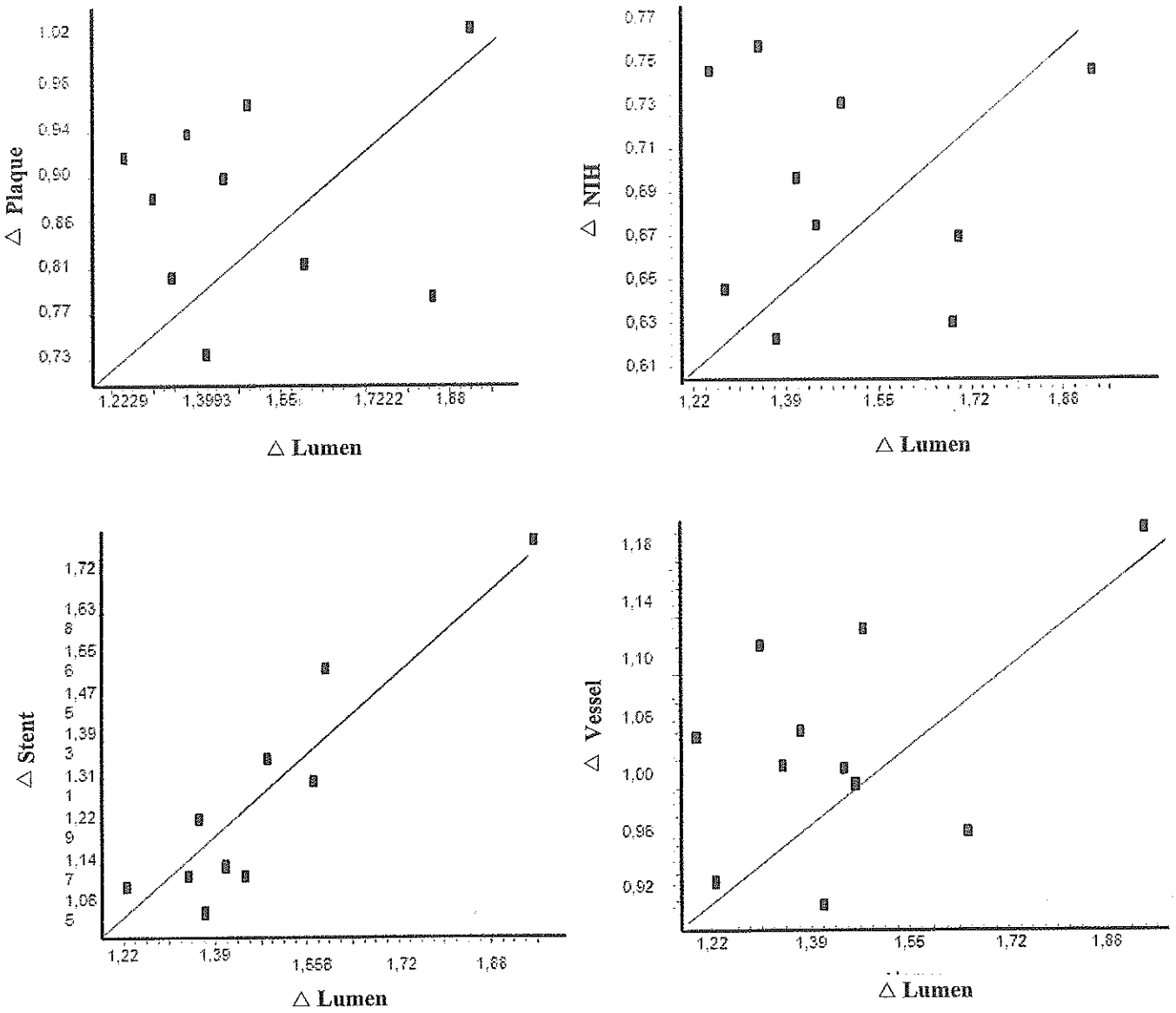

Figure 3. *Correlation between the △ (Post minus Pre) measurements of lumen volume and stent plaque, neointimal hyperplasia (NIH) and vessel volume in the in-stent restenosis (ISR) group.*

Both QCA and IVUS analyses were performed using the same in-hospital core laboratory by senior fellows under the supervision of the departments' directors. None of the participants in this research project had any conflict of interest.

Statistical analysis. Continuous variables are expressed as mean ± standard deviation (SD). Comparisons between time intervals, procedural and follow-up measurements were performed in each patient using the two-tailed paired t-test. Categorical variables were described by counts and percentages and tested with the Fisher's exact test. The correlation between △ volume parameters was tested with the Pearson's test. Probability values < 0.05 were considered statistically significant.

Results

Population data. Between October and November 2005, a total of 60 patients who matched the inclusion and exclusion criteria were consecutively enrolled in this study (Group I: $n = 43$, and Group II: $n = 17$). The mean age of the study populations were 62 ± 11.6 years (Group I) and 53 ± 9.4 years (Group II), with 26% and 18% being diabetic, respectively. In Group I, 73% of lesions were diffuse and fibrocalcified, while in Group II, 72% were considered diffuse according to Mehran's classification.[18] Baseline clinical and angiographic data are summarized in Table 1. There were no failures to cross the lesion with this new device in either group.

Procedure and clinical results. *Group I.* AngioSculpt full inflation was uniformly achieved at a mean pressure of 7.1 ± 3.5 atm.

Final average inflation pressure was 10.7 ± 2.8 atm. All patients were successfully pretreated with the AngioSculpt catheter, and no major dissection or vessel perforation was observed. Two patients had minor dissections after AngioSculpt predilatation that were completely sealed with the stent implantation. Angiographic and procedural success were achieved in all cases. None of the patients had inhospital or 30-day MACE (death, myocardial infarction or target lesion revascularization). At 6 months, no deaths or acute myocardial infarctions were registered in this group. Five patients (10.2%) had ischemia-driven need for repeat revascularization.

Group II. For the treatment of restenotic lesions, AngioSculpt full inflation was uniformly achieved at higher pressure than for *de novo* lesions (10.4 ± 3.1 atm vs. 7.1 ± 3.5 atm for Group I; $p = 0.02$). Also, final balloon inflation pressure was higher among these patients (14.3 ± 3.1 atm vs. 10.7 ± 2.8 atm; $p = 0.03$). As in Group I, angiographic and procedural success were achieved in all cases. Again, no inhospital adverse cardiac event occurred among these patients. At 6-month follow up, binary restenosis (stenosis > 50%) was observed in 6 patients (35.2%). Four patients (23.5%) presented with recurrent ischemia-driven restenosis requiring additional percutaneous procedures with DES implantation.

Angiographic and IVUS results. *Group I.* The first 20 patients were submitted to IVUS prior to intervention, after AngioSculpt balloon inflation and immediately after stent deployment. One of them was excluded from the final analysis since the images were deemed inadequate for a reliable interpretation.

Table 2 displays QCA and IVUS data for this cohort. The average AngioSculpt balloon-to-coronary artery ratio was 0.77 ± 0.02. Between preintervention and post-AngioSculpt inflation, the minimal lumen diameter (MLD) nearly doubled from 0.89 ± 0.24 mm to 1.6 ± 0.4 mm, resulting in an acute gain of ~0.7 mm following the use of this new device.

Notably, post-Angiosculpt IVUS images were suggestive of circumferential "scoring" marks consistent with the geometry of the nitinol spirals (Figure 2). No major dissection or vessel perforation was observed in this group. IVUS detected 2 type-A dissections after balloon inflation which were completely sealed after stent deployment. Postprocedure MLD and area significantly increased. QCA final MLD and IVUS final stent area were 2.91 ± 0.41 mm and 6.6 ± 1.0 mm², respectively (Table 2). Final minimum area (in-stent) was ≥ 6.5 mm² in 85% of the cases with *de novo* coronary lesions.

Group II. Balloon slippage (or "watermelon seeding" phenomenon) was not observed in this group. The AngioSculpt balloon-to-coronary artery ratio averaged 1.19 ± 0.02. QCA demonstrated an acute gain of 1.64 mm after AngioSculpt inflation, resulting in a postprocedural MLD of 2.55 ± 0.32 mm. At 6 months, late loss was of 0.54 mm (Table 3).

Final minimum area (in-stent) ≥ 6.5 mm² was achieved in 82% of the cases. Serial IVUS was

Table 2. Angiographic and ultrasonographic measurements in Group I (n =19).

Parameters	Pre-ASC	Pre-ASC	Post-Stenting	p-Value
QCA – MLD (*mm*)	0.89 ± 0.24	1.59 ± 0.39	2.91 ± 0.41	< 0.01†
QCA – DS (%)	69.11 ± 7.85	46.26 ± 14.25	6.77 ± 2.1	< 0.01†
QCA – acute gain (*mm*)	*	0.7	*	*
IVUS – MLA (*mm²*)	1.94 ± 0.86	2.66 ± 0.93	6.6 ± 1.0	< 0.01†

†*Pre- versus post AS and post AS versus post stenting*
DS = diameter of stenosis; ASC = AngioSculpt® balloon; MLA = minimum lumen area; MLD = minimum lumen diameter; QCA = quantitative coronary angiography; IVUS = intravascular ultrasound

Table 3. Quantitative coronary angiography and intravascular ultrasound volumetric analysis in Group II (n = 14).

Parameters	Preintervention	Postintervention	6-Month Follow Up	p-Value
Quantitative Coronary Angiography				
MLD (*mm*)	0.91 ± 0.22	2.55 ± 0.32	2.01 ± 0.68	< 0.01†
DS (%)	68.21 ± 6.27	15.74 ± 8.37	34.51 ± 17.92	< 0.01†
Acute gain/late loss (*mm*)	N/A	1.64	0.54	< 0.01*
Parameters	**Preintervention**	**Postintervention**	**6-Month Follow Up**	**p-Value**
Intravascular Ultrasound				
MLA (*mm²*)	2.04 ± 0.47	4.55 ± 2.2	3.74 ± 0.64	< 0.01*
Vessel volume (*mm³*)	449.4 ± 150.1	431.8 ± 145.2	448.1 ± 125.3	0.4
Lumen volume (*mm³*)	160.5 ± 71.1	190.5 ± 68.1	165.2 ± 64.3	0.3
Stent volume (*mm³*)	252 ± 101.8	268.75 ± 82.9	259 ± 78.2	0.2
Plaque volume (*mm³*)	288.9 ± 85.2	241.40 ± 83.5	283 ± 78.3	0.1
NIH volume (*mm³*)	91.5 ± 30.9	78.2 ± 27.4	88.2 ± 37.9	0.05†
NIH volume obstruction (%)	36.6 ± 9.3	26.7 ± 8.7	31 ± 14.1	0.03†

Denotes significance between pre- versus postprocedure intravascular ultrasound (IVUS) measurement and also between postprocedure and 6-month IVUS follow up
†*Denotes significance between pre- and post-IVUS measurement. No statistically significant difference was noticed between postprocedure and 6-month IVUS measurement*
MLD = minimum lumen diameter; DS = diameter of stenosis; MLA = minimum lumen area

Table 4. Angiographic measurements in Group II.

Parameters	Preintervention	Postintervention	6-Month Follow Up	p-Value
MLD (mm)	0.91 ± 0.22	2.55 ± 0.32	2.01 ± 0.68	< 0.01†
DS (%)	68.21 ± 6.27	15.74 ± 8.37	34.51 ± 17.92	< 0.01†
Acute gain (mm)	N/A	1.64	N/A	N/A
Late loss	N/A	N/A	0.54	N/A

†Pre- versus post AngioSculpt® and post AngioSculpt versus 6-month follow up
MLD = minimum lumen diameter; DS = diameter stenosis

attempted in all patients from Group II. However, in 3 cases, adequate images could not be obtained. Therefore, 14 individuals (82%) with a baseline and follow-up IVUS study were included in an IVUS subanalysis. QCA and volumetric analysis are listed in Tables 3 and 4. Percentage volume obstruction decreased significantly between pre- and postprocedure. There was a nonsignificant increase in stent and lumen volumes as well as in plaque and NIH volumes between postprocedure and follow-up IVUS examination. Additionally, we observed a strong linear correlation between △ luminal volume and △ stent volume pre- and postprocedure (Figure 3). This finding points to a better stent expansion as the main mechanism of acute gain after AngioSculpt use for the treatment of ISR.

Discussion

To the best of our knowledge, this study represents the first-in-man demonstration of safety and feasibility of this novel device for the treatment of *de novo* and restenotic coronary lesions. The use of the AngioSculpt balloon catheter was associated with good immediate results for both *de novo* and restenotic lesions. For the treatment of ISR, this device showed promising intermediate-term results.

Histologic and IVUS observations have shown that excessive plaque burden and intense plaque calcification strongly correlate with poorer stent expansion.[17] IVUS studies have demonstrated a consistent association between modest final stent area (< 6.5 mm² after BMS and < 5.0 mm² after DES) and stent thrombosis and restenosis.[4,5,18] In the present study, patients with *de novo* lesions pretreated with AngioSculpt achieved a final stent area of 6.6 ± 1.0 mm². Importantly, no final minimal stent area < 5.0 mm² was observed in either group.

A cumbersome scenario in interventional cardiology is the treatment ISR. The use of balloon angioplasty with conventional balloon catheters versus BMS for the treatment of restenotic lesions was compared in 450 patients enrolled in the RIBS trial (Restenosis Intra-stent: Balloon angioplasty versus elective Stenting).[19] Patients randomized to receive another stent (n = 224) had less inhospital MACE (1.3% vs. 4.9%; p = 0.039). However, after 1 year of clinical follow up, event-free survival and binary restenosis were comparable between the groups. It is important to mention that balloon slippage during the treatment of ISR was reported in up to 12% of the cases in that trial, and its occurrence has been related to poorer clinical outcomes with a significant increase in restenosis recurrence when compared to those in whom the "watermelon-seeding" phenomenon was not evident (56% vs. 37%; p = 0.017).[10] In the present study, use of the AngioSculpt balloon catheter was not associated with balloon slippage when used for treatment of either *de novo* or ISR lesions.

The use of a DES might be an attractive alternative in this complex scenario. Recently, the RIBS 2 trial randomized 150 patients with BMS restenosis to either balloon angioplasty alone (n = 74) or DES implantation (n = 76).[20] At the end of 1-year follow up, the primary endpoint of the study — the binary restenosis rate — was significantly reduced in the DES group (11% vs. 39%; p < 0.001). However, especially in developing countries, where economic issues may prevent the widespread use of these novel stents, AngioSculpt, costing as much as ten times less than currently-available DES, might represent a less expensive and safe alternative to treat ISR lesions, with acceptable mid-term clinical results.

Study limitations. This was not a randomized study and does not have a control arm treated with a conventional semi-compliant/noncompliant balloon catheter. The limited number of patients in each group precludes more definitive clinical conclusions. The lack of 6-month IVUS follow up in the group with *de novo* lesions prevents any further assessment of the long-term impact of this novel device used prior to stent implantation.

Conclusions

In this pilot study, the AngioSculpt device proved to be feasible and safe for the treatment of complex coronary lesions. Six-month results suggest that the use of this novel device is an attractive option for the percutaneous approach to treat restenotic coronary lesions and should be assessed in a larger, more complex cohort of patients.

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Lotto 25

Changing the landscape of balloon angioplasty for coronary artery disease

AngioSculpt® PTCA

Scoring Balloon Catheter

Rapid Exchange Delivery System

NGC medical spa

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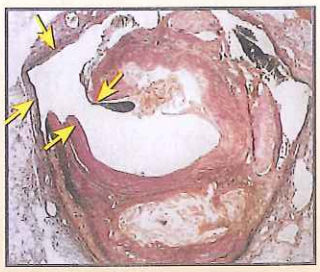
The AngioSculpt Scoring Balloon Catheter: A new dimension in patient outcomes

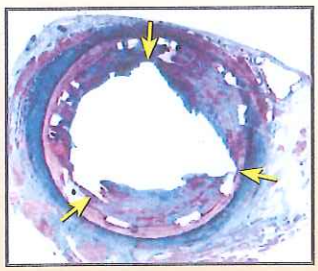
The AngioSculpt Scoring Balloon Catheter transforms the landscape of treating coronary artery disease. It is an essential tool in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR), for the purpose of improving myocardial perfusion. When used for pre-dilatation prior to stenting, AngioSculpt has been proven to yield a 33%-50% greater luminal gain than either direct stenting or pre-dilatation with a conventional angioplasty balloon catheter.[1]

The innovative nitinol scoring element scores the plaque circumferentially, providing a precise and predictable solution to even the most difficult lesion challenges. As demonstrated in clinical studies, AngioSculpt was used successfully in treating fibro-calcific, bifurcation and ostial lesions. AngioSculpt provides the versatility and effectiveness required of a new technology together with the simplicity and deliverability of a high performance balloon catheter.

REDUCED DISSECTION RATES AND ELASTIC RECOIL



Severe dissection post-POBA of human coronary artery[3]



Post-AngioSculpt scoring of porcine ISR[4]

A NEW MEASURE OF SUCCESS

- Procedural success rate of 98.5%, with 76% of lesions being types B2/C[2]
- Freedom from major adverse cardiac events 97.5%[2]
- Proven effective in complex calcified (35%), bifurcation (29%) and ostial (13%) lesions[2]
- Significantly low dissection rate of 13.6%[2] versus ~30% for POBA[5]
- No device slippage (even in ISR) for more accurate placement and no "geographic miss"[2]
- Zero perforations as confirmed by an independent core laboratory[2]

AngioSculpt® PTCA

Scoring Balloon Catheter

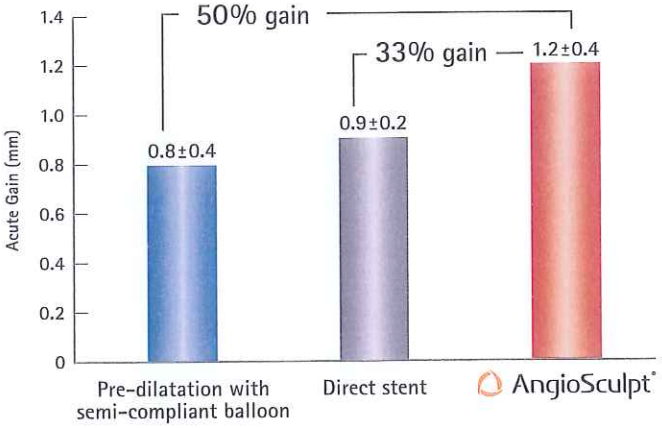
Rapid Exchange Delivery System

A new dimension in lesion preparation

BETTER FINAL POST-STENT DIMENSIONS

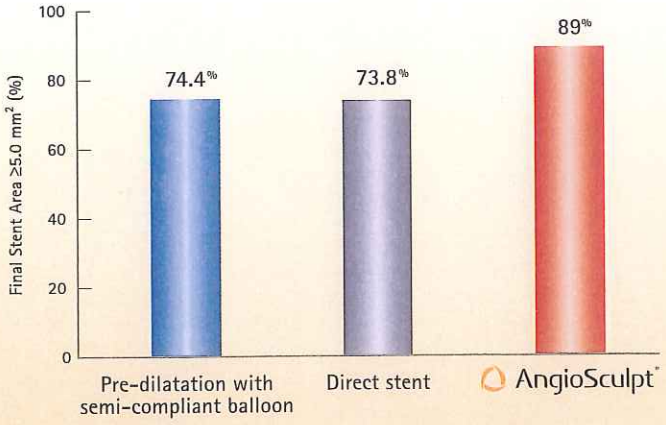
- Clinical studies show that final stent luminal dimensions are an important predictor of better long-term results[6]
- Pre-dilatation with AngioSculpt yields a 33%–50% greater luminal gain than direct stenting or pre-dilatation with a conventional angioplasty balloon catheter ($p<0.001$)[1]
- Pre-dilatation with AngioSculpt resulted in a post-stent luminal area ≥5.0 mm^2 89% of the time, compared to only 74% with direct stenting or pre-dilatation with a conventional angioplasty balloon catheter ($p<0.001$)[1]
- AngioSculpt achieved larger post-stent luminal dimensions than direct stenting or pre-dilatation with a conventional balloon regardless of the type of lesion plaque morphology (i.e., soft, fibrotic, calcific or mixed plaque)[1]

MORE LUMINAL GAIN ($p<0.001$)[1]

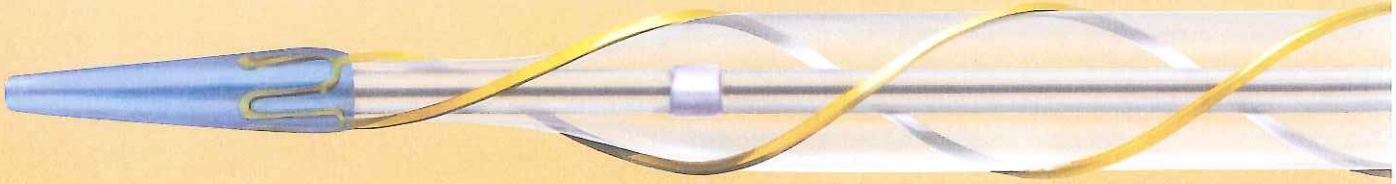


Note: There was no statistically significant difference between the results for pre-dilatation with a conventional angioplasty balloon and direct stenting.

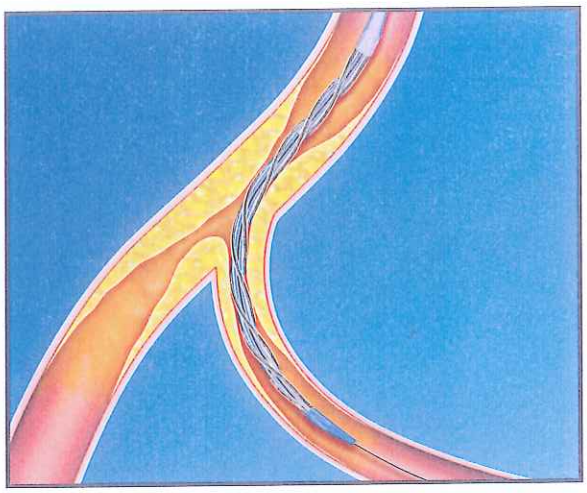
BETTER FINAL LUMINAL DIMENSIONS ($p<0.001$)[1]



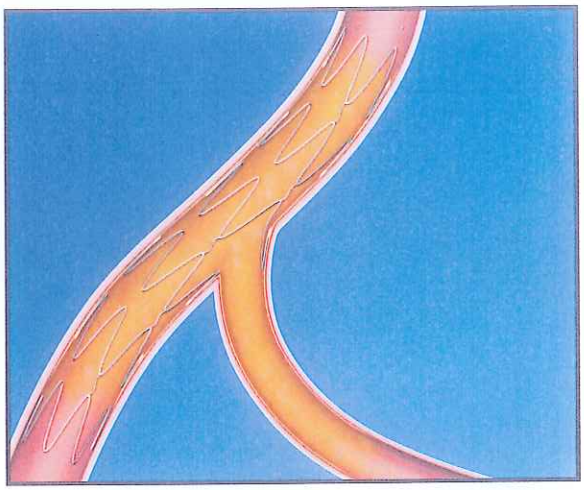
Note: There was no statistically significant difference between the results for pre-dilatation with a conventional angioplasty balloon and direct stenting.



A versatile tool for treating bifurcation lesions



Pre-treatment: AngioSculpt placed at side branch in bifurcation lesion



Post-treatment: AngioSculpt used as stand-alone treatment in side branch and pre-dilatation tool in main branch

The clinical challenges common in bifurcation lesions—dissection, slippage and plaque shifting—can make a lengthy procedure even longer. AngioSculpt offers physicians an effective, time-saving tool for treating the unique challenges of bifurcation lesions.

- No device slippage[2] for precise and predictable treatment of the target lesion
- Uniform, radial, scoring forces beneficial for treating elastin-rich ostial lesions
- Low dissection rates[2] may lead to reduced need for "bail-out" stenting
- Electropolished nitinol edges provide a margin of safety in complex anatomy
- Better final luminal dimensions in the main branch post-stenting[1]

AngioSculpt® PTCA

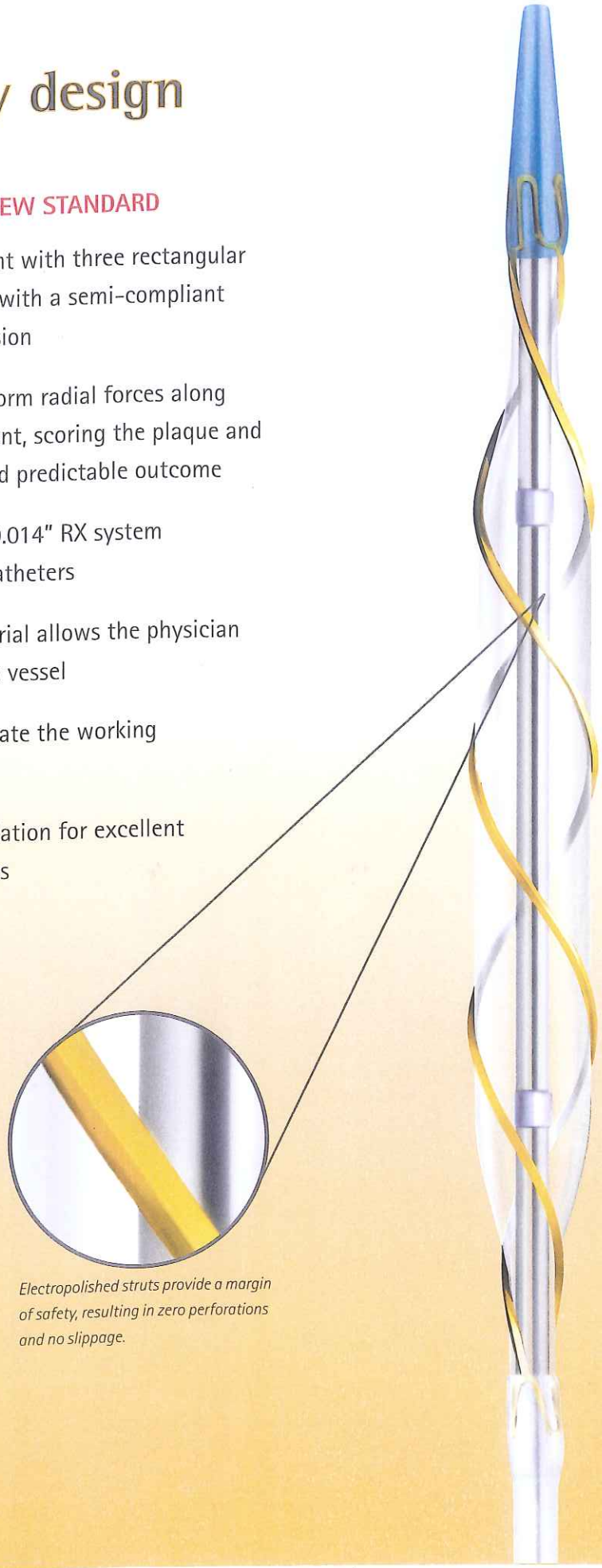
Scoring Balloon Catheter

Rapid Exchange Delivery System

Innovation by design

TECHNOLOGY THAT SETS A NEW STANDARD

- Flexible nitinol scoring element with three rectangular spiral struts works in tandem with a semi-compliant balloon to score the target lesion
- Balloon inflation focuses uniform radial forces along the edges of the nitinol element, scoring the plaque and resulting in a more precise and predictable outcome
- Low crossing profile (~2.7F), 0.014" RX system compatible with 6F guiding catheters
- Semi-compliant balloon material allows the physician to tailor the device size to the vessel
- Two radiopaque markers indicate the working ends of the scoring balloon
- Nitinol-enhanced balloon deflation for excellent rewrap and recross capabilities



Electropolished struts provide a margin of safety, resulting in zero perforations and no slippage.

The AngioSculpt Scoring Balloon Catheter

COMPLIANCE CHARACTERISTICS

Pressure (atm)	Balloon Diameter (mm)			
	2.0	2.5	3.0	3.5
2	1.88	2.28	2.73	3.19
4	1.91	2.35	2.79	3.26
6	1.95	2.40	2.88	3.37
8	2.01	2.49	3.01	3.51
10	2.08	2.59	3.16	3.65
12	2.15	2.69	3.27	3.73
14	2.22	2.77	3.36	3.81
16	2.28	2.85	3.43	3.86
18	2.32	2.89	3.50	3.91
20	2.37	2.95	3.57	3.97
22	2.39	2.99	3.63	–

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ORDERING INFORMATION

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)	Guidewire Compatibility	Guide Catheter Compatibility	Catheter Length (cm)
2001-2010	2.0	10	0.014"	6F	137
2001-2015	2.0	15	0.014"	6F	137
2001-2020	2.0	20	0.014"	6F	137
2001-2510	2.5	10	0.014"	6F	137
2001-2515	2.5	15	0.014"	6F	137
2001-2520	2.5	20	0.014"	6F	137
2001-3010	3.0	10	0.014"	6F	137
2001-3015	3.0	15	0.014"	6F	137
2001-3020	3.0	20	0.014"	6F	137
2001-3510	3.5	10	0.014"	6F	137
2001-3515	3.5	15	0.014"	6F	137
2001-3520	3.5	20	0.014"	6F	137

To learn more about the clinical advantages of the AngioSculpt Scoring Balloon Catheter, please contact your AngioScore distributor today.

The AngioScore PTCA Scoring Balloon Catheter Rapid Exchange (RX) design is not commercially available in the USA.

CE Mark Granted for Coronary and Peripheral Applications
CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

SAFETY SUMMARY

INDICATIONS
The AngioSculpt Scoring Balloon Catheter is indicated for the treatment of a hemodynamically significant coronary artery stenosis, including in-stent restenosis, for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS
The AngioSculpt catheter should not be used for the following:
- Coronary artery lesions unsuitable for treatment by percutaneous revascularization.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS
This device is intended for single (one) use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
Balloon pressure should not exceed the rated burst pressure (RBP). [The RBP is based on results of invitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization.]
PTCA with the AngioSculpt device should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed on site (or at a nearby facility) in the event of a potentially injurious or life-threatening complication. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
Proceed cautiously when using the AngioSculpt catheter in a freshly deployed bare metal or drug eluting stent. The AngioSculpt catheter has not been tested for post-dilation of stents or in lesions distal to freshly deployed stents in clinical studies. Bench testing has shown no additional risk when inserting or withdrawing the AngioSculpt catheter through stents (no interference with stent struts, no retention of or damage to AngioSculpt catheter).
Use the catheter prior to the "Use Before" (expiration) date specified on the package.

PRECAUTIONS
Prior to angioplasty, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used.
Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the catheter system. During and after the procedure, appropriate antiplatelet, anticoagulant and coronary vasodilator therapy consistent with institutional practice or coronary stent procedures should be provided to the patient.
Do not rotate the catheter shaft in excess of 180 degrees when the tip is constrained.
Do not rotate the catheter luer hub in excess of five (5) turns during use.
Do not advance or retract the AngioSculpt catheter over the floppy portion of the guide wire.
Catheter manipulation, including advancement and retraction, should be performed by grasping the hypotube shaft.
If unusual resistance is felt when the catheter is being manipulated or if it is suspected that the guide wire has become kinked, carefully remove the entire catheter system (AngioSculpt catheter and steerable guide wire) as a unit.
If fluoroscopic guidance indicates that the AngioSculpt catheter has advanced beyond the end of the guide wire, withdraw the catheter and reload the wire before advancing again.

COMPLICATIONS
Possible complications include, but are not limited to, those listed below:
Death; Heart Attack (Acute myocardial infarction);Total occlusion of the treated coronary artery;Coronary artery dissection, perforation, rupture, or injury; Pericardial tamponade
No / slow reflow of treated vessel; Emergency coronary artery bypass (CABG); Emergency percutaneous coronary intervention; CVA/stroke; Pseudo-aneurysm; Re-stenosis of the dilated vessel ; Unstable chest pain (angina); Thrombo-embolism or retained device components; Irregular heart rhythm (arrhythmias, including life-threatening ventricular fibrillation); Severe low (hypotension) / high (hypertension) blood pressure;Coronary artery spasm; Hemorrhage or hematoma; Need for blood transfusion; Surgical repair of vascular access site; Creation of a pathway for blood flow between the artery and the vein in the groin (Arteriovenous fistula); Drug reactions, allergic reactions to x-ray dye (contrast medium); Infection.

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