



PICC vecchi e nuovi, come scegliere

Mauro Pittiruti

PICC vecchi e nuovi

Silicone baritato

Silicone trasparente (solo il Groshong PICC)

Poliuretano

Poliuretano impregnato con ioni argento

Poliuretani 'coated' con antisettici/antibiotici

Poliuretano trattato con Endexo

Poliuretano power-injectable

Quale materiale per i PICC?

- Il **Silicone** è spesso definito come il più biocompatibile, anche se i **poliuretani** di terza generazione (comparsi negli anni 90) hanno dimostrato caratteristiche simili al silicone in termini di durata e di incidenza di infezioni e trombosi.
- Dal 2005 in poi, sono in uso anche **poliuretani power-injectable** ultraresistenti, in grado di resistere alle alte pressioni sviluppate dai 'power injectors' radiologici. I PICC in poliuretano 'power injectable' hanno il vantaggio di consentire flussi più elevati.

I nuovi poliuretani

Brand	Composizione Chimica
Tecoflex	Polietere Alifatico
Tecothane	Polietere Aromatico
Carbothane	Policarbonato Alifatico
Chronoflex	Policarbonato Alifatico
Pellethane	Polietere Aromatico

Power injectability

Risulta da due caratteristiche:

- 1) Poliuretano particolarmente resistente (di nuova generazione)
- 2) Connessioni particolarmente resistenti

Quale materiale per i PICC?

Pochi sono gli studi che hanno paragonato i diversi materiali:

- Silicone – SIL
- Poliuretano – PUR
- Poliuretano power injectable – P-PUR
- Polietilene – PE
- Polivinilcloruro – PVC
- Politetrafluoroetilene - TEFLON

Rischio di infezione

Non ci sono evidenze che la scelta tra SIL vs. PUR vs. P-PUR possa influire sul rischio di infezione.

Il rischio di infezione è ovviamente correlato ad altri fattori:

- educazione dello staff
- appropriata indicazione del VAD
- protocollo di inserzione
- protocollo di gestione
- etc.

Rischio di trombosi

Non ci sono evidenze di alcuna differenza tra SIL vs. PUR vs. P-PUR in termini di trombosi.

Il rischio di trombosi venosa da PICC è ovviamente correlato ad altri fattori:

- puntura ecoguidata vs. 'blind'
- rapporto tra diametro della vena e calibro del catetere
- corretta posizione della punta
- uso di sistemi sutureless
- etc.

Rischio di rottura - conclusioni

Le evidenze dimostrano che il SIL è più soggetto a complicanze meccaniche (rotture, dislocazioni) rispetto al PUR

E' anche plausibile che il P-PUR possa dimostrarsi ancora più vantaggioso a tale riguardo

A comparison of silicone and polyurethane PICC lines and postinsertion complication rates: a systematic review

Tammy Seckold, Sandra Walker, Trudy Dwyer

Central Queensland University, Queensland - Australia

JVA 2015

Results: Overall the PICCs complication rates ranged from 8 to 47.9%. While both lines saw similar overall rates upon closer observation the strengths and weaknesses of both lines are shown.

Polyurethane PICC lines were found to provide lower rates of infection, dislodgment, thrombus and rupture complications.

Mixed results were found with catheter line occlusions, overall averages showing polyurethane lines slightly higher rates than silicone. Oncology patients however saw opposite results.

Performance clinica

Il PUR è superiore al SIL in termini di flusso

I PICC in P-PUR sembrano promettere una performance clinica superiore sia al SIL che al PUR:

- alti flussi (fino a 5 ml/sec), anche a lumi multipli
- possibilità di iniezione di mdc
- misura della press.venosa centrale (*se non-valvolati*)
- resistenza ai traumi meccanici
- disostruzione più facile
- stesso costo dei PICC in PUR (*se non-valvolati*)

Rischio di occlusione

Non vi sono differenze tra SIL e PUR in termini di occlusione.

Il P-PUR potrebbe avere vantaggi (disostruzione più facile)

- Il rischio di occlusione sembra correlato ad altri fattori, quali ad esempio la adozione di un protocollo adeguato di FLUSH e LOCK del sistema.

Un ultimo punto, ancora a proposito del materiale

Viene spesso riferito che l'uso di chemioterapici in base alcolica (taxani) sarebbe una indicazione all'uso di cateteri in silicone.

COSA C'E' DI VERO ?

Prima considerazione

Se è vero che teoricamente i poliuretani sono più sensibili del silicone all'effetto dell'alcool, effettivi danni ai cateteri non sono mai stati dimostrati, nè *in vivo* nè in studi ben condotti *in vitro*.

THE EFFECTS OF PROLONGED ETHANOL EXPOSURE ON THE MECHANICAL PROPERTIES OF POLYURETHANE AND SILICONE CATHETERS USED FOR INTRAVASCULAR ACCESS

Christopher J. Crnich; Jeremy A. Halfmann; Wendy C. Crone; Dennis G. Maki

ABSTRACT

BACKGROUND: Products containing alcohol are commonly used with intravascular devices at insertion, to remove lipids from occluded intravascular devices used during parenteral nutrition, and increasingly for the prevention and treatment of intravascular device-related bloodstream infection. The effects of alcohol on the integrity of intravascular devices remain unknown.

METHODS: Two types of widely used commercial peripherally inserted central catheters, one made of polyetherurethane and one made of silicone, were exposed to a 70% ethanol lock solution for up to 10 weeks. Mechanical testing was performed to identify force-at-break, stress, strain, modulus of elasticity, modulus of toughness, and wall area of ethanol-exposed and control catheters.

RESULTS: No significant differences between exposed and unexposed catheters were identified for any of the mechanical parameters tested except for a marginal reduction in the modulus of elasticity for both polyetherurethane and silicone catheters and minor increases in the wall area of polyetherurethane catheters.

CONCLUSIONS: These data indicate that exposure to a 70% ethanol lock solution does not appreciably alter the integrity of selected commercial polyetherurethane and silicone catheters. Given the greatly expanded use of alcoholic solutions with intravascular devices of all types, we believe that manufacturers would be well advised to subject their catheters and other intravascular devices to formal testing of the type employed in this study (*Infect Control Hosp Epidemiol* 2005;26:000-000).

This was the first study to systematically evaluate the effect of ethanol on the integrity of two types of vascular catheters commonly used in clinical practice. The findings suggest that a 70% ethanol lock solution has a negligible impact on the mechanical properties of polyetherurethane and silicone catheters, despite continuous exposure times as long as 10 weeks. These findings should allay fears about the use of alcohol-containing antiseptic solutions with vascular catheters made of silicone and aromatic polyetherurethanes and should prompt further study of ethanol as an anti-infective lock solution for the prevention⁸ and treatment⁷ of intravascular device-related BSI in clinical practice.

Seconda considerazione

I poliuretani di terza generazione (es. Carbothane), ovvero quelli utilizzati per i PICC power injectable, sono resistenti all'alcool.

LONG TERM POLYURETHANE CATHETER ALCOHOL COMPATIBILITY I, PHYSICAL AND RHEOLOGICAL STUDIES

Lecon Woo¹, John Wesley MD², Maryellen Zibell², Christopher Gardner² and William Anderson²

¹LWoo Associates LLC, Libertyville IL 60048

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Abstract

Thermoplastic urethanes (TPU) offer broad property range, processing flexibility, and biocompatibility for medical applications. Alcohol based disinfectants have a long history of effective and safe use. Expanding on earlier rheology molecular weight data indicating minimal reduction, we conducted a long term compatibility study covering all known urethane types in a hemo-dialysis setting with a simulated clinical exposure protocol for 90 days. After 90 days exposure, minor changes in physical properties on the catheter body and components were detected, often similar to the saline control. Most importantly, resultant properties far exceeded ISO requirements for catheters.

Introduction

TPU catheters are prominent in device applications and increasingly, they are subjected to longer duration use, and exposed to a wide variety of chemically active agents. Alcohol based disinfectants are the most widely used for its long history of safety and effectiveness. To understand the compatibility of polyurethane devices and alcohol exposure, we conducted both fundamental material response and device performance studies. For example, it was pointed out in our earlier studies (1,2), that due to TPU's complex annealing behavior, vastly different properties can result from thermal history and could at least in part account

components and connections exposed to the alcoholic disinfectant were studied.

Experimental

Continuing our previous studies where more detailed procedures are fully described, we evaluated hydrolytic molecular weight degradation upon exposure to alcoholic disinfectants with melt rheology with the well established relationship for linear polymers (4-5),

$$\eta = K Mw^{3.4} \quad (1)$$

Where η is the steady shear limiting viscosity

Mw is the weight average molecular weight

Five TPU based hemo-dialysis long term indwelling catheters chosen to cover all known commercial polyurethane types were studied. They included (A) Tecoflex®, (B) Tecothane®, (C) Carbothane®, (D) Pellethane®, and (E) Chronoflex® (6-10). Sample A uses an aliphatic polyurethane with ether soft segments. Samples B and E are ether soft segment aromatic polyurethanes, Sample C contains a polycarbonate soft segment and Sample E's soft segment is also polycarbonate based but differs from C. These catheters range in size from 10 Fr to 14.5 Fr and from 24 to 55 cm in length. Figure 1 describes a typical catheter and all exposed areas and testing locations indicated.

Abstract

Thermoplastic urethanes (TPU) offer broad property range, processing flexibility, and biocompatibility for medical applications. Alcohol based disinfectants have a long history of effective and safe use. Expanding on earlier rheology molecular weight data indicating minimal reduction, we conducted a long term compatibility study covering all known urethane types in a hemo-dialysis setting with a simulated clinical exposure protocol for 90 days. After 90 days exposure, minor changes in physical properties on the catheter body and components were detected, often similar to the saline control. Most importantly, resultant properties far exceeded ISO requirements for catheters.

PICC Day Genova 2014



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**

A comparative study on the mechanical behavior of polyurethane PICCs

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ABSTRACT

Purpose: This study describes a comparative analysis of eight commercial polyurethane, single-lumen peripherally inserted central venous catheters (PICCs) from different vendors. The aim was to investigate the mechanical response of the catheters providing objective and quantitative data to support a comparison among them. Such data could help nurses and physicians to select a central venous catheter (CVC) not only on the basis of the expected dwell duration or of the assessment of the vessels at the desired insertion site but also of the chemical and mechanical properties of the CVC and of the projected response of the body to these properties.

Methods: An experimental procedure was defined and tests were performed to assess some main characteristics of the PICC lines, including macro and microgeometric features, chemical and physical properties, and mechanical response. Preliminary measurements were performed to accurately define all geometric characteristics, including length, inner and outer diameters, and any inherent initial curvature of the catheter. Micro-geometric features were investigated using surface roughness analysis, optical microscopy, and scanning electron microscopy. Mechanical properties were studied by means of dynamic mechanical thermal analysis, simple uniaxial tensile tests, and kinking tests.

Results: Results are discussed in order to compare the different PICC lines. In particular, they show that polyurethane catheters can have a different mechanical behavior, which might play a role in the onset of pathologic processes and result in an increased risk and incidence of catheter-related complications.

Conclusions: This study provides useful information that can help identifying and facilitate the choice of a PICC.

Keywords: Comparative study, Mechanical properties, PICCs

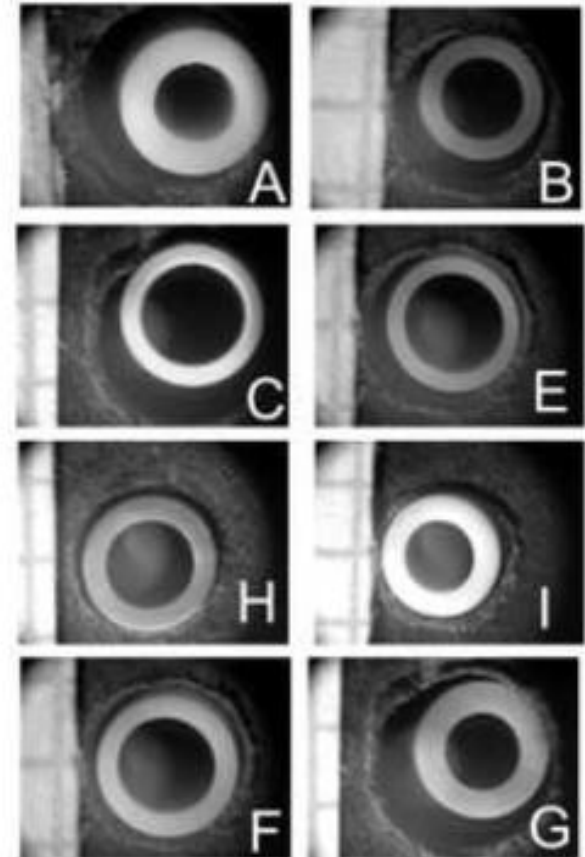
JOURNAL OF VASCULAR ACCESS

Experimental investigation on the mechanical behaviour of polyurethane PICCs after long term conservation in in vivo like conditions

--Manuscript Draft--

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ID	Manufacturer	Model
A	Alfamed	MD 01 02282
B	Bard	6175118 Power picc
C	Cook	G12987 TurboFlo
E	Argon	384465 L-Cath
F	Vygon	1294.115 Lifecath PICC
G	BBraun	044 39002 Celsite PICC-Cel
H	AngioDynamics	12102603
I	HealthLine	A14H-05160



Eight 5 Fr single lumen catheters from as much different vendors were considered as samples. Several specimens were cut from each of them and kept in bath at 37°C for 1, 2, 3 and 6 months. Two fluids were used to simulate in vivo like conditions, i.e. ethanol and Ringer-Lactate solutions, the first one being chosen in order to reproduce a typical chemical environment of oncologic drugs. The test plan included swelling analyses, uniaxial tensile tests and Dynamical Mechanical Thermal Analysis.

Results and Conclusions

Results show that all tested samples are chemically and mechanically stable in the studied conditions, in fact no significant weight variation was observed in all samples even after six months of immersion in Ethanol solution. Uniaxial tensile tests confirm such response. Curves obtained for each sample after different immersion durations in the two fluid solutions are very similar each other, particularly for strains lower than 10%.

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Infatti...

Circa l'85% dei PICC attualmente venduti in USA (circa 3 milioni/anno) sono PICC power injectable*, in poliuretano di terza generazione, e vengono usati comunemente per la infusione di chemioterapici in base alcolica.

(idem per i PORT power injectable con catetere in poliuretano)

*Fonte: Bard Corp., USA



FEATURES

A Polyurethane PICC Designed Specifically for the Interventional Radiologist.

Poly RadPICC[®] catheters combine the strength and versatility of polyurethane with high flow rates and small French sizes. A kink-resistant hub enhances catheter strength and increases patient comfort. Poly RadPICC[®] catheters also feature excellent radiopacity.

Polyurethane body

Provides strength, versatility and high flow rates in a small French size catheter

Highly radiopaque catheter

Blend of barium and polyurethane provides high radiopacity while maintaining catheter strength

Reverse taper hub

Gently plugs the insertion site and provides excellent kink resistance

Longer extension legs

Promote easy application of occlusive dressing

High durometer extension legs

Offer improved durability and greater resistance to alcohol





products PRO-PICC® CT INJECTABLE CATHETERS

PICCS

Pro-PICC®

Vascu-PICC®

Max Barrier Kits

Midline

Navigator®

BioNavigation™
System

Pediatric
Vascu-PICC®

features & benefits

- Catheters are approved for both CECT Injections and Infusion Therapy.
- Design allows for CT injections for diagnostic imaging at up to 5cc/sec at 300psi.
- Thermosensitive, polyurethane material is both alcohol and iodine compatible.
- Available in single, dual, and triple lumen configurations.
- MRI compatible.

Features & Benefits

Ordering Info

Brochures

Product Video

IFUs

Reduced Taper

Our 3F Pro-PICC® CT combines the smallest proximal diameter and shortest taper length without compromising power injection rates.



Alcohol & iodine compatible
See our [Site Care page](#) for more
information on agent compatibility.



Terza considerazione

Il rischio (REALE) di rottura da sollecitazioni meccaniche, legato alla fragilità del silicone, è assai più rilevante del rischio (TEORICO) di lesioni da danno chimico.

La nostra esperienza

Nel 2012, sei episodi di rottura di Groshong PICC

tutte rotture del tratto intravascolare

tutti i cateteri erano usati con pompa

tutti e 6 i PICC erano usati con taxoli

Nessun episodio di rottura con PICC in PUR

Il DH Oncologico decide di sospendere l'uso di PICC Groshong per chemioterapia

Quindi

Non vi è nessuna evidenza che i PICC in silicone abbiano alcun vantaggio o alcuna indicazione preferenziale rispetto ai PICC in poliuretano.

Vi sono altresì evidenze che l'utilizzo di PICC in silicone limita la performance del presidio e aumenta il rischio di complicanze meccaniche.

PICC in poliuretano trattato

1) PUR impregnati con ioni argento

Inefficace

Aumenta la rigidità/ scarsa leggibilità dei numeri

Anche il trattamento dei CICC con ioni argento si è rivelato inefficace come prevenzione delle infezioni

*(il trattamento con ioni argento è invece
provatamente efficace per i cateteri venosi ombelicali)*

PICC in poliuretano trattato

2) PUR rivestito con antisettici (CHG)

Da poco in commercio in Europa

Presunta efficace anti-infettiva

Ipotizzata una efficacia antitrombotica (in realtà: estrapolata da dati sperimentali – dubbi – che suggerivano una minore formazione di guaina fibroblastica)

Esistono soltanto 3 studi clinici:

- 2 positivi (ma statisticamente fasulli)
- 1 negativo (statisticamente ineccepibile)

PICC in poliuretano trattato

3) PUR rivestito con antibiotici (minociclina+rifampicina)

Non ancora in commercio in Italia

Costo elevato

Possibile efficacia anti-infettiva, suggerita da una mezza dozzina di studi clinici di diverso valore statistico (vedi meta-analisi recente di Chopra)

Dubbi quindi sulla costo-efficacia

PICC in poliuretano trattato

4) PUR impregnato con antitrombotici (Endexo)

Già in commercio in Europa

Costo assai elevato

Possibile efficacia antitrombotica

Non vi sono studi clinici convincenti: esistono solo sei abstracts, di diversa qualità statistica.

Lo studio migliore suggerisce un effetto statisticamente significativo, ma clinicamente insignificante (riduzione delle trombosi sintomatiche dal 3% al 2%)

Quindi: dubbi sulla costo-efficacia

II PICC

Altre caratteristiche speciali

- Possibilità di trimming prossimale
- Reverse tapering
- Punta assottigliata
- Valvola in punta (Groshong PICC)
- Valvola prossimale

Trimming prossimale

Possibile per due tipologie di PICC:

- PICC valvolati distali (Groshong)
- Easy-PICC

PICC Groshong

- Inutilità della valvola (vedi oltre)
- Maggior rischio di malfunzione (spec.: PWO)
- Silicone = maggiore fragilità = più alta incidenza di rotture e dislocazioni
- Difficoltà nella sostituzione su guida
- Difficoltà nella esecuzione dell'ECG intracavitario
- Costo elevato
- Da evitare

Easy-PICC

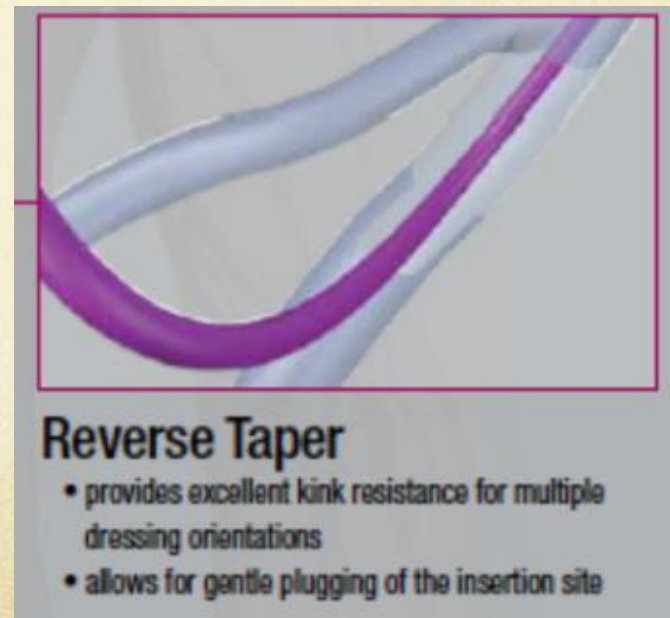
- Ideali per la tecnica dell'ECG intracavitario
- Possibilità di tunnellizzazione retrograda
- Ora disponibili anche power injectable
- Mancano ancora studi che ne dimostrino i vantaggi clinici

Reverse Tapering

Variabile per entità (diametro)

Variabile per lunghezza

Adottato da alcune ditte, e non per tutti i prodotti



Reverse tapering

Inventato da/per i radiologi interventisti, per aumentare la maneggevolezza di cateteri troppo sottili

Vantaggi

- Migliore emostasi del sito di emergenza (?)
- Minor rischio di dislocazione (?)
- Minor rischio di traumi meccanici del tratto esterno (?)
- Maggiore maneggevolezza del tratto esterno

Reverse tapering

Svantaggi

- Maggior rischio di trombosi venosa nel punto di inserzione (?)
- Difficoltà nella esecuzione della manovra dell'ECG intracavitario
- Difficoltà nella tunnellizzazione del PICC

Radiology. 2010 Jul;256(1):312-20. doi: 10.1148/radiol.10091860.

Triple-lumen peripherally inserted central catheter in patients in the critical care unit: prospective evaluation.

Trerotola SO¹, Stavropoulos SW, Mondschein JI, Patel AA, Fishman N, Fuchs B, Kolansky DM, Kasner S, Pryor J, Chittams J.

Author information

Abstract

PURPOSE: To prospectively evaluate outcomes associated with use of a triple-lumen (TL) peripherally inserted central catheter (PICC) in the intensive care unit (ICU) setting.

MATERIALS AND METHODS: Patients were prospectively enrolled in this HIPAA-compliant, institutional review board-approved study. Informed consent was obtained. All patients were in one hospital's ICUs and needed intermediate-term central venous access requiring three lumina. A 6-F tapered TL PICC was placed by a bedside nursing-based team with backup from the Interventional Radiology department. Placement complications, as well as long-term complications, were recorded. At catheter removal, ultrasonography (US) of the veins containing the TL PICC was performed to detect occult venous thrombosis. Regardless of indication for removal, catheters were sent for culture to detect colonization.

RESULTS: The study was stopped prematurely after 50 of a planned 167 patients were enrolled when a scheduled interim analysis detected a venous thrombosis rate that was considered unacceptably high by the study oversight committee (thrombosis was symptomatic in 20% of patients [10 of 50]). Venous thrombosis (symptomatic or asymptomatic) was detected in 26 of 45 patients (58%; 95% confidence interval [CI]: 43%, 72%) examined with US. Documented catheter-related bloodstream infection did not occur (0%; 95% CI: 0%, 7%); colonization was detected in three of 29 catheter tips sent for culture (10%; 95% CI: 2%, 27%). Catheter malfunction and dislodgment occurred in one patient each.

CONCLUSION: The TL PICC design used in this study resulted in unacceptably high venous thrombosis rates. Even when used in a high-risk setting for infection (ie, the ICU), rates of clinically evident infection and colonization were absent and low, respectively.

Comment is

J Vasc Interv Radiol. 2014 Jan;25(1):85-91.e1. doi: 10.1016/j.jvir.2013.10.009. Epub 2013 Nov 21.

Peripherally inserted central catheter thrombosis--reverse tapered versus nontapered catheters: a randomized controlled study.

Itkin M¹, Mondschein JI², Stavropoulos SW², Shlansky-Goldberg RD², Soulen MC², Trerotola SO².

⊕ Author information

Abstract

PURPOSE: To compare the thrombosis rate, ease of insertion, bleeding rate, and complications of a nontapered peripherally inserted central catheter (PICC) versus a reverse tapered PICC.

METHODS: This was a prospective randomized, controlled trial conducted in single center. All patients 18-90 years old requiring PICC insertion were considered for the study. All patients were followed until PICC removal. Ultrasound examination of the arm was performed at PICC removal or at 28 days. There were 332 patients randomly assigned--164 to the nontapered PICC group and 168 to the reverse tapered PICC group.

RESULTS: The overall thrombosis rate was 71.9%. The thrombosis rate was 70.4% in the nontapered PICC group and 73.4% in the reverse tapered PICC group ($P = .58$). The symptomatic thrombosis rate was 4.3% in the nontapered PICC group and 3.6% in the reverse tapered PICC group ($P = .75$). The complete thrombosis rate was 15.6% in the nontapered PICC group compared with 20.8% in the reverse tapered PICC group ($P = .44$). There was a statistically significantly higher thrombosis rate in patients with cancer (71.9% vs 66.7%, $P = .002$).

CONCLUSIONS: This study showed a high incidence of thrombosis of peripheral veins used for PICC insertion. The implication of this thrombosis is significant in light of the morbidity and potential mortality associated with this condition. A difference in thrombosis rate between devices could not be detected in this study.

Published by SIR on behalf of The Society of Interventional Radiology.

Submitted by on Thu Mar 8 21:47:14 2007

Could someone please elaborate for the the advantage of a reverse tapered PICC with consideration to "plugging the sub-q tract?" By plugging this tract, is the main purpose to minimize bleeding? Would a pressure dressing not suffice, if this is the intended reasoning? Anyway, what if it does bleed? Also why is the taper in the Bard PICC's begin at 7 cm? The Boston Scientific PICC's also have a reverse taper, but it begins at 3 cm, not 7 cm. I know from my experience of 11 years of PICC placement that I have NEVER accessed a vein 7 cm deep. Most commonly it is between 2cm and 3cm. I am trying to convince myself that reverse taper is a good thing and I know that there are Bard educators who can help me understand this! Many thanks in advance for you explanations.

The reverse taper has nothing to do with power injection at all

The reverse taper is not new. It was established by Cook Medical at least 7-10 years ago if not longer. The Cook PICC line was silicone based and predominately placed in radiology by an MD. This dual lumen catheter was 6 french and the single lumen was 5 french. The biggest nursing facility placing this PICC line was MD Anderson and they placed the 5 French single lumen PICC line and 6 French dual lumen PICC line in oncology patients (about 2,000 - 3,000 a year back then) with the reverse taper. Yes those were the French sizes used to delivery chemotherapy at MD Anderson in patients who were prone to thrombosis. I like other clinicians am not buying the theory that a larger French size has a higher thrombosis rate. The Grove study is not valid any longer as it does not compare apples to apples. I am in the process of evaluating this theory and all the papers published to date to write a paper. The first three including Grove are so full of major flaws and holes in design.

The reverse taper as Lynn has pointed out was invented for the usage of upper arm placement of a PICC line with portable ultrasound and modified seldinger technique by IR who were using those high-tech tools way before the RN's. As these patients would bleed post insertion, have pistoning of their catheters or kinking (especially kinking). When placing a PICC line in the upper arm kinking is a major factor as you are going deeper into the vessel versus a superficial placement and the reverse taper alleviated that issue. Tamponading of the vessel was also a plus.

The design of this product by Cook was not a marketing tool as at that time Cook had the majority of PICC business in the IR Suites. Their design was a response to the requests of the IR physicians. As RN's are now as high tech as IR's I see the reverse taper to be an advantage. Not all power injectable PICC lines have the reverse taper. Some of the PICC lines have the same original design without the taper.

There is no established study or link to claim or prove that the reverse taper contributes to an increased rate of thrombosis.

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Could someone please elaborate for the the advantage of a reverse tapered PICC with consideration to "plugging the sub-q tract?" By plugging this tract, is the main purpose to minimize bleeding? Would a pressure dressing not suffice, if this is the intended reasoning? Anyway, what if it does bleed? Also why is the taper in the Bard PICC's begin at 7 cm? The Boston Scientific PICC's also have a reverse taper, but it begins at 3 cm, not 7 cm. I know from my experience of 11 years of PICC placement that I have NEVER accessed a vein 7 cm deep. Most commonly it is between 2cm and 3cm. I am trying to convince myself that reverse taper is a good thing and I know that there are Bard educators who can help me understand this! Many thanks in advance for you explanations.

The reverse taper has nothing to do with power injection at all

The reverse taper is not new. It was established by Cook Medical at least 7-10 years ago if not longer. The Cook PICC line was silicone based and predominately placed in radiology by an MD. This dual lumen catheter was 6 french and the single lumen was 5 french. The biggest nursing facility placing this PICC line was MD Anderson and they placed the 5 French single lumen PICC line and 6 French dual lumen PICC line in oncology patients (about 2,000 - 3,000 a year back then) with the reverse taper. Yes those were the French sizes used to delivery chemotherapy at MD Anderson in patients who were prone to thrombosis. I like other clinicians am not buying the theory that a larger French size has a higher thrombosis rate. The Grove study is not valid any longer as it does not compare apples to apples. I am in the process of evaluating this theory and all the papers published to date to write a paper. The first three including Grove are so full of major flaws and holes in design.

The reverse taper as Lynn has pointed out was invented for the usage of upper arm placement of a PICC line with portable ultrasound and modified seldinger technique by IR who were using those high-tech tools way before the RN's. As these patients would bleed post insertion, have pistoning of their catheters or kinking (especially kinking). When placing a PICC line in the upper arm kinking is a major factor as you are going deeper into the vessel versus a superficial placement and the reverse taper alleviated that issue. Tamponading of the vessel was also a plus.

The design of this product by Cook was not a marketing tool as at that time Cook had the majority of PICC business in the IR Suites. Their design was a response to the requests of the IR physicians. As RN's are now as high tech as IR's I see the reverse taper to be an advantage. Not all power injectable PICC lines have the reverse taper. Some of the PICC lines have the same original design without the taper.

There is no established study or link to claim or prove that the reverse taper contributes to an increased rate of thrombosis.

Reverse tapering

CONCLUSIONI

Probabilmente, più utile che nocivo se è di lunghezza limitata ($< 2\text{cm}$)

Probabilmente, più nocivo che utile se è di lunghezza eccessiva ($> 2\text{cm}$)

Punta assottigliata

Ipotesi (mai dimostrata) che una punta più morbida e più sottile possa essere meno traumatica e meno associata a trombosi.

VANTAGGI

- ????

SVANTAGGI

- costringe a scegliere ogni volta il PICC di lunghezza presumibilmente più appropriata e/o a lasciare un tratto extracutaneo assai lungo

PICC VALVOLATI

Valvolati distali in silicone (Groshong)

Svantaggi: maggiore incidenza di complicanze meccaniche (rotture esterne e interne), maggiore incidenza di malfunzioni, non utilizzabili in radiologia, difficili da sostituire su guida

Valvolati prossimali in PUR power injectable

Rispetto ai Groshong: meno complicanze meccaniche, più facile disostruzione, utilizzabili per mdc, facilmente sostituibili su guida

N.B.: tutti i PICC valvolati (prossimali e distali) costano più dei PICC non valvolati

Groshong PICC



Valvola distale (in punta)
Catetere a punta chiusa
Silicone

PICC Navylist



Valvola prossimale
Catetere a punta aperta
Poliuretano

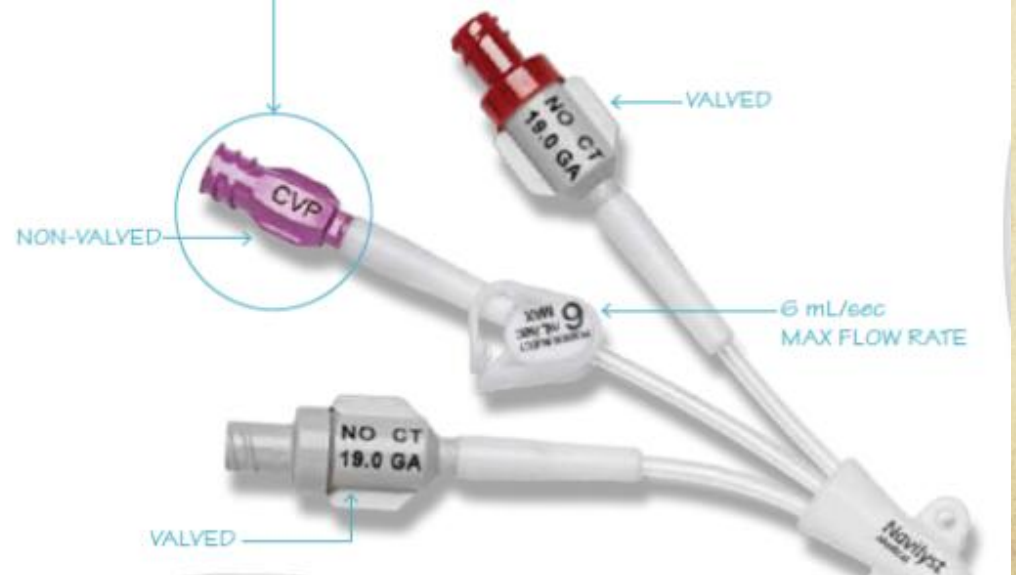
Xcela® PICC with PASV® Valve Technology



PICC Xcela Navylist

Introducing the
Xcela® Hybrid PICC.

Three lumens, **two** valves,
and **one** reliable way to monitor CVP.



Valvola prossimale
Catetere a punta aperta
Power injectable



Power PICC Solo - Bard



Valvola prossimale
Catetere a punta aperta
Power injectable

MA PERCHE' UTILIZZARE I PICC VALVOLATI ?

1. Evitare eparina?

Oggi ha poco senso: evidenze che la eparinizzazione non è utile comunque, anche nei non valvolati

- cfr. Consensus GAVeCeLT sul lock 2016
- Cfr Linee guida INS 2016

2. Prevenire le occlusioni?

La valvola previene le occlusioni ?

Quali studi sono disponibili
in letteratura?

Groshong PICC and home care: an opportunity.

Clinical experience after the first 200 implants

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ABSTRACT: Peripherally Inserted Central Catheters (PICC) represent an alternative for critical patient care, and are safer to implant in home patients.

The authors report on their experience with the first 200 4 Fr Groshong PICC implanted during the last 18 months. The procedure can be easily applied at home (98% successful implant rate), without the need for fluoroscopic or ultrasound guidance. Moreover, the authors believe that the X-ray control after implant is not strictly necessary. After 11,570 days/catheters, only 5 devices were explanted because of complications: 4 because of sepsis and peripheral phlebitis, and the last was explanted by another medical staff for unclear reasons. The complications needing no explanation were a total of 32: for 12 of them the external portion of tube was damaged during use, while for the other 20 the internal clots were resolved with forced flushing.

The authors conclude that Groshong PICC can be considered the gold standard for home care management of critical patients, taking into account the quality of pure silicon, the presence of a valve and the specially-made closed-tip.

200 Groshong PICC – 20 occlusioni

Hoffer 1999

Randomizzato, 362 pazienti

PICC valvolati prossimali vs. PICC non valvolati

- PICC valvolati = meno complicanze totali ($p < .02$)
- Non differenze significative per % infezioni
- Non differenze significative per % occlusioni

Hoffer 2001

Randomizzato, 100 pazienti

PICC valvolati prossimali (PUR) vs. PICC valvolati distali (silicone)

- I PICC in silicone = più complicanze meccaniche ($p < .01$)
- Non differenze significative per % infezioni
- Non differenze significative per % occlusioni

Burns 2005

Studio retrospettivo >12,000 PICCs

PICC valvolati prossimali in PUR (PASV) vs. PICC non valvolati di vario tipo

- PICC valvolati = meno occlusioni e meno infezioni ($p < .0001$)
- Studio statisticamente e scientificamente molto criticabile
 - 'time effect'
 - La maggior parte dei pediatrici = non valvolati
 - Rivista senza 'peer review'
 - Conflitto di interessi macroscopico ('database and statistical analyses provided by Boston Scientific')

Pittiruti 2009

Prospettico, non randomizzato, 198 pazienti

PICC valvolati distale (silicone) vs. PICC non valvolati (PUR)

- PICC in silicone = più complicanze meccaniche
- Non differenze significative per % infezioni
- Non differenze significative per % occlusioni

Di Giacomo 2009

Prospettico, non randomizzato

PICC valvolati distale (silicone) vs. PICC non valvolati (PUR) vs. PICC non valvolati (PUR power)

- Power PICC = meno complicanze meccaniche
- Power PICC = meno occlusioni

Ong 2010

Prospettico randomizzato, 326 pazienti

PICC con valvola distale (SIL) vs. PICC con valvola prossimale (PUR)

- Nessuna differenza in % occlusioni
- Nessuna differenza in complicanze meccaniche
- Maggiore incidenza di infezioni e trombosi locali nei SIL vs. PUR ($p < .001$)

Alport 2012

Randomizzato, 53 pazienti

Power PICC valvolati prossimali vs. power PICC non valvolati

- Nessuna differenza

Miyagaki 2012

Randomizzato, 26 pazienti

PICC con valvola distale (SIL) vs. non valvolati (PUR)

- Nessuna differenza in % complicanze

Johnston 2012

Randomizzato, 102 pazienti

PICC valvolati prossimali (PUR) vs. non valvolati (PUR) vs. valvolati distali (SIL)

- Nessuna differenza tra i gruppi in % occlusioni

The effect of peripherally inserted central catheter (PICC) valve technology on catheter occlusion rates - The 'ELeCTRiC' study

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³Centre for Applied Medical Statistics, University of Cambridge

ABSTRACT:

Purpose: Peripherally Inserted Central Catheters (PICCs) are increasingly being used to provide short to medium-term central venous access. The current study was designed to test the hypothesis that PICC valve technology does not influence PICC occlusion rates.

Methods: Intensive care unit (ICU) patients who required a PICC were randomized to one of three types of dual lumen PICC (open ended non-valved, Groshong valve, PASV valve). PICC occlusions were recorded and managed with a protocol that used urokinase.

Results: A total of 102 patients were recruited to the study. The overall risk of occlusion per catheter was 35% (95% CI 26% to 44%). The overall rate of occlusion was 76 occlusions per 1000 catheter days (95% CI 61 to 95). Presence or type of valve did not significantly influence this rate (open-ended non-valved PICC 38% of catheters, 79 occlusions per 1000 catheter days; Groshong 38% of catheters, 60 occlusions per 1000 catheter days; PASV 27% of catheters, 99 occlusions per 1000 catheter days). The dose of urokinase required to treat PICC occlusions did not significantly differ between PICC types.

Conclusions: Valved PICCs do not appear to influence PICC occlusion rates.

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Conclusions: Valved PICCs do not appear to influence PICC occlusion rates.

Il nostro studio: Pittiruti 2014

J Vasc Access 2014; 00 (00): 000-000

ORIGINAL ARTICLE

DOI: 10.5301/jva.5000280

A prospective, randomized comparison of three different types of valved and non-valved peripherally inserted central catheters

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JVA 2014

Progetto iniziale

Paragonare tre tipi di PICC valvolati in uso presso il nostro DH Oncologico, in termini di malfunzionamento e occlusioni:

- Groshong PICC, Bard (SIL, valvola distale)
- Power PICC Solo, Bard (P-PUR, valvola prossimale)
- PASV PICC, Navilyst (P-PUR, valvola prossimale)

...prima di iniziare lo studio...

...episodi ripetuti di rottura di cateteri Groshong :

6 rotture di Groshong PICC

2 rotture di Groshong Midline

tutte nel tratto intravascolare

tutti i cateteri erano usati con pompa

tutti e 6 I PICC erano usati con taxoli

Il DH Oncologico decide di sospendere l'uso di PICC
Groshong per chemioterapia con pompa

Nuovo progetto...

Paragonare tre tipi di PICC power injectable in uso per chemioterapia presso il nostro DH Oncologico:

100 Power Solo PICC, Bard (valvola prossimale)

100 PICC with PASV, Navilyst (valv.prossimale)

100 Pro-PICC, Medcomp (non valvolati)



Metodo

- DH Oncologia Medica, Università Cattolica, Roma
- 300 pazienti oncologici adulti
- Studio prospettico randomizzato (3 gruppi)
 - Valvola Solo vs. valvola PASV vs. non-valvolati
- PICC 4Fr monolume inseriti per chemioterapia
- Tutti i PICC inseriti secondo il protocollo SIP
- Tutti i PICC trattati con il medesimo protocollo di FLUSH/LOCK

Protocollo di Flush/Lock per I PICC (UCSC, 2012)

1. Flush con 10ml di fisiologica (tecnica 'push/pause') prima e dopo ogni infusione
2. Flush con 20ml di fisiologica (tecnica 'push/pause') dopo prelievo o dopo infusione di emoderivati o lipidi o mdc
3. Utilizzo esclusivo di NFC a pressione neutra
4. Lock con fisiologica (no eparina)

Endpoints

- Endpoint primario
 - Malfunzionamento da occlusione o limitazioni del flusso
- Endpoints secondari
 - Trombosi venosa
 - Infezione
 - Complicanze meccaniche
 - Rottura
 - Dislocazione

Endpoint primario: malfunzionamento

1) Flusso

- Ritorno venoso
- Flusso a caduta (con e senza NFC)
- Flusso con pompa (con e senza NFC)

2) Incidenza di occlusione

- Occlusione completa (no infusione, no aspirazione)
- Occlusione parziale (infusione o aspirazione difficili)
- PWO (infusione ok, aspirazione impossibile)
- % occlusioni risolte con semplice flushing
- % occlusioni risolte con urokinasi
- % PICCs rimossi per occlusione irreversibile

Risultati

61 Power Solo 2 PICCs, Bard

60 PASV PICCs, Navilyst (55 Xcela + 5 BioFlo)

59 ProPICC, Medcomp

Studio interrotto a **180** pazienti (rispetto ai 300 previsti), a causa di 3 episodi di rottura di Power Solo PICCs (nel tratto intravascolare).

La Direzione ha sospeso l'uso dei Power Solo (altri 3 episodi di rottura si erano verificati in pazienti al di fuori dello studio)

Risultati –endpoint primario

	Solo Valve (n=61)	PASV (n=60)	No valve (n=59)
Occlusioni irreversibili	1	-	-
Occlusioni reversibili*	2	1	2
PWO**	1	-	1
Riduz.flusso a caduta***	19	39	-
Rimossi per occlusione	1		

- Tutte risolte con flushing di fisiologica

** entrambe irreversibili

*** difficoltà con la infusione per gravità, ma non con la pompa

Risultati – endpoints secondari

	Solo Valve (n=61)	PASV (n=60)	No valve (n=59)
Infezione (CRBSI)	-	-	-
Trombosi sintomatica*	-	1	-
Trombosi asintomatica**	2	1	1
Dislocazione	-	-	-
Rottura intravascolare***	3	-	-
Rimossi per rottura	3	-	-

* Catetere (BioFlo), non rimosso; eparina bpm 100 unità/kg/12h

** Cateteri non rimossi – nessuna terapia

*** non chiara la patogenesi (probabilmente, un lotto difettoso)

Conclusioni

- 1) In presenza di un protocollo appropriato di Flush/Lock e utilizzando NFC a pressione neutra, la eparinizzazione del PICC è superflua.
- 2) L'utilizzo di PICC in P-PUR sembra associarsi comunque, valvola o non valvola, ad un basso rischio di occlusione e ad una facile disostruzione senza il ricorso a trombolitici.

Conclusioni

- 3) La presenza di una valvola prossimale non sembra associarsi a vantaggi.
- 4) La presenza di una valvola prossimale si associa ad una possibile difficoltà alla infusione a caduta.
- 5) Il costo più elevato dei PICC valvolati rispetto al costo dei non valvolati non sembra giustificato da una migliore performance clinica.

Zerla 2015

Ovvero:

Il 'colpo di grazia' alla teoria che i
PICC Groshong in silicone si
associano a minori complicanze
occlusive e trombotiche

Zerla

JAVA, September 2015 Volume 20, Issue 3, Pages 169–176

Open- vs Closed-Tip Valved Peripherally Inserted Central Catheters and Midlines: Findings from a Vascular Access Database

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Zerla 2015

Abstract

Today's patients are more complex in terms of comorbidities and other conditions requiring multiple, long-lasting therapies such as chemotherapy, total parenteral nutrition, blood transfusion or blood component infusions, and frequent blood sampling. The use of central venous catheters represents an important aspect of care for many patients. It is essential to inform health care workers of the risks associated with central venous catheters such as systemic and infectious complications, mechanical complications, and/or thrombotic complications. To maintain monitoring of our peripherally inserted central catheter team's activity, we developed and adopted a database in which all the data regarding each catheter are recorded. By doing that, we have improved catheter management, clinical efficiency, as well as achieved a cost reduction. We implanted 1416 vascular access devices in 1341 patients of both sexes (632 male and 709 female) for a total of 135,778 vascular access device-implant days between March 2010 and December 2013 for several indications. We have followed-up total complications and we correlated them with the need for catheter removal. The results were that open-tipped catheters resulted in both more complications and a greater need for removal.

Zerla 2015

	PICC open-ended	Groshong PICC	
Setting	Hospital	home	
#	173	620	
Cath-days	15819	102888	
Complications	28 (16.1%)	72 (12%)	
Occlusions	23	62	P=0.2134 n.s.
PWO	12	53	P=0.6380 n.s.
Thrombosis	5 (2.8%)	13 (2%)	P=0.5638 n.s.
Infection	5 (2.9%)	2 (0.3%)	P=0.0067
Infection/1000 cath days	0.31	0.01	

In sostanza

Nonostante i notevoli 'bias' statistici del lavoro (studio retrospettivo; i PICC a punta aperta erano tutti usati in ospedale e i PICC valvolati tutti a domicilio), alcuni dati sono incontrovertibili:

- I PICC (sia in silicone che in poliuretano) si associano ad un rischio trombotico al di sotto del 3%
- I PICC si associano (sia in ospedale che a domicilio) ad un basso rischio infettivo, al di sotto di 0.5 infezioni per 1000 giorni catetere



Impossibile visualizzare l'immagine. La memoria del computer potrebbe essere insufficiente per aprire l'immagine oppure l'immagine potrebbe essere danneggiata. Riavviare il computer e aprire di nuovo il file. Se viene visualizzata di nuovo la x rossa, potrebbe essere necessario eliminare l'immagine e inserirla di nuovo.

Zerla 2015

Conclusioni

Paragonando in modo retrospettivo, non controllato, le complicanze di 173 PICC in poliuretano a punta aperta utilizzati in ambito ospedaliero vs. quelle di 620 PICC valvolati in silicone utilizzati in ambito domiciliare, non si sono evidenziate differenze significative nella incidenza di occlusioni (13,3% vs 10%, $P = 0.21$) o di trombosi (2.8% vs 2%, $P = 0.56$), sebbene i PICC utilizzati a domicilio fossero ovviamente associati ad un rischio infettivo minore (0.31 vs 0.01 infezioni/1000 gg catetere).

Quindi

- I PICC sono un dispositivo per accesso centrale particolarmente sicuro in termini di complicanze trombotiche e complicanze infettive
- Non vi sono differenze di performance clinica tra i PICC valvolati in silicone e i PICC a punta aperta in poliuretano (a parte il costo del presidio, assai maggiore per i PICC valvolati in silicone)

Nostra esperienza (2008-2015)

Pittiruti M, Sica S, Scoppettuolo G, Francia S et al (in press)

- 285 PICC
 - 185 auto-HSCT + 100 allo-HSCT
 - 185 PICC in silicone + 100 PICC in PUR power
- CRT 5.2%
 - No diff allo vs auto trapiantp
 - No diff silicone vs. poliuretano

Nostra esperienza (2008-2015)

<i>Complicanze</i>	<i>PICC in PUR n=100</i>	<i>PICC in SIL n=185</i>	<i>Significatività Test Chi quadro</i>
Ematoma	0	0.5%	n.s.
Malposizionamento	0	2.2%	p < 0.05
Malfunzionamento/occlusioni	0	6.0%	p < 0.01
Trombosi	5%	4.3%	n.s.
Batteriemia PICC-correlata	3%	2.7%	n.s.
Contaminazione PICC	4%	5.4%	n.s.
Batteriemia non correlata a PICC	13%	13.5%	n.s.
Rimozione accidentale	1%	1.08%	n.s.
Rimozione per sepsi	0%	1.6%	n.s.
Rimozione per TVP	2%	2.7%	n.s.
Rimozione per malfunzionamento	0%	0.5%	n.s.

Scelta del PICC

- PICC in silicone vs. poliuretano power ?
 - Poliuretano power = costo inferiore, maggiore versatilità d'uso e minore incidenza di complicanze costose (rottture, occlusione, dislocazioni)
- PICC valvolati vs. PICC a punta aperta ?
 - la presenza di una valvola non ha nessuna evidenza scientifica di efficacia ma aumenta del 50-150% il costo del presidio

In conclusione: attenzione alla scelta
del materiale dei PICC

**EVITARE I CATETERI VALVOLATI, SIA A
PUNTA CHIUSA CHE A PUNTA APERTA**

- Nessun vantaggio, alti costi, più alta % di complicanze

ABBANDONARE IL SILICONE

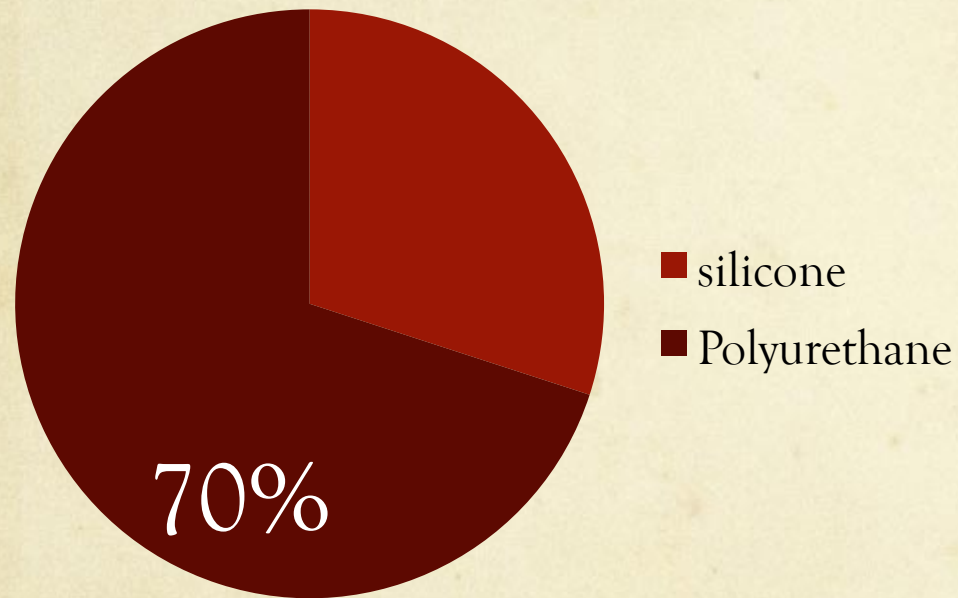
- Nessun vantaggio, alti costi, più alta % di complicanze

**PREFERIRE SEMPRE E COMUNQUE I PICC
IN POLIURETANO POWER INJECTABLE**

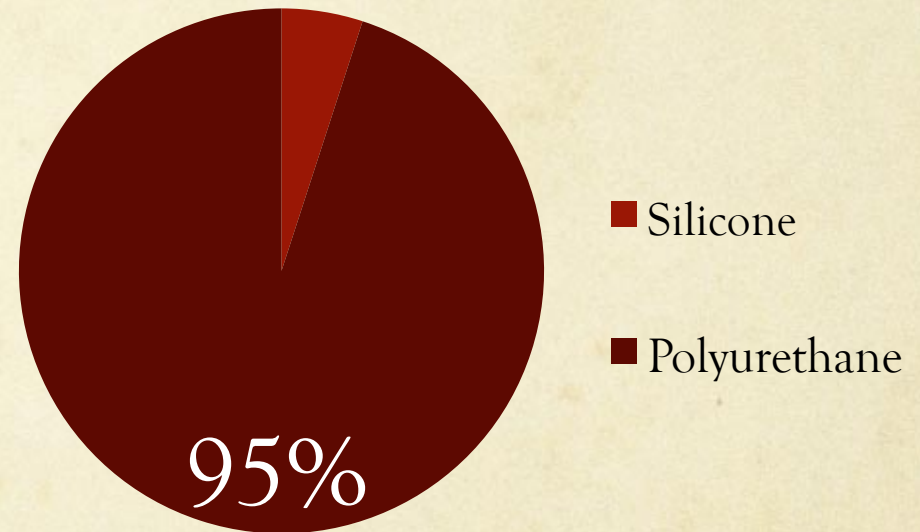
Polyurethane versus Silicone Use USA:

PICC line Market Transition

2012 Material Usage



2019 Material Usage



Scelta del PICC oggi (2017)

Poliuretano III generazione

Power injectable

A punta aperta

Non valvolato

Considerazioni finali

- Non esiste nella letteratura scientifica un solo studio clinico che abbia mai dimostrato il vantaggio di utilizzare PICC in silicone piuttosto che in poliuretano.
- Non esiste nella letteratura scientifica un solo studio clinico che abbia mai dimostrato il vantaggio di utilizzare PICC con valvola Groshong.

DOMANDE FINALI

Quale è il razionale per continuare ad utilizzare PICC in silicone?

Quale è il razionale per continuare a utilizzare PICC con valvola Groshong ?



GAVeCeLT
Gli Accessi Venosi Centrali a Lungo Termine

**Grazie
dell'attenzione**

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