Title: The Pēpi Splint Project

Protocol
Version 2: Date 1 March 2020

Host Organisation (Sponsor)
Victoria University of Wellington

Funding
Funding has been secured from a Faculty of Health grant from Victoria University Wellington Ref 22337 which will fund the research nurse and support data collection.

The Universal Trial Number (UTN) is U1111-1249-0775

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The Steering Committee will take overall responsibility for all aspects of the study.

The site investigators will be responsible for the day to day management of the Pēpi Splint Project and reporting to the Steering Committee. They will be supported by the principal investigator and research nurse.

This study protocol follows the SPIRIT guidelines[1, 2]

Introduction

Project Summary
Iatrogenic skin injury in hospitalised babies is common. Most babies who are admitted to a Neonatal Intensive Care Unit require a peripheral intravenous catheter (PIVC) for fluids, medication and nutrition. PIVCs (drips) are placed inside a vein and are the most commonly

used device in unwell babies, with many babies requiring multiple drips. PIVCs are secured to the baby's limb using splints and adhesive dressings. Removing the adhesive dressing (Elastoplast) frequently tears the fragile neonatal skin, causing pain, increasing the risk of infection and possibly lasting skin damage. Following a traumatic event experienced by a baby, whānau and staff within the Neonatal Intensive Care Unit at Waikato Hospital. We sought to design a new splint. The Pēpi Splint is made from medical silicone. It secures the PIVC to the baby without the need for adhesive dressings to be applied to the baby's skin.

We propose a stepwise investigation. The first phase is a prospective intervention proof-of-concept pilot study to determine the effectiveness and acceptability of the Pēpi Split. We will recruit 30 Neonatal babies > 1000g who will require a PIVC as part of routine treatment in the Wellington Regional Hospital Neonatal Intensive Care Unit. Babies enrolled in the study will be cared for in the same way as those not in the study, with the addition of the Pēpi Splint. The study will run for as long as the Pēpi Splint remains in place. We estimate this period will vary between babies from 12 to 72 hours. Data will be collected from clinicians about the effectiveness and from the parents about the acceptability of the Pēpi Splint. These data will later be analysed by the Steering Committee.
If the Pēpi Splint is found to be effective and acceptable parents, we may proceed to a randomised controlled trial.

It is possible that the we will be able to considerably reduce the incidence of iatrogenic skin injuries in one of our most vulnerable populations, medically fragile babies.

Background and rationale

Skin injuries are the most common iatrogenic injuries in hospitalised babies[3, 4] which increases the risk of infection (local and systemic), and can lead to fluid and electrolyte imbalance and temperature instability. The skin injury can cause complications which prolong hospitalisation and can result in permanent scarring [5]. Peripheral intravenous catheters (PIVCs) are the most common device used in hospitalised, unwell and fragile babies, as intravenous therapy is fundamental to their care. Many babies require admission to hospital. There are approximately 60,000 births annually within New Zealand. Of these babies, 4,500 (8%) are born prematurely and 3,500 (6%) are born smaller than expected[6]. Most of these babies will be admitted to a Neonatal Intensive Care Unit and will require a PIVC for the administration of fluids, nutrition and medications.

PIVCs can be difficult to place and many babies require more than one during their hospitalisation [7]. However, data regarding the duration of PIVCs or the number required for any given baby are few[7] and none within New Zealand. The duration of PIVCs varies from < 12 to 72 hours. Predicting which babies will suffer skin injury has been found to be complex and multifactorial. Reducing harm to those requiring health care is a global health priority.

A key priority of the New Zealand Health Quality and Safety Commission is to reduce the incidence of skin damage in hospitalised patients. Primarily, the focus of this work is in adult patients[8]. Skin injuries in babies are more difficult to assess due the fragility and depth of the skin. Australian authors have recently proposed a skin injury assessment tool[9]. Generally skin injuries related to the use of a PIVC and splint are caused by removing plasters attached to the skin, causing epidermal stripping. Pressure areas can also be caused from the Elastoplast tapes. Extravasation injury occurs when the PIVC migrates from the vein into the tissues, this is a common injury related to the fragility of neonatal veins and the solutions infused via the PIVC, and while it can be, is not generally related to the splint and securing. It is essential that the PIVC insertion site is visible to the bedside nurse

in order to assess for any redness or swelling[10], as a key priority for the bedside nurse is to reduce the risk of iatrogenic injury.

It is recommended that the PIVC is secured with a splint or board on the limb in order to adequately immobilise the joint and reduce the risk of venous damage resulting from flexion of the joint. Within both New Zealand and Australia, the majority of PIVCs are secured to the limb of the baby using a splint and Elastoplast. In clinical practice, despite careful removal of the Elastoplast, the skin of the baby is frequently damaged. Data about these injuries are not routinely collected, despite attempts to do so. However, more serious events are reviewed. In late 2015 the tip of a finger was accidently amputated during the removal of an Elastoplast adhesive dressings from an Argyle IV Support Board™ on the left hand of a baby in the Neonatal Intensive Care Unit at Waikato Hospital[11] and similar injuries in other centres have been documented[12].

Following the Serious Events Review and Report to the Health and Disability Commissioner, an unsuccessful search for an alternative product was conducted. The opportunity to design an alternative splint was proposed. This led to a collaboration between Dr Deborah Harris (Neonatal Nurse Practitioner) and Mr Mike Williams (Mike Williams Design Limited), both from the Waikato, to investigate whether an improved splint which did not require application of Elastoplast adhesive dressing to the baby's skin but successfully secured PIVCs, could be developed. This resulted in the development of the Pēpi Splint (PCT/NZ2019/0050052).

The Pēpi Splint is made from PlatSil® Silicone Gel and aluminium, a very light and flexible metal which is non-magnetic. PlatSil® Silicone Gel is a product commonly used in prosthetics, and to treat cleft lip scarring in babies[13]. We are unable to find any evidence of harm caused to babies due to the use of silicone gel. Elastoplast can easily be applied to the Silicone gel and therefore no adhesive tapes are required on the baby's skin. The Pēpi Splint is ambidextrous can be used on both arms and legs and weighs only 45 grams. Therefore, a baby requiring the splint is able to spontaneously move the affected limb. In addition, the Pēpi Splint is both durable and could be washed and sterilised if required. https://www.youtube.com/watch?v=wjcbvEVVUSU&t=96s

We are now planning a stepwise approach for this project. We will seek to determine the effectiveness and acceptability of the Pēpi Splint within the Neonatal Intensive Care Unit.

Should the Pēpi Splint be found to be effective and acceptable we may proceed to either an equivalence or superiority randomised controlled trial comparing the Pēpi Splint with the currently used splint and identify important barriers to changing practice.

Research outcome
To determine if the Pēpi Splint is effective and acceptable in the clinical environment so that a randomised controlled clinical trial may be performed

Specific aims for Proof of Concept phase

To determine if the Pēpi Splint is effective and acceptable to parents:
supports the intravenous catheter and does not cause any skin redness or damage
Is acceptable to parents

Trial design

Proof of Concept, prospective intervention study

PICOT

Participants	Neonates ≥30 weeks' gestational age, > 1000 g and admitted to the Neonatal Intensive Care Unit whom require an intravenous catheter.
Intervention	Application of the Pēpi Splint.
Control	Not required.
Primary outcome	The Pēpi Splint is effective and does not cause harm as measured by the bedside clinician
Planned sample size	30 babies
Timing of assessment	Assessment for the primary outcome will be for the duration that the Pēpi Splint remains on the baby.

Methods: Participants, Interventions

Study setting Neonatal Intensive Care Unit at Wellington Regional Hospital

Inclusion criteria

- Babies requiring the placement of a PIVC

Exclusion criteria

- Current Weight ≤ 1000 grams
- Gestational age < 30 completed weeks' gestation
- Any skin condition preventing the attachment of the Pēpi Splint
- Major congenital abnormalities
- Terminal conditions

Interventions

Education

Clinical staff will be provided with education about the application of the Pēpi Splint

After written informed consent is obtained and an eligible baby requires an intravenous infusion, a clinician will select and apply the appropriately sized Pēpi Splint. There will be two sizes available, for babies weighing ≤ 2,500 or > 2,500g. When an enrolled baby requires a PIVC the clinical staff will select the appropriate Pēpi Splint for the size of the baby and apply to the baby. The duration of the study will be from the time that Pēpi Splint is applied until removal of the splint and the exit photos are taken.

Study Assessments
Bedside nurses currently assess the skin and limbs of babies and in particular the areas of skin where such as PIVCs are in place. In order to minimise increased workload these routine clinical observations and recordings will be used to assess the skin for the duration of the study period [14]

Detailed data about the Splint will also be collected
A data collection sheet will be completed by a clinician which includes:

- Participant demographic date
- Length of time that the splint was in place
- Whether the Pēpi Splint supported the peripheral intravenous catheter
- Ease of application and removal
- Any concerns regarding the splint
- Perceived comfort level for each participant by both staff and parents
- There will be space for comments
- Photos will be taken with the Pēpi Splint *in situ*[9]

Parental questionnaire
Parents will be asked to complete a simple questionnaire about what they liked and disliked about the Pēpi Splint.
Questionnaires will be later electronically entered into a database.

Images
Standardised photos will be taken on a camera of the Pēpi Splint following application and after removal of the splint. All images will include a white tape measure which will allow for colour correction and measurement of any injury. All images will be deidentified and identified only by the participants study number and stored electronically by Dr Deborah Harris [9].

Outcomes

Primary Outcome
The proportion of babies in which the Pēpi Splint was determined by the bedside nurse to have supported the secured the PIVC for the required time. The proportion of babies who experience an adverse event related to the Pēpi Splint.

Secondary outcomes
The acceptability of the Pēpi Splint as reported in the parents' response in the questionnaire
The parents experience of participating in the Pēpi Splint project as reported in the questionnaire

Participant timeline

	Enrolment	
TIMEPOINT	$-t_1$	***Data collection***
ENROLMENT:		
Eligibility screen	X	
Informed consent	X	
Recruitment		
Baseline data	X	
Demographics and contacts	X	
INTERVENTIONS:		
Pēpi Splint applied		X
Pēpi Splint removed		X
ASSESSMENTS:		
Data collection completed		X
Photos taken		X
Parent questionnaire		X

Sample size

The primary reason for this Proof of Concept phase is to determine if the Pēpi Splint will support the PIVC and any adverse events related to the use of Pēpi Splint.

We do not expect any adverse events. We have determined that using a sample size of 30 where no adverse events have been observed, we can be assured that the 95% upper band on the rate of adverse events will be less than 10% (3/30 = 0.1). This will provide enough evidence to justify the progression to a randomised controlled trial[4].

Recruitment

Recruitment will be face to face and babies will be enrolled following admission to the Neonatal Intensive Care Unit. It is likely that most babies will have previously had an PIVC for treatment or fluids. The study will be advertised on posters within the Neonatal Intensive Care Unit and parent information sheets will be available. Research staff and clinicians from the Neonatal Intensive Care Unit will be able to recruit a whānau into the study, most commonly this will be the bedside nurse.

Engagement and Responsiveness with Māori

This protocol was developed in consultation with Ms Tamara Miles, whose third child was born prematurely, and required PIVCs during her hospitalisation. Ms Miles identifies as Māori (Raukawa, Ngāpuhi) and is a Steering Group Member. Ms Miles will assist with ongoing Māori engagement, and ensure that study processes are culturally appropriate. Additionally, Ms Miles will continue to provide cultural support to the research team.

Ms Miles (Raukawa, Ngāpuhi) and Mrs Leanne Colmer (Tarawhiti) who is the Social Worker within the Neonatal Intensive Care Unit at Waikato Hospital, developed both the name and logo for the project. The Pēpi Splint project has been reviewed by the Manager of Māori Health at Waikato District Health Board and received support.

At Wellington Regional Hospital the Whānau Care Services Manager Cheryl Goodyer (Manager – Capability Māori Health Development Group, Chairperson of the Research Advisory Group Māori) has reviewed the project and was supportive. In addition, a formal application for the Pēpi Splint Project has been made to RAG-M.

We require 30 babies to participate. Within Wellington Regional Hospital 20% of the admitted babies are identified as being of Māori ethnicity. We hope to be able to recruit at least 6 Māori babies. Due to the small numbers of babies required for this initial phase of the project we will be unable to determine any similarities between Māori and non-Māori babies.

Data collection, Management and Analysis

Data will be collected into Case Report Forms (CRFs) which will be held at the bedside during the study period.

Retention

If a participant withdraws from the study, consent will be sought to use the data collected up to the point of withdrawal.

Data management

Data will be checked for logic errors by the research nurse. All data will be independently electronically entered by two investigators and later compared for agreement. Variations between data entries will be compared and discussed.

Statistical methods

Statistical analysis will be performed with JMP v14 and R v 3.61.

Descriptive Analyses

Categorical data will be presented as number and percent and continuous data will be presented as mean, standard deviation or median and inter-quartile range, as appropriate. Count data will be presented as median and inter quartile range. Denominators will be given for all outcomes

Primary Analyses

For the splint to be considered for use in clinical care we need to know if it will hold the intravenous catheter in place and whether skin damage or irritation occurs.
Two exact 95% confidence intervals will be calculated, one for the proportion of babies in which the Pēpi Splint was judged by the clinical team to have supported the PIVC, and one for the proportion of babies who experience an adverse event. Secondary outcomes will be to determine the acceptability of the Pēpi Splint to both parents and clinical staff.

Monitoring

Safety Monitoring.
A Safety Monitoring (harms) procedure has been established. The Safety Monitor will advise the Steering Committee. A Data Monitoring Committee (DMC) has not been established for the Proof of Concept study. However, if we proceed to a randomised controlled trial a DMC will be established.

Harms
An adverse event will be skin damage attributed to the use of the Pēpi Splint by the senior clinician within the Neonatal Intensive Care Unit. If skin damage is considered to be caused by the Pēpi Splint (skin irritation or injury or pressure areas) the splint will be removed, and appropriate clinical care will be provided by the clinical team. Standardised photos[9] will be taken of any injury and forwarded along with the report for review by the Safety Committee within 24 hours. The Safety Committee will review and report back to the Steering Committee.
Extravasation/infiltration injury occurs when the PIVC migrates from the vein into tissues. This is a common injury caused largely by the fragility of the babies' veins and necessary medications and fluids. We will collect the number of babies who have extravasation injuries. However, as these injuries are common in the NICU this injury will not be an endpoint. If we proceed to a randomised controlled trial, we could include extravasation/infiltration injury as a secondary outcome.

Ethics and Dissemination

Research ethics approval
National ethics approval will be obtained from the Health and Disability Ethics Committee (HDEC) prior to commencement.

Locality Approval
Institutional approval will be obtained from Capital and Coast District Health Board (CCDHB) prior to commencement at that site.

Protocol Amendments
All amendments to the final version of this protocol will require review and approval of the Steering Committee, and will be submitted to HDEC and DHB Research Offices, as appropriate. All amendments, including approval date, will be recorded with this protocol.

Consent
All parents identified will be given a parent information sheet, followed by a discussion with a member of the clinical team. Written informed consent will be sought. A copy of the consent form will be kept with the baby's notes and a copy given to the parents. Babies will be enrolled in the study following informed consent prior to the peripheral intravenous catheter being placed.

Withdrawal from the Study
Parents will be able to discontinue participation in the study at any time. If parents do choose to withdraw, we will seek permission to include all data collected in analysis. If parents do not want their data to be included in the analysis, all data will be returned to the whānau.

Enrolment
It is expected that babies will be enrolled following admission to the Neonatal Intensive Care Unit. It is likely that most babies will have previously had an PIVC for treatment or fluids. A clinician (nurse or doctor) who has attended education sessions about the Pēpi Splint Project will be able to enrol a baby (whānau) into the study.

Confidentiality
Healthcare professionals involved in the care of babies in the Neonatal Intensive Care unit will identify eligible families. All data collected including NHI number, entry criteria met, and the signed consent form will be held by the principal investigator in a locked office and on a password protected computer. All data collected about families whose babies are not ultimately recruited to the study will be destroyed, although signed consent forms will be retained.

Access to health information collected during the study will be limited to recruitment staff. A secure database will hold any identifiable data separately from the trial data and access to this will be limited to the investigators. Only a study number will identify all study data.

All participant research data and study records will be retained and stored for 10 years after the child has turned 16 years old.

At the completion of the study, all electronic data will be permanently digitally archived within the Victoria University of Wellington for archiving and data sharing according to international best practice.

Declaration of Interests
Investigators will declare any financial, intellectual or other potential conflicts of interest, as outlined by the International Committee of Medical Journal Editors (ICMJE), to the Steering Committee[15]. The Steering Committee will decide on how any conflicts of interest are to be managed.

Access to Data
The Steering Committee will have access to the full de-identified dataset and oversee analysis, interpretation and reporting of results. Approval will be sought from the Steering Committee prior to publication of study data. Care will be taken to avoid duplication in reporting of results.

Dissemination Policy
Results of the study will be presented at relevant conferences and published in a peer-reviewed scientific journal.

Authorship policy
The Council of Science Editors standards for authorship will be applied. The Steering Committee will be responsible for planning manuscripts and resolving authorship disputes. Investigators and study personnel who do meet the criteria for authorship will be acknowledged as non-author contributors.

Study Management

Steering Committee
The Steering Committee will take overall responsibility for all aspects of the study, meetings will be held monthly or more frequently if required. Matters arising between meetings may be dealt with by email. The Principal Investigator will be responsible for maintaining a record of correspondence and minutes of meetings.

Site Investigators
The Site Investigators who will have overall responsibility for satisfying local governance requirements, recruitment, assessments, data collection and integrity. They will be supported by the principal investigator and research nurse.

Finance and Insurance
This is a non-commercial study, participants in New Zealand will be covered by provisions of Accident Compensation Commission .

Significance

If the Proof-of-Concept trial shows that the Pēpi Splint is effective and acceptable to both clinical staff and parents, then we will have data to proceed to a randomised controlled trial. The Pēpi Splint has the potential to reduce the incidence of iatrogenic skin injuries in babies compared to current standard practice, thus decreasing harm, reducing pain and improving the outcomes for hospitalised babies and their whanau.

Timeline

2017	Completion of the development phase Report back to the senior clinical team
	Report to Health and Disability Commissioner about the development of the Pēpi Splint
10 May 2018	Patency gained Pēpi Splint (PCT/NZ2019/0050052).
December 2018	Waikato Māori Consultation and Protocol Development
July 2019	Proof-of-concept project development
	Consultation with Senior NICU Clinical Team at Waikato Hospital – Approval to proceed gained.
July 2019	Establishment of the Safety Officer (Committee)
September 2019	Health and Disability Ethics Committee application
	Pēpi Splint Available
December 2019	Health and Disability Ethics Committee - Declined
March 2020	Reapplication to the Health and Disability Ethics Committee
March 2020	Reapplication to the Regional Research Advisory Group Māori (RAG-M) and Child Health Committee
May 2020	Recruitment commence
October 2020	Review of Findings and Report to the Clinical team
November 2020	Dissemination of findings to families and the Perinatal community

Budget justification

We estimate that we will need a Research Assistant/Nurse for 4 hours/baby.
We require a Grade 2 Neonatal nurse grade[16]
Key tasks for the Research Nurse include

- Recruitment of families to the study
  Data collection and ensuring that all data collection sheets are completed and entered electronically.
- Administration - Organising meetings and taking minutes for the Steering Group Committee
- Assisting with education to the Neonatal Intensive Care Unit Staff about the project.

Research Assistant/Nurse to work 4 hours/baby, s/he is paid $39.95/hour = (4 hours @ $39.95) x 30 = $4.794.00

All Pēpi Splints will be provided by Mike Williams Design Limited.
The camera has been provided by the Faculty of Health for the duration of the data collection period.

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