CHeRP IRB Additional Protocol Information:

In addition to the CHeRP SmartForms, all protocols must include the following sections. If a section is not applicable for the current protocol please indicate why this is the case. Please note that a complete protocol consists of the CHeRP forms and the information provided in this form.*

TITLE: A novel taping technique for improved intravenous (IV) catheter securement

VERSION: 7/21/2023

A. Specific Aims/Objectives

The primary outcome is to determine the taping method that provides the best securement of the catheter (has the maximum force resistance) and the taping method that can best withstand a simulated accelerated pull designed to mimic what may occur if a child rapidly pulls on the IV tubing or if a provider or family member may accidentally pull or trip on the tubing of a novel taping technique for intravenous (IV) securement. This novel technique will be compared to two common techniques (over-under and a technique utilized by nursing staff in Boston Children's Hospital's Emergency Department (BCH ED)).

B. Background and Significance

Up to 90% of all patients require an IV during their hospital visit, yet IV catheters have an unacceptable, 35% to 60% failure rate.[1-5] Dislodgement is an important contributing factor of IV failure, however, there has been minimal research to improve taping techniques. Currently, the two most commonly taught and used taping techniques are the over-under (Chevron) and horizontal.[6,7,8] Unfortunately, these methods have failed to provide adequate securement of the IV, leading to complications such as delayed treatments and extended hospitalizations.[1,2,5] In a prospective study done from June 2018 to March 2019 at Hadassah Medical Center, 40.9% of admitted children with peripheral IVs were observed to have complications and 34.6% of these complications, the largest percentage, were attributed to dislodgement.[5] A cross-sectional descriptive survey study collected information from clinicians about the occurrence of accidental dislodgement, frequency, and possible impact on activities, among other questions. Over 95% of respondents considered dislodgement to be a safety risk and 68% of respondents indicated that dislodgements occur often, daily or multiple times every day.[9] Moreover, a point of concern raised by patients is the pain associated with additional IV insertions. Minimizing this may enhance patient experience and overall patient satisfaction.

These indications call for urgent change. Not only does dislodgement of IV catheters carry clinical significance for patients, it leads to increased workloads for clinicians and additional medical costs to families.[1] We hypothesize that our novel taping can offer a more reliable technique for securing IV catheters, granting a reduction in both treatment interruptions and extended hospital stays.

C. Preliminary Studies

In 2017, Stace et al. compared the security of horizontal and over-under techniques by measuring the mean force to dislodge a catheter from staff volunteers.[6] Patel et al. had two related publications. The first examined the effectiveness of different combinations of tape types and taping methods by measuring the pullout force of an IV. One of the limitations of this study was the utilization of a PVC pipe to mimic the forearm instead of human subjects. The second publication was similar but reported on the force required to dislodge an IV with various tapes and skin preparations.[7,8] Found et al. compared different taping methods using locally available tapes to determine the dislodgement force required to detach IVs from a PVC pipe.[10] The latter three were published in 1994, 1995, and 2000, respectively, warranting updated research. Moreover, it should be noted that Patel's studies were completed in the United States, whereas Found's study was in Australia, highlighting this as a global concern.

Although the literature surrounding specific taping techniques are limited, several dressing studies have been published. Most recently, a study at the University of Freidburg Medical Center examined dislodgement forces and cost effectiveness of four different types of dressings, which showed the combination of sterile gauze and elastic polyester fleece to be most effective.[4] SAVE, a pragmatic, randomized controlled, superiority trial conducted at two institutions in Queensland, Australia, described no difference between the four different dressing types studied with a peripheral IV failure rate of 38-43%.[3] A limitation of these studies is the unmodified use of the horizontal and over-under techniques, which our novel taping plans to address.

Lastly, there have been retrospective reviews advocating for additional research to be pursued. Most notably, Helm et al. and Corley et al. stressed the opportunities that lie with persistent high rates of IV failures.[1,2] Jackson held an audit of peripheral venous catheter (PVC) restarts at one institution, during August-October 2010 v. August-October 2011. An internal review of 6500 peripheral catheters showed 36% of catheters failed due to dislodgement. Between the two years, the securement methodology was modified at the institution, leading to a reduction of dislodgement, leakage, and infiltration factors. The modification also led to a drastic increase (factor of 2.94) of catheters lasting at least 72 hours.[11] The call-to-actions coupled with a lack of innovation around taping methods signify a dire need of any solution, which this novel taping hopes to address.

D. Design and Methods

(1) Study Design

This is a prospective, single-blinded, randomized research study that will take place at Boston Children's Hospital (BCH).

(2) Patient Selection and Inclusion/Exclusion Criteria

Inclusion criteria: Staff from Boston Children's Hospital who have volunteered to participate.

Exclusion criteria: Individuals under the direct supervision of any study investigators, individuals with excessive hair in the AC on either arm (which may cause pain to the subject), individuals with fragile and/or non-intact skin in the AC region, individuals who have already participated (no re-enrollments), adhesive allergies, and individuals who decline to participate.

(3) Description of Study Treatments or Exposures/Predictors

A member of the study team will identify staff volunteers of varying age, race, and sex to participate in the study. Verbal consent will be obtained and a time and location to carry out study procedures will be confirmed. Subjects will have measurements captured with 3 different taping methods (BCH-ED, over-under, and novel) in 2 unique directions (retrograde and 90-degrees), totaling 6 measurements.

With the staff volunteer sitting in an up-right position with their elbow bent at a 90-degree angle, a research staff member will attach an IV catheter to the subject's anterior cubital (AC) fossa but will ***not*** puncture the skin. The IV catheter will only be taped superficially on the subject's skin to simulate IV placement. The taping method of choice (BCH ED, over-under, or novel)will be applied based on the randomized schedule. The randomization scheme will be provided by department biostatistician, Steven Staffa. A towel will be placed over the AC region, blinding the research team member who will be measuring the force to the taping technique (Fig. 1).

Fig. 1. IV Catheter placed on subject's AC with taping method/towel positioning.

Once covered, a second researcher will enter the room to assist with dislodgement procedures. Maximum force measurements will be collected using the Shimpo FGV-100XY

Digital Force Gauge, 100 lbs. The gauge comes with an attached hook as used in Stace et al. that can hook onto the IV (Fig. 2).[6]

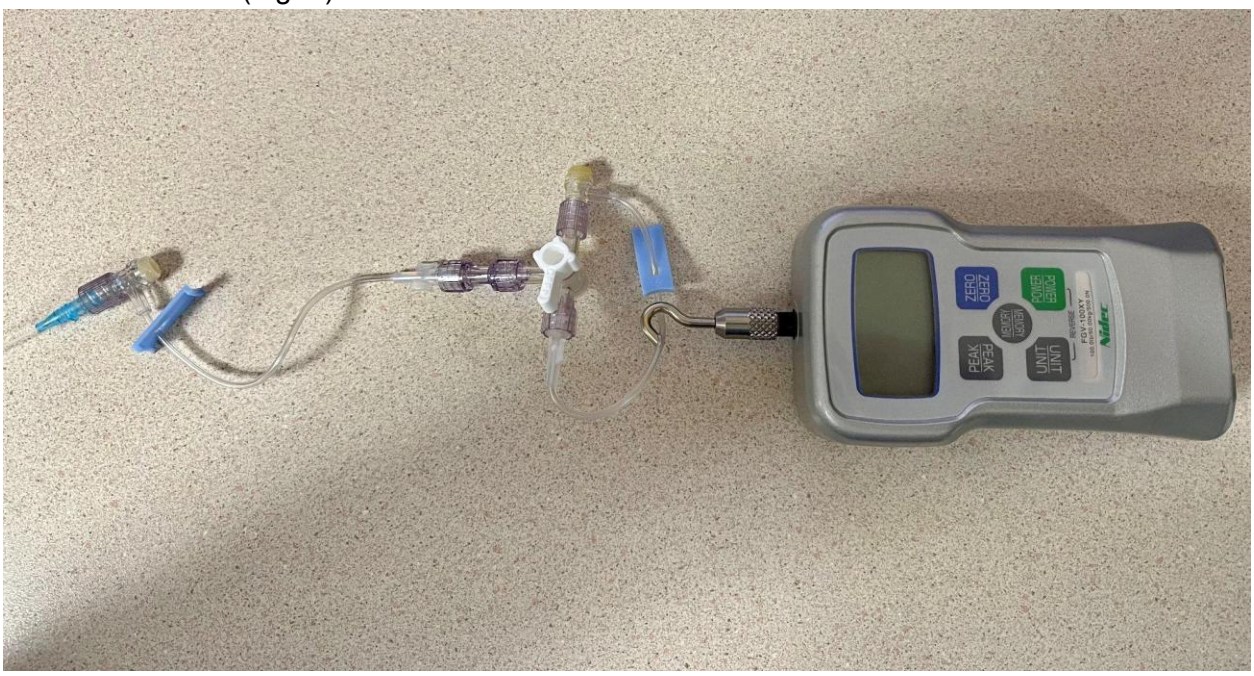

Fig. 2. Force transducer and IV catheter attached.

Once hooked, the second researcher will crank the handle until the force gauge measurement drops which signifies that the catheter has dislodged and/or the tape is removed from the (Fig. 3). These steps will be repeated using the remaining taping methods and directions.

Fig. 3. Force transducer and hand wheel test stand.

(4) Definition of Primary and Secondary Outcomes/Endpoints

Our primary outcome is to determine the taping method that provides the best securement of the catheter: i.e., has the maximum force resistance Moreover, it is to determine the taping method that can best withstand a simulated accelerated pull designed to mimic what may occur if a child rapidly pulls on the IV tubing or if a provider or family member may accidentally pull or trip on the tubing.

(5) Data Collection Methods, Assessments, Interventions and Schedule (what assessments performed, how often)

Data will be collected in real time, utilizing the Shimpo FGV-100XY Digital Force Gauge, 100 lbs. and recorded on a case report form (CRF). The Shimpo FGV-100XY Digital Force Gauge will provide a maximum force of each recording and be zeroed prior to new data collection. The maximum force measurement is frozen on the screen until zeroed again, preventing any data ambiguity or loss. Table 1 (below) shows how our data will be collected.

Subject ID:	Taping Methodology		
	Novel	BCH ED	Over-Under
Retrograde Force (N)			
AC region (right/left)			
90 Degrees Force (N)			
AC Region (right/left)			

Table 1. Example of CRF

(6) Study Timeline (as applicable)

We will recruit subjects over a period of 6 months. Although only 30 subjects are needed for data analysis, our target will be to recruit up to 40 subjects within the same period to account for any withdrawn.

E. Adverse Event Criteria and Reporting Procedures

We do not anticipate any adverse events as this is a minimal risk study, but any adverse events would be reported to the necessary groups per BCH and IRB guidelines.

F. Data Management Methods

Data collected from the Shimpo FGV-100XY Digital Force Gauge, 100 lbs. will be manually recorded in real time on a CRF and any electronic storage will be within the BCH

network. Study ID numbers will be assigned to each participant, and results will be de-identified. Only research members will have the ability to link the ID number with identifiable information.

G. Quality Control Method

A member of the research team will complete periodic audits to assure data accuracy and quality. Data will be verified by the investigator prior to analysis.

H. Data Analysis Plan

Calculations will be based on a two-tailed Student's t-test for an effect size of 1 standard deviation. Stata 13.2 will be used for data analysis (StataCorp, College Station, TX).

I. Statistical Power and Sample Considerations

Based on the work of Stace et al. and the assistance of Steven Staffa (Anesthesia Department Biostatician), power calculations yielded a total sample size of 30 participants to demonstrate a difference of 1 standard deviation with a power of 90%.[6] We plan to recruit 40 volunteer subjects to account for potential dropouts.

J. Study Organization

The principal investigator for this study will be Dr. Pete Kovatsis, an Attending Anesthesiologist at Boston Children's Hospital.

K. References

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** If you are an investigator submitting an IND or IDE, this document alone does not constitute and complete protocol. You must submit your full IND/IDE application as an attachment for this section.*