

Sutureless Securement Device Reduces Complications of Peripherally Inserted Central Venous Catheters

Alvin J. Yamamoto, MD, Jeffrey A. Solomon, MD, Michael C. Soulen, MD, James Tang, MD, Kim Parkinson, RN, Richard Lin, MD, and Gregory J. Schears, MD

PURPOSE: This study was conducted to evaluate the performance of a sutureless adhesive-backed device, StatLock, for securement of peripherally inserted central venous catheters (PICCs). Earlier studies have demonstrated that StatLock significantly reduces catheter-related complications when compared to tape. The purpose of this study was to determine whether a sutureless securement device offers an advantage over suture in preventing catheter-related complications.

MATERIALS AND METHODS: 170 patients requiring PICCs, which were randomized to suture ($n = 85$) or StatLock ($n = 85$) securement were prospectively studied. Patients were followed throughout their entire catheter course, and PICC-related complications including dislodgment, infection, occlusion, leakage, and central venous thrombosis were documented. Catheter outcome data were compared to determine if statistically significant differences existed between the suture and StatLock groups.

RESULTS: The groups had equivalent demographic characteristics and catheter indications. Average securement time with StatLock was significantly shorter (4.7 minutes vs 2.7 minutes; $P < .001$). Although StatLock was associated with fewer total complications (42 vs 61), this difference did not achieve significance. However, there were significantly fewer PICC-related bloodstream infections in the StatLock group (2 vs 10; $P = .032$). One securement-related needle-stick injury was documented during suturing of a PICC.

CONCLUSION: The sutureless anchor pad was beneficial for both patients and health care providers. Further investigation to determine how StatLock helps reduce catheter-related blood stream infections is necessary.

Index terms: Catheters and catheterization • Central venous access

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Abbreviation: PICC = peripherally inserted central (venous) catheter

PERIPHERALLY inserted central venous catheters (PICCs) are commonly used for intermediate to long-term in-

travenous therapy in hospitalized and home-care patients. Central venous catheters have been associated with a variety of postinsertion complications, including infection, phlebitis, central venous thrombosis, catheter dislodgment, leakage, and occlusion. The most common PICC complications include dislodgment in 5%–31% and bloodstream infection in 2%–20%, resulting in premature catheter removal in nearly one third of all patients (1–6).

Bloodstream infection is a significant complication of indwelling central venous catheters. It is estimated that 16,000 patients develop catheter-related sepsis each year, with an associated mortality of 12%–25% (7). The

attributed cost of treating these infections has been estimated to be between \$3,700 and \$29,000 per case (7). Preventative strategies are needed to decrease the risk of catheter-related bloodstream infections.

Needle-stick injury poses a significant risk to health care providers. Current figures report the needle-stick injury rate to be 25–39 per 100,000 sutures used (8). However, it is estimated that only 5% of needle-stick injuries are actually reported (9). New federal legislation mandates the use of needle-less devices to reduce the risk of needle-stick injury (10).

Traditionally, central venous catheters have been secured with tape or

From the Division of Interventional Radiology (A.J.Y., J.A.S., M.C.S., J.T., K.P.), Hospital of the University of Pennsylvania; and Department of Anesthesia and Critical Care Medicine (R.L., G.J.S.), Children's Hospital of Philadelphia, Philadelphia, Pennsylvania. Received May 18, 2001; revision requested June 26; revision received September 15; accepted September 24. From the 2001 SCVIR Annual Meeting. This study was supported by an educational grant from Venetec International, San Diego, CA. Address correspondence to G.J.S., Department of Anesthesiology, Mayo Clinic, Marry Brigh 2-752, 200 First St., SW, Rochester, MN 55905; E-mail: schears.gregory@mayo.edu

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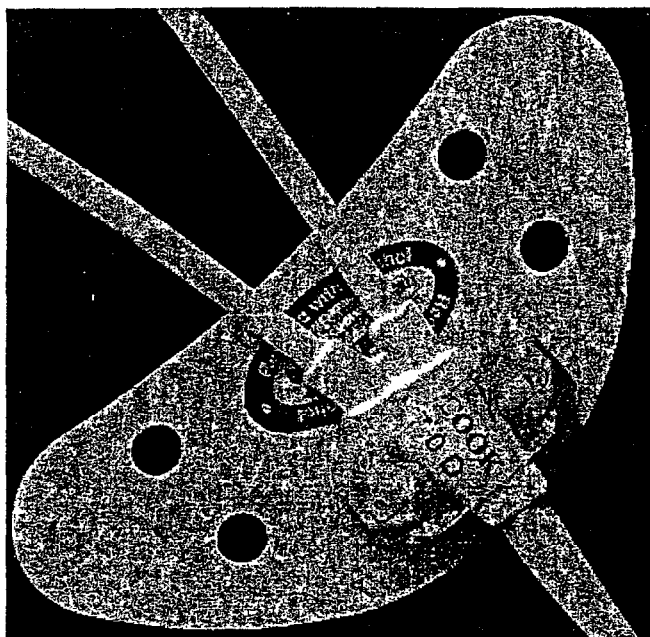


Figure. StatLock securement device for PICCs and central venous catheters holding a double-lumen Cook PICC.

suture, although no prospective randomized trials have demonstrated superiority of one technique versus another. Recently, StatLock (Venetec International, San Diego, CA) was introduced as a sutureless alternative to tape or suture for securement of PICCs and other central venous catheters. This device consists of a sterile, latex-free, adhesive-backed anchor pad containing two plastic posts that secure onto the PICC with a locking clamp (Fig). Although previous studies comparing the sutureless device to tape have demonstrated an overall reduction in catheter-related complications by 45%–72% (11–13), it is uncertain how well this device performs in comparison to suture.

A randomized, prospective study was conducted to compare a sutureless securement device for PICCs with suture in an adult population, and to determine what impact it would have on catheter complications.

MATERIALS AND METHODS

Study Design

Approval to conduct this prospective, randomized trial was granted by the institutional review board. Each study subject gave verbal informed consent before enrollment. The randomization was performed with con-

sealed envelopes that designated patients to receive the standard securement with interrupted 2-0 Prolene (Ethicon, Somerville, NJ) or StatLock.

Catheter Insertion

An educational program reviewed the current suture method and introduced StatLock to staff members of the interventional radiology section. Single and double-lumen PICCs (Cook, Bloomington, IN) were inserted under direct sonographic and fluoroscopic guidance by physicians, as previously described (1). Demographic data, indication for placement, catheter type and dimension, and length of time required to secure the PICC were recorded during each case. Immediately after PICC placement, the operator noted all difficulties encountered and assigned ease (application/attachment of device or suture) and satisfaction (strength of securement) scores with the securement technique used, based on a 10-point scale (1 = least ease or satisfaction; 10 = most ease or satisfaction).

Study Participants

Eighty-five patients enrolled in each group (Tables 1,2). Both groups

shared similar age, sex, and race characteristics. The catheter type, vein used, arm used, and catheter indications were also similar. In addition, the prevalence of comorbid conditions was similar in both treatment groups.

Patient Follow-up

Research assistants examined inpatients daily and followed discharged patients by phone every other day. Semipermeable transparent polyurethane dressings were changed on all inpatients every 3 days or more frequently if necessary, according to hospital protocol. Sutures were inspected during each dressing change for signs of loosening, deterioration, or breakage. The sutureless device was changed every 6 days to comply with the hospital dressing change policy. Sutures or StatLock devices that were loose or broken at the time of dressing change were immediately replaced. Home infusion nurses were instructed to change dressings, replace anchor pads, and inspect sutures weekly in discharged study patients.

Definitions

Completion of the intended course of therapy constituted planned catheter removal. Catheter removal before completion of the intended treatment course as a result of dislodgment, infection, phlebitis, thrombosis, catheter leakage, or occlusion was categorized as unplanned removal.

Catheter dislodgment was defined as accidental removal or movement that resulted in the loss of function. Movement greater than 0.5 cm without loss of function was categorized as catheter migration, even though the catheter tip may have no longer remained in a central position. Catheters were categorized as connected or heparin locked based on the predominant intravenous connection status recorded in the patient chart.

Catheter-related bloodstream infections were confirmed upon isolation of identical organisms from both line and peripheral blood cultures or defervescence of symptoms after PICC removal, in accordance with Centers for Disease Control guidelines (12). A suspected PICC-related bloodstream infection constituted failure to meet the criteria for a confirmed line infec-

Table 1
Study Patient Characteristics

Category	Suture (n = 85)	StatLock (n = 85)	P Value
Mean age \pm SD (y)	57 \pm 14.6	54 \pm 16.9	NS
Sex			
Male	48	49	NS
Female	37	36	NS
Race			
White	64	61	NS
Black	18	22	NS
Other	3	2	NS
Catheter type			
Single lumen	41	39	NS
Double lumen	44	46	NS
Vein used			
Basilic	80	76	NS
Cephalic	3	5	NS
Brachial	2	4	
Indication for PICC*			
Antibiotics	62	60	NS
Total parenteral nutrition	20	19	NS
Intravenous fluids	12	9	NS
Chemotherapy	13	13	NS
Blood draws	10	13	NS
Blood products	4	5	NS
Other	5	6	NS

* Patients had multiple indications for PICC placement.

tion despite a strong suspicion by the primary medical team.

A diagnosis of cellulitis was established on the basis of skin tenderness, erythema, edema, and purulent exudate that resolved with antibiotic treatment and/or catheter removal. The presence of a tender, erythematous, palpable venous cord after the course of the catheterized vein established the diagnosis of phlebitis. Suspected central venous thrombosis was confirmed by duplex ultrasound or venography. Inability to infuse the catheter despite attempts to clear the obstruction, according to standard hospital protocol, was categorized as unresolvable occlusion.

Statistical Analysis

Statistical analysis was performed with the Stata software package, version 6.0 (Stata, College Station, TX). A sample size was projected with use of a two-tailed alpha of 0.05 and a beta of 0.2, expecting a complication rate difference between both groups of 50% or greater. Normally distributed variables were compared with use of unpaired Student *t*-tests. Non-normally

distributed variables, such as incidence rate and proportions, were treated as nonparametric, and groups were compared with use of either the Wilcoxon rank-sum test or exact binomial probabilities.

RESULTS

Insertion Data

Twenty-five different operators used the suture technique and 28 operators used the StatLock. Average securement time was 4.7 minutes in the suture group and 2.7 minutes in the sutureless group ($P < .001$). The average securement ease/satisfaction scores were 7.2/7.3 for suture and 7.0/7.1 for StatLock ($P = \text{NS}$ in both cases), respectively. Two patients could not be enrolled into the study. Excessive bleeding prevented adhesion of the StatLock in the first patient and the PICC catheter wing fractured during attachment to the posts of the anchor pad in the second patient. One case of operator needle-stick injury was documented during the suture technique.

Outcome Data

The average catheter dwell time was 35 days \pm 38 in the suture group and 33 days \pm 42 in the StatLock group (Table 3). Unplanned removal occurred in 31 of 85 patients (36%) in the suture group and 20 of 85 (24%) in the StatLock group ($P = \text{NS}$). Line connection status was predominantly connected in 36 of 50 patients (72%) who underwent unplanned catheter removal and in 26 of 120 patients (21%) who successfully completed their catheter course ($P < .001$). All cases of accidental dislodgment occurred while catheters were connected to intravenous tubing. However, no significant difference in overall line connection status was observed between suture and StatLock groups.

Sixty-one complications were documented in the suture group and 42 in the StatLock group. Several patients had more than one documented complication event during their catheter course. Complications included catheter dislodgment, migration, systemic infection, cellulitis, leakage, occlusion, and central venous thrombosis. Overall catheter dislodgment rates were similar between groups (12 suture vs 10 StatLock; $P = \text{NS}$). In addition, catheter migration without loss of function did not vary significantly between groups (nine suture vs five StatLock; $P = \text{NS}$). Broken or loose sutures required repeat securement or reinforcement in 18 patients and caused nine migrations and two dislodgments. Seventeen patients had detached or loosened anchor pads that required replacement prior to the regularly scheduled change and resulted in five migrations and three dislodgments. In two patients receiving home infusion therapy, follow-up revealed that improper use of the sutureless device resulted in accidental dislodgment.

Follow-up revealed a significant difference in the number of systemic infections (10 suture vs. two StatLock; $P = .0032$). In addition, the difference in confirmed catheter-related bloodstream infections was found to be significant (eight suture vs one StatLock; $P = .04$). In all patients with confirmed and unconfirmed line infections, PICCs were removed and antibiotic therapy was initiated.

Cellulitis, catheter leakage, unre-

Table 2
Comorbid Conditions

Category	Suture (n = 85)	StatLock (n = 85)	P Value
Infection*	27 (32)	35 (41)	NS
Malnutrition†	19 (22)	14 (16)	NS
Cancer	13 (15)	19 (22)	NS
HIV	8 (9)	4 (5)	NS
Diabetes	6 (7)	4 (5)	NS
Congestive heart failure	4 (5)	5 (6)	NS
Transplant	4 (5)	1 (1)	NS
Coagulopathy	2 (2)	1 (1)	NS
Chronic obstructive pulmonary disease	1 (1)	2 (2)	NS
Renal failure	1 (1)	0	NS

Note.—Numbers in parentheses are percentages.

* Infection: surgical wound (n = 28); osteomyelitis (n = 13), pneumonia (n = 10), sinusitis (n = 6); cellulitis (n = 5).

† Malnutrition: gastrointestinal surgery (n = 24); inflammatory bowel disease (n = 9).

Table 3
Catheter Outcome

Category	Suture (n = 85)	StatLock (n = 85)	P Value
Indwell time			
Total (d)	2,934	2,796	NS
Mean ± SD	35 ± 38	33 ± 42	NS
Unplanned removal	31 (36)	20 (24)	NS
Total PICC complications	61	42	NS
Incidence rate*	21/1,000	15/1,000	NS
Catheter dislodgment	12 (14)	10 (12)	NS
Incidence rate*	4.1/1,000	3.6/1,000	NS
Catheter migration†	9 (11)	5 (6)	NS
Systemic infection	10 (12)	2 (2)	.032
Confirmed	8	1	.040
Suspected	2	1	NS
Combined incidence*	3.4/1,000	0.7/1,000	.028
Cellulitis	5	3	NS
Leak	2	1	NS
Occlusion	4	3	NS
Central venous thrombosis	1	1	NS
Securement detached or loose	18	17	NS

Note.—Numbers in parentheses are percentages.

* Incidence reported per 1,000 catheter days.

† Migration did not result in loss of function.

solvable occlusion, and central venous thrombosis comprised the remaining 19% and 17% of complications resulting in unplanned removal in the suture and StatLock group, respectively. Neither suture nor StatLock was associated with skin hypersensitivity. In addition, no cases of phlebitis were documented in this study.

Unplanned removal resulted in 17 PICC restarts in the suture group and 10 in the StatLock group ($P = NS$). In

addition, unplanned removal resulted in 14 new peripheral intravenous lines in the suture group and seven in the StatLock group ($P = NS$).

DISCUSSION

A prospective, randomized study was conducted in two well-balanced patient groups comparing suture technique to a sutureless anchor pad for PICC securement. The anchor pad sig-

nificantly reduced the length of time required to secure catheter to skin. Operators who used StatLock expressed equivalent ease and satisfaction with the device compared to suture technique. Follow-up demonstrated that StatLock secured catheters as well or better than suture, it significantly reduced line infections, and it had a trend toward fewer overall catheter-related complications. In addition, from a health care provider standpoint, StatLock avoided the additional risk of needle-stick injury associated with suturing.

Two prospective clinical trials and one retrospective study have compared tape to StatLock in the hospital, skilled nursing facility, and home-care settings (11–13). These studies demonstrated that the sutureless anchor pad took significantly less time to apply, was not prone to skin hypersensitivity, and reduced catheter complications by 45%–72% (11–13). In addition, an as-yet-unpublished prospective randomized trial comparing suture to StatLock in pediatric patients suggested a trend toward reduced catheter-related infections; however, the sample size was not large enough to specifically test this variable (14).

The primary pathogenesis of catheter-related bloodstream infection occurs via migration of skin flora through the percutaneous entry site (15). Suturing is thought to promote bacterial colonization at the catheter site and may explain why patients in the suture group had a greater likelihood of developing bloodstream infection. Unlike suture, StatLock avoids disruption of the skin around the catheter entry site and may decrease the degree of bacterial colonization present. In our experience, removing StatLock at regular intervals facilitated a more thorough cleansing of the catheter site than the more stationary catheters that were held in place by suture.

Limitations of this study were related to statistical power, categorization of line infection, and follow-up of discharged patients. Because differences of less than 50% were often observed between groups, the statistical power may have been below the desired value of 0.8. Although Centers for Disease Control guidelines were used because of their clinical practicality in categorizing confirmed versus suspected catheter-related blood-

stream infections, these criteria are imprecise. Finally, follow-up of patients receiving home infusion may have led to underreporting of catheter-related complications. To supplement follow-up conducted via telephone, patients were seen during outpatient clinic visits. Moreover, we dealt with several home infusion companies, each following different protocols for PICC care. One of the primary challenges of this study was to implement adequate education for all participating home-infusion caregivers on the proper use of StatLock. Improper application of the StatLock device by home-infusion caregivers may have contributed to catheter complications more often than recognized through follow-up.

CONCLUSION

The availability of StatLock as an alternative to tape and suture for securement of PICCs poses several clinical implications. It significantly reduces line infections. StatLock performs as well or better than suture in preventing catheter-related complications, particularly dislodgment and migration. In addition, it avoids the additional hazards associated with operator needle-stick injury and complies with recent federal guidelines.

Future investigation must focus on how StatLock reduces catheter-related bloodstream infection and how this device may impact patient outcome and health care costs.

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STATLOCK[®] CATHETER SECUREMENT DEVICE SIGNIFICANTLY REDUCES CENTRAL VENOUS CATHETER COMPLICATIONS

AUTHORS

Gregory J. Schears, MD

Assistant Professor of Anesthesia

Department of Anesthesia & Critical Care Medicine

Catherine Liebig

Department of Anesthesia & Critical Care Medicine

Ann Marie Frey, RN, BSN

Department of Nursing

Rosetta Chiavacci, RN, BSN

Department of Anesthesia & Critical Care Medicine

Kathleen Harris, RN, BSN

Department of Anesthesia & Critical Care Medicine

Richard J. Lin, MD

Assistant Professor of Pediatrics

Department of Anesthesia & Critical Care Medicine

Andrew T. Costarino, MD

Director, Fellowship Program

Department of Anesthesia & Critical Care Medicine

Mark A. Helfaer, MD

Director, Critical Care Medicine

Endowed Chair Critical Care Medicine

Department of Anesthesia & Critical Care Medicine

The Children's Hospital of Philadelphia (Affiliated with University of Pennsylvania Medical Center)

Philadelphia, PA

ABSTRACT

Central venous catheters (CVCs) and percutaneously inserted central venous catheters (PICCs) are associated with significant morbidity. Three prospective, randomized trials compared suture/tape to StatLock[®] (SL) for impact on catheter complications; only securement varied. The three trials were Study 1: Pediatric PICC threaded tape vs. SL, Study 2: Pediatric CVC suture vs. SL, and Study 3: Adult PICC suture vs. SL. Demographics and catheter complications were recorded, and statistical analysis was performed: Study 1—significance for unplanned removals in favor of SL (4 vs. 14); Study 2—SL similar securement to suture, though SL was significantly faster and decreased unplanned removals; Study 3—SL performed like sutures, though significantly fewer catheter

infections (0 vs. 5). There were two needlestick injuries with sutures. SL outperformed sutures/tape in all three trials. It reduced catheter complications and avoided needlesticks. A best practice for catheter securement must be reconsidered.

INTRODUCTION

Three major catheter-related health care problems are addressed in this article. The morbidity of central venous catheters due to infection and dislodgment and the risk of needlestick injuries to the health care providers with suturing can be significantly reduced using a novel method of catheter securement, the SL catheter securement device (Venetec International, San Diego, CA).

▼ Computers, Technology, and Devices

Percutaneously inserted central venous catheters (PICCs), and nontunneled central venous catheters (CVCs) are important medical devices that allow stable access to provide parenteral nutrition, IV fluids, medications, and monitoring. The exact number of PICCs and CVCs placed each year is unknown but is estimated to be several million.¹ Unfortunately, central catheters are associated with a number of significant complications, including dislodgment, infection, occlusion, and death.²⁻⁶ These complications lead to prolonged hospitalizations and additional treatments (such as courses of IV antibiotics), and they often require replacement with another invasive catheter.^{1,2} We have been studying an adhesive-backed catheter securement device that promises to help reduce these complications: the SL.

BACKGROUND

Decisions regarding the method of catheter securement are based on personal experience and local practice, but not on data. No studies have prospectively compared securement methods for their impact on catheter-related complications. Until recently, PICCs have predominantly been held in place with tape, though there is an increasing trend to suture them. CVCs are typically sutured. Taping requires less equipment and is generally easier to perform. Threaded tape allows the securement to be performed in a sterile manner. Unfortunately, adherence of tape beyond the first day is unpredictable, and many practitioners feel that it is less secure than sutures. Suture securement relies on the strength of the suture and the integrity of the skin at the suture site to hold the catheter in place. Suturing is uncomfortable for the patient and may require additional local anesthetic and sedation. The sutured sites may become inflamed, and this can contribute to increased bacterial colonization at the catheter insertion site.

Non-tunneled CVCs are a major source of morbidity and mortality and account for 90 percent of all catheter-related bloodstream infections.⁷ Prospective studies attribute 10 percent to 25 percent mortality to central venous catheter infections.^{1,2} The patient's skin is felt to be the most important source of bacterial

contamination. Heavy colonization of the catheter insertion site increases the risk of catheter-related infections.^{5,8}

Suturing also places the healthcare provider at risk for a needlestick injury.⁹ Needlestick injuries are a serious occupational threat and may result in transmission of an infectious disease such as HIV or hepatitis B virus.¹⁰ Whether they cause infection or not, needle stick injuries can have a significant emotional impact to the health care worker and result in costly postexposure treatments.

To assess the impact of SL on rate of complications for PICCs and CVCs, we conducted three prospective, randomized clinical trials. The institutional review board approved all three trials. Sample size was projected using an alpha of 0.05 and a beta of 0.2, expecting a complication rate difference of 50 percent or greater. Consent was obtained, and patients were randomly assigned to either the hospital standard or SL group, using a blinded-envelope method. Catheters were inserted and maintained based on hospital protocols, with the only variation being the type of securement. Patients were followed daily while in the hospital, or if discharged and at home, patients were called by a member of the research team at least every other day for the duration of the indwelling catheter and visited at least weekly by a home health care nurse. We obtained demographic/insertion data, including age, gender, catheter type, vein used, reason for insertion, patient activity level, and recorded catheter-related complications, including dislodgment, infection, and occlusion. The health care provider who inserted the catheter assessed the ease of securement and his or her satisfaction with the securement for each patient. We recorded potential risk factors for dislodgment, including patient activity level and IV tubing connection status. A cost analysis was performed (Study 1). Normally distributed variables were compared, using unpaired *t*-testing. Nonnormally distributed variables were treated as nonparametric, and were compared using Wilcoxon rank sum tests.

The three trials were as follows:

Study 1—A comparison of sterile threaded tape (former standard for PICCs at Children's Hospital of Philadelphia [CHOP]) to SL for PICC securement. PICCs were placed in 100 pediatric patients by the CHOP IV team. The purpose of the study was to compare rate of complications and do a cost analysis.

Study 2—A comparison of suture (former standard for CVCs at CHOP) to SL for CVC securement. CVCs were placed in 100 pediatric patients by CHOP PICU fellows. The purpose of the study was to compare rate of complications for the two methods.

Study 3—A comparison of suture (standard for PICCs at the Hospital at the University of Pennsylvania [HUP]) to SL for PICC securement. PICCs were placed by interventional radiology residents in 120 (study ongoing) adult patients at HUP. The primary purpose of the study was to compare rates of infection. Other complications were also monitored.

SOLUTION

A novel catheter securement device, the SL, takes advantage of the safety and ease in application of tape combined with the strength of sutures (see Figure 1). SL works through increased surface area contact and the bond between the adhesive and skin. SL is not prone to tissue reaction, is latex free, and is FDA approved. SL is superior to tape because it raises the catheter off the skin, providing an uninterrupted surface of adhesion under the catheter. It is also resistant to moisture. Because it does not disrupt the skin at the point of securement, it is less likely to promote colonization with bacteria. Weekly dressing and securement pad changes allow easy cleaning of the entire surface, potentially reducing the likelihood of bacterial colonization.

It appears to have the strength of sutures, though it avoids needles for securement. Thus it eliminates potential needlestick injury to the health care provider. The catheter is fastened to the adhesive pad by inserting its prongs through the wings of the catheter and then placing a locking clamp. The adhesive pad can easily be

removed with alcohol, and the catheter can be removed from the pad by twisting off the prongs.

RESULTS

Study 1—Pediatric PICC SL vs. Threaded Tape

Patient demographics are summarized in Table 1. Both groups were statistically equivalent for age, gender, catheter days, catheter type, venous site, percentage of time connected to IV tubing, average number of invasive lines per day, average activity score, and reason for catheter insertion. The typical study patient was ambulatory for most of his or her treatment course, spent much of the time "heparin locked," and required the PICC for the treatment of some infection.

Table 2 summarizes securement-related data. Securement ease and securement satisfaction were assigned by the member of the IV team placing/securing the line. Compared with threaded tape, the SL device was quickly accepted as a satisfactory means of securement by the users and it decreased overall securement time. SL provided more days for the original securement and required fewer securement changes.

Table 3 summarizes the outcome of the PICC lines for both groups. PICC lines prematurely removed, due to a complication prior to intended course completion, were lumped into the unplanned removal group. There was a significant difference between the rates of dislodgment between the two groups, with the SL outperforming threaded tape. Consistent with this finding is the decreased rate of migrations (partial dislodgments) for SL. The rate of nonresolvable occlusions was not statistically different. There was no difference for the rate of suspected infection. Patients whose PICC was secured with threaded tape were more likely to require a peripheral IV to complete their intended treatment course than were patients secured with SL.

Both groups had one "other" category cause of catheter removal. In the standard method group a catheter breakage was the cause. With the SL

group, one patient developed erythema around the securement and near the insertion site, and the line was removed. When the adhesive pad was removed, there was redness under the pad as well. This was treated with a topical antibiotic and resolved in two days. Most likely this represented a skin reaction to the adhesive. The patient had no history of tape allergies. Of note, we applied the adhesive pad to two patients with known tape allergies for the duration of their catheter insertion, and they showed no allergic reaction to the SL.

Table 4 summarizes the costs associated with PICC placement, maintenance, complications and overall cost of a PICC per completed PICC course. SL increased placement costs by \$89.00, or \$1.78 per PICC, which did not reach statistical significance. Costs related to maintaining line securement were significantly different, with threaded tape being \$7.83 and SL \$3.07 per PICC ($p < 0.05$). Complication costs were significantly different between the two groups, with threaded tape being \$328.68 and SL \$71.11 per PICC ($p < 0.05$). This difference resulted from far fewer additional radiograms, line placements, dressing changes, securement changes, IR procedures, home care visits, and emergency department visits. Total average costs per PICC of \$604.88 for threaded tape and \$344.34 for SL were not statistically different.

Study 2—Pediatric CVC-SL vs. Suture

Table 5 shows similar characteristics for both securement groups. Securement was achieved faster with SL than with suture and was preferred. One needlestick injury was recorded in the suture group (see Table 6). Table 7 shows similar performance for suture and SL, though SL tended toward significance for fewer unplanned removals and infections.

Study 3—Adult PICC –SL vs. Suture

Table 8 again shows very good similarity between the two randomized groups. There was a significant difference in the number of documented bacterial catheter infections for the suture group (5) versus the SL group (0) (see Table 9). The other complications did not achieve statistical significance. One needlestick

injury was recorded in the suture group (see Table 9).

OUTCOMES

Study 1—Pediatric PICC SL vs. Threaded Tape

SL significantly reduced unplanned removals, maintenance interventions, and catheter-related complications. Maintenance and complication costs were significantly reduced.

Study 2—Pediatric CVC-SL vs. Suture

The health care providers securing the catheters preferred SL to sutures and found SL faster to apply. SL performed similarly to sutures for rate of dislodgment, and it tended toward significantly fewer catheter-related infections. SL had significantly fewer unplanned removals than sutures.

Study 3—Adult PICC –SL vs. Suture

SL performed similarly to sutures for rate of dislodgment. SL showed significantly fewer catheter-related infections.

CONCLUSION

Overall, in these three prospective, randomized studies, SL consistently had fewer catheter-related complications. As a means of securement, SL performed as well as sutures. It offered the added benefit of decreased catheter-related infections compared to sutures, presumably due to decreased skin colonization around the insertion site. Because it is needleless, it eliminated the risk of suture-related needlestick injury during securing of the catheter. SL is not perfect, and attention needs to be paid to regular assessment of catheter securement and changing the device weekly with dressing changes. Based on our studies, the use of SL should significantly benefit patients requiring PICCs and CVCs, and it should improve safety for our health care providers.

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From The Children's Hospital of Philadelphia
‡Departments of Anesthesiology and Critical Care
Medicine, and the *Department of Nursing,
Philadelphia, Pennsylvania.

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Computers, Technology, and Devices

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CONTACT INFORMATION

Greg Schears, MD
Children's Hospital of Philadelphia
34th and Civic Blvd.
Philadelphia, PA 19104
(215) 590-5505
schears@email.chop.edu

Table 1. Study 1: Study Patient Characteristics*

Category	Threaded tape (standard)	SL	<i>p</i>
Patients in group	50	50	NS
Average age: years \pm SD	8.9 \pm 5.6	9.7 \pm 6.1	NS
Sex: males/females	20/30	21/29	NS
Average catheter days (\pm SD)	14.2 \pm 9.5	14.0 \pm 8.4	NS
Catheter type: single lumen/double lumen	38/12	41/9	NS
Vein used: basilic/cephalic	37/13	35/15	NS
Arm used: left/right	28/22	35/15	NS
Percentage of time connected to IV tubing \pm SD	21 \pm 35.0	28 \pm 40	NS

* SD = standard deviation.

Table 2. Study 1: Operator and Patient Securement Information*

Category	Threaded tape (standard)	SL	<i>p</i>
Operator satisfaction average (range, median)	8.7 (4–10, 9)	8.5 (4–10, 9)	NS
Securement time: minutes \pm SD	1.4 \pm 0.57	0.97 \pm 0.50	< .05
Days of original securement \pm SD	9.0 \pm 6.0	13.7 \pm 12.4	< .05
Total securement changes required	39	12	< .05

* SD = standard deviation.

Table 3. Study 1: Summary of PICC-Related Complications*

Category	Threaded tape (standard)	SL	<i>p</i>
Number of unplanned removals (%)	14 (28)	4 (8)	< .05
Dislodgments (%)	5 (10)	0	< .05
Migrations (%)	14 (28)	6 (12)	< .05
Migration average distance, in mm \pm SD	39 \pm 32	17 \pm 9	< .05
PICC restarts (%)	7 (14)	2 (4)	NS
PIV's secondary to PICC complication (%)	14 (28)	4 (8)	< .05
Total occlusions(%)	12 (24)	6 (12)	NS
Nonresolvable occlusions (%)	7 (14)	2 (4)	NS
Suspected infections (%)	4 (8)	1(2)	NS
Confirmed infections (%)	1 (2)	1 (2)	
Other (%)	1 (2)	1 (2)	NS

* SD = standard deviation, PIV = peripheral IV.

Table 4. Study 1: Cost Categories for PICC Lines

Category	Threaded tape (standard)	SL	<i>p</i>
Insertion costs (per PICC)	\$13,418.50 (\$268.37)	\$13,507.50 (\$270.15)	NS
Maintenance costs (per PICC)	\$391.56 (\$7.83)	\$153.66 (\$3.07)	< .05
Complication costs (per PICC)	\$16,434.31 (\$328.68)	\$3,555.65 (\$71.11)	< .05
Total costs (per PICC)	\$ 30,244.37 (\$604.88)	\$17,216.81 (\$344.34)	NS

Table 5. Study 2: Study Characteristics*

Category	Suture	SL	<i>p</i>
Patients in group	50	50	NS
Average age, in years \pm SD	5.2 \pm 5.8	5.9 \pm 5.8	NS
Gender: males/females	25/23	30/21	NS
Average catheter days \pm SD	8.2 \pm 8.4	6.6 \pm 4.5	NS
Percentage of time connected to IV	97%	90%	NS
Average # lines (range, median)	2.4, (1–6, 2.1)	2.9 (1–6, 2.8)	NS

* SD = standard deviation.

Table 6. Study 2: Securement Data

Category	Suture	SL	<i>p</i>
Securement time, in minutes \pm SD	6.4 \pm 3.9	2.4 \pm 2.2	< .05
Ease range, median	5–10, 8.	5–10, 10	< .05
Satisfaction range, median	5–10, 9	5–10, 10	< .05
Needlestick injury	1	0	

Table 7. Study 2: Summary of CVC-Related Complications

Category	Suture	SL	<i>p</i>
Unplanned removal (%)	12 (24)	6 (12)	NS
Infection (%)	7 (14)	2 (4)	NS
Dislodgment (%)	0	2 (4)	NS
Leak (%)	1 (2)	0	NS
Occlusion (%)	3 (6)	0	NS

Table 8. Study 3: Patient Characteristics

Category	Suture	SL	<i>p</i>
Number of patients	50	59	
Age, in years \pm SD	56.7 \pm 17.7	54.2 \pm 17.8	NS
Catheter days \pm SD	25.0 \pm 28.4	22.2 \pm 30.2	NS
Securement time, in minutes \pm SD	2.1 \pm .3	2.9 \pm 2.7	NS

Table 9. Study 3: Summary of PICC-Related Complications

Category	Suture	SL	<i>p</i>
Planned removal (%)	25 (50)	34 (58)	NS
Bacterial infection (%)	5 (10)	0	< .05
Dislodgement (%)	2 (4)	4 (7)	NS
Leaking (%)	1 (2)	0	NS
Occlusion (%)	2 (4)	2 (3)	NS
Needlestick injury	1	0	

Figure 1. SL Cathether Securement Device Holding a Single-Lumen PICC

