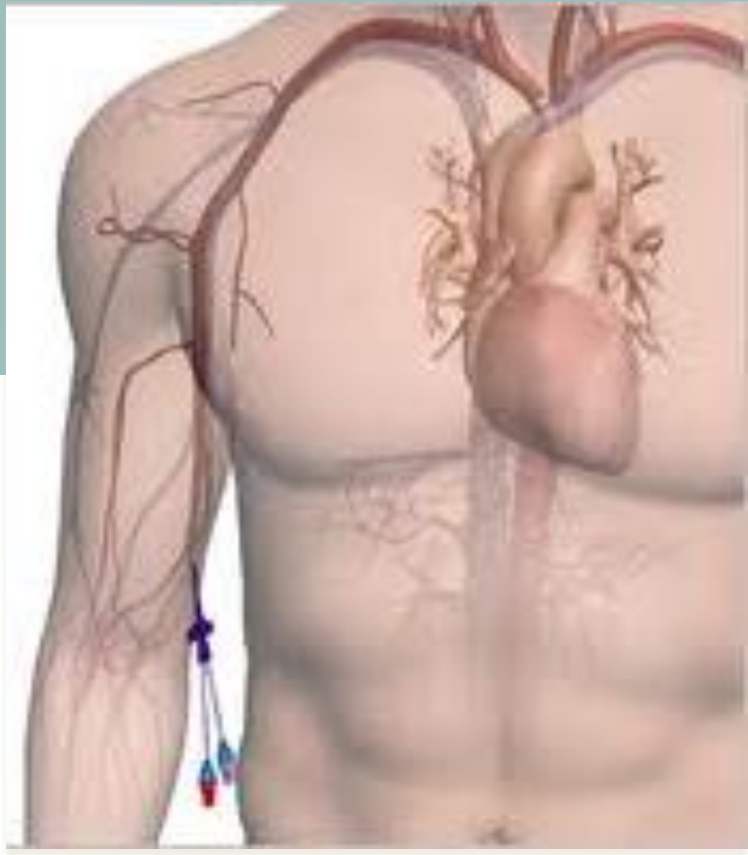
GAVeCeLT
Gli Accessi Venosi Centrali a Lungo Termine

XIII PICC DAY – VERONA, 4 DICEMBRE 2019

SCELTA DEL MATERIALE DEI PICC E PREVENZIONE DELLE COMPLICANZE MECCANICHE

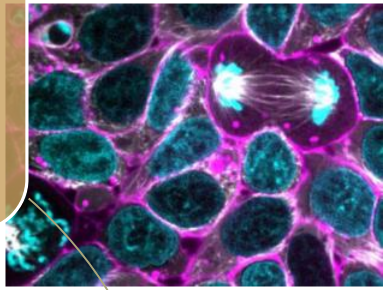


IN SUPREMÆ DIGNITATIS · 1343 ·

Francesca Di Puccio
Dipartimento di Ingegneria Civile e Industriale
Università di Pisa

BIOINGEGNERIA @ DICI

Biologia



Chimica

Meccanica

ASPETTI DI MECCANICA DEI PICC

Tubicini di plastica …

ASPETTI DI MECCANICA DEI PICC

Acta Radiologica: Diagnosis Volume 4, 1966 - Issue sup260

I. MECHANICAL PROPERTIES OF CATHETERS

The manipulation of a catheter into a peripheral branch of the vascular tree with or without the aid of a steering instrument is regarded as a mechanical problem. Factors of importance are shape and mechanical characteristics of catheter, steering instrument and blood vessels. The explanations of the mechanisms involved in the steering of catheters are based on the following mechanical properties of the catheters.

When a catheter or a guide wire is passed from the femoral artery into the aorta its shape is adapted to the vessels. The catheter is elastically deformed during the passage through the vessels. When an advancing catheter tip touches a vessel wall, forces of equal magnitude arise on the catheter and on the vessel wall. The forces acting on the catheter cause a deflection or straightening of it. The forces acting on the vessel wall should be as small as possible to minimize the risk of mechanical damage to the vessel wall.

Catheters for angiography should have suitable mechanical characteristics concerning flexural rigidity, torsional rigidity, buckling and kinking resistance, and tensile strength. Another requirement is a small outer diameter in order to make the catheters less traumatic. But, on the other hand, a large inner diameter and a suitable wall thickness are necessary in order to permit a high flow-rate of contrast medium through the catheter. The ideal catheter should be made of a material that is radiopaque, that can be sterilized, that has a low friction coefficient and that does not favour clot formation.

ASPETTI DI MECCANICA DEI PICC

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deformabile per adattarsi a geometria dei vasi
E
abbastanza **rigido** per inserimento

diametro esterno piccolo x non danneggiare
E
diametro interno grande per garantire flusso

Design of Medical Devices That Meet Contradictory Requirements -> OTTIMIZZAZIONE

ASPETTI DI MECCANICA DEI PICC

deformabile per adattarsi a geometria dei vasi
E
abbastanza **rigido** per inserimento

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+

Radiopachi

<u>Resistere a pressioni ‘elevate’</u>

Resistere a ‘sostanze chimiche’

Mantenere le proprietà nel tempo

Superfici antimicrob./antitrombogen.

Cost – effective

……

ASPETTI DI MECCANICA DEI PICC

Tubicini di plastica …

deformabile per adattarsi a geometria dei vasi
E
abbastanza **rigido** per inserimento

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……

paziente

LA RIGIDEZZA DEI PICC

deformabile per adattarsi a geometria dei vasi

E

abbastanza **rigido** per inserimento

Silicone

Poliuretano

Materiale

Geometria

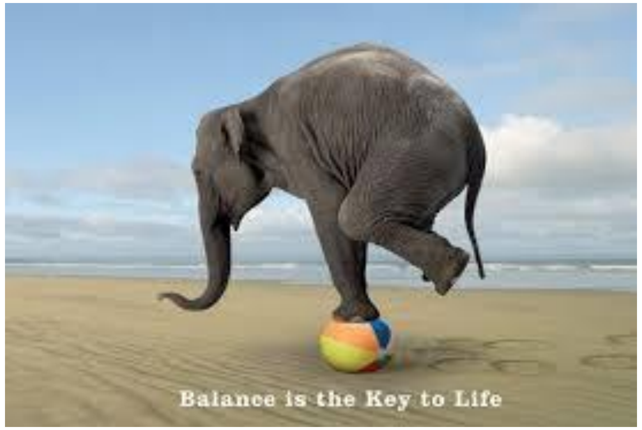
Diametro interno

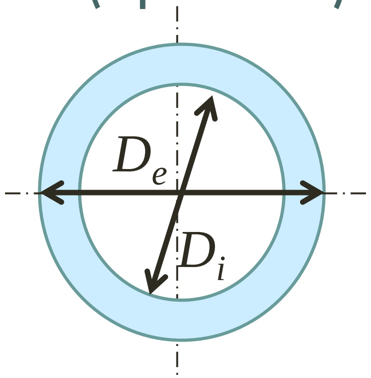
Diametro esterno

(Spessore)

4 MPa vs 10 -100 MPa

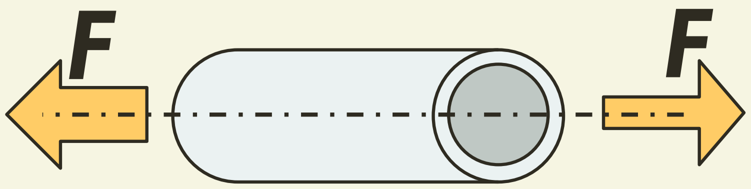
Rigidezza del materiale ***E***





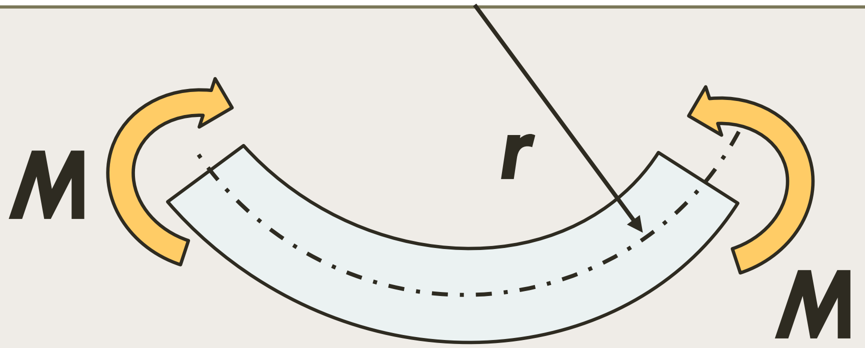
Rigidezza PICC → Quale rigidezza???

LA RIGIDEZZA DEI PICC



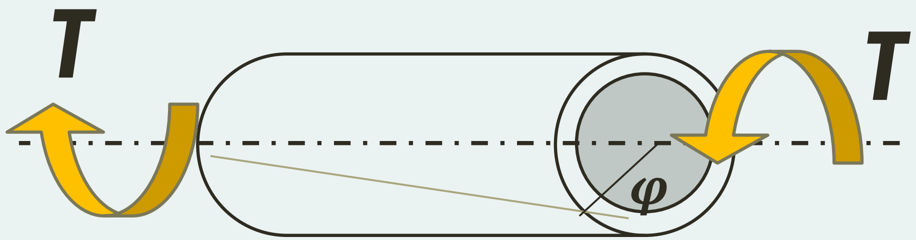
Rigidezza ***assiale***
forza/allungamento

$$\frac{F}{\Delta l} = E\,\frac{\pi}{4\,l}\left(D_e^2 - D_i^2\right)$$



Rigidezza ***flessionale***
momento/curvatura
(c=1/r)

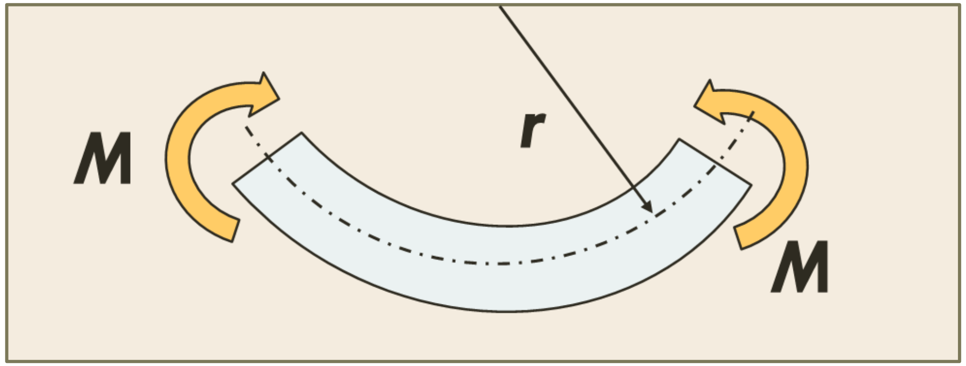
$$\frac{M}{c} = E\,\frac{\pi}{64}\left(D_e^4 - D_i^4\right)$$



Rigidezza ***torsionale***
momento/angolo

$$\frac{T}{\varphi} = E\,\frac{\pi\left(D_e^4 - D_i^4\right)}{64\,l\,(1+\nu)}$$

LA RIGIDEZZA DEI PICC

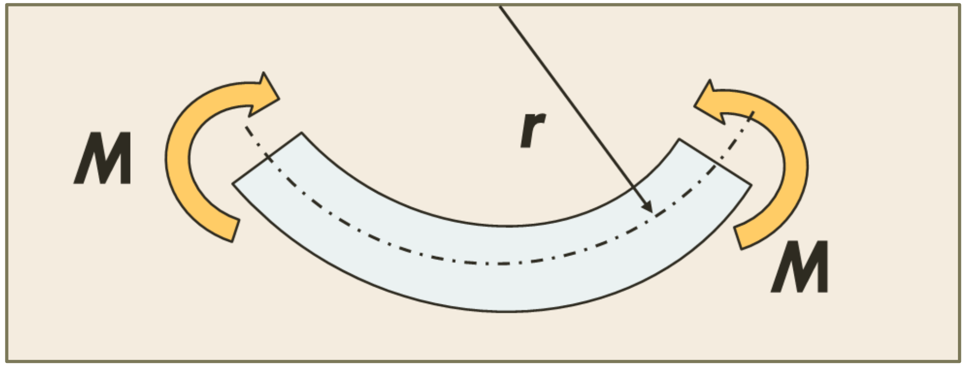


Modello di calcolo semplificato:

- Materiale elastico lineare (E)
- PICC inizialmente diritto
- Piccola variazione di geometria

$$\frac{M}{c} = \underbrace{E}_{\text{Materiale}} \frac{\pi}{64} \underbrace{\left(D_e^4 - D_i^4\right)}_{\text{Geometria}}$$

LA RIGIDEZZA DEI PICC

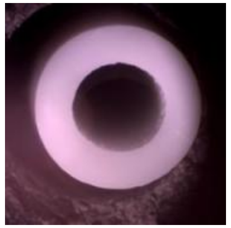
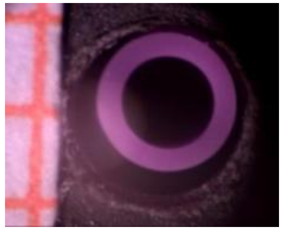
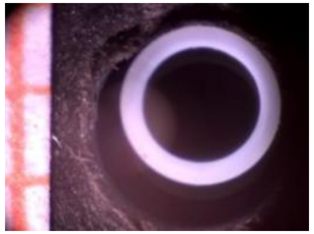
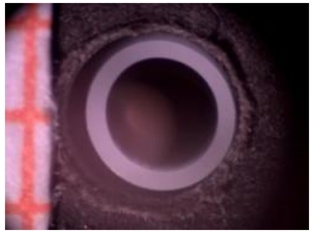
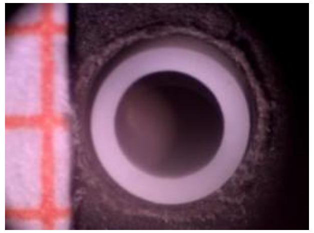
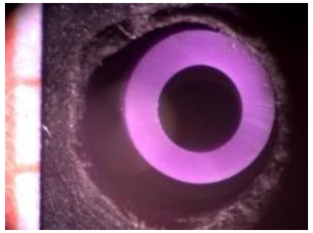
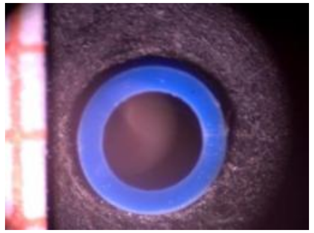
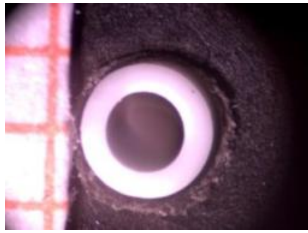


$$\frac{M}{c} = E\,\frac{\pi}{64}\underbrace{\left(D_e^4 - D_i^4\right)}_{\text{Geometria}}$$

Materiale

TABLE II - PICC geometrical features

Sample	Outer diameter $2\,r_o$ (mm)	Inner diameter $2\,r_i$ (mm)	Thickness (mm)
A	1.66	0.98	0.34
B	2.08-1.63	0.87	0.38
C	2.3-1.7	1.25	0.22
E	1.73	1.28	0.22
F	1.74	1.18	0.28
G	1.64	0.89	0.37
H	1.74	1.22	0.26
I	1.76	1.03	0.36

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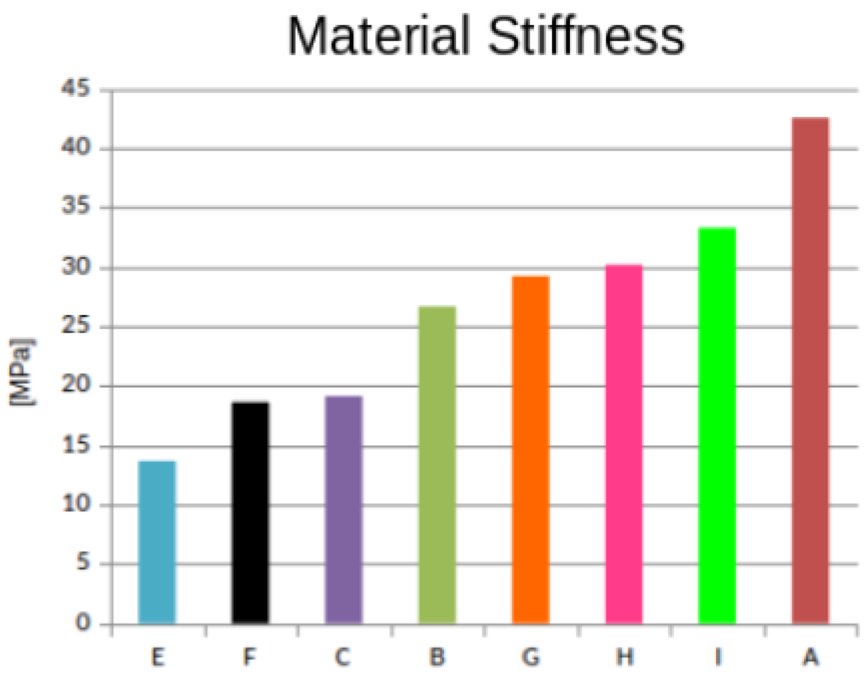
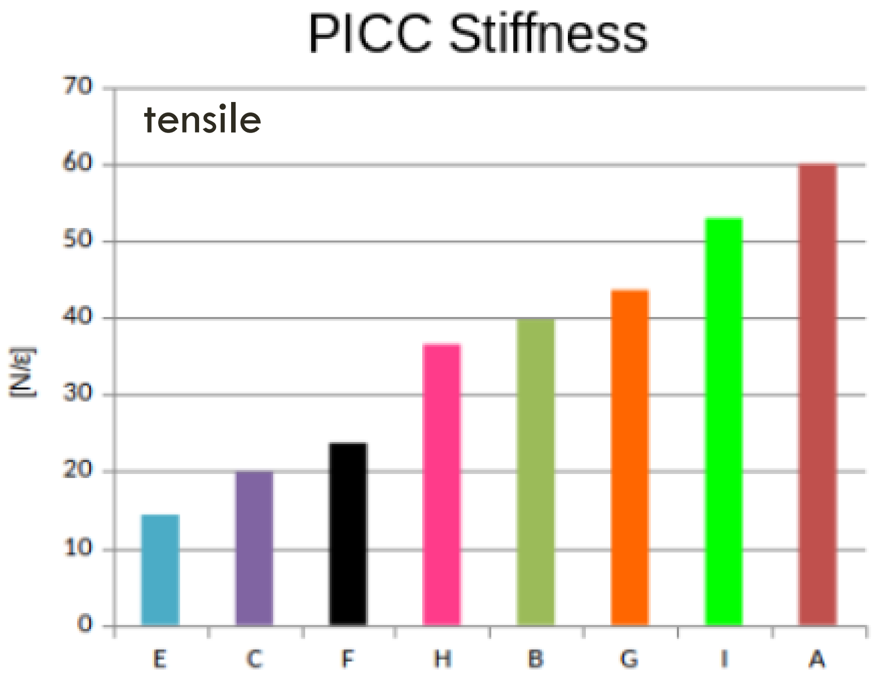
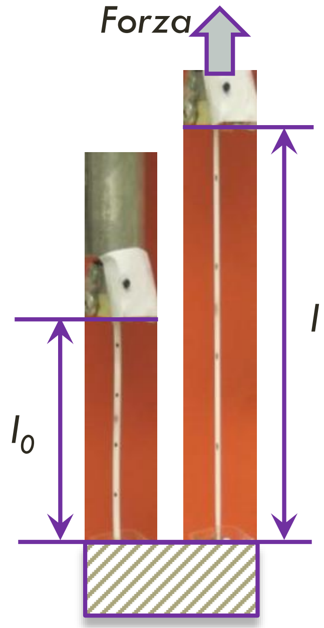


$$E$$



$$F\,\frac{l}{\Delta l} = E\,\frac{\pi}{4}\left(D_e^2 - D_i^2\right)$$



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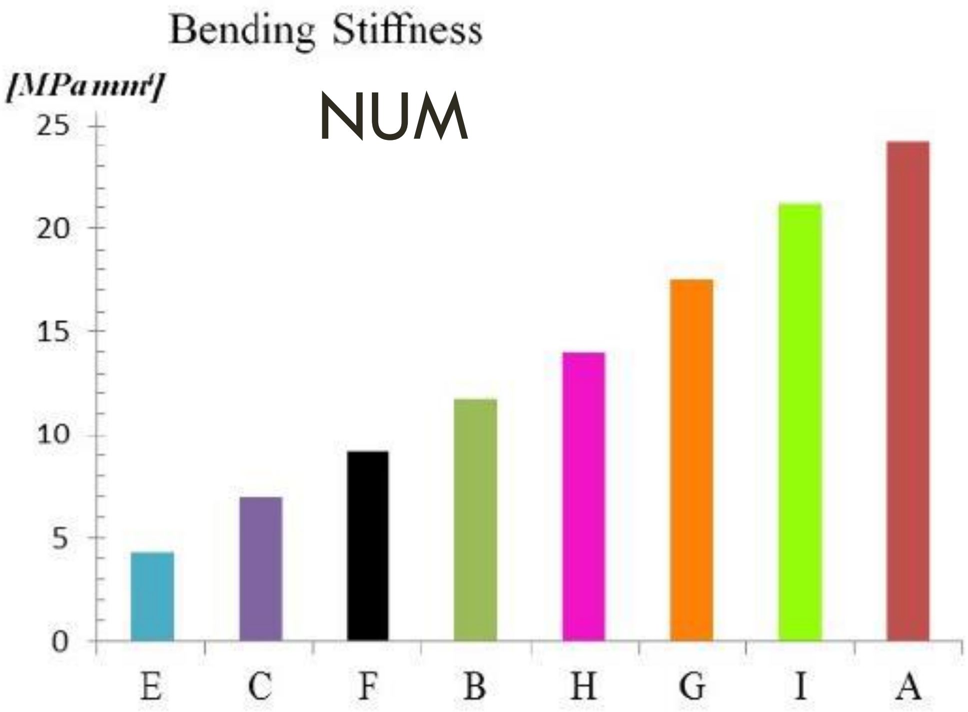

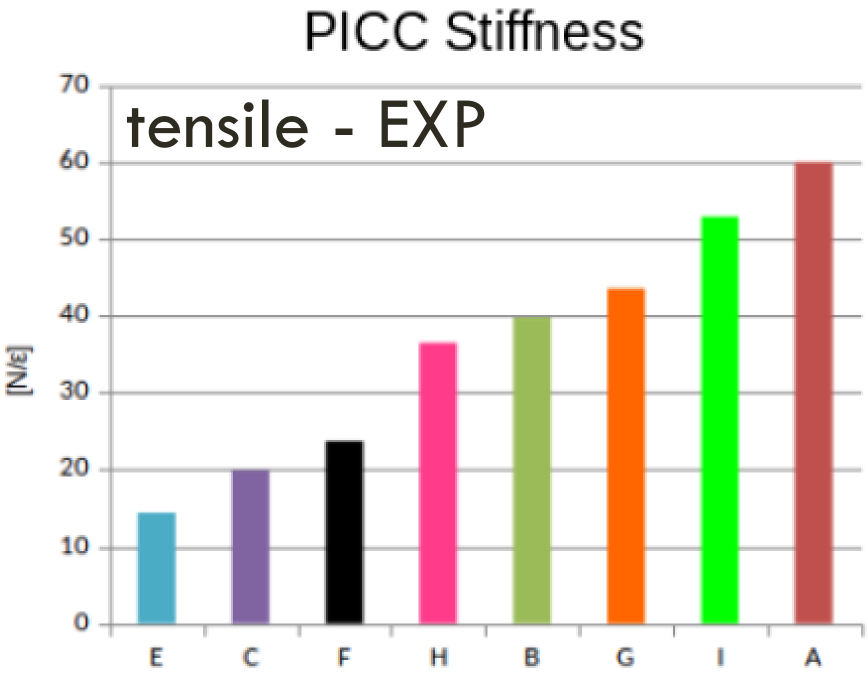

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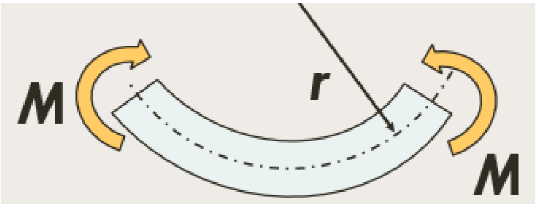
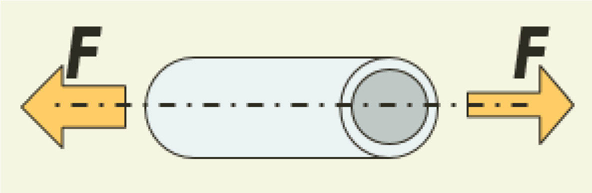
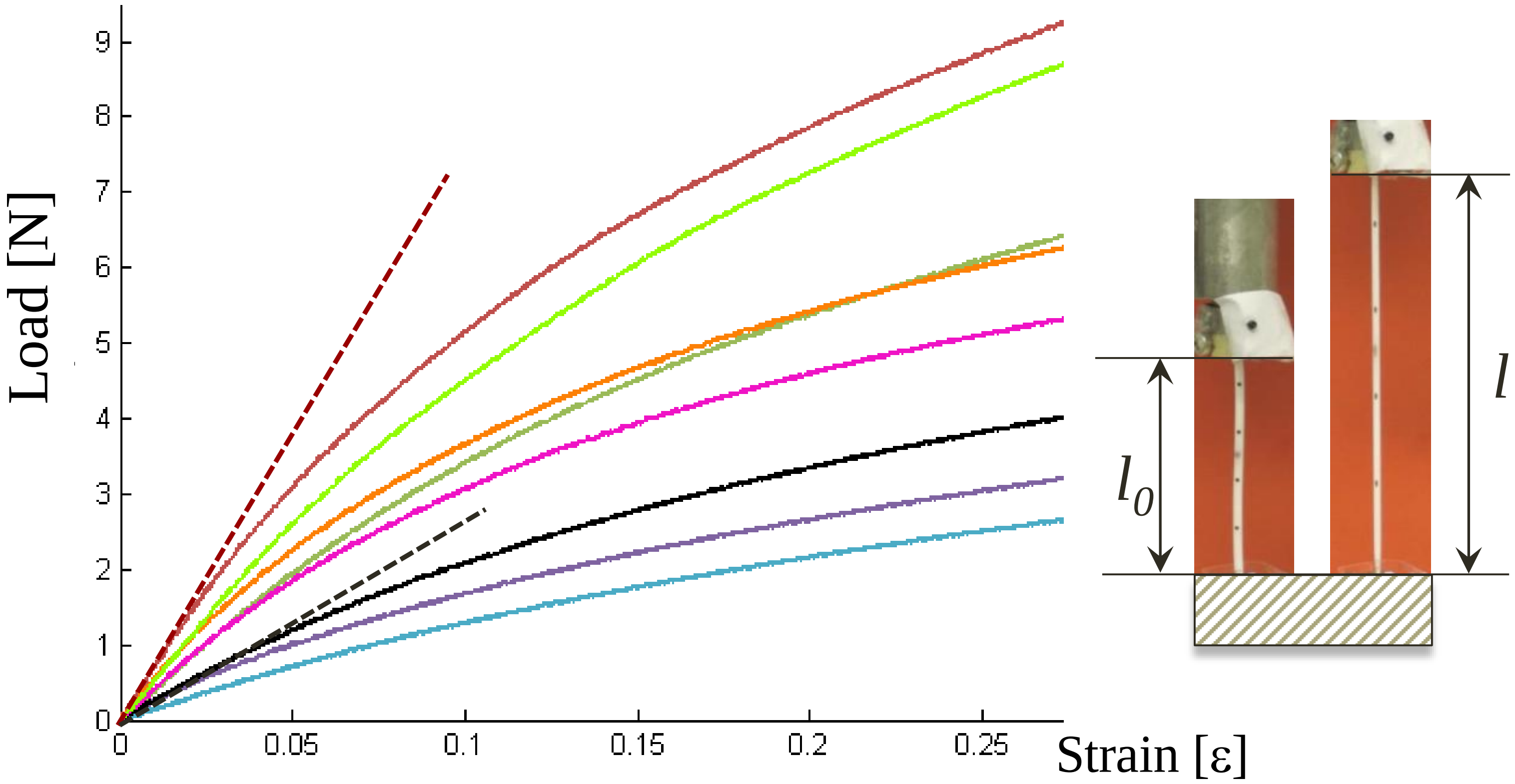




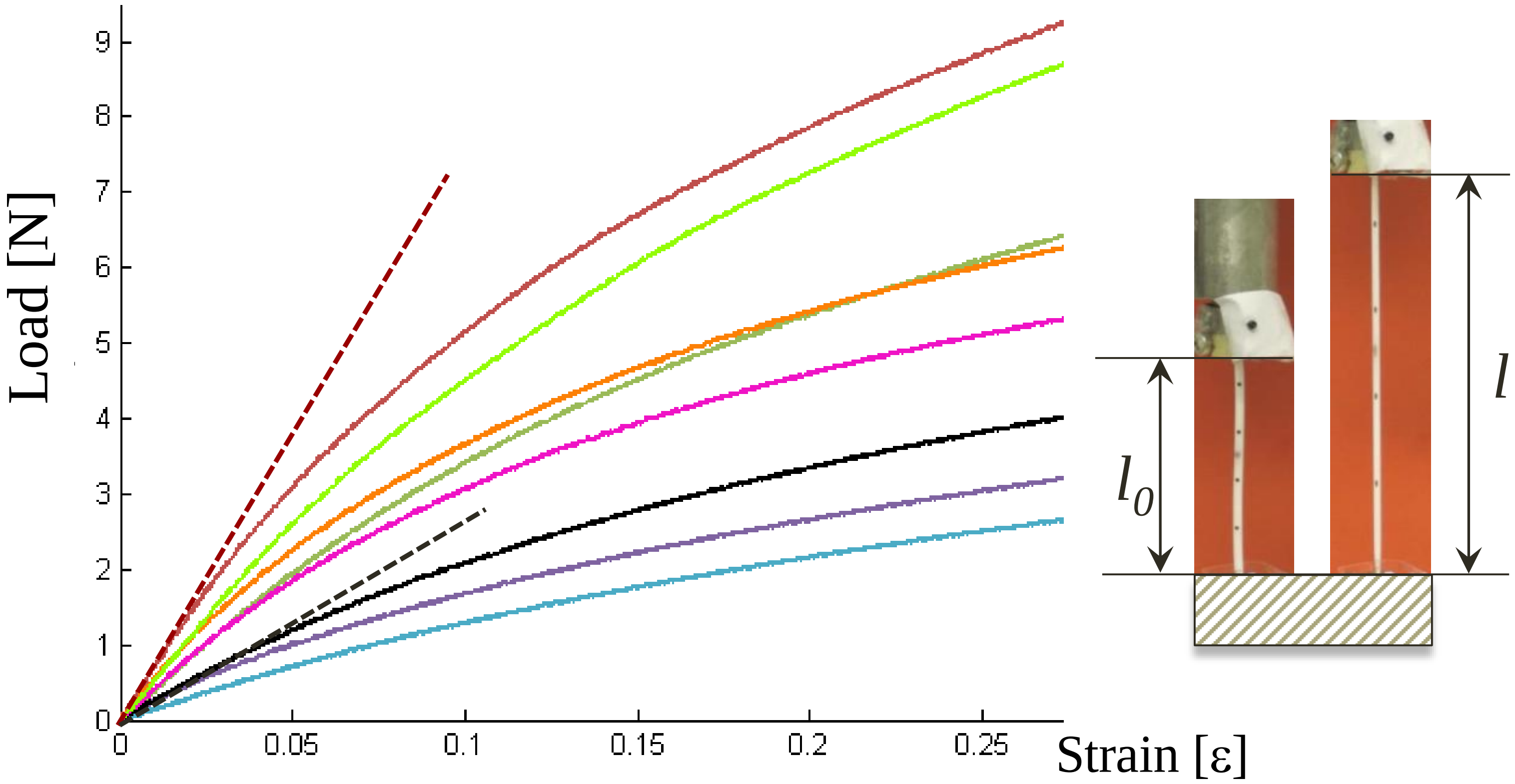
LA RIGIDEZZA DEI PICC

PICC/Materiale andamento <u>non lineare</u>



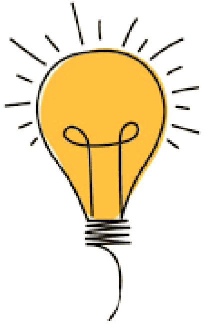
LA RIGIDEZZA DEI PICC

PICC/Materiale andamento <u>non lineare</u>



<u>Difficoltà di valutare il comportamento effettivo dei PICC (temperatura, velocità di deformazione...): Relazione tra prove in lab e condizioni in-vivo</u>

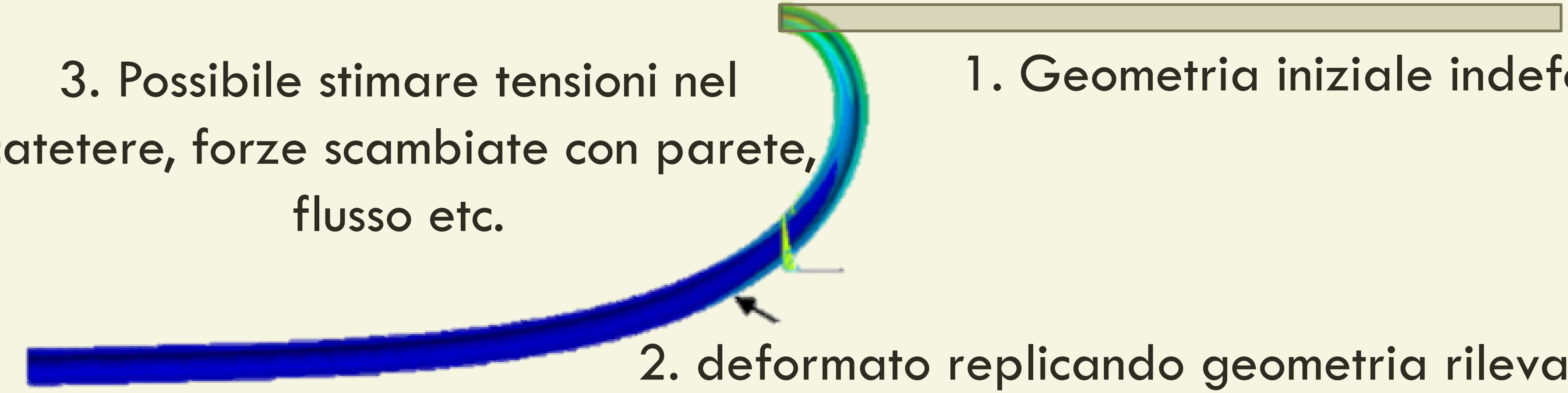
SIMULAZIONE NUMERICA



Strumenti di calcolo: Analisi agli elementi finiti

Modello virtuale di PICC

Geometria e
proprietà del materiale
(non lineari)



1. Geometria iniziale indeformata

2. deformato replicando geometria rilevata in-vivo

3. Possibile stimare tensioni nel catetere, forze scambiate con parete, flusso etc.

DAL BENDING AL BUCKLING E AL KINKING

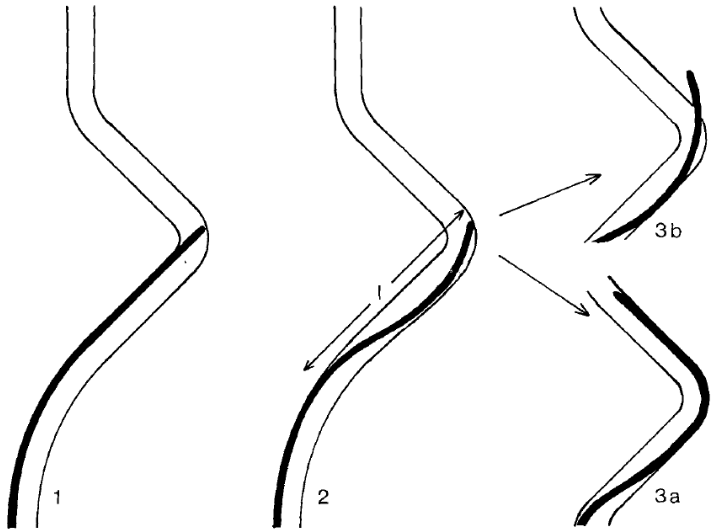
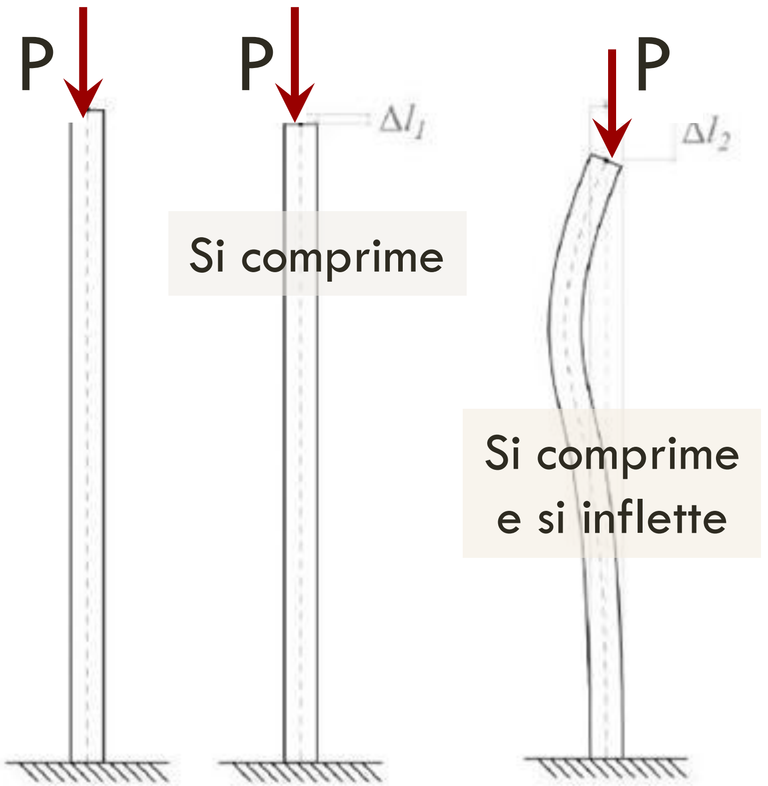
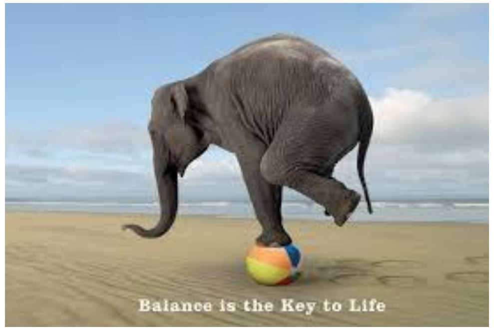


Fig. 5. Buckling of catheter in a tortuous vessel.

$$P = \frac{\pi^2 \ EI}{(\beta l)^2} = \frac{\pi^3 E(D^4 - d^4)}{64(\beta l)^2}$$





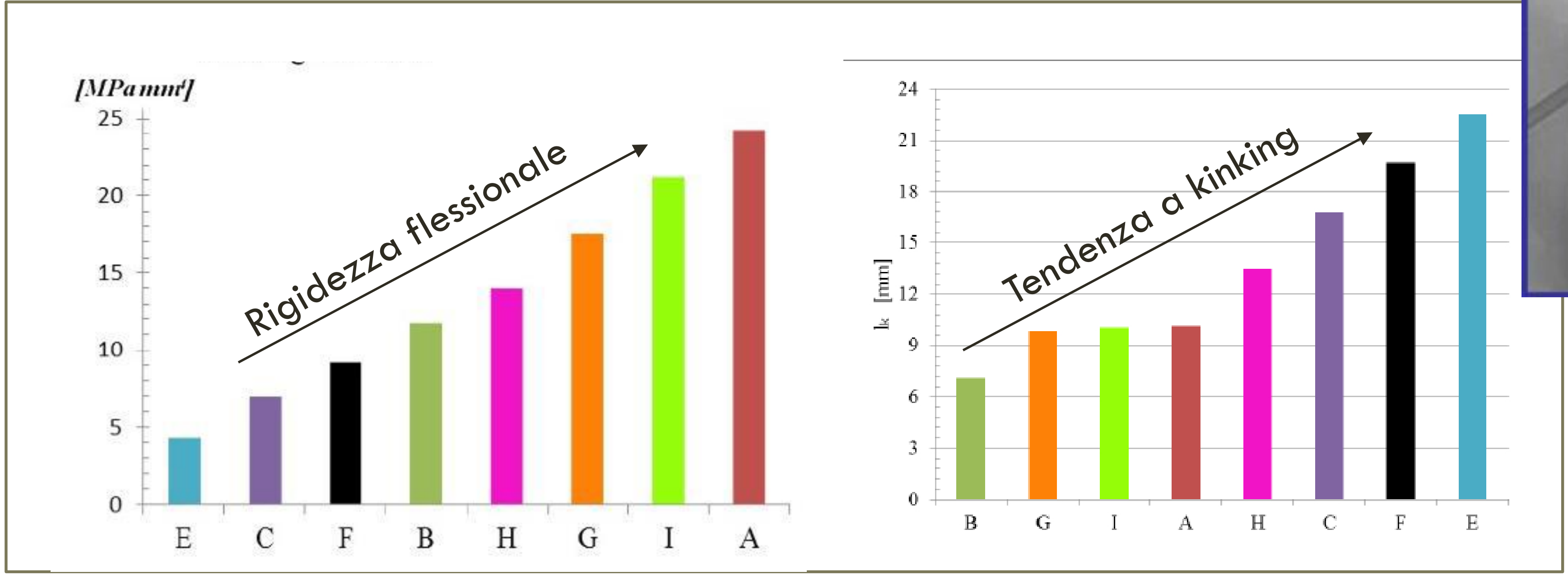
Buckling: catetere si inflette soggetto a carico normale

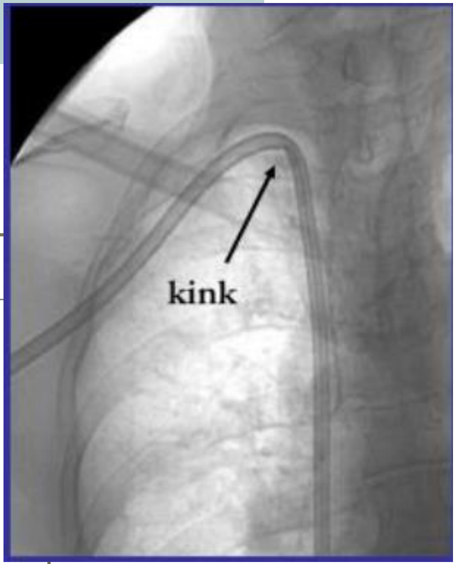
Rigidezza flessionale bassa

desiderabile anche con basso carico per superare le curve

BENDING, BUCKLING E KINKING

Kinking: strano fenomeno!



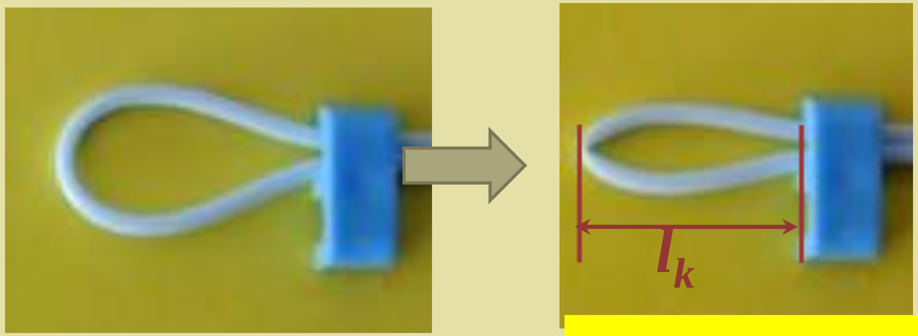


Tendenza a kinking quasi inversamente legata alla rigidezza flessionale

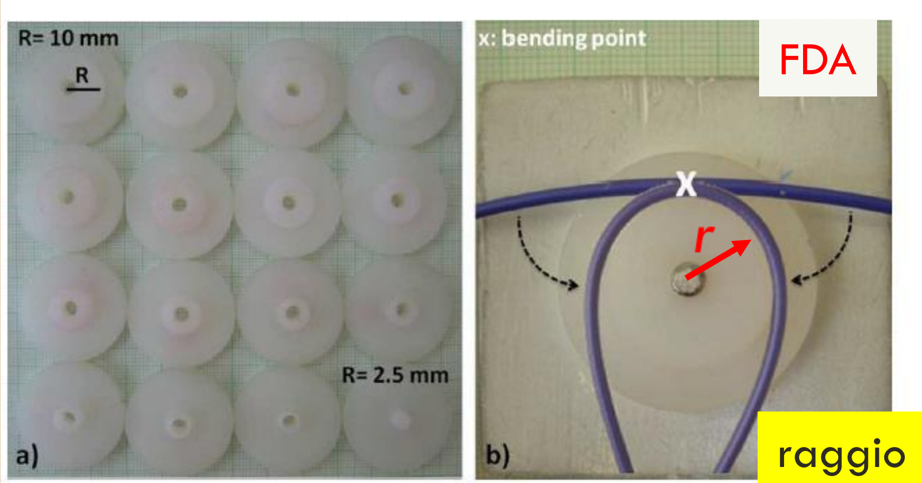
<u>Come valutare la tendenza a kinking?</u>

RESISTENZA A KINKING

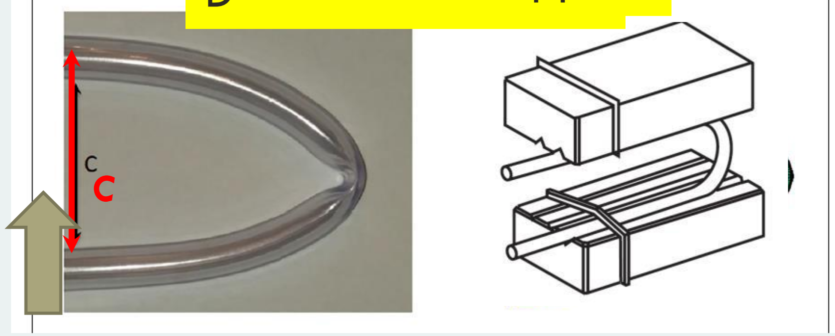
Vari indicatori presenti in letteratura



Distanza da supporti

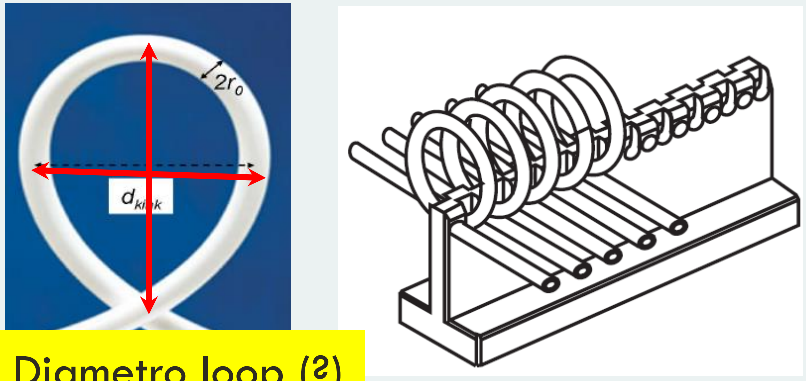


raggio



D Distanza da supporti

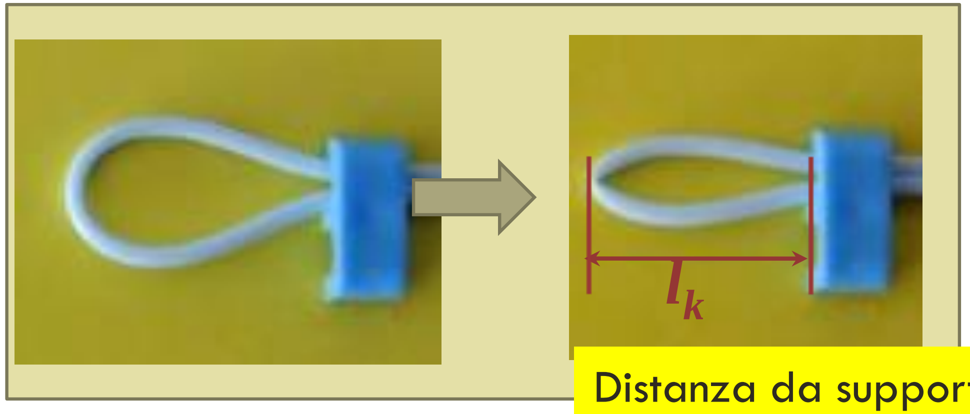
ISO 13868
kinked when the initial **flow** through the straight tube is **reduced by more than 50%**



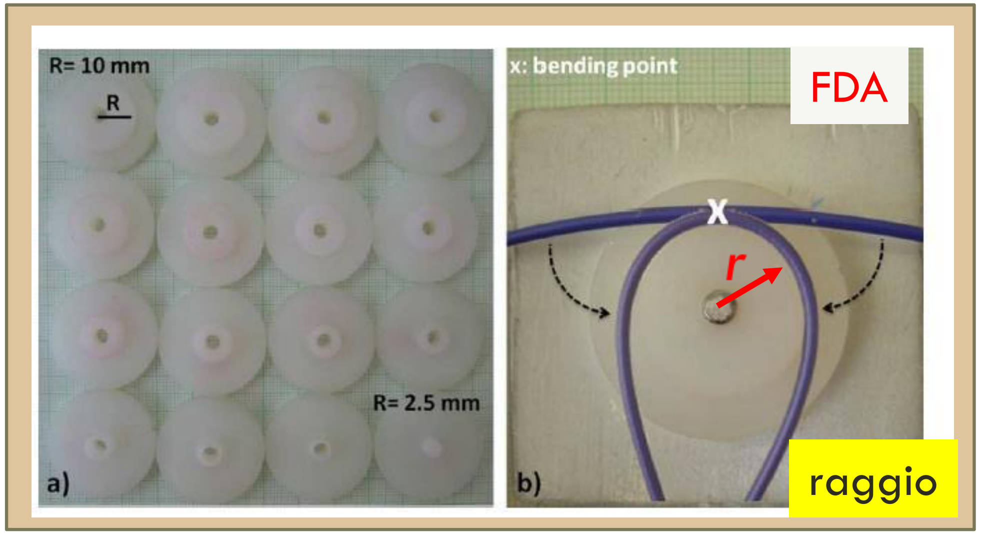
Diametro loop (?)

RESISTENZA A KINKING

Vari indicatori presenti in letteratura

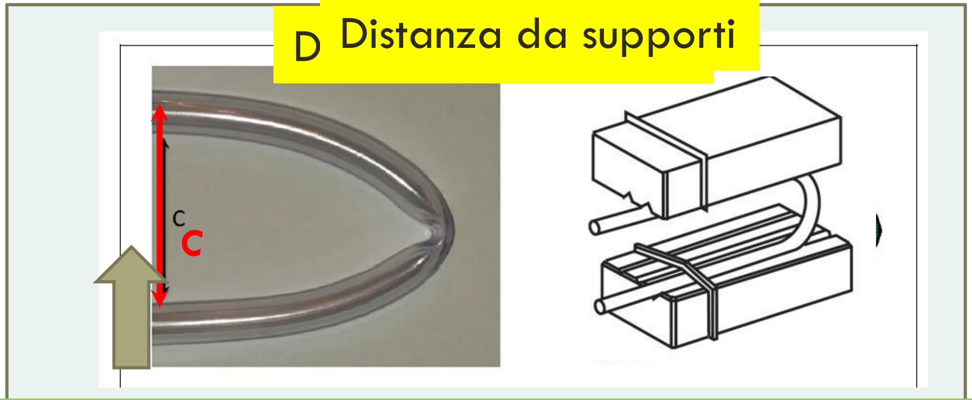


Distanza da supporti



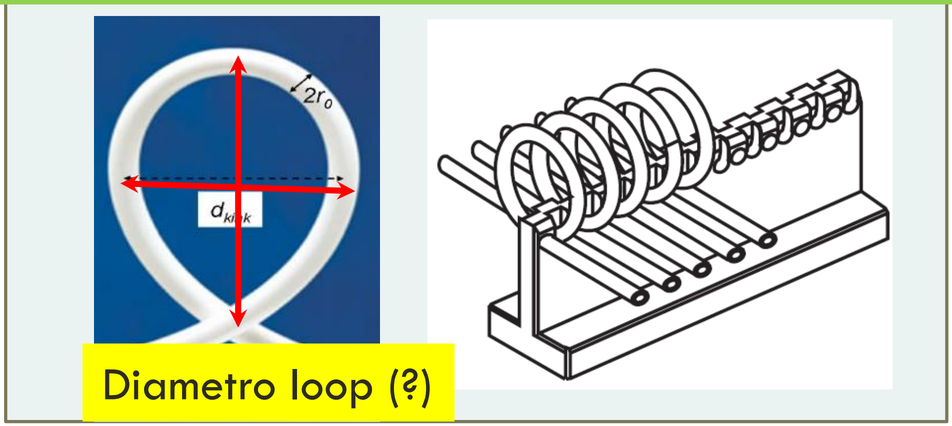
FDA

raggio



D Distanza da supporti

Quale è il parametro più rappresentativo del comportamento in vivo?



Diametro loop (?)

COMPLICANZE MECCANICHE

- Occlusione (8.2%)

a fibrin sheath, medication precipitate, or catheter tip, thrombus, kinking or the catheter tip being positioned against a vessel

- Dislodgement (5.4%)

partial, complete, and accidental removal of the PICC tip from the correct position

- Rottura (3.9%)

Breakage of a CVAD is most commonly due to the use of excessive force, causing a split in the structure of the device, intentional or accidental

Ullman 2015 Complications of Central Venous Access Devices: A Systematic Review, PEDIATRICS Volume 136, number 5, November 2015

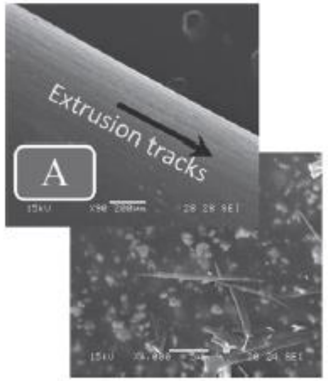
COMPLICANZE MECCANICHE

- Occlusione
  - kinking
  - Accrescimento tessuto
    - rugosità superf < 0.2 µm
    - Coating

Surface analysis of long-term hemodialysis catheters made of carbothane (poly(carbonate)urethane) before and after implantation in the patients' bodies

2018

Marta Nycz[1]*, Ewa Paradowska[1], Katarzyna Arkusz[1], Bartosz Kudliński[2], Elżbieta Krasicka-Cydzik[1]



According to authors' results, the designated roughness parameters of brand new catheters are 10 times smaller than this value. However, as a result of the catheter contact with body fluids, its surface is covered by layer, what affects in the surface roughness changes (Table 3). This biological layer is also called "conditioning film", which facilitates the adhesion of microorganisms to catheter surface. This film is formed shortly after implantation of the catheter in the patient's body and can mask functional group of antimicrobial coatings which are often impregnated catheters [3]. This may be the reason why coatings are not sufficiently effective.

COMPLICANZE MECCANICHE

Rottura

- Esterna (hub)
- Catetere

Poco documentate

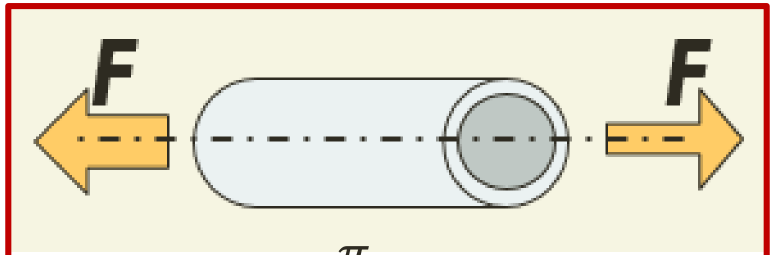
Dipende dalle condizioni di carico

- **Statica**
- Dinamica (carichi ripetuti)
- Ageing (chimico/meccanico)

Resistenza

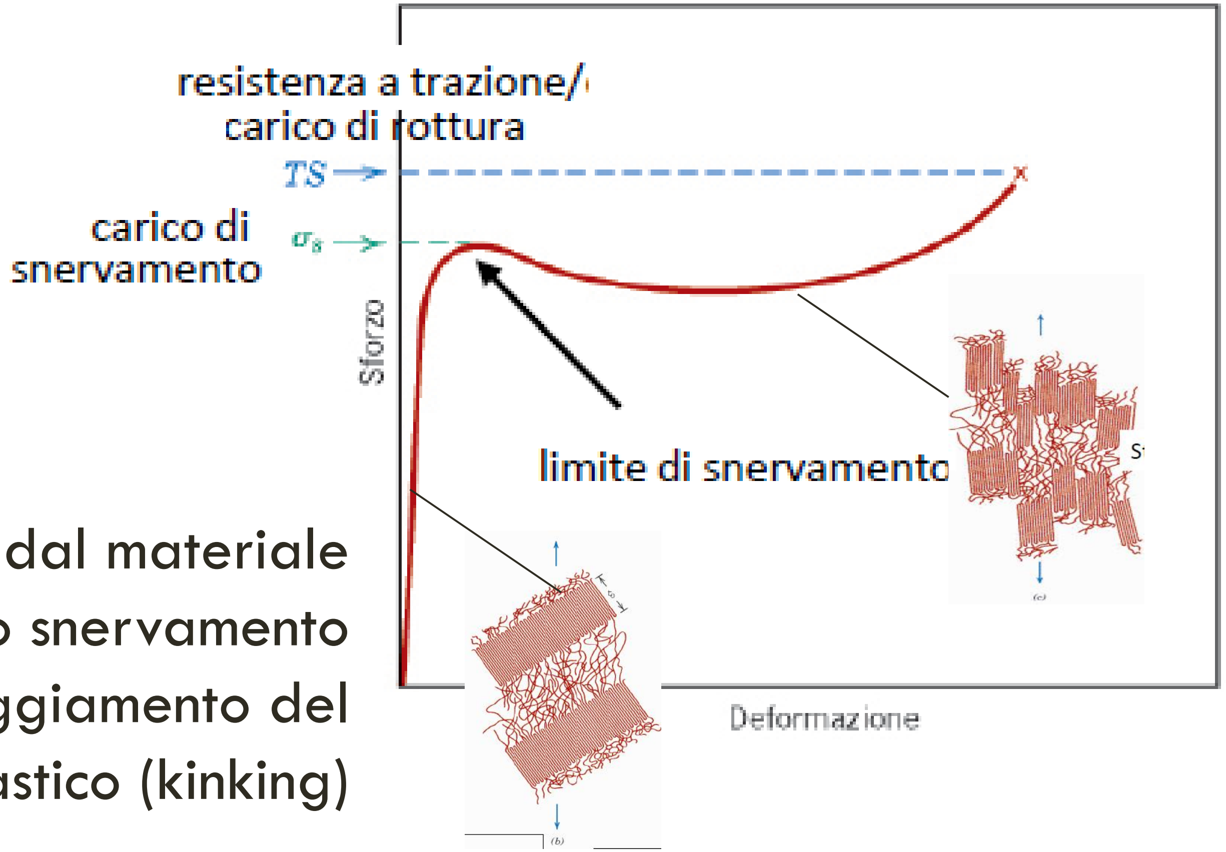
ROTTURA - RESISTENZA

Statica



$$\sigma = F/\frac{\pi}{4}\left(D_e^2 - D_i^2\right)$$

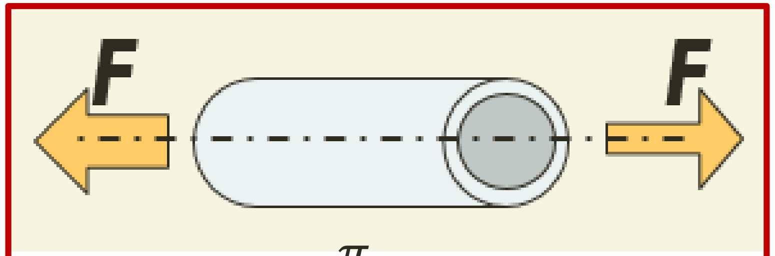
Curva di trazione, es.



- Dipende dal materiale
- Campo elastico: sotto snervamento
- Se superato danneggiamento del materiale in campo plastico (kinking)

ROTTURA - RESISTENZA

Statica



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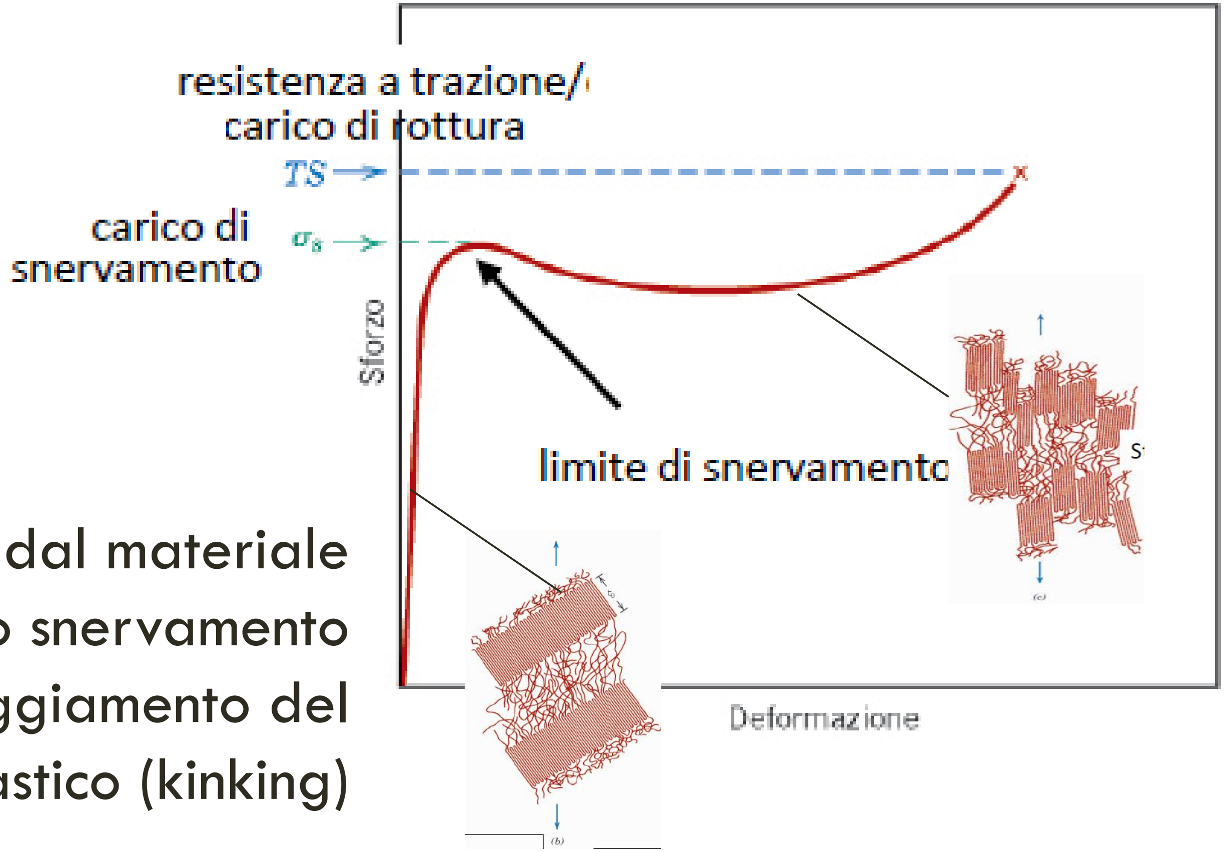


- Dipende dal materiale
- Campo elastico: sotto snervamento
- Se superato danneggiamento del materiale in campo plastico (kinking)

ROTTURA - RESISTENZA

Statica

Normativa – Carico di rottura minimo garantito
(non dipende da materiale)

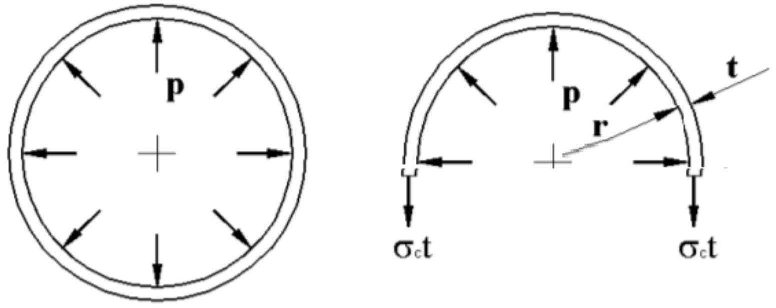
Smallest outside diameter of tubular portion of test piece mm	Minimum peak tensile force *N*
≥ 0,55 < 0,75	3
≥ 0,75 < 1,15	5
≥ 1,15 < 1,85	10
≥ 1,85	15

Facilmente verificato,
Valore rappresentativo?

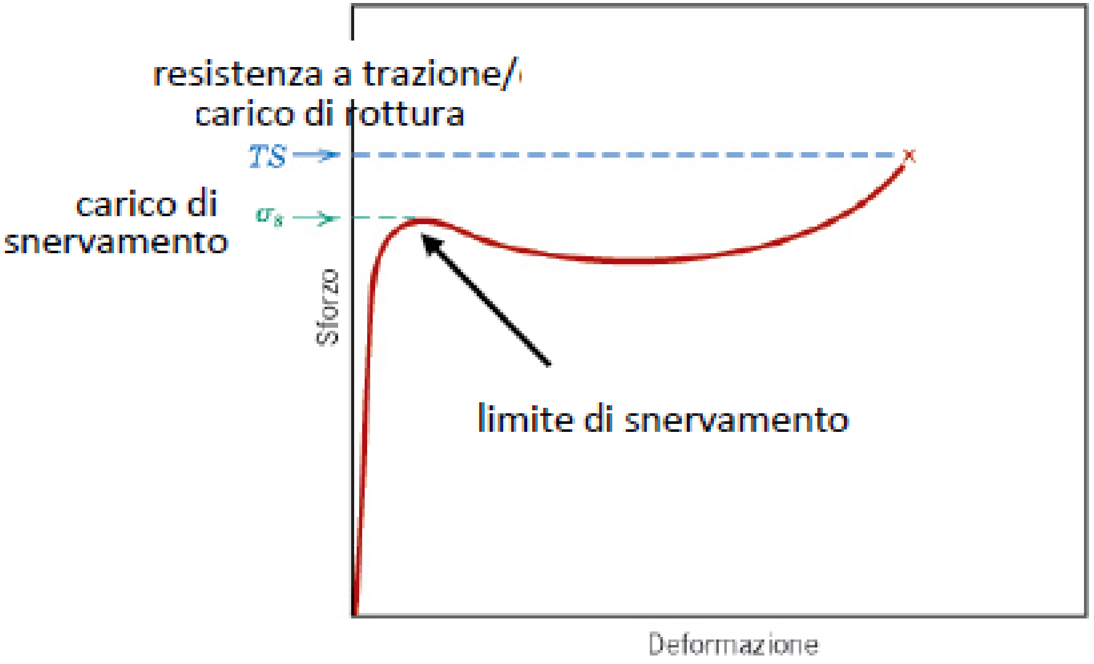
ROTTURA - RESISTENZA

Statica

- Pressione



$$\sigma_c = \frac{pr}{t}$$



Normativa: prove a scoppio (300 psi)

ROTTURA - RESISTENZA

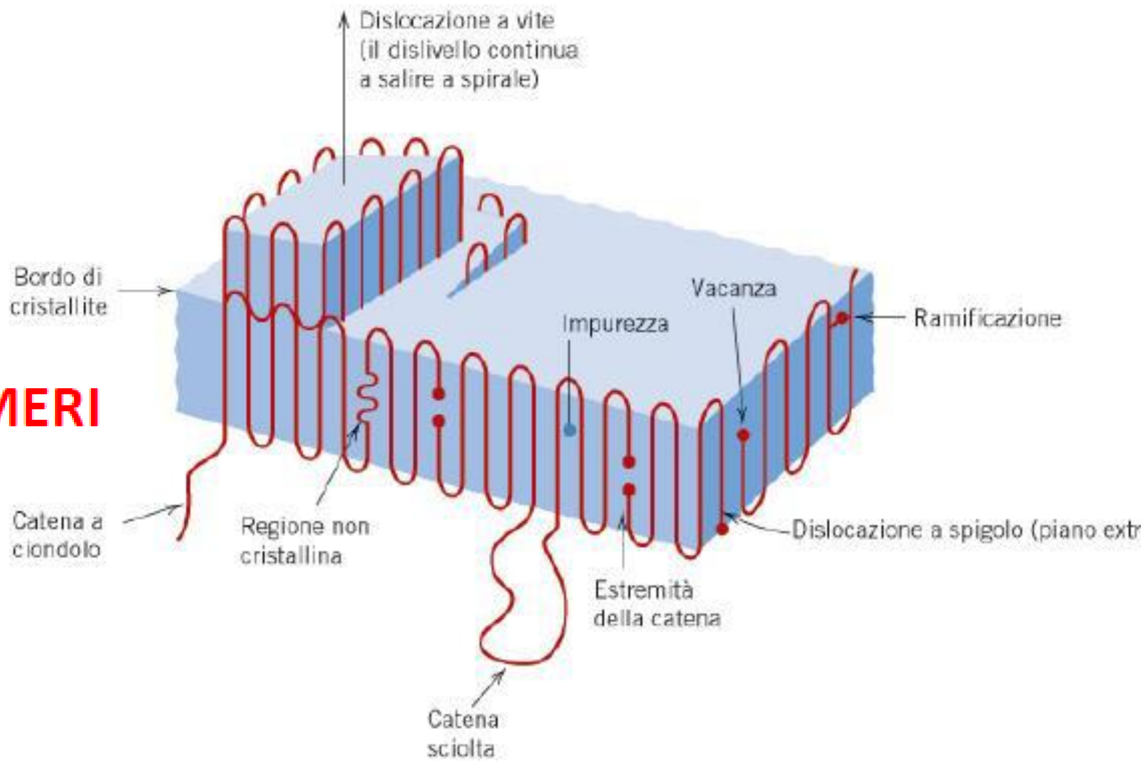
Dinamica (carichi ripetuti)

Rottura avviene ad un carico minore se ripetuto (**accumula danno**)

Si sovrappone ad altri fenomeni

<u>Non previsto dalle normative</u>

DIFETTI NEI POLIMERI



ROTTURA - RESISTENZA

Ageing/Danneggiamento

Condizione di 'lavoro' continua nel tempo per mesi, combinazione di fattori diversi:

- Carichi
- Sostanze chimiche
- temperatura
- Biologici

This micro-fissure phenomenon, known as environmental stress cracking
biodegradazione

Osservazioni in-vivo
Difficili da replicare in laboratorio
Prove di trazione dopo aver tenuto campioni in condizioni di prova
Non ci sono indicazioni in normativa

CONCLUSIONI

PICC tubini di platica non tanto banali!

Rigidezza dei PICC dipende da materiale (temperature, etc) + geometria

Caratteristiche meccaniche/geometria risultato di compromesso/ottimizzazione

Normative evidenziano alcuni limiti, ripensare prove

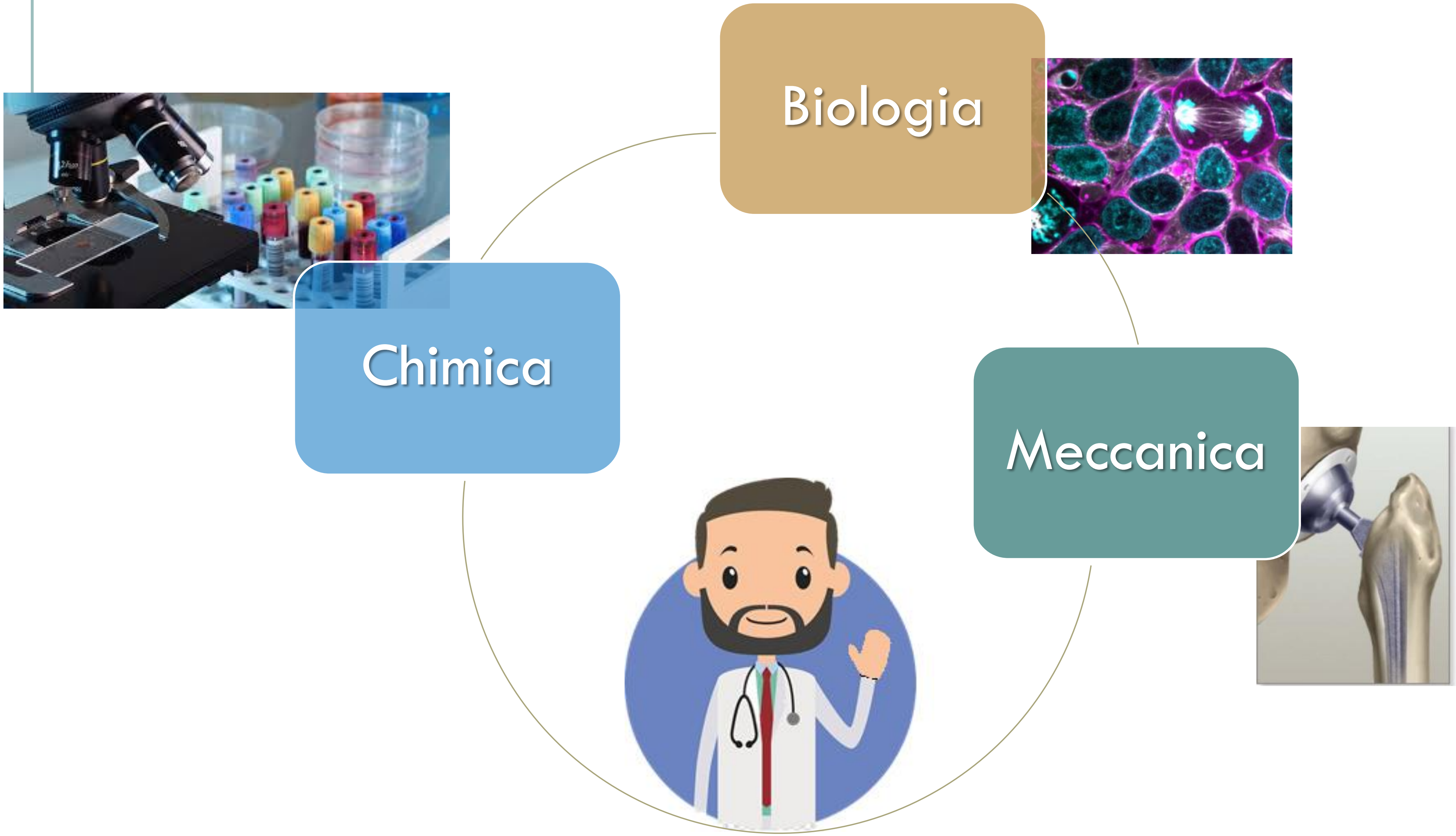
Rottura poco documentata, maggiori informazioni per migliorare prestazioni

2019

Peripherally inserted central catheter design and material for reducing catheter failure and complications (Protocol)

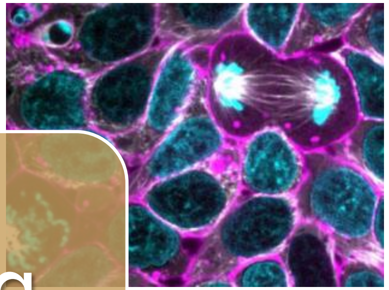
Citation: Schults JA, Kleidon T, Petsky HL, Stone R, Schoutrop J, Ullman AJ. Peripherally inserted central catheter design and material for reducing catheter failure and complications. *Cochrane Database of Systematic Reviews* 2019, Issue 7. Art. No.: CD013366. DOI: 10.1002/14651858.CD013366.

SINERGIE!



ASPETTI DI MECCANICA DEI PICC

BIOINGEGNERIA @ DICI



Biologia

Prof. M.G. Cascone

Chimica

Prof. L. Lazzeri

Prof. L. Gallone

Meccanica

Prof. F. Di Puccio

Ing. L. Mattei