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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard Implanted Port Catheter Products Liability Litigation	MDL No. 3081 **PLAINTIFFS' SUBMISSION OF CASES FOR BELLWETHER GROUP 1**

In accordance with Case Management Order Nos. 10 and 32, Plaintiffs submit this memorandum in support of their proposed cases for inclusion in Bellwether Group 1. Plaintiffs propose that the Court select the following six cases:

- *Cook, Robert* – No. 2:23cv1975 (infection), Defendants' pick
- *Divelbliss, Kimberly* – No. 2:23cv1627 (fracture), Plaintiffs' pick

- *James, Peter* – No. 2:23cv2669 (fracture), Plaintiffs' pick
- *Lattanzio, May* – No. 2:24cv0680 (infection), Plaintiffs' pick
- *Miller, Wanda* – No. 2:24cv0612 (thrombosis), Mutual pick
- *Sours, Jay* – No. 2:23cv1706 (infection), Plaintiffs' pick

Of the Discovery Group 1 cases, those six cases are most representative of the devices, failure modes, and injuries that are at issue in this MDL.

Plaintiffs' six selections represent a mix of three infection cases, two fracture cases, and one thrombosis case. The parties agreed in meet and confer discussions that representativeness necessitated selection of three infection cases. The parties also agreed in meet and confer that at least one fracture case and one thrombosis case should be selected. The real difference between the parties with respect to which mix of injuries should be tried is whether the sixth and final bellwether case should be a fracture case or a thrombosis case. Trying Plaintiffs' selections will provide the most comprehensive and broadly predictive information about the strengths and weaknesses of the varied claims and defenses in the inventory.

I. Representativeness is the *Sine Qua Non* of Effective Bellwether Trials.

The primary purpose of bellwether trials in multidistrict litigation is to produce meaningful insights into the strengths, weaknesses, and value of the various claims, defenses, and evidence in order to inform resolution of the broader pool of cases. *See In re E.I. du Pont de Nemours & Co. C-8 Pers. Inj. Litig.,* 54 F.4th 912, 919 n.3 (6th Cir. 2022) (bellwether trials "serve the twin goals of being informative indicators of future trends and catalysts for an ultimate resolution"); *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997) ("A bellwether trial [is] designed to achieve [a] value ascertainment function for settlement purposes or to answer troubling causation or liability issues common to the universe of claimants[.]"). For bellwether trials to fulfill that purpose, the cases chosen to serve as bellwethers must be "representative of the range of cases" in the MDL. Manual for Complex Litigation § 22.315 (4th ed. 2024); *Chevron*, 109 F.3d at 1019. Representativeness requires accurately capturing not just

the general device and injury categories in an MDL but also accounting for "substantively important" variables within those categories that may significantly impact and guide evidentiary issues, liability determinations, and damages measures throughout the inventory. *See* Fallon et al., *Bellwether Trials in Multidistrict Litigation*, 82 Tulane L. Rev. 2323, 2344-45 (2008) (explaining that a representative bellwether process focuses on "major variables" with "clear lines of demarcation" that address "the most predominant and important issues"). A bellwether selection process that "strays" from the "path" of representativeness "will likely resolve only a few independent cases and have a limited global impact." *Id*. at 2343.

II. The Parties Agree on the Representative Injury Composition for Five of the Six Cases in Bellwether Group 1.

Plaintiffs propose a mix of cases that will be most representative of the full range of devices, claims, and injuries at issue in this MDL. That proposed composition is: three infection cases, two fracture cases, and one thrombosis case. This composition, together with the specific individual plaintiffs whose cases are proposed as bellwethers in each category, offers a broader and more meaningful test of the key issues in this litigation than Defendants' proposals to date.

Defendants are in near agreement with Plaintiffs' proposed composition of injuries. In advance of this filing and in the days since the April 17, 2025 exchange of proposed bellwether trial lists, the parties met and conferred on multiple occasions. Although the parties did not reach complete agreement, they were able to reach agreement on the injury types that should be represented in *five* of the six trial cases.

First, the two sides agree there should be three infection cases in Bellwether Group 1. This is consistent with the prevalence of infection cases on the docket and the critical factual variations (such as patient characteristics, exposure and latency times, and injury severity) that may bear on liability, specific causation, and damages. The parties also agree that at least one fracture case should be included in Bellwether Group 1. Finally, the two sides agree that the *Wanda Miller* case, a thrombosis case, should be

included as well. The only remaining dispute regarding the general composition of Bellwether Group 1 is whether the sixth and final case should involve a second fracture case or thrombosis case.[1,2]

III. The Sixth Bellwether Group 1 Case Should be a Fracture Case.

To ensure a truly representative bellwether process that provides meaningful insights into the broader universe of cases—as opposed to repeated trials on the same narrow facts untethered to critical nuances in the inventory—Plaintiffs respectfully submit that the final case should be a fracture case.

Fracture cases are a key segment of the MDL docket and they include "substantively important" factual variables that necessitate at least two separate trial cases in order for the bellwether process to produce broadly informative verdicts. The most important issue for the Court to understand about fracture cases is the anatomical placement site of the implantable port catheter. The devices are placed via the subclavian vein or the internal jugular vein. Each approach features important, but distinct, risks

[1] Of the 11 total cases included in the parties' respective lists of proposed bellwether trials, there is only one additional thrombosis/occlusion case (*Hicks*, *Judy* Case No. 2:23-cv-1703), which was included in the Defendants' list; thus, Defendants advocate for the inclusion of that case, which Plaintiffs believe to be duplicative of the *Miller* case, and its selection would be to the exclusion of a second fracture case that would provide the Court and parties with key information about a fracture case featuring either subclavian placement or internal jugular placement, a key issue in this litigation.

[2] The plaintiffs final offer of compromise, which was declined by the Defendants, included three infection cases, two fracture cases and one thrombosis case. Of those six cases, four were included in the Defendants' proposed list of cases for inclusion in Bellwether Group 1 (including the case mutually selected by both sides) while only three were identified in the plaintiffs' list (again including the parties' mutual pick). Further, the proposal would have resulted in four of the six trial cases featuring a polyurethane catheter and two featuring a silicone catheter. Plaintiffs' proposed fracture cases, one of which was a selection by Plaintiffs and the other of Defendants, would have addressed subclavian placement and internal jugular placement, respectively. Finally, the plaintiffs' final proposal included at least one defense selection in each injury category.

and benefits. Defendants' own Instructions for Use ("IFUs") state that pinch-off[3] can occur with subclavian placement, not with internal jugular placement. Further, Defendants have repeatedly represented to regulators, physicians, and the public that catheter fractures occur primarily from pinch-off, which exclusively occurs with subclavian vein placements. At trial, Defendants will undoubtedly argue pinch-off as a defense in subclavian fracture cases, a defense they do not have in internal jugular cases (of which they notably selected none). Fractures following internal jugular vein placements, where pinch-off cannot occur, directly contradict Defendants' representations and are critical for the jury's evaluation of the defect and Defendants' warnings. Consequently, to accurately and fairly test the fracture claims, the bellwether pool must include at least two fracture cases: one involving an internal jugular placement and one involving a subclavian placement. Without representation of both placement types, any mix of cases would fail to capture the full scope of one of the most predominant and important issues in this MDL.

To ensure a comprehensive and fair analysis of this critical issue unique to the fracture cases, Plaintiffs nominated one case featuring placement of the port catheter via the subclavian vein and the other via the internal jugular vein. In short, Plaintiffs took care to select cases that were most representative of the litigation as a whole.

With respect to any distinction between silicone and polyurethane catheter materials, Plaintiffs' factual and legal theories apply to both materials. Both materials induce the same interrelated biological reactions that cause thrombosis and infection. Both materials are susceptible to fracture. And both materials could have been made safer with essentially the same alternative designs—*e.g.*, anti-fouling and/or antimicrobial technologies to reduce the occurrence of thrombosis and infection,

[3] Pinch-off or pinch-off syndrome occurs, only in subclavian placement, when the catheter is compressed between the clavicle and first rib, potentially leading to blockage or even fracture of the catheter. Defendants' Instructions for Use for the products at issue make specific mention of pinch-off syndrome and set forth information regarding how the implanting physician can avoid the same, which Plaintiffs claim is inadequate.

reinforcement for fracture, and stronger warnings. Indeed, no matter the catheter material, infection and thrombosis are so interrelated in terms of pathogenesis and prevention that jury verdicts in infection cases will have some application to and be instructive in thrombosis cases, and vice versa.

Defendants cannot easily win a case on either catheter material, which is likely why they selected *only* polyurethane cases. As brief background, in the lead up to the filing of this Memorandum, and as ordered by the Court in Case Management Order No. 32, the parties exchanged lists of six cases for inclusion in Bellwether Group 1 on April 17, 2025. Of those six cases, Plaintiffs proposed three cases involving silicone catheters (which includes Groshong) and three involving polyurethane catheters (also known as ChronoFlex). Defendants' choices were all polyurethane. And Defendants' sole fracture case featured subclavian placement of the device, meaning Defendants did not propose a fracture case featuring placement via the internal jugular vein, the type of fracture case in which Defendants are without a potential pinch-off defense.

From a representativeness standpoint, Defendants proposed approach of selecting *only* polyurethane cases is particularly problematic for evaluating the fracture inventory because it is empirically well-established that fracture occurs at a much higher rate with silicone port catheters than with polyurethane. *See*, *e.g.*, Ex. A, Balsorano et al., *Fractures of totally implantable central venous ports: more than fortuity. A three-year single center experience*, 15(5) J. of Vascular Access 391 (2014) (18.5% Groshong fracture rate); Ex. B, Hwang et al., *Tunneled Infusion Catheter Breakage: Frequency and Repair Kit Outcomes*, 19 J. of Vascular & Interventional Radiology 201 (2008) (fracture rate of 11.78% for Bard silicone catheters versus 5.58% for standard polyurethane).

Thrombosis cases, on the other hand, only require a single trial to accomplish the aims of the bellwether process. There are only two potential thrombosis cases in Discovery Group 1, the parties agree on one (*Miller*), and Defendants selected the only other (*Hicks*). Trying both cases would provide little information because the cases are

essentially the same. Indeed, case-specific discovery has shown the two cases are factually indistinguishable in all "substantively important" respects—both involve ChronoFlex catheters, both involve a more than 12-month latency period, and both resulted in blood clots that occluded the plaintiff's catheter and disrupted her primary care. Because of this significant factual overlap, trying both cases will produce largely duplicative information, as the second trial will teach little beyond the first. Given the limited number of bellwether trials set to occur in this MDL, the opportunity costs of trying materially identical thrombosis cases is far too great——critical substantive variables in the fracture inventory will go ignored and the finite resources of the parties and the Court will be diverted from other more broadly informative measures of merit and value, thus undermining the purposes of multidistrict litigation.

Thrombosis cases are also different because of their significant scientific overlap with infection cases. Again, the same biological mechanisms that cause thrombosis are triggering events for infection, and vice versa, and the safer alternative designs relevant to preventing infections—specifically, antimicrobial and antifouling surface modifications—also directly address the pathogenesis of thrombosis and occlusion. Scientific and clinical evidence demonstrates that antifouling technologies, by preventing protein adhesion, not only reduce bacterial colonization (the precursor to infection) but also reduce fibrin and platelet accumulation (the precursor to thrombosis and occlusion). Thus, safer alternatives for infection prevention inherently overlap with thrombosis and occlusion prevention, making infection cases uniquely valuable for testing multiple claims at once. In other words, jury verdicts in the three infection cases will provide meaningful guidance in thrombosis cases. Not so with fracture cases, which involve distinct warning and design defects and rely on fundamentally different safer alternative designs focused on improving catheter strength, flexibility, and resistance to mechanical degradation.

For these reasons, Bellwether Group 1 should be comprised of three infection cases, two fracture cases, and one thrombosis case. Plaintiffs' proposed bellwether

selections are better aligned with the issues central to the litigation and will more effectively serve the purpose of the bellwether process—providing meaningful information about the strengths and weaknesses of the claims and defenses across the broad spectrum of cases.

IV. Plaintiffs' Proposed Cases

Consistent with the above and foregoing, Plaintiffs propose that Bellwether Group 1 be comprised of the following cases[4]:

A. *Robert Cook – Infection*

Robert Cook is 46 years old and resides in Minnesota. On August 24, 2022, he underwent internal jugular placement of a Bard PowerPort MRI Implantable Port, which was paired with a ChronoFlex catheter, for chemotherapy administration at the Mayo Clinic. On September 3, 2022, he was diagnosed with a catheter-related blood stream infection that escalated to sepsis and required a six-day hospitalization, IV antibiotics, and removal of his port catheter, all of which delayed his chemotherapy treatment and caused emotional distress, among other things.

Mr. Cook's case is a compromise selection for Plaintiffs. It is true Mr. Cook's case was nominated by each side for inclusion in PFS/DFS Group 1 in July 2024. In December 2024, Defendants proposed it for inclusion in Discovery Group 1 and Plaintiffs eventually agreed for purposes of reaching a compromise on the agreed upon list of 15 cases advanced in this process at that time. Most recently, this case was included only on the Defendants' list of proposed cases for Bellwether Group 1. Thus, this is Defense selection and Plaintiffs, in the spirit of cooperation, are willing to agree to its inclusion in Bellwether Group 1. Further, Plaintiffs agree this case is representative of short-latency infection cases in this MDL—that is, cases in which the plaintiff's port catheter caused an infection within days or weeks of implantation—which is a

[4] Even at this point, Plaintiffs remain willing to make compromise selections in order to arrive at a truly representative group of cases in Bellwether Group 1. To that end, Plaintiffs' list, as stated herein, includes one mutual selection, one defense selection and four Plaintiffs' selections.

substantively important variable in a core dispute over the merits of the parties' causation arguments across varying timelines.

B. *Kimberly Divelbless – Fracture*

Kimberly Divelbless is 54 years old and resides in New Mexico. Ms. Divelbliss has had multiple implanted port catheters, due to her need for infusion of intravenous immunoglobulin due to a diagnosis of common variable immunodeficiency disease. The device at issue in this case was a PowerPort Implantable Port Groshong Catheter (silicone) that was placed via her subclavian vein for intravenous immunoglobulin infusions on July 13, 2017. On December 13, 2019, a catheter fracture with embolization of a catheter fragment to the right atrium was diagnosed and the Bard port catheter removed on December 16, 2019. Based on the opinion of her treating cardiologist, that led to a non-ST-segment elevation myocardial infarction ("NSTEMI") and permanent cardiac damage. The offending device had to be removed immediately, and she has undergone multiple cardiac ablation procedures, as well as placement of a pacemaker, to treat the consequences of the permanent cardiac damage she has experienced. She continues to experience chest pain, arrhythmias, and palpations attributable to the catheter failure/fragment and requires ongoing, medically necessary treatments for her significant catheter-related conditions.

Plaintiffs propose Ms. Divelbliss's case as a bellwether because it is representative of the fracture cases involving subclavian placement of an implantable port catheter. That is a key subset of fracture cases because Defendants intend to defend most, if not all, fracture cases involving subclavian placement by claiming such occurred as a result of pinch-off syndrome or substandard care on the part of the implanting physician rather than any defect with the device. Such cases also raise the key issue of the adequacy of Defendants' warnings to implanting physicians and patients alike with regard to subclavian placement/pinch-off Additionally, this is a case involving a plaintiff who has had multiple implantable port catheters placed, which remained for varying lengths of time, all of which is representative of multiple plaintiffs in this

litigation. Finally, this case features significant, ongoing economic and non-economic damages and not only is Ms. Divelbliss entitled to her day in Court regarding the same, but a verdict in her case would provide tremendous guidance to all parties with regard to the value of significant-damage and injury cases like this one.

C. *Peter James – Fracture*

Peter James is 72 years old and resides in New York. On September 20, 2017, Mr. James underwent internal jugular placement of a PowerPort isp MRI Implantable Port (paired with a silicone catheter), for chemotherapy administration. On December 27, 2021, a catheter fracture with migration of fragments to his right atrium and right ventricle was diagnosed, which necessitated femoral retrieval of the fragments and removal of the implanted port catheter. Mr. James currently experiences pain, disfigurement, and scarring at the implant site, as well as emotional distress.

Plaintiffs propose Mr. James's case as a bellwether because it is representative of the other, essential segment of fracture cases, meaning those involving internal jugular placement. Given that many cases in this MDL feature internal jugular vein placement and the critical dispute about the extent to which port catheters fracture in the absence of pinch-off, which again, only occurs with subclavian placements, a jury's assessment of the merits of an internal jugular case involving fracture will be important to the resolution of this litigation.

D. *May Lattanzio – Infection*

May Lattanzio is 81 years old and resides in Florida. On August 16, 2013, Ms. Lattanzio underwent subclavian placement of a PowerPort MRI Implantable Port, paired with a silicone catheter, for chemotherapy administration. Approximately four months later, she was diagnosed with sepsis caused by her implanted port catheter, which required hospitalization, antibiotic therapy, and removal of the device, which occurred on December 13, 2013. Ms. Lattanzio also developed scarring and bulging of her brachial vein after it had to be used as an alternative site for the intravenous administration of chemotherapy.

Plaintiffs propose Ms. Lattanzio's case as a bellwether trial because it is representative of numerous infection cases filed and to be filed in this MDL. Moderate-latency cases, like Ms. Lattanzio's, are common infection in the litigation and thus a trial in her case will provide relevant jury feedback that will be useful in the future during efforts to resolve cases with that similar characteristic.

E. *Wanda Miller – Thrombosis*

As discussed above, Wanda Miller's case is the only mutual selection on the parties' respective Bellwether Group 1 lists.

Ms. Miller is 73 years old and resides in Pennsylvania. On January 29, 2021, she underwent subclavian placement of a Bard X-Port Duo MRI Implantable Port (paired with a ChronoFlex catheter) for chemotherapy administration. Approximately two years later, she was diagnosed with right atrial thrombus, which necessitated treatment with IV heparin and Lovenox injections (twice daily for multiple weeks), followed by Pradaxa (a long-term oral anticoagulant). Ms. Miller's device was subsequently removed; however, she remains at increased risk of future injury and now suffers ongoing fear and anxiety as a result of this experience.

Given the mutual selection of this case, by the two sides, Plaintiffs believe this case should be included in Bellwether Group 1. And, Plaintiffs believe the inclusion of this case is all that is necessary with regard to thrombosis cases in Bellwether Group 1. It was selected by both sides and adequately represents the thrombosis cases on file in this litigation.

F. *Jay Sours – Infection*

Jay Sours is 72 years old and resides in Illinois. On July 2, 2019, Mr. Sours underwent internal jugular placement of a PowerPort isp MRI Implantable Port, paired with a silicone catheter, for immunoglobulin infusions in treatment of chronic inflammatory demyelinating polyneuritis. On March 24, 2022, he was diagnosed with a cather-related blood stream infection ("CRBSI") that led to sepsis, osteomyelitis, and even a septic right knee. Those conditions required hospitalization, antibiotics, and

removal of his implanted port catheter. Pus was detected in the port pocket at the time of explant. Mr. Sours continues to experience pain and limited mobility of the lower back, hip, and right knee as a result of his CRBSI.

Plaintiffs propose Mr. Sours's case as a bellwether trial because it, too, is representative of a substantial portion of infection cases in this MDL. Because of the longer latency period, a bellwether trial in Mr. Sours's case will enable the parties to test the outer temporal limits of their respective causation theories. If liability is established, the litigation would also benefit from a jury's valuation of a CRBSI case involving severe injuries and damages such as those suffered by Mr. Sours.

V. Conclusion

Based on the foregoing, Plaintiffs respectfully request that the Court select the following cases for Bellwether Group 1:

- *Cook, Robert* – No. 2:23cv1975 (infection)
- *Divelbliss, Kimberly* – No. 2:23cv1627 (fracture)
- *James, Peter* – No. 2:23cv2669 (fracture)
- *Lattanzio, May* – No. 2:24cv0680 (infection)
- *Miller, Wanda* – No. 2:24cv0612 (thrombosis)
- *Sours, Jay* – No. 2:23cv1706 (infection)

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on April 28, 2025, a true and correct copy of the foregoing pleading was filed electronically through the CM/ECF system, which will send notice of filing to all CM/ECF participants.

/s/ Rebecca L. Phillips
Rebecca L. Phillips

EXHIBIT A

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ORIGINAL ARTICLE

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

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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**

Accepted: March 13, 2014

INTRODUCTION

Long-term vascular accesses are often required in patients undergoing chemotherapy, total parenteral nutrition and/or long-term antibiotic treatment. Totally implantable venous access devices (Ports) represent the mainstay for infusion therapy in these settings and many studies have demonstrated their safety and reliability (1-6). Amongst the possible late mechanical complications, lesions of the catheter wall represent a rare but potentially severe condition, whose natural history can vary from a partial rupture—asymptomatic or associated with catheter malfunction—up to a complete catheter fracture with embolization of the ruptured fragment. Risk factors for catheter rupture have been poorly investigated, though some attempts have been made to correlate such complication with the type of device, its site of placement, the duration of catheter use, etc. (7-10). Unfortunately, it is difficult to investigate the natural history of damage to the catheter wall; partial ruptures can be viewed as the beginning for more serious events, such as catheter fracture and embolization, or may be clinically silent and remain undiagnosed.

The objective of this study was to investigate the incidence and risk factors for catheter ruptures in a series of ports removed for complications or end of use.

MATERIALS AND METHODS

All ports removed at our institution from January 2011 to June 2013 were considered. All removed ports had been inserted over a period ranging from February 2007 to May 2013, according to a standardized protocol including ultrasound-guided percutaneous venipuncture (out-of-plane or in-plane approaches) and electrocardiogram-guided positioning of the tip.

Removal of ports was carried out in the operating room, under local anesthesia with ropivacaine 0.75% (10 mL). An incision was performed on the skin in the area over the port chamber. Then the chamber was isolated by dissection of the surrounding tissues. The tissues around the catheter were dissected and the catheter was slowly pulled out. Once removed, each catheter was checked by inspection and saline instillation so as to evaluate the integrity of the device itself and rule out possible ruptures.

Data were collected in a database which was prospectively created and progressively updated by the operators who inserted and removed catheters. Recorded parameters included age, sex, disease, date of insertion and intraprocedural complications. Variables regarding the insertion technique were also registered, including insertion site (right vs left; innominate vein vs internal jugular vein (IJV)), catheter diameter (Fr), catheter material, tip configuration (open tip vs Groshong valve tip) and type of ultrasound guidance approach (out-of-plane vs in-plane).

Metric data were tested for normal distribution with the Kolmogorov-Smirnov test. An unpaired *t*-test was used to compare variables between groups of patients. A χ^2 test was performed when appropriate. Odds ratios for different parameters were calculated. Statistical significance was set at two-side $p<0.05$.

RESULTS

Over the considered period, 338 ports were removed: 273 ports with silicon open-ended catheters (Celsite port, BBraun, Melsungen AG, Germany) and 65 ports with silicon closed-ended, Groshong-valved catheter (Groshong port, Bard Access, Bard, Salt Lake, US). All open-ended catheters had been inserted via an "in-plane" approach, while 51 out of 65 (78%) Groshong-valved catheter had been inserted via an "out-of-plane" approach.

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' demographic and clinical data, site of insertion, type of device and ultrasound technique of fractured ports are reported in Tables I and II.

As mentioned, all fractured catheters were Groshong catheters (silicon, closed tip with Groshong valve). In all cases, the site of catheter rupture was at the entry point through the vein wall. All fractured catheters had been inserted in the IJV, via an "out-of-plane" approach.

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). Results are shown in Table III.

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.

DISCUSSION

Rupture of the catheter connected to a port is a rare but potentially severe complication. Lin et al (7) reported rates of port rupture of 2.17%; in their study all ports had been inserted in the subclavian vein, and the most common site of fracture was located at the junction between the injection port and the catheter. In the medical literature, the incidence and magnitude of catheter ruptures are extremely variable, covering a wide spectrum of clinical situations which include asymptomatic ruptures, catheter malfunctions, pinch-off syndrome, full fracture with intravascular embolization of a catheter fragment (11-20). At any case, the natural history of a catheter rupture cannot be predicted, and any

TABLE I - PATIENTS AND RUPTURED PORT DATA

Ruptured catheters, n (% of total)	12 (3.55)
Sex (M/F)	5/7
Mean age (yrs) (SD)	59.3 (11.1)
Disease (% of fractured ports)	
Breast cancer	5 (41)
Lung cancer	1 (8)
Gastrointestinal cancer	4 (33)
Sarcoma	1 (8)
Non-Hodgkin lymphoma	1 (8)
Cause of removal	
End of use	6 (50)
Bloodstream infection	1 (8)
Catheter occlusion	3 (25)
Extravasation	2 (16)
Site of insertion	
Right internal jugular vein	11 (92)
Left internal jugular vein	1 (8)

TABLE II - RUPTURED PORT DATA

Patient	Site of insertion	Site of fracture	Catheter days	Ultrasound approach	Type of port
1	Right IJV	13.5 cm	589	Out-of-plane	Groshong port
2	Right IJV	14.5 cm	1,080	Out-of-plane	Groshong port
3	Right IJV	14 cm	1,860	Out-of-plane	Groshong port
4	Left IJV	16.5 cm	1,705	Out-of-plane	Groshong port
5	Right IJV	15 cm	1,116	Out-of-plane	Groshong port
6	Right IJV	15 cm	1,488	Out-of-plane	Groshong port
7	Right IJV	14 cm	992	Out-of-plane	Groshong port
8	Right IJV	15 cm	1,023	Out-of-plane	Groshong port
9	Right IJV	15 cm	990	Out-of-plane	Groshong port
10	Right IJV	14 cm	1,123	Out-of-plane	Groshong port
11	Right IJV	13 cm	1,842	Out-of-plane	Groshong port
12	Right IJV	12.5-13-13.5-14.5 cm	1,792	Out-of-plane	Groshong port

IJV = internal jugular vein.

TABLE III - RISK FACTORS FOR PORT RUPTURE

	n (ruptured/total)	%	Odds ratio (95% CI)	p
Site of insertion				
Right internal jugular vein	11/270	4	2.84 (0.36-22.43)	0.32
Left internal jugular vein	1/68	1.4		
Sex				
Male	5/89	5.5	2.05 (0.63-6.65)	0.22
Female	7/249	2.8		
Mean age (yrs)				
Ruptured	59.3			0.76
Nonruptured	60.1			
Type of ports				
Groshong tip (BARD)	12/65	18.5	127.8 (7.45-2,191.6)	0.0008
Open tip (Celsite, BBraun)	0/273	0		
Ultrasound approach				
Out-of-plane	12/51	23.5	181.9 (10.56-3,133.94)	0.0003
In-plane	0/287	0		

CI = confidence interval.

lesion of the catheter wall could be considered as a clinically nonrelevant phenomenon or as a starting point for a more extensive and full fracture, which can result in severe complications.

In our series, we identified three key features common to all ruptures: the type of catheter (closed tip, silicon Groshong catheters), the site of the lesion (entry point into the vein wall) and the type of ultrasound approach ("out-of-plane" puncture of the IJV). Closed-tip silicon Groshong catheters and out-of-plane ultrasound approach were statistically significant risk factors for catheter ruptures (p=0.0008 and 0.0003, respectively).

Silicon catheters can only tolerate pressures up to 50-60 psi, and silicon peripherally inserted central catheters

(PICCs) are known to be associated with a higher risk of rupture if compared to polyurethane PICCs (21-25). Pressures developed by peristaltic pumps commonly used for chemotherapy administration in oncologic patients may exceed 50 psi, but it is questionable whether such high pressures might reach the catheter itself, considering the "bottleneck" effect of the Huber needle and of the reservoir (26). On the other hand, the pulse of the peristaltic pumps could exert a chronic mechanical stress, resulting in damage to the most vulnerable portion of the catheter wall. In this sense, the entry through the vein wall may represent the point of maximal catheter angulation, which generates maximal resistance to flow, as well as the site of maximal mechanical tension. This is in contrast with previous series, where the most common site of fracture is reported at the junction between the injection port and the catheter (7, 14); in this sense, these different fracture sites could refer to different kinds of lesions, each with its own risk factor. Furthermore, "out-of-plane" ultrasound-guided puncture of the IJV is invariably associated with a more vertical pathway and a narrower angle at the entry point into the vein wall. All these factors could have played an important role in determining the observed lesions.

An interesting issue is that more than 50% of fractured ports were clinically asymptomatic, and catheter lesions were accidental findings during scheduled port removal. This confirms the fact that the natural history of the catheter damage cannot be adequately predicted, and the risk that these asymptomatic fractures might lead to more severe events cannot be excluded. In other words, the real incidence of catheter rupture cannot be easily estimated, because many of these ruptures are compatible with a well-functioning port.

The obvious limit of our study is that we cannot speculate about how many of such ruptures were clinically relevant (i.e., how many of such ruptures would have developed into a complete fracture with embolization of a catheter fragment). Also, our incidence of ruptures (12 out of 338) might not be accurate, since we might have missed some catheter ruptures of ports inserted at our hospital but not yet removed or removed in other institutions.

However, some final considerations might be offered. First, the actual advantage of using ports connected with Groshong silicon catheters should be questioned, since such catheters are more expensive and, according to our data, more fragile than standard catheters. Furthermore, ultrasound-guided "out-of-plane" puncture of the IJV should be discouraged: "in-plane" ultrasound-guided puncture of the IJV or of the innominate vein appears to be safer, both in terms of insertion complications (i.e., no risk of accidental arterial puncture) and in terms of a more favorable angle of the catheter at the entrance into the vein. Given our patients' series, out-of-plane puncture of the IJV represented a statistically significant risk factor for catheter rupture. However, an important limitation of our study was the lack of randomization when the catheter was placed.

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EXHIBIT B

Tunneled Infusion Catheter Breakage: Frequency and Repair Kit Outcomes

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PURPOSE: To determine the frequency of tunneled infusion catheter breakage and the durability of a repair kit used to repair damage to the external catheter segment, avoiding catheter replacement.

MATERIALS AND METHODS: With use of a quality assurance database, 724 silicone tunneled infusion catheters placed between July 2002 and September 2005 were identified. The repair kit outcomes portion of the study focused on 10-F triple-lumen catheters ($n = 433$), the type placed most frequently in our practice and that with the most repairs available for analysis. To compare durability, nonrepaired catheters and those requiring repair were compared by using Cox proportion hazard regression.

RESULTS: Breakage occurred in 53 of 443 (12%) 10-F triple-lumen catheters, three of 64 (5%) 10-F dual-lumen catheters, four of 159 (3%) 11-F triple-lumen catheters, four of 12 (33%) 9.6-F single-lumen catheters, and eight of 56 (14%) 9-F double-lumen catheters. In the 10-F subset, the mean time to catheter breakage was 60 days. The mean catheter days for the nonrepaired group (143 days) and the repaired group (145 days) were not significantly different (χ^2, 0.071; hazard ratio, 1.07; $P = .79$). Mean catheter dwell after repair was 79 days. The failure rate for the repair kit was 14% (seven of 51 attempts).

CONCLUSIONS: Tunneled infusion catheter breakage is common. Given the high breakage rates observed for many catheter designs, the development of more durable catheters should be a priority for catheter manufacturers. Until more durable catheters are developed, the catheter repair kit studied is an easy, effective, durable, and relatively inexpensive solution for the repair of external segment damage in tunneled infusion catheters.

J Vasc Interv Radiol 2008; 19:201–206

Abbreviation: t-PA = tissue-type plasminogen activator

TUNNELED infusion catheters have brought great benefit and convenience in the delivery of modern medical treatments such as chemotherapy and total parenteral nutrition. Like most medical devices, however, tunneled infusion catheters are not without problems, including occlusion, catheter fracture, catheter obstruction, infection, and venous thrombosis (1–6). These complications can range from nuisances that interrupt care to life-threatening events.

Catheter fracture is an event that is not typically life-threatening, provided it is recognized and treated. However, catheter fracture can interfere with the delivery of therapy, depending to some extent on the degree of damage. In addition, a fractured catheter poses a risk of hemorrhage and air embolus; thus, damaged catheters must be removed or repaired. Damage may occur anywhere along a catheter but most commonly occurs in the external portion. Some catheter manufacturers sell repair kits to fix such damage. If an appropriate length of the external catheter remains, the damaged portion of the catheter can be cut off, and a new hub can be attached to enable the continued use of the same catheter. This process is easy to learn and takes no longer than 15 minutes when performed by an experienced individual.

Although catheter repair kits are in widespread use, a literature search revealed only one case report describing the process without follow-up (7) and a report of repair kit outcomes for peritoneal catheters in a small group of patients ($n = 7$) (8). The purpose of this study was to determine the efficacy of one brand of repair kit for tunneled infusion catheters in terms of immediate and long-term outcomes.

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Table 1
Breakage Rates According to Catheter Design

Type of Catheter	No. of Catheters Placed	No. of Broken Catheters	No. of Catheters Repaired	No. of Repairs Performed
10-F triple lumen	433	53 (12.2)	48 (90)	51
10-F dual lumen	64	3 (4.7)	1 (33)	1
11-F triple lumen	159	4 (2.5)	1 (25)	1
9.6-F single lumen	12	4 (33)	4 (100)	5
9-F dual lumen	56	8 (14)	4 (50)	4

Note.—Numbers in parentheses are percentages.

Furthermore, we sought to determine the frequency of catheter damage for various types of tunneled infusion catheters in use in our institution.

MATERIALS AND METHODS

Institutional review board approval and Health Insurance Portability and Accountability Act waiver were received for this retrospective study. The data were obtained from a prospectively created quality assurance database (Hi-IQ; Conexys, Woonsocket, RI) maintained for patients receiving tunneled central venous catheters in our institution. All catheters undergoing repair during the period studied were included. The catheters were placed by either an attending interventional radiologist with 1–20 years experience in venous access procedures or an interventional radiology fellow or resident under the supervision of an attending interventional radiologist. Catheters were placed according to published technique (9,10). Strict sterile technique was observed at all times. Prophylactic antibiotics were not administered, per published recommendations (6). All catheters were placed with use of real-time ultrasonographic guidance for jugular venipuncture with a 21-guage needle and coaxial introducer system (Micropuncture; Cook, Bloomington, Ind) and with fluoroscopic guidance for catheter placement and tip positioning. Catheters used included 9-F dual-lumen and 11-F triple-lumen polyurethane infusion catheters (Ventra; Deltec, St Paul, Minn) and 9.6-F single-lumen, 10-F dual-lumen, and 10-F triple-lumen silicone infusion catheters (Hickman; Bard Access Systems, Salt Lake City, Utah). Catheters were secured with 2-0 nylon suture until cuff incorporation or removal.

Postoperative care included daily flush with 10 mL of normal saline and 5 mL of heparin lock daily (100 U/mL) when not in use. Nurses were instructed to use syringes no smaller than 10 mL during flush. Damaged catheters were clamped with a hemostat or similar device between the damaged portion and the patient until repair could be performed to avoid hemorrhage or air embolus; if the damage was to only one extension of a multilumen catheter, the clamp was placed on the damaged extension only and the use of the remaining lumens continued until repair was performed. In general, repairs were performed the same day for completely unusable catheters and the same or next day for partially usable catheters (eg, those with only a single extension damaged).

All catheters with damage to an external segment were included in the initial analysis. The exact location of damage was not always recorded, nor was the suspected cause of damage (flushing-related, traction on the catheter, scissors during dressing repair, etc) consistently available (see Discussion). Damage included holes in the external segment, frank rupture or tear, transection, and hub breakage. Damage to the tunneled or intravascular segment cannot be repaired with the kit and was technically excluded; however, during the study period no catheter was exchanged or removed for such damage. Data collected included date of placement, indication for catheterization, type of catheter, site of catheterization, modality for localization of vein, initial complication, late complication, date of catheter removal, reason for removal, and number of catheter days. Patient age was not collected as part of the quality assurance program; all patients were adults older than 18 years.

A total of 724 tunneled infusion catheters were placed in 611 patients in our department during the study period. During the course of the study, 433 10-F triple-lumen catheters were placed in 355 patients. There were 53 broken catheters (12%), of which 48 (91%) had a total of 51 repair attempts (ie, three were repaired twice) by using an external segment repair kit (Hickman Catheter Repair Kit; Bard Access Systems) (**Table 1**). The repair kits were composed of an external catheter segment (single, dual, or triple lumen), povidone-iodine swabs, atraumatic clamp, scalpel, surgical mask, sterile gown, sterile gloves, sterile drape, syringe, and adhesive. All catheters repaired in this study were made of silicone. For all catheter repairs, the manufacturer's instructions were followed with slight variation. Repairs were done in the interventional radiology recovery room or at bedside. In brief, under sterile conditions with the operator wearing the cap, mask, gown, and gloves, the catheter was atraumatically clamped just central to the breakage site. The catheter was cut just central (ie, on the patient side) to the breakage site or just central to the extension hub if one of the extensions was broken. The extension apparatus was discarded. The new extension, flushed and clamps applied, was fitted to the remaining portion of the catheter by using the metal cannulae (**Figs 1** and **2**). The silicone sleeve was passed over the repair site and silicone adhesive applied to the inner surface of the sleeve from both ends by using the supplied cannula, taking care to fully encircle the catheter. In most cases, a 2-0 silk suture was passed around each end of the silicone sleeve to make the repair

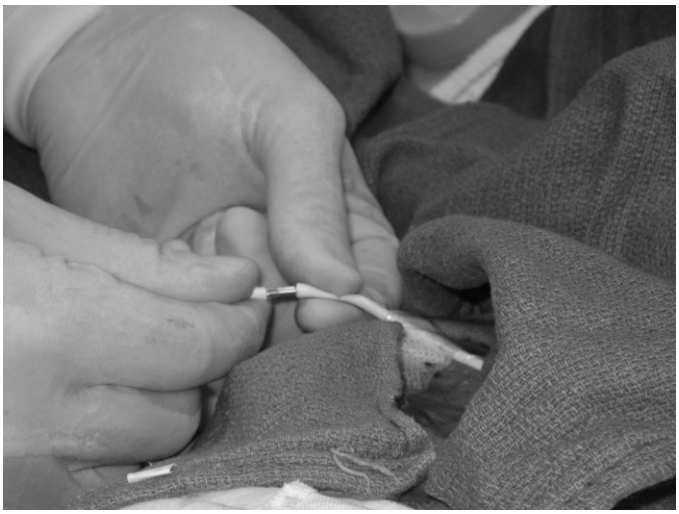

Figure 1. The new extension is connected to the remaining catheter segment by inserting the metal cannula into the appropriate lumens.

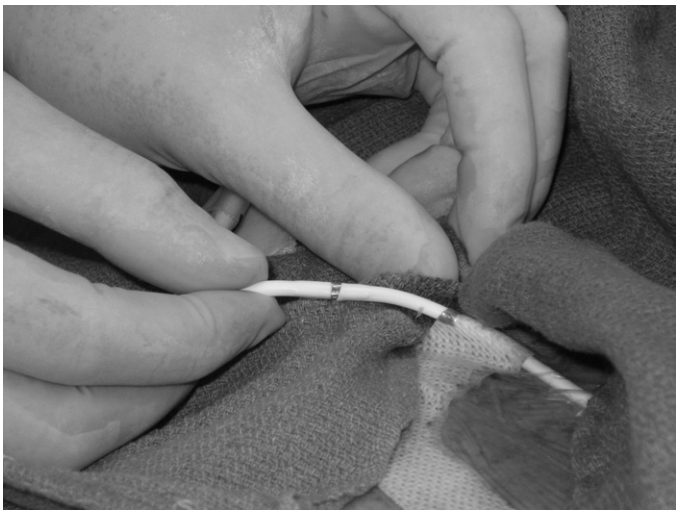

Figure 2. The cannula is fully inserted. Note that the short gap between catheter segments is normal.

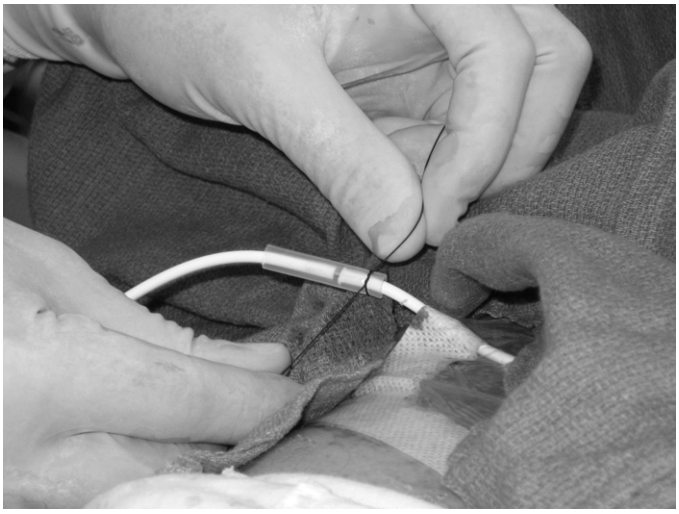

Figure 3. A 2-0 silk suture collar is placed to help secure the repair while the glue dries. Note that this is not part of the instructions for use in the kit.

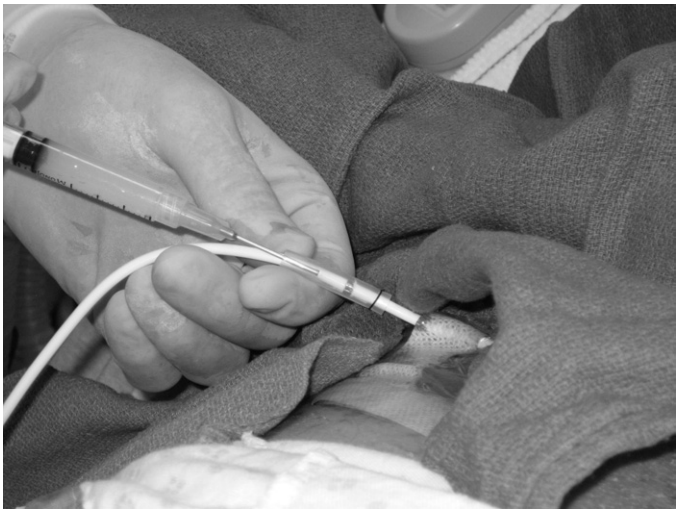

Figure 4. Silicone adhesive in inserted along the inside of the sleeve by using the syringe and applicator provided in the kit.

more secure, although there was slight variation from operator to operator in this step (**Figs 3–5**). The catheter lumens were then gently flushed. In the event of occlusion, a 0.018- or 0.025-inch hydrophilic guide wire (GlideWire; Terumo Medical, Elkton, Md) was passed through the lumen to restore patency and 2 mg of tissue-type plasminogen activator (t-PA) (Genentech, South San Francisco, Calif) was instilled into the affected lumen for 30 minutes, aspirated, and the lumen was flushed. Use of the catheter was avoided if possible for 12 hours to allow the adhesive to set; however, if the catheter was considered indispensable, use was allowed.

For the repair kit outcome analysis, only patients receiving 10-F triple-lumen silicone catheters between July 2002 and September 2005 were included; follow-up through March 2006 was included. The repair kit analysis was limited to these catheters because the largest number of repairs was performed in this group; in other catheter designs, the number of repairs was too small for meaningful analysis (**Table 1**). Variables examined included durability of the repaired catheter, repair failure, and survival of the catheter. Durability examines at which points the repairs fail. Repair failure compares the number of repairs that fail versus repairs that do not fail. Survival is the number of catheter days, which was compared between the repaired and nonrepaired catheters. Repair failure was defined as immediate failure (ie, unable to repair the catheter) or failure to resume therapy because of leaking at the repair site or rupture of the newly replaced segment. If therapy was successfully resumed and the catheter subsequently became damaged, this was considered a new event.

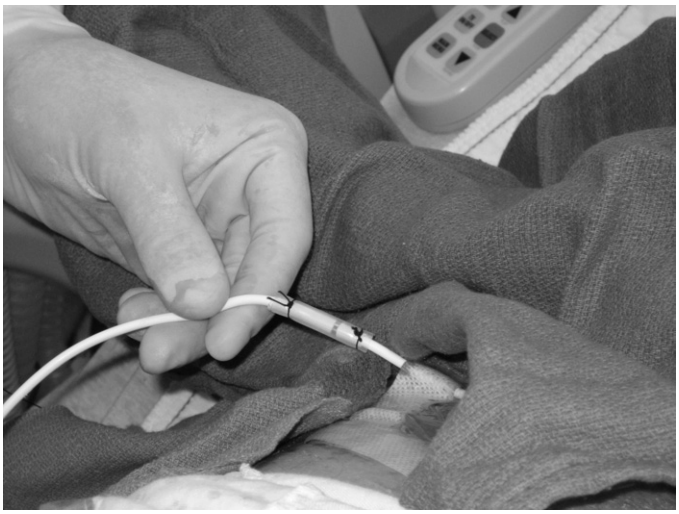

Figure 5. Completed repair with silk suture collars at both ends of the silicone sleeve.

Statistical Analysis

Follow-up data were missing from two of the 48 repaired catheters; these catheters were removed from analysis for survival of repair statistics. If the catheters were indwelling on March 10, 2006, then the catheter was censored after that point. Summary statistics, cross-tabulations, and time-to-event analyses were generated to assess the effect of repaired catheter with those not needing repair. After the initial assessment, we performed a time-to-event analysis. The event time in this study was time until end of therapy or death (due to reasons unrelated to the catheter). Catheter removal for all other reasons (infection, fell out, occluded, and other) was considered censored. Specifically, we wanted to test the hypothesis that a repaired Hickman catheter can be used to extend catheter survival.

For the data analysis, we used the Cox proportion hazards regression procedure in SAS (11), which accounts for censored and noncensored data. The proportion hazards regression procedure performs regression analyses of survival data on the basis of the Cox proportional hazards model (12). The Cox semiparametric model is widely used in the analysis of survival data to explain the effect of explanatory variables on survival times.

We also assessed the association between catheter type and breakage rate. These initial evaluations were followed by a formal statistical assessment with the Fisher exact test. This is a nonparametric test, designed to assess the statistical association between two categorical variables without making any explicit assumptions about the sample distribution. This is the preferred method when any of the contingency table cell sizes are less than five (13).

RESULTS

The breakage rates for various catheter types are shown in **Table 2**. There was an overall significant difference among types (P = .0001), and it was driven mostly by the fact that the breakage rate for the 9.6-F single-lumen catheter is different than that of the 10-F dual-lumen and 10- and 11-F triple-lumen catheters. In addition, the breakage rate of the 11-F triple-lumen catheter is significantly different from that of the 9.6-F single-lumen, 9-F dual-lumen, and 10-F triple-lumen catheters. No complications (eg, bleeding, air emboli) related to catheter breakage occurred.

The repair success rate was 86% (44 of 51 catheters). Six initial repairs and one repeat repair failed immediately (thus, the failure rate was 14% [seven of 51 catheters]). All seven catheters were removed after repair failed.

The mean time to repair was 59.8 days, and the average catheter dwell after the repair was 78.6 days. The mean total catheter days for the repaired group was 143.4, and the mean total catheter days for the nonrepaired group was 145.4. Thus, there was no statistically significant difference in the survival of repaired versus undamaged catheters (χ^2, 0.071; hazard ratio, 1.07; P value, .79). The median catheter survival time for repaired catheters was 147 days, whereas the median survival days for those not requiring repair was 119 (**Fig 6**). The reasons for ultimate removal of successfully repaired catheters were end of therapy (n = 11), indwelling at the end of study date (n = 4), patient death (n = 9), infection (n = 12), torn extension (n = 2), patient induced (n = 2), and catheter occlusion (n = 1).

DISCUSSION

As can be seen in **Table 1**, breakage of tunneled infusion catheters is not a rare occurrence in a busy hospital. Such breakage interrupts care at best, and can theoretically lead to life-threatening complications such as air emboli and bleeding. Catheter repair kits are a useful tool for managing catheter breakage, coupled with aggressive measures to avoid breakage such as limiting flush syringes to 10 mL and larger, avoiding power injection of catheters not designed for this purpose, and care when changing dressings to avoid cutting the catheter. Although repair kits have been available for more than 2 decades, outcomes data describing their use are virtually nonexistent (7). Likewise, although catheter breakage has been previously described, we were unable to find any descriptions of rates of breakage or comparative data for various designs despite a diligent literature search.

With respect to breakage rates, some interesting observations can be made. For triple-lumen catheters, the 11-F device had a significantly lower breakage rate. Conversely, the 9-F dual-lumen device, from the same vendor as the 11-F device, had more than twice the breakage rate, although the difference was not statistically significant in the small sample. Indeed, the 9-F double-lumen catheter had such a high breakage rate (compared with historical quality assurance data from another institution with regard to the 10-F dual-lumen catheter) that this prompted us to change vendors and use the 10-F dual- and triple-lumen devices instead. Both catheters are

Table 2
Comparison of Breakage Rates for Various Catheter Types

Type of Catheter	10-F Dual Lumen	11-F Triple Lumen	9.6-F Single Lumen	9-F Dual Lumen	10-F Triple Lumen
10-F dual lumen	. . .	.4	.01	.11	.09
11-F triple lumen	.4	. . .	.0001	.003	.0001
9.6-F single lumen	.01	.0001	. . .	.2	.055
9-F dual lumen	.11	.003	.2	. . .	.67
10-F triple lumen	.09	.0001	.055	.67	. . .

Note.—Data are *P* values, which were determined with the Fisher exact test.

made of silicone. The lumens of the 11-F triple-lumen catheter are 1.3, 0.9, and 0.9 mm, and those of the 10-F triple-lumen catheter are 1.4, 0.8, and 0.8 mm; the lumen sizes of the 9-F dual-lumen catheter are 1.2 and 0.4 mm, and those of the 10-F dual-lumen catheter are 1.3 and 1.3 mm. Given these parameters, it is not surprising that the 10-F dual-lumen catheter performed with a low breakage rate, as in our experience most breakage is related to flushing to try to overcome catheter occlusion (related to lumen diameter), although other causes exist as outlined earlier. The significant difference in breakage rates between 10- and 11-F triple-lumen catheters is more difficult to explain on the basis of luminal diameter alone; however, with nearly equal lumen diameter and slightly larger French size, the 11-F catheter may have slightly thicker walls and thus be more resistant at least to flushing-related rupture. Of course, the best solution, already adopted in a widespread fashion in peripherally inserted central catheters (where lumen diameter is even smaller), may be the use of polyurethane catheters, which are far stronger for a given diameter and lumen size than silicone. Such catheters are becoming more readily available; we have already adopted a 10-F dual-lumen polyurethane design and are eagerly awaiting a 10-F triple-lumen polyurethane design to address our breakage problems. Pending the availability of such a design, our data would suggest that the best outcomes may be achieved with the 11-F triple-lumen and 10-F dual-lumen catheters, although because of larger diameter the 11-F triple-lumen catheter theoretically might increase the risk of venous thrombosis.

With respect to repair kit outcomes, the results of our study show that 10-F triple-lumen Hickman catheters with external segment repairs have nearly identical survival as catheters not requiring external segment repairs. Repair is successful in the vast majority of broken catheters and is durable. Thus, the repair kit can be confidently used until such time as improvements in catheter design have eliminated the breakage problem. It is interesting that a large-scale study about the efficacy of peritoneal dialysis catheter repair kits has been published (8). The process of splicing and gluing the external segment described by Usha et al (8) is very similar to the process we have described. Usha et al focused on infections and survival after repair but did not compare survival of repaired versus nonrepaired peritoneal catheters. Their focus on infection reflects the concern that repairs are done in an environment considerably less controlled with regard to sterility than that in which original insertion was done. However, neither we nor Usha et al found infection to be a problem after repair.

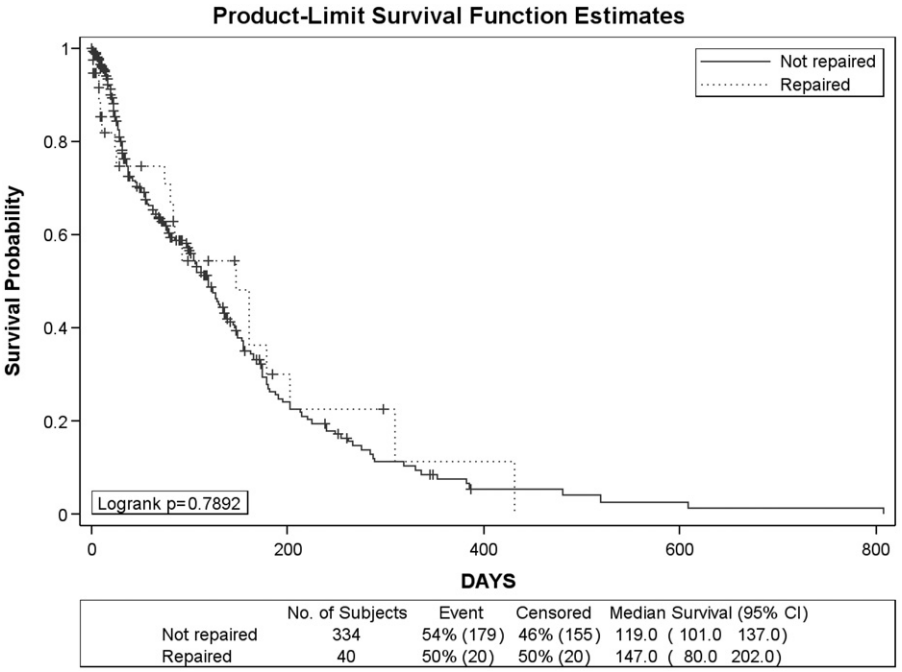

Figure 6. Graph shows the survival curves for repaired and nonrepaired catheters. *CI* = confidence interval.

Worth noting is the apparent cost-effectiveness of these repair kits and their ease of use. As of May 2007, the cost of the repair kit is $175.00; the cost of a 10-F triple-lumen catheter is $268.00. Of course, the cost of a new catheter is dwarfed by the associated costs of the insertion procedure. Given the identical outcomes of repaired and nonrepaired catheters, it does not take a formal analysis to recognize that re-

pair kits are highly cost-effective. The ability to use the kits at bedside or in a clinic setting further reduces the need to transport the patient to the interventional radiology department for repair. The kits are easy to use and intuitive; although not specifically studied herein, in our hands catheter repairs take less than 15 minutes including preparation time.

Since the time of this study, we have introduced several modifications to our hospital protocols and our repair technique that we believe may have improved our outcomes and are worthy of mention. First, we discovered that t-PA for treating catheter withdrawal occlusion was being delivered to the inpatient units in the 1-mL syringes used to prepare the aliquots in the pharmacy. We believe that, at least on occasion and perhaps more often, the 1-mL syringe was being used to deliver the t-PA and may have contributed to rupture due to the high pressures that can be generated with small syringes. We have since convinced the pharmacy to deliver t-PA in 10-mL syringes; it is still too early to determine if this has reduced the rupture rate. Second, because we frequently found occlusion of the catheter after the repair (likely the inciting cause of the rupture in the first place), we now use a wire to clear all lumens before the repair is done and routinely use t-PA dwell after repair unless the damage was clearly not related to clot (eg, accidental transection during a dressing change). Although these measures may slightly increase the cost of repair, we believe the added effort may be worthwhile. Again, it is too early to determine if these changes have had an effect on outcomes.

There are limitations of this study. First, this study was retrospective. It would be impractical at best and possibly unethical to subject patients to a randomized study of repair versus replacement. We believe the large number of observations lends strength despite the retrospective nature and all of the associated problems of a retrospective design. Another limitation was the lack of consistent recording of specific segment breakage and specific cause of breakage (eg, flushing-related, traction on the catheter, scissors during dressing repair). Although knowledge of these causes might help prevent damage in the future, we do not believe knowledge of the cause of catheter failure is crucial to repair kit outcomes, the main focus of the study. Finally, we studied only one brand of repair kit, and these results may not be applicable to other repair kits.

In conclusion, the tunneled infusion catheter repair kit studied is an effective and durable alternative to catheter replacement. We believe that repair should always be the first approach to external segment damage in these catheters, and replacement should be reserved for the rare failure of repair kits.

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