

PERIPHERAL INTRAVENOUS CATHETER SECUREMENT IN INFANTS

PERIPHERAL INTRAVENOUS CATHETER SECUREMENT IN INFANTS IN THE
NEONATAL INTENSIVE CARE UNIT

By

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ABSTRACT

Objectives: The quality of securement directly impacts the functionality, duration of patency and likelihood of a complication for a given peripheral intravenous catheter. The objective of the study was to determine which method of peripheral intravenous catheter securement, StatLock or Tegabear dressing was more effective by comparing duration of catheter patency and complication rates.

Study Design & Method: A quasi-experimental study using the Model for Improvement was conducted in a neonatal intensive care unit of a tertiary care hospital. Infants requiring insertion of a peripheral intravenous catheter for parenteral nutrition or administration of medications were eligible to participate. The study was conducted over a 4-month period and was divided into two phases, with each phase lasting two months.

Results: A total of 363 peripheral intravenous catheters were inserted in 175 infants. There were 211 catheters secured with StatLock and 108 secured with Tegabear dressing. There were 42 catheters which were unable to use StatLock or Tegabear dressing and were secured with a combination of transparent dressing/ tape. There were two peripheral intravenous catheters inserted where the method of securement was not indicated. The groups were similar with regards to all demographic variables except postmenstrual age, where the Tegabear group consisted of a larger proportion of older infants ($p < 0.001$). There was no significant difference in the mean duration of catheter patency between the StatLock and Tegabear group (46.04 hours versus 45.33 hours respectively), $p = 0.84$. Complication rates and reasons for catheter removal did not significantly differ between

the two groups ($p=0.78$ and $p=0.93$ respectively). The proportion of catheters that used an arm board was significantly greater with the Tegabear dressing (23.8%) compared to 10.5% with StatLock ($p=0.002$). Twenty one percent ($n=23/108$) of the catheters secured with the Tegabear dressing required reinforcement with tape or transparent dressing whereas no catheters in the StatLock group needed to be reinforced ($p<0.001$).

Conclusion: Catheter dwell time and complication rates did not differ significantly between StatLock and Tegabear dressing. However, when evaluating a new product, it is important to consider that there is often a learning curve that must be overcome. A larger study with a more rigorous design such as a randomized controlled trial is needed to validate or dispute the study findings. In the meantime, nurses must exercise individual and independent judgment when selecting a securement method most appropriate for their patient.

To my family, for their endless love and support
To Anthony, for your love, patience and for always
reminding me to believe in myself

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To my parents, I believe that this thesis and subsequent degree belongs to you as much as it does to me. This is as much your success as it is mine. Thank you for your love, patience and unwavering support throughout this chapter of my life.

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CHAPTER 1: Introduction and Background

Background to the Study

Peripheral intravenous therapy is one of the most common treatments provided in the Neonatal Intensive Care Unit (NICU). Peripheral intravenous (PIV) catheters provide the means for administering fluids, parenteral nutrition, blood products and medications (Pettit, 2003; Franck, Hummel, Connell, Quinn, & Montgomery, 2001). Peripheral intravenous access is ideal for short-term infusion therapy; however, there are several limitations to the types of fluids that may be infused (Beauman & Swanson, 2006). For instance, the volume, pH, and osmolality of solutions infused through a PIV are limited to avoid complications (Beauman & Swanson, 2006). The preterm and sick neonate is more vulnerable to skin injury and complications from extravasation compared to the more mature, healthy infant. This increased propensity for complications related to venipuncture and intravenous infusions can be attributed to their immature skin structures, flexible subcutaneous tissue, small veins, and poor venous integrity (Beall, Hall, Mulholland, & Gephart, 2013). Consequently, maintaining a patent peripheral intravenous catheter in the neonate is limited by vascular diameter and integrity, volumes and the concentration of IV solutions or medications (Beauman & Swanson, 2006; Maki & Ringer, 1999; Pettit, 2003). More importantly, it is often the most critically ill neonates who require prolonged intravenous fluid therapy.

Accessing the vascular system necessitates penetration of the skin and stabilization of the catheter in situ. Risks associated with PIV catheter placement and maintenance with continuous infusions include pain, risk of sepsis, phlebitis, infiltration, leaking, occlusion, dislodgement and necrosis of tissues (Beauman & Swanson, 2006; Pettit, 2003; Phelps & Helms, 1987). Consequently, increased number of attempts at placement of intravenous catheters may potentiate these risk factors. In the neonatal intensive care unit the average dwell time of peripheral intravenous catheters reported in the literature ranges from 15 to 54 hours (Batton, Maisels, & Appelbaum, 1982; Franck, et al., 2001; Johnson & Donn, 1988; Stanley, Meister & Fuschuber, 1992; Pettit, 2003; Tobin, 1988).

Although peripheral intravenous catheters are routinely used in the NICU, the risk of complications remains high. Non-elective removal of a PIV catheter as a result of complications occurs in up to 78% of insertions and can lead to untimely removal of up to 95% of the devices (Franck, et al., 2001). It is difficult to ascertain precise complication rates due to a lack of consistent definition for complications, significant variation in reporting among different facilities, and studies focused on specific complications (Pettit, 2003).

Catheter securement and stabilization is increasingly recognized as an important intervention in intravenous therapy and maintenance (Alekseyev, Byrne, Carpenter, Franker, Kidd & Hulton, 2012). Inadequate PIV catheter securement contributes significantly to complications (Bausone-Gazda, Lefaiver & Walter, 2010). When a peripheral intravenous catheter is not properly secured, motion and micro-motion within the vessel cause injury to the vein, thereby leading to phlebitis, infiltration, leaking at the insertion site, and pain (Bausone-Gazda et al., 2010; Schears, 2006). With securement and stabilization, less movement of the catheter occurs at the insertion site, and the catheter is less likely to be dislodged (Gorski, 2007).

It has been proposed that proper securement of PIV catheters can reduce the number of risk factors associated with continuous infusion, thereby decreasing the need for repeated cannulization. Reducing the number of invasive procedures sick infants are exposed to in the NICU is of critical importance for the clinician. Routine replacement of peripheral intravenous catheters is not recommended in neonates given the challenges associated with their small, fragile veins and limited vascular access (Pettit, 2003; Oishi, 2001).

Optimal securement of the peripheral intravenous catheter is increasingly being recognized for improving duration of patency and reducing complications. Further research to investigate optimal methods of peripheral intravenous catheter securement is needed.

Purpose of the Study

Currently, there is no consensus on the optimal method of PIV catheter securement due to the paucity of scientific research in the neonatal population. Unplanned catheter restarts produce pain and discomfort for infants, delay in infusion therapies, and increase the cost of care (Delp & Hadaway, 2011). More importantly, prolonged patency of peripheral intravenous catheters is an important issue in the NICU given the limited number of useful veins for catheter insertion in neonates. Determining optimal securement methods for peripheral intravenous catheters is therefore a vital component of catheter care to reduce complications and increase dwell times. The main purpose of the study is to quantitatively determine which method of securing peripheral intravenous catheters, StatLock or Tegaderm 1610, is more effective in increasing catheter dwell time and reducing complication rates in infants in the neonatal intensive care unit (NICU).

The research question that guided this study was, “Is there a difference in the mean catheter dwell time when StatLock, a securement device with an adhesive anchor combined with a transparent dressing is used versus 3M Tegaderm 1610 dressing, to secure a peripheral intravenous catheter?” The second question was, “Is there a difference in the complication rate when StatLock combined with a transparent dressing is used to secure a peripheral intravenous catheter versus using 3M Tegaderm 1610 dressing?”

Hypotheses

1. H_0 : There will be no difference in duration of patency between peripheral intravenous catheters secured with 3M Tegaderm 1610 dressing and those secured with StatLock combined with a transparent dressing.
2. H_0 : There will be no difference in the rate of complications between peripheral intravenous catheters secured with 3M Tegaderm 1610 dressing and those secured with StatLock combined with a transparent dressing.

Definition of Terms

In order to simplify the terms used and ensure clarity, the following terms will be used for the remainder of this document:

1. *StatLock* will refer to the combination of StatLock and a transparent dressing for securing peripheral intravenous catheters.
2. *Tegabear* will refer to the 3M Tegaderm 1610 IV securement dressing.
3. *Insyte* catheters will refer to 24 gauge Insyte-N Autoguard catheters used in the Neonatal Nurseries, which can be secured with either StatLock or Tegabear dressing.

The following is a list of terms and their meanings used in this study.

1. *Dwell time*- the time between insertion and removal (elective or because of complications) of the peripheral intravenous catheter measured in hours.
2. *Phlebitis*- inflammation of a vein noted by clinical signs of redness and edema.
3. *Infiltration*- leakage of fluid into the surrounding tissue noted by clinical signs of localized edema.
4. *Leaking* – leakage of intravenous fluids or blood at the insertion site.
5. *Blocked*- obstructed flow of intravenous fluids through the catheter.
6. *Dislodgement*- accidental partial or complete removal of the catheter from the body.
7. *Extravasation/ IV burn*-inadvertent administration of a vesicant solution or medication into the surrounding tissue as evidenced by skin blistering, blanching or a blackened area indicating tissue death.
8. *Flush*- a mini bolus (0.5-1 mL) of 0.9% sodium chloride delivered directly into the hub of the t-connector via syringe (10 mL pre-filled saline syringe).
9. *Postnatal age*- the time elapsed after birth described in days.
10. *Postmenstrual age (PMA)*- the time elapsed in weeks between the first day of the last menstrual period and birth (gestational age) plus the time elapsed after birth (chronological age).

Significance of Study

This study evaluated the most effective securement method for peripheral intravenous catheters in neonates. Identifying the most effective method of peripheral intravenous catheter securement will contribute to the current knowledge regarding intravenous practices in neonates.

Insertion of peripheral intravenous catheters is a painful procedure for infants, therefore, improving how PIV catheters are secured and stabilized, will help reduce complications and increase duration of catheter patency. Additional issues that must be considered include the potential for prolonged hospital stay as a result of catheter-associated complications, delays in therapy, and the impact on patient/family satisfaction (Schears, 2006; Sheppard, LeDesma, Morris & O'Connor, 1999). Thus, reducing complications will lead to a reduction in downstream activity as well as time associated with the reassessment of a failed PIV, additional supplies for the PIV replacement, and reduce the risk for needlestick injury (Schears, 2006). Most importantly, it will mean reducing the number of painful PIV restarts for infants who require ongoing intravenous therapy in the neonatal intensive care unit. Taking all of these factors into consideration as well as the factor of enhanced patient comfort, routine use of a securement device on PIV catheters is an essential component of IV therapy in neonates who have limited vascular access. Lastly, results from this study will also provide information that can be applied to clinical settings and future research that can help improve current intravenous therapy in infants in the NICU.

CHAPTER 2: Literature Review

The purpose of this literature review is to examine what is known about peripheral intravenous therapy in infants more specifically, within the context of the neonatal intensive care unit (NICU). A review of the literature has indicated paucity in the specific research pertaining to securement and stabilization of peripheral intravenous catheters in infants.

The electronic databases that were searched included: Cumulative Index to Nursing & Allied Health Literature (CINAHL), Cochrane Database, Ovid MedLine, and PubMed. Key terms included: ‘intravenous therapy’, ‘peripheral intravenous catheters’, ‘neonatal intensive care unit’, ‘infants’, ‘newborn’, ‘neonate’, ‘complications’, ‘catheter life span’ ‘securement’, and ‘stabilization’. Key terms were searched individually and in combination with other search terms, as appropriate. Limits applied to the search included the English language only. A total of 36 articles were included in this review, including quantitative research studies, review articles, quality improvement projects and descriptive reports. The breakdown of references used for this literature review include: 26 quantitative studies, 1 quality improvement project, 9 review articles, and the Infusion Nursing Society (INS) practice standards. Two text books were used to provide an overview on vascular anatomy and physiology, with a focus on infants rather than adults. Literature included in this review was from Canada, United States of America, Australia and India.

The literature review is structured to first explain peripheral venous anatomy and physiology and explain factors that affect the life span of peripheral intravenous catheters and commonly reported local complications. The review then describes studies that have examined factors other than method of securement that influence the life span of PIVs in infants in the

NICU. The review then focuses on the current state of knowledge related to securement and as a means of improving the life span of PIVs.

Peripheral Venous Anatomy and Physiology

Intravenous therapy involves the administration of fluids, blood products and medications directly into the vascular system. Nurses and others responsible for administering therapy must therefore have an understanding of the anatomy and physiology of vascular structures and related systems.

The veins, due to their abundance and location, provide the most readily accessible route for intravenous therapy. The vascular network develops from the mesoderm early in gestation between 60 to 70 days (Drolet, & Esterly, 2002). During the early stages of development, all vessels are capillaries. During the second week of gestation, blood vessels begin to differentiate into arteries, veins, and capillaries. The blood vessels are composed of three layers: the tunica adventitia (also known as tunica externa), tunica media, and tunica intima. By the third or fourth week of gestation, the different layers of the blood vessel are developed. However, unlike adults, the strength and functionality of these layers are immature in the newborn. Furthermore, blood vessels in the neonate are characterized by an immature muscle layer and decreased vessel diameter (McCullen, & Pieper, 2006). Consequently, perfusion is less than that seen in older children or adults, and the veins are at a greater risk for complications associated with venipuncture and delivery of intravenous fluids and medications (Drolet & Esterly, 2002; McCullen & Pieper, 2006).

The *tunica adventitia*, the outermost layer, is composed mainly of connective tissue with a network of collagen and elastic fibers (Lawson, 1998; Pettit, 2003). This arrangement protects

the vein's structure by allowing it to roll away from external trauma (Hadaway, 2001; Pettit, 2003).

The middle layer of the vessel wall, the *tunica media*, is a thick layer of connective tissue comprised of smooth muscle and elastic fibers (Pettit, 2003). The elastic ability of the muscle fibers allows the vein to stretch and tolerate changes in blood pressure and volume (Hadaway, 2010). Nerve fibers, which stimulate the veins to contract or relax, are located in this middle layer. Additionally, these nerve fibers continuously receive impulses from the vasoconstrictor center in the medulla, which keeps the vessels in a state of tonus (Weinstein, 2007, p. 60). Vascular spasms in the vein can occur as a result of changes in temperature or by mechanical or chemical irritation (Beauman & Swanson, 2006; Weinstein, 2007, p. 60). Consequently, these spasms can result in difficulty visualizing or accessing the vein (Beauman & Swanson, 2006, p. 194).

The innermost layer, the *tunica intima* is a single layer of tightly configured smooth flat endothelial cells with several layers of subendothelial tissue lying along the length of the interior of each vessel (Beauman & Swanson, 2006). The configuration of this cell layer prevents fluid from escaping the vasculature into the tissue (Hadaway, 2001). Furthermore, these endothelial cells release substances such as nitric oxide and prostacyclin; which alter the vascular tone and regulate blood flow (Hadaway, 2001; Pettit, 2003). Under normal conditions, this smooth surface lets the cells and platelets to flow through the blood vessels without interruption (Weinstein, 2007). When endothelial cells are injured, the subendothelial layer is exposed and the inflammatory and coagulation process is initiated, leading to phlebitis and thrombosis (Pettit, 2003). Therefore, it is imperative to maintain the integrity of this layer in order to promote blood flow. Caution must be taken to avoid roughening this surface when performing a venipuncture or

removing a needle from a vein (Weinstein, 2007). Injury to the tunica intima can be caused by various factors such as the use of a catheter that is too large for the vein, difficult or forceful advancement of the catheter, infusion of solutions with extremely low or high pH, infusion of hypotonic or hypertonic solutions, placement in an area of flexion, and catheter movement due to poor stabilization (Beauman & Swanson, 2006).

Factors Affecting the Life Span of Peripheral Intravenous Lines

Several therapies required for the survival of vulnerable infants contain properties making them harmful to the peripheral vasculature (Pettit, 2003). Recognition of factors affecting the life span of peripheral intravenous catheters may be critical in identifying the population at risk for infiltration and plan corrective actions to prolong the life span of PIVs in this group (Gupta, Ruchi, Basu & Faridi, 2003). The osmolality, pH level, and chemical properties of all solutions and drugs need to be assessed in order to determine the suitability for infusion into a peripheral vein (Pettit, 2006; Pettit, 2003). These are important factors must be taken into consideration as it directly impacts the complications that may arise and the duration of patency of peripheral intravenous catheters.

Osmolality

Osmolality, also referred to as tonicity, refers to the number of particles suspended in a solution (Pettit, 2006). Normal serum osmolality is 280-295 mOsm/kg (Shutak, 2000). All solutions infused through the peripheral vein should have an osmolality that reflects that of the serum in order to prevent vessel damage, phlebitis, infiltration, thrombosis and fluid shifts (Gazitua, Wilson, Bistran & Blackburn, 1979; Pettit, 2006; Pettit, 2003). Solutions that approximate 280-300 mOsm/L are considered *isotonic*, whereas solutions with an osmolality

greater than the serum are referred to as hyperosmolar or *hypertonic* (Perucca, 2010). A hypertonic solution draws fluid into the intravascular compartment from the endothelial cells and interstitial compartments (Evans & Dixon, 2006; Stranz, 2002). Parenteral nutrition, dextrose concentrations greater than 10%, and phenobarbital are some of the hyperosmolar solutions provided to infants in the NICU (Pettit, 2006). Alternatively, when the osmolality is less than that of the serum, the solution is hypo-osmolar or *hypotonic* (Stranz, 2002). Hypotonic solutions cause fluid to shift out of the blood vessels and into the cells and interstitial compartments (Evans & Dixon, 2006; Stranz, 2002).

The osmolality of infused solutions affects the innermost layer of the vein called the intima. The vein intima can be injured by administration of hyperosmolar solutions, especially if administered into a small vessel (Perucca, 2010). The exact osmolality at which damage to the vein and consequent phlebitis occurs is unknown. Furthermore, the duration of exposure to varying osmolar solutions may affect vein tolerance (Kuwahara, Asanami, & Kubo, 1998). Animal experimental studies best define the traumatic effect of osmolality and pH, as these parameters can be isolated (Stranz, 2005).

Tolerance osmolality of peripheral vessels has been demonstrated through animal studies. In an experimental study using a rabbit model, Kuwahara and colleagues examined varying infusion rates and osmolality on venous phlebitis. Test solutions ranging in osmolality from 539 to 917 mOsm/kg were infused into the rabbit ear veins for 8, 12, and 24 hours. Upon completion of the infusions, the veins were examined histopathologically and graded based on findings of loss of venous endothelial cells, inflammatory cell infiltration, edema and thrombus. The peripheral tolerance was directly related to the osmolality and duration of the infusion. In this model, the infusion tolerance of peripheral venous cells was estimated to be 820 mOsm/kg for 8

hours, 690 mOsm/kg for 12 hours, and 550 mOsm/kg for 24 hours indicating the tolerance osmolality fell as the duration of infusion increased. Thus, slow infusion was more apt to cause phlebitis than high rate infusion for a given solution (Kuwahara, et al., 1998). Even though increasing the infusion rate decreased the duration of infusion and phlebitis, the infusion rate is often limited by the bioavailability of its nutrient components. Thus, the researchers proposed that parenteral nutrition solutions should be infused at as high a rate as is compatible with nutrient bioavailability (Kuwahara, et al., 1998). Lastly, to reduce the phlebotic potential of IV solutions, the osmolality should be as low as possible (Kuwahara, et al., 1998). One of the study's limitations was that the authors failed to provide a rationale for using rabbit ear veins as a model for infusion phlebitis. The generalizability of these experimental results to human venous tissue, let alone neonates is unclear. According to the investigators, the infusion conditions in this study might provide a model for the most sensitive patients who have poor blood flow and narrow veins (Kuwahara, et al., 1998). Although human tolerance of osmolality and pH differs from that of animals, the relationships remain-the incidence of phlebitis increases as osmolality increases (Stranz, 2005).

Human studies measuring the effects of osmolality-induced phlebitis have arrived at different conclusions. A study in adults found that restricting the infusate osmolality to 450 mOsm/L reduced the risk of chemical phlebitis (Gazitua, Wilson, Bistran & Blackburn, 1979). Medications and IV solutions with an osmolality between 450 and 600 mOsm/L were found to have a moderate risk of chemical phlebitis and those with an osmolality greater than 600 mOsm/L the risk of chemical phlebitis was 100% (Gazitua, et al., 1979). This was a key study in establishing 500 mOsm/L as the outer limit of peripheral vein tolerance (Stranz, 2005).

Newborn infants requiring intensive care often receive a substantial number of medications while in the NICU, including intravenous hyperosmolar substances (Pereira-da-Silva, Henriques, Videira-Amaral, Rodrigues, Ribeiro & Virella, 2002). In 1983, Ernst and colleagues conducted a study in which they measured the osmolality of 64 medications as well as 23 formulas or nutritional supplements used in the NICU. Osmolality was determined by both vapour pressure and freezing point depression (Ernst, Williams, Glick, & Lemons, 1983). Several medications possessed significantly elevated osmolalities which included: alprostadil, phenytoin, digoxin and phenobarbital (Ernst et al, 1983). Additionally, the high osmolalities may not be due to the drug themselves rather they may result from pharmaceutical additives that are often used, such as propylene glycol, ethanol, sorbitol, and preservatives (Ernst et al., 1983). Many intravenous medications are routinely diluted prior to use and therefore the type of diluent used affects a medication's osmolality. For instance, with the use of specific diluents such as sterile water or 0.45% normal saline, the osmolality of medications that mimic serum osmolality can be achieved (Stranz, 2002).

Since Ernst and colleagues' study, few reports have been available regarding the osmolality of new drugs used in the care of sick neonates. Even though this information is available in text books primarily used by pharmacists, it is not readily available for healthcare providers in the NICU (Pereira-da-Silva, et al., 2002). Thus, Pereira-da-Silva and colleagues conducted a study which measured the osmolality of medications and some solutions commonly administered intravenously in the NICU. In this study, osmolality was measured by freezing point depression (Pereira-da-Silva, et al., 2002). Antimicrobials, vasoactive drugs, diuretics, anticonvulsants, glucose and electrolyte solutions were some of the substances analyzed. Drugs requiring reconstitution were diluted with sterile water or with the diluent provided with the drug

according to the manufacturers' directions (Pereira-da-Silva, et al., 2002). Results indicated that the osmolality of most substances were similar to that of plasma range values (285-295 mOsm/kg). However, there were some drugs that were significantly hypo-osmolar with mean values of <90 mOsm/kg which included vancomycin, atropine, propanalol, morphine, vitamin K and dobutamine (Pereira-da-Silva, et al., 2002). Drugs that were found to be markedly hyperosmolar with mean values of 1000-2500 mOsm/kg included: 8.4% sodium bicarbonate, 7.5% potassium chloride, furosemide Aquedux, pyroxidine and 30% dextrose in water. Lastly a few drugs that were extremely hypertonic with mean values of >2500 mOsm/kg included: phenobarbital, phenytoin, alprostadil, digoxin, and diazepam (Pereira-da-Silva, et al., 2002). Depending on the trademark, there were discrepancies in osmolalities in some drugs at the same concentration which highlights the importance of selecting more isotonic solutions for IV administration. Based on the available data, the Infusion Nurses Society (INS) Standard of Practice recommends limiting the osmolality of peripherally infused substances to less than 600 mOsm/L (Infusion Nurses Society, 2006).

pH

pH is a significant factor when considering vascular access and intravenous therapy. The pH of a solution refers to the concentration of hydrogen ions (Stranz, 2002). The normal pH of solutions is 7, which is neutral. In contrast, the pH for acid solutions ranges from 0 to 7 and for alkaline solutions ranges from 7 to 14. The normal blood pH is 7.35 to 7.45.

There are no human studies that control for the phlebitic potential of a range of pH values. However, animal studies have been conducted to determine the pH that peripheral veins can tolerate (Kuwahara, Asanami, Kawauchi & Kubo, 1999). In Kuwahara et al.'s (1999) study,

IV nutrient solutions with different pHs (ranging from 4.52 to 6.71) were infused into rabbit ear veins (n=6 rabbits), and the veins were examined histopathologically. Comparing 6 or 8 hour infusions through peripheral veins, a solution with a pH of 4.5 resulted in a 100% incidence of severe phlebitic changes; at a pH of 5.9 caused mild to moderate phlebitic changes in 50% of cases; at a pH of 6.3 caused mild damage in 20% of cases; and at a pH of 6.7 rarely caused any phlebitic changes (Kuwahara et al., 1999). Additionally, a 24-hr infusion of a solution with a pH of 6.49 caused no histopathologic changes in 3 rabbits, suggesting that the tolerance pH does not change when infusion duration increases. Since the peripheral vein was able to tolerate a pH of 6.49 and pH 6.72, the researchers estimated the tolerance pH to be approximately 6.5. Thus, to eliminate the acidic factor causing phlebitis, the pH of peripheral intravenous solutions should be ≥ 6.5 provided that the stability of the solution is not compromised (Kuwahara et al., 1999).

Limiting the pH within an acceptable range of 5 to 9 reduces trauma to the vein intima that would otherwise lead to phlebitis and thrombosis (Pettit 2006; Stranz 2002). In the NICU, vancomycin and gentamicin are some examples of medications with an acidic pH, whereas alkaline medications include ampicillin, acyclovir and phenobarbital (Pettit, 2006). Most solutions of dextrose have an acid pH of about 4, whereas other solutions have a pH of 5 to 6.35 (Wright, 1996). Total parenteral nutrition which is hyperosmolar is more of an irritant than dextrose or saline solutions (Hecker, Duffy, Fong & Wyer, 1991). As a result, the INS recommendations include limiting the pH to 5 to 9 for peripheral infusions (INS, 2006).

Chemical Properties of Solutions and Medications

The classification of a solution or medication as an irritant or vesicant is an important factor to consider when selecting the type of venous access. There are instances in which a

solution or medication's inherent chemical composition may be caustic to the vein, despite being isotonic and having a physiologic pH (Pettit, 2003). An irritant is a medication or solution that may cause itching, phlebitis or reaction along the vessel or at the site of injection, whereas a vesicant medication or solution can potentially cause blistering, tissue sloughing or necrosis when it leaks from a vein or unintentionally injected into surrounding healthy tissues (Bullock-Corkhill, 2010). Examples of vesicants include calcium solutions, amphotericin B, and meropenem (Pettit, 200; Stranz, 2005). Thus in infants requiring ongoing therapy with vesicant or irritant medications, central venous access is warranted in order to minimize damage to peripheral veins (Pettit, 2006).

The chemical properties of various solutions and medications in addition to osmolality and pH are significant factors that impact the incidence of complications and functional life span of peripheral intravenous catheters. As such, when studying the impact catheter securement on duration of catheter patency and complication rates, these other confounders must be taken into consideration.

Local Complications associated with Peripheral Intravenous Therapy

Infiltration/Extravasation

Infiltration is the most common complication of infusion therapy in neonates (Duck, 1997; Pettit, 2006). It accounts for 23% to 78% of complications and 43% result in skin, tissue, muscle or nerve damage (Beauman & Swanson, 2006; Pettit, 2003). Infiltration refers to the "inadvertent administration of non-vesicant solutions or medications into the surrounding tissue" (Infusion Nurses Society, 2006, p S87). Extravasation on the other hand describes the

“inadvertent administration of a vesicant solution or medication into the surrounding tissue” (Infusion Nurses Society, 2006, p S86).

Several theories have been proposed on how infiltration occurs. The first theory is that the catheter punctures the vein wall during initial insertion or the vein ruptures due to movement of the catheter in the vein, which results in fluid leaking into the surrounding tissues (Pettit & Hughes, 1993). Another theory is that inflammation and vasoconstriction occur when there is damage to the vein endothelium. The resulting inflammation impedes blood flow around the catheter and flow from the catheter. Consequently, pressure increases within the vein, which enlarges the catheter insertion hole, leading to rupture or leakage of fluid into the surrounding tissue (Beauman & Swanson, 2006; Hecker, 1992). The third theory suggests that the osmolality, pH or chemical composition of solutions or medications leads to significant irritation of the venous endothelium which damages the tunica intima thereby allowing fluid to leak into the tissue, without creating a hole in the vein (Beauman & Swanson, 2006; Pettit, 2003). Clinical signs of infiltration are often non-specific and may be confused with other complications such as phlebitis, infection, venous stasis or thrombosis (Pettit, 2003). Some common signs of infiltration include edema, redness and leaking at the insertion site (Beauman & Swanson, 2006; Pettit, 2003). As the amount of infiltration fluid increases, blanching of the skin may also be observed (Pettit, 2003). Lastly, blistering is a characteristic sign of extravasation and results from infiltration of vesicants, leading to tissue damage (Infusion Nurses Society, 2006; Pettit, 2003). Several pharmacologic agents have been shown to contribute to intravenous extravasation injuries which include hypertonic solutions such as dextrose solutions greater than 5 percent and parenteral nutrition (PN); hyperosmolar and acidic solutions such as calcium and potassium solutions; significantly alkaline drugs such as sodium bicarbonate (Pettit & Hughes, 1993).

Furthermore, vasopressors such as dopamine, dobutamine, epinephrine and norepinephrine have been shown to cause tissue necrosis secondary to intense vasoconstriction of the smooth muscle around capillaries which then results in ischemia (Pettit & Hughes, 1993). Lastly, the use of some antibiotics such as ampicillin, gentamicin, vancomycin, amphotericin B, penicillin, tobramycin and erythromycin, have the potential to cause severe local reactions and necrosis which can lead to extravasation (Pettit & Hughes, 1993). Thus, nursing's awareness of potential hazards of IV therapy is critical to reducing infiltration and extravasation.

Phlebitis

Phlebitis which is the inflammation of the vein intima is another common complication of intravenous therapy (Perucca, 2010). Inflammation occurs due to irritation to the endothelial cells of the vein intima, creating a rough cell wall where platelets easily adhere (Perucca, 2010). Phlebitis is characterized by pain and tenderness along the course of the vein, erythema, inflammatory swelling with a feeling of warmth at the site, streak formation and a palpable venous cord (Perucca, 2010). Phlebitis results from a combination of mechanical, chemical and bacterial factors (Beauman & Swanson, 2006; Perucca, 2010; Pettit 2003). Neonates tend to have less phlebitis and more infiltration compared to adults (Wright, 1996). The exact mechanism is unclear, however, a possible explanation is that neonates have proportionately smaller veins which are more reactive and constrict more completely, resulting in infiltration rather than phlebitis (Wright, 1996). In neonates, the reported incidence of phlebitis is less than 1% to 11.3% (Batton, et al., 1982; Franck, et al., 2001; Johnson & Donn, 1988; Stanley, et al., 1992; Tobin, 1988; Webb, 1987).

Mechanical phlebitis can occur during catheter insertion (Pettit, 2003). Mechanical phlebitis occurs when there is mechanical trauma to the endothelial cells that line the vein wall which then activates the clotting cascade (Beauman & Swanson, 2006). The anatomical location of the catheter, gauge size, catheter material and inadequate stabilization/securement are predisposing factors for mechanical phlebitis (Beauman & Swanson, 2006; Garland, Dunne, Havens, Hintermeyer, Bozette, Wincek, et al., 1992; Perucca, 2010; Pettit, 2003). With insertion in areas of flexion, frequent catheter movement causes irritation to the vein intima which can lead to injury and result in phlebitis (Perucca, 2010). Additionally, insertion of a large catheter in a vein that has a smaller lumen than the catheter also irritates the vein causing inflammation and phlebitis (Beauman & Swanson, 2006; Perucca, 2010). Catheter material can also influence the incidence of phlebitis. Catheters made of polyurethane such as Vialon, are softer, more thermoplastic and flexible than Teflon catheters, thereby causing less venous irritation and a lower incidence of phlebitis (Perucca, 2010; Stanley, et al., 1992). Lastly, inadequately secured catheters have a tendency to move in and out of the vein, allowing the catheter tip to irritate the vein intima resulting in phlebitis (Perucca, 2010).

Chemical phlebitis is associated with the vein endothelium's response to the properties of the solutions or medications being delivered (Pettit, 2003). Factors contributing to chemical phlebitis include the osmolality, pH, and chemical properties of the infusate, and infusion rate (Beauman & Swanson, 2006; Perucca, 2010; Pettit, 2003). The more acidic an IV solution or medication is, the greater the risk of phlebitis (Perucca, 2010). In addition, the vein intima can be irritated and injured by the administration of hyperosmolar solutions (osmolality greater than 600 mOsm/L), especially if they are infused at a rapid rate or through a small vein (Gazitua, et al., 1979; Kuwahara et al., 1998; Perucca 2010). Infusion rate is a risk factor for developing

phlebitis, where a slower rate causes less venous irritation than a rapid rate (Perucca, 2010). With rapid infusion rates, a larger concentration of medications and solutions come into contact with the vessel wall which irritates the veins and lead to phlebitis (Perucca, 2010). Conversely, slower infusion rates provide longer time for absorption, with hemodilution of smaller amounts of solutions or medications (Perucca, 2010). Furthermore, particulate matter in solutions or medications when infused can irritate the vein intima, resulting in inflammation and phlebitis (Pettit, 2003). In-line filters are therefore recommended to prevent infusion of particulates (Hecker, 1992; Perucca, 2010).

Bacterial phlebitis is rare in peripheral intravenous therapy and is described as inflammation of the vein intima associated with a bacterial infection (Beauman & Swanson, 2006; Perucca, 2010). Potential causes include introduction of skin organisms during insertion secondary to poor skin antisepsis, contamination of the catheter, tubing access sites, catheter hub, and intravenous solutions (Beauman & Swanson, 2006). Symptoms of bacterial phlebitis include swelling, erythema, increased warmth of the surrounding tissue and or purulent drainage from the insertion site (Beauman & Swanson, 2006).

Leaking

In neonates, the reported incidence of PIV leaks is 2% to 27.6% (Franck, et al., 2001; Johnson & Donn, 1988; Stanley, et al., 1992). However, the literature is unclear whether leaking is a symptom of phlebitis or infiltration or a separate phenomenon. For instance, catheter dislodgement from the vein, damage to the catheter or hub of the connecting tubing, or infiltration enables the intravenous solutions or medications to escape from the body (Pettit, 2003).

Occlusion

The reported incidence of occlusion associated with PIV therapy in neonates is 4% to 26% (Franck, et al., 2001; Stanley, et al. 1992; Webb, 1987). The main cause of catheter occlusion is thrombus formation caused by fibrin or coagulated blood products (Perdue, 2001). When the catheter is not properly saline-locked between infusions, blood enters the catheter tip which leads to occlusion. Moreover, ineffective flushing between incompatible solutions or medications allows the formation of a precipitate that eventually blocks the catheter (Perdue, 2001).

Summary

In summary, the initial section of this literature review provided an overview of key factors that influence the life span of peripheral intravenous catheters. Injury to the innermost layer of the vein, the tunica intima can be caused by various factors such as osmolality, pH and inherent properties of solutions and medications infused. The most common local complications associated with peripheral intravenous therapy in neonates include infiltration, phlebitis, leaking, occlusion, and dislodgement. The next section of the literature review will focus on clinical studies that have examined various factors that may influence catheter life span and complication rates in infants requiring intensive care.

Peripheral Intravenous Catheters in the Neonatal Intensive Care Unit

A small number of clinical studies were found that focused on factors that influenced the life span of PIVs in infants, specifically within the context of the NICU (Appendix A). Various factors influence the length of time a peripheral intravenous catheter remains in situ. The material the catheter is made of, its gauge in relation to the size of the vein, insertion site,

osmolality, pH, and chemical properties of infusates, all directly affect the efficacy and duration of PIVs (Pettit, 2006; Evans & Dixon, 2006; Pettit, 2003).

Catheter material

Over the years technology has evolved from stainless steel to rubber and different forms of plastic as the material used to manufacture catheters inserted into a vein (Hadaway, 2010). Stainless steel catheters are rigid, thereby preventing its successful use for infusion (Hadaway, 2010). Consequently the use of stainless steel catheters, are limited to blood sampling procedures (Hadaway, 2010). Teflon (polytetrafluoroethylene) is a carbon-based polymer that forms a very stiff material that can kink (Hadaway, 2010). Polyurethane is a urethane-based polymer composed of alternating groups of soft and hard sections that offer strength and flexibility required for a catheter (Hadaway, 2010). Several studies have compared different catheter materials and how it affects complication rates and length of time a catheter remains in situ.

In 1982, Batton et al. examined the rate of phlebitis and duration of catheter life in premature neonates by comparing the Teflon catheter with the stainless steel needle. In this randomized controlled trial a total of 58 catheters- 28 steel needles and 30 Teflon catheters-were used in 34 infants between 26 and 35 weeks gestational age. The mean duration of steel needles was 15.4 hours compared to 49.5 hours for Teflon catheters. All steel needles had to be removed because of infiltration whereas only 57% of the Teflon catheters infiltrated. The study concluded that Teflon catheters lasted 3 times longer than steel needles with no apparent increase in complications, thereby recommending the preferential use of the Teflon catheter in low birth weight infants requiring intravenous therapy. Limitations of Batton et al.'s study are lack of sample size calculation, small sample size, and its lack of a universal definition indicating the presence of phlebitis.

Phelps and Helms (1987) also examined which variables increased the incidence of infiltration or reduced the time to infiltration of PIVs. The sample consisted of infants less than one year of age who were admitted to the Level II nursery. Over a 10 month period, 151 infusions involving 78 patients were evaluated prospectively. Fifty-eight percent of PIVs were infiltrated by 36.3 hours. The time to infiltration was significantly reduced for steel catheters compared to Teflon catheters ($p=0.02$) however, duration means were not provided. Study limitations included its small sample size, and reporting of patients' age. Rather than reporting age in months, it would have been more useful to report age by gestation. Such information would have been helpful in discerning whether important differences exist between preterm and term infants in terms of complications and catheter life span.

Webb (1987) compared steel and Teflon catheters as a method for maintaining intravenous therapy in preterm infants in the NICU. The study consisted of a convenience sample of 200 preterm infants where the first 100 infants requiring IV therapy received steel needles and the next 100 preterm infants received Teflon catheters for IV therapy. There was a significant difference in the mean number of insertion attempts in which steel needles required a mean of 7.04 compared to 2.32 attempts for Teflon catheters. Interestingly, no significant difference was found in the mean catheter life span between the steel needles (26 hours) and Teflon catheters. (27.15 hours). This finding was contradictory to Batton et al. (1982) and Phelps and Helms' (1987) studies. The reason for this contradictory result is uncertain. However in this study, the infants in the Teflon group were of lower gestational age (mean 35.45 weeks vs. 37.3 weeks) than infants in the steel needle group, spent more hours ventilated, received IV therapy for more days, and had longer length of stay in the NICU. Consequently, the Teflon group's more compromised condition may have necessitated more diagnostic procedures and

treatments, thereby exposing them to more handling (Webb, 1987). This increased handling may have resulted in increased disruption to the catheter site of insertion, leading to complications that would necessitate removal and restarting a new PIV catheter. Limitations of this study included its lack of randomization which may have resulted in significant differences in baseline characteristics of infants in the steel and Teflon groups therefore results of the study should be interpreted with caution.

Based on the results of the above studies, Teflon catheters were recommended for intravenous therapy in infants because they offered ease of insertion and lower rates of complications when compared to steel needles. However, more recent studies in adult populations have shown that catheters constructed from polyurethane provide longer duration of infusion and substantially less phlebitis than those made of Teflon (Maki & Ringer, 1999; McKee, Shell, Warren & Campbell, 1989). Recent advances in the quality and properties of polyurethane have resulted in a high-strength, softer material patented as Vialon (Foster, Wallis, Paterson & James, 2002). Vialon is a high-strength material that may offer advantages over lower-strength materials such as Teflon (McKee, et al., 1989). Specifically, Vialon material results in a smooth surfaced catheter that remains firm to allow easy insertion (McKee, et al., 1989). Once inside the vein, the change from room temperature to body temperature increases Vialon's softness and flexibility, allowing the catheter to float into the vein as opposed to lying against the intima (Hadaway 2010; McKee, et al., 1989) (Figure 1). Furthermore, there is an attraction for moisture which also increases the flexibility when placed in the bloodstream (Hadaway, 2010). This characteristic softening of Vialon after placement into a vein and results from adult studies suggest that Vialon may also reduce the rate of infiltration in neonates (Stanley, Meister, & Fuschuber, 1992).

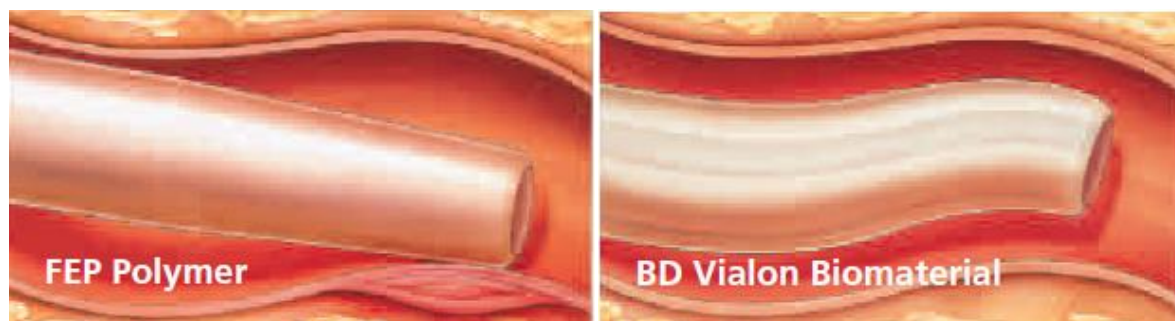


Figure 1. Comparison of Teflon and Vialon catheters once inside the body. Teflon remains firm upon insertion into the vein whereas Vialon becomes soft and pliable once inside the body. Adapted from “*Complications of Intravenous Therapy: A Randomized Prospective Study Vialon vs. Teflon*” by J. McKee, J. Shell, T. Warren, and V. Campbell, 1989, *Journal of Intravenous Nursing*, 12(5), p. 289. Copyright by the Journal of Intravenous Nursing, 1989.

In 1992, Stanley et al. conducted a comparative clinical trial assessing risk factors contributing to infiltration, including a comparison of Teflon and Vialon catheters as a means of IV therapy in neonates (Stanley, Meister, & Fuschuber, 1992). The study sample consisted of 771 PIVs with postnatal age ranging from 1 to 67 days. The gestational age of infants was not provided. Vialon catheters had a significantly longer mean dwell time than Teflon catheters (41 hours vs. 36.2 hours respectively, $p=0.041$). Furthermore, Vialon catheters reduced the risk of infiltration by 18% in the entire sample and by 35% in the higher risk low-weight (≤ 1500 g) subsample. The authors ascribe this finding to Vialon’s characteristic softening when warmed to body temperature and hydrated in the bloodstream (Stanley, et al., 1992). Additionally, the median time to infiltration was 9 hours greater for Vialon catheters (median 51 hours) compared to Teflon catheters (median 42 hours). Lack of blinding of NICU staff is a potential source of bias however, since infiltration is a potentially serious complication, it is unlikely that nurses would be inclined to ignore it. A second potential source of bias is the difference in catheter length, where Teflon catheters were 1.6 cm and Vialon catheters were 1.9 cm (Stanley, et al.,

1992). One would expect that the direction of bias would be to favour the Teflon rather than Vialon catheters (Stanley, et al., 1992). However, since the effect of catheter length was not studied, it is unclear to what extent a 0.3 cm difference in catheter length affected the results of the study. Lastly, the gestational age of patients in each group would have been useful information to determine if there were differences in preterm and term infants. Based on the studies reviewed, identification of catheter material as a risk factor for infiltration is important since the type of catheter used can be easily manipulated by the clinician.

Studies in adults and Stanley et al.'s (1992) study in neonates have shown that catheters made from Vialon reduced the risk of infiltration and provided longer duration of patency than those made of Teflon catheters. As a result, newer PIV catheters made of Vialon have been widely adopted for use in the Neonatal Nurseries at McMaster Children's Hospital.

Catheter size

A wide range of catheter sizes are available. Gauge is the external diameter of the intravascular part of the catheter (Rivera, Strauss, van Zundert, & Mortier, 2005). Gauge size is represented by a number; the smaller the number, the larger the catheter (Rivera et al, 2005). Selection of the appropriate catheter gauge is dependent on the size and location of the vein. The literature suggests that catheter size may influence the duration of catheter patency and complications. As a result, several studies involving infants in the NICU have examined the impact of catheter gauge on functional duration of PIVs and rate of complications. However, such studies have yielded conflicting results.

Catheter size was found to impact duration of patency and complication rates only in studies that have utilized several different catheter gauges within their sample (Phelps& Helms,

1987; Tripathi, Kaushik & Singh, 2008). Larger catheters were found to have a longer dwell time and smaller catheters were found to increase the risk of infiltration and phlebitis (Phelps & Helms, 1987; Tripathi, et al., 2008). The proposed hypothesis is that IV insertion causes injury to the endothelium of veins. Consequently, clotting and sludging caused by the friction of formed elements of blood cells in and around plastic portions further augments the initial injury that occurs with IV insertion (Tripathi, et al., 2008, p. 186). Larger catheter sizes may function as supports to the bruised endothelium and reduce complications (Tripathi, et al., 2008). However, one must also keep in mind that patients in whom larger catheters were inserted tended to be older and larger infants, which may also impact catheter life span and complication rates (Tripathi, et al., 2008).

Conversely, in other studies in which Teflon catheters were used exclusively, the duration of catheter life span was not related to gauge size (Franck, et al., 2001; Smith & Wilkinson-Faulk, 1994; Tobin, 1988). The reason for conflicting results is unclear. Tobin's study (1988) was conducted to assess the life span of Teflon catheters and examine factors which contributed to catheter life and phlebitis in neonates. This study was comprised of 72 neonates between 24 to 43 weeks gestational age with birth weights ranging from 900 grams to over 6000 grams. Teflon catheters used were either 22 or 24 gauge. Tobin (1988) did not find catheter gauge to influence the functional life span of Teflon catheters. Limitations of this study included its small sample size and the investigator did not specify the proportion of the sample received 22 gauge and 24 gauge catheters which could affect whether or not catheter size influenced functional life span of PIVs.

In 1994, Smith and Wilkinson-Faulk conducted a comparative descriptive study in order to identify the effect of cannula size, insertion site, brand type, blood transfusion, and unit setting

on the life span of IVs in hospitalized infants. This study consisted of 250 data sheets gathered from charts of infants 12 months of age and under in the NICU, PICU and general pediatric units, in a children's medical center in southwest, United States. Results showed that catheter size did not make a statistically significant difference in catheter life span. However, of note is that 92.9% of the sample was comprised of 24 g Teflon catheters which may therefore explain these findings.

In 2001, Franck, et al. conducted a quality improvement clinical audit in a single NICU, to identify insertion practices, catheter life span, influencing factors and complications with PIVs. Over a 2-month period, a total of 264 PIVs were inserted in 57 infants. Eighty-four percent (n=220) of the PIVs were 24 gauge, ten percent were 22 gauge (n=27) and in six percent of the cases, catheter gauge was not recorded (Franck, et al., 2001, p. 35). Franck et al (2001) did not find catheter gauge to influence duration of PIV therapy. This finding was consistent with Tobin's (1988) and Smith and Wilkinson-Faulk's (1994) findings of no difference in the use of gauge size when using Teflon catheters. However, similar to Smith and Wilkinson-Faulk's study, the limited variability of gauge size may be the contributing factor to the finding that catheter size did not affect the functional life span of PIV catheters (Franck, et al., 2001; Smith & Wilkinson- Faulk, 1994).

In the neonatal intensive care unit the most commonly used size is a 24 gauge PIV catheter. Similarly, 24 gauge catheters were used exclusively in the present study which compared two different methods of catheter securement. Thus, the potential effect of catheter size on dwell time and complications was excluded.

Insertion site

Commonly selected sites for peripheral IVs in neonates include the hands, forearm, feet, legs and scalp. The infant's history, physical examination, and medications must be taken into consideration when selecting a peripheral intravenous site (Duck, 1997). Studies in the neonatal population have resulted in contradictory findings regarding whether or not insertion site affects the lifespan of peripheral intravenous catheters.

Batton et al (1982), Phelps & Helms (1987); Tobin (1988), Smith & Wilkinson-Faulk (1994) and Gupta et al. (2003) did not find insertion site to affect functional life span of PIV catheters. These studies used 22-25 gauge steel needles and Teflon catheters.

Conversely, in a study assessing risk factors contributing to infiltration, Stanley et al. (1992) found insertion site to be a predictor of infiltration where the risk associated with insertion into the scalp or foot was about 1.6 times compared to other sites, particularly the hand (Stanley, et al., 1992, p. 885). Additionally, Franck et al. (2001) found that functional catheter life span was influenced by insertion site ($\chi^2=25.99$, $p=0.0001$), with upper extremity insertions tending to last longer than 2 days. Peripheral intravenous catheters placed in the upper extremities appear to be less prone to failure from leaking or infiltration than catheters placed in the scalp or lower extremities (Franck, et al., 2001). Furthermore, the reason for removal was influenced by insertion site, where PIVs inserted in the lower extremities were associated with more frequent leaking whereas scalp placements more often occluded (Franck, et al., 2001, p. 36).

Similarly, Tripathi and colleagues found a significant difference in catheter life span based on insertion site ($p<0.05$). Specifically, catheter patency was longest for insertion sites on the dorsum of the hand (49.6 ± 22.4 hrs), whereas it was the shortest at the wrist (23.6 ± 11.2 hrs) ($p<0.05$). Duration of patency was also significantly shorter if the catheter was inserted close to

a joint (mean 32.5 ± 17.8 hours) compared to when it was inserted away from a joint (mean 46.1 ± 16.6 hours) ($p < 0.05$). In contrast, there was a no significant difference in length of catheter patency for lower extremity versus upper extremity veins. Therefore, the results of this study have shown that veins on the dorsum of hands are best whereas wrist and scalp veins are least desirable. This finding is consistent with Franck et al.'s (2001) study in which PIVs placed in the upper extremities were less prone to failure.

Parenteral Nutrition

Clinicians working in the neonatal intensive care unit often encounter challenges in helping to meet the basic nutritional requirements and supporting the growth needs of high-risk and preterm infants (Bakewell-Sachs & Brandes, 2004). Often times, infants born prematurely are deprived of transplacentally acquired nutrient stores and have rapid extrauterine growth rates (Bakewell-Sachs & Brandes, 2004). Additionally, other high-risk infants have specific needs associated with illness-related metabolic demands and physiologic instability (Bakewell-Sachs & Brandes, 2004, p. 205). Parenteral nutrition (PN) is indicated for initiation of nutritional support for preterm infants and can be used concurrently with enteral nutrition to provide partial daily requirements for certain infants (Bakewell-Sachs & Brandes, 2004). Parenteral nutrition refers to the administration of specialized nutrition intravenously (Krzywda, & Meyer, 2010).

Intravenous nutrients are distributed to the portal venous system for metabolic processing by the liver (Krzywda & Meyer, 2010, p. 316). PN provides nutrition for patients who are unable to receive sufficient nutrition with oral feedings, enteral feeding and supplements (Krzywda & Meyer, 2010).

Parenteral nutrition solutions consist of a complex mixture of macronutrients such as protein, carbohydrates and water; and micronutrients such as electrolytes, vitamins and trace elements-

all of which are critical for the maintenance of normal metabolism and growth (Krzywda & Meyer, 2010). Generally, macronutrients (dextrose and fat) are utilized as an energy source and for structural substrate support (proteins and fats). Micronutrients on the other hand, help support a wide array of metabolic activities essential for cellular function, such as fluid balance, enzymatic reactions and electrophysiological processes (Krzywda & Meyer, 2010).

The existing research studies evaluating factors influencing the life span of the PIV are small and often yield conflicting results (Pettit, 2003). Most reports are observational, quality improvement accounts or small clinical trials. Similar to other factors discussed, the impact of PN on the life span of PIVs has been inconsistent.

In their randomized clinical trial, Phelps and Helms (1987) found that the time to infiltration was greatly decreased with administration of parenteral nutrition and medications compared to 5% or 10% dextrose. In this study there were a total of 151 infusions in which fifty-six of them contained 5% dextrose solution, fifty-two contained 10% dextrose and forty-three were parenteral nutrition solutions. Only 29% of the infusions had parenteral nutrition solutions however, no lipid emulsions were infused. It has been shown in other studies that continuous infusion of lipid emulsions simultaneously with parenteral nutrition solutions significantly prolongs the life span of the PIV (Phelps, & Cochran, 1989)

In 1989, Phelps and Cochran conducted a non-randomized study which prospectively evaluated the effect of continuous infusion of parenteral nutrition solutions with and without lipid emulsion on the incidence of and time to infiltrations of PIVs in infants. Ninety-seven PIV catheters were studied in 53 infants who received 10% dextrose (n=34), 10% dextrose/ 2% amino acids (n=30) or 10% dextrose/2% amino acids/lipid emulsion (n=33). Dextrose, amino acid, electrolyte and mineral content were standardized for the dextrose/amino acid and

dextrose/amino acid/lipid emulsion groups. The probability of infiltration was greater for patients receiving dextrose/amino acid than for those receiving either dextrose or dextrose/amino acid/lipid emulsion ($p=0.01$). The mean catheter dwell time was significantly shorter for the dextrose/amino acid solutions ($26.3 \text{ hours} \pm 3.3 \text{ hrs}$) compared to the dextrose ($54.9 \pm 7.8 \text{ hrs}$) and dextrose/amino acid/lipid emulsion ($43.6 \pm 4.2 \text{ hrs}$) groups. The exact mechanism for the protective effect of lipid emulsion is unknown but may result from the hemodilution of the final solution's osmolarity and prevention of dextrose/amino acid induced changes in the endothelium (Phelps & Cochran, 1989).

In 1992, Garland et al conducted an observational study involving 303 patients in a pediatric intensive care unit to determine complication rates and associated risk factors. Of the 654 Teflon catheters studied, 52% of the sample consisted of infants 0-12 months of age. Infusion of parenteral nutrition with continuous intravenous lipid emulsions increased the risk of phlebitis (OR 2.9, $p=0.002$). The high osmolarity of parenteral nutrition solutions may explain the association with phlebitis (Garland, et al., 1992). Given that the infusion of lipids has been shown to prolong PIV catheter life span in patients receiving hyperalimentation, the risk of phlebitis due to infusion of parenteral nutrition alone may be even higher (Garland, et al., 1992). Although this study included infants less than 12 months of age, the complication rates and associated risk factors occurring during intravenous therapy in children in a pediatric intensive care unit may not be applicable to infants in the neonatal intensive care unit who are often born preterm, experience different diseases, receive different medications, and are at greater risk for nosocomial infections. Similarly, in a randomized controlled trial, Stanley et al. (1992) found that infusion of parental nutrition solutions was associated with 1.5 times the risk of infiltration

when compared to other infusates in both the total sample and in the low-weight subsample (≤ 1500 g).

Conversely, several studies in neonates did not find infusion of parenteral nutrition to influence the functional life span of peripheral intravenous catheters. In Tobin's study (1988) assessing the functional life span of Teflon catheters, the type of intravenous solution and infusion of lipids were not significantly associated with duration of catheter life. Similarly, Johnson and Donn (1988) found no significant differences associated with the use of parenteral nutrition on the life span of peripheral intravenous catheters. Lastly, Gupta et al. (2003) also found that the use of parenteral nutrition was not significantly associated with catheter life span.

In summary, studies that have examined the influence of parenteral nutrition on functional life span of peripheral intravenous catheters in neonates have yielded mixed results. Limitations of the studies reviewed are their observational, non-randomized design and small sample sizes. However, studies conducted in animals and adults, have established that osmolality of intravenous solutions play a significant role in the life span of PIV catheters (Gazitua, et al., 1979; Kuwahara, et al., 1999; Kuwahara, et al., 1998). Therefore it is imperative that all solutions infused through the peripheral vein have an osmolality that reflects that of the serum in order to prevent vessel damage, infiltration, phlebitis and fluid shifts (Gazitua, et al., 1979; Pettit, 2006; Pettit, 2003).

Medications

Intravenous administration of certain medications can cause soft-tissue injury, resulting in decreased catheter life span (Gupta, et al., 2003). Medications vary in their chemical composition, pH and osmolality- all of which influence life span of PIVs and lead to

complications (Pettit, 2003). Nurses need to have timely access to resources that quantify and describe the properties such as osmolality, pH and chemical composition of IV solutions and medications to ensure correct administration and reduce the risk of preventable complications (Pereira-da-Silva et al., 2002).

Several studies have examined whether administration of medications affected the duration of catheter life and rates of complications. Phelps & Helms (1987) found that infusion of medications significantly reduced the time to infiltration. Medications that were administered included: ampicillin, gentamicin, phenobarbital, phenytoin, aminophylline, nafcillin and moxalactam (Phelps & Helms, 1987). The data was analyzed for combination rather than individual medications (Phelps & Helms, 1987). In this study, administration of any intravenous medication was correlated with a 1.8 fold increase in the incidence of infiltrations, regardless of medication type (irritating versus non-irritating). Phelps and Helms proposed that the mechanism of medication administration and not the drug itself was likely responsible for this finding since irritating and non-irritating medications had similar effects. Pushing a medication as opposed to infusing it slowly could result in more infiltrations and shorter catheter life span (Phelps and Helms, 1987). Although the influence of medications on PIV life span was not one of the factors explored, Smith and Wilkinson-Faulk (1994) found that the mean life span of PIVs in which non-irritating medications were infused lasted one hour longer than those in which known irritants were infused. This finding was similar to Phelps & Helm's (1987) study, which found no difference in the rate of infiltration between PIVs in which irritating and non-irritating medications infused.

Johnson & Donn (1988) prospectively surveyed PIV catheter use in a NICU to ascertain the rate of complications and factors influencing the life span of a PIV catheter. Rather than simply

noting the use or non-use of a particular medication during the life of a PIV catheter, the investigators assigned a weighted fraction in which the number of days in which medication was used divided by the PIV life span in days (Johnson & Donn, 1988, p. 968). This strategy enabled the investigators to conduct a detailed assessment of factors influencing PIV life span or complications. No significant difference in catheter life span was associated individually with morphine, phenobarbital, ampicillin or calcium gluconate. However, data was not analyzed for combinations of medications. Pancuronium, a skeletal muscle relaxant, was correlated with a longer catheter median life span. Specifically, in patients not receiving pancuronium, the median life span was 30 hours, whereas the median life span was 50 hours in patients who received this drug ($p=0.05$) (Johnson & Donn, 1988). However, the researchers hypothesized that the longer catheter life span in patients receiving pancuronium was most likely due to the paralyzing effect of the drug which limited the movement of the PIV catheter (Johnson & Donn, 1988).

Gupta and colleagues (2003) conducted an observational study to examine the life span of peripheral intravenous catheters in a NICU of a developing country. Out of 186 catheters, 166 (89%) were used for administering fluids and medications, whereas the remaining 11% were used for only delivering medications. In this study, Cefotaxime was the only drug that was found decrease catheter life span, where the median catheter lifespan was 36 hours compared with those not receiving the drug (median 47 hours) ($p=0.007$). The mechanism of IV medication administration could have significantly increased the peripheral line pressure and may have been associated with the decreased time to infiltration, rather than the drug itself (Gupta, et al., 2003).

Blood Products

Several studies have sought to determine whether infusion of blood products is associated with a longer PIV catheter dwell time. Once again the evidence has been conflicting. Johnson &

Donn (1988) and Gupta et al (2003) did not find a significant difference in catheter life span when blood products were administered through the PIV catheter. Conversely, Tobin (1988) found that 80% of the 15 PIVs in which blood products were administered tended to last significantly longer, at least 24 hours (Tobin, 1988). Similarly, Smith & Wilkinson-Faulk (1994) also found that the life span of PIVs was significantly longer ($p=0.048$) when blood products were administered. Experts hypothesized that the compatible pH of blood may have buffered the PIV for the acidic solutions being infused into the vascular system (Tobin, 1988).

Patient Characteristics

Several studies have looked at patient characteristics such as age, gender, weight and level of activity to determine whether it influenced rates of complications and functional life span of peripheral intravenous catheters. Studies involving infants in neonatal intensive care units have found that gestational age, gender and weight did not affect the dwell time of peripheral intravenous catheters (Batton, et al., 1982; Franck, et al., 2001; Gupta, et al., 2003; Johnson & Donn, 1988; Phelps & Helms, 1987; Tobin, 1988).

In 1988, Tobin examined infant variables such as weight and level of activity, to assess whether these variables were related to duration of catheter life. The study sample consisted of 72 infants between 24 to 43 weeks gestational age (mean 33.79 weeks), weighing between 900 grams to 6110 grams (mean 2356.94 grams). Only the level of activity was found to be a predictor of PIV catheter life span (Tobin 1988, p. 38). Among the 18 infants who were rated to have the highest levels of activity, 15 (83%) infants had PIV catheters that lasted less than 24 hours. Therefore, infants who were rated by the bedside nurses as being frequently active were more likely to have PIV catheters that lasted less than 24 hours (Tobin, 1988). Shorter dwell

times could be attributed to the frequent movement of the catheter at the site of insertion which then leads to dislodgement (Tobin, 1988). Stanley et al. (1992) found postnatal age to be a significant predictor of infiltration in neonates. In this study, the risk of infiltration for infants 5 days of age or older was approximately 1.5 times the risk of those less than 5 days old (Stanley, et al., 1992, p. 885). However, this finding may be related to increased physical activity after the first four days life (Stanley, et al., 1992).

Conversely, studies in pediatric units which included infants and children in their sample have found age to be predictive of the functional life span of peripheral intravenous catheter (Garland, et al., 1992; Foster et al, 2002; Tripathi, et al., 2008). In Garland and colleagues' study conducted in a single PICU, age (≤ 1 year) was found to be one of the most important predictors of extravasation (Garland, et al., 1992). Of the 654 PIV catheters, 52% accounted for infants ≤ 1 year of age. The increased extravasation risk in children younger than 1 year of age may be attributed to the difficulty in placing and securing PIV catheters in this age group (Garland, et al., 1992, p. 1149). Age as a strong predictor of extravasation and hence catheter lifespan may have been due to the heterogeneity of the study sample.

Similarly, Foster and colleagues conducted a descriptive study of peripheral intravenous in patients admitted to a pediatric unit in Australia (Foster, Wallis, Peterson & James, 2002). Over a 5-month period, 496 catheters were inserted into 436 pediatric patients including neonates, infants and children. Of the PIVs, 152 (30.6%) were inserted into infants (18.5% in neonates), and 344 (69.4%) into children. Neonates and infants had more than 5 times the risk of phlebitis when compared to children greater than 1 year of age (Foster, et al., 2002). However, one of the main challenges in examining complication rates such as phlebitis associated with PIV catheters is the lack of a universal definition. For instance, the Infusion Nursing Standards (INS) phlebitis

scale ranks the extent of phlebitis by how many symptoms are present however, such a scale is not appropriate for neonates since pain assessment in preverbal children is often difficult (Foster, et al., 2002). Consequently, phlebitis is defined differently in various studies making it difficult to compare complication rates across studies. Thus, in order to be able to make meaningful and accurate comparisons across epidemiologic studies, future studies should include the development of a standard definition of phlebitis associated with neonatal PIVs.

In Tripathi and colleagues' (2008) study involving pediatric patients (neonates to 12 year olds), age was found to have a significant positive correlation with duration of catheter patency. Infants less than 1 year of age had the shortest duration of catheter patency (mean of 40.38 hours) compared to those older than 1 year (Tripathi, et al., 2008, p. 184). While the incidence of infiltration was statistically higher in infants less than 1 year of age, there was no significant difference in the rate of phlebitis. This finding may be because infiltration is more dependent on keeping the hand still, whereas phlebitis results from injury secondary to the chemical nature of the fluids and drugs or by physical trauma to the endothelium (Tripathi, et al., 2008, p. 186).

Although Smith and Wilkinson-Faulk's (1994) study did not specifically examine age and weight, results indicated that PIV catheters in the general pediatric units lasted significantly longer (mean 53.62 hours) than those in the NICU (mean 36.84 hours) ($p=0.017$). In the NICU, 70% of PIV catheters were non-electively discontinued compared to only 50% in the general pediatric units. Thus, other factors such as age, activity level, fragility of veins and method of securement, could also have contributed to the differences in functional lifespan of PIV catheters (Smith and Wilkinson-Faulk, 1994, p. 546).

In summary, studies in the NICU did not find age, gender and weight to influence the functional lifespan of peripheral intravenous catheters (Batton, et al., 1982; Franck, et al, 2001; Gupta, et al., 2003; Johnson & Donn, 1988; Phelps & Helms, 1987; Tobin, 1988). Conversely, studies in pediatric wards which have included neonates, infants and children have found age to significantly affect duration of catheter patency. Overall, studies conducted in pediatric wards have found that PIV catheter lifespan was significantly shorter in infants less than 1 year of age (Foster, et al., 2002; Garland, et al., 1992; Smith & Wilkinson-Faulk, 1994; Tripathi, et al., 2008). Differences in findings can be attributed to the heterogeneity of the samples in pediatric studies, whereas the samples are more homogenous in studies conducted only in the NICU. Lastly, level of patient activity was consistently found to influence catheter lifespan.

Peripheral Intravenous Catheter Securement

Splints

Neonates requiring hospitalization in the neonatal intensive care unit (NICU) routinely undergo peripheral venous cannulation for administration of intravenous fluids and medications. Often times, multiple peripheral venous cannulations are needed in order to provide fluids and medications for prolonged periods (Dalal, Chawla, Singh, Agarwal, Deorari & Paul, 2009). The use of splints to immobilize and provide stability to the limb is a common practice used to prolong the functional lifespan of PIV catheters. Few studies have evaluated the effect of application of splints on functional duration of PIV catheters in the neonatal population (Appendix B).

Tripathi and colleagues conducted a randomized controlled trial (RCT) to determine whether the use of splints and heparin flushes affected PIV catheter lifespan. Children were

randomized to either heparin flush or saline flush and within each group each child was alternatively given a PIV catheter with or without splints (Tripathi, et al., 2008, p. 183). Preassembled splints made of cardboard wrapped bandage, of various sizes were placed by nurses in a standard fashion (Tripathi, et al., 2008). The use of splints compared to no splint significantly prolonged duration of catheter patency, with a mean duration of 50.29 hours compared to 39.75 hours respectively ($p < 0.005$) (Tripathi, et al., 2008, p. 185). A synergistic effect was found with the use of heparin flush and splint (mean 52 hours $\pm$ 24 hours, $p < 0.05$). Phlebitis was significantly decreased when splints were used (Tripathi, et al., 2008).

To date, only two studies involving neonates have examined whether the use of splints influenced the functional life span of peripheral intravenous catheter. Splint application was one of the factors examined by Gupta and colleagues in a prospective survey of PIV practices in a single NICU in India (Gupta, et al., 2003). In this study, splints were used at the discretion of staff nurses however a description of the splint was not provided. A splint was used in 69 (37.1%) catheters. No significant differences in the functional lifespan of PIV catheters were found for various factors including the application of splints.

Similarly, a more recent RCT was conducted by Dalal and colleagues which aimed to evaluate the efficacy of splinting the joint on the functional duration of peripheral intravenous catheter in neonates (Dalal, et al., 2009). Over an 8-month period, 54 preterm and term neonates were enrolled into the study, where 69 cannulations were performed and included into the study. Both groups were comparable with regards to baseline characteristics and in the type of fluids administered. The mean functional catheter lifespan was less in the splint group compared to the no-splint group, although this difference was not statistically nor clinically significant (23.5 hours (SD 5.9) vs. 26.9 hours (SD 15.5); mean difference -3.3, 95% CI: -11 to 4.3, $p = 0.38$)

(Dalal, et al., 2008). This difference was more evident in neonates less than 30 weeks gestational age; however the number of patients in this group was too small to arrive at any conclusions (Dalal, et al., 2009). Extravasation at the catheter site was the most common reason for catheter removal in both groups (84 % vs. 76.5% of cases). The authors hypothesized that when splints are used and are proximally secured with tape, the resulting pressure placed on the draining veins may consequently promote extravasation (Dalal, et al., 2009).

Peripheral Intravenous Catheter Securement Devices

Various methods of catheter securement are available, including different types of tape, suture and more recently, specifically engineered securement devices (Frey & Schears, 2006). According to the Infusion Nursing Standards of Practice, manufactured catheter stabilization devices are the preferred method of stabilization over other methods and should be used whenever possible (Infusion Nurses Society, 2006). Until recently, little attention has been paid to the method of securement of peripheral intravenous catheters and, in particular, the role of improved securement in preventing complications. Increasingly, clinicians are recognizing that securement technique is critical since it can impact catheter motion, which may contribute to complications (Frey & Schears, 2006).

Only one method, the StatLock catheter securement device, has been evaluated extensively in prospective and randomized controlled trials. StatLock's features include an adhesive footplate which comes into complete contact with the skin and a catheter-locking mechanism that sits on top of the pad, thereby providing securement near the insertion site (Appendix D) (Bard Access Systems, 2012; Frey & Schears, 2006). When added to peripheral intravenous catheters, the StatLock device reduces catheter tip micro-motion compared to tape

alone, providing greater stability thereby, increasing functional duration of catheters and minimizing complications (Schears, 2006; Smith, 2006).

The introduction of StatLock, the first engineered catheter securement device, led to several studies examining outcomes of short peripheral intravenous catheters secured with StatLock compared to the common practice of application of tape to secure PIV catheters. The first study conducted by Wood (1997) was a prospective, non-randomized sequential study of PIV catheter securement in a 175-bed hospital adult setting involving four different units: the emergency department, intensive care unit, medical unit and surgical unit (Wood, 1997). Two methods of catheter securement were compared: transparent dressing and tape (control group) versus transparent dressing and StatLock (study group). The study evaluated 105 PIV catheters and was divided into 2 phases: phase 1 consisted of the control group which used transparent dressing and tape, and phase 2 consisted of the study group using a transparent dressing over the insertion site and StatLock securement device (Wood, 1997). There was a 45% reduction in overall complications and unscheduled IV restarts when transparent dressing and StatLock was used compared to transparent dressing and tape ($p=0.025$) (Wood, 1997). Catheter dislodgement occurred in 42% of the control group compared to only 2% in the study group, accounting for a 40% reduction in dislodgement (Wood, 1997). There was also an 8% decrease in infiltrations and the average catheter dwell time increased by 21 hours in the StatLock group compared to the transparent dressing/tape group. Limitations of the study included the non-randomized design and small sample size. Since the study was conducted in two phases, at different times, the two groups differed in terms of primary diagnoses with more patients experiencing cardiovascular disease in the control group (60% versus 31%), whereas there were more patients with pulmonary disease in the study group (25% versus 16%) (Wood, 1997). The distribution of

patient age in the study sample was not provided and this could influence the catheter dwell time, number of IV restarts and complications.

Similarly, Sheppard and colleagues (1999) conducted a sequential, prospective study to explore whether the use of a StatLock securement device on short peripheral catheters influenced catheter dwell time and rates of catheter-related complications. The study was conducted in two phases in a single nursing and rehabilitation center involving adult patients (Sheppard, et al., 1999). During Phase 1, 15 PIV catheters were secured with a transparent dressing and tape and in Phase 2 15 catheters were secured with StatLock and a transparent dressing. Gender, average length of treatment, IV fluids, antibiotic administration, and conditions that might predispose to catheter complication were similar in both groups (Sheppard, et al., 1999). Catheters secured with Statlock and transparent dressing had a significantly longer average dwell time (94.8 hours versus 58.8 hours) and significantly fewer total complications (65 versus 155, $p=0.001$) (multiple complications were noted for some catheters) compared to catheters secured with transparent dressing and tape (Sheppard, et al., 1999). The number of unscheduled PIV catheter restarts was significantly fewer in the Statlock group compared to the transparent dressing and tape group (55 versus 24; $p<0.005$) (Sheppard, et al., 1999). StatLock reduced the time spent managing PIV catheter dislodgements by 13.5 minutes per patient. Study limitations included a non-randomized design and small sample size.

In 2006, Smith evaluated the number of peripheral intravenous catheters surviving to the 96-hour scheduled change protocol in three different groups, using a prospective, sequential cohort design (Smith, 2006). The study was conducted in a community hospital. The first group (73 adult patients) used non-sterile tape; the second group (38 adult patients) used StatLock; and the third group used HubGuard (300 adult patients), consisting of dye-cut foam adhesive strips

(Smith, 2006). As part of the unit's routine quality improvement studies, 6 months after completion of this study, an additional 248 adult patients using StatLock, were evaluated. The use of non-sterile tape securement resulted in an 8% 96-hour survival rate; Hubguard produced a 9% 96-hour survival rate, while both groups using StatLock resulted in a 52% survival rate to 96 hours (Smith, 2006). However, several limitations in this study need to be addressed. The author failed to provide a description of the study setting and sample, making generalizability and comparison across groups difficult. The different sample sizes in the three groups of this study could bias the results. Finally, this study was not a randomized controlled trial with matched samples in all phases. A randomized controlled trial would establish the superiority of one securement method over another. Nevertheless, the mechanical securement device, StatLock delivered longer PIV catheter dwell times which are consistent with other studies.

An additional large trial was undertaken consisting of pooled data from product evaluations at 83 hospitals throughout the United States, comparing StatLock with the standard practice using tape for PIV securement in adults and children (Schears, 2006). During the product trials, 10 164 patients, 18 months of age or older, requiring 15 004 PIVs were followed for up to 72 hours or to the completion of therapy, whichever came first (Schears, 2006). There were 9955 PIVs in the tape group and 5049 PIVs in the StatLock group. The primary outcome variables were unscheduled restarts, overall complications and specific complications (e.g. phlebitis) (Schears, 2006). In the tape groups there were 4123 (70.7%) unplanned restarts whereas the StatLock group required only 717 (16%) unplanned restarts within a 72-hour period (Schears, 2006). The need for unscheduled PIV restarts was reduced by 76% when StatLock was used compared to tape ($p=0.0001$) (Schears, 2006, p. 226). Additionally, there was an 80% reduction in the rate of phlebitis with the use of the StatLock securement device. The relative

risk of phlebitis with tape was 5.082, more than 5 times greater than with StatLock, which was statistically significant ($p < 0.001$) (Schears, 2006, p. 227). Lastly, there was a statistically significant difference in the rate of total complications, with 47.6% in the tape group compared to 16% in the StatLock group ($p < 0.001$), representing a 67% reduction in total complications (Schears, 2006). The data suggested that the use of a catheter stabilization device such as StatLock for securing peripheral intravenous catheters was superior to tape in reducing the rate of unscheduled PIV restarts and complications. Based on the reduced complications, an annual cost savings of \$18,000 per hospital on PIV materials and a combined savings of \$227,000 on materials, complication costs and nursing time were estimated (Schears, 2006, p. 227). This observational study is subject to several types of bias, given the lack of randomization and blinding. Since patients in the study were enrolled sequentially rather than concurrently, selection bias may have occurred. Variations in practices regarding insertion and maintenance of peripheral intravenous catheters among the various hospitals could have influenced the outcome of the study. However, this trial included the largest group of patients ever reported evaluating catheter securement methods. The literature provides two other studies (Sheppard et al, 1999; Wood, 1997) that compared tape securement of PIV catheters with StatLock. In these studies, StatLock reduced the rates of unscheduled restarts by 71.4% (Wood, 1997), and 56.4% (Sheppard et al, 1999), respectively. Moreover, the complication rates were reduced by 69.2% (Wood, 1997) and 58.1% (Sheppard et al, 1999). These findings are consistent with the data presented in Schears' report for the pooled product trials.

Studies that have evaluated the StatLock securement device have focused primarily on adults, thereby limiting the ability to generalize results to the neonatal population (Appendix C). To date, only one non-randomized unpublished study conducted in the Neonatal Intensive Care

Unit at McMaster Children's Hospital, has evaluated the use of a securement device in neonates. In 2005, Blatz conducted a prospective non-randomized study to determine whether the use of a stabilization device such as StatLock would increase the length of time that PIVs lasted in infants cared for in the NICU. The study compared StatLock with transparent dressing and tape for securing peripheral intravenous catheters in neonates. A significant difference in dwell time was found in a subset of PIVs ($n=372$) secured with StatLock ($44.2 \text{ hrs} \pm 29.2 \text{ hrs}$) compared to PIVs ($n=485$) secured with transparent dressing and tape ($36.9 \text{ hrs} \pm 23.5 \text{ hrs}$) ($p<0.001$). The dwell time for the PIVs secured with Statlock was considerably longer, indicating that improved fixation appears to prolong the length of time of a PIV in a neonate (Blatz, 2006). Limitations of this study included a historical control group comparison from 2003 and non-randomized design (S. Blatz, personal communication May 10, 2012).

More recently, modified securement dressings with catheter securement properties have become available. Specifically, the 3M Tegaderm 1610 securement dressing has been developed, which combines a transparent polyurethane film with a soft cloth reinforcement for added security (3M, 2012). Additional features of this dressing include a deep notch design, which seals around the catheter, further stabilizing and securing the catheter (Appendix E). Also included are two sterile tape strips to allow firm fixation of the PIV catheter (McCann, 2003). The Tegaderm 1610 is a 5 cm x 5.7 cm sterile dressing that has been safely used in the pediatric population. McCann (2003) conducted a small evaluation study of Tegaderm 1610 in children between the ages of five months and twelve years of age (McCann, 2003). The study evaluated the Tegaderm 1610 dressing based on seven criteria: application, initial adhesion, overall adhesion, security of the cannula, observation of the site, ease of removal and skin condition after removal. Results of this evaluation study showed a positive overall rating of the Tegaderm

1610 throughout the seven criteria. In 82% of the cases, Tegaderm 1610 was rated 5 (excellent) or 4 (McCann, 2003). However, the study has several limitations which include a non-randomized design. The study was a small product evaluation using a questionnaire that was completed by members of the IV team and other nurses who inserted the PIVs. Data on important outcomes such as PIV catheter dwell times and complication rates would have provided additional information that would have been useful for clinicians.

The Tegaderm 1610 dressing has not been evaluated for securing peripheral intravenous catheters in neonates. What is unknown is whether this type of modified dressing is more effective than StatLock in reducing complication rates, increasing IV dwell times, and reducing costs associated with peripheral intravenous therapy. Various factors such as an infant's size, and site of IV catheter insertion can influence whether or not a PIV catheter can be secured with StatLock. Thus, evaluation of other methods for securing PIV catheters is essential. To date, studies evaluating peripheral intravenous catheter securement in neonates are limited. Research is needed to assess the most effective method of peripheral intravenous catheter securement for infants in the neonatal intensive care unit. Doing so will provide further guidance on practices surrounding peripheral intravenous therapy in the NICU. Lastly, substantial cost savings may also be realized since nursing time for PIV catheter placement and the supplies needed to establish vascular access would be significantly reduced.

CHAPTER 3: Conceptual Framework

In this chapter, the conceptual basis of this study is reviewed. Conceptual frameworks provide a “frame of reference, for organizing thinking, as a guide for what to focus on, and for interpretation of results” (Rycroft-Malone & Bucknall, 2010, p. 28). The Model for Improvement and Plan-Do-Study-Act framework guided the development of the study methods.

Model for Improvement

Quality improvement should be part of an ongoing process in every organization (Franck, et al., 2001). Evidence-based practice should reflect results of current and relevant research, and the randomized controlled trial is considered the gold standard of research methodology. However, the clinical setting does not always lend itself to the testing conditions of a randomized controlled trial. Nonetheless, assessment of the efficacy and impact of a change needs to be made. Most quality improvement methodologies provide a mechanism for iterative testing of ideas and redesign of process or technology based on lessons learned (Marcellus & Harrison, 2012).

The *Model for Improvement* (Langley, Nolan & Nolan, 1994) offers a practical approach to the assessment of change, providing a balance between the need for action and the need for evidence (Brock, Nolan & Nolan, 1998) -this is ‘research in action’. The Model for Improvement incorporates the Plan-Do-Study-Act (PDSA) cycle which was originally developed by Walter Shewhart as the Plan-Do-Check-Act (PDCA cycle). W. Edwards Deming modified Shewart’s cycle to PDSA, replacing “Check” with “Study” (Marcellus & Harrison, 2012) (Figure 2). The Model for Improvement has been developed to precede the use of the PDSA Cycle (Taylor, McNicholas, Nicolay, Darzi, Bell & Reed, 2013). The underlying principle is that improvement

comes from the application of knowledge and the model provides a framework for individuals or teams to gain and apply knowledge (Langley et al., 1994). Any approach to improvement should be based on building knowledge and on the appropriate application of that knowledge.

The Model for Improvement consists of two parts that are of equal importance. The first, the ‘thinking part’ consists of three fundamental questions which help the researcher focus the research question, current knowledge base and study design. The three initial questions to be addressed as part of the initial planning phase: What are we trying to accomplish? How will we know if a change is an improvement? What changes can be made that will result in improvement? (Langley et al., 1994). These questions help lay the foundation for the desired improvement and provide the framework for the “trial-and-learning” approach of the PDSA model (Langley, Nolan, Nolan, Norman & Provost, 1996). The second part of the Model for Improvement can be regarded as the ‘doing part’, which is comprised of the Plan-Do-Study-Act (PDSA) Cycle that will assist one in implementing a proposed change.

In the first question, “*What are we trying to accomplish?*” stakeholders identify areas of concern and set goals for a quality improvement initiative. These goals must be measurable and based on a specific length of time. The developed goals should address a specific population, such as infants in the NICU requiring the insertion of PIV catheters for intravenous therapy, in which the quality improvement initiative is directed. Goals should be brief and concise (Langley et al., 1996). QI goals can address a wide array of clinical issues ranging from enhancing patient safety to reducing length of hospital stay.

The second question, “*How will we know that a change is an improvement?*” focuses on the need to establish both measures and a timeline in which the improvement is expected to

occur (Langley et al., 1996). Measures must be feasible, valid and reliable. Although improving patient outcomes may be the fundamental goal, it is also essential to include process measures to evaluate the implementation of the plan itself. Outcome measures include pre and post testing to determine if the desired change led to a clinical improvement (Plsek, 1999). Thus, it is critical that process and outcome data are readily available in order to ascertain the impact of the QI initiative and provide direction for the next steps (Langley et al., 1996).

The third question, *“What changes can we make that will result in an improvement?”* is a critical element of the Model for Improvement. Ideas for a proposed change can arise from various thought processes, including critical thinking about a current process, outside observations, literature review of scientific journals, creative thinking, or previous experiences of similar situations (Plsek, 1999). Initial ideas for change may be based on logical and scientific foundations with proven merit that can stimulate additional ideas that lead to an applicable improvement (Plsek, 1999). It is important to note that not all ideas for change lead to actual improvements in care and may even negatively affect other clinical functions. Thus, ideas for quality improvement initiatives must be carefully planned and evaluated prior to being implemented. Lastly, the change concept must be adapted to one’s local context in order to increase commitment to the proposed change (Plsek, 1999).

Within the proposed PIV securement study, the three questions aimed at “building knowledge” were used to help the researcher focus the research question, knowledge base and research design.

1. *What are we trying to accomplish? (What is the aim?)*

Short-term PIV catheters remains the most commonly used vascular access device for administration of parenteral nutrition and medications in neonates, however 95% of PIV catheters are removed due to complications such as infiltration, leaking, occlusion, phlebitis and dislodgement (Pettit, 2003; Franck, et al., 2001; Wright, 1996). Preterm and sick neonates are more vulnerable to skin injury and complications from extravasation injury compared to their healthy term counterparts (Beall, Hall, Mulholland, & Gephart, 2013). Furthermore, preterm neonates are at an increased risk of complications from venipuncture and IV infusions due to their immature skin structures, flexible subcutaneous tissue, small blood vessels and poor venous integrity (AWHONN, 2013; McCullen, & Pieper 2006). Thus, the goal of nursing care is to prevent skin breakdown whenever possible, as well as to reduce the need for frequent re-cannulation to establish vascular access. Recent recommendations from the Centers for Disease Control and Prevention (2011) indicate PIVs in children need to be replaced only when clinically indicated, as long as they are functioning properly and there are no signs of complications (O'Grady, Alexander, Burns, Dellinger, Garland, Heard et al., 2011). Strategies such as better IV securement for increased patient safety and comfort are needed in order to prolong functional lifespan of PIVs while preventing complications of infiltration, extravasation, leaking, occlusion, phlebitis and dislodgement (Alekseyev, et al., 2012). Catheter securement and stabilization should be used to preserve the integrity of the PIV catheter to prevent catheter movement and loss of access (Alekseyev, et al., 2012). Thus, the process of securing PIV catheters could be significantly improved, resulting in longer duration of patency and fewer PIV restarts which means less pain and discomfort for neonates. Furthermore, improvement in PIV securement would lead to cost savings derived

from reduced nursing time for unscheduled restarts and a reduction in supplies needed to establish vascular access.

2. *How would we know if a change is an improvement? (What do we need to measure?)*

Outcome indicators of PIV dwell time as measured in hours, and complication rates were measured in the study. In addition, the rate of PIV catheter dislodgment which is closely related to securement methods were monitored. The aim was to improve the method of catheter securement without sacrificing quality of care. Prolonged duration of catheter patency, reduction in catheter dislodgement and complication rates would signify improvements in patient outcomes. Additionally, compliance with the new Tegabear dressing for securing peripheral intravenous catheters was used as a process measure to evaluate the success of its implementation in clinical practice. If improvements occur in both outcome indicators and process measures, then it can be concluded that the QI initiative was effective.

3. *What change can we make that will result in improvement?*

A review of the literature revealed that methods for securing PIV catheters commonly employed either the use of transparent dressing and tape or the StatLock securement device. Although studies in adults have found StatLock to be superior to transparent dressing and tape for securing PIVs, various factors preclude its use in preterm and sick neonates. For instance, the infant's size and site of the IV catheter insertion can influence whether or not a PIV catheter can be secured with StatLock. Moreover, there is no consensus on the optimal method of PIV catheter securement due to the paucity of scientific research in neonates. Recently, modified securement dressings with catheter securement properties have become available. Thus, the primary change was the implementation and evaluation of a new Tegabear dressing.

After these three fundamental questions are addressed, the theory and experience suggests that successful organizations then set in place small-scale tests of change in Plan-Do-Study-Act (PDSA) cycles (Plsek, 1999).

Model for Improvement

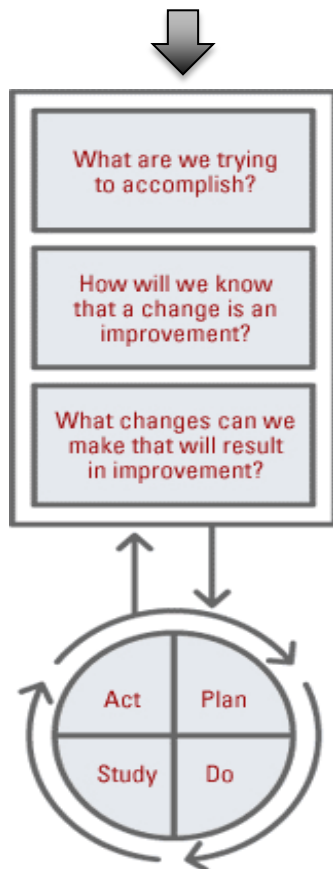


Figure 2. Conceptual model as used for study adapted from “Model for Improvement”

(Langley et al., 1994).

Testing a change: the Plan-Do-Study-Act (PDSA) Cycle

The PDSA cycle provided a framework for testing and implementing the change. It provides a method for structuring iterative development of change, either as a sole method or as part of wider quality improvement approaches, such as the Model for Improvement (Taylor et

al., 2013). The cycle not only focuses on building knowledge but also on testing the change (Langley et al., 1994).

The PDSA cycle has its origins from industry and Walter Shewhart and Edward Deming's articulation of iterative processes which eventually became known as the four stages of PDSA (Taylor, et al., 2013). Historically, the PDSA cycle was developed to facilitate change in the manufacturing and service industries however, several health care studies have since employed the Model for Improvement (or aspects of it) (Taylor et al., 2013).

The PDSA cycle consists of a four-stage cyclic learning approach to adopt changes aimed at improvement (Taylor, et al., 2013). During the '*Plan*' stage, a problem is identified with a precise problem statement and the appropriate performance measure is selected to evaluate or monitor the problem solving effort (Langley et al., 1996; Taylor et al., 2013). Based on the predetermined measurements, a prediction is made about how the upcoming initiative will result in improvement (Langley et al., 1996). Additionally, processes to carry out the desired change or initiative in terms of who, what, when and where, are planned (Langley et al., 1996).

During the '*Do*' stage of the quality improvement initiative, interventions are developed and implemented on a small scale such as a pilot study (Langley et al., 1996; Taylor et al., 2013). A pilot study enrolls a small number of participants and may be particularly helpful for an organization to learn how a large-scale project might work in practice (Grady & Hulley, 2007). In addition, a small-scale pilot study can provide data on the feasibility of measurements, reactions to the intervention and any discomfort that may result (Grady & Hulley, 2007). The change is tested, data is collected and the change is evaluated to determine if it resulted in the desired improvement (Langley et al., 1996). During this stage, unexpected problems or outcomes

may arise (Taylor et al., 2013). Thus, it is critical that these unanticipated occurrences are documented and analyzed during the next phase by stakeholders, with feedback from group members affected by the unexpected outcomes (Taylor et al., 2013).

During the ‘*Study*’ phase, the data resulting from the pilot study are analyzed and the actual outcome is compared to the desired outcome (Langley et al., 1996; Stikes & Barbier, 2013). Outcome data are analyzed and new knowledge gained as a result of the pilot study is assessed (Langley et al., 1996). Furthermore, the analysis also includes process evaluation to determine if the pilot study was carried out as planned and what, if any, unexpected problems occurred (Taylor et al., 2013). The data is then summarized and additional trials or a large scale implementation may be considered (Taylor et al., 2013).

The ‘*Act*’ phase entails identifying any required modifications, acting on what was learned, and identifying the next steps to inform a new cycle (Stikes & Barbier, 2013; Taylor et al., 2013). Based on the results, the change is either accepted or abandoned, in which case the cycle starts again (Langley, 2009). The iterative approach of the PDSA cycle allows lessons learned from one cycle to inform the next cycle. Moreover, ineffective changes also result in learning, which is a key principle behind the PDSA cycle (Taylor et al., 2013).

Rationale for Using the Plan-Do-Study-Act Model

The PDSA model is the improvement framework that was used in this study because of its easy adaptability in any clinical setting. The model presents a pragmatic scientific method for testing changes in complex systems (Taylor et al., 2013). Possible ideas for improvement can be readily tested in a rapid succession of small trials, trying different variations of ideas and experimenting with what approach works best in a specific clinical setting (Langley et al., 1996).

The four stages of the PDSA cycle parallel the scientific experimental method of formulating a hypothesis, collecting data to test this hypothesis, analyzing and interpreting the results and drawing conclusions to iterate the hypothesis (Taylor et al., 2013). Similar to the scientific experimental method, the PDSA cycle promotes prediction of the outcome of a test of change and subsequent measurement over time to evaluate the impact of an intervention on the process or outcomes of interest (Taylor et al., 2013). Measurement of data over time helps understand inherent variation in complex systems, increase awareness of other factors affecting processes or outcomes, and understand the impact of an intervention (Taylor et al., 2013). The philosophy of the PDSA model is that “the most effective way to make changes in health care processes and outcomes is to test a relatively small change in a process, learn from it, and then make further changes so that the cumulative effect over time may be one of major change and improvement” (Stikes & Barbier, 2013, p. 84). Given the complexity of the neonatal intensive care unit and the various factors affecting the functional dwell time of peripheral intravenous catheters, the impact of PIV securement is best studied through the PDSA cycle.

CHAPTER 4: Methods

PLANNING PHASE: Identifying and Designing the Quality Improvement Study

Continuous quality improvement in healthcare focuses on reducing errors and complications and improving outcomes by increasing consistency and adherence to evidence-based practice standards (Franck et al., 2001). Quality improvement (QI) necessitates monitoring of clinical indicators that can be used to evaluate the quality of essential patient care interventions (Batalden & Stoltz, 1993). QI also entails the identification of best practices, implementation of interventions to improve adherence with best practices, and audits to determine if the expected improvement in outcomes was achieved (Franck et al., 2001, p. 34).

The Plan-Do-Study-Act Model was used as a framework to guide the development of the study, implementation, and analysis of the results. '*Planning*' is the first stage in the PDSA Model and as such methods employed in the current study will be discussed in this chapter.

Planning the QI study

Many NICUs have put in place practice standards or guidelines to ensure consistency in the practice of PIV insertion and maintenance. Often times, PIV guidelines may indicate the number of attempts per IV inserter, considerations for use of analgesics and comfort measures, the method of securing the PIV catheter, and maintenance of the PIV and indications and procedure for removal (Franck et al., 2001). Every two to three years, an audit of peripheral intravenous (IV) practices is conducted in the Neonatal Nurseries at McMaster Children's Hospital. The clinical audit often involves collecting data on the prevalence of complications with PIVs and identification of influencing factors. Historically, approximately 600 peripheral

intravenous catheters are followed over a 4-month period. The present study is a subset within the larger quality improvement audit of peripheral intravenous practices in the Neonatal Nurseries.

Aim of the study

The study used the Plan-Do-Study-Act cycle to evaluate two peripheral intravenous catheter securement methods, StatLock versus Tegabear dressing, by comparing duration of patency and rates of complications. The objective was to determine which securement method was more effective in increasing catheter dwell time and reducing complication rates in infants in the Neonatal Nurseries. Both quantitative and qualitative data were collected and assessed over a 4-month period.

Research Question and Predictions

The research question that guided this study was:

1. *Is there a difference in the mean catheter dwell time when StatLock, a securement device with an adhesive anchor combined with a transparent dressing is used versus Tegabear dressing, to secure a peripheral intravenous catheter?*

The second question was:

2. *Is there a difference in the complication rate when StatLock combined with a transparent dressing is used to secure a peripheral intravenous catheter versus using Tegabear dressing?*

The above research questions were investigated through the testing of the following null hypotheses:

Null Hypothesis 1: There will be no difference in duration of patency between peripheral intravenous catheters secured with Tegabear dressing and those secured with StatLock combined with a transparent dressing.

Null Hypothesis 2: There will be no difference in the rate of complications between peripheral intravenous catheters secured with Tegabear dressing and those secured with StatLock combined with a transparent dressing.

Setting

The study was conducted in the Neonatal Nurseries at McMaster Children's Hospital in Hamilton, Ontario. This is a teaching hospital that is the referral center for a geographically defined region in central-west Ontario, delivering approximately 25 000 infants per year. The Neonatal Nurseries provides a complete spectrum of neonatal intermediate and tertiary care.

The Neonatal Intensive Care Unit consists of 47 beds, which provides care for infants from LHIN 3 and LHIN 4, who require tertiary neonatal care. The annual admission rate is approximately 1500 infants who are either inborn or are referred to the NICU from the surrounding region. The NICU consists of five pods: A, B, C, D and E. Pods A, B, D, and E consist of 10 beds each, whereas Pod C consists of 7 beds. The infant stabilization room (ISR) is a separate area in the Labour and Delivery unit where high-risk infants are transferred to and stabilized within the first hour of life prior to admission to the NICU. The Intermediate Care Nursery has 14 beds and provides secondary level care.

Study Design

A prospective, open-label, non-randomized design was used for the present study. Limited resources, including time constraints, precluded conducting a randomized controlled trial. Rigorous quasi-experiments or observational studies, using comparison groups have been recommended for healthcare quality improvement (Kleinman & Dougherty, 2013). Thus, a quasi-experimental pilot study was conducted which was more consistent with the PDSA cycle. The use of quasi-experimental designs is an advantage when methods of catheter securement are

evaluated in patient care situations (Hanchett, 1999). The study evaluated the effectiveness of two different peripheral intravenous catheter securement methods: Tegabear dressing and StatLock. The study was conducted over a 4-month period from July 25, 2012 to November 12, 2012, and was divided in two phases with each phase lasting 2 months.

The primary outcome of the study was *catheter dwell time*, which is defined as the time between insertion and removal of the catheter (elective or because of complications) measured in hours. Secondary outcomes of the study include *rates of complications*, which lead to the removal of the peripheral intravenous catheter. Complications included redness, edema, blanching, blockage and leaking. *Catheter dislodgement*, defined as the catheter pulling out from the skin, was also examined since this complication could be caused by inappropriate securement of the peripheral intravenous catheter. *Electively discontinued* PIVs were also included as a secondary outcome and defined as catheters that were removed without clinical signs of infiltration, phlebitis, occlusion, leaking, extravasation or the need for a central venous catheter.

Sample

All infants admitted in the Neonatal Nurseries, who required a peripheral intravenous catheter for IV maintenance fluids, parenteral nutrition, or administration of medications, were eligible to participate in the study. Furthermore, PIV catheters inserted for transfusion of blood products and saline locked for ongoing care were also eligible to participate in the study.

Inclusion Criteria

In the Neonatal Nurseries at McMaster Children's Hospital, nurses certified in PIV insertion self-select the type of catheter to be inserted based on personal preference, site of insertion, and an infant's size. The 24 gauge Insite catheter is the most commonly used catheter,

accounting for approximately 60% of the PIVs inserted in the Neonatal Nurseries. The Insyte catheter is made of Vialon and is the only catheter in the Neonatal Nurseries that can be secured with either StatLock or Tegabear dressing. Thus, only infants in whom a 24 gauge Insyte catheter was successfully inserted were included in the study.

Exclusion Criteria

Infants in whom a peripheral intravenous catheter other than the 24 gauge Insyte catheter was selected for insertion were excluded from the study, since the other catheters could not be secured with a StatLock. Insyte catheters inserted solely for transfusion of blood products or diagnostics tests, which were removed immediately after the procedure had been completed, were excluded from the study.

Sample size

A two-sided test for comparing means is required in order to determine whether there is a difference in the mean IV dwell time between StatLock and Tegabear. The previous 2009 PIV audit in the Neonatal Nurseries found that the average dwell time of Insyte catheters was 41.7 hours (S. Blatz, personal communication, January 6, 2011). On the basis of a Type I error of 0.05, a Type II error of 0.2 (power 0.8), and a clinically significant difference of 6 hours in the mean IV dwell time, a sample size of 960 was needed. In order to account for 10% drop out/missing data, a final sample size of 1056 Insyte catheters was required (Appendix F).

It is important to note that past audits of IV practices in the NICU, conducted every two to three years, have typically resulted in a total of 600 IVs followed over a 4-month period, where Insyte catheters typically accounted for 60% of IVs inserted (S. Blatz, personal communication, May 10, 2012). Therefore, based on the sample size calculation, a total of 1760

IVs would need to be followed in order to obtain the required sample of 1056 Insyte catheters. Such a large sample size is not feasible for the present single-centre study, given limited resources and a time frame of 16 weeks. Instead, a more pragmatic approach was chosen consisting of an evaluation study comparing two methods of IV securement, as a subset of a larger audit of current IV practices in the NICU. In this audit 600 IVs were followed prospectively, in which Insyte catheters would typically account for 60% ($n=360$) of the total IVs inserted. Therefore, taking into account 10% missing data/drop out, the final sample size required for the present study was 396 Insyte catheters.

Procedures

In order to facilitate recruitment of eligible infants, educational in-services were provided to nurses in the Neonatal Nurseries (NICU and ICN) two weeks prior to beginning the study. Taking into account staffing issues and patient acuity in the unit, the researcher and supervisory committee felt that the best way to reach nursing staff was to provide educational in-services at the bedside. This was accomplished by the researcher providing small group in-services in each pod. Furthermore, a list of registered nurses certified at PIV insertion, such as the transport team, admission nurses, and charge nurses, was obtained from the Neonatal Nurseries' Education Clinician to ensure that these individuals participated in the educational in-services. During these in-services, nurses were oriented to the purpose of the study, inclusion and exclusion criteria, IV insertion and securement methods and completion of data collection forms. Since the Tegabear dressing was a new product that was not used in the NICU, nurses were also shown how to apply the Tegabear dressing when securing PIV catheters using a mannequin. A total of 84 NICU nurses were reached with the small-group educational in-services, with 63% (30/48) of these nurses certified at IV insertion participated in the educational in-services.

Standard procedure regarding IV insertion was maintained using the Neonatal Nurseries IV insertion and maintenance policy and procedure (Appendix G). Standardized step-by-step procedure for securing an IV with either StatLock or Tegabear, were also used (Appendix H-I). Step-by-step instructions for the securement of PIVs with either StatLock or Tegabear were posted in high visibility areas such as the IV cart and supply cupboards in each pod, staff washrooms, and on the research bulletin board across from the nursing lounge. The instructions were also sent to all nurses via email through the hospital secured network. Registered nurses chose insertion sites according to personal preference and availability of veins.

In the event that the 24 gauge Insite catheter could not be secured with the securement method being evaluated (Tegabear or StatLock), the catheter was secured using a transparent dressing and clear tape, which was consistent with current practice in the Neonatal Nurseries. Lastly, an arm board was used at the nurse's discretion based on the site of IV insertion and infants' level of activity.

Instruments

Since the present study is a subset of a larger audit of PIV practices in the Neonatal Nurseries, the data collection form that was previously developed for auditing IV practices in the Neonatal Nurseries was modified to include data needed for this study (Appendix J-K). Data was collected prospectively on demographic variables such as postmenstrual age (PMA), postnatal age, gender, current weight; factors related to insertion such as site and time of insertion; method of securement; type of IV fluid(s) and medication(s); reason for and timing of removal.

The demographic data enabled comparison of the control (StatLock) and experimental group (Tegabear). Clinical data provided information on potential confounding variables such as

medications, concentration of infusing dextrose solution, parenteral nutrition, and administration of blood or blood products as bolus infusions.

In order to determine which medications to include in the data collection form, the NICU pharmacist was consulted to identify the most common medications used in the Neonatal Nurseries, focusing on those that were most irritating to the vein. The most commonly used medications included: ampicillin, gentamicin, caffeine citrate, vancomycin, cefazolin, cefotaxime, furosemide, dopamine, morphine and fentanyl (S. Gray personal communication, June 6, 2012). Dopamine, morphine and fentanyl are often administered as continuous infusions and are therefore included in a separate category (continuous infusions) in the data collection form. Medications used in the NICU that are the most irritating to the vein include: vancomycin, dopamine, sodium bicarbonate, acyclovir, erythromycin and amphotericin B (S. Gray personal communication, June 6, 2012; Hecker, 1992; Pereira-da-Silva et al., 2002). Lastly, complications are expressed as symptoms rather than diagnoses in an effort to make nursing observations less subjective.

Content validity of the data collection sheet was assessed by three independent health care professionals with expertise in the neonatal field. The data collection sheet was adapted from one used in a study investigating PIV securement (Blatz, 2006).

Ethical considerations

Procedure for Approval of the Study

Approval for this study was obtained from the student's supervisory committee, as well as the Neonatal Research Committee at McMaster Children's Hospital. The study underwent

ethical review by the Research Ethics Board at McMaster University and Hamilton Health Sciences. Approval to proceed with the study was provided on July 19, 2012 (Appendix L).

Since the study was part of a quality improvement initiative, written consent from parents was not required. However, parents were informed verbally about the study and an information sheet (Appendix M) explaining the purpose of the study, procedures, potential risks and benefits, was provided. Lastly, an information sheet summarizing the study was also provided to the nursing staff in the Neonatal Nurseries (Appendix N).

Provision of Patient Safety, Privacy and Confidentiality

The anonymity of each subject was protected. Initially, hospital identification number and study number on the data collection forms identified infants. Once data collection was completed and entered into the Statistical Package for Social Sciences (SPSS) version 20 for Windows, the researcher anonymized the data by deleting the subjects' hospital identification number and used only the study number. All information was stored in a secure password-protected hospital network drive and password-protected computer. Completed data collection forms were stored in a locked filing cabinet (researcher's home office) and accessible only to the research team (student principal investigator, thesis supervisor and supervisory committee). The data collection forms and all materials arising from the study will be appropriately disposed as confidential waste five years after completion of the study.

The insertion of PIV catheters is currently performed by nurses certified in intravenous insertion who follow the NICU policy and procedure. Since the Tegabear dressing had not been previously used in the NICU, a potential safety issue was a lack of familiarity with its use. Therefore, prior to study commencement, staff education was provided by the researcher

regarding the proper application of the Tegabear dressing for securing Insite catheters. An information sheet summarizing the study and procedure for securing peripheral intravenous catheters was also provided to nurses, posted in the IV cupboards and on the Neonatal Nurseries website. The posted information reinforced and standardized the care of the patient. Lastly, standard practice in the NICU involves monitoring all peripheral intravenous sites on an hourly basis. Nurses were instructed to notify the researcher in the event that an infant had an adverse skin reaction to either the StatLock or Tegabear dressing.

In addition to ensuring the safety of infants in the study, another critical factor was to consider how the study impacted staff nurses in the NICU. In order to minimize undue stress to nurses and streamline workload demands, a single data collection form was used for this study, integrating the larger audit of IV practices in the NICU. The data collection form was colour-coded to delineate between Pods that were using either Statlock (pink forms) or Tegabear (blue forms).

Risks and Benefits to Study Subjects

Risks

The risks associated with intravenous cannulization should not differ between the Tegabear and the StatLock group. The common risks associated with the insertion of any intravenous catheter include: air embolism, venous thrombosis, phlebitis, and infiltration (Batton, et al., 1982; Maki & Ringer, 1991; Phelps & Helms, 1987). All efforts were made to reduce these risks by utilizing experts who were knowledgeable in the policy and procedure of intravenous insertion.

Although the study evaluated two different methods of securing peripheral intravenous catheters, there was minimal to no risk for harm to infants in the NICU. StatLock has been safely used in the NICU for securing Insite catheters. Tegabear, the new securement dressing, has also been safely used in pediatric patients. More importantly, the standard practice of hourly assessment of intravenous sites contributes to reducing the rates and severity of complications.

Benefits

The study did not benefit infants directly. However, results of the study will help inform future practice in the NICU regarding optimal methods for securing peripheral intravenous catheters. Insertion of PIV catheters is a painful procedure for infants, therefore, improving how PIV catheters are secured, may help reduce complications and increase duration of catheter patency. Most importantly, it could reduce the number of painful PIV restarts for infants requiring intravenous therapy in the NICU.

Improving peripheral intravenous catheter securement also benefits nurses in the NICU because reducing complications can lead to a reduction in downstream activity such as lower rates of PIV catheter restarts, thereby improving nurse safety by reducing blood exposure and needlestick injuries(Callaghan, Copnell, & Johnston, 2002). Reducing the rate of catheter restarts as a result of complications could help conserve nurses' time, crucial with the increasing patient acuity and workload demands.

Lastly a PIV restart represents additional product costs for the IV replacement. Although challenging to assess the true total costs associated with one securement method over another, an exclusive focus on the measurable costs of the products used to start IVs is an important factor in the decision as to how an institution secures its PIVs. When comparing the costs of the 2

securement methods, each StatLock costs \$5.15 compared to Tegabear dressing which costs \$0.50. Furthermore, when StatLock is used, the PIV must first be secured with a tegaderm transparent dressing, an additional cost of \$0.17. This translates to a total cost of \$5.32 when StatLock is used for PIV securement. If the Tegabear dressing is found to be as effective as StatLock, then this would translate to a potential cost-saving of \$4.82 per PIV catheter insertion.

Data Collection

Since the study was part of an audit of IV practices in the Neonatal nurseries, registered nurses were asked to complete the data collection form upon insertion and removal of all peripheral intravenous catheters. Standard nursing practice in the NICU involves nurses conducting systematic hourly IV site assessments to monitor for complications. Infants were followed until the peripheral intravenous catheter was removed. When the peripheral intravenous catheter was removed, the nurse caring for the infant completed the data collection form indicating the date and time of removal, reason(s) for IV removal, and the type of solution(s) and medications administered through the IV. In addition, for infants in whom Insite catheters were inserted, nurses were asked to indicate whether they were able to use Tegabear or StatLock to secure the IV and if not, indicate reason(s) why. In order to maximize data collection for all infants enrolled in the study, the researcher reviewed the data collection forms on a daily basis to ensure completion and accuracy through verification with the daily flowsheet and electronic documentation. Daily flow sheets and electronic documentation were used to complete missing information in the data collection forms.

Data Analyses

All data analysis was performed using IBM Statistical Package for Social Sciences version 21 for Windows. Data were analyzed based on method of securement device used. The analysis of patient characteristics and outcome variables were summarized using descriptive measures expressed as mean (standard deviation) or median (minimum –maximum) for continuous variables and frequencies, expressed as percentage for categorical variables. The Chi-square test or Fisher's exact test were used for comparison of categorical variables. The Chi-square test of independence was used to test the difference in proportions in two or more independent groups (Polit, 1996). The Fisher's exact test was used to test the difference in proportions when the expected frequency for a cell was less than 5 (Polit, 1996)

Details of timing of placement and removal of PIVs allowed for the calculation of PIV life span in hours. Assessing for normality assumption was taken into account to determine if parametric statistical tests could be employed (Ghasemi & Zahediasl, 2012). The distribution of the study sample was assessed both visually and through normality tests. Specifically, the histogram, and boxplot were used for visually checking for normality of PIV catheter life span (Ghasemi & Zahediasl, 2012). Furthermore, the Shapiro-Wilk test which is based on the correlation between the data and the corresponding normality scores was used. The Shapiro-Wilk test provides better power than other types of normality tests and is appropriate for small sample sizes, but can also handle sample sizes as large as 2000 (Ghasemi & Zahediasl, 2012).

Initially, a two-tailed Student t test was planned to test the first null hypothesis; there would be no difference in catheter dwell time when StatLock is used to secure a peripheral intravenous catheter compared to Tegabear. The data was not normally distributed and was skewed to the right (Figure 3; Appendix O, Figures O1-4). Additionally, the Shapiro-Wilk test p-

values were <0.001 indicating that the PIV lifespan was not normally distributed for the StatLock and Tegabear group (Appendix P). A log transformation was performed to normalize the data and to determine whether parametric tests could be used. However, despite log transformation, the distribution was still skewed which was confirmed by examining the skewness and kurtosis z scores for each securement method, looking at the Shapiro-Wilk test p-value and through visual examination of histograms, and box plots (Appendix Q, Figures Q1-Q5). The sample did not meet the assumptions for the use of parametric statistics and thus, non-parametric statistical tests were used because of the non-normal distribution. The Mann Whitney test was used to compare the StatLock and Tegabear groups for duration of PIV placement.

In this study, the time from insertion of the PIV catheter to the occurrence of a complication or the end of the study observation period was captured. Such data are referred to as survival data and necessitate special methods for their analyses. Survival analysis is used to analyze data in which the time until a given event is of interest (Bewick, Cheek & Ball, 2004). A *complication* referred to any event that required the removal of the PIV catheter. A patient whose observation finished without complication (e.g. PIVs that were removed because they were no longer needed) was referred to as a *censored* case. Failure to take censored cases into account can produce serious bias in estimates of distribution of survival time (Rich, Neely, Paniello, Voelker, Nussenbaum & Wang, 2010). Therefore, data from censored cases (n=76) were taken into account by the Kaplan Meier survival analysis to calculate the probability of the terminal event at any time period under study. The Kaplan-Meier curves and estimates of survival data has been widely used when dealing with differing survival times (time-to-event) where not all the patients continue in the study (Rich et al., 2010). This method of analysis was preferred to the life table analysis since the even times were exact rather than being divided into intervals (Gupta,

et al., 2003). Log-rank test was used to compare survival curves since all terminal events were weighted equally. Specifically, the log-rank test was used to test the null hypothesis of no difference between survival functions of the StatLock and Tegabear groups.

The second null hypothesis was that there would be no difference in the rate of complications between the StatLock group and the Tegabear group. To test the second hypothesis, the Chi-square test was used. An α (alpha) level of 0.05 was used throughout the statistical analysis.

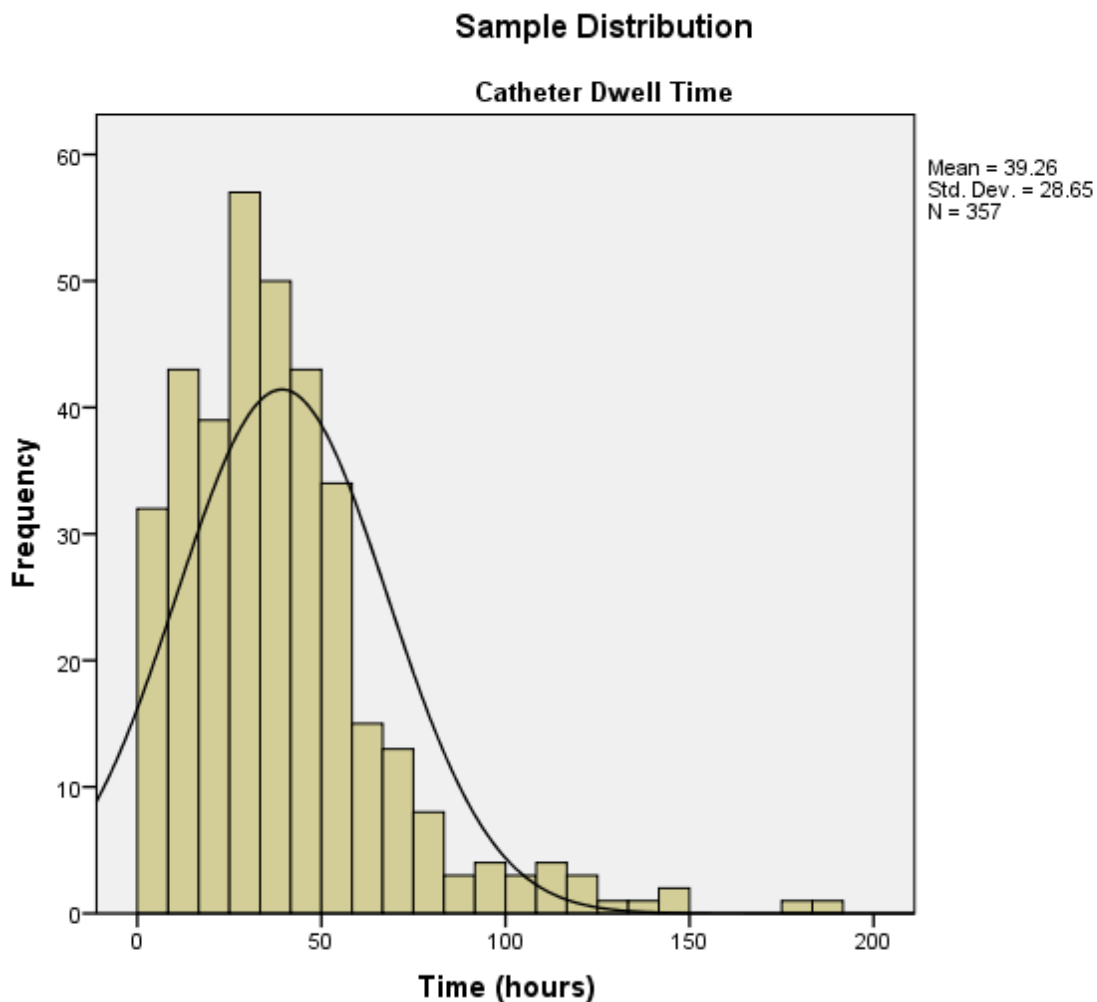


Figure 3. Sample distribution of PIV catheter duration of patency.

CHAPTER 5: Study Implementation and Results

Modifications to the Planned Process

The study was initially designed as a pre-intervention and post-intervention study. The pre-intervention phase was aimed at collecting baseline data where standard practice was to use StatLock for securing Insyte catheters whenever possible. During the second phase, the new dressing, Tegabear would be used to secure Insyte catheters and results would be compared with the pre-intervention phase. However, after presenting the study to the Neonatal Research Committee (NRC) for approval, it was recommended that StatLock and Tegabear be evaluated simultaneously in order to minimize bias. This was accomplished by assigning one half of the Neonatal Nurseries to use StatLock and the other half to use Tegabear in Phase 1 and then switching the location in Phase 2.

“Doing”: Implementing the Study

The study was conducted in 2 phases over a 4-month period from July 25, 2012 to November 12, 2012 (Appendix R). In Phase 1 of the study (July 25-Sept 17), the new dressing, Tegabear was evaluated in Pods A, B and C, whereas StatLock was used in Pods D, E, Intermediate Care Nursery (ICN) and infant stabilization room (ISR). In Phase 2 (Sept 18-Nov 12), Tegabear dressing was used in Pods C, D, E and ICN, whereas StatLock was used in Pods A, B and ISR.

In Phase 1 of the study 198 Insyte catheters were inserted where 124 (62.6%) were secured with StatLock, 55 (27.8%) used Tegabear, 18 (9.1%) used a transparent dressing with tape, and 1 catheter (0.5%) where the method of securement was unknown (Appendix S). Since the study involved trialing a new securement dressing, it was important to evaluate how well

nurses used the assigned securement method. In the Pods that were assigned to use StatLock, 121 Insys catheters were inserted, with 90% (109/121) following the assigned securement method, and 10% (12/121) secured with transparent dressing and tape. In the Pods that were assigned to the Tegabear dressing, 76 Insys catheters were inserted with 72.4% (55/76) secured with Tegabear, 19.7% with StatLock (15/76), and 7.9% (6/76) with transparent dressing and tape. One issue that arose based on feedback from the nursing staff was that the Tegabear dressing was not adhering to the skin when applied, often requiring reinforcement with transparent tape or dressing. However, the researcher was unable to delineate whether this issue was related to lack of familiarity with using the new dressing or a defect in the Tegabear dressings that were used. Additional education was provided and modifications were made to how the cloth steri-strips provided with the Tegabear dressing could be used to provide added securement. A 2-page information sheet addressing frequently asked questions was disseminated on August 2, 2012, to all staff through their work e-mail and posted in high visibility areas (Appendix T). Furthermore, in discussion with the research supervisory committee and Neonatal Nurseries' education clinician, a decision was made to replace all Tegabear dressings that were stocked in the Neonatal Nurseries. A new supply of Tegabear dressings was ordered and the lot numbers were compared with the ones previously used in the Neonatal Nurseries to ensure that they were different. The new Tegabear dressings arrived on September 17 and were used for Phase 2 of the study.

During the second phase of the study a total of 165 Insys catheters were inserted in which 87 (52.7%) used StatLock, 53 (32.1%) used Tegabear, 24 (14.5%) used transparent dressing with tape, and 1 (0.6%) catheter where the method of securement was unknown (Appendix S). Specifically, in the areas assigned to the StatLock group, there were 63 Insys

catheters in which 88.9% (56/63) used the assigned securement device, 9.5% (6/63) used transparent dressing with tape, and 1.6% (1/63) used Tegabear. In the areas assigned to the Tegabear dressing, 101 Insite catheters were inserted where 51.5% (52/101) used the assigned dressing, 30.7% (31/101) used StatLock, and 17.8% (18/101) used transparent dressing and tape. In this phase, there were several challenges related to nurses' lack of adherence with using the Tegabear dressing in designated clinical areas in the Neonatal Nurseries. To ensure that procurement of clinical data was optimized, the researcher was in the unit 3 times a week to collect data forms, restock IV carts with data forms and ensure that the IV carts were stocked with the assigned securement device or dressing. In doing so, the researcher discovered that StatLocks were being stocked in Pods that were supposed to be using the Tegabear dressing, which could account for the 31% non-compliance in the Tegabear group. The researcher reinforced the purpose of the study and the only way to determine which securement method was more effective was to evaluate the Tegabear dressing while at the same time, document issues encountered with its use.

Evaluating the effectiveness of a change intervention should rely on multiple sources of information. In addition to outcome measures such as catheter dwell time and complication rates, feedback provided by staff was also critical in determining the utility of the Tegabear dressing for securing PIVs in infants in the NICU. In this study, a comments section was included in the data collection form and nurses were encouraged to provide detailed feedback regarding issues they encountered with either StatLock or Tegabear, indicating reasons why they were unable to use the assigned securement method. Evaluation and feedback at the individual, team and system levels using 'hard data' (e.g. audits) or 'soft data' (e.g. feedback from health care professionals about the intervention) enable health care professionals to be more receptive to implementing

PIV securement practice changes (McCormack, Kitson, Harvey, Rycroft-Malone, Titchen & Seers, 2002).

“Studying”: Evaluating the Results

During the “Study” phase of the PDSA cycle, outcomes are critically appraised, feedback is sought and changes are made based on the data (Lipshutz, Fee, Schell, Campbell, Taylor, Sharpe, et al., 2008). Steps in this phase included: analyzing the data collection forms, monitoring the use of StatLock versus Tegabear, and obtaining feedback from nurses on Tegabear dressing. A total of 363 Insyte catheters were inserted in 175 infants over the 4-month period. While some infants were studied more than once, each PIV insertion site enrolled was naïve to prior catheterization. Therefore, each infusion site was considered an independent event. The majority of the Insyte catheters were inserted in the NICU accounting for 85.4% (310/363), 9.1% (33/363) in the Intermediate Care Nursery (ICN) and 5.5% (20/363) in the Infant Stabilization Room (ISR).

Demographic Patient Characteristics

A total of 363 Insyte catheters were placed in 175 infants, for a mean of 2.1 PIVs per infant. However, the number of PIVs per infant ranged widely, from 1 to 16. The sample consisted of infants 23 to 54 weeks’ postmenstrual age (PMA) (mean 34.46 ± 4.99 weeks), with postnatal age ranging from 1 to 212 days (mean 18.31 ± 29.64 days). Weights ranged from 420 to 5290 grams (mean 2111 ± 52.26 grams). Fifty-four percent of the sample were male (n=195) and forty-six percent were female (n=168). There were 211 catheters in the StatLock group and 108 catheters in the Tegabear group. An unanticipated finding of a third group where catheters were secured with a transparent dressing and tape, accounted for the remaining 11.6% (n=42) of the

catheters. The third group was distinctly different from the StatLock and Tegabear groups; consisted mainly of infants who were younger (23-34 weeks PMA) and mostly weighed less than 1500 grams (55%). A summary of patient and peripheral intravenous infusion characteristics of the three groups are provided in Appendix U (Table S1-S2). Since the intent of the study was to compare the StatLock and Tegabear groups, these two groups will be the focus when discussing the main results.

The StatLock and Tegabear groups were similar with regards to all of the demographic variables except for postmenstrual age (Table 1). There was a significant difference in postmenstrual age between the two groups, $\chi^2 (3, n=319) = 21.5, p<0.001$. In the StatLock group, approximately 51.2% of the infants were between 29-34 weeks PMA compared to 25.9% in the Tegabear group. There were fewer infants between 35-39 weeks PMA in the StatLock group compared to the Tegabear group (24.2% versus 45.4%, respectively).

Peripheral Intravenous Catheter Characteristics

Complete data regarding insertion attempts was obtained for 361 PIVs. In 209 cases (57.9%), insertion was accomplished on the first attempt, 121 cases (33.5%) where insertion was accomplished in 2-3 attempts, and 31 cases (8.6%) where insertion was accomplished after 4-8 attempts. Postnatal age did not influence the number of insertion attempts $\chi^2 (10, n=360) = 6.16, p=0.80$. When comparing the two groups, insertion of the PIV was accomplished after a mean of 1.79 attempts in the StatLock group and 1.61 attempts in the Tegabear group (Table 2). There was no significant difference between the two groups in terms of number of insertion attempts $\chi^2 (2, n=319) = 3.92, p=0.14$. When looking at the entire sample, 167 PIVs (46%) were inserted into veins of the hand, 87 (24%) in the foot, 40 (11%) in the scalp, 35 (9.6%) in the leg or ankle; and 31 (8.5%) in the veins of the arm/antecubital/wrist. There was no significant

difference between the StatLock and Tegabear groups in terms of insertion site, χ^2 (4, n=318)=2.30, $p=0.68$.

Approximately 89% (322/363) of the PIVs were placed for infusion of nutrition (total parenteral nutrition or dextrose-containing fluids) with or without medications. Specifically, 180 (49.6%) of PIVs infused amino acids/lipids, 120 (33.1%) infused D10W, 15 (4.1%) infused Neostarter (composed of D10W with protein and calcium), and 7 (2%) infused a combination of dextrose and saline solution. Electrolytes, minerals and trace elements were individualized to meet the needs of each patient. There was no significant difference between the StatLock and Tegabear groups in terms of proportion of PIV catheters in which parenteral nutrition was infused χ^2 (1, n=318)=1.41, $p=0.24$. In addition, 227 PIVs (62.5%) were used for medication administration, where the majority of catheters had multiple medications infused. Antibiotics were among the most commonly administered medications accounting for 46 % of PIV catheters (167/363). Ampicillin, gentamicin, cefazolin, flagyl, cefotaxime, and vancomycin were among the most commonly administered antibiotics. Caffeine citrate was the second most commonly used medication, accounting for 19.3% (70/363) of PIV catheters and the remaining 18.2% (66/363) of PIVs were used for a wide variety of other medications, including opioids (7.7 %), antiviral agents (1.4%), antifungals, insulin (0.8%), sedatives (0.6%) and paralyzing agents (0.6%). When the StatLock and Tegabear groups were compared, there was no significant difference in the proportion of PIV catheters in which medications were administered χ^2 (1, n=317)=0.39, $p=0.54$. Blood products were administered in 69 (19%) PIV catheters and in some cases more than one blood product was administered. Packed red cells, platelets and fresh frozen plasma were among the most commonly used blood products. The proportion of PIV catheters through which blood products were administered did not differ significantly between the two

groups, 18.6% in the StatLock group and 16.7% in the Tegabear group $\chi^2 (1, n=318)=0.18$, $p=0.68$. Lastly, 62 (17.4%) PIV catheters were saline locked and the proportion did not differ significantly between the StatLock and Tegabear groups, 15.8% versus 14% respectively $\chi^2 (1, n=316)= 0.17$, $p=0.68$.

For the 355 cases where the use or non-use of an arm board was documented, only 54 (15.2%) PIVs required an arm board. The proportion of Insite catheters that used an arm board was significantly greater at 23.8% in the Tegabear group compared to 10.5% in the StatLock group $\chi^2 (1, n=314)=9.69$, $p=0.002$. Reasons for using an arm board were also examined, however there were missing data in both groups: 36% (8/22) in the StatLock group and 12% (3/25) in the Tegabear group. In most cases, the use of an arm board depended on the infant's level of activity, site of insertion and for added security. There were no significant difference in reasons for using an arm board $\chi^2 (2, n=35) =1.76$, $p=0.41$. There was also a larger proportion, 21.3% (23/108) of catheters in the Tegabear group that needed to be reinforced with tape or transparent dressing whereas no PIV catheters in the StatLock group required reinforcement $\chi^2 (1, n=274)=38.6$, $p<0.001$.

Table 1.

Comparison of Study Group Characteristics

Characteristics	StatLock	Tegabear dressing	<i>p-value</i>
Location of Placement (%)			
NICU	177 (83.9)	96 (88.9)	
ICN	18 (8.5)	12 (11.1)	
ISR	16 (7.6)		
Total	211	108	
Postnatal Age (days)			
Median (Range)	4 (1-212)	8 (1-135)	

Mean ± SD	17.22 ± 31.94	20.28 ± 27.21	
No. (%)			
0-2 days	68(32.4)	22 (20.6)	0.23
3-7 days	60 (28.6)	29 (27.1)	
8-15 days	25 (11.9)	19 (17.8)	
16-30 days	18 (8.6)	12(11.2)	
31-59 days	27 (12.9)	16 (15)	
>60 days	12 (5.7)	9 (8.4)	
Total	210	107	
Postmenstrual Age (weeks)			
Mean ± SD	34.46±4.95	35.34 ± 4.55	
Median (Range)	33 (23-54)	35.2 (25-43)	
No. (%)			
23-28 weeks	15 (7.1)	10 (9.3)	<0.001*
29-34 weeks	108 (51.2)	28 (25.9)	
35-39 weeks	51 (24.2)	49 (45.4)	
>40 weeks	37 (17.5)	21 (19.4)	
Total	211	108	
Gender			
No. (%)			0.65
Male	117 (55.5)	57 (52.8)	
Female	94 (44.5)	51 (47.2)	
Total	211	108	
Weight (grams)			
Median (Range)	1900 (506-4340)	2345 (800-5290)	
Mean ± SD	2102.22 ± 959.06	2305.35 ± 1010.31	
No. (%)			0.76
<1000 g	28(13.3)	10 (9.3)	
1000-1499 g	39 (18.5)	21 (19.4)	
1500-2499 g	76 (36)	36 (33.3)	
2500-3499	43 (20.4)	25 (23.1)	
>3500 g	25 (11.8)	16 (14.8)	
Total	211	108	

*statistically significant $p < 0.05$

Table 2*Comparison of Peripheral Intravenous Catheter Characteristics by Securement Method*

Characteristic	StatLock	Tegabear dressing	p-value
Insertion Site (%)			
Scalp	22 (10.4)	14 (13)	0.68
Hand	105 (49.8)	45 (42)	
Foot	48 (22.7)	30 (28)	
Arm/Antecubital/wrist	16 (7.6)	9 (8.4)	
Leg/Ankle	20 (9.5)	9 (8.4)	
Total	211	107	
No. of insertion attempts (%)			
Mean ± SD	1.79±1.16	1.61±1.02	0.14
Range	1-8	1-6	
1 attempt	115 (54.5)	69 (63.9)	
2-3 attempts	75 (35.5)	34 (31.5)	
4-8 attempts	21 (10)	5 (4.6)	
Total	211	108	
Arm board (%)			
Yes	22 (10.5)	25 (23.8)	0.002*
No	187 (89.5)	80 (76.2)	
Total	209	105	
Reinforced (%)			
Yes	0	23 (21.3)	<0.001*
No	211(100)	85 (78.7)	
Total	211	108	
TPN (%)			
Yes	112 (53.3)	50 (46.3)	0.24
No	98 (46.7)	58 (53.7)	
Total	210	108	
Medications (%)			
Yes	130 (62.2)	71 (65.7)	0.54
No	79 (37.8)	37 (34.3)	
Total	209	108	
Blood Products (%)			
Yes	39 (18.6)	18 (16.7)	0.68
No	171 (81.4)	90 (83.3)	
Total	210	108	

Saline Locked (%)			0.68
Yes	33 (15.8)	15 (14)	
No	176 (84.2)	92 (86)	
Total	209	107	
Complication (%)			0.78
Yes	165 (78.9)	83 (77.6)	
No	44 (21.1)	24 (22.4)	
Total	209	107	
Reason for IV Removal (%)			0.93
Edematous	82 (50)	40 (48.8)	
Blocked	13 (7.9)	6 (7.3)	
Redness	28 (17.1)	11 (13.4)	
Leaking	24 (14.6)	16 (19.5)	
Dislodged	15 (9.1)	8 (9.8)	
Burn	2 (1.2)	1 (1.2)	
Total	164	82	
Dwell time (hours)			0.63
Median (min-max)	34.17 (0.5-183)	32.67 (1-190.92)	
Mean $\pm$ SD	39 $\pm$ 28.43	37.7 $\pm$ 28.57	

*statistically significant difference $p < 0.05$

PIV Catheter Dwell Time

Complete data was obtained for 169 infants where the total duration of patency of peripheral catheters (n=169; 5 with IV dwell time missing) summed up to 14015.27 hours, for a mean of 82.9 hours per infant (~3.5 days/infant). The data available for 357 catheters was not normally distributed and was skewed to the right (*Figure 3, Figures O1-O3*). The Shapiro Wilk test for normality was statistically significant ($p < 0.001$) confirming that the distribution for PIV dwell time was not normally distributed. Because the distribution of catheter dwell time was non-normal, non-parametric statistical tests were used. Specifically, the Mann-Whitney U Test was used to determine whether there is a difference in IV dwell time between StatLock and Tegabear. The mean duration of patency in the StatLock group was 39 $\pm$ 28.43 hours compared to 37.7 $\pm$ 28.57 hours in the Tegabear group. Based on the Mann-Whitney U test, there was no

statistically significant difference in duration of patency between the StatLock and Tegabear groups ($p=0.63$) (Appendix V). However, in order to take into account censored cases ($n=76$), that is PIVs that were either electively removed or lost to follow-up, Kaplan Meier survival analysis was used to compare survival curves of the StatLock and Tegabear groups (Figure 4). No statistically significant difference was found in the mean survival time between the StatLock and Tegabear groups (46.04 hours versus 45.33 hours, respectively) ($\chi^2=0.04$, $df=1$, $p=0.84$, long-rank test) (Appendix W). The mean survival time for the transparent dressing/tape group was 55 hours which was also not statistically significant when compared to StatLock and Tegabear ($\chi^2=2.49$, $df=2$, $p=0.29$, log-rank test) (Appendix W).

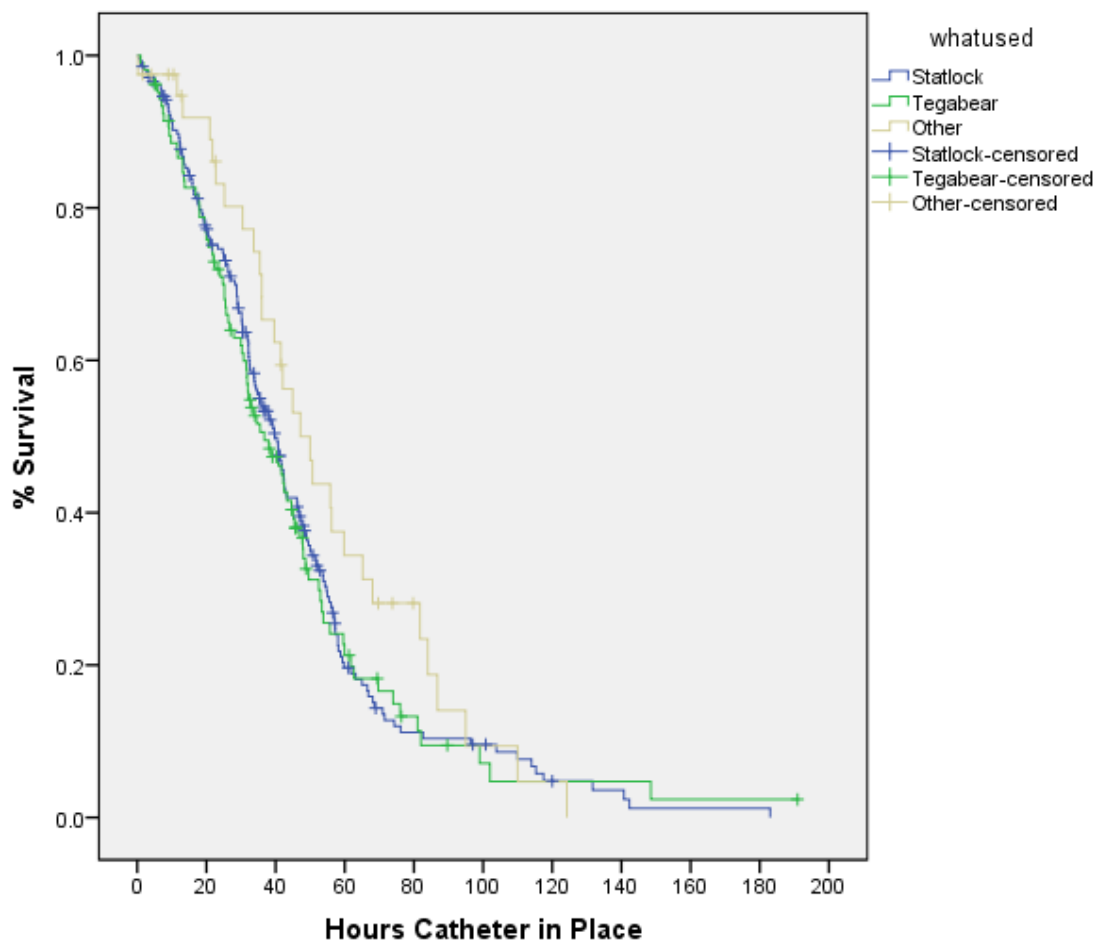


Figure 4. Kaplan-Meier survival curve based on method of PIV securement.

Complication Rates and Reasons for PIV Removal

The majority of PIV catheters (76.6%) (278/363) were discontinued due to complications. In the StatLock group, 165 (78.2%) catheters were discontinued as a result of complications and 44 catheters (20.9%) were electively removed. Similarly, 83 (76.9%) of catheters in the Tegabear group were removed due to complications and 24 (22.2%) were electively discontinued. The two groups were compared with respect to complication rates which showed no significant difference between StatLock and Tegabear dressing, $\chi^2(1, n=316) = 0.079$, $p=0.78$ (Table 3, Appendix X). When examining the StatLock and Tegabear groups, the most common reason for PIV removal were the presence of: edema (49.6%), leaking (16.3%), redness (15.9%), dislodgement (9.3%) and occlusion (7.7%). Reasons for catheter removal or loss of patency were also examined and there were no significant differences between the StatLock and Tegabear groups, $\chi^2(5, 246) = 1.33$, $p=0.93$ (Table 4). There were 2 incidences of an IV burn/extravasation occurring on the same patient whose PIV catheter was secured with StatLock. This patient was a term infant who required an esmolol infusion due to supraventricular tachycardia. In contrast, there was one incidence of an IV burn/extravasation occurring in a term infant whose PIV catheter was secured with Tegabear dressing. This patient's PIV was used to administer parenteral nutrition and antibiotics (cefazolin and metronidazole). None of the patients required treatment with hyaluronidase. Two infants died due to complications of prematurity, one in the StatLock group and the other in the Tape/transparent dressing group. The infant in the StatLock group was born at 25 4/7 weeks who suffered from necrotizing enterocolitis and subsequent intestinal perforation-care was withdrawn on this infant. The second infant was born at 24 2/7 weeks required multiple blood transfusions and died due to complications of pulmonary hemorrhage.

Table 3*Comparison of Complication Rates by Securement Method*

Complication	Securement Method		χ^2	df	p-value
	StatLock (%) (n=209)	Tegabear (%) (n=107)			
Yes	165 (78.9)	83 (77.6)	0.079	1	0.78
No	44 (21.1)	24 (22.4)			

Table 4*Reasons for Catheter Removal or Loss of Patency by Securement Method*

Reason for Removal	Securement Method		χ^2	df	p-value
	StatLock (%) (n=164)	Tegabear (%) (n=82)			
Edematous	82 (50)	40 (48.8)	1.33	5	0.93
Occluded	13 (7.9)	6 (7.3)			
Red	28 (17.1)	11 (13.4)			
Leaking	24 (14.6)	16 (19.5)			
Dislodged	15 (9.1)	8 (9.8)			
Burn	2 (1.2)	1 (1.2)			

Study Compliance

Out of 177 Insite catheters that were assigned to the Tegabear group, approximately 60% (n=107) used the assigned dressing, 26% used StatLock, (n=46) and 13.6% used transparent dressing/tape (n=24) instead (Appendix S). This accounted for 39.5% (70/177) non-compliance rate in the Tegabear group. Specifically, during Phase 1 of the study, 19.7% (15/76) of the

catheters were secured with StatLock instead of the Tegabear dressing and this rate increased to 30.7% (31/101) in Phase 2. Feedback was sought from the nursing staff and the most commonly cited issues with the Tegabear were: the dressing was too large (11%) (8/70); would not stick (11%) (8/70); was not secure enough (10%) (7/70), difficult IV access (7%) (5/70), and the dressing was not available (16%) (11/70) (Table 5). One of the reasons for the non-availability of the Tegabear dressing was that StatLock was being stocked in the IV boxes in pods assigned to the Tegabear group. Consequently the researcher had to routinely check and ensure that the appropriate securement dressing was stocked in each pod.

Table 5

Reasons for Not Using Tegabear dressing by alternate Securement Method

Reason	Securement Method	
	StatLock (%) (n=46)	Transparent Dressing/Tape (%) (n=24)
Won't stick	5 (10.9)	3 (12.5)
Too large	-	8 (33.3)
Not secure enough	5 (10.9)	2 (8.3)
Not available	5 (10.9)	6 (0.25)
Difficult IV access	5 (10.9)	-
Not sure how to use	1 (2.1)	1 (4.2)
Forgot	2 (4.3)	-
Don't like it	2 (4.3)	1 (4.2)
Missing data	21 (45.7)	3 (12.5)

Similarly, not all PIV catheters in the StatLock group adhered to the allocated securement method. Out of 184 Insite catheters that were assigned to the StatLock group, 89.7% (n=165) used the assigned securement device, 9.8% (n=18) used transparent dressing/tape, and 0.5% (n=1) used Tegabear dressing (Appendix S). In 14 out of 18 cases (77.8%), reasons were provided for not using the StatLock securement device. Commonly documented reasons for not using the StatLock securement device were that it was too large (16.7%), the site of PIV insertion was not conducive to placement of the StatLock (e.g. near a joint, ankle) (27.8%), the StatLock device would not snap in place (11.1%) or it was not available (16.7%) (Table 6). Additionally, there were three instances where the plastic platform of the StatLock device caused bruising or abrasion of the skin.

Table 6*Reasons for Not Using StatLock*

Reason	Securement Method
	Transparent Dressing/Tape (%) (n=18)
Would not snap on	2 (11.1)
Not right position	5 (27.8)
Too big	3 (16.7)
Not available	3 (16.7)
other	1 (5.5)
Missing data	4 (22.2)

Summary of Findings

This study evaluated two methods of securing peripheral intravenous catheters, the StatLock device and Tegabear dressing, by comparing catheter dwell time and complication rates. Baseline characteristics were comparable between the two groups except for postmenstrual age. Several issues were encountered with the Tegabear dressing which included its large size, poor adherence to the skin and inadequate catheter security. In Phase 2 of the study, a new lot of Tegabear dressings were used to address the poor dressing adherence observed in Phase 1. Despite of these measures, a larger proportion of catheters secured with the Tegabear dressing required the addition of an arm board and reinforcement with transparent dressing/tape. Using the log-rank test, no significant difference in duration of catheter patency was found between catheters secured with StatLock compared to those secured with the Tegabear dressing. Complication rates and reasons for PIV removal did not differ significantly between the two groups. The findings of this study supported the null hypothesis postulated a priori.

CHAPTER 6: Discussion of the Next Steps

‘Acting’: Taking the Next Steps

The aim of this study was to explore optimal securement of peripheral intravenous catheters in neonates. Increasingly, clinicians are recognizing that vital role that method of securement plays in minimizing catheter motion and hence duration of catheter patency and complications (Frey & Schears, 2006). However, the general literature on PIV catheter securement and stabilization in the context of the NICU is limited. Furthermore, the 2011 Infusion Nursing Standards of Practice and CDC recommend replacement of the short peripheral catheter only when clinically indicated- in instances when complications arise. The challenge of establishing vascular access in infants who often have a limited number of useful veins highlights the importance of interventions that prolong the patency of PIV catheters. As such, the study was undertaken to determine which method of securing peripheral intravenous catheters, StatLock or Tegabear dressing, was more effective in increasing duration of catheter patency and reducing complication rates in infants in the Neonatal Intensive Care Unit (NICU).

This study contributed to the PIV catheter securement and stabilization literature in several ways. Most studies to date have compared StatLock, the first engineered catheter securement device, with the common practice of application of tape to secure short peripheral intravenous catheters (Schears, 2006; Smith, 2006; Sheppard, et al., 1999; Wood, 1997). These studies conducted primarily in adults have found that catheters secured with StatLock had a significantly longer average dwell time and fewer total complications compared to catheters secured with transparent dressing and tape (Schears, 2006; Smith, 2006; Sheppard, et al., 1999; Wood, 1997). Conversely, only one observational unpublished study conducted in the NICU has compared StatLock with transparent dressing and tape for securing PIVs (Blatz, 2006). This

study found a 7-hour difference in duration of catheter patency, in favour of StatLock (Blatz, 2006). More recently, dressings with catheter securement properties, such as the Tegabear dressing, have become available. Although the Tegabear dressing has been safely used in pediatric patients, it has not been evaluated for securing PIVs in neonates (McCann, 2003). The current study is the first of its kind in the neonatal population and largest to date to investigate two methods of catheter securement by comparing duration of patency and incidence of complications. The results demonstrated that there was no significant difference in duration of catheter patency and rate of complications between PIV catheters secured with StatLock versus Tegabear.

The *Model for Improvement* by Langley et al (1994) which incorporates the Plan-Do-Study-Act (PDSA) Cycle was used to guide the current study. The PDSA Cycle was used as a framework for testing the new Tegabear dressing in the NICU, reviewing the results and summarizing what was learned (Figure 5). Thus, the 'Act' phase, the final component of the PDSA Cycle, entails refining the change based on what was learned. Based on results of the study, the change is either accepted or abandoned, in which case the PDSA cycle starts again (Langley, et al., 2009).

This chapter begins with a review of the major findings from the study. The overall findings and those specific to each phase of the study are discussed in relation to the relevant questions, hypotheses tested, and in relation existing literature. The main conclusion and theoretical and practical implications of the study are discussed- recommendations are also proposed.

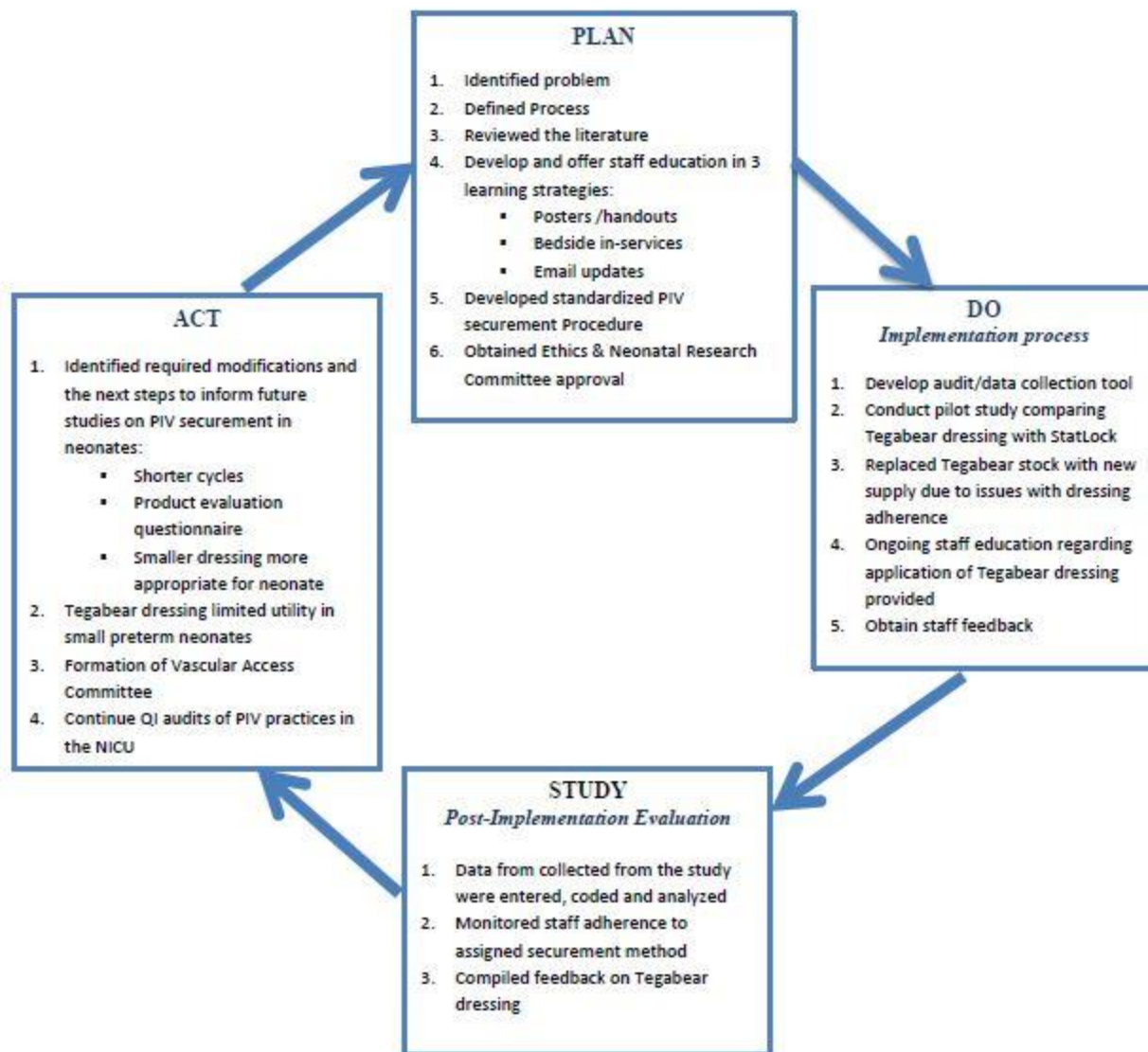


Figure 5. Application of the PDSA Cycle to PIV Catheter Securement in the NICU.

Review of Findings

PIV Catheter Securement and Dwell Time

The primary aim of the current study was to determine whether there was a significant difference in duration of patency of PIV catheters based on method of securement. Using survival analysis which took into account electively discontinued PIV catheters, the mean survival time for PIVs secured with StatLock was 46.04 hours compared to 45.33 hours for those

secured with a Tegabear dressing. A difference of 0.7 hours is neither clinically nor statistically significant ($p=0.84$). However, the two groups differed significantly in numbers where the Tegabear group consisted of 108 PIV catheters compared to 211 catheters in the StatLock group. This reported duration of catheter patency falls within the reported ranges found in the literature. Studies indicate that the average dwell time of peripheral catheters in the neonatal intensive care unit ranges from 27.15 to 52.6 hours for a catheter-style device (Franck et al., 2001; Johnson & Donn, 1988, Stanley et al., 1992; Tobin, 1988). Specifically, Stanley and colleagues found Vialon catheters to have a mean dwell time of 41 hours, which is consistent with the mean survival times observed in the present study.

Although the study sought to compare the StatLock securement device with Tegabear dressing, an unanticipated third group which consisted of catheters secured with transparent dressing and tape accounted for 12% of the study sample. The estimated mean survival of PIVs for this third group was 55 hours, accounting for a 9 to 10 hour difference when compared to StatLock and Tegabear dressing. Although the difference was not statistically significant ($p=0.288$), one may argue that a mean prolongation in the duration of catheter patency by 9-10 hours is clinically significant. Future studies that evaluate PIV catheter securement methods should include a survey of clinicians' views on what would be considered a clinically important prolongation in catheter dwell time in the NICU. However, several factors must be considered. For instance there was a greater proportion of PIV catheters secured with transparent dressing/tape that were saline locked, which could affect dwell time. Additionally, infants whose PIVs were secured with transparent dressing or tape tended to be younger where 64% (27/42) were ≤ 34 weeks postmenstrual age. This finding highlights the limited utility of both StatLock and Tegabear in younger and smaller infants. A plausible explanation for the longer duration of

patency in infants of more premature infants may be attributed to their decreased level of activity when compared to older, term infants. This finding is consistent with Tobin's (1988) study involving infants between 24 to 43 weeks gestational age where the level of activity was found to be a predictor of PIV catheter life span (Tobin, 1988). The shorter duration of patency of PIV catheters may be due to frequent movement of the catheter at the site of insertion which can lead to complications such as infiltration, phlebitis and catheter dislodgement (Tobin, 1988). Similarly, Stanley et al. (1992) found postnatal age to be a significant predictor of infiltration in neonates where the risk of infiltration for infants 5 days of age or older was 1.5 times greater than the risk of infants less than 5 days old. This finding may be related to increased physical activity after the first four days of life (Stanley et al., 1992).

Activity Level and Arm boards

Although activity level was not directly assessed in this study, nurses indicated an infant's level of activity as one of the common reasons for using an arm board. When looking at the entire sample, there was a trend towards an increased proportion of arm boards used in infants as postmenstrual age increased. However, other factors could be attributed to use of an arm board such as the site of insertion, specifically whether the PIV catheter is inserted near a joint or area of flexion. Twenty-four percent of PIVs in the Tegabear group used an arm board compared to only 10.5% in the StatLock group, which was statistically significant ($p=0.002$). Moreover, results were also significantly different when the StatLock and Tegabear were compared to the tape/transparent dressing group where 17.1% of PIVs used an arm board ($p=0.008$). A limited number of studies in neonates have examined the impact of splint application on the functional life span of PIVs (Dalal et al., 2009; Gupta et al., 2003). In Gupta et al.'s study, splints were used at the discretion of staff nurses and no significant difference in the

functional life span of PIV catheters was found for application of splints. Similarly, an RCT by Dalal et al. (2009) found the mean functional catheter life span was less in the splint group compared to the no-splint group however, this difference was only 3.3 hours which was not statistically significant (23.5 hours $\pm$ 5.9 vs. 26.9 hours $\pm$ 15.5; 95% CI -11 to 4.3, $p=0.38$) (Dalal et al., 2009, p. F396). The difference was more evident in preterm infants <30 weeks (Dalal et al., 2009). Poor vascular tone in addition to thin, immature veins of premature infants, places them at greater risk of extravasation even in the presence of slight external pressure that may occur with the use of splints (Dalal et al., 2009). Therefore, careful securement of splints is imperative, since any tourniquet effect created by improper or overly tight taping could worsen the effects of infiltration (Amjad, Murphy, Nylander-Hosholder & Ranft, 2011).

Complications

While the use of PIV catheters is commonplace in the NICU, modern catheter style devices are associated with complication rates of up to 78%, resulting in non-elective removal of PIV catheters (Pettit, 2006). Infiltration is the most common complication of infusion therapy in neonates (Duck, 1997; Pettit, 2006). In the current study, 76.6% (278/363) of PIVs were discontinued due to complications, which is consistent with the incidence reported in the literature.

The current study differs from most of the published literature involving neonates in that complications were reported as symptoms rather than categorizing either as infiltration, extravasation or phlebitis. This was done because of the overlap of symptoms between infiltration and phlebitis. For PIV catheters that were discontinued due to complications, the most common reasons for removal included: edema (48.2%), leaking (17.6%), redness (15.5%), dislodgement (9.7%) and occlusion (7.6%). These findings are consistent with the reported

ranges of complications associated with PIVs that have been compiled from the literature: edema (29-45.2%); erythema/redness (7-44%); leaking (2-27.6%); occlusion (4-26%); dislodgement 2% (Batton, et al., 1982; Franck, et. al., 2001; Gupta, et al., 2003; Johnson & Donn, 1988; Pettit, 2003; Tobin, 1988; Webb, 1987).

The second objective of the study was to determine if there was a difference in the rate complications between StatLock and the Tegabear dressing. No significant difference was found in the rate of complications and reasons for PIV removal between the two groups and therefore the null hypothesis could not be rejected. However, one must consider the interventions that could have confounded these results. Specifically, a number of PIV catheters secured with Tegabear required additional reinforcement with transparent dressing or tape.

Challenges with Tegabear Dressing

One of the main challenges of this study was that the Tegabear dressing was not used in the manner recommended by the manufacturers, that is, with no additional dressings or tapes. Twenty-one percent (n=23/108) of the catheters secured with the Tegabear dressing required additional reinforcement either with transparent dressing or tape whereas, none of the catheters in the StatLock group were reinforced with tape. In several cases, extra tapes or a transparent dressing was placed on top of some area of the Tegabear dressing which was contrary to the intention of the researcher. Additional reinforcement of the Tegabear dressing may have been needed, possibly due to inadequate adherence of the dressing thereby compromising catheter security. Thus it is unknown whether catheter security would have been compromised in these patients had the Tegabear dressing not been reinforced. Problems with Tegabear dressing adherence was observed in infants nursed in humidified incubators where their moist skin prevented the dressing from sticking properly, causing the edges of the dressing to lift off the

skin. Similar to Callaghan et al.'s study which tested a similar larger dressing in pediatric patients, adherence of the dressing was a problem in patients who were diaphoretic (Callaghan, et al., 2002). Another possible reason for the use of extra reinforcement is the staff's lack of expertise in applying the Tegabear dressing. Often times, the efficacy of a new product depends not only on the product itself, but also on how it is used (Drummond, Griffin, & Tarricone, 2009). Consequently, there is often a 'learning curve' associated with a new product and thus, user skills and training can have important impacts on its performance (Sorenson, Tarricone, Siebert, & Drummond, 2011). The learning curve refers to the culmination of experience, lessons learned and knowledge that one gains when performing a specific function or task (Sorenson, et al., 2011; Waldman, Yourstone & Smith, 2003). Therefore, as use increases with each neonatal nurse, product use and technique, as well as expertise increase over time. More importantly, there were instances where the Tegabear dressing was too large which necessitated trimming the adhesive cloth section, which may have jeopardized its securement properties. A closer look at reasons for non-use of the assigned securement method revealed that in 33% of the cases (8/24) the Tegabear dressing was too large compared to 16.7% (3/18) in the StatLock group. Although there were instances where nurses were unable to use both StatLock and the Tegabear dressing in the smaller infants, the practicality of the Tegabear dressing may have been more limited by its size.

Study Compliance

Intervention fidelity refers to the degree that the intervention was delivered as designed or planned (e.g. compliance, completeness) (Sidani & Braden, 1998). Often times, the individuals who deliver the intervention, are in a position of key influence on whether a study is successful or not (Eborall, Dalloso, Daly, Martin-Stacy, & Heller, 2014). Thus, their fidelity to

the intervention is critical. Furthermore, with interventions that cannot be blinded, such as method of PIV catheter securement, minimizing variation in delivery can be challenging (Eborall, et al., 2014).

Adherence to the intended securement method was a major challenge in this study. The compliance rates differed significantly between the StatLock and Tegabear groups, 89.7% vs. 60% respectively. A closer look at catheters assigned to the Tegabear dressing revealed that non-compliance rate increased from 19.7% in Phase 1 to 30.7% in Phase 2 of the study. Analysis of the comments provided by the nurses highlighted important limitations of the Tegabear dressing which included its large size, poor adherence, and lack of security.

Given that nurses in the Neonatal Nurseries rotate between different pods and the intermediate care nursery, some nurses may have been unaware of the assigned securement method, suggesting the education provided may have been insufficient. In this study, educational interventions were divided into educational materials and educational outreach. Educational materials included information about the PIV practice audit and the embedded PIV securement study using a variety of methods for delivery such as handouts, posters, and e-mails. Educational outreach included educational in-services that were provided by going to each pod in the NICU and the ICN. Feedback from the nurses regarding the usefulness of the educational interventions during each phase of the study was not sought and would have further assisted the researcher in revising or tailoring educational strategies to the needs of the unit. Furthermore, the degree of reach for static materials (e.g. posters, handouts) as part of the educational interventions aimed at nurses in the unit was challenging to quantify since fluctuations in the number of staff occurred during the course of the study.

More importantly, another possible explanation for the non-compliance in the Tegabear group was a lack of “buy-in” and personal equipoise on the part of the nursing staff. Similar to clinical equipoise, personal equipoise exists when the clinician involved in the study has no personal preconceived preference or is truly uncertain about the overall benefit or harm of an intervention to his/her patient (Alderson, 1996; Cook & Sheets, 2011). However, equipoise can also change early in the course of a study as interim data become available (Gifford, 2000). Furthermore, since the allocation to each securement method was not concealed, nurses observed PIV securement succeed or fail in one arm of the study. This may have led some nurses to lose personal equipoise as it became evident that the Tegabear dressing was too large and would not adhere properly in the more preterm and smaller infants. Additionally, as reflected by the comments provided, nurses were appropriately concerned about catheter security in infants who required multiple IV restarts and in whom intravenous access was difficult to establish. For the nurses in this study, equipoise could be regarded as “responsible” uncertainty, partly because it entailed the balancing of benefit and harm (Garcia, Elbourne, & Snowdon, 2004). The lack of genuine uncertainty regarding the effectiveness of Tegabear dressing along with their views that StatLock was superior may have been sufficient enough to reduce nurses’ compliance with the study. Thus, what is important here is, the difference in the amount of evidence that would warrant a preference for Tegabear dressing over StatLock for a given present patient and the amount of evidence that would be enough to warrant policy decision about PIV catheter securement for future patients in the NICU (Gifford, 2000). Finally, it is unclear to what degree the variations in practice among nurses could have influenced the results of this study.

Strengths and Limitations of the Study

Catheter securement and stabilization is an essential intervention in IV therapy and maintenance (Alekseyev, et al., 2012). The importance of catheter securement is reflected in the increasing number of studies evaluating the effectiveness of IV securement devices and dressings in the adult population. However, the literature on securement of short peripheral intravenous catheters and PIV-associated complications in neonates is lacking. This study is the first of its kind in the neonatal population, and the largest to date to compare a catheter securement device (StatLock) and an integrated securement dressing (Tegabear).

Several limitations in the study deserve mention. First, the current study was conducted in a single NICU thereby, limiting the applicability of this information to other settings. Other units would be encouraged to examine their own vascular access practices and culture. A similar study carried out in a broader setting would assist in validating the results of this study. Second, the current study was not a randomized, controlled trial with matched samples. The two groups were not comparable for a number of factors (e.g. postmenstrual age, and use of arm board) and it was difficult to control for all confounding variables. Third, the sample sizes were small and may have been underpowered to detect statistically significant differences between StatLock and Tegabear dressing. Furthermore, the sample sizes differed considerably between the two groups, with significantly more infants in the StatLock group (n=211) compared to the Tegabear group (n=108). Given the unequal sample sizes between the two groups, the possibility of a *Type II error*, where a significant difference exists in catheter dwell time and complication rate between StatLock and Tegabear, could not be excluded.

A fourth limitation was that nurses were not blinded to the type of securement method used. Prior to this study, StatLock was used for securing 24 gauge Insite catheters for 7 ½ years

in the Neonatal Nurseries. Consequently, the process of drawing attention to a new method of securement using the Tegabear dressing, could have altered how meticulously PIV catheters were inserted, secured and maintained (Schears, 2006). Furthermore, lack of blinding may have led to biased ascertainment of outcomes where nurses may have been tempted to report more complications with the Tegabear dressing compared to StatLock. The nursing staff had a preferential use for StatLock, accounting for non-compliance in 46 cases.

Lastly, each phase of the study may have been too long which caused the study to lose its momentum. Phases of the study can be likened to cycles in the PDSA model, and the length of time between each study phase may have decreased the level of participation or adherence to the assigned securement methods. Thus, caution is required in interpreting these results. A randomized controlled trial utilizing a smaller-sized dressing that is more appropriate for neonates is needed in order to indisputably establish the superiority of one securement method over another.

Study Implications

Implications for Clinical Practice

Intravenous cannulation is one of the most frequently performed procedures in the Neonatal Intensive Care unit and is generally perceived as a routine, relatively minor procedure. As a result, its impact on neonates is often overlooked. Neonates, especially those who are premature, are highly vulnerable to procedural stress and experience significant pain during venipuncture. Challenges in placing a peripheral intravenous line in neonates is a very common and frustrating experience for nurses and parents alike. Fewer IV re-cannulations can reduce the infant's pain experience, parental stress, and conserve supplies and professional time in an

already busy unit. Thus, securement and stabilization of peripheral intravenous catheters is a vital component of catheter care in order to prevent complications and unscheduled IV restarts which have a considerable impact on nursing time, a tremendously valuable healthcare resource (Bolton, 2010). Nurses are in an ideal position to mitigate the short and long-term consequences of intravenous therapy and multiple intravenous cannulations. Several factors can affect the choice of a product, including efficacy, patient safety and comfort, ease of use, nursing time and cost. Although this study did not find a statistically significant difference in PIV catheter dwell time and complication rate between the Tegabear dressing and StatLock, the nurse must exercise individual and independent judgement when selecting a securement method most appropriate for their patient.

Given the cost pressures in today's healthcare, it is important for nurses, clinicians and managers to keep in mind that the cost of intravenous therapy includes the cost of materials, complications, unscheduled restarts, and extended length of hospital stay secondary to complications (Sheppard, et al., 1999). This study did not include a cost analysis due to time constraints, a lack of money and resources. Given the current fiscal restraints, it is essential that new interventions provide maximal benefits for their costs. Each Tegabear dressing cost \$0.50 to evaluate, transparent dressings cost \$0.17, and StatLock cost \$5.15. A transparent dressing is required for initial catheter securement prior to application of StatLock, which translates to a total cost of \$5.32. Although this translates to a potential cost savings of \$4.82 per PIV catheter if Tegabear dressing is used, other important factors must be considered. For instance, the longevity of the Tegabear dressing is an important consideration since there was an increased trend towards the need for additional reinforcement with transparent dressing/tape and use of

arm boards in this group compared to StatLock. Such interventions are potential confounders that could have led to the comparable catheter dwell times observed in the Tegabear group.

Although results of this study reveal that implementation of the Tegabear dressing was unsuccessful, important lessons were learned during the process which is a fundamental principle behind the PDSA cycle (Taylor, et al., 2013). Specifically, several barriers were encountered which highlighted the need for PIV securement dressings and devices that are more appropriate for smaller, preterm infants. Furthermore, the impact of a learning curve is an important consideration when new products are introduced into clinical practice. Most new products have a learning curve wherein clinicians receive initial training once the product is released for use and subsequently improve with experience (Fargen, Frei, Fiorella, McDougall, Myers, Hirsch & Mocco, 2013). Thus, early trials evaluating the effectiveness of the Tegabear dressing are likely to overestimate complications and underestimate effectiveness because nurses have limited experience with the Tegabear dressing. Consequently early studies (such as the present study) are likely to show no difference in outcomes (or potentially worse) compared with the standard of care therapies (Fargen, et al., 2013). This highlights the importance of conducting subsequent studies, after nurses have gained experience and acquired proficiency in utilizing the Tegabear dressing for securing PIV catheters in the NICU. As such, one can foresee how early testing of a new product, has a bias towards rejection. Given the study findings, the researcher is unable to recommend the widespread adoption of the Tegabear dressing for securement of PIV catheters neonates. However, more studies are needed to establish the effectiveness of the Tegabear dressing in neonates. While early studies are critical in detecting products that are unsafe, further studies may just be as important in acquiring the true risks and benefits of a new product (Fargen, et al., 2013). Future clinical evaluation studies should incorporate a product evaluation

questionnaire addressing several key attributes of a dressing: ease of application, initial adhesion, overall adhesion, security of the PIV catheter, observation of the site, ease of removal and skin condition after removal (McCann, 2003). The outcome from such a questionnaire would provide the information needed to determine the suitability of a catheter securement dressing/ device in neonates.

From a quality improvement (QI) perspective, several important lessons were learned that could inform future PIV catheter securement and stabilization practice initiatives using the PDSA cycle. First, future QI initiatives should include the development of a vascular access committee, who can serve as internal facilitators to promote practice changes related to intravenous therapy in the NICU (Ellsbury & Ursprung, 2010). Members of this committee should exhibit a shared vision to improve intravenous therapy practices, and hold positions in the unit that could influence practice changes (Ellsbury & Ursprung, 2010). As is often recommended, the committee should be interdisciplinary and should represent all key stakeholders, including frontline nursing staff, management and hospital leaders (Lipshutz, et al., 2008). There may be opportunities to bolster participation by using strategies such as identifying frontline nurses who will champion the process change in the NICU (Lipshutz, et al., 2008; Marcellus, Harrison, & MacKinnon, 2012). Once a vascular access committee has been formed, regular meetings could be organized to ensure that the intervention is being delivered as planned and to clarify any issues that might arise during the intervention implementation (Resnick, Inguito, Orwig, Yahiro, Hawkes, Werner, et al., 2005).

Second, shorter PDSA cycles are more effective in building momentum of change in contrast with large-scale change efforts that involve comprehensive data collection and one time, all-or-nothing implementation (Plsek, 1999, p. 206). The literature on quality improvement

initiatives in healthcare settings suggests that it is better to run small cycles of change soon, as opposed to larger ones after a long time (Plsek, 1999). The rationale being, that each cycle, if done properly, is informative and provides a basis for further improvement (Berwick, 1998).

Next, process measures indicating whether a desired change has been successfully made in a targeted process are essential short-term measures of success of a project (Ellsburly & Ursprung, 2010). Monitoring compliance with the change intervention and PIV guidelines would be optimized through the use of electronic health records (EHR) (Yu, Allison, & Houston, 2008). EHR that incorporates information on vascular access such as: type of catheter, size, number of insertion attempts, site of insertion, method of securement and type of dressing used; date and time of insertion/removal; and reason for removal. In this study, EHR of patients were used to supplement the missing data from incomplete data collection forms. Thus, EHR systems can provide the advantage of easy data accessibility and monitoring of patient clinical measures for future audits of intravenous practices in the NICU (Yu, Allison, & Houston, 2008). An EHR system can therefore be a very useful tool for applying quality improvement methodology to routine practice in the NICU.

Implications for Research

The management and care of intravenous devices is continuously changing as new evidence, guidelines and advances in technology emerge. However, the objective measurement of peripheral intravenous safety and efficacy in the neonatal intensive care unit is often an overlooked area in assessing the quality of patient care (Franck, et al., 2001). The Infusion Nurses Society's 2011 recommendations suggested that there is insufficient evidence to support the use of a dressing alone as a stabilization device. However, with recent advances in

technology, dressings with securement properties have become available. Several studies involving adult patients have emerged comparing the StatLock stabilizations device to engineered catheter securement dressings. Unfortunately, there is less advancement in the development of IV securement devices/dressings specifically designed for infants and neonates. Consequently, catheter securement in neonates has not been a high priority in prospective research as evidenced by the lack of published studies to date. Given the current state of scientific knowledge described in Chapter 2, related to factors that affect duration of catheter patency and complication rates, it is essential to determine whether method of PIV catheter securement improves or worsens outcomes for neonates and infants in the NICU. Thus, as innovative securement devices or dressings become available, there is a need for more studies that prospectively evaluate the utility of these products in the NICU by examining its impact on complication rates and duration of PIV catheter patency.

As a scientific undertaking, the efficacy of PIV securement methods and their assertion of preventative benefits should be measurable utilizing standard research protocols (Hanchett, 1999). Currently, IV securement science has predominantly utilized quasi-experimental designs which can be an advantage when products are evaluated in patient care situations such as the neonatal intensive care unit. However, future research needs to adopt a rigorous study design such as a randomized controlled trial, to study the efficacy of different methods of catheter securement. A controlled study design will ensure that confounding variables such as age, infusion of parenteral nutrition, medications, and use of splints, are equally distributed between the control and study groups. This type of research is essential not only as validation, but also as the groundwork for new knowledge upon which all clinicians can continue to build.

Lastly, there are also philosophical obstacles that researchers must consider. Specifically, human interactions and interpretation related to a product or technique are more challenging to measure but nevertheless are an essential component in the successful implementation of any clinical process (Hanchett, 1999). Researchers in PIV securement must take into consideration the influence of staff attitudes, perception of value, readiness for behavioural change, as well as patient comfort and satisfaction. Attitudes, perceptions and beliefs can be evaluated by seeking feedback from front-line staff. Moreover, the feedback obtained from front-line staff, is an essential source of data for user satisfaction and possible product or process modifications to improve the effectiveness of the PIV securement device/dressing. Furthermore, future studies need to examine measurable costs based on supplies used to initiate PIVs, method of catheter securement, and costs of unscheduled PIV restarts and complications.

Conclusion

The increased awareness of the importance of catheter securement as a component of IV maintenance represents not only important technological advancements, but also a challenge to the established paradigm of IV securement. From a logical standpoint, the traditional IV securement paradigm was based on the premise that all IVs needed to be secured with tape (Hanchett, 1999; Hanchett, 2000). While recognizing the need for securement of IV catheters, the new paradigm of IV securement also emphasizes the importance of tailoring methods to the needs of individual patients (Hanchett, 2000). As the science of IV securement evolves, manufacturers as well as clinicians are recognizing the need for more rigorous studies.

This study compared the effectiveness of the Tegabear dressing and StatLock in securing PIV catheters in infants in the neonatal intensive care unit and intermediate care nursery. The

results indicate that there was no significant difference in duration of catheter patency and complication rates between the two groups. There was a trend towards increased need for reinforcement and arm board use with the Tegabear dressing compared to StatLock. Additionally, the Tegabear dressing was more limited by its large size and modifications employed by nurses to enable its use in smaller, preterm infants, may have jeopardized its securement properties. Consequently, the aforementioned limitations combined with loss of personal equipoise may have led to the reduced compliance in the Tegabear group. However, one must also consider the learning curve that must be overcome with the introduction of a new product in a complex clinical setting such as the NICU. The adoption of a new method of catheter securement is dependent on whether it improves patient outcomes in clinical practice, and expedites the completion of specific PIV routines. Furthermore, the emerging science of IV securement is also influenced by social and economic values that demand greater accountability in all areas of patient care delivery (Hanchett, 1999). As part of continuous quality improvement initiatives, the PDSA cycle provides a useful framework for testing micro and macro level changes in clinical practice. In order to improve quality of care, we as practitioners must question all that we do and look for alternatives that can help improve outcomes and reduce complications in our tiniest and most vulnerable patients.

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Appendix A

Summary of Studies on Peripheral Intravenous Catheter Dwell times and Complications

Authors	Study Design and Purpose	Setting & Sample Characteristics	PIV Device	Duration (hours)	Complications	Other Findings	Limitations/ Comments
Batton, Maisels & Appelbaum (1982)	RCT to determine whether steel needle vs Teflon catheter was more effective for IV therapy in preterm infants	N=34 infants (58 PIVs) GA: 26-35 wks	25 g steel needle (n=28)	15.4±13.2 hrs (mean±SD)	Infiltration (100%)	No difference in phlebitis rates in steel vs Teflon catheters	Small sample Single centre Lacked a universal definition indicating the presence of phlebitis
			24 g Teflon catheter (n=30)	49.5±30.9 hrs (mean ± SD)	Infiltration (57%) Erythema (37%)		
Phelps & Helms (1987)	RCT to evaluate influence of 11 variables on incidence & time to infiltration of PIVs in infants	Single Level 2 Nursery N=78 infants (151 PIVs) Age: < 1 yr	20-25 gauze steel & Teflon catheters	Mean time to infiltration: 36.3± 33.53 hrs	58% infiltrated Time to infiltration decreased significantly for steel needles vs Teflon, administration of medications, parenteral nutrition	Steel needles & increased catheter gauge were risk factors related to early infiltration Infusion of medications & parenteral nutrition reduced time to infiltration Infusion occlusion alarms did not consistently detect	Single centre Age in months and not gestational age reported Unable to single out any particular drug responsible for infiltration since the data was analyzed for combination rather than individual medications

						infiltration	
Webb (1987)	Non-randomized study comparing the effectiveness of steel needles vs Teflon catheters for preterm infants	N=200 infants GA: 25-41 wks BW: 710-4570g	100 steel needles	Steel needles: 26 hours (mean)	Edema (55%), Leaking (12%) Redness (8%)	Mean number of IV insertion attempts significantly lower in Teflon group vs. scalp vein group (2.32 vs 7.04)	Single-centre Non-randomized Groups not comparable (patients in Teflon group smaller and sicker) No information about site of insertion Catheter size (gauge) not reported
		Steel needle: Mean GA=37.3 wks Mean BW=2752.41 g					
		Teflon catheter group: Mean GA 35.45 wks Mean BW 2225.95 g	100 Teflon catheters	Teflon catheters: 27.15 hours (mean)	Edema (36%), leaking (20%), occlusion (26%)		
Tobin (1988)	Observational study to assess duration of life of Teflon catheter used for IV therapy in neonates, incidence of phlebitis and factors which contribute to catheter life	Setting: 40-bed tertiary care NICU in California N=72 infants GA: 24-43 wks (mean: 33.79 wks) PNA: 1-140 days (mean: 28.01)	22 or 24 g Teflon catheter	Mean: 30.1 hours (range 20 mins-98.5 hrs)	Infiltration most common complication Erythema (44%) Phlebitis (7%)	Low level of activity & administration of blood through PIV were positively correlated with duration of catheter patency No difference in catheter life span between different sites (scalp, hands and feet)	Small sample size Single center study

	and phlebitis Variables examined: gestational age, weight, IV site, gauge, rate, type of solution, level of activity, blood transfusion	days) Weight: 900-6110 g (mean: 2356.94 g)					
Johnson & Donn (1988)	Prospective survey of PIV catheter to determine rate of complications and factors influencing catheter lifespan	Setting: single-center NICU in United States N=69 patients (199 PIVs) GA: 26-48 wks	24 g Teflon catheter	33 hours (median)	Infiltration (63%)	Weight, age, type and rate of fluid administration and type of medication (except pancuronium bromide) had no significant effect on functional life span of PIVs	Sample characteristics not well described (e.g. weight, insertion site) Some factors influencing PIV lifespan may have been missed due to insufficient number of patients in examination of specific medications Data not analyzed for combination of medications
Phelps & Cochran (1989)	Observational study to evaluate prospectively the effect of continuous	Sample: 53 infants (97 PIVs) 3 groups: 10% dextrose (n=34)	22 or 24 gauge Teflon catheters	Dextrose/AA: 26.3±3.3 hrs (mean±SEM) Dextrose: 54.9±7.8 hrs	Infiltration (for entire sample): 47% at 48hrs, 68% for all time Mean time to infiltration:	Time to infiltration is prolonged and probability of infiltration with infusion of either dextrose along or	Non-randomized Unblinded

	administration of lipid emulsion on incidence & probability of, and time to infiltration of PIV sites in infants receiving parenteral nutrition	10% dextrose/2% AA (n=30) 10% dextrose/2% AA/lipids (n=33) PNA: 1 day-11.9 months No significant difference between groups with respect to age, race, gender, weight, medications, catheter size, and site of insertion		(mean±SEM) Dextrose/AA/lipid: 43.6±4.2 hrs (mean±SEM)	42.1±33.7 hrs (median 31.8, range 1-188 hrs) Incidence of infiltration among 3 groups not different (p>0.05): 10% dextrose: 71% Dextrose/AA: 66% Dextrose/AA/lipid: 67% Probability of infiltration greater for dextrose/AA than for those receiving dextrose or dextrose/AA/lipids (p=0.01)	dextrose/aa/lipid compared to dextrose/aa without lipid emulsion	
Garland, Dunne, Havens, Hintermeyer, Bozette, Wincek, et al. (1992)	Observational study to determine incidence of complications and associated risk factors during PIV therapy in children	Setting: Pediatric Intensive Care Unit in Wisconsin N=303 (654 PIVs) Infants 0-1 month (n=156) Infants 1-12 months (n=186)	Teflon catheter (gauge not stated)	83±47 hrs (range= 12-274 hrs)	Extravasation (28%) for PIVs in situ for <72hrs Phlebitis (13%) with infusions of lorazepam & aminophyllin Colonization (11%); frequently	Most important determinants of extravasation: age (≤1 year), catheter time in situ (≤72 hrs) and infusion of antiepileptics Factors that ↑ phlebitis risk: hyperalimentation,	Size of Teflon catheters not stated

					with CONS	catheter location	
Stanley, Meister, & Fuschuber, 1992	RCT assessing risk factors contributing to infiltration, including a comparison of Teflon and Vialon catheters	Setting: NICU at Harris Hospital Methodist Forth Worth, Texas N=771 in infants aged 1 to 67 days	24 gauge Teflon catheter (n=406) 24 gauge Vialon catheter (n=365)	36.2± 32 hrs (Mean ±SD) 41±33.1 hrs (Mean±SD) Vialon catheters remained in situ 9 hrs more than Teflon catheters before infiltrating (Vialon 51 hrs vs. Teflon 42 hrs)	<i>Infiltration:</i> 54.2% in Vialon vs. 58.1% Teflon <i>Leaking:</i> 16.4% Vialon vs. 14.3% Teflon <i>Phlebitis:</i> 9.6% Vialon vs. 11.3% Teflon <i>Blocked:</i> 4.7% Vialon vs 5.4% Teflon <i>Dislodged:</i> 2.7% Vialon vs 3% Teflon	Vialon catheters reduced the risk of infiltration by 18% in the total sample & by 35% in the higher risk low-weight (≤ 1500 g) subsample Infiltration was 1.5 times more likely to occur in infants ≥ 5 days vs those < 5 days Infiltration was 1.6 times more likely for scalp PIVs than hand Hyperalimentation associated with 1.5 times the risk of other infusates	Staff members not blinded to the type of catheter used Different catheter lengths; Teflon catheters were 1.6 cm long and Vialon catheters were 1.9 cm long; catheter length was not one of the variables studied Sites were inspected at least every 8 hours instead of every hour
Smith & Wilkinson-Faulk (1994)	Descriptive study to determine effect of insertion site, catheter size and brand type, blood and unit setting on the lifespan of	Setting: NICU, PICU and general pediatric units at a children's medical center in Southwest N=250 infants $\leq$ yr of age; 124 PIVs from NICU, 124 from general	24 g Teflon catheter (92.9% of the sample)	Mean for entire sample was 45.12 hours Electively discontinued IVs (n=100) had a mean life span of 49.74 hrs vs. 42.04 hrs for non-electively	70% of IVs in NICU were non-electively removed vs 50% in general pediatric units	No significant difference in life span of non-electively discontinued IVs by insertion site, cannula size, or brand type IVs in which blood was infused lasted longer than those without blood products	Specific complications not discussed Unable to compare catheter types (steel vs. Teflon) because of small number of steel needles in sample (n=2) Did not examine the effect of medications on IV catheter life span

	PIVs in infants	pediatric unit & 2 from PICU		discontinued IVs (n=150) Non-electively discontinued IVs in infants on the general pediatric units lasted longer (53.6 hrs) than those in NICU (36.84 hrs)			
Franck, et al. (2001)	Quality improvement audit to establish baseline data on prevalence of PIV complications and identify influencing factors	Setting: Tertiary level NICU in a large West Coast City N=57 infants (264 PIVs) GA at birth: 25.5-42 weeks BW: 0.58-4.89 kg Age at time of PIV insertion: 0-137 days	24 gauge Teflon catheter (84%) 22 gauge Teflon catheter (10%) Gauge not reported (6%)	Mean duration: 2.19 days (52.56 hrs) Range: 0-11 days (0-264 hrs)	Infiltration: 106/203 (52.2%) Leaking: 56/203 (27.6%) Occluded: 30/203 (14.8%) Elective removal: 11/203 (5.4%) Lower extremity placements associated w/ more frequent leaking; scalp PIVs more often occluded	Postnatal age influenced number of insertion attempts (older infants required more attempts) Insertion site influenced duration of PIV PIVs in upper extremity more likely to last >48 hours (p=0.0001) Duration of PIV not related to catheter size	
Foster, Wallis, Paterson, &	Descriptive study to describe PIV	Sample included neonates, infants and children	22 gauge & 24 gauge Vialon	42.35±29.22 hours(range: 2.5 to 189.5 hrs)	Elective removal: 74.6% Phlebitis: 6.6%	↑ phlebitis risk with younger age; longer PIV dwell time,	Heterogenous sample with only small number of neonates

James (2002)	use, management and associated incidence of phlebitis in a pediatric unit	N=436 pediatric patients (496 PIVs) 152 (30.6%) inserted in infants (18.5% in neonates) 344 (69.4%) PIVs inserted in children	catheters			medication administration Neonates were 5 ½ times more likely to have some degree of phlebitis Retrospective analysis of 29 positive blood cultures showed that in 2 neonates, a CRBSI may have developed from a PIV; CONS was most common organism	Difficult to make comparison about phlebitis rate from other studies because no standardized phlebitis scale used Retrospective analysis of CRBSI
Gupta et al (2003)	Observational study to determine factors affecting the survival of PIVs: rate, glucose infusion rate, and medications	Setting: NICU in India N=78 neonates (186 PIVs) GA: 28 to 42 weeks BW: 750-4100 g	24 gauge over the needle Teflon catheters	Mean 40.8±27.6 hours (range 1-136 hours) Median survival time of PIV expressed by Kaplan-Meier survival analysis=40 hrs	Infiltration: 161/186 (86.6%) Swelling 84/186 (45.2%) Leaking/dislodgement 50/186 Blocked 17/186 Redness 10/186 No longer needed 25/186	BW, gestation, splint use, fluid and glucose infusion rate, site of cannulation, and administration of ampicillin, gentamicin, vancomycin, phenobarbitone, blood products did not affect median life span of PIVs Duration of PIV decreased with cefotaxime	Single center 32-bed neonatal unit in developing country All infusions by gravity drips Low nurse to patient ratio (1:4 during the day & 1:8 at night) could have affected PIV dwell time (e.g. later detection of complications)

GA=gestational age; PNA= postnatal age; BW=birth weight; AA=amino acid

Appendix B

Summary of Studies on the Use of Splints for PIV Catheters

Authors	Study Design and Purpose	Setting & Sample Characteristics	PIV Device	Duration (hours)	Complications	Other Findings	Limitations/ Comments
Tripathi, Kaushik & Singh (2008)	Single blind, randomized controlled trial to prospectively analyze impact of heparin flushes and the use of splints on patency of PIV catheters and complication rates	Setting: general pediatric ward of a children's hospital in India N=88 patients (377 PIVs) Age: <30 days: 32%; 30 days-1 year (35%); 1-5 years (22%); >5 years (11%) Gender: 63% males; 37% females Heparin flush: Yes=170 No=207 Splint Yes=181 No=196	22 or 24 gauge catheters (BD Venflon or Neoflon)	22 g catheters: 48.6±20.8hrs (mean±SD) 24 g catheters: 42.1±20.3 hrs (mean±SD) <i>Heparin flush</i> ($p<0.05$): Yes: 48.21±23.19 hrs No: 39.43±18.95 hrs Catheter patency significantly longer for heparin vs saline flushes <i>Splint</i> ($p<0.005$): Yes: 50.29±20.92 hrs No: 39.75±21.39 hrs	Statistically higher incidence of complications in children < 1 yr vs children > 5 yrs ↑ complications with duration of catheter use (>50% chance of complication when >96 hrs of use) ↑ phlebitis with: wrist insertion site (22% vs 14% compared to other sites, $p<0.05$); 24 g catheters (21% vs 14% for 22 g catheters; $p<0.05$)	Younger age, wrist and scalp insertions, and 24 gauge catheters were associated with shorter duration of PIV patency and increased complications Catheter patency longest for insertion site on dorsum of hands (49.6±22.4 hrs) and shortest at the wrist (23.6±11.2hrs; $p<0.05$) Catheters close to a joint had shorter duration of patency compared	Results may not be generalizable due to wide range of age and diseases in study sample Need further studies specific to the NICU

		Heparin flush & splint: Yes=81 No=90		Use of splint vs no splint increased catheter patency <i>Heparin flush & splint (p<0.05):</i> Yes: 52±24.4 hrs No: 31.22±7.17	↑phlebitis with heparin flushes ↓ phlebitis with splints	to those inserted away from joint (mean 32.5±17.8hrs vs. 46.1±16.6 hrs; p<0.05) Medications had no significant effect on phlebitis/infiltration	
Dalal, et al., (2009)	Randomized controlled trial to evaluate the efficacy of limb splinting on functional duration of PIVs in neonates	Setting: NICU of a tertiary care hospital N=54 neonates (69 PIVs); n=33 in splint group n=36 in no splint group Both groups comparable in BW, GA, site of insertion and nature of fluids administered	24 gauge Teflon catheters (BD Neoflon)	Splint group: 23.5±15.9 hrs vs. No-splint group: 26.9±15.5 hrs (p=0.38)	Extravasation at insertion site most common reason for PIV removal (84% in splint group vs 76.5% in no-splint group)	Difference in mean functional duration of patency was more in neonates < 30 wks GA, but this group was too small to make firm conclusions	Unable to blind observers monitoring for signs of removal

GA=gestational age; PNA= postnatal age; BW=birth weight

Appendix C

Summary of Studies on PIV Catheter Securement Methods

Authors	Study Design	Purpose	Setting & Sample	PIV catheter	Outcomes	Findings	Limitations
Wood (1997)	Prospective open label study divided into 2 phases, each phase lasting 2 months <i>Phase 1:</i> transparent dressing/tape (control group) <i>Phase 2:</i> transparent dressing over insertion site and StatLock (study group)	To evaluate the frequency of PIV catheter complications by comparing two methods of securement: transparent dressing and tape versus transparent dressing and Statlock	Setting: Sierra View Hospital, 175-bed community hospital Sample: 105 initial IV placements in patients ≥ 18 years of age Transparent dressing/tape=55 Statlock =55	Short peripheral catheter (BD Insyte)	Unscheduled restarts Total complications, Dislodgement Infiltration Average dwell time	StatLock/transparent dressing group showed 45% reduction in complication rate and IV restarts Dislodgement: 40% reduction in StatLock group (42 % in control group vs 2% in StatLock group) Infiltration: reduced by 8% (22% in control group vs. 14% in StatLock group) Mean dwell time extended by 21.1 hours (StatLock 65 hrs vs 43.9 hrs in control group)	Non-randomized Lack of blinding

Sheppard, LeDesma, Morris, & O'Connor (1999)	Prospective controlled study in 2 phases Phase 1- transparent dressing + tape Phase 2- StatLock	To explore whether the use of a StatLock securement device on short peripheral catheters can affect average catheter dwell times and overall complication rates	Setting: Glencrest Nursing and Rehabilitation Center Sample: 30 patients (15 in control group & 15 in StatLock group); baseline characteristics comparable	18-, 20-, or 22 gauge Surflo PIV catheters	Unscheduled restarts Total complications Infiltration Phlebitis Average catheter dwell time Time spent managing PIVs	Fewer complications in Statlock group compared to transparent dressing/tape group (65 vs 155 complications; $p=0.001$) <i>Dwell time:</i> StatLock secured catheters had a mean dwell time of 94.8 hrs vs 58.8 hrs for tape-secured catheters <i>Unscheduled catheter restarts</i> significantly lower in StatLock group vs transparent dressing/tape group (24 vs. 55; $p=0.005$) StatLock ↓ total time spent managing PIVs by 13.5 mins/patient	Non-randomized design Small sample size
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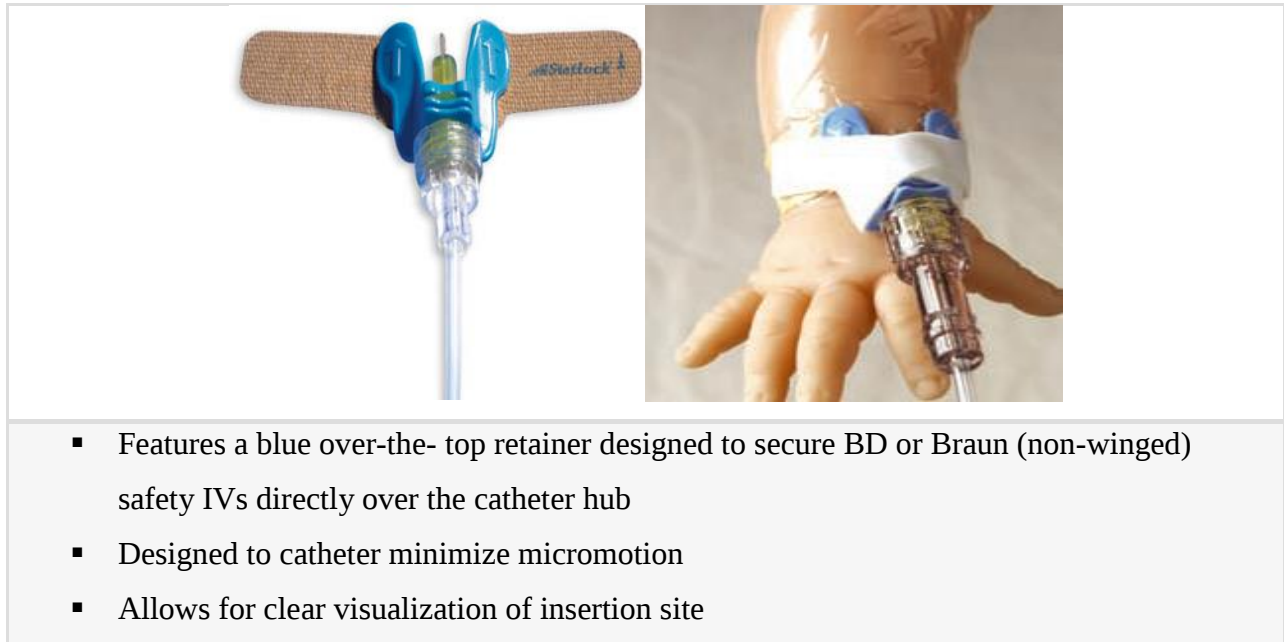
Smith (2006)	Prospective sequential clinical trial	To determine if any of 3 methods (nonsterile tape, HUB-guard, and StatLock) for PIV catheter securement would increase the average survival time of catheters to implementation of a 96-hour change-protocol	Setting: Holmes Regional Medical Center, Florida Tape group: 73 adults StatLock: 38 adults (phase 1); 248 adults (Phase 2) Hubguard: 300 adults	20-, 22-, 24 gauge BD Insyte Autoguard	Survival to 96-hour scheduled change protocol	Survival to 96-hour scheduled change protocol: Non-sterile tape (8%); StatLock (52%); Hubguard (9%) Pooled StatLock outcomes significantly different from -tape group ($p < 0.001$) & Hubguard ($p < 0.001$)	Non-randomized Sample characteristics not described Sample sizes differed significantly
Schears (2006)	Report summarizing the pooled data from prospective product trials comparing tape to a standardized PIV catheter-stabilizing device (StatLock)	To compare StatLock with tape to determine whether a catheter stabilization device can reduce the rate of PIV restarts and complications	Setting: 83 hospitals; all hospitals followed a mandatory 72-hour PIV change Sample: 10164 patients ≥ 18 months of age requiring PIVs; patients were followed up for 72 hours or to the completion of therapy 15 004 PIVs inserted: 9955 tape group & 5049	Not available	Unscheduled restarts Total complications Phlebitis	PIV restarts: 70.7% in tape group vs. 16.6% in StatLock group ($p = 0.0001$); representing a 77% reduction in unscheduled PIV restarts <i>Total Complications:</i> 47.6% tape group vs. 16% StatLock group ($p < 0.001$); representing a 67% reduction <i>Phlebitis:</i> 3.6% tape group vs. 0.7% StatLock group ($p < 0.001$); overall 80% reduction Annual cost savings of	Non-randomized Unblinded Selection bias possible since patients enrolled sequentially <i>Hawthorne effect</i> likely since study drew attention to a new securement method Variations among hospitals with how PIVs were maintained could have influenced

			StatLock			\$18000/hospital on IV materials & combined annual savings of \$227,000 on materials, complication costs, & nursing times were estimated	results
Callaghan, Copnell & Johnston (2002)	Prospective, open-label, non-randomized study conducted in 3 phases Phase 1: audit of current catheter dressing practice over 3-month period Phase 2: education program for staff on application of Tegaderm 1633 dressing Phase 3: introduction & evaluation of Tegaderm 1633 dressing over a 6-month period	To compare the effect of two methods of peripheral catheter securement (Tegaderm 1633 dressing vs. adhesive tape) on the incidence of complications in children and adolescents	Setting: Emergency department and 3 general medical and surgical units of the Royal Children's Hospital, Melbourne Australia Sample: 364 patients in whom 407 PIV catheters inserted; 212 PIVs in tape group; 195 in Tegaderm 1633 group Children in control group significantly younger and had shorter LOS More children in study group had higher incidence of	20-, 22-, 24 gauge	Complications of PIV therapy Securement devices	Increased reinforcement of dressing in tape group at ≥ 48hrs; difference was significant at 96 hours Tegaderm 1633 dressing (study group) had better dressing adherence and less reinforcement No significant difference in phlebitis or extravasation	Control and study groups were not comparable for several factors Tegaderm 1633 dressing not used in manner recommended by manufacturer; used tape for extra reinforcement Variation in practice among nurses may have influenced results

			pre-existing infection & skin condition				
McCann (2003)	Product evaluation in which data was collected over a 2-month period	To determine if Tegaderm 1610 dressing was clinically effective and acceptable in the pediatric setting.	Setting: hematology, oncology, infectious disease immunology and bone marrow transplant units Sample: children between the ages of 5 months and 12 years of age 100 Tegaderm 1610 dressings applied by 17 nurses	Not available	Ease of application, initial adhesion, overall adhesion, security of cannula, observation of site, ease of removal & skin condition after removal	More child-friendly and cost-effective than Opsite IV 3000 (standard dressing used) as it eliminated the need for steri-strips 51% of nurses rated Tegaderm 1610 overall as excellent Generally scored 5 (excellent) or 4 in each of the performance indicators and there was no negative grading (score 1 or 2)	Not a comparative study in which the Opsite IV 3000 was not evaluated with the same methods Small study; Tegaderm 1610 evaluated only by 17 nurses Did not provide description of children in sample (distribution of ages, sex, diagnoses) Would have been more useful if compared Tegaderm 1610 to standard dressing (Opsite IV 3000) in terms of IV dwell times and rate of complications

Appendix D

Peripheral Intravenous Catheter Securement: StatLock Securement Device



Adapted from Bard Access Systems. Statlock IV Ultra Neonate Stabilization Device. Retrieved March 11, 2012 from <https://bardaccess.com/statlock-neonate-iv-ultra.php?section=Resources>.

Appendix E

Peripheral Intravenous Catheter Securement: Tegabear Dressing



Features include:

- Deep notch design for a better seal and reduced edge-lift around the catheter
- Sterile tape strips for anchoring hubs, lumens or tubing
- Soft cloth tape reinforcement for added strength and security of dressing
- Tegaderm transparent film over insertion site allows easy monitoring

Adapted from: 3M Tegaderm Transparent Dressings: 1610 and 1655 with added secural.

Retrieved March 11, 2012 from http://www.berovan.com/brochure%5C3M_Tegabear.pdf

Appendix F

Sample Size Calculation

The formula for the sample size for comparison between two means for a two-sided test is as follows:

$$n=2 \left[\frac{\left(\frac{z_{\alpha/2} + z_{\beta}}{2} \right) \sigma^2}{\mu_1 - \mu_0} \right]^2$$

Where n = the sample size required in each group

σ = standard deviation of the primary outcome variable

$z_{\alpha/2} = 1.96$

$z_{\beta} = 0.84$, the standard normal deviate corresponding to statistical power 80%

Inserting the required formula gives:

$$2 \left[\frac{(1.96 + 0.84 (33.20848))}{6} \right]^2$$

=480 catheters in each group

If one takes into account 10% missing data,

$$960 \times 0.10 = 96$$

$$960 + 96 = 1056 \text{ catheters}$$

The final sample size would be 1056 Insyte catheters. However, since Insyte catheters typically account for 60% of PIVs inserted in the Neonatal Nurseries, 1760 PIVs would need to be followed in order to obtain the required sample size of 1056 Insyte catheters.

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Appendix G

NICU Standard Policy & Procedure for Insertion of Insyte-N Autoguard

1. When inserting an Insyte catheter, use a pre-filled syringe with normal saline, connect the syringe to a microbore extension set and flush the tubing with saline
2. Put on gloves. Cleanse insertion site with chlorhexidine gluconate (CHG) alcohol using friction and a circular motion for 30 seconds, from the insertion site outward. Allow the area to dry at least 30 seconds.
3. Apply tourniquet proximal to and as close to the insertion site as possible. Minimize the time the tourniquet is applied; avoid using it in areas of compromised circulation, or in the scalp.
4. Grasp the catheter on the contoured grip of the flash back chamber. The bevel position of the stylette should be facing upward for correct venipuncture and the “release button” safety mechanism is facing up.
5. For the Insyte-N, the stylette may be rotated prior to insertion, to facilitate easy separation once the vein has been cannulated. Do NOT advance the catheter tip beyond the bevel of the needle.
6. To aid insertion, hold the skin taut. This anchors the vein and stretches the overlying skin for venipuncture. This point is vital to the procedure.
7. Enter the vein at a 15° to 20° angle with a single smooth motion. Go in “low and slow”. Entry into the vessel is indicated by a flow of blood into the flash back chamber. Advancement should be continued for 0.5cm more, then keeping the stylette stationary push forward on the catheter hub. Gentle, gradual advancement of the catheter may help to prevent puncturing the back wall of the vein. Once the catheter is threaded, press the “auto sheathing” white button to automatically remove the stylette into the safety chamber.
8. Release the tourniquet and flush the IV with normal saline to ensure patency.

Appendix H

Procedure for PIV Catheter Securement

Tegabear Securement Dressing

1. Peel the liner from the dressing, exposing the adhesive.
2. Position the dressing so the notch fits snugly around and under the catheter hub. The insertion site should be visible through the transparent film window.
3. Press the dressing into place. The soft cloth tabs can be overlapped under the catheter hub to protect the skin.
4. Slowly remove the frame while smoothing down the dressing edges. Smooth the dressing from the center toward the edges, using firm pressure to enhance adhesion.
5. Use sterile tape strips to secure hub, lumens and/or tubing.

StatLock

1. Position the catheter so the push-tab points up.
2. Apply the transparent dressing over top of the catheter hub.
3. Place the StatLock on top of the transparent dressing. Orient the StatLock device anchor pad with arrows pointing toward the catheter insertion site. Press the retainer over the catheter hub to capture push-tab in either open slot. Press on top of the retainer (not on sides) underneath the hub of the catheter.
4. Peel away the paper backing from the Statlock device anchor pad, one side at a time.
5. To cushion retainer edges, slide the provided Statlock device foam adhesive strip under the retainer edges. Form a chevron over the Statlock device retainer & hub.
6. Remove the saline syringe and attach the saline filled extension set to the Insyte catheter.
7. Loop the extension set back alongside the catheter and tape it over the top of the transparent dressing.

Appendix I

Tegabear Dressing Application Instructions



1. Peel the liner from the dressing, exposing the adhesive.



2. Position the dressing so the notch fits snugly around and under the catheter hub. The insertion site should be visible through the transparent film window.



3. Press the dressing into place.



4. The softcloth tabs can be overlapped under the catheter hub to protect the skin. You may need to trim the tabs if they are too large or long.



5. Slowly remove the frame while smoothing down the dressing edges. Smooth the dressing from the center toward the edges, using firm pressure to enhance adhesion.



OR



6. Use the sterile tape strips to secure the catheter hub and extension tubing. The sterile tape strip can be placed on top of the catheter hub OR chevron underneath the hub for added securement.

Appendix J

Data Collection Form-Tegabear Dressing

NOTE: The proposed study comparing two peripheral intravenous catheter securement methods is a subset of a larger audit of PIV practices in the Neonatal Intensive Care Unit. The highlighted areas of the data collection form are not relevant for this study, but are collected for the purposes of the audit of IV practices in the Neonatal Intensive Care Unit.

Neonatal Nurseries IV Catheter Evaluation 2012

Patient ID # _____

Postmenstrual age (PMA): _____ weeks

Current Age: _____ days

Present Weight: _____ grams

Gender: Male _____ Female _____

IV Insertion: _____ @ _____ hr.
dd mm yy

Bed # _____

Stabilization device used: Tegabear Yes No

(If No, indicate why _____)

**Please indicate if any modifications (e.g. cutting to make smaller) were made to Tegabear in order to be able to use it

Insertion Information:

Name of inserter (list each attempt on new line)	Type of catheter			Other	Selected site
	Insyte N	Intima	AbboCath		
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					

+ for additional attempts, please use back of form

Sucrose given prior to IV start? Yes No (If No, state reason _____)

Was an arm board used? Yes No (If Yes, state reason _____)

IV Removal: Date: _____ Time: _____ hr.

Reason:

☐ Discontinued/ no longer needed, without complications

☐ Dislodged/ kicked out

☐ Complications observed: please circle all relevant criteria

Red Puffy / Edematous Blunched

Blocked Leaking Other: _____

Solution(s)/ Continuous Infusion(s): Please circle all relevant solutions/ continuous infusions given through this PIV before its removal.

Amino Acids Lipids Neostarter D5W D10W

Packed Red Cells Fresh frozen plasma Platelets Dopamine

Morphine Fentanyl Sodium Bicarbonate Other: _____

Intermittent Medications: Please circle all relevant medications given through this PIV before its removal.

Ampicillin Gentamicin Vancomycin Caffeine Citrate

Cefazolin Cefotaxime Furosemide Acyclovir

Erythromycin Amphotericin B

Appendix K

Data Collection Form - StatLock

NOTE: The proposed study comparing two peripheral intravenous catheter securement methods is a subset of a larger audit of PIV practices in the Neonatal Intensive Care Unit. The highlighted areas of the data collection form are not relevant for this study, but are collected for the purposes of the audit of IV practices in the Neonatal Intensive Care Unit.

Neonatal Nurseries IV Catheter Evaluation 2012

Patient ID # _____ Postmenstrual age (PMA): _____ weeks Current Age: _____ days Present Weight: _____ grams Gender: Male _____ Female _____	IV Insertion: _____ @ _____ hr. dd mm yy Bed # _____ Stabilization device used: StatLock Yes No (If No, indicate why _____)
---	--

Insertion Information:		Type of catheter			Other	Selected site
Name of inserter (list each attempt on new line)	Insyte N	Intima	AbboCath			
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						

+ for additional attempts, please use back of form

Sucrose given prior to IV start?	Yes	No	(If No, state reason _____)
Was an arm board used?	Yes	No	(If Yes, state reason _____)

IV Removal: Date: _____ Time: _____ hr.

Reason:

☐ Discontinued/ no longer needed, without complications

☐ Dislodged/ kicked out

☐ Complications observed: please circle all relevant criteria

☐ Red ☐ Puffy / Edematous ☐ Blatched
☐ Blocked ☐ Leaking ☐ Other: _____

Solution(s)/ Continuous Infusion(s): Please circle all relevant solutions/ continuous infusions given through this PIV before its removal.

Amino Acids	Lipids	Neostarter	D5W	D10W
Packed Red Cells	Fresh frozen plasma		Platelets	Dopamine
Morphine	Fentanyl	Sodium Bicarbonate	Other: _____	

Intermittent Medications: Please circle all relevant medications given through this PIV before its removal.

Ampicillin	Gentamicin	Vancomycin	Caffeine Citrate
Cefazolin	Cefotaxime	Furosemide	Acyclovir
Erythromycin	Amphotericin B		

Appendix L

Research Ethics Board (REB) Approval Letter



RESEARCH ETHICS BOARD



REB Office, 293 Wellington St. N., Suite 102, Hamilton, ON L8L 8E7
Telephone: 905-521-2100, Ext. 42013
Fax: 905-577-8378

Research Ethics Board
Membership

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Chair/Ethics Representative
Donald Arnold MD, MSc FRCP(C)
Hematology & Thromboembolism
Uma Athale, MBBS, MD, M.Sc. FRCPC
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Emergency Medicine
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Pathology & Molecular Medicine
Ed Younglai PhD
Obstetrics/Gynecology

July 19, 2012

Kniessl Wagan, RN, BScN
Masters Student

**RE: *Peripheral Intravenous Catheter Securement in Infants in the
Neonatal Intensive Care Unit***

Dear Kniessl:

This will acknowledge receipt of your e-mail dated July 13, 2012 which enclosed a copy of the above-named study proposal; version 1 dated July 12, 2012. We wish to confirm this study has been reviewed by a member of the REB Executive and we agree this is a quality assurance study and therefore, does not require formal submission. This study satisfies the ethical requirements of the Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board. You may proceed with your project.

The Hamilton Health Sciences/McMaster Health Sciences Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations.

PLEASE QUOTE THE ABOVE-REFERENCE PROJECT NUMBER ON
ALL FUTURE CORRESPONDENCE

Sincerely,

Suzette Salama, PhD
Chair, Research Ethics Board

Appendix M

Parent Study Information Sheet

Peripheral Intravenous Catheter Securement in infants in the Neonatal Intensive Care Unit

Thank you for taking the time to read this document. We would like to tell you about a research study currently in progress. Your baby's participation is voluntary and if you choose not to have your baby participate, it will not change the care of your baby in the hospital.

What is the purpose of this study?

An intravenous (IV) is a thin, plastic tube that is put into a vein. It is through this tube or “catheter” that your baby is given fluids, nutrients, and medications. Once a catheter is put into a vein, it is important to keep the catheter fixed in place. If a catheter is not secured well, it can move within or rub against the vein wall, which can irritate or injure the vein. When a vein is injured, the site where the catheter was placed can look red, and puffy. The catheter must be taken out because the vein can no longer be used.

The purpose of this study is to find out the best way to keep (secure) the IV once it is in a vein, so that we can lower complications and increase the length of time an IV lasts. StatLock is what we use in our neonatal intensive care unit, which “snaps” onto the catheter, locking it in place. Tegabear is another product that we could use for securing an IV, which is a clear dressing with a soft cloth border that helps keep an IV in place. We will be looking at one type of IV catheter, called “Insyte”, which can be secured either with a StatLock or Tegabear. We would like to find out which of these two products is the best way to keep an IV in place.

What will happen to my baby in this study?

If your baby needs an IV and an “Insyte” catheter is put in, your baby's IV will be secured either with a StatLock or Tegabear. Your baby's nurse will regularly check your baby's IV site to make sure it is okay. Your baby will be followed up until the IV is taken out, either because of a complication (red, puffy, leaking, blocked, or kicked out) or the IV is no longer needed.

What are the possible risks of this study?

There are no significant harms or risks related to this study. StatLock has been safely used for securing IVs in the NICU. Tegabear has also been safely used in infants. However, since babies have sensitive skin, the bedside nurse will carefully monitor your baby's IV site so that if some redness or rash occurs, it can be identified right away.

What are the potential benefits of this study?

We hope that the information from this study will help improve how we secure IVs in the Neonatal Intensive Care Unit. Putting in an IV is a painful procedure for babies so improving the way we secure IVs will help lower complication rates and increase the length of time an IV lasts. Most importantly, it will mean reducing the number of IV restarts or pokes for babies who need an IV.

What identifying information will be recorded?

Your baby's name will not be recorded. Instead, your baby's hospital identification number will be recorded to help us keep track of the data collected and make sure that we do not have missing information. We will also be recording your baby's gestational age, and weight at the time an IV is inserted, which will help us compare results across different groups of babies in this study.

Will taking part in this study be kept confidential?

Yes, taking part in this study will be kept confidential. At the beginning of the study your baby will be given a study number. Once data collection forms are complete and we have all the information needed, we will take your baby's hospital identification number off and use only the study number. This number will be used when studying the data. Information that is collected on your baby will be stored on a password-protected computer, accessible by the researchers only without the baby's identification number. We will not release any information that would allow your baby to be identified.

When is this study happening?

This study will begin July 25, 2012 and will end November 12, 2012.

Who should I contact if I have questions or concerns about the study?

If you have questions or need more information about the study, please contact:

Principal Investigator/Faculty Supervisor: Dr. Susan Blatz, Clinical Nurse Specialist, Neonatal Nurseries (905) 521-2100 ext. 76349 email: blatz@hhsc.ca	Student Investigator: Kniessl Wagan, RN, BScN MScN Candidate McMaster University (905) 869-0116 email: wagank2@mcmaster.ca
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If you have concerns or questions about your baby's rights as a participant or about the way the study is conducted, contact the Chair of the HHS/FHS Research Ethics Board at 905 521-2100, Ext. 42013.

Appendix N

Study Information Sheet for NICU Staff

Peripheral Intravenous Catheter Securement in infants in the Neonatal Intensive Care Unit

Thank you for taking the time to read this document. Your participation is important to us and we thank you for helping us learn how to improve the care we provide our babies in the NICU.

Background

Peripheral intravenous therapy is a common aspect of management of infants in the neonatal intensive care unit (NICU). Poor catheter securement contributes to the occurrence of complications which result in premature removal of peripheral intravenous catheters. When a PIV is not properly secured, motion and micromotion within the vessel cause injury to the vein, which leads to phlebitis, infiltration, leaking at the insertion site, pain, and dislodgement. Therefore, catheter securement is important in reducing complications as well as increasing the length of time an IV lasts.

Study Purpose

The purpose of the study is to compare two methods of securing peripheral intravenous catheters, the Statlock versus 3M Tegabear dressing. Statlock is the securement device currently used in the NICU. The 3M Tegabear dressing combines a transparent polyurethane film with a soft-cloth reinforcement, and includes a deep notch design, for added catheter securement. However, what is not known is which method of securement is more effective. In order to evaluate the effectiveness of one securement method over another, the study will compare the length of time an IV lasts and the number of complications that occur.

Inclusion Criteria

- Infants who have a 24 gauge Insyte-N Autoguard catheter successfully inserted for IV maintenance fluids, total parenteral nutrition, or medications
- Insyte-N Autoguard catheters inserted for administration of blood products or diagnostic tests that are saline locked

Exclusion Criteria

- Infants who do not have a 24 gauge Insyte-N Autoguard catheter
- Insyte-N Autoguard catheters that are inserted solely for transfusion of blood products or diagnostic tests, which are to be removed after the procedure has been completed

Study Design

This study is a prospective, non-randomized evaluation study. This study will be conducted in two phases and is a subset of a larger audit of PIV practices in the Neonatal Intensive Care Unit at McMaster Children's Hospital. Each phase of the study will last 2 months. In Phase 1, Tegabear dressing will be used in Pods A, B and C whereas, StatLock will be used in Pods D, E, Intermediate Care Nursery (ICN) and ISR. In Phase 2 of the study, StatLock will be used in Pods A, B and ISR whereas Tegabear dressing will be used in Pods C, D, E and ICN. In both phases of the study, infants will be followed until their peripheral intravenous catheter is removed either as a result of a complication or it is no longer needed.

Sample size: A total of 396 Insyte-N Autoguard catheters will be needed for this study.

Data gathered: described on the data collection sheet

As the RN what do I need to do?

- For every PIV, complete a data collection form.
- For those baby's with a 24 gauge Insyte inserted, indicate whether you were able to use Tegabear or StatLock to secure that IV AND if NO, indicate reason why you were not able to use Tegabear or StatLock
- Write the demographic information, insertion and removal information, solution and medication information on the data collection form for ALL PIVs inserted

Benefits/Harm

This study will not benefit infants directly. However, the results will help us to determine the best method for securing peripheral intravenous catheters that would decrease rates of complications and increase the length of time an IV lasts. PIV insertion is a painful procedure, therefore, increasing the length of time an IV lasts will mean less pokes for infants who require an IV. We do not anticipate additional harm to the babies but need to collect this information to confirm this assumption.

Study Period

The study will begin July 25, 2012 and will end by November 12, 2012.

Who should I contact if I have questions or concerns about the study?

If you have questions or need more information about the study, please contact:

Principal Investigator/Faculty Supervisor: Dr. Susan Blatz, Clinical Nurse Specialist, Neonatal Nurseries (905) 521-2100 ext. 76349 email: blatz@hhsc.ca	Student Investigator: Kniessl Wagan, RN, BScN MScN Candidate McMaster University (905) 869-0116 email: wagank2@mcmaster.ca
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Appendix O

Distribution of PIV Dwell based on Securement Method

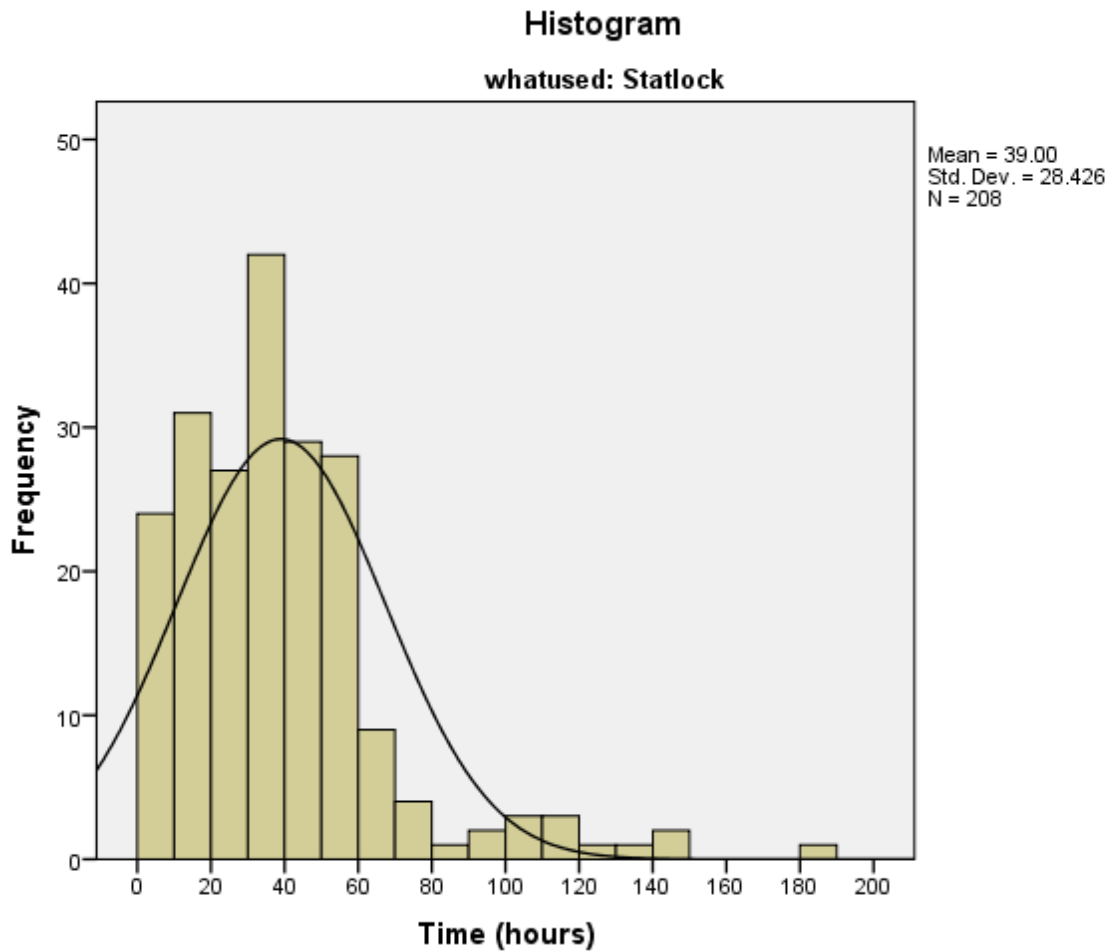
Figure 1. Sample distribution of PIV dwell time for StatLock group

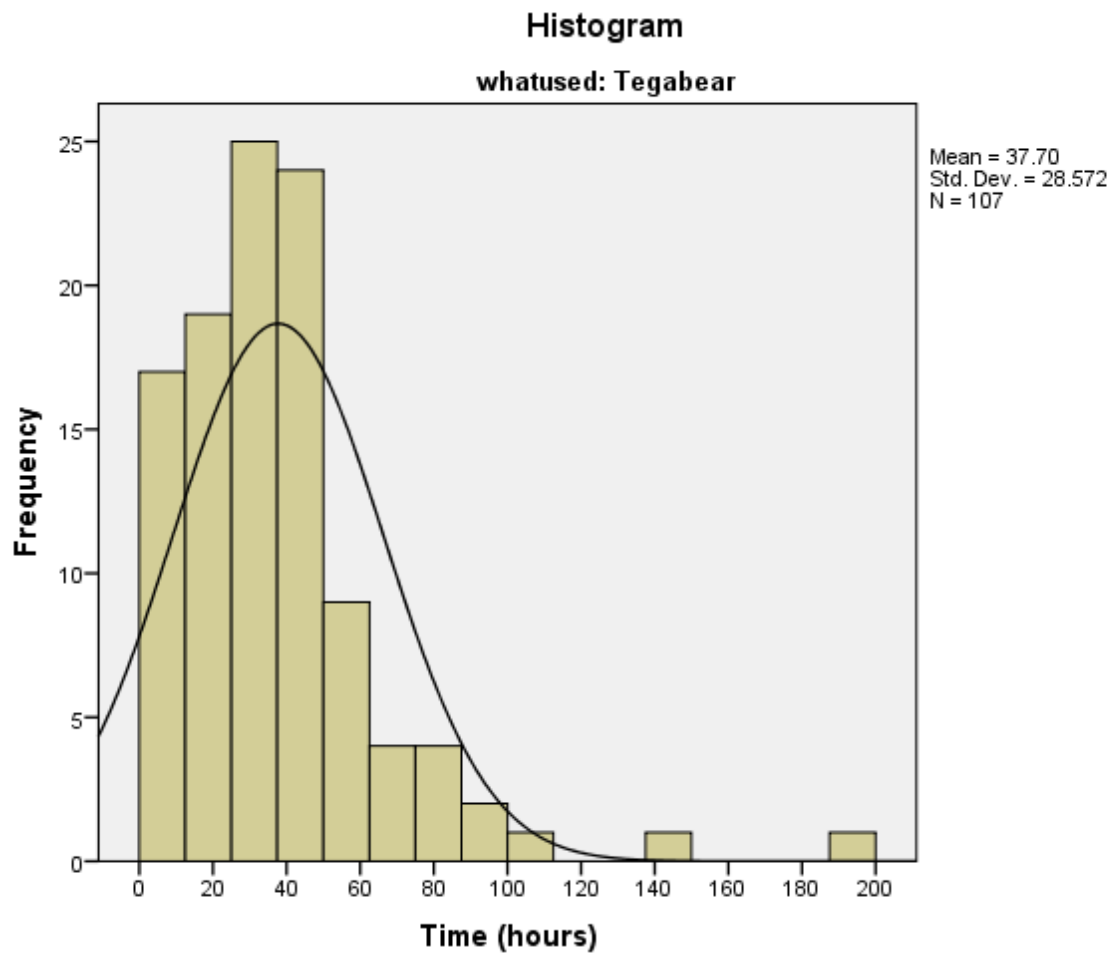
Figure 2. Sample distribution of PIV dwell time for Tegabear group

Figure 3. Distribution of PIV dwell time for Tegaderm/Tape group

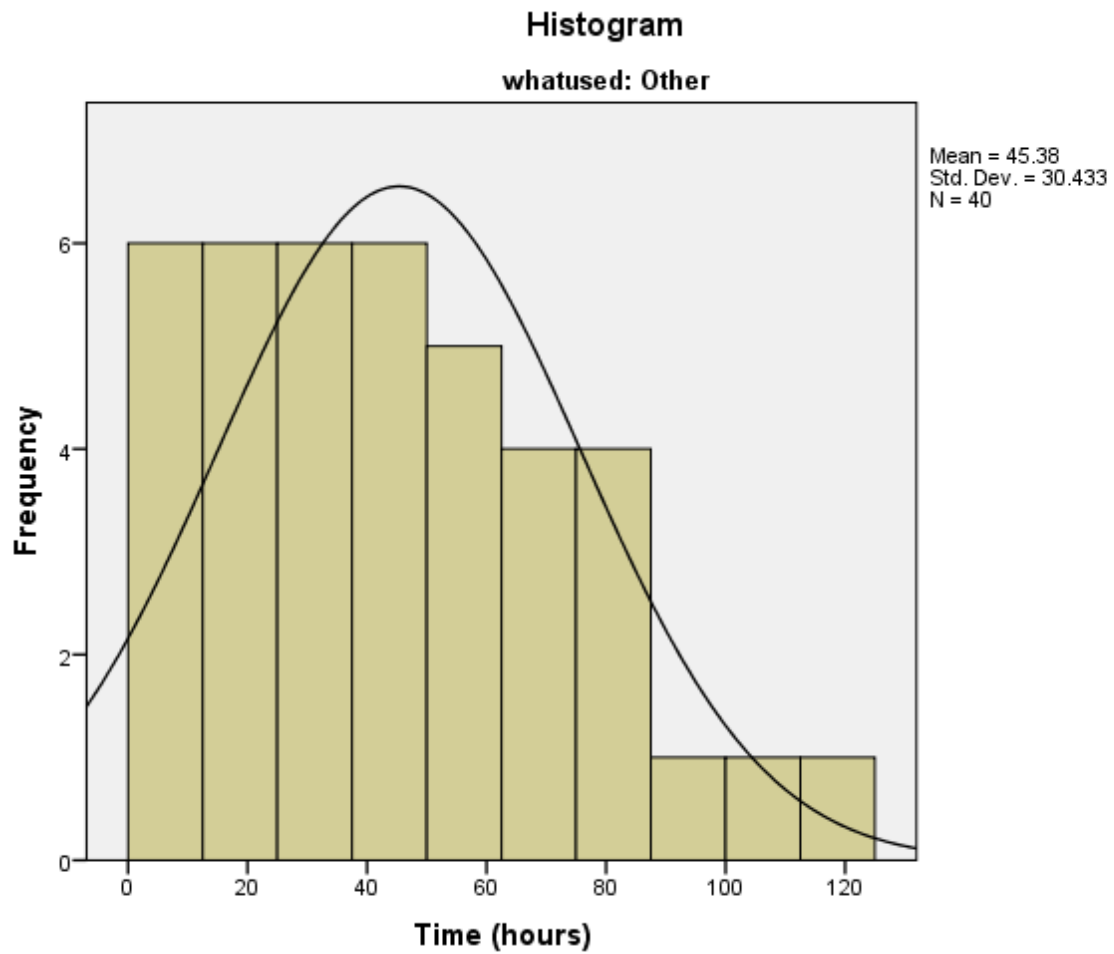
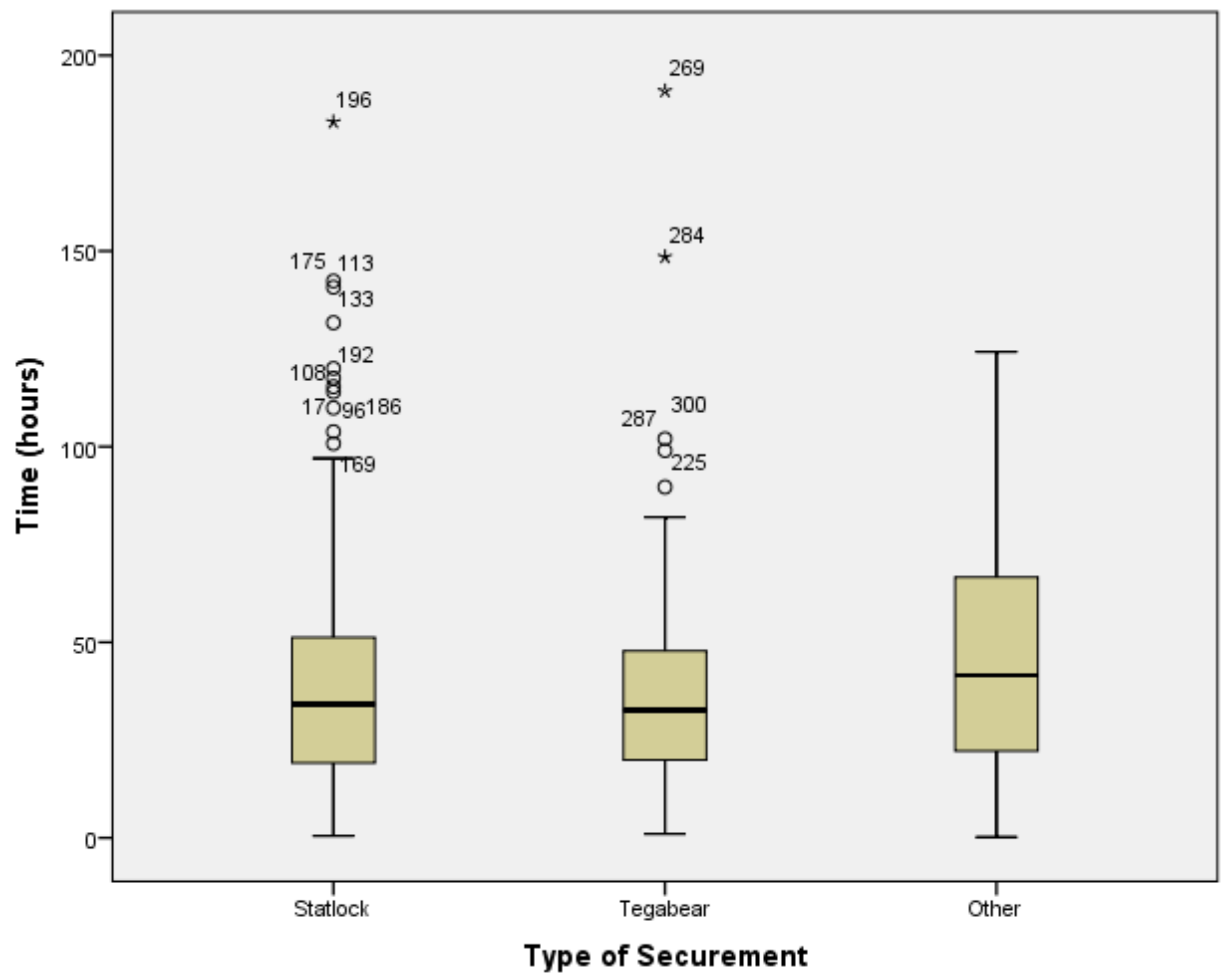


Figure 4. Boxplot based on type of PIV securement.

Appendix P

Shapiro-Wilk Test of Normality using SPSS

Tests of Normality							
	whatused	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
time	Statlock	.111	208	.000	.867	208	.000
	Tegabear	.134	107	.000	.833	107	.000
	Other	.093	40	.200 [*]	.960	40	.173

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Appendix Q

Log Transformed Distribution of Dwell Time based on Type of PIV Securement

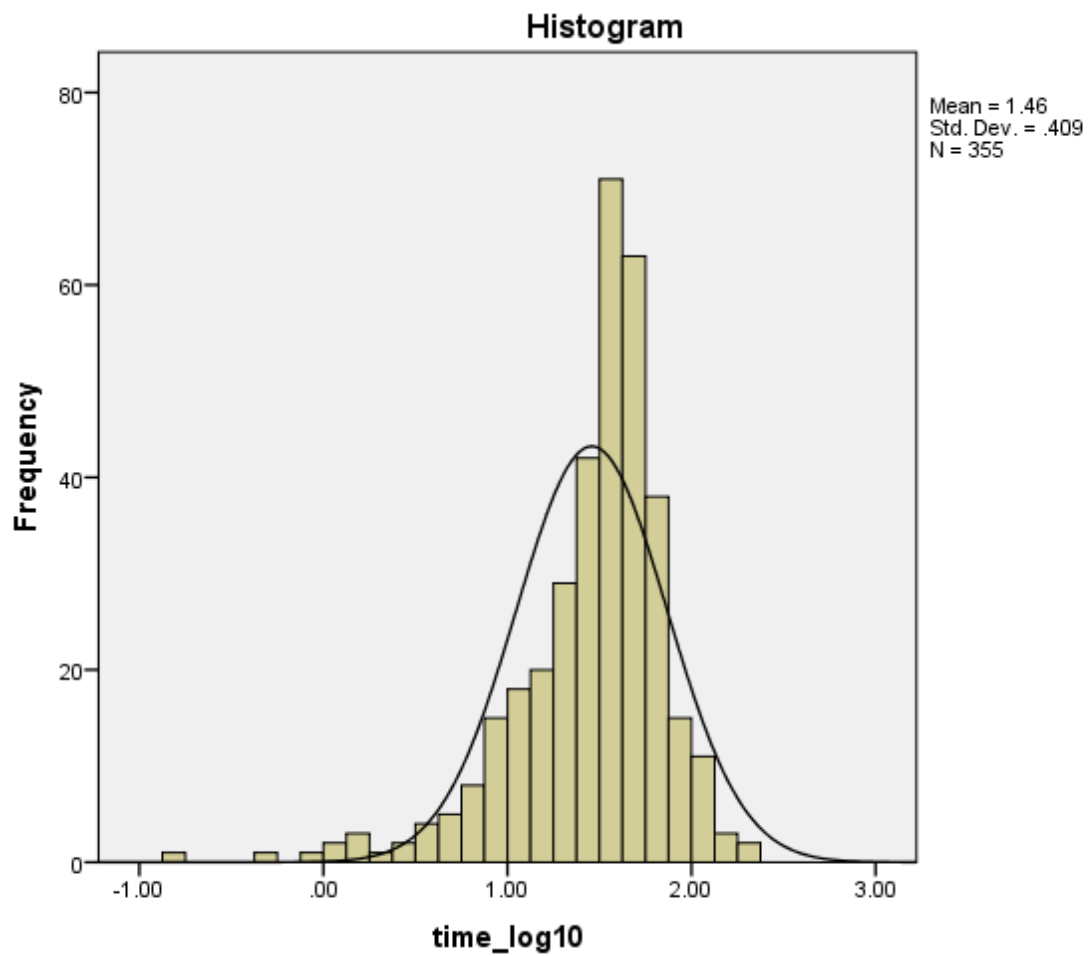
Figure 1. Study sample distribution showing that is skewed to the left despite log transformation.

Figure 2. Log transformed distribution of PIV Dwell Time for the StatLock group that is skewed to the left.

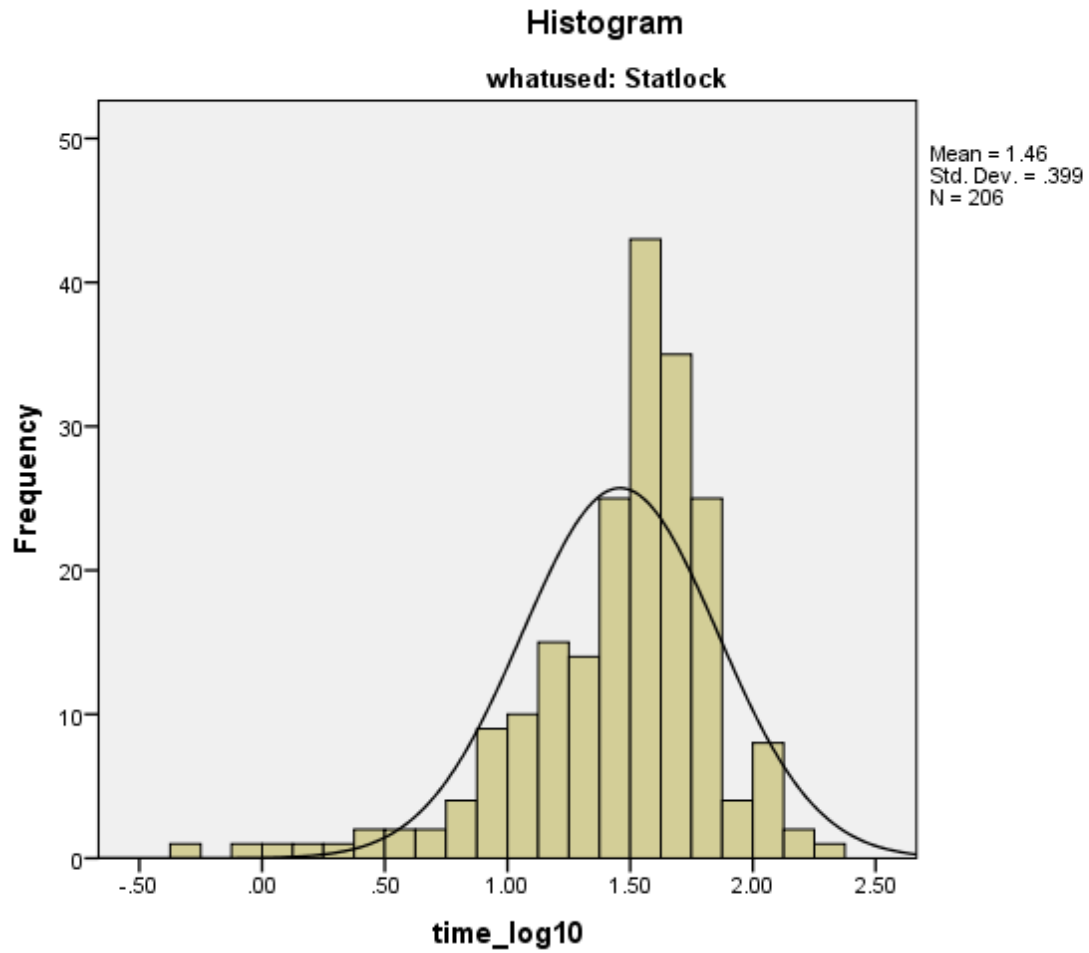


Figure 3. Log transformed distribution of PIV Dwell Time for the Tegabear group that is skewed to the left.

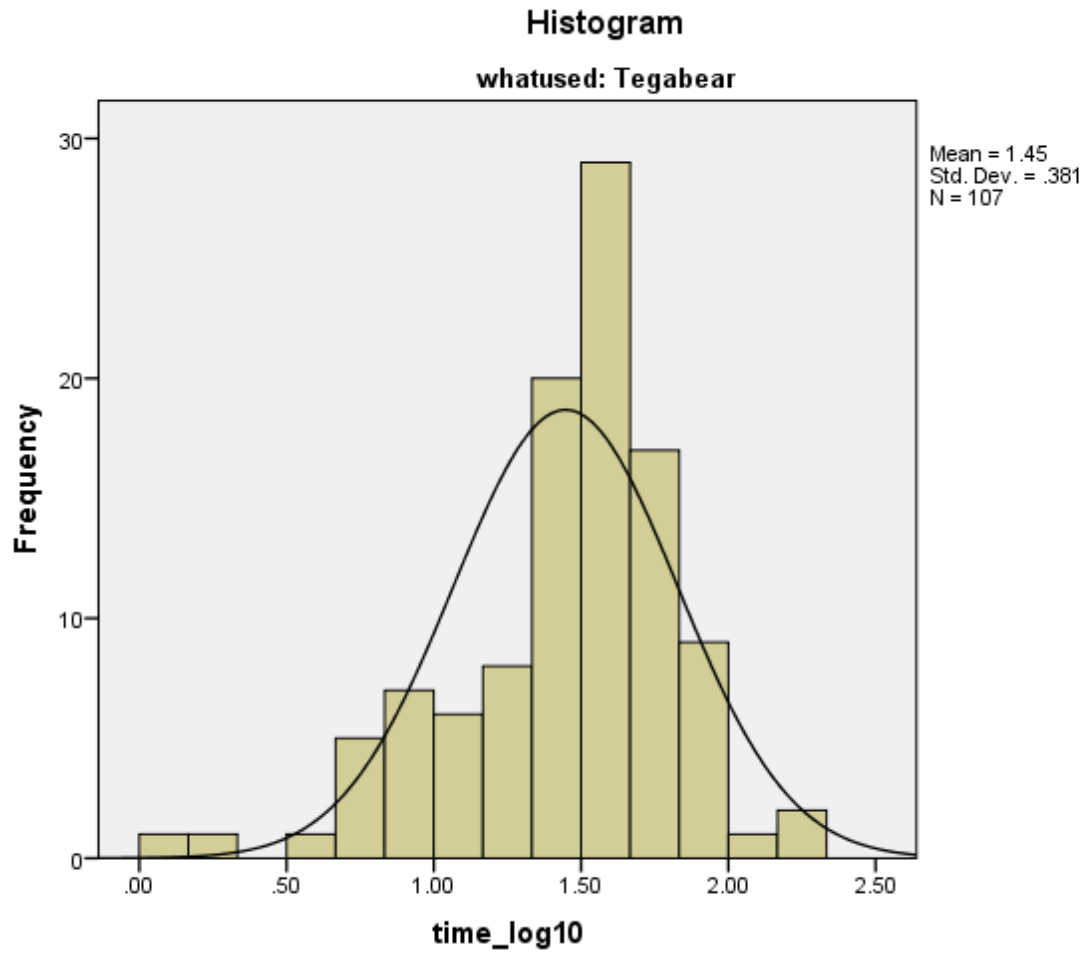


Figure 4. Log transformed distribution of PIV Dwell Time for the Tegaderm/Tape group that is skewed to the left.

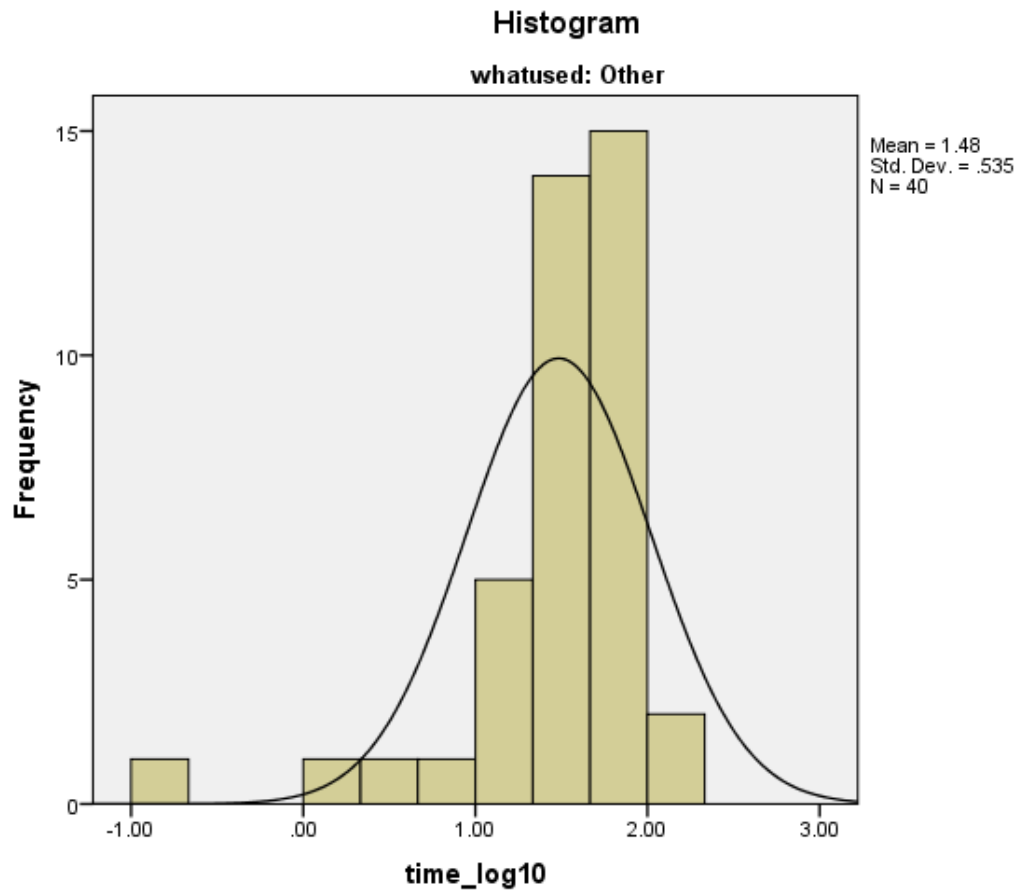
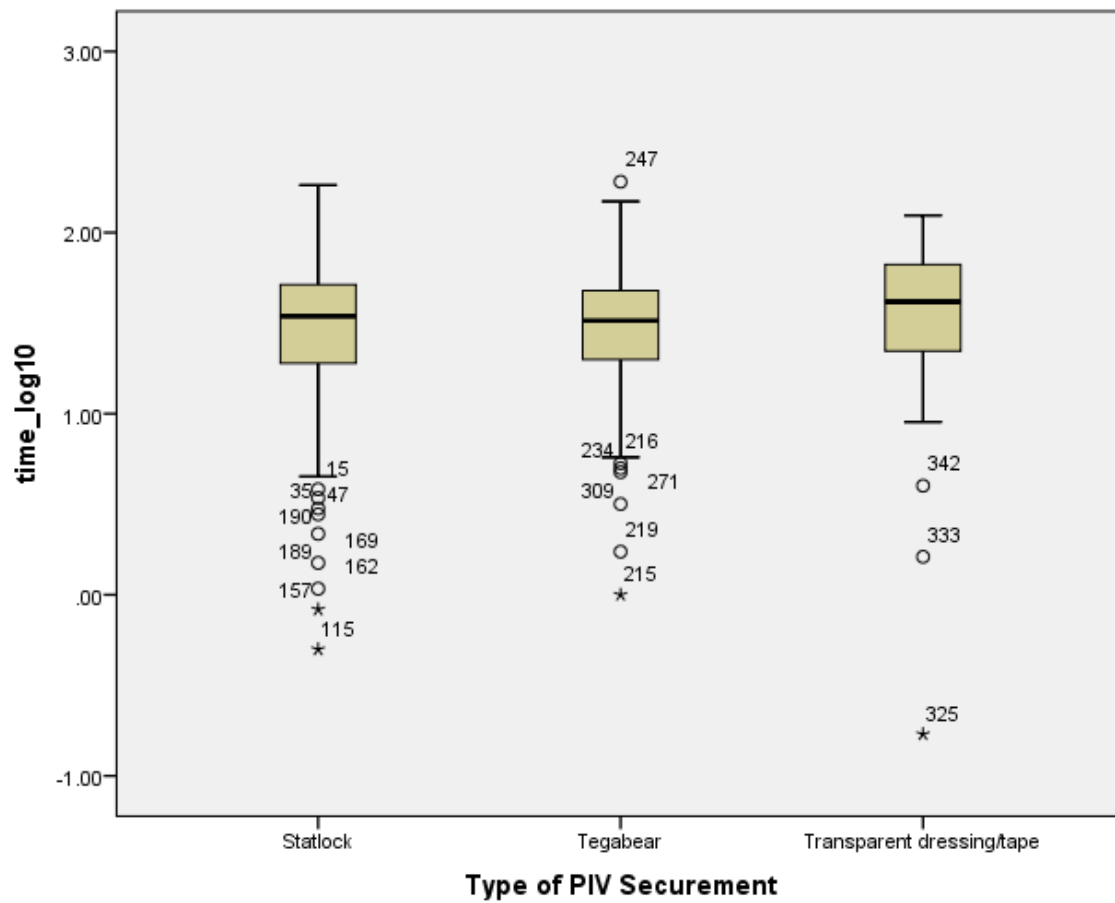
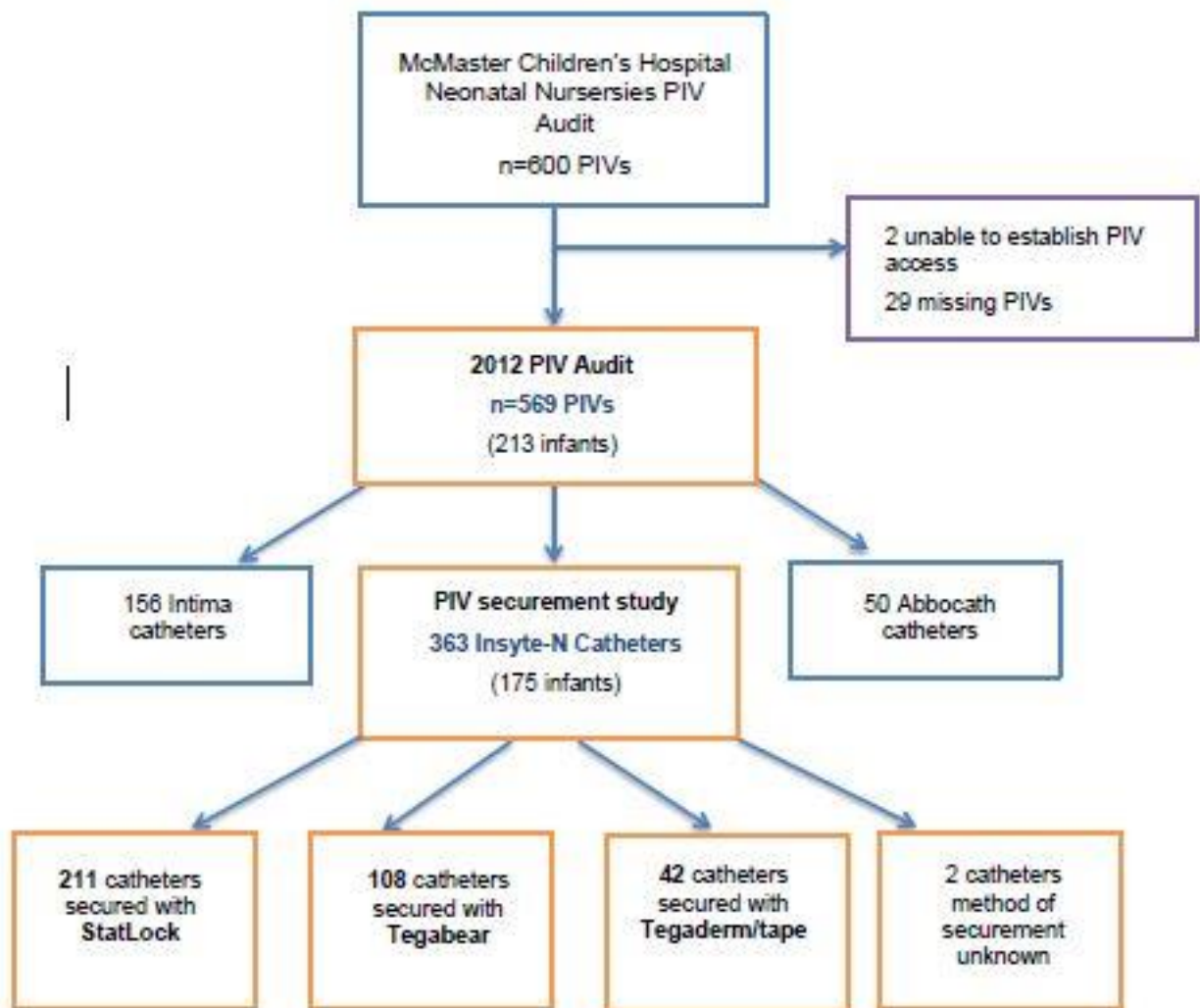


Figure 5.Boxplot of log transformed PIV dwell time based on type of PIV securement.



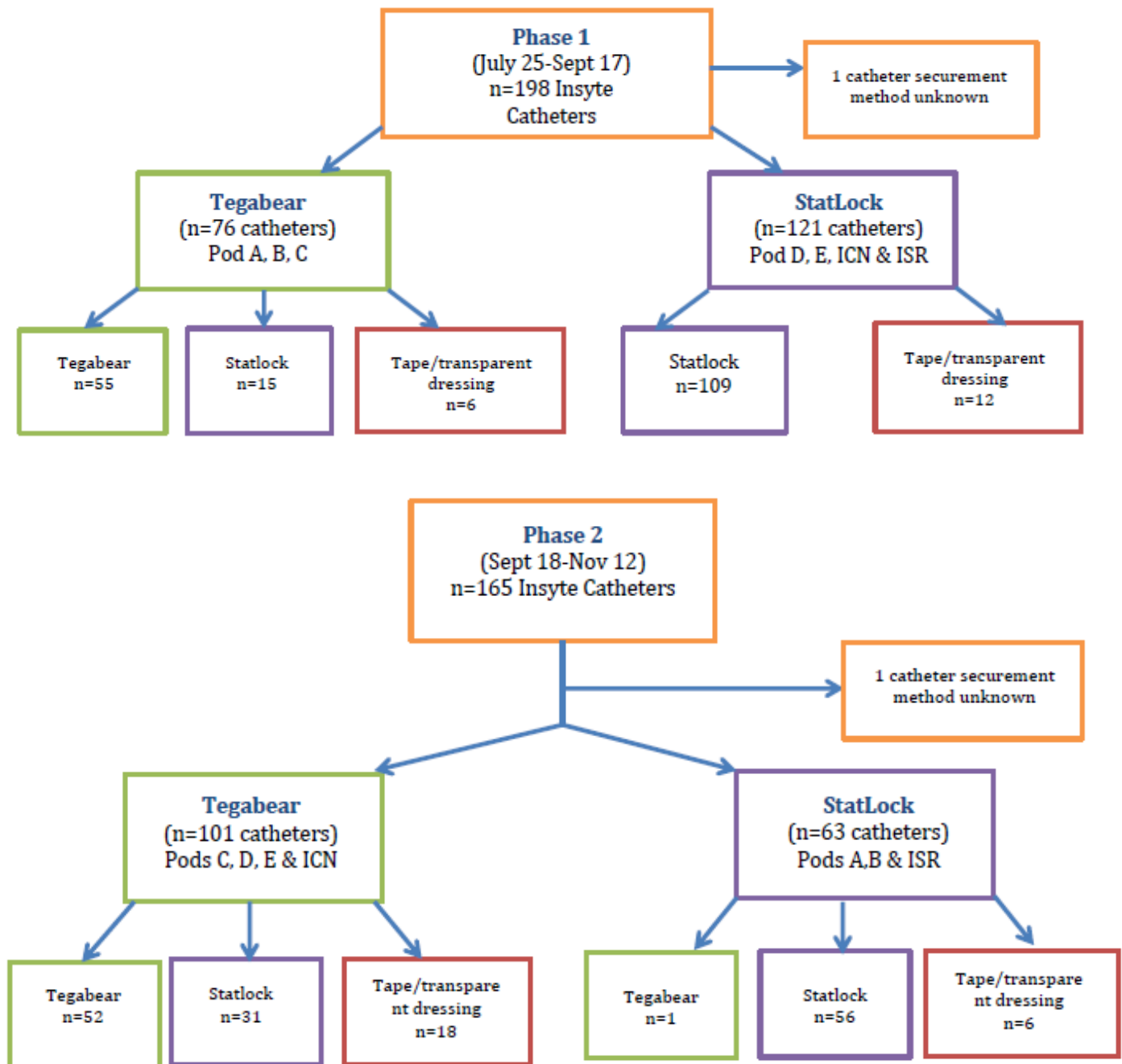
Appendix R

Flowchart of the Study and Group Allocation by Securement Method



Appendix S

Flowchart outlining Study Phase by Securement Method



Appendix T

Information Sheet addressing Frequently Asked Questions

Hello to the Neo RNs, & APNs,

We are in the second week of the PIV audit & Tegabear trial. Education in-services have been provided over the last 2 weeks to 84 nurses. We would like to thank everyone for taking the time to fill out the PIV Audit forms. We hope to answer the question of which securement device provides the best outcome. ****To ensure the proper evaluation of the Tegabear and minimize bias in the trial as much as possible, use Tegabear and not StatLock for securing PIVs in Pods A, B & C.****

We also wanted to address a few questions you may have regarding the Tegabear dressing & PIV Audit.

What Pods are we trialing Tegabear ? Pods A, B & C

What Pods are we using StatLock ? Pods D, E, L2N & ISR

What do I do if I have a smaller baby and the Tegabear dressing is too big?

- Trim the bottom cloth part of the dressing **before** application
- Trim a little bit of the top, transparent part of the dressing **before** application. If you do this, it may be difficult to peel the dressing off the paper liner therefore, you would need to peel it from the bottom cloth part.
- Indicate in the audit form that you had to modify/ cut the dressing

How far down the catheter hub do I place the notched/cloth part of the Tegabear dressing?

- Place the notched part of the dressing just above the “push tab” (where the StatLock clicks into place) of the Insyte catheter

Once I have applied the Tegabear dressing, how do I secure the catheter hub using the steri-strips provided?

- Place one of the steri-strips under the catheter hub to form a chevron
- Place the second steri-strip across/ directly on top of the catheter hub to prevent it from moving up and down



What do I do if I am unable to use the Tegabear to secure my baby's PIV?

- Briefly describe reason you were not able to use Tegabear
- Use tegaderm & tape to secure PIV

What do I do after a PIV is inserted?

1. Take a PIV Audit form located in the IV caddy box. Complete the first half of the audit form which includes:
 - date & time of insertion
 - type of cannula inserted
 - site of insertion
 - number of attempts
 - securement device used (StatLock or Tegabear) & if unable to why*
 - infant's current gestational age & current age in days
 - current weight
 - gender
 - use of sucrose
 - use of armboard
2. Keep the PIV Audit form in the baby's chart until that PIV is removed/discontinued

What do I do when a PIV is removed?

- Indicate the date & time of removal
- Indicate reason for removal: discontinued/no longer needed WITHOUT complications, dislodged/kicked out, complications (e.g. red, puff/edematous, blanched, leaking, blocked)
- Select all relevant solutions, continuous infusions & medications given through that PIV

Where do I put completed PIV audit forms?

- Place completed PIV Audit form in pocket folder located inside or outside the IV cupboards in Pods A, B, D, & E.
- In L2N, place the completed forms in the pocket folder on the right side of the IV metal cart.

If you have any questions about the evaluation audit, please let us know (Susan Blatz, Kniessl Wagan) and we will find the best answer we can.

Appendix U

Summary of Patient and PIV Characteristics based on Securement Method

Table S1. Study Group Characteristics

Characteristics	StatLock	Tegabear dressing	Tegaderm/tape	<i>p-value</i>
Location of Placement (%)				
NICU	177 (83.9)	96 (88.9)	36 (85.7)	
ICN	18 (8.5)	12 (11.1)	3 (7.1)	
ISR	16 (7.6)		3 (7.1)	
Total	211	108	42	
Postnatal Age (days)				
Median (Range)	4 (1-212)	8 (1-135)	7 (1-79)	
Mean $\pm$ SD	17.22 $\pm$ 31.94	20.28 $\pm$ 27.21	19.45 $\pm$ 23.96	
No. (%)				0.23*
0-2 days	68(32.4)	22 (20.6)	10 (23.8)	0.15**
3-7 days	60 (28.6)	29 (27.1)	11 (26.2)	
8-15 days	25 (11.9)	19 (17.8)	7 (16.7)	
16-30 days	18 (8.6)	12(11.2)	1(2.4)	
31-59 days	27 (12.9)	16 (15)	5(11.9)	
>60 days	12 (5.7)	9 (8.4)	8(19)	
Total	210	107	42	
Postmenstrual Age (weeks)				
Mean $\pm$ SD	34.46 $\pm$ 4.95	35.34 $\pm$ 4.55	32.21 $\pm$ 5.71	
Median (Range)	33 (23-54)	35.2 (25-43)	32 (23-43)	
No. (%)				
23-28 weeks	15 (7.1)	10 (9.3)	11 (26.2)	<0.001*†
29-34 weeks	108 (51.2)	28 (25.9)	16 (38.1)	<0.001**†
35-39 weeks	51 (24.2)	49 (45.4)	8 (19)	
>40 weeks	37 (17.5)	21 (19.4)	7 (16.7)	
Total	211	108	42	
Gender (%)				
Male	117 (55.5)	57 (52.8)	19 (45.2)	0.65*
Female	94 (44.5)	51 (47.2)	25 (54.8)	0.47**
Total	211	108	42	

Weight (grams)				
Median (Range)	1900 (506-4340)	2345 (800-5290)	1387 (420-4290)	
Mean $\pm$ SD	2102.22 $\pm$ 959.06	2305.35 $\pm$ 1010.31	1667.14 $\pm$ 1023.68	
No. (%)				0.76*
<1000 g	28 (13.3)	10 (9.3)	15(35.7)	0.01***†
1000-1499 g	39 (18.5)	21 (19.4)	8 (19)	
1500-2499 g	76 (36)	36 (33.3)	11 (26.2)	
2500-3499	43 (20.4)	25 (23.1)	5 (11.9)	
>3500 g	25 (11.8)	16 (14.8)	3 (7.1)	
Total	211	108	42	

*comparing StatLock and Tegabear dressing

** comparing StatLock, Tegabear dressing and Tegaderm/Tape

† statistically significant ($p < 0.05$)

Table S2. Peripheral Intravenous Catheter Characteristics

Characteristic	StatLock	Tegabear	Tegaderm/Tape	p-value
Insertion Site (%)				
Scalp	22 (10.4)	14 (13)	4 (9.5)	0.68*
Hand	105 (49.8)	45 (42)	17 (40.5)	0.68**
Foot	48 (22.7)	30 (28)	9 (21.4)	
Arm/Antecubital/wrist	16 (7.6)	9 (8.4)	6 (14.3)	
Leg/Ankle	20 (9.5)	9 (8.4)	6 (14.3)	
Total	211	107	42	
No. of insertion attempts (%)				0.12*
Median (Range)	1 (1-8)	1 (1-6)	1 (1-8)	0.27**
Mean $\pm$ SD	1.79 $\pm$ 1.16	1.61 $\pm$ 1.02	1.88 $\pm$ 1.50	
1 attempt	115 (54.5)	69 (63.9)	25 (59.5)	
>1 attempt	96 (45.5)	39 (36.1)	17 (40.5)	
Total	211	108	42	
No. of insertion attempts (%)				0.14*
1 attempt	115 (54.5)	69 (63.9)	25 (59.5)	0.31**
2-3 attempts	75 (35.5)	34 (31.5)	12 (28.6)	
4-8 attempts	21 (10)	5 (4.6)	5 (11.9)	
Total	211	108	42	
Arm board (%)				0.003* [†]
Yes	22 (10.5)	25 (23.8)	7 (17.1)	0.008** [†]
No	187 (89.5)	80 (76.2)	34 (82.9)	
Total	209	105	41	
TPN (%)				0.24*
Yes	112 (53.3)	50 (46.3)	18 (42.9)	0.30**
No	98 (46.7)	58 (53.7)	24 (57.1)	
Total	210	108	42	
Medications (%)				0.54*
Yes	130 (62.2)	71 (65.7)	26 (63.4)	0.83**
No	79 (37.8)	37 (34.3)	15 (36.6)	
Total	209	108	41	
Blood Products (%)				0.68*
Yes	39 (18.6)	18 (16.7)	12 (28.6)	0.24**
No	171 (81.4)	90 (83.3)	30 (71.4)	
Total	210	108	42	

Saline Locked (%)				0.68*
Yes	33 (15.8)	15 (14)	14 (34.1)	0.01**†
No	176 (84.2)	92 (86)	27(65.9)	
Total	209	107	41	
Complication (%)				0.78*
Yes	165 (78.9)	83 (77.6)	30 (75)	0.85**
No	44 (21.1)	24 (22.4)	10 (25)	
Total	209	107	40	
Reason for IV removal (%)				0.93*
Edematous	82 (50)	40 (48.8)	12 (40)	0.81**
Blocked	13 (7.9)	6 (7.3)	2 (6.7)	
Red	29 (17.1)	11 (13.4)	3 (10)	
Leaking	24 (14.6)	16 (19.5)	9 (30)	
Dislodged	15 (9.1)	8 (9.8)	4 (13.3)	
Burn	2 (1.2)	1 (1.2)	0	
Total	164	82	30	
Dwell time (hours)				0.63*^
Median	34.17	32.67	41.55	0.29**~
Minimum-Maximum	(0.5-183)	(1-190.92)	(0.17-124.25)	
Mean ± SD	39± 28.43	37.7 ± 28.57	45.38 ± 30.43	

* comparing StatLock and Tegabear dressing

** compared StatLock, Tegabear dressing and Tegaderm/Tape

† statistically significant ($p < 0.05$)

^Mann-Whitney U test

~Kruskal-Wallis test

Appendix V

SPSS Output for Mann-Whitney Test comparing PIV Dwell Time
based on Securement Method

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
time	315	38.5591	28.43687	.50	190.92
whatused	319	1.34	.474	1	2

Mann-Whitney Test**Ranks**

	whatused	N	Mean Rank	Sum of Ranks
time	Statlock	208	159.76	33229.50
	Tegabear	107	154.58	16540.50
	Total	315		

Test Statistics^a

	time
Mann-Whitney U	10762.500
Wilcoxon W	16540.500
Z	-.477
Asymp. Sig. (2-tailed)	.633

a. Grouping Variable: whatused

Appendix W

SPSS Output of Kaplan Meier Survival Analysis Comparing PIV Dwell Times

Case Processing Summary

whatused	Total N	N of Events	Censored	
			N	Percent
Statlock	208	165	43	20.7%
Tegabear	106	83	23	21.7%
Other	40	30	10	25.0%
Overall	354	278	76	21.5%

Means and Medians for Survival Time

whatused	Mean ^a				Median			
	Estimate	Std. Error	95% Confidence Interval		Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
Statlock	46.037	2.708	40.730	51.345	39.820	2.447	35.024	44.616
Tegabear	45.329	4.251	36.996	53.662	36.750	4.260	28.400	45.100
Other	55.004	5.524	44.177	65.832	50.000	5.945	38.347	61.653
Overall	46.912	2.128	42.741	51.083	40.670	1.713	37.313	44.027

a. Estimation is limited to the largest survival time if it is censored.

Overall Comparisons: StatLock vs Tegabear

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	.039	1	.843
Breslow (Generalized Wilcoxon)	.373	1	.541
Tarone-Ware	.254	1	.614

Test of equality of survival distributions for the different levels of whatused.

Overall Comparisons: StatLock, Tegabear, Transparent drsg/tape

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	2.487	2	.288
Breslow (Generalized Wilcoxon)	4.345	2	.114
Tarone-Ware	4.059	2	.131

Test of equality of survival distributions for the different levels of whatused.

Appendix X

SPSS Output for Chi-Square Test comparing Complication Rates based on Securement Method

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
complication * whatused	316	99.1%	3	0.9%	319	100.0%

complication * whatused Crosstabulation

			whatused		Total
			Statlock	Tegabear	
complication	Yes	Count	165	83	248
	No	Count	44	24	68
Total		Count	209	107	316

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.079 ^a	1	.778	.774	.442
Continuity Correction ^b	.019	1	.891		
Likelihood Ratio	.079	1	.779		
Fisher's Exact Test					
Linear-by-Linear Association	.079	1	.778		
N of Valid Cases	316				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 23.03.

b. Computed only for a 2x2 table