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Medical Device +
Pharmaceutical Technology

Volume 3
Issue 2, Mar 2006
€3.45 (incl. taxes)
www.blackdotpublishing.com

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CREGANNA
MEDICAL DEVICES

Creganna Medical Devices
Parkmore West
Galway
Ireland
sales@creganna.com
Tel +353 91 757801
Fax +353 91 757850

www.creganna.com

DESIGNING HYPOTUBE BASED CATHETER SHAFTS

Recent research has indicated that shaft design is a crucial element to the functionality of hypotubes. Maura Leahy, Product Manager for Creganna Medical Devices, outlines the approach to optimising design.

Up until the last decade, the gold standard for treating heart disease was open heart surgery, or heart bypass surgery where veins are harvested from a patient's leg and grafted around the heart to "by pass" clogged and blocked heart arteries.

Open heart surgery is a highly traumatic and risky procedure for a patient as the heart is stopped during the operation and both blood circulation and breathing is performed artificially by a machine. Hospital stays are long and recovery periods extensive.

In the last 10 years, angioplasty (or PTCA) has emerged as a minimally invasive alternative to open heart surgery. During angioplasty, a patient is treated in a "Cath Lab" under a mild sedative and local anaesthetic. A small incision is made in the upper thigh and a catheter is fed from the incision site up to the heart and into the clogged artery.

The cardiologist then uses a "balloon" on the tip of the catheter to unclog the artery by compressing the fatty matter in the artery. A stent can then be placed in the artery using a balloon catheter. The stent acts as a tiny metal scaffold to keep the artery open. The procedure takes about one hour and the patient can typically leave the hospital within 24 hours with minimal recovery time.

Hypotube Catheter Shafts

In a typical angioplasty balloon catheter the

tip of the catheter, the distal end, is a balloon, while on the other end, the proximal end, is a hub. The hub remains outside of the patient during the procedure and the cardiologist uses the hub to inflate/deflate the balloon. The link between the hub outside the body and the balloon at the site of the clogged artery is known as the catheter shaft or the hypotube.

A hypotube is a long metal tube with micro-engineered features along its length. It is typically 0.75 meters (29.53 inches) to 1.25 meters (49.22 inches) long and is a critical component of the balloon catheter.

The hypotube has a number of key functions:

- It helps the cardiologist to navigate the vascular anatomy to the site of the clogged artery.
- It assists the cardiologist to ensure accurate placement of the balloon and stent at the site of the clogged artery.
- As the conduit that enables the inflation and deflation of the balloon.

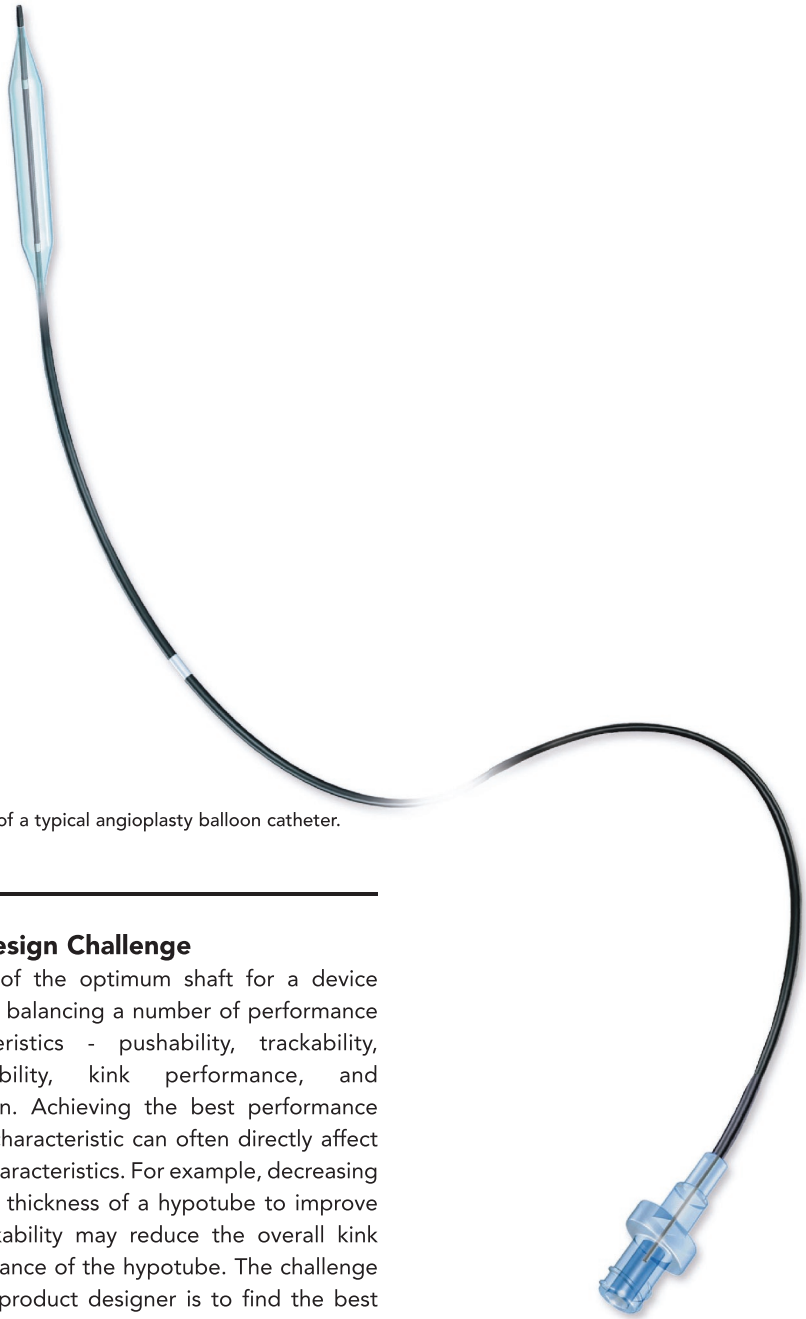
Hypotube shafts are used in minimally invasive interventions due to their combination of push, trackability, torque and kink resistance. These performance characteristics have established the hypotube as the device shaft of choice for PTCA applications. Recognising these superior performance benefits, medical device

manufacturers are now adopting hypotube based device shafts in new application areas, such as neurology, peripheral vascular interventions and imaging.

Hypotube shafts are generally produced from medical grade stainless steel. Material combinations, for example, metal hypotubes with polymer over jackets have become available in recent years.

Research – the End User

A recent study by medical technology specialists, Cambridge Consultants, revealed that leading cardiologists from the USA and Europe call for greater innovation in the design of hypotubes. Cardiologists participating in the study indicated that catheter delivery systems are the first key step in successful stent treatment, as delivery systems are what enable stents to arrive at the target lesion. While cardiologists are generally satisfied with current delivery systems, they expressed the need for improvements to hypotube design and performance characteristics. In particular, improvements in kink resistance, pushability, lubricity and lower profile were identified as to be of value by those surveyed. The study highlights the need for device manufacturers to continue to optimise hypotube design. Superior design begins with a good understanding of hypotube design characteristics.



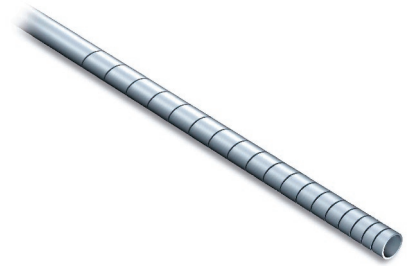
Design of a typical angioplasty balloon catheter.

The Design Challenge

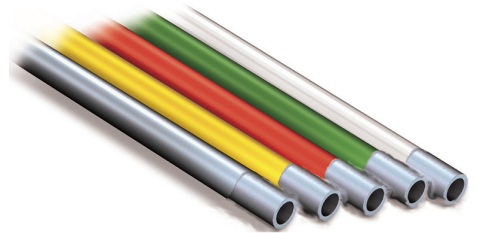
Design of the optimum shaft for a device requires balancing a number of performance characteristics - pushability, trackability, torqueability, kink performance, and transition. Achieving the best performance in one characteristic can often directly affect other characteristics. For example, decreasing the wall thickness of a hypotube to improve its trackability may reduce the overall kink performance of the hypotube. The challenge for the product designer is to find the best possible combination of characteristics for their particular application.

There are five key areas to consider when designing a hypotube shaft.

- Push – the ability of a device to transmit a longitudinal force from the proximal end of the shaft to the distal end. When push is optimised in combination with other hypotube design features it will be easier for the physician to manoeuvre the device to the exact treatment site.
- Torque – the ability of the device shaft to transmit a rotational displacement along the length of the device. Rotational movements by the physician translate efficiently to the device tip within the anatomy when torque performance is high.
- Kink performance – also known as kink resistance, is the ability of a device shaft to maintain its cross sectional profile



Laser profiled metal hypotubes with a spiral type design can assist in maximising trackability.



Applying a polymer jacket to a metal hypotube is a popular choice when high lubricity is a key design requirement. Choosing a unique colour for the polymer jacket can also assist to differentiate a product.



A broad range of shapes and form features are available that facilitate the attachment of transitioning elements to the hypotube distal end. a) skive transition, b) welded wire attachment and c) a slot with crimp.

How to optimise hypotube performance		
Characteristic	Goal	Design options
Push	Increase push	- Maximize the cross-sectional area of the device. - Maximize the modulus of elasticity by using a stiffer material. - Maximize tensile strength.
Torque	Increase torque	- Maximize the polar moment of inertia of the tube. - Maximize the shear modulus using a stiffer material.
Kink Performance	Increase kink resistance	- Maximize wall thickness. - Maximize the ductility of the material.
Trackability	Lower tracking forces	- Select a low friction outer layer or coating.- Reduce the modulus of elasticity. - Reduce the wall thickness of the device. - Reduce the outer diameter of the shaft.
Transition	Optimise transition zone	- Increase the flexibility of the distal end of the shaft. - Remove some of the material from the distal end of the shaft. - Add a component of intermediate stiffness to the transition area

during compressive deformation. When kink performance (resistance) is high, the physician can rely on the device shaft to negotiate difficult routes without fracturing or breaking.

- Trackability – describes the ability of a device to travel through complex anatomies and is influenced by a number of factors including the shaft flexibility, strength and its friction within the anatomical environment. Trackability describes the “feel” of the device to the physician when manipulating and positioning the treatment device.
- Transition – refers to the change in stiffness along the device shaft. Physicians prefer a device shaft that is flexible at the distal end and stiff at the proximal end as it maximises the push and torque performance of the device. A well-designed transition along the device shaft will also decrease the likelihood of kinking.

Optimising Design

The key design characteristics of the hypotube and the options available to the design engineer to optimise each of these attributes are outlined in Table 1 (above).

Design Options

As hypotube technology continues to advance many design options are available

to the engineer to maximise performance of the hypotube.

Into the Future

During the last few years the focus of the minimally invasive medical device industry has been on new and innovative treatment devices, such as drug eluting stents. It could be assumed that hypotube based delivery systems are a mature technology and have developed as far as is possible, but hypotubes have not been standing still.

New hypotube technologies, solutions and products continue to emerge. For example, a recent innovation is a new hypotube with up to 40% improvement in kink resistance in comparison with conventional hypotubes. This improvement in kink performance is achievable without adversely affecting other hypotube design characteristics.

The evolution of the hypotube is evident in its adoption as the delivery system of choice for applications other than PTCA. Leading medical device manufacturers have correctly identified the opportunity to adapt a high performance delivery system, already trusted among its customer base as the delivery platform for new and emerging minimally invasive therapies.

CREGANNA

MEDICAL DEVICES

Address

Creganna Medical Devices
Parkmore West
Galway
Ireland
Tel +353 91 757801
Fax +353 91 757850

Contacts

Brad Edworthy - VP Global Sales
3145 Fernbrook Lane North,
Plymouth, MN 55447, U.S.A.
Tel: +1 763 201 1360
Fax: +1 763 201 1370
Email: brad.edworthy@creganna.com

Eric T. Meyer - Sales Manager-Western
North America
4743 Narragansett Avenue,
San Diego, CA 92107, U.S.A
Tel: +1 619 223 2389
Fax: +1 619 223 2146
Mobile: +1 619 379 0044
E-mail: eric.meyer@creganna.com

Web Address

www.creganna.com