

Effect on PICC Lines of 1 , 3 Months of Immersion at 37°C in Ringer's and Ethanol Solution

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Introduction

Collaborative research activity on PICC characterization by Pain Therapy Unit & Dept. Civil and Industrial Engineering, Pisa

Aim

Comparison of 5 Fr PICCs from the main manufacturers based on geometrical, mechanical and chemical properties for defining catheter performance criteria

Alphamed Bard Cook Argon Vycon Braun AngioDynamics Healtline

2013 AVA Conference
Preliminary results on 4 major vendors' products

2014 AVA Conference
Results on 8 PICCs & new tests after 30 days of immersion in Ringer Lactate and Ethanol solution

MATERIALS & METHODS

SAMPLES & ACTIVITY PLAN

Samples: 5 Fr 1-lumen polyurethane PICC from 8 major vendors

Activity plan

PART 1

PICC general features
Geometrical and mechanical properties of the PICC as new (dry, room temperature)

SAMPLES & ACTIVITY PLAN ★

Samples: 5 Fr 1-lumen polyurethane PICC from 8 major vendors

Activity plan

PART 1

PICC general features
Geometrical and mechanical properties of the PICC as new (dry, room temperature)

PART 2

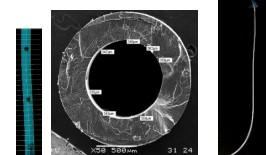


in vivo like response
Samples were immersed in **Ringers Lactate** and **ethanol solutions @ 37°C** for **up to 3 months** before mechanical tests

ACTIVITY PLAN: PART 1

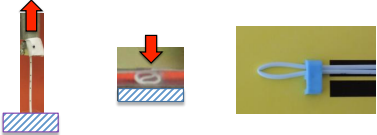
General features:
Packaging
Real geometry

▪ kit composition and packaging
▪ geometrical characteristics:
○ outer diameter, thickness, length
○ PICC initial shape/twistedness



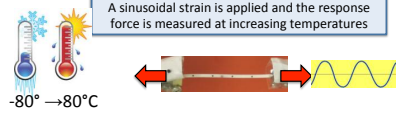
ACTIVITY PLAN: PART 1

General features: Packaging Real geometry	- kit composition and packaging - geometrical characteristics: - outer diameter, thickness, length - PICC initial shape/twistedness
Mechanical props @ room temp	- Tensile and compression tests - kinking tests



ACTIVITY PLAN: PART 1

General features: Packaging Real geometry	- kit composition and packaging - geometrical characteristics: - outer diameter, thickness, length - PICC initial shape/twistedness
Mechanical props @ room temp	- Tensile and compression tests - kinking tests
Mechano-Chemical props	Dynamic mechanical thermal analysis (DMTA) A sinusoidal strain is applied and the response force is measured at increasing temperatures



ACTIVITY PLAN: PART 2



IMMERSION

Samples were immersed up to 6 months @ 37° in

- Ringer Lactate (RL) solution
- Ethanol (E) solution (10%) to simulate the effect of oncologic drugs

Procedure:

- each PICC was divided in several segments and weighted/measured.
- Samples were kept in fluids @ 37° (by an egg cup) for 30 90 and 180 days

ACTIVITY PLAN: PART 2



IMMERSION

Samples were immersed @ 37 in RL and E solutions for 30 and 90 days

Swelling

Weight variation pre-post immersion (precision scale sensitivity: 0.1 mg)

ACTIVITY PLAN: PART 2



IMMERSION

Samples were immersed @ 37 in RL and E solutions for 30 90 and 180 days

Swelling

Weight variation pre-post immersion

Mechanical props @ 37°C

- Tensile tests at two strain rates (0.1 and 1 min⁻¹) @ 37° on wet specimens
- Relaxation (force vs. time) for holding the sample stretched at 30%

Mechano-Chemical props

DMTA (-80°C → 80°C) on dried samples

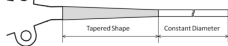
PART 1 RESULTS

PICC AS NEW

Part 1: General features

Geometry				
Sample	Outer diameter (mm)	Inner diameter (mm)	Thickness (mm)	Length (nominal) (cm)
G1	2.02-1.64*	0.89	0.37	61 (60)
G2	1.66	0.98	0.34	55.3 (55)
G3	1.73	1.28	0.22	60 (60)
G4	1.74	1.18	0.28	60.2 (60)
G5	2.27-1.74*	1.22	0.26	65.1 (65)
G6	2.23-1.76*	1.03	0.36	61.5 (60)
G7	2.08-1.63*	0.87	0.38	56.7 (55)
G8	2.3-1.7*	1.25	0.22	60.0 (60)

* Tapered



Part 1: Packaging

Catheter & guidewire packaging affects the PICC initial shape

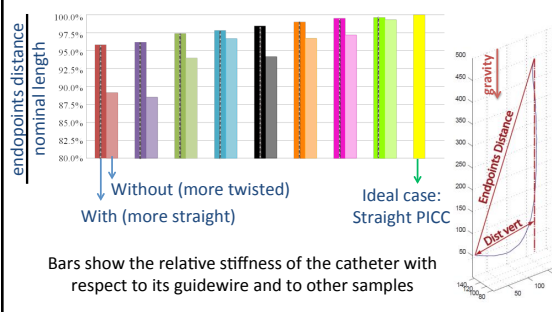
P1	• free	circular shape	gw in
P2	• free	U-shape	gw in
P3	• rigid shell	spiral shape	gw apart*
P4	• compliant shell	U-shape	gw in
P5	• ad-hoc package	U-shape	gw-in
P6	• rigid shell	spiral shape	gw in
P7	• free	circular shape	gw apart
P8	• free	circular shape	gw in

*guidewire packaged in a rigid shell



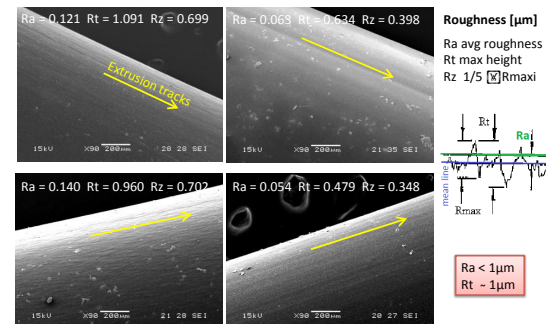
Part 1: initial twistedness

Initial shape of the PICC with/without guidewire



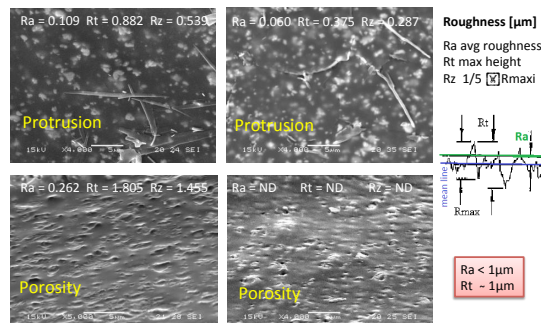
Part 1: surface micro-features

External surface: SEM analysis and roughness



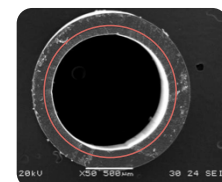
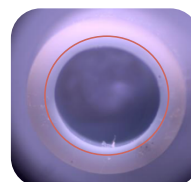
Part 1: surface micro-features

Inner surface: SEM analysis and roughness

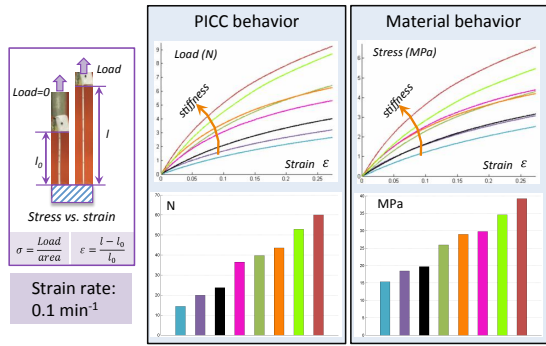


Part 1: special cases

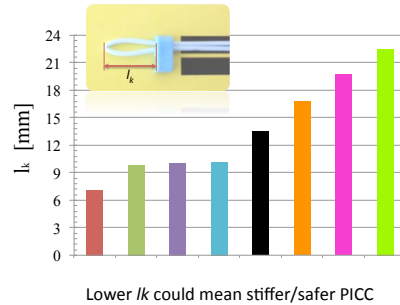
Microscopy images showed the presence of a double layer in one sample



Part 1: Tensile tests

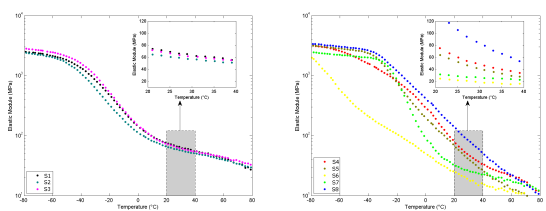


Part 1: Kinking tests



Part 1: DMTA tests

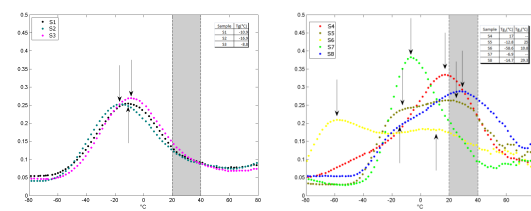
Elastic modulus (stiffness) vs. temperature



3 samples are made of similar material

Part 1: DMTA tests

Damping ratio vs. temperature



Arrows roughly indicate the positions of the glass transition temperatures

Chemical and Mechanical characterization of PICCs: preliminary results

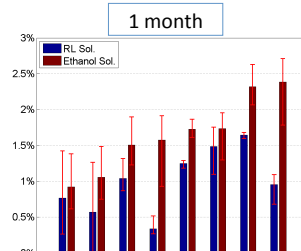
PART 2 RESULTS IN VIVO LIKE BEHAVIOUR

Part 2: Swelling



% weight variations after 1 2 3 6 months in Ringer Lactate /Ethanol solution @ 37° (Mean value of 4 samples extracted from each catheter)

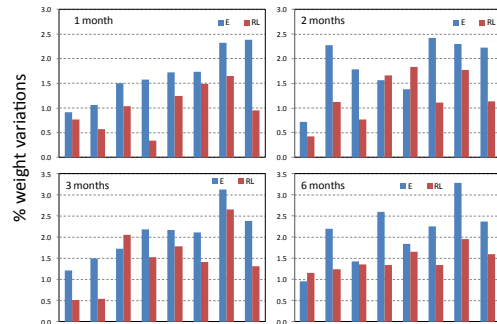
- Variations < 2.5%
- Variations RL < Ethanol
- After 24h back to the pre-immersion weight



Part 2: Swelling



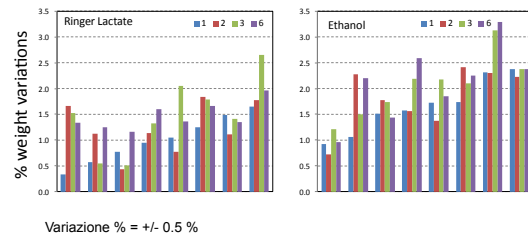
Effect of the fluid at different duration



Part 2: Swelling



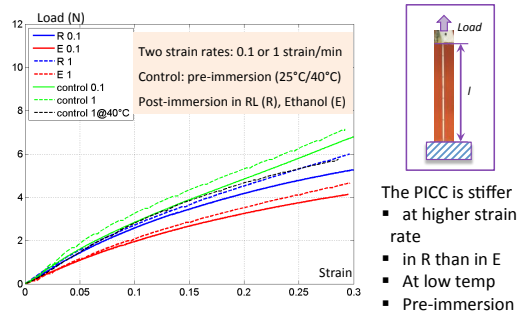
Effect of the duration for each fluid



Variazione % = +/- 0.5 %

Part 2: Tensile tests

Example of comparison of load-strain curves

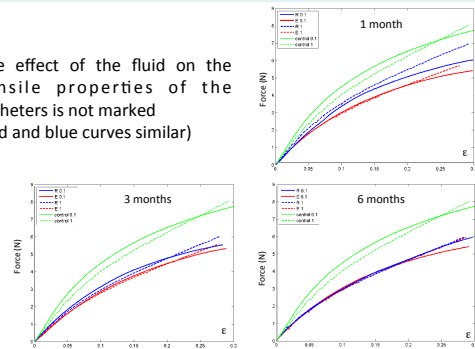


- The PICC is stiffer
- at higher strain rate
- in R than in E
- At low temp
- Pre-immersion

Part 2: Tensile tests



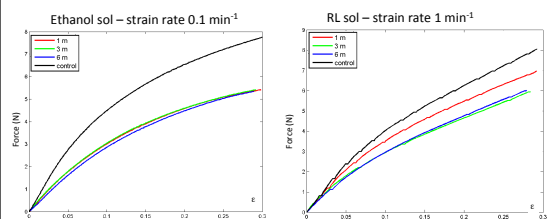
The effect of the fluid on the tensile properties of the catheters is not marked (red and blue curves similar)



Part 2: Tensile tests



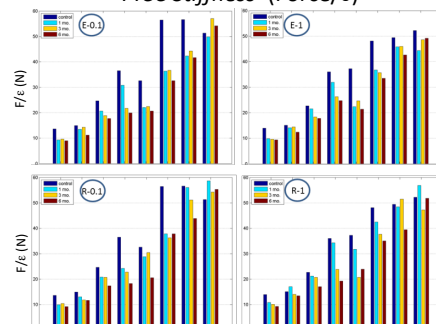
Also the effect of the duration on the tensile properties of the catheters is not marked



Part 2: Tensile tests



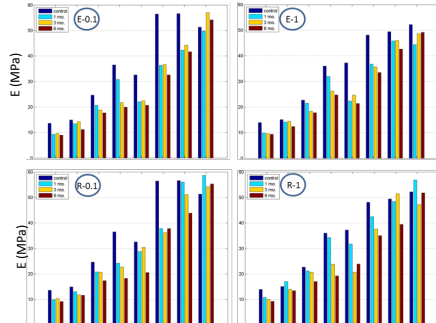
PICC Stiffness (Force/ε)



Part 2: Tensile tests

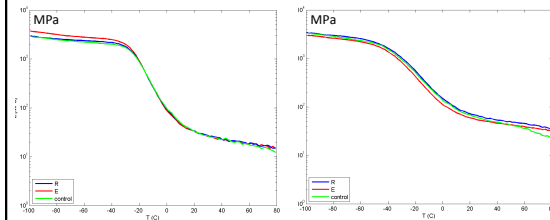


Material Stiffness (elastic modulus $E = \sigma/\epsilon$)



Part 2: DMTA tests

Elastic modulus (stiffness) vs. temperature



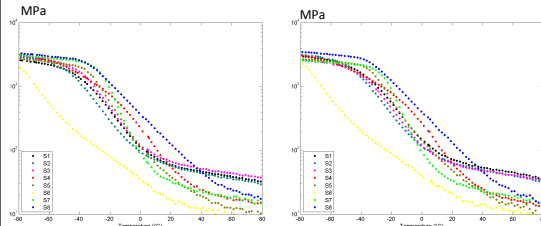
Example of comparison of pre-post immersion curves
→ Small differences (log scale)

Part 2: DMTA tests

Elastic modulus (stiffness) vs. temperature

Ethanol solution

RL solution

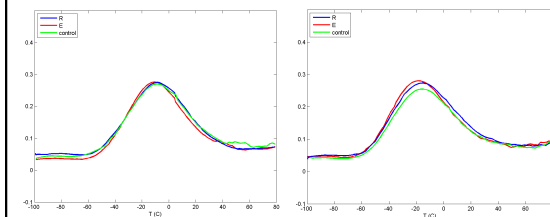


Comparison of the 8 samples

Part 2: DMTA tests

Damping ratio vs. temperature

Risposta e smorzamento della sollecitazione



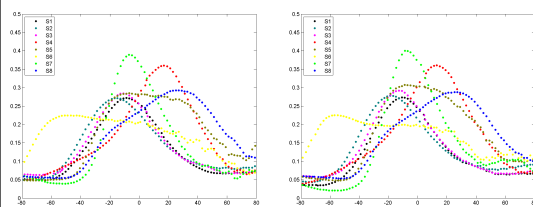
Example of comparison of pre-post immersion curves

Part 2: DMTA tests

Damping ratio vs. temperature

Ethanol sol

RL sol



Comparison of the 8 samples

CONCLUSIONS

Conclusions

Some main results of this comparison among 8 PICCs in their as new or in-vivo like conditions can be summarized:

PART 1 As new

- 1) Packaging influences the initial twistedness of catheter
- 3) Some PICCs are tapered in the first 10 cm and have an outer diameter about 2-2.3 mm (5 Fr $\approx$ 1.7 mm)
- 4) Catheter inner diameter goes from 0.87 up to 1.28 mm
- 5) The mechanical response (@25°C) spans a wide range:
 - PICC stiffness: 12-50 N/strain
 - Material stiffness: 14-78 MPa
- 6) Mechanical properties vary markedly with temperature, particularly in the range 20°-40°C.

Conclusions

PART 2 In-vivo like condition

- 1) Weight variations were <2.5% after 30 days @37°C in RL/Ethanol solutions
- 2) Weight variations in Ethanol > Weight variations in RL
- 3) Pre-immersion weight was recovered in 24 h
- 4) Relaxation behavior after rapid stretching appears to correlate well with weight variations
- 5) The post-immersion mechanical response varied lightly
- 6) **Its likely that no chemical reactions happened between catheter and fluids -> Apparently, Ethanol does not damage polyurethane**