



**Title: Peripherally Inserted Central Catheter (PICC) Stabilization Devices: Clinical and Cost-Effectiveness and Guidelines for Use**

**Date:** 11 June 2008

**Context and policy issues:**

The traditional means of securing intravenous catheters includes tape and sutures, although both have drawbacks.<sup>1</sup> Tape has a high failure rate and suturing is uncomfortable for the patient.<sup>1</sup> Micro-movement of catheters can result in complications such as phlebitis, infiltration, extravasation, dislodgement, disconnection and infection.<sup>2</sup> Recent Infusion Nursing Standards of Practice recommend the use of a manufactured catheter stabilization device to secure vascular catheters.<sup>3</sup> The Occupational Safety and Health Administration suggests that manufactured securement devices be considered as a means to avoid needlestick injuries related to suturing.<sup>4</sup> One securement device available for peripherally inserted central catheters (PICCs) is the StatLock<sup>®</sup> PICC Plus, manufactured by Venetec International.<sup>1</sup> It consists of an adhesive anchor pad with a clip to attach the PICC. Information on the potential benefits and costs of manufactured securement devices, such as Statlock<sup>®</sup>, is required to inform healthcare purchasing decisions.

**Research questions:**

1. What is the clinical effectiveness of stabilization devices compared with tape and sutures for securing PICCs and preventing dislodgements and complications?
2. What is the cost-effectiveness of stabilization devices compared with tape and sutures for securing PICCs?
3. What are the guidelines for use of stabilization devices for securing PICCs?

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**Methods:**

A limited literature search was conducted on key health technology assessment resources, including OVID MedLine, OVID CINAHL, The Cochrane Library (Issue 2, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2003 and May, 2008 and are limited to English language publications only. No filters were applied to limit the retrieval by study type. The literature search was supplemented by hand-searching bibliographies.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews and meta-analyses are presented first. These are followed by economic evaluations, randomized controlled trials, observational studies and evidence-based guidelines.

**Summary of findings:**

No health technology assessments or systematic reviews were identified. No randomized controlled trials (RCTs) were found within the 5 year timeframe so the search was supplemented with a hand-search of bibliographies. Two RCTs published prior to 2003 were identified. Two guidelines were also found. Potentially relevant observational studies that were published prior to 2003 are listed in Appendix 1.

*Randomized controlled trials*

The two RCTs identified are summarized in Appendix 2, Tables 1 and 2.<sup>5-8</sup> One of these studies included a cost analysis.<sup>6-8</sup>

In Yamamoto *et al.*'s study,<sup>5</sup> 170 adults were randomized to have their PICC secured with either sutures or the StatLock<sup>®</sup> device. Patients were followed as inpatients and outpatients for complications with their PICC. The patients enrolled had an average age 54 to 57 years, and had similar co-morbidities between study groups. In over 70% of patients, antibiotic infusion was the reason for PICC insertion. The total catheter indwell time was 2,934 and 2,796 days for all patients in the suture and StatLock<sup>®</sup> groups respectively (average indwell time was 35 and 33 days per patient, p value not significant).<sup>5</sup>

Unplanned removal of the PICC was reported in 36% and 24% of the suture and StatLock<sup>®</sup> groups respectively (not significant). The total PICC complication rate was also not significantly different. In the suture group, 21 complications were reported for every 1,000 catheter days. In the StatLock<sup>®</sup> group, the incidence rate was 15 complications per 1,000 catheter days. Although the total complication rate was not significant, the rate of systemic infections were significantly higher in the suture group compared to the StatLock<sup>®</sup> group (incidence rate of 3.4 versus 0.7 per 1,000 catheter days, p=0.028). The rate of other complications (catheter dislodgement or migration, cellulitis, leakage, occlusion, or central venous thrombosis) was similar between groups. Eighteen patients had broken or loose sutures and seventeen patients had a loose or detached StatLock<sup>®</sup> device that required unexpected replacement. One needlestick injury was reported in the suture group.<sup>5</sup>

One other RCT was identified. Because a full text copy of the study was not available, the data available from review articles is summarized.<sup>6-8</sup> This limited our ability to assess the validity of the study and the data presented must be interpreted with caution.

A total of 100 hospitalized pediatric patients were randomized to have their PICC line stabilized by either sterile tape or the StatLock<sup>®</sup> device. Unplanned removals were significantly lower in the StatLock<sup>®</sup> group than in the tape group (8% versus 28% respectively,  $p < 0.05$ ). Dislodgements were also significantly reduced with the use of StatLock<sup>®</sup> (0% with StatLock<sup>®</sup> versus 10% with tape,  $p < 0.05$ ). The number of PICC restarts, occlusions, confirmed or suspected PICC infections were not significantly different between groups.<sup>6-8</sup>

A cost analysis was also conducted. PICC insertion costs were US\$268 in the tape group and US\$270 in the StatLock<sup>®</sup> group. Maintenance and complication costs were both significantly lower in the StatLock<sup>®</sup> group than the tape group. The total cost of insertion, maintenance and managing complications was US\$344 for StatLock<sup>®</sup> and US\$605 for tape.<sup>6,7</sup> Without access to the full study, it is not possible to assess the results of this cost analysis and to determine if it can be generalized to the Canadian setting.

### *Guidelines*

Two guidelines were identified and further details are provided in Appendix 3.<sup>2,9</sup> One was developed in Canada,<sup>2</sup> and the other in the US.<sup>9</sup> Information on one guideline was only available from the National Guideline Clearinghouse summary.<sup>9</sup> Both provided guidance on the care of central and peripheral intravenous catheters. Neither guideline made specific recommendations on which type of securement method was optimal. Tape, sterile strips, sutures and manufactured securement devices were all listed as acceptable securement methods.<sup>2,9</sup>

### *Limitations*

Overall, the data available was sparse, with no systematic reviews or health technology assessments available.

The RCT by Yamamoto *et al.*<sup>5</sup> was limited by inadequate statistical power to detect differences on some outcomes. Although out-patients were contacted by phone or seen during outpatient clinic visits, the authors reported that incomplete follow-up may have led to under reporting of PICC complications. No estimate of the extent of missing data was provided.

We were unable to verify the results reported or to assess the validity of the second RCT<sup>6-8</sup> because we could not obtain a copy of the full report. In addition, PICC complications were presented as percentages instead of the number of events per 1,000 catheter days. This limited our ability to compare results between the two RCTs. It is unclear if the results of the cost analysis are generalizable to the Canadian setting.

### **Conclusions and implications for decision or policy making:**

Limited data was identified on the use of securement devices for PICC stabilization. Although the data available is promising, it is not clear if stabilization devices reduce the incidence of complications with PICCs. No economic evaluations were identified and only limited cost information was reported in one RCT and therefore, no conclusions can be drawn regarding the cost-effectiveness of stabilization devices.

Two nursing guidelines for the management of vascular access devices were identified, and both recommended tape, sterile strips, sutures and manufactured securement devices as acceptable securement methods. If hospitals are considering using securement devices instead

of sutures or tape, perhaps costs and the potential to reduce needlestick injuries should be taken into account. Further clinical and cost-effectiveness studies may be required to aid in decision-making.

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9. Access device guidelines: recommendations for nursing practice and education [summary]. In: *National Guideline Clearinghouse* [database online]. Rockville (MD): National Guideline Clearinghouse; 2008. Available: [http://www.guideline.gov/summary/summary.aspx?ss=15&doc\\_id=8338&nbr=004666&string=intravenous+AND+catheter](http://www.guideline.gov/summary/summary.aspx?ss=15&doc_id=8338&nbr=004666&string=intravenous+AND+catheter) (accessed 2008 Jun 6).
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## Appendix 1:

### Additional References on the Use of Securement Devices for PICCs

1. Wood D, Bowe-Geddes L. A comparative retrospective analysis of two securement techniques for peripherally inserted central catheters (PICC) and midlines in the homecare setting. *J Vasc Access Devices* 1997; 2(3):11-16.  
Summary: Restrospective chart review of patients with PICC or midline catheters in a homecare setting. A total of 178 patients were evaluated. Transparent dressing, Steri-Strips and tape were compared to transparent dressing and Statlock<sup>®</sup> securement device. Complications were reported in 47% of patients with tape and Steri-Strips, and 35% of patients with StatLock.<sup>7</sup>
2. McMahon D. Evaluating new technology to improve patient outcomes: a quality improvement approach. *J Infus Nurs* 2002 25(4):250-55. [PMID: 12131507](#)

Appendix 2: Study Characteristics and Outcomes of the RCTs Evaluating Securement Devices for PICCs

Table 1: Study Characteristics

Study, design	Population, Setting	Comparators	Number of patients	Follow-up	Allocation concealment*	Comments
<b>Yamamoto et al.<sup>5</sup></b>  <b>RCT</b>	Adults with PICC (single or double lumen) in an inpatient and outpatient setting	StatLock®  Suture (interrupted 2-0 Prolene)  Dressings were changed every 3 to 7 days; StatLock replaced every 6 or 7 days.	170	Inpatients were examined daily. Outpatients contacted by phone every other day. Home infusion nurses inspected site weekly.	Unclear  Method reported as concealed envelopes	Study funded by the manufacturer (Venetec).  Two patients were not enrolled due to failure of StatLock device at the time of PICC insertion.  Limitations: follow up may not have been complete after discharge; statistical power may be inadequate; there were numerous care providers in the community and improper use of StatLock may have led to complications.
<b>Frey et al.<sup>6</sup></b> <b>Moureau et al.<sup>7</sup></b> <b>Frey et al.<sup>8</sup></b>  <b>RCT</b>	Children with PICC in a hospital setting  Neonates were excluded	StatLock®  Sterile tape (Steri-Strips)  Transparent dressings were used in both groups	100	Unable to assess	Unclear  Method reported as concealed envelopes	Unable to assess the validity of study.  Results should be interpreted with caution.

\* Allocation concealment refers to methods used to prevent foreknowledge of the treatment assignment during the patient enrolment process. Studies with inadequate or unclear allocation concealment have been associated with exaggerated treatment effects.<sup>10</sup> Allocation concealment is considered adequate if one of the following methods were used: central randomization; serially numbered, opaque and sealed envelopes; numbered or coded containers; or pharmacy controlled allocation. Allocation concealment is inadequate if alternation, reference to case record number, date of birth or a similar systemic method is used. If allocation concealment is not reported or the description fits neither category it is considered unclear.

RCT=randomized controlled trial; PICC=peripherally inserted central catheter

Table 2: Study Outcomes

Study	Comparators (number of patients)	Number of unplanned removals	Number of complications (Incidence rate*)	Catheter dislodgment (Incidence rate*)	Systemic infection† (Incidence rate*)	Cellulitis	Leak	Occlusion	Central venous thrombosis
Yamamoto <i>et al.</i> <sup>5</sup>	Suture (85)	31	61 (21/1,000)	12 (4.1/1,000)	10 (3.4/1,000)	5	2	4	1
	StatLock® (85)	20, NS	42 (15/1,000) NS	10 (3.6/1,000) NS	2 (0.7/1,000) p<0.05	3, NS	1, NS	3, NS	1, NS
Frey <i>et al.</i> <sup>6</sup> Moureau <i>et al.</i> <sup>7</sup> Frey <i>et al.</i> <sup>8</sup>	Tape (50)	28%	74%	10%	10%	NR	NR	24%	NR
	StatLock® (50)	8%, p<0.05	30% (p value not reported)	0%, p<0.05	4%, NS			12%, NS	

\* Incidence per 1,000 catheter days; † confirmed and suspected PICC related infections; NR=not reported; NS=not statistically significant; PICC=peripherally inserted central catheter

Appendix 3: Guidelines on the Use of Securement Devices for PICCs

Guidelines	Registered Nurses' Association of Ontario <sup>2</sup>	Oncology Nursing Society <sup>9</sup>
<b>Objectives</b>	To provide evidence-based support for nurses related to the care and maintenance of vascular access devices, client education and safety.	To describe different types of access devices, their insertion, maintenance, monitoring and potential complications. To describe educational needs and clinical competency for nurses.
<b>Population</b>	Adult clients with a central or peripheral venous access device in institutional or community care.	Adult and pediatric patients with cancer.
<b>Catheter securement recommendations</b>	<p>"Nurses must stabilize the vascular access device in order to:</p> <ul style="list-style-type: none"> <li>- promote assessment and monitoring of the vascular access site;</li> <li>- facilitate delivery of prescribed therapy; and</li> <li>- prevent dislodgement, migration, or catheter damage." </li></ul>	
<b>Additional guidance</b>	<p>"In addition to securement using dressings, the following adjuncts can be used to further secure the vascular access device: tape or sterile surgical strips; sutures; securement devices; and stabilization dressings (specially designed securement and dressing products)."</p>	<ul style="list-style-type: none"> <li>- Secure the PICC with tape, SteriStrips or Statlock</li> <li>- Some PICC may be best secured into place with sutures.</li> <li>- Several manufacturers have developed PICC line securing devices.</li> </ul>
	<p>"Securement devices must be changed at least every seven days."</p>	
<b>Grade of evidence</b>	Level III: evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.	Not stated