Silicon vs. polyurethane in 2018

Mauro Pittiruti

5th World Congress on Vascular Access
Silicon vs. polyurethane in 2018

Is silicon associated with less risk of infection?
Is silicon associated with less risk of thrombosis?
Is silicon more fragile than polyurethane?
Do we need silicon for the infusion of some special drugs?
Silicon is NOT associated with a decreased risk of infection
Infection risk?
Infection risk

SIL better than PUR (old PUR!) in a very old study
  McDonald 1977

PUR better than SIL in old studies
  – Linder 1984
  – Rudin 1990

PUR and PE quite the same in old clinical studies
  – Poisson 1991
  – Touquet 1992

(though PUR better than PE in in-vitro studies)
Infection risk

In this century, clinical studies did not show difference between PUR vs SIL

- Beau 1999
- Hoffer 2001
- Pittiruti 2009
- Cohen 2011
- Miyakagi 2012

One clinical study suggested that PUR (PICC with proximal valve) vs. SIL (PICC with distal valve)

- Ong 2010
Infection risk

Catheter material

Although catheter material may be an important determinant of CR-infection, evidence available to HICPAC when developing their guidelines was inconclusive and they were unable to draw any specific conclusions about the contribution of catheter material to CR-infections.²⁰⁹,²¹⁵ Teflon® and polyurethane catheters have been associated with fewer infections than catheters made of polyvinyl chloride or polyethylene. There is no additional evidence that demonstrates conclusively that CR-infection rates vary with different materials.²⁰⁶ In England, short-term CVAD are almost always made of polyurethane and long-term tunnelled catheters are usually made of silicone.

epic2: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England

ESPEN Guidelines on Parenteral Nutrition: Central Venous Catheters (access, care, diagnosis and therapy of complications)
Mauro Pittiruti a, Helen Hamilton b, Roberto Biffi c, John MacFie d, Marek Pertkiewicz e

There is limited evidence to suggest that the catheter material is important in the etiology of catheter-related sepsis. Teflon, silicone and polyurethane (PUR) have been associated with fewer infections than polyvinyl chloride or polyethylene. Currently all available CVCs are made either of PUR (short-term and medium-term) or silicone (medium-term and long-term); no specific recommendation for clinical practice is made.
Type of Catheter Material. Polytetrafluoroethylene (Teflon®) or polyurethane catheters have been associated with fewer infectious complications than catheters made of polyvinyl chloride or polyethylene [36, 253, 254]. Steel needles used as an alternative to catheters for peripheral venous access have the same rate of infectious complications as do Teflon® catheters [33, 34]. However, the use of steel needles frequently is complicated by infiltration of intravenous (IV) fluids into the subcutaneous tissues, a potentially serious complication if the infused fluid is a vesicant [34].
Infection risk

Infection risk apparently higher for PE and PVC if compared to PTFE, PUR e SIL
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

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.
Infection risk: bottom line

No evidence that SIL may be associated with a lower risk of infection if compared to PUR.

On the contrary:
1) One review on PICCs suggest the opposite
2) PUR may be treated and modified with antibiotic coverage or antiseptic impregnation, so to get material resistant to infection
Silicon is NOT associated with less risk of catheter-related thrombosis
Thrombotic risk?
Thrombotic risk

Very old studies suggested some differences

- Curelaru 1983: SIL > PE
- Curelaru 1984: PUR = PE
- Pottecher 1984: PUR and SIL > PE
- Linder 1984: PUR > SIL
Thrombotic risk

In this century, clinical studies did not show differences between PUR vs. SIL.

- Beau 1999
- Pittiruti 2009
- Bonizzoli 2011
- Miyakagi 2012
Thrombotic risk

The source is Galloway & Bodenham 2004, a narrative review that does not suggest the superiority of SIL vs. PUR in terms of thrombotic risk; the review suggests that SIL may be better in terms of infection (on the basis of the 1977 study by McDonald !)
3. Role of device or material in minimizing the risks

Currently, a wide variety of central venous catheters are commonly used in medicine. Major design efforts have been undertaken to develop catheters that minimize trauma to blood vessels and are less thrombogenic. Catheter types and materials have undergone major design changes and continue to evolve. Randomized trials and prospective observations indicate an inherent superiority of silicone and second-third-generation polyurethane over more rigid materials, such as polyvinyl chloride (PVC), tetrafluoroethylene, and polyethylene as well (23-29). Pure silicone-valved catheters exhibited a lower rate of thrombosis when compared with barium-added open-ended silicone ones in a randomized trial (30). The number of catheter lumens is a major predictor of catheter thrombosis. Triple-lumen Hickman catheters failed at 3 times the rate of double-lumen catheters (31).

Conclusions of the Consensus

Silicone and second-third-generation polyurethane catheters are less thrombogenic than polyethylene or PVC ones. A lower diameter catheter and a single lumen might be protective against the risk of central venous thrombosis.

Strength B recommendation.
Catheter-related central venous thrombosis: the development of an Italian nationwide Consensus Paper

R. BIFFI¹, M. Pittiruti², C. Campisi³, ON BEHALF OF THE GAVeCeLT* COMMITTEE FOR THE CONSENSUS PAPER ON CATHETER-RELATED CENTRAL VENOUS THROMBOSIS

¹Dept. of Surgery, European Institute of Oncology, Milan - Italy
²Dept. of Surgery, Gemelli Hospital, Catholic University of Sacred Heart and IASI - CNR/Shock Pathophysiology Section, Rome
³Dept. of Surgery, San Pietro Hospital and Institute of Biotechnologies, CNR, Rome - Italy

*GAVeCeLT is the Italian Study Group for Long-Term Central Venous Access

Randomized trials and prospective observations indicate an inherent superiority of silicone and second-third-generation polyurethane over more rigid materials, such as polyvinyl chloride (PVC), tetrafluoroethylene, and polyethylene as well.


2008 SOR guidelines for the prevention and treatment of thrombosis associated with central venous catheters in patients with cancer: report from the working group

P. Debourdeau¹, D. Kassab Chahmi², G. Le Gal³, I. Krieger⁴, E. Desruennes⁵, M.-C. Douard⁶, I. Elalamy⁷, G. Meyer⁸, P. Mismetti⁹, M. Pavič¹, M.-L. Scrobohaci¹⁰, H. Lévesque¹¹, J. M. Renaudin¹² & D. Farge¹³ on behalf of the working group of the SOR

No recommendation about material
In vitro and ex vivo data confirm that silicone, and 2nd and 3rd generation polyurethane catheters are less thrombogenic than polyethylene or PVC ones, and should be preferred for long-term use (Grade C).
Thrombotic risk

No recommendation about material
International clinical practice guidelines for the treatment and prophylaxis of thrombosis associated with central venous catheters in patients with cancer

No recommendation about material
Thrombotic risk

PE, PTFE and PVC have apparently higher risk than PUR and SIL
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

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.
**Intra-cavitary ECG is an effective method for correct positioning of the tip of tunneled Groshong catheters**

Giuseppe Capozzoli, Gino Accinelli, Loris Fabbro, Roberta Pedrazzoli, Franco Auricchio

Anesthesia and Intensive Care Unit, Bolzano Central Hospital - Italy

**ABSTRACT**

*Background:* Intra-cavitary electrocardiography (ECG) is a well-known method for correct positioning of the tip of central venous catheters (CVC). A significant increase in the P wave, as registered by the intra-cavitary electrode, signals the entrance of the catheter into the right atrium.

*Methods:* In this prospective observational study, 155 consecutive oncologic patients were enrolled for cannulation of the right or left internal jugular vein for insertion of a tunneled Groshong catheter. In 150 patients the tip was positioned by means of intracavitary ECG. Five patients with atrial fibrillation (N=4) or pacemaker in place (N=1) were excluded from the study. As the P-wave amplitude began to increase, the catheter was secured in that position and the insertion depth was registered.

*Results:* Intra-cavitary ECG was always apt to detect the increase in the P wave. On the post-operative chest x-ray all Groshong catheters except two were in the correct position.

*Conclusions:* The need for chest x-ray or fluoroscopy may be virtually eliminated by using the ECG technique.

In two cases, after an apparently uneventful intravascular ECG, the post-operative chest x-ray indicated that the catheter was malpositioned (tip in the left brachio-cephalic vein). No significant cardiac arrhythmias caused by catheter positioning or intravascular electrocardiographic registration were recorded.
Thrombotic risk: bottom line

No evidence that SIL may be associated with a lower risk of thrombosis if compared to PUR.

On the contrary:
1) One review on PICCs suggest the opposite
2) The instability of SIL, both inside and outside the vessel may indirectly favor the thrombosis
3) PUR may be treated and modified with antithrombotic agents, so to get material theoretically resistant to thrombosis
The Sturgeon Axiom

Complication Rates Observed in Silicone and Polyurethane Catheters of Totally Implanted Central Venous Access Devices Implanted in the Upper Arm

Jasmin D. Busch, MD, Maren Vens, PhD, Catherine Mahler, MD, Jochen Herrmann, MD, Gerhard Adam, MD, and Harald Ittrich, MD
The authors state that their study on PICC-ports proves that the thrombotic risk of PUR is higher than SIL.

But:
1) The study is retrospective
2) They compared 5Fr SIL catheters vs. 6Fr PUR catheters. Obviously, the incidence of thrombosis is slightly higher in the 6Fr catheters.
3) The definition of thrombosis includes also the lumen occlusion due to clots (!!!)
But it gets even worse...

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Jasmin D. Busch, MD, Maren Vens, PhD, Catherine Mahler, MD, Jochen Herrmann, MD, Gerhard Adam, MD, and Harald Ittrich, MD

- ‘...contrast venography-guided vein access was achieved...’ ??
- ‘...fluoroscopic confirmation of correct catheter tip positioning at the cavoatrial junction (defined as 2 vertebral bodies below the carina)...’ ??
Silicon is more fragile than polyurethane
Risk of mechanical complications

Catheter damage and/or dislodgement are more frequent in SIL than in PUR

- Rudin 1990
- Beau 1999 (p<.01)
- Hoffer 2001 (p<.01)
- Pittiruti 2009
- Cohen 2011 (p<.005)
Groshong PICC and home care: an opportunity. Clinical experience after the first 200 implants

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¹ Rep. Analgesic and Palliative Therapy Unit, ASL Frosinone, Frosinone - Italy
² Biomedical Campus, Rome - Italy
³ National Research Council, Institute of Biomedical Technologies, Rome - Italy

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 : 12 ruptures
Nerve damage secondary to removal of fractured PICC fragment

Qian Q. Mou, Yun X. Wang, Qiong H. Xu, Xia Liu, Ying J. Li
Division of Thoracic Oncology, Cancer Center, West China Hospital, Sichuan University, Chengdu - PR China

ABSTRACT

Purpose: To increase awareness of peripherally inserted central catheter (PICC) fracture and necessary nursing assessment to identify development of nerve injury after removal of the PICC fracture.

Methods: This is a case review of a cancer patient with fractured PICC and the postoperative symptoms leading to nerve injury.

Results: The reason for PICC fracture is the fragility of silicon. Secondary surgical intervention of a PICC fragment resulted in nerve damage from a hematoma placing pressure on the median nerve in the arm.

Conclusions: It is necessary to use power injectable polyurethane PICCs. It is vital to have a clear understanding of signs and symptoms of nerve impingement in the arm when monitoring a post-operative patient. Assessment of neurological status, circulation, swelling and patient complaints of pain are all necessary functions of the nurse in caring for this type of patient.

Keywords: Fracture, Nerve injury, Nursing implications, Peripherally inserted central catheter (PICC)

Results: The reason for PICC fracture is the fragility of silicon.
Percutaneous retrieval of PICC fractures via the femoral vein in six cancer patients

Qi Wang, Bin Xiong, ChuanSheng Zheng, GanSheng Feng, Ming Liang, HuiMin Liang

Department of Radiology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan - People’s Republic of China

ABSTRACT

Purpose: To investigate the feasibility and safety of the interventional technique of retrieving the fractured peripherally inserted central catheter (PICC) segments within the vessels via the femoral vein.

Methods: From July 2007 to January 2012, we performed percutaneous retrieval of PICC fractures in six cancer patients who accepted chemotherapy via PICC. The fractures occurred during the traction of the catheter and were diagnosed with chest plain film radiography and/or computed tomography. The patients included four cases of ovarian cancer, one case of breast cancer and one case of cervical cancer. The fractures were retained in the vessels of the patients for 1 to 10 days. According to the location of the ends of the PICC fractures, three methods were employed using the most commonly used interventional devices in the digital subtraction angiography suite.

Results: The PICC fractures were located in the subclavian vein, superior vena cava, right atrium, right ventricle or pulmonary arteries. During the procedures, a goose neck snare, pigtail catheter and stone basket catheter were used individually or in combination. The PICC fractures were removed successfully in all six patients via unilateral or bilateral femoral vein access. No major complications occurred during the operation or the follow-up period of 7 to 10 days.

Conclusions: Via femoral vein access, PICC fractures could be removed with common interventional instruments such as a goose snare, basket catheter and pigtail catheter. The interventional retrieval is a safe, convenient and minimally invasive method for the removal of PICC fractures.

Keywords: Cancer, Fracture, PICC, Retrieval
Patients and Methods

Patients

The patients in this study included four cases of ovarian cancer, one case of breast cancer and one case of cervical cancer. The patients received chemotherapy via PICC. The PICC catheters were silicone Groshong*, NXT PICC and Groshong* NXT ClearVue PICC (Bard Access System, Salt Lake City, USA).
JOURNAL OF VASCULAR ACCESS
Use of peripherally inserted central venous catheters (PICCs) in children receiving autologous or allogeneic stem cell transplantation
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in literature. So, the last 3 PICCs were implanted without tunneling. The mechanical complication rate was high (46%) and related to external rupture of the device (5 cases) and temporary obstruction (1 case). However these complications were easily resolved with additional saline flushing or lock therapy with Urokinase solution in case of catheter obstruction, and repair of the catheter in the other cases, with maintenance of the same device in all patients. So high number of external rupture of the device was due to the initial choice to use only silicone PICC; they were appreciate and easily managed from the nurses because very similar to the CICCs used before but more fragile than polyurethane devices. Probably the choice of a power injectable polyurethane PICC would have reduced the incidence of this complication.
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**JOURNAL OF VASCULAR ACCESS**

In vitro study on the use of a two-component cyanoacrylate glue as sealant at the exit site of peripherally inserted central catheters

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To investigate possible degradation after several weeks of contact with glue, distinct pads were prepared and conserved in an egg incubator at 34°C and relative humidity of 60% so to reproduce \textit{in vivo} like conditions (Fig. 1 d). Once the desired duration was reached, the due pad was taken out from the incubator and each sample carefully removed from the skin support (Fig. 1e). This step was critical but necessary to observe the PICC surface underneath the glue. In all polyurethane catheters, when detaching the sample from the pad, the glue remained upon the artificial skin, thus exposing the catheter surface to be analyzed (Fig. 1 e). The silicon catheter (Groshong, Bard) could not be tested: it was weaker than the glue so it broke during the attempt to remove it from the skin pad.
To investigate possible degradation after several weeks of contact with glue, distinct pads were prepared and conserved in an egg incubator at 34°C and relative humidity of 60% so to reproduce *in vivo* like conditions (Fig. 1d). Once the desired duration was reached, the due pad was taken out from the incubator and each sample carefully removed from the skin support (Fig. 1e). This step was critical but necessary to observe the PICC surface underneath the glue. In all polyurethane catheters, when detaching the sample from the pad, the glue remained upon the artificial skin, thus exposing the catheter surface to be analyzed (Fig. 1e). The silicon catheter (Groshong, Bard) could not be tested: it was weaker than the glue so it broke during the attempt to remove it from the skin pad.
Comparison of three peripherally-inserted central catheters: pilot study.

Di Giacomo M.

Abstract
Peripherally-inserted central catheters (PICCS) are non-tunelled, central catheters inserted through a peripheral vein of the arm. They are 50-60 cm long and are usually made of either silicone or second-third generation polyurethane. PICCs can be used for prolonged, continuous or intermittent infusion therapies (up to 3 months) both in hospitalized patients and in patients treated as outpatients, in a hospice, or at home. When establishing a vascular service it is key to select a PICC that meets the requirements of safety, cost-effectiveness, high resistance (ability to take increasing fluid volumes with high pressure devices) and durability, and low complications rate. The complications and dwell times of three different PICCs were studied: coated polyurethane, valved silicone and power-injectable. The study was conducted at the chemotherapy suite at the author's hospital with the aim of selecting the right PICC based on low incidence of complications, resistance and enhanced dwell time. Results show a low incidence of complications and long dwell time among patients with the power-injectable PICC. Furthermore, this study demonstrated a reduction on the rate of occlusion and rupture with power-injectable PICCs, which makes them safer to use for administration of chemotherapy and other vesicant agents, as well as for the management of patients in critical care.
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

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.
Fractures of totally implantable central venous ports: more than fortuity. A three-year single center experience

Paolo Balsorano¹, Giulia Galducci¹, Ilaria De Fanti¹, Samuel Kagan Evans², Angelo Raffaele De Gaudio¹, Cecilia Pelagatti³

¹Department of Health Science, Section of Anaesthesiology, Intensive Care and Pain Medicine, AOUC Careggi, Florence - Italy
²Department of Pulmonary and Critical Care Medicine, Rhode Island Hospital, Providence, RI - USA
³Department of Oncology, Section of Anesthesiology and Intensive Care, AOUC Careggi, Florence - Italy

ABSTRACT

Purpose: Totally implantable venous access devices (Ports) represent the mainstay for infusion therapy in patients undergoing chemotherapy, total parenteral nutrition and/or long-term antibiotic treatment. Amongst mechanical complications, lesions of the catheter wall represent a rare but potentially severe condition. We report our experience with the accidental detection of catheter ruptures in a series of ports removed for complication or for end of use.

Methods: All ports removed from January 2011 to June 2013 were considered. All removed ports had been inserted according to a standardized protocol including ultrasound-guided percutaneous venipuncture (out-of-plane or in-plane approaches) and electrocardiogram-guided positioning of the tip. Once removed, each catheter was checked by inspection and saline instillation in order to evaluate the integrity of the device itself and rule out possible ruptures.

Results: In over 338 removed ports, 12 Groshong catheters out of 65 (18.5%) had evidence of partial rupture of the catheter wall. Amongst considered variables, “out-of-plane” approach and type of port (silicon, closed tip with Groshong valve) were the only ones significantly associated with catheter ruptures (p=0.0003 and 0.0008, respectively). We could detect no evidence of rupture in any silicon open-ended catheter (Celsite ports) or in any catheter inserted by “in-plane” approach to the vein.

Conclusions: The actual advantage of using port connected with Groshong silicon catheters should be questioned, since apparently they are more fragile than standard catheters. Furthermore, ultrasound-guided “out-of-plane” puncture of the internal jugular vein should be discouraged.

Key words: Catheter fractures, Catheter ruptures, Groshong catheters, Port mechanical complications, Totally implantable access devices, Vascular access mechanical complications
Twelve Groshong catheters out of 65 (18.5%) had evidence of partial rupture of the catheter wall. Seven out of 12 ruptured devices were normally functioning at the time of removal: 6 had been removed due to end of use, while 1 had been removed due to catheter-related bloodstream infection. The other five cases of rupture were associated either with catheter occlusion (three cases) or with extravasation (two cases). Patients’ demo-
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Retained embolized fragment of totally implantable central venous catheter in right ventricle: it is really necessary to remove?

Tazzioli G, Gargaglia E, Vecchioni I, Papi S, Di Biasio P, Rossi R.

Abstract

INTRODUCTION: Central venous catheters are often required in oncologic patients for long-term safe administration of chemotherapeutic agents, antibiotics, and parenteral nutrition. Rupture of these devices and intracardiac migration is a rare complication.

METHODS: We report one spontaneous rupture and embolization of a totally implantable vascular access device (TIVAD) in an asymptomatic patient.

RESULTS: A 50-year-old woman received a TIVAD silicone catheter & FR for adjuvant chemotherapy. After 3 years of port time in situ, during a follow-up control, a catheter malfunction was found and radiologic investigations showed a rupture and migration of the catheter to the right ventricle. The attempt to remove the fragment under fluoroscopic control using the femoral route was unsuccessful. We did not try a surgical approach because of the complete absence of symptomatology and hemodynamic impairment.

CONCLUSIONS: The catheter rupture and intracardiac embolization is a rare complication associated with totally implantable or tunneled central venous catheters. When such an event happens, the patient should be managed by expert hemodynamists or interventional radiologists making an effort to remove the fragment without surgical measures. When the intravascular percutaneous route fails, the possibility to leave the fragmented catheter in heart chambers should be evaluated, being surgery questionable in asymptomatic patients.
Fracture of totally implanted central venous access devices: a propensity-score-matched comparison of risks for Groshong silicone versus polyurethane catheters

Soichi Kojima¹, Takao Hiraki², Hideo Gobara¹, Toshihiro Iguchi¹, Hiroyasu Fujiwara¹, Yusuke Matsui², Toshiharu Mitsuhashi², Susumu Kanazawa¹

¹ Department of Radiology, Okayama University Medical School, Okayama - Japan
² Department of Epidemiology, Okayama University Medical School, Okayama - Japan
ABSTRACT

Purpose: To evaluate retrospectively the fracture risk of totally implanted venous access devices connected to Groshong silicone (SC) versus polyurethane (PU) catheters, inserted via the internal jugular vein.

Materials and methods: The study population comprised 384 SC and 221 PU central venous catheters implanted via the internal jugular vein. The presence of catheter fracture was evaluated. Variables possibly related to catheter fracture were evaluated. First, in order to determine the factors associated with fracture, fracture rates were compared with the log-rank test between the two groups divided by each of the variables. Then, in order to adjust for potential confounders, propensity-score matching of the variables was employed in the two catheter groups. Finally, the rates of fracture were compared between the two propensity-score-matched catheter groups.

Results: There were 16 cases of catheter fracture, for an overall fracture percentage of 2.6% (16/605). All 16 cases of fracture occurred in the SC catheter group. Smaller patient body mass index (p = 0.039), deeper catheter tip position (p = 0.022), and SC catheters (p = 0.019) were significantly associated with fracture. With the propensity-score-matching method, 180 cases were selected in each catheter group. Comparison of the two propensity-score-matched groups showed that fracture rates for SC catheters remained significantly (p = 0.018) higher than those for PU catheters.

Conclusions: Ports connected to Groshong SC catheters – when implanted via the internal jugular vein – posed a higher risk of fracture than did ports connected to PU catheters.

Keywords: Breakage, Central venous catheter, Fracture, Polyurethane, Risk, Silicone
ABSTRACT

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Materials and methods: The study population comprised 384 SC and 221 PU central venous catheters implanted via the internal jugular vein. The presence of catheter fracture was evaluated. Variables possibly related to catheter fracture were evaluated. First, in order to determine the factors associated with fracture, fracture rates were compared with the log-rank test between the two groups divided by each of the variables. Then, in order to adjust for potential confounders, propensity-score matching of the variables was employed in the two catheter groups. Finally, the rates of fracture were compared between the two propensity-score-matched catheter groups.

Results: There were 16 cases of catheter fracture, for an overall fracture percentage of 2.6% (16/605). All 16 cases of fracture occurred in the SC catheter group. Smaller patient body mass index (p = 0.039), deeper catheter tip position (p = 0.022), and SC catheters (p = 0.019) were significantly associated with fracture. With the propensity-score-matching method, 180 cases were selected in each catheter group. Comparison of the two propensity-score-matched groups showed that fracture rates for SC catheters remained significantly (p = 0.018) higher than those for PU catheters.

Conclusions: Ports connected to Groshong SC catheters — when implanted via the internal jugular vein — posed a higher risk of fracture than did ports connected to PU catheters.

Keywords: Breakage, Central venous catheter, Fracture, Polyurethane, Risk, Silicone.
Totally implantable ports connected to valved catheters for chemotherapy: experience from 350 Groshong devices

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ABSTRACT: Purpose: There are few studies regarding the use of totally implantable valved ports for chemotherapy. The objective of this study was to analyze the results obtained from consecutive implantation of 350 devices.

Methods: Adult patients submitted to port insertion in veins of the superior vena cava system over a 17-month period (July 2006 to December 2007) were considered. The device used was composed of a titanium and silicone rubber port (Dome Port™; Bard Inc, Salt Lake City, UT) connected to an 8.0 Fr silastic Groshong™ catheter tube. Follow-up was conducted on outpatient data and during clinical readmissions, until the device was removed or the patient died.

Results: Three hundred and fifty devices, total of 74,691 days in situ, were inserted, with a median follow-up of 176 days. There were 11 early complications (3.1%) and 49 late complications (14%), 21 of these (6%) were considered major ones. Early complications comprised four instances of phlebitis of the external jugular, three of pocket infection, two of technical failure, and two of ecchymosis. Late complications comprised 33 instances of withdrawal difficulty, 12 of port-related bacteremia, two of deep venous thrombosis, one of occlusion and one of catheter fracture. Out of the 350 catheters implanted, 258 (73.5%) were still being used, 73 (21%) remained in use until the patient died, five (1.5%) were removed at the end of the treatment and 14 (4%) were removed because of complications.

Conclusions: There was a low rate of major complications associated with this valved system justifying its use. (J Vasc Access 2010; 11: 17-22)
There were two types of mechanical complications among this sample of patients, which did not occur in our previous study (16): excessive angulation (two patients) in the subcutaneous pathway of the catheter, leading to malfunctioning (early complication) and one case of catheter fracture associated with embolization (15, 24, 25) (late complication). For these patients, a new device had to be implanted and, in the case of catheter fracture, endovascular intervention was necessary, thereby causing additional costs. These complications resulted mainly from technical failure and could have been avoided, although there was an association with the characteristics of the catheter (thin and malleable). Classical technical precautions should be respected while inserting this type of catheter: construction of gentle curves along its subcutaneous pathway and avoidance of a very medial puncture when undertaking the infraclavicular access to the subclavian vein.

Due to early thrombosis (8, 17, 26) associated with the catheter pathway, it is essential to follow the protocol of anticoagulation and use a catheter of appropriate size (4 Fr) in the subclavian vein.
There were two types of mechanical complications among this sample of patients, which did not occur in our previous study (16): excessive angulation (two patients) in the subcutaneous pathway of the catheter, leading to malfunctioning (early complication) and one case of catheter fracture associated with embolization (15, 24, 25) (late complication). For these patients, a new device had to be implanted and, in the case of catheter fracture, endovascular intervention was necessary, thereby causing additional costs. These complications resulted mainly from technical failure and could have been avoided, although there was an association with the characteristics of the catheter (thin and malleable). Classical technical precautions should be respected while inserting this type of catheter: construction of gentle curves along its subcutaneous pathway and avoidance of a very medial puncture when undertaking the infraclavicular access to the subclavian vein.

Due to these technical (8, 17, 26) associated with...
Silicone and polyurethane tunneled infusion catheters: a comparison of durability and breakage rates.


Author information

Abstract
PURPOSE: To examine the overall durability and breakage rates of dual-lumen silicone catheters in comparison with power-injectable dual-lumen polyurethane catheters.

MATERIALS AND METHODS: Patients who received a 10-F dual-lumen silicone catheter or 9.5-F dual-lumen polyurethane catheter between January 2002 and July 2009 were identified through a quality assurance database. Medical records were reviewed retrospectively. A total of 117 silicone and 94 polyurethane catheters were identified in 192 patients. Reasons for catheter placement and removal were recorded, as were cases of breakage and repairs. Catheter durability was compared; survival analysis was also performed.

RESULTS: Breakage occurred in nine of 117 silicone catheters (8%) and none of 94 polyurethane catheters (P = .005). Most catheters were placed for malignancy (162 of 211; 77%); nonmalignant indications such as total parenteral nutrition accounted for 49 out of 211 catheters (23%). The mean silicone catheter dwell time was 99 days (11,612 total catheter-days), and the mean polyurethane catheter dwell time was 78 days (7,362 total catheter-days). There was no significant difference in overall duration of function (ie, survival) between silicone and polyurethane catheters (P = .12). The infection rates were 3.6 per 1,000 catheter-days for silicone catheters and 3.5 per 1,000 catheter-days for polyurethane catheters (P value not significant).

CONCLUSIONS: There were fewer catheter fractures with the polyurethane catheter compared with the silicone catheter, although there was no difference in the total access site service interval for the two catheter types.
Evidence shows that SIL – being softer and more fragile than PUR – is more prone to mechanical complications (catheter damage, dislodgement) if compared to PUR.
Silicon is NOT mandatory for alcohol-based drugs
An urban legend reports that alcohol-based chemioterapeutic drugs (taxols) should be exclusively delivered via SIL catheters.

IS THIS TRUE?
First consideration

In the medical literature, there are no reports of damage to PUR catheters secondary to exposure to alcohol-based drugs: not in vivo, not 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 polyurethane 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 polyurethane and silicone catheters and minor increases in the wall area of polyurethane catheters.

CONCLUSIONS: These data indicate that exposure to a 70% ethanol lock solution does not appreciably alter the integrity of selected commercial polyurethane 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 prevention and treatment of intravascular device–related BSI in clinical practice.
Second consideration

New generation polyurethane (e.g. Carbothane), typically used for power injectable PICCs, are alcohol-resistant.
Traditionally, hemodialysis catheters were made of one of two materials: silicone or polyurethane. However, each of these materials presented a serious problem with catheter care. Silicone is greatly weakened by iodine; polyurethane is resistant to iodine but significantly structurally degraded by alcohol. In the past, when using catheters of these materials, caregivers had to be careful not to expose the given catheter to its respective nemesis. Over time, structural degradation has led to torn catheter tips, which may break free and travel into the pulmonary artery. The newest advance in catheter material is carbothane, which has all the advantages of its predecessors but is resistant to both iodine and alcohol. It is stronger than polyurethane, allowing it to have thinner walls and retain the same physical properties as polyurethane catheters. Most catheters on the market today are made of carbothane and have proven enhanced biocompatibility.
LONG TERM POLYURETHANE CATHETER ALCOHOL COMPATIBILITY I,
PHYSICAL AND RHEOLOGICAL STUDIES

Lecon Woo1, John Wesley MD2, Maryellen Zibell2, Christopher Gardner2 and William Anderson2
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2Excelsior Medical, Neptune, NJ

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 ),

\[ \eta = K \text{Mw}^{\gamma} \]

Where \( \eta \) 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
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.
Effect on PICC Lines of 1, 3 Months of Immersion at 37°C in Ringer's and Ethanol Solution

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L. Angelini, A. Baù, E.M. Calabrò, F. Di Puccio, G. Gallone, S. Mainardi
Dep. Civil and Industrial Engineering, University of Pisa
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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¹Pain Therapy Unit, S. Chiara Hospital, Pisa - Italy
²Department of Civil and Industrial Engineering, University of Pisa, Pisa - Italy

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

**Manuscript Number:** JVA-D-17-00083

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

**Short Title:** Mechanical Behaviour of PICCs in in vivo like conditions

**Article Type:** Original Research Article

**Section/Category:** Oncology

**Keywords:** central venous catheters, indwelling catheters, polyurethane, mechanical properties, material degradation

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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%.
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.

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As a matter of fact…

Approximately 85-90% of PICCs currently sold in USA are power injectable PICCs in new generation polyurethane, and they are commonly used for delivery of alcohol-based chemioterapeutic drugs.

(same is for power injectable ports with PUR catheters)
The Morpheus Smart PICC

Engineered for Life™
The Morpheus® SMART PICC provides clinicians with a comprehensive line of CT compatible PICC kits that offer True French size catheters with the shortest taper in the industry.

Best in Class Flow Rate
CT Rated and labeled for CT injection.

All-Carbothane® catheter
The chemically resistant all-Carbothane catheter offers proven drug compatibility.

Smart Taper™ Technology
The Smart Taper™ reverse taper technology is designed with the shortest taper in the industry.

Highly Visible Material
Superior product visibility, complete with radiopaque markings with centimeter spacing provide increased visibility, easier catheter placement and tip confirmation.

True French Sizing
True French size catheter means less catheter in the patient.
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
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Reverse taper hub
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Longer extension legs
Promote easy application of occlusive dressing

High durometer extension legs
Offer improved durability and greater resistance to alcohol
**Reduced Taper**

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

**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.

**Alcohol & iodine compatible**

See our Site Care page for more information on agent compatibility.
**Pro-PICC® CT**

Material: Polyurethane

medcompnet.com/pro-picc

**Compatible Site Care Agents:**
- Chlorhexidine Gluconate 2% and 4%,
- Betadine® Solution (10% Povidone Iodine),
- 70 / 30% Alcohol,
- Hydrogen Peroxide,
- < 0.057% Sodium Hypochlorite,
- Antimicrobial Ointments and Creams (Mupirocin, Polymyxin),
- Silver Sulfadiazene Cream 1%
Third consideration

The risk of catheter damage due to mechanical injury – related to the fragility of SIL – is real.

The risk of catheter damage due to chemical injury is conjectural.
Our experience

In 2012, we had six episodes of rupture of silicon PICCs (Groshong)
all ruptures were in the intravascular tract
all catheters were connected with an i.v. pump
all PICCs were used for taxol infusion
No episodes of rupture while using polyurethane PICCs.
Conclusions
Central venous access devices in pediatric malignancies: a position paper of Italian Association of Pediatric Hematology and Oncology

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8 Pediatric Surgery Unit, University Policlinic Hospital, Modena - Italy
9 Pediatric Immunology and Bone Marrow Transplantation Unit, San Raffaele Telethon Institute for Gene Therapy (HSR-TIGET), “San Raffaele” Scientific Institute, Milan - Italy
10 Institute for Maternal and Child Health, IRCCS “Burlo Garofolo”, Trieste - Italy
Choice of material

MTVAs and LTVAs are made of catheters of different materials, either silicon or polyurethane. There is no evidence of any difference between silicon and polyurethane in terms of risk of infective and thrombotic complications in the adult or in the pediatric population (13, 14). Silicon catheters have traditionally been the first choice for LTVA in pediatric patients (11, 15-18), although polyurethane catheters—and specially power injectable polyurethane catheters, which are made of third-generation polyurethanes—are as biocompatible as silicone catheters but less fragile; also, they are compatible with higher flow rates and are ideal for injection of contrast medium (19).
Take home message

- There is no evidence that SIL might have any advantage over PUR in terms of biocompatibility or of risk of infection or thrombosis.

- There is evidence that SIL – being more fragile than PUR – is associated with increased risk of mechanical complications (rupture of the extravascular or intravascular tract, tip migration, dislodgement, etc.)

- The most appropriate material for external catheters is PUR.
Thank you for your attention

www.gavecelt.info

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