

Original article

Fracture of totally implanted central venous access devices: a propensity-score matched comparison of risks for Groshong silicone versus polyurethane catheters

Short title: Fracture of totally implanted central venous access devices

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Type of Manuscript: Original Research

Word count: 3000

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Conflict of interest: none

IRB statement: This study was approved by the institutional review board of Okayama University Medical School (approval number 1507-058).

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 ($P = .039$), deeper catheter tip position ($P = .022$), and SC catheters ($P = .019$) 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 ($P = .018$) higher than those for PU catheters.

Conclusion: 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: central venous catheter; fracture; breakage; silicone; polyurethane; risk

INTRODUCTION

Central venous (CV) catheters have been widely used for safe delivery of chemotherapeutic agents and parenteral nutrition to patients. However, CV catheters can cause various problems. During the procedure, hemorrhage and pneumothorax may occur [1–4]. Late complications include arrhythmias, nerve palsy, infection, wound dehiscence at the port, catheter obstruction, and venous thrombosis [3–5]. Another serious late complication is catheter fracture, which occurs with an incidence of 0–4% [3, 4, 6–8]. Partial fracture may lead to leakage of the chemotherapeutic agent or nutrition into the subcutaneous tissue through a fractured catheter, resulting in subcutaneous pain, swelling, and inflammation [6, 9]. Total fracture indicates a transected catheter, which may migrate into the right chamber of the heart, leading to arrhythmia and pulmonary artery thrombosis [10].

A comparison of the fracture risks for silicone (SC) versus polyurethane (PU) CV catheters has been the focus of several studies. Four studies [11–14] showed a greater risk of rupture of SC catheters, whereas another study [15] showed the opposite result. A systematic review [16] showed that fracture rates were almost identical for the two catheter types. Thus, the comparative risk of fractures for SC versus PU CV catheters remains controversial. The purpose of the present study, therefore, was to evaluate retrospectively the fracture risk for SC versus PU CV catheters implanted via the internal jugular vein (IJV).

MATERIALS AND METHODS

The ethics committee at our institution approved this retrospective study (approval number 1507-058). The requirement for informed consent for data to be used experimentally was waived due to the study's retrospective nature.

Study Population

The study population comprised 605 totally implanted venous access devices connected to catheters inserted via the right IJV between April 2008 and January 2014 at our institution. The vast majority (596/605) of the patients were adult; mean age of the patients at the time of implantation was 60.1 years \pm 15.1 (standard deviation). Catheters implanted via the left IJV or the subclavian vein (SCV) during the period were excluded from the study. All 384 catheters implanted between April 2008 and June 2011 were 8-F valved SC catheters with an inner diameter of 1.5 mm (Gröshong X-port isp; Bard, UT, USA). Since July 2011, the catheters were 5-F open-ended PU catheters with an inner diameter of 1.1 mm (Anthrone P-U catheter; TORAY, Tokyo, Japan). Thus, all 221 catheters implanted between July 2011 and January 2014 were PU catheters.

Techniques for CV Catheter Implantation

Informed consent, including acknowledgment of the risk of catheter fracture, was obtained from patients before the procedure. The procedure was performed by an experienced interventional radiologist or a fellow or resident under the direct supervision of an experienced interventional radiologist.

The techniques for implanting the two types of catheters were quite similar. After a local anesthetic was administered, an 18-G needle was percutaneously inserted into the right IJV under ultrasonographic guidance. A 0.035-inch guide wire was then introduced into the right atrium using fluoroscopy, followed by a peelable sheath. Through the sheath, the CV catheter was advanced until its tip reached the superior vena cava (SVC), at which point the sheath was peeled away. A subcutaneous pocket was created for implanting the reservoir port in the right subclavian chest wall. Then, the catheter was passed from the venous puncture site to the pocket through the subcutaneous tissue using a metal tunneler. The catheter was connected to the port and flushed with heparinized saline. The port was sutured to the fascia and then the pocket was closed. Finally, a chest radiograph was obtained with the patient in a supine position. Oral administration of prophylactic antibiotic started on the day of the procedure and continued for three days.

The puncture level of the IJV, the level of the catheter tip within the SVC, or the location of port implantation at the subclavian region was not strictly determined and was left to the physician's judgment. After implantation, the CV catheters were used for administering chemotherapeutic agents or parenteral nutrition and were never used for administration of contrast medium with a power injector. Maintenance of the CV catheters was in accordance with the manufacture's recommendation. The CV catheters were removed when they caused complications, when they were no longer necessary, and/or when the patients requested

catheter removal.

Collection of Variables for Analyses

Variables possibly related to catheter fracture were evaluated. These included patient factors (sex, age, and body mass index), procedural factors (level of catheter insertion into the IJV, catheter tip position, angle of the catheter at the site of insertion into the IJV, and reservoir port position), and catheter factors (catheter type and catheter purpose).

Procedural factors were evaluated on the final chest radiograph during the procedure (Fig. 1). The site of catheter insertion into the IJV was deemed at the flexure of the catheter; the level of insertion was categorized into cervical or thoracic by using the center of the C7/Th1 disk as the borderline level. Catheter tip position was expressed as the distance between the carina and the catheter tip. When the tip was above or below the carina, the distance was expressed as a positive or negative value, respectively. Flexure of the catheter was expressed as the angle between the line that was cranially extended from the ascending part of the catheter and the line that was cranially extended from the descending part of the catheter. Reservoir port position was expressed as the distance measured between the clavicle and the port along the catheter.

Identification of Catheter Fracture

As soon as catheter malfunction or patient symptoms possibly related to the port system developed, the patient was referred to our department for fluoroscopic evaluation of

the port system. First, the catheter was evaluated to determine if there was total fracture (i.e., catheter transection). When total fracture was not demonstrated, contrast material was administered through the port. When leakage of contrast material along the catheter was demonstrated, partial fracture was diagnosed. In addition, total fracture was occasionally identified incidentally in asymptomatic patients by observation of follow-up chest radiographs.

Statistical Analysis

The percentage of fractures and the implantation period was compared between the two catheter groups with the chi-squares test and the Student *t*-test, respectively. In cases of fracture, the implantation period was measured from the date of implantation to the date when catheter fracture was diagnosed. While partial fracture was always noticed due to patient symptoms, total fracture could be identified incidentally on a chest radiograph. In cases of no fracture, the implantation period was measured from the date of implantation to the earlier date of either the last/latest date of a chest radiograph showing no transection of the catheter or the last/latest date of catheter use without symptoms.

Then, the above-mentioned variables were compared between the two catheter groups with the Fisher's exact or the chi-squared test for categorical values and the Student *t*-test for continuous values. The rates of fracture were then compared with the log-rank test between the two groups divided by each of the variables in order to determine the factors

associated with fracture. Catheter fracture was defined as a terminal event. Patient death, loss to follow-up of the patients, and removal of catheters without catheter fracture were considered censored.

Finally, in order to adjust for potential confounders, propensity-score matching was employed (see the Discussion). Propensity scores were calculated using a logistic regression model based on the variables other than catheter type. Propensity-score matching paired each subject from the SC catheter group with a subject from the PU catheter group, based on the similarity of their propensity scores. Greedy matching (or the so-called “nearest neighbor matching”) was used as the matching algorithm in this study. Using greedy matching, a subject is first selected at random from one group and subsequently paired with the subject in the other group with the closest propensity score [17]. One-to-one matching without replacement and caliper were performed. The variables were again compared between the two catheter groups using the propensity-score matched pairs, and the rates of fracture were compared between the two propensity-score matched catheter groups.

For all analyses, $P < .05$ was considered statistically significant. Analyses were performed using the Statistical Package for the Social Sciences (SPSS) software (version 22.0; IBM, Armonk, NY).

RESULTS

The median and mean implantation periods for all catheters were 223 days and 375 days, respectively. There were 16 cases of catheter fracture, for an overall fracture percentage of 2.6% (16/605). The incidence of fracture was 0.07/1000 catheter days. The median implantation period in the 16 cases of catheter fracture was 542 days (mean, 621 days; range, 10–1152 days). Nine and seven cases showed total and partial fracture, respectively. Twelve cases of partial or total fracture developed subcutaneous swelling, skin reddening and/or pain at the port or along the subcutaneous catheter tract. In the remaining four cases, total fracture was incidentally found by observation of a chest radiograph.

In 14 of 16 cases, the fracture was detected around the flexure of the catheter (i.e., at the site of insertion into the vein). In the remaining two cases, the fracture occurred at the catheter 2–3 cm from the reservoir port. In all cases of total fracture, the fractured catheter migrated into the right chamber of the heart, the pulmonary artery, or the coronary sinus. All migrated catheters with the exception of one that migrated into the coronary sinus were percutaneously removed using endovascular techniques. In the case of migration into the coronary sinus, we left the catheter in there because of a risk of injury of the coronary sinus possibly leading to cardiac tamponade during endovascular removal.

All 16 cases of fracture occurred in the SC catheter group. Thus, the percentage of fracture was 4.2% (16/384) and 0% (0/221) in the SC catheter group and the PU catheter group, respectively; the percentage of fracture was significantly ($P = .005$) higher in the SC

catheter group. The implantation period was significantly ($P < .001$) longer in the SC catheter group (mean, 425 days) than in the PU catheter group (mean, 278 days). The following variables were significantly different between the two catheter groups: insertion level of the catheter ($P < .001$), catheter tip position ($P < .001$), flexure angle of the catheter at the insertion site ($P < .001$), reservoir port position ($P < .001$), and catheter purpose ($P = .004$) (Table 1).

The log-rank tests to determine the factors associated with fracture showed that smaller patient body mass index ($P = .039$), deeper catheter tip position ($P = .022$), and the SC catheter ($P = .019$) were significantly associated with fracture (Table 2). The estimated fracture rates in the SC catheter group were 1.0% at 6 months, 2.2% at 12 months and 7.8% at 24 months, while those in the PU catheter group were all 0%. Thus, the rates of fracture in the SC catheter group were significantly ($P = .019$) higher than those in the PU catheter group.

With the greedy propensity-score matching method, 204 SC catheters and 41 PU catheters were excluded. Then, 180 cases were selected in each catheter group. No variable was significantly different between the two propensity-score matched catheter groups (Table 3). The estimated fracture rates in the SC catheter group were 1.5% at 6 months, 2.7% at 12 months, and 8.8% at 24 months; those in the PU catheter group were all 0% (Fig. 2); thus, the

rates of fracture in totally implanted venous access devices connected to the Groshong SC catheter were significantly ($P = .018$) higher than those in the PU catheter.

DISCUSSION

Wu et al. [8] retrospectively investigated fractures in 1507 implanted CV catheters, including four catheter types: 8.1-F PU catheters, 8-F SC catheters, 6.6-F PU catheters, and 6-F PU catheter. Most (1058/1507) implanted catheters were introduced into the SVC via the right cephalic vein with the cut-down method; the remaining catheters were introduced via the IJV, the SCV, and other veins. The percentage of fractures was 3.9% (59/1507). Multivariate analysis showed that female sex, catheters implanted via the SCV, and catheter type were independent risk factors for fracture. As for catheter type, the majority (86%, 51/59) of fractures occurred in 8.1-F PU catheters. Given that almost all (50/51) fracture of 8.1-F PU catheters occurred at the locking nut area, the authors attributed the fracture to a locking nut made of metal.

In our study, the SC catheter group showed higher percentage of fracture than did the PU catheter group. This result alone was not sufficient to show a greater risk of fracture for SC catheters, as the implantation period was longer in the SC catheter group. Thus, the rates of fracture were estimated, resulting in higher rates of fracture in the SC catheter group. However, this result obtained with univariate analysis was still insufficient to prove the

relationship between catheter type and fracture due to the presence of potential confounders.

In general survival analysis, a multivariate analysis, such as the Cox proportional hazards model, is used for minimizing the effects of potential confounders. However, we considered that such an analysis was not applicable to our cohort because of the absence of fracture in the PU catheter group, which interfered with the accurate estimation of hazard ratios and their *P* values.

Propensity-score matching is a statistical technique that matches potentially exchangeable patients on their propensity scores, which are defined as the probability of assignment to a particular intervention or exposure given a set of observed covariates (i.e., potential confounders). This technique was first published by Rosenbaum and Rubin in 1983 [17]. Using this technique, the causal effect of intervention or exposure by comparing health outcomes of matched pairs could be estimated. In this study, propensity-score matching successfully eliminated the differences in variables that were possibly related to fracture. With the propensity-score matching method, the SC catheter group still showed significantly higher fracture rates.

We located five previous studies [11–15] on SC versus PU implanted or non-implanted, peripherally or centrally inserted CV catheters. The results of the studies are summarized in Table 4. With respect to peripherally inserted CV catheters, a prospective randomized trial [11] showed a higher rate of rupture for SC catheters, but the difference was

not significant. A retrospective study [12] also showed a significantly higher rate of rupture for SC catheters. A systematic review [16] showed that fracture rates were almost identical although somewhat higher in SC catheters. With respect to centrally inserted CV catheters, two retrospective studies [13, 14] showed that SC catheters posed a significantly higher risk of fracture. In contrast, a prospective randomized study by Vandoni [15] indicated the opposite result. In their study, 10 of 13 fractures were caused by mechanical friction between the clavicle and the first rib (the so-called “pinch-off” syndrome [18]).

We assume that the risk of fracture may vary by the vein inserted and the material for the CV catheter. Thus, our study included CV catheters implanted via a specific vein and consisting of only one type of material for each catheter type. Our results suggest that the SC CV catheters implanted via the IJV posed a higher risk of fracture than did the PU catheters. SC rubber is inherently inferior in mechanical strength and abrasion resistance than is PU rubber. We assume that such characteristics of the material are substantially attributable to fracture. In addition to material, the size was different between the two catheter types. Considering the outer and inner diameters, the wall thicknesses of the SC and PU catheters were 0.6 mm and 0.3 mm, respectively. The SC catheters pose a greater risk of fracture despite having a wall twice as thick, which seems to support our assumption that the material weakness of the SC catheter is a substantial factor contributing to fracture. Another difference was the presence of a valve. The valve of the SC catheters is pressure-sensitive and does not

open until a certain positive pressure is provided, unlike the open-ended PU catheters. Thus, more positive pressure may be applied to the lumen of the SC catheter until the valve opens. However, we do not believe that the slight increase in pressure for a very limited time contributed to catheter fracture.

In terms of catheter fracture, the IJV route has advantages and disadvantages over the SCV route. The IJV route is associated with less angulation at the flexure of the catheter, leading to greater risk of catheter kinking [19, 20]. Further, more catheter movement is likely during rotation and flexion of the neck. We presume that the greater likelihood of kinking and more movement of the catheters via the IJV may cause fracture of the SC catheters with the material weakness. By contrast, the IJV route enables freedom from pinch-off syndrome, which may explain the different result between our study and the study by Vandoni et al. [15].

This study had several limitations. First, it had a retrospective design and lacked randomization. Another limitation was the potential for residual confounders. For example, the association of patient activity with fracture was not evaluated. However, patient activity was quite difficult to evaluate because this was a retrospective study and it was variable over time for patients who were nutritionally depleted or who had undergone chemotherapy for advanced cancer. Operator-induced bias (from interventional radiologists and catheter nurses) was not also evaluated because many operators participated in implantation and management of the catheters. All catheters were inserted via the IJV and only one product in each type of

catheter was evaluated in this study. Thus, our results may not be applicable to CV catheters implanted via other veins or products from other manufactures. For example, Balsorano et al. [21] evaluated the presence of fracture in 65 Gröshong SC catheters versus 273 Celsite SC catheters. They revealed that 12 (18%) Gröshong SC catheters had fracture, versus no fracture with the Celsite SC catheters. Thus, a risk of fracture of SC catheters may be variable depending on a product.

In conclusion, Groshong SC catheters implanted via the IJV posed a greater risk of fracture than did PU catheters, likely due to a material weakness.

Acknowledgements: none

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Table 1

Characteristics of silicone versus polyurethane catheters

			Silicone	Polyurethane	<i>P</i> Value
Sex	Male	<i>n</i>	199	100	.12
	Female	<i>n</i>	185	121	
Age (y)		Mean ± SD	59.5 ± 15.4	61.2 ± 14.5	.18
Body mass index (kg/m ²)		Mean ± SD	21.4 ± 4.1	21.6 ± 4.9	.57
Level of catheter insertion	Cervical	<i>n</i>	191	76	< .001*
	Thoracic	<i>n</i>	193	145	
Catheter tip position (mm)		Mean ± SD	-22.9 ± 17.4	-15.2 ± 14.1	< .001*
Angle of catheter (°)		Mean ± SD	49.6 ± 15.5	59.2 ± 14.7	< .001*
Reservoir port position (mm)		Mean ± SD	17.0 ± 12.3	11.8 ± 9.5	< .001*
Purpose of catheter	Chemotherapy	<i>n</i>	332	171	.004*
	Nutrition	<i>n</i>	52	50	

Note: SD = standard deviation.

*Statistically significant difference.

Table 1 legend

The following variables were significantly different between the two catheter groups: insertion level of the catheter ($P < .001$), catheter tip position ($P < .001$), flexure angle of the catheter at the insertion site ($P < .001$), reservoir port position ($P < .001$), and catheter purpose ($P = .004$).

Table 2

Fracture rates according to various variables

		<i>n</i>	Fracture rate (%)			<i>P</i> -value
			6 mo	12 mo	24 mo	
Sex	Male	299	0	0	6	.49
	Female	306	1.3	2.8	5.4	
Age (y)	<60	237	0.6	1.7	6.5	.67
	≥60	368	0.8	1.4	5	
Body mass index (kg/m ²)	<21	295	0.5	1.6	10.1	.039*
	≥21	310	0.8	1.5	1.5	
Level of catheter insertion	Cervical	267	1	1	4	.48
	Thoracic	338	0.5	1.9	7.1	
Catheter tip position (mm)	<-20	295	0.5	0.5	1.4	.022*
	≥-20	310	0.9	2.5	10.4	
Angle of catheter (°)	<50	224	1.3	2.4	7.1	.15
	≥50	381	0.3	0.9	4.6	
Reservoir port position (mm)	<15	316	0.9	1.6	7.9	.11
	≥15	289	0.5	1.4	3.6	
Catheter type	Silicone	384	1	2.2	7.8	.019*
	Polyurethane	221	0	0	0	
Purpose of catheter	Chemotherapy	503	0.7	1.6	5.2	.82
	Nutrition	102	0	0	14.3	

*Statistically significant difference.

Table 2 legend

The log-rank tests to determine the factors associated with fracture showed that smaller patient body mass index ($P = .039$), deeper catheter tip position ($P = .022$), and the SC catheter ($P = .019$) were significantly associated with fracture.

Table 3

Characteristics of silicone versus polyurethane catheters after propensity-score matching

			Silicone	Polyurethane	<i>P</i> -value
Sex	Male	<i>n</i>	83	85	.83
	Female	<i>n</i>	97	95	
Age (y)		Mean ± SD	61.0 ± 13.7	60.3 ± 14.7	.66
Body mass index (kg/m ²)		Mean ± SD	21.8 ± 4.2	21.7 ± 5.0	.80
Level of catheter insertion	Cervical	<i>n</i>	77	71	.52
	Thoracic	<i>n</i>	103	109	
Catheter tip position (mm)		Mean ± SD	-17.2 ± 14.8	-16.8 ± 13.6	.81
Angle of catheter (°)		Mean ± SD	56.3 ± 13.7	57.1 ± 14.8	.59
Reservoir port position (mm)		Mean ± SD	11.6 ± 9.5	12.6 ± 9.9	.35
Purpose of catheter	Chemotherapy	<i>n</i>	151	147	.58
	Nutrition	<i>n</i>	29	33	

Note: SD = standard deviation.

Table 3 legend

With the greedy propensity-score matching method, 204 SC catheters and 41 PU catheters were excluded. Then, 180 cases were selected in each catheter group. No variable was significantly different between the two propensity-score matched catheter groups.

Table 4

Summary of previous studies on fracture of silicone versus polyurethane central venous catheters

Authors	Study design	Catheter implantation	Inserted level (vein)	Outer diameter of catheter		Percentage of fracture		<i>P</i> -value
				Silicone	Polyurethane	Silicone	Polyurethane	
Ong et al. ^[11]	Prospective randomized	No	Peripherally inserted (midarm vein)	4-F	4-F	3.6% (7/194)	1.0% (2/198)	.10
Di Giacomo et al. ^[12]	Retrospective	No	Peripherally inserted (midarm vein)	5-F	5-F	20% (20/100)	0% (0/200)	<.001
Cohen et al. ^[13]	Retrospective	No	Centrally inserted (Mainly internal jugular vein)	10-F	10-F	8% (9/117)	0% (0/94)	.005
Hwang et al. ^[14]	Retrospective	No	Centrally inserted (internal jugular vein)	9.6-F or 10-F	9-F or 11-F	11.8% (60/509)	5.6% (12/215)	.011
Vandoni et al. ^[15]	Prospective randomized	Yes	Centrally inserted (subclavian vein)	8.4-F	5.7-F or 6-F	1.4% (1/74)	7.8% (12/154)	<.01

Table 4 legend

We located five previous studies on SC versus PU implanted or non-implanted, peripherally or centrally inserted CV catheters. The results of the studies are summarized.

Figure legends

Figure 1. Procedural factors possibly related to catheter fracture. The reservoir port position is expressed as the distance measured between the clavicle and the port along the catheter.

The catheter tip position is expressed as the distance between the carina and the catheter tip.

The flexure of the catheter is expressed as an angle between the line that is cranially extended from the ascending part of the catheter and the line that is cranially extended from the descending part of the catheter.

Figure 2. Propensity-score matched fracture rates of 180 silicone catheters versus 180 polyurethane catheters. The estimated rates of fracture for the silicone catheters were 1.5% at 6 months, 2.7% at 12 months, and 8.8% at 24 months; those of polyurethane catheters were all 0%. These differences were significantly different ($P = .018$).

Figure.1

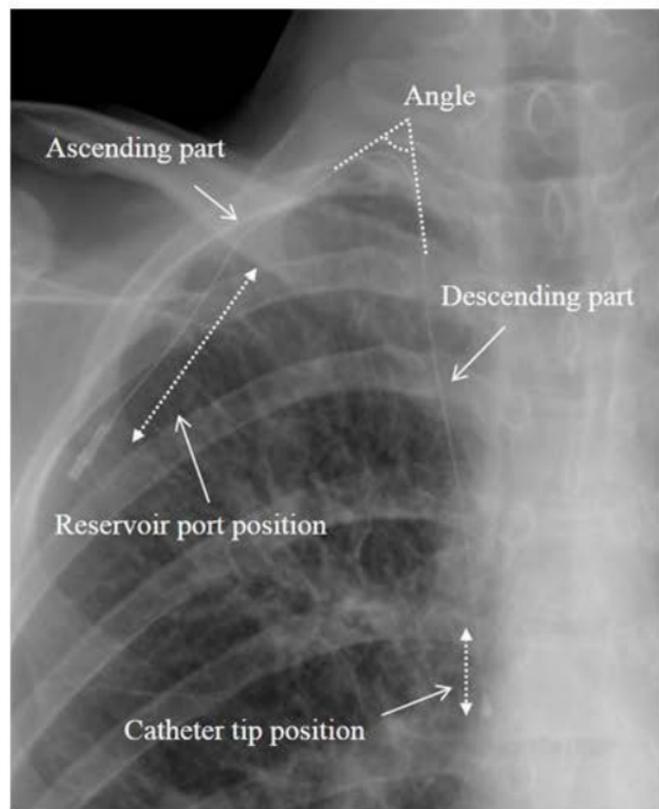
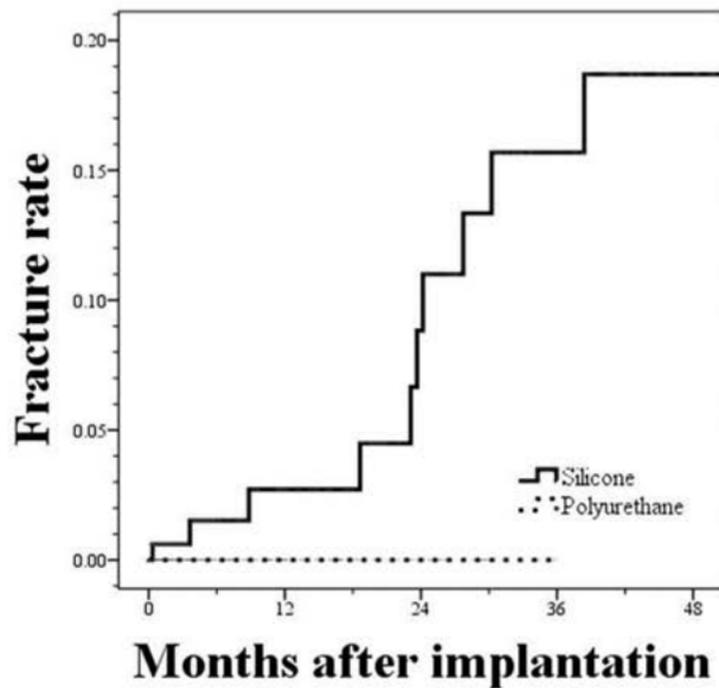


Figure.2



No. at Risk

Silicone

180

69

41

29

11

Polyurethane

180

55

21

0