Heriot-Watt University School of Textiles and Design

Evaluating standardized pressure for garments used in scar management

Pressure for Burns Scar Therapy

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MSc Research (textiles)

Abstract

Pressure garments are used to treat scars after major trauma such as burns to suppress the over development of scars. Pressure garments can alleviate the patients discomfort caused by the appearance of the developing scar tissue as well as pain and itching that can be experienced. Some hospitals have in house teams making bespoke pressure garments for patients. The current method used in UK hospitals applies a reduction factor of between 10 and 20% to produce garments. There is little evidence of the pressure delivered by in-house or any pressure garments as pressure sensor equipment is often not available, time consuming and difficult to use and therefore pressure is not measured in clinics at garment fitting. An audit of pressures delivered by 8 previously made pressure garments was conducted. The fabric that had been used to make those garments was tested and a Pressure Garment Design (PGD) Tool was made based on the equations generated from this test data. The historical patient and garment dimensions were entered to the PGD tool. The audit showed that the reduction factor of 20% had exerted between 15mmHg and 54mmHg on these patient's limbs.

A pilot study was then undertaken to compare the standard 20% reduction factor method to the 'Laplace Law' method of calculating pressure garment dimensions using a PGD tool. 4 participants were enrolled in the study. Three garments were produced for each participant to trial, one using the reduction method currently used and two that were designed to exert known pressures of 15mmHg and 25mmHg. The garments were worn and washed in rotation for approximately 8 weeks. As is standard practise in clinic, all garments were assessed by the therapist to ensure they were suitable for use by the Participant and the scars assessed for maturation. Prior to issuing the garments and during the study the pressure delivered by the garments was measured using a PICOPRESS pressure monitor.

The manual method of calculating garment dimensions using a calculator is time consuming and less accurate than The Pressure Garment Design tool, which proved easy to use, and versatile for the quick adjustment of measurement and pressure values for producing finished garment dimensions. The measuring process and resulting data highlighted problems with measuring pressure on such small limbs. The pressure delivered using all garments varied on the individual due to variations in soft tissue and bony areas and an ability to only measure pressure on flatter body parts of the smallest

limbs, which indicates that pressure readings taken on the individual may not be a true indication of the average pressure delivered.

The data collected from the Pressure Garment design tool, predicted pressures and the pressure readings on the cylinder, confirmed that the Pressure Garment Design Tool can be used to produce garments capable of delivering a known pressure, and that the reduction factor method delivers a varied pressure in an individual garment on different limb circumferences ranging from 52mmHg on a 17.2cm circumference to 15mmHg on a 37.2cm circumference.

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I would like to thank my friends and colleagues at Sheffield Children's Hospital who helped and supported me in completing this project and Lisa Macintyre for her invaluable drive and enthusiasm.

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Chapter 1: Background and aims

Sheffield Children's Hospital's burns and plastics service supplies bespoke pressure garments for patients, made by an in-house team. Across the U.K. there are enough teams supplying bespoke pressure garments made in-house to support a Pressure Therapy Interest group. The teams of technicians meet once a year and support each other through a social media site to discuss design developments for pressure garments. A main part of these meetings is given to discussing new developments in treatments and how we can adapt and enhance our skills to maintain an outstanding service. At several meetings the delivery of pressure has been discussed, and through the work of Lisa Macintyre at Heriot-Watt University the group has become aware of the possibility of applying new techniques to pressure garment design. The specialist service provided by technicians in-house has a very low profile and its role in providing excellence in pressure therapy is not completely understood even by those professionals aware of it.

Sheffield Children's Hospital, burns and plastics department specialises in treating burns trauma for the under 16's. The technicians who make the garments are based on a different site and rarely see the patients. This makes the success of garment fit an outstanding achievement and therefore relies heavily on excellent communication skills and expertise by all the team. The experience of the therapist is essential to assess the best and safest pressure delivery to the individual. This comes through practice and cannot be mastered easily. This situation also makes changes in practice very challenging as the therapists have been applying a manual method of reducing measurements referred to as the Reduction Factor, producing garments with effectiveness. The garment dimensions are calculated by reducing the patient measurements by a standard reduction factor or percentage of the body measurement, a 20% reduction factor is applied at the Sheffield Children's Hospital. There are however challenging fitting situations that require a lot of adjustments to garments once they are made and garments that just need to be 'tweaked'. Further, literature reports that using a standard reduction factor on all garments results in different pressures being exerted on different sized patients.

The success or not of the pressure therapy using in-house garments can only be supported by observational information. There is no data on the actual pressures delivered to patients using in-house garments, and therefore no knowledge of the pressures that are effective for different levels of burns. It is difficult to collect pressure readings as the practice requires time and precision which is difficult with younger patients. When training new staff to understand the best fit for pressure therapy the reasoning is subjective and therefore leads to a variety of fitting techniques within a team due to differences in therapist's ability. Therapists gain experience through the touch and the feel of the garments and not through the knowledge of the pressure being delivered. The evidence of healing or not is the only guide as to understanding which 'fit' worked, which is not easy to explain. To support the future use of pressure garment therapy the International Society for Burn Injury (ISBI) have highlighted how important it is to collect information regarding pressure delivery [1].

With the development of new technology such as 3D scanning and University supported research projects being promoted as the way forward, management of large institutions become enthusiastic about updating services and promoting special skills and services that require expensive and ground-breaking technology. Some special areas of treatment, such as pressure therapy would benefit from an update in the understanding of the interaction between the body, fabric performance and garment design techniques and how to apply it to deliver the best care possible. As measuring pressure during garment fitting is not easy to do as standard practice it would be beneficial to produce garments with a known pressure using an easy to apply computer-based programme.

Pressure garments are used to treat scars after major trauma such as burns and should be worn for 23.5 hours to deliver effective therapy. To wear pressure garments for such a long time presents challenges of patient compliance especially if the fit is not good. These garments are made using body measurements taken in clinic and manually applying a reduction factor to create tight fitting garments from fabrics containing elastane. The reduction factor is used to apply pressure, if a standard reduction factor is used then the pressure will vary depending on the size of the limb and the fabric used [2]. Producing garments manually using a standard reduction factor means there is no evidence of the pressure being delivered [3]. Pressure sensor equipment is difficult to use in clinic and

because of this very little work has been done in collecting data regarding actual pressure delivery [4]. The normal manual method of design for garments does not consider the impact that limb size or fabric tension has on pressure being delivered.

Being trained in technical garment making and having worked at Sheffield Children's Hospital for just under 10 years the opportunity arose for me to conduct a research project, as a part-time Masters (MSc) by research student, using the Pressure Garment Design tool. The burns therapists welcomed the prospect of studying pressure delivery more closely and understanding the how the Pressure Garment Design tool could be used in our normal working environment. The main targets of the research were to establish the range of pressures that had been delivered by garments made in our department recently by conducting a small audit, and to evaluate how easy the PGD tool was to use for real patients in a hospital environment using a pilot study.

The Pressure Garment Design tool was introduced in 2013 but has never tested by therapists in a clinical environment. Applying it to clinical practice would test out the application of the Pressure Garment Design tool, in a practical setting to assess its ease of use and accuracy in predicting garment size and pressure delivery. The application of the Pressure Garment Design tool in clinical practice may help to provide information regarding pressure guidelines for the treatment of scars without the need to measure pressure directly, which has proved to be a challenge and is not currently standard practice. There was a unique opportunity to apply garment making experience and pressure garment knowledge to an understanding of the complications of pressure monitoring in a burns service. The burns service at Sheffield Children's Hospital provided facilities that were ideal for the study, so a proposal was submitted to the research department for approval.

Aim

To compare garments produced using the Garment design tool and the manual method to establish the most effective delivery of 'ideal' pressure and fit for burns therapy.

Objectives

1. To build a pressure garment design tool for the sleek knit fabric used at Sheffield Children's Hospital.
2. To establish the pressure used historically at Sheffield Children's Hospital for pressure garment therapy.
3. To establish how easy, it is to use the PGD tool in a hospital environment and compare this to the traditional, manual, method of calculating pressure garment dimensions.
4. To compare the pressures exerted by garments made using reduction factor and Laplace Law using the pressure garment design tool method for production of final pattern.
5. To establish whether the consideration of fabric stretch and patient dimensions using the Laplace Law offers a more effective therapy garment.

Chapter 2: Literature review

2.1 Overview of scar trauma and the need for pressure

Pressure therapy is used to treat scar tissue caused by a burn accident or related surgery. If left unchecked deep scar tissue damage can become raised and extremely taut causing unsightly and uncomfortable contractures, raised and lumpy areas, which may require surgery later. Skin damaged areas are treated to prevent the development of hypertrophic (over nourished) and or keloid (hard) scars. The application of pressure for a prolonged period has been found to control collagen synthesis by reducing the vascular and nutrient perfusion in the scar which causes the problems [1,2,3,5,6]. The findings of several studies highlight that no one method delivers the ideal outcomes when treating burns and that it is the combination and the expertise of the therapists that provide good scar management [1,7,8,9]. Despite there being no consensus regarding ideal pressures and effectiveness for scar outcomes, it is recommended that pressure be applied using silicone gel, silicone gel sheeting or pressure garments, or a combination of these methods [1,9]. Although it is hard to define the benefits of pressure garment therapy, it is accepted as the best method to control hypertrophic scars and other trauma sites. It is recognised that to deny this treatment would be unethical [1,7,9].

2.1.1 *Current methods of delivering pressure therapy*

Pressure garments have been used since the early 1970s and are widely used as the main treatment after burns trauma [1,3,4,5,6,7,8,9]. There are various other methods used to treat scars with new developments available including silicone gel and gel sheeting which can be used alone or in conjunction with pressure garments. There is general acceptance of the use of pressure garments for the control of scar healing although studies do not provide a definitive reason for their effectiveness [1,7,8]. In an overview of research related to pressure garment therapy Anzarut et al (2009) and Ai et al (2017) point out that research has a lack of data evidence related to pressure levels, to support their effectiveness [5,8]. The evidence to support the effective use of pressure therapy is mainly observer based and reliant on therapists visual and touch assessment of healing [1,7,8].

The review of randomised control trials by Ai et al (2017) screened databases to give a better overview of information, which they found to support positive outcomes for pressure therapy between 15-25mmHg used to treat scars [8].

From the late 1980's there has been concern regarding the adverse effects of applying pressure and causing skeletal deformity, especially in children where growth can be affected as pressure is applied over a prolonged period [3]. The ISBI practice guidelines for burns care (2016) does state that contractures may occur at flexion surfaces over joints and that exercises, and splinting are advised to prevent deformities [1]. Ai (2017) could find no evidence to indicate it is a major issue in present day treatment although regularly mentioned in studies which may be due to historical information being cited and not recent studies or that the problems were related to areas such as the head, which requires much lower pressures or different methods to protect the jaw and teeth [8].

Pressure garment manufacture has seen some developments in commercial designs available since being introduced in 1970. There are some different fabrics available with the development of elastane-based products that enhance the stretch and tensile strength of a fabric although sleeknit cotton Lycra and powernet are the most widely used for in-house garments [3]. The research reviewed indicates there are a variety of pressure levels being used for scar therapy ranging from 9mmHg to 52mmHg in commercial products and in-house garments [3,4,10]. This wide range of pressures is seen in the reduction factor method that reduces the garment size by the same amount regardless of limb size and fabric tension. This means that a larger garment, made for a larger body delivers less pressure than a garment made for a small body. This is because the fabric tension is the same in both garments but when spread over a larger body it exerts less pressure.

2.2 Types of garments

Pressure garments are available from commercial manufacturers who provide a range of garments in standard sizes. These will usually require adjustment as fit is rarely perfect due to the individual's measurements not being used and the garments need to be very close fitting to achieve pressure for therapy. However, some manufacturers and in-house garments use the patient's measurements to produce bespoke garments that give a more accurate fit for pressure delivery.

Garments are produced commercially or in-house using warp or weft knitted fabrics which have an elastic component that exerts pressure on the body due to the reduction in

garment size compared to the body it is to fit [2]. There are also manufacturers that supply fully fashioned weft knitted garments that are knitted using the patient measurements to produce panels to the required size to apply pressure, these are then sewn together.

2.2.1 *Methods of manufacture*

The availability of a range of sewing and knitting machines influences the construction methods used in commercial and in-house garments. The way the garment is sewn together, and the type of seams and stitching used has an impact on the fit and pressure exerted. Fig. 1 is an example of a commercial glove [11].

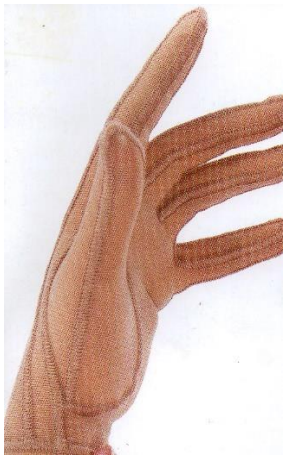


Figure 1. Commercial glove showing seam structure [11]

Some of the more expensive commercial garments use construction techniques that involve the use of layered panels or fabric panel combinations giving variations in pressure delivery specifically designed for the individual. Commercial garments are constructed using industrial sewing machines that use multiple threads to create a flat locked seam and overlock machines that stitch together and finish seams in one action. The garments may have complex panels to achieve a more tailored and fashionable look. These garments are aesthetically appealing, especially when supplied in an array of colour combinations but they are not as quickly produced as in-house garments. For adults who can purchase garments independently they are much more attractive and probably more likely to be worn. These garments are not an option for many as the available funding does not cover their cost, or the turn-around is not quick enough for the urgency of therapy needs. If the garments do need alterations there may be a delay in pressure therapy being delivered whilst the alterations are made.

Figure 2. Examples of garments made in-house (SCH)

In-house garments are usually constructed using very small zig-zag stitch to create small external seams on a domestic sewing machine, some examples can be seen in Fig.2. These seams have a raised edge on the outside of the garment but smooth on the inside. The garment pieces are kept as simple as possible which enables quick and easy adjustments to be made without the need for completely new garments. In-house garments generally require fewer alterations at first fit as they are produced soon after measurements are taken and made up by the team involved in patient assessment [3]. The fabric choice for these garments is quite restrictive and may perhaps lead to non-compliance of wear due the lack of aesthetic appeal. In-house garments are made by technicians within the hospital and can therefore be made up very quickly and alterations quickly carried out. Additional garments can be quickly made at regular intervals giving better consistency in garment performance. This is an advantage as the fabric tension deteriorates during wash and wear for all pressure garments.

2.3 Delivering pressure

As the provision of pressure garments involves more than one therapist during assessment and fitting of the garment the scope of variables is big. Each process will be influenced by the experience and knowledge of the professional involved and this may not be the same person during any repeated processes. Commercial and in-house made pressure garments are not tested for the applied pressure during fitting, it is therefore the expertise of the therapist that influences suitable fit, using a ‘pinch test’ to gauge how easy it is to use pull the fabric away from the body using two fingers or just the touch and feel of the garment on the area to be treated [2,3]. Some commercial garments are made using a

computerised design system that delivers a specified pressure, but again this is not assessed in normal clinical practise and can therefore not be confirmed as being accurate at fitting [2,3]. The fitting can be a very subjective process as there is no stated ideal pressure and the person fitting the garments may not be consistent in their assessment technique or experience. The therapist must develop a clear understanding of the outcomes of good and bad scar management and be able to understand how to change the item being used as required. Most alterations are minute as the decrease or increase, if too much, can slow down healing or cause scar breakdown. The reliance on the therapist to understand the concept of effective pressure delivery without knowing the pressure delivered by garment they are fitting leaves plenty of scope for inconsistency. Macintyre and Baird looked at the construction techniques used for in-house garments and concluded that there was a lack of consistency in the approach to pressure delivery and manufacture, not only at each hospital but within the same team [2].

2.3.1 *Calculating pressure to be delivered*

Initially the notion of reducing the size of the garment to introduce pressure seems logical, but by how much? There are different thoughts about the most useful pressures to be applied ranging from 10mmHg to 25mmHg. Different methods are used to reduce the patient's measurements so that the garments produced deliver pressure. [1,3,5,8,10].

2.3.2 *Reduction factor*

Garments made in-house by technicians apply the reduction method to produce the garments that are smaller than the body they are to fit [3]. The therapist or the technician takes the patient's measurements at regular intervals over the section requiring pressure and marks them on a measurement chart. A reduction factor of between 10-20% is manually applied to calculate the smaller dimensions required for the patterns to produce garments that will apply pressure. The reduced measurements are then used to produce the pattern for the individual. This pattern is used for all garments made until a review of fit is done. The reduction factor method has been used in-house and by some smaller companies since the 1970's and it is a trusted method. But the reduction factor used varies between hospitals and between the people in the teams measuring for the garments as there are no guide lines for the use of the reduction factor in practice[2]. The reduction factor method does not deliver a consistent pressure overall and the actual pressure being

delivered when the garment is issued is not known. Macintyre and Baird (2005, 2006) investigated the methods used to produce garments in the NHS and outline the inconsistency found in the reduction factor used, the skills base for making up the garments and the assessments used to review the garment fit. The variation in the methods of applying the reduction factor and the differences in expectations of the therapy delivered would indicate that there is a definite need for a more suitable method of calculating pressure for therapy [2,3].

2.3.3 *Laplace's Law*

Some commercial manufacturers provide a made to measure service which enables garments to be made using the patient's measurements. The measurements are taken by the therapist at regular intervals, using specific measuring techniques as outlined on measurement charts provided by the manufacturer. See Fig. 3 for an example of measuring techniques [11].

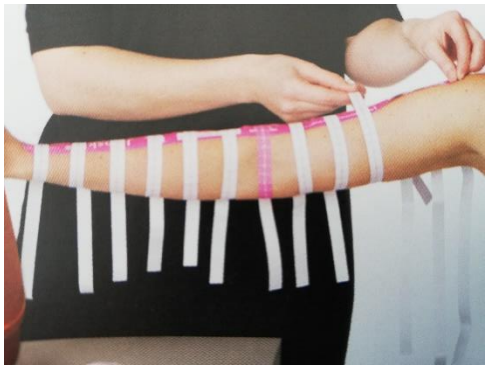


Figure 3. Circumferential measurement technique [11]

This information is then transferred into a computer aided design programme which applies the Leplace law or the reduction factor to calculate the finished size to exert graduated pressure and produces the pattern pieces for the garment. Commercial production sometimes applies the law of Leplace using computer design techniques.

The measurements are sent from the hospital with an outline of the desired outcome pressure and the pattern is then produced for the individual. It is pointed out by Macintyre and Baird (2006), that the pressures delivered using these methods of manufacture are assumed by the therapists to be accurate [3,4,7]. Several studies have looked at the comparison between commercial garments and found the fit and comfort to be good based on patient feedback and scar assessment [3,6,9,10].

2.3.4 *Laplace's law and its use*

Laplace's Law is a formula used to explain the surface tension of an object such as a bubble or a water droplet that enable it to form a shape. The original theory relates to the wall tension and radius of a cylinder to express the pressure difference that occurs between the pressure pushing the two halves of a cylinder apart and the wall tension pulling the two halves together.

The basis of this law is;

$$pressure = \frac{tension}{radius} \quad (4,13)$$

Laplace's law is widely used to calculate the pressure delivered on a cylinder of know radius by a fabric under a known tension [4,12]. Macintyre (2007) and Tyler (2015) highlight that the application of Laplace's law needs to be amended to be applied to the circumferential measurements taken for the fitting of pressure garments as opposed to the radius. The radius of the body is not uniform having asymmetrical and concave areas, therefore the formula using a radius would not be applicable [4,12]. Laplace's Law can be applied to calculate the pressure delivered by a fabric using a known tension, to a cylinder of a known dimension [2,4,14].

Macintyre highlights that fabric performance around the limb needs to be considered as the variation in limb circumference influences fabric tension [2,4]. As the circumference increases the fabric tension decreases when applying a standard reduction factor. Consequently, fabric tension influences pressure delivery which is highlighted in the results of the audit undertaken to support the research into the fabric performance [4].

Fig. 4 shows how starting at a limb circumference of 40.9 the fabric delivers a mean pressure of 18.6 but at a circumference of 69.9 the fabric delivers a pressure of 8.1. This chart also shows the use of the Leplace law to predict a known pressure using the Pressure Garment Design tool [4].

Mean circumference	40.9 cm	45.2 cm	47.5 cm	47.6 cm	47.7 cm	48.3 cm	48.7 cm	49.4 cm	49.5 cm	52.2 cm	56.0 cm	56.9 cm	63.8 cm	69.9 cm
Laplace predicted pressure in mmHg	18.0	16.3	15.6	15.6	15.5	15.3	15.2	15.0	14.9	14.2	13.2	13.0	11.6	10.6
Mean measured pressure in mmHg	18.6	14.2	13.7	14.7	14.3	15.8	16.1	13.3	13.2	16.1	12.9	14.5	11.2	8.1
Standard deviation of measured pressure	1.0	0.6	1.2	1.0	0.6	1.1	1.8	0.5	1.1	1.0	2.0	1.0	1.3	2

Figure 4. NHS Audit Pressures exerted on volunteers' left thigh by pressure garment sleeves (4)

2.3.5 *Fabric properties and pressure delivery*

The properties of the fabrics used in pressure therapy are very important in delivering a consistent pressure and how they perform during wear especially during activities. The amount of elastane and the multiple directions of stretch are crucial in an overall even fit, especially as the variation in limb dimensions and structure demand as much precision as possible [3,10,14]. The structure of the fabric used not only influences the fit but also has influence on the healing of the scar, coarser fabrics can cause the scar site to become sore and breakdown if the scar site is unstable, but the coarser fabric can also have positive influence on thicker scar areas [14]. Individuals respond in different ways, so it is essential to be able to supply where possible the most suitable fabric for their needs. The stages of healing may also require a change in the fabrics used. Sleeknit warp knitted fabric sometimes contains cotton or nylon or a mix combined with a percentage of an elastane-based product which produces a soft feel garment with a gloss side and a matt side. This softer fabric is favoured for children's garments and more sensitive skin. Powernet is a nylon-based fabric with an elastane product content having an open or mesh appearance which makes it slightly rougher in texture and not having such a soft feel. Powernet is used more widely in adult's garments and for those who have well matured scars. Powernet is favoured for thicker scar areas which can respond to the tensile properties of powernet that are different to the sleeknit [2,14]. Both fabrics are supplied

to hospitals by Spentex Ltd for in house garments [2,3]. It is important to note that not only does each fabric type have different performance and properties but also each new batch of fabric will vary [2].

2.3.6 *Laplace Law made simple*

The Laplace Law is difficult to apply in practice and until recently has not been accessible in a user-friendly format for use by technicians and therapists in a hospital. Macintyre and Ferguson have combined the Law of Laplace and the fabric equation data from load-elongation tests to develop an Excel spreadsheet containing formula for converting measurements into known pressure sizing. Each new batch of fabric must be tested to obtain fabric load after stretch. The load elongation data is then converted and built into the Excel spreadsheet, known as the Pressure Garment Design tool. The therapist or technician enters the pressure required and the patient's measurements into the relevant boxes on spreadsheet. The outcomes on the spread sheet indicate the sizes of a garment and the desired pressure this would require. The spread sheet can be saved and kept in the patient's record and printed out for use by the technicians to produce the garment. This process has been tested in the lab and found to be accurate within ±1mmHg [14]. This computer-based Pressure Garment Design Tool is easy to use and understand with the relevant formula hidden in the background

The format for the spreadsheet has been adapted to apply the reduction factor method also. This spread sheet uses the fabric data and measurements to state the pressure that will be applied if the reduction factor is not adapted to allow for body dimensions and the impact on fabric stretch [14]. Fig. 5 is an example of how the Pressure Garment Design Tool looks.

		Input patient length below	Input patient circumference below	Input desired pressure for this circumference	full pattern circumference (no seam allowance)	pattern width if cut on the fold (no seam allowance)	pressure delivered or 'not possible' warning
	length from wrist to armpit	cm					
	length from wrist to elbow	cm					
	length from elbow to armpit	cm					
1	circumference at point A: wrist*		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between A and B	cm					
2	circumference at point B		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between B and C	cm					
3	circumference at point C		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between C and D	cm					
4	circumference at point D		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between D and E	cm					
5	circumference at point E		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between E and F	cm					
6	circumference at point F		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between F and G	cm					
7	circumference at point G: elbow*		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between G and H	cm					
8	circumference at point H		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between H and I	cm					
9	circumference at point I		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between I and J	cm					
##	circumference at point J		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between J and K	cm					
##	circumference at point K		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between K and L	cm					
##	circumference at point L		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between L and M	cm					
##	circumference at point M		cm	mmHg	0.0 cm	0.0 cm	not possible
	distance between M and N	cm					
##	circumference at point N: upper arm*		cm	mmHg	0.0 cm	0.0 cm	not possible

Figure 5. The Pressure Garment Design Tool for applying the Laplace Law

2.4 Reasoning behind the level of pressure

Research has not been able to clarify the precise ideal pressure for scar treatment, only that some pressure is better than none [1,2,7,10,]. Historically most researchers believed that a pressure of 24/25 mmHg (capillary pressure) was necessary for scar healing [1,9]. This is believed to control collagen synthesis by limiting the blood supply carrying oxygen and nutrients to the scar tissue [1,10]. Pressure helps to control collagen production, keeping it to near normal levels which is not possible if scars are left to heal without therapy. The levels of pressures being applied in practice are between 5-55mmHg [9]. A long term with in-wound study by Engrav et al found that the minimum effective pressure for wound healing was 15mmHg and that pressure should not exceed 40mmHg [6]. There is some question about the interaction of the pressure garment and the need to overcome capillary pressure which would control the supply of blood and nutrients to the damaged area [3,5,8]. Based on the level of capillary pressure it is suggested that the pressure applied needs to be above 24mmHg to achieve this and get good results. This is within the range that is acceptable for therapy and delivers good results of scar management but has been identified as causing some discomfort and

itching. The control of capillary pressure is important to the control of scar healing and cannot be overlooked even though results are seen at lower pressures [5]. There are guidelines on the lowest effective pressure of 15mmHg for hypertrophic scars, which several papers state to be effective [5,6,8]. Also, the studies have advised against the application of pressures of 40mmHg and above as they can cause complications such as maceration, skin break down, and paraesthesia, tingling or burning sensations [3,5,6]. The amount of confusing information regarding the best and most effective pressure points towards the fact that there is no ideal as the individual responds differently for a variety of reasons, depth of burn, age, skin type, healing. What does come out of this is that an effective low-level pressure is 15mmHg, and an effective higher pressure is 25mmHg. It would therefore be useful to be able to produce garments with a known pressure that allows therapists to establish a base level for treatment and collect data from outcome measures, such as scar depth and colour, to support pressure therapy.

2.4.1 *Monitoring of pressure*

It is not standard practice to monitor pressure using technical equipment as it is time consuming and difficult during therapy sessions, partly due to the type of equipment available as well as the clinical time and support available [8,12,14,15,16]. Measuring and fitting small children for pressure garments is especially challenging as it is very difficult to keep them still, pressure measurements are therefore not possible. To be able to monitor pressure using pressure sensor equipment when precious time is required for scar assessment is not a priority in normal clinical practice. This is difficult to appreciate when so many research papers and organisations recommend its benefits [,1,5,7,8,9]. Therefore, there is a lack of data to clarify the pressure being applied in burns therapy [8]. This is true of in-house and commercial garments as measurements are not taken after fitting to confirm the accuracy of pressure delivery [8].

A study by Williams et al in 1998, tried to acquire pressure readings using a Talley monitor, but it had inconsistent results due to machine or sensor malfunction [9]. Engrav et al (2010) reported consistent results using an I-Scan monitor during a long-term study but other studies bring its accuracy into question. Tyler discusses the findings of swain (2005) and Macintyre (2011) which bring into question the accuracy of the I-scan sensors especially regarding the calibration which if not set accurately confounds the readings.

Although the I-scan sensor used by Macintyre was small, when used on the body variable surfaces and limb shape affected the sensor readings.

Although there are some technical advances in the development of pressure sensor equipment that supposedly operate in small areas and with the required accuracy to provide precise readings the smallest circumferences still cause problems. One of the issues is a sensor pads able to register readings lower than 10mmHg which is desirable for accuracy in many situations. Tyler provides an overview of the different types of systems suitable for monitoring garment pressure reading (2015) and discusses those that offer the most reliable functions for repeated measures. In summary Tyler finds that the PicoPress and the Kikuhime monitors provide the best flexibility for clinical use and have been updated regularly as advancements are made in technology [12]. Both these systems use small inflatable balloons that are supposed to be easily placed under pressure garments compared to other systems. In truth placement of sensors must be exact so that they are not distorted, and the readings affected [12,15,16]. Compared to older style bulky or large sensors they offer the opportunity for more precision, but practitioners would still need training and knowledge to acquire accurate information.

A study by Van den Kerckhove et al (2007) looked at the effective use of the Kikuhime pressure sensor equipment in clinical use and found it to be reliable even between different observers. This was trialled in a clinical setting on patients, to assess its reliability, and under these conditions worked well [15]. The findings of this study did suggest that there should be no issues using the Kikuhime sensor in a clinical setting for research into pressure delivery and the reproducibility results support this. Tyler cited a further study by Brophy-Williams et al (2014) that supports its effectiveness in delivering consistent pressure readings [12]. Candy et al (2009) looked at the Pliance X System for use to monitor pressure delivery of garments on patients and found it to be suitable for objective measurements in a clinical setting. This system includes very thin sensors 10mm in diameter, capable of monitoring pressure at lower levels although not sensitive below 10mmHg. The system comes with an electronic analyser and software to support single or multiple sensor use.

However, there is still little data available and there has been no change in clinical practice due partly to a lack of understanding of the need to monitor pressure delivery during normal clinical conditions. Even with the technical advancement in sensor monitors

which may enable lower interface pressures to be measured by trained staff, there is not time or funding to support this.

One problem is the high cost of the equipment available commercially, systems that could be used in clinical settings require funding and is not seen as a priority with so many demands on budgets.

2.4.2 *Checking for pressure in clinical practice*

The standard method used for fit is the therapists 'pinch' test which, is subjective and dependent on experience [3,9]. Therefore, it has no scientific grounding or supporting justifications apart from patient healing which is very difficult to quantify without data. Atiyeh et al (2013*),* point out that the monitoring of interface pressures and clinical outcomes will help to deliver data that will support the benefits of pressure therapy [7]. This is reinforced by the report from the ISBI that recommends that good clinical practice needs to involve regularly monitoring pressure applied as without this, evidence cannot be collated to support the use of the therapy in today's scientific climate [4].

From the research it is clear many rely on the fact that manufacturers and technicians produce garments to deliver a certain pressure and therefore do not take any pressure readings. A meta-analysis conducted by Ai et al (2017) collated an overview of criteria used in the study of pressure therapy highlighting how few recorded actual pressure [8]. Of those studies highlighted none looked at garments produced by therapy technicians or therapists using the 20% reduction method. No evidence has been found to suggest that pressure garments made in-house are monitored for pressure delivery [2,14].

2.4.3 *Clinical practice and outcome measures*

As it has not been clinical practice to monitor pressure using sensor readings and to study variations due to limb size and fabric performance it is necessary to change the assessment of pressure garments to support the advancement in the scientific evidence for pressure therapy [1,4]. Atiyeh et al (2013*),* highlight the importance of knowing the pressures being delivered to understand the best treatment outcomes [7]. The ISBI guidelines and Anzarut et al state that there is no clear data to support the use of pressure garment therapy and no clear data to support the application of a specific pressure [1,10]. In contrast, the findings of Van den Kerckhove et al and Engrav et al, provide some evidence with pressure readings, and assessment of scars showing that there are positive changes to

confirm pressure therapy does work to reduce scar thickness [5,6]. Considering the findings of others that pressure garment therapy needs to have evidence to support its ongoing use, and reasons for applying a specific pressure, new approaches need to be used to establish a method that at least gives an indication of the pressures delivered [2]. Using a method of garment design that provides a known pressure means that there is no need to use pressure sensor equipment to confirm the pressure being delivered.

2.5. Alternative approaches

The limitations of pressure monitoring have not been eased by technology as the sensitivity of the equipment to monitor low interface pressure is reliant on having enough time to ensure correct readings. Therapists and technicians are under pressure to provide quick turnaround of patients, influencing the delivery of a quality service. Using pressure sensor equipment requires equipment, time and precision to obtain useful readings. This is not always possible under pressured time constraints of clinical practice.

The research available highlights how difficult it is to be sure of the pressure delivered without monitoring, especially in in-house garments due to the nature of the reduction method which is known to deliver a wide range of pressures as highlighted by Macintyre et al (2006) [3]. ISBI guide lines state that the delivery of a quality service requires data collection and research in burns services [1]. To enable this the provider needs to allow this to be facilitated as part of clinic time which is not possible given the demands on NHS time and budget restrictions.

It would be beneficial for all garments including those made in-house to be produced using a system that enables better and more consistent precision. The reduction factor method is easy to apply but delivers a far from ideal product in a modern clinic. Pressure monitoring should be used to support the development of excellence in pressure therapy [1,2]. The techniques used to analyse damaged tissue and scars have become more precise and treatments are more refined meaning less surgery due to a better understanding of the extent of damage and recovery implications. It would beneficial to be able to provide pressure garments with a known pressure to ensure the most up to date techniques are being used. The manufacture of high-performance technical fabrics and the availability of sensitive pressure monitoring equipment capable of measuring low interface pressures and fabric properties, should offer the opportunities to collect data regarding fabric performance and pressure delivery given the time and resources

[4,12,13]. This information can be used to produce garments capable of delivering a known pressure that could be adjusted and applied to the individuals needs for scar management [4,14].

2.5.1 *The development of the Pressure Garment Design (PGD) Tools*

After extensive research into the effect of fabric tensile stretch properties on pressure delivery Macintyre introduced a new method for calculating the dimensions of pressure garments using the Laplace Law in 2007 [4], however it was very complicated to do manually and so was not widely adopted. The focus of the Pressure Garment Design tool development was to produce an easy to use method to indicate the pressure delivery, either a reduction factor or Leplace Law method that could be used by those producing garments in-house to understand the best effective pressure for scar management [14]. In 2012 she introduced 2 PGD tools one for monitoring the pressures exerted by garments made using the standard reduction factor method and another for calculating pressure garment dimensions designed to exert specific pressures as determined by the therapist [14]. The application of this method in clinical practice could support the collation of important data regarding scar management without the need to use pressure sensor equipment which is not practical in clinics. The Pressure Garment Design tool, although easy to use and applied commercially, is a new approach for in-house NHS garments. Being able apply it in clinical practice will influences the acceptance of therapists for future implementation.

The Pressure Garment Design tool can be used to apply a Reduction Factor or the Laplace Law, both of which uses an Excel spreadsheet, containing a series of equations to relate fabric tension and circumference to pressure [14].

The Reduction method Pressure Garment Design tool is based on the methods used in-house to produce garments which applies a reduction factor to the circumferential measurement, but the tool also produces predicted pressure information from the fabric analysis data applied to the formula used in the spreadsheet. This enables the user to see the levels of pressure being used to treat the scar [14].

The Pressure Garment Design Tool applying the Leplace Law is based on the circumferential measurement of the body part and the fabric tension profile. This method

when applied gives a better overall fit with variable allowances for the limb shape but delivering known pressures. By implementing the Leplace Law, Pressure Garment Design Tool [14], it will be possible to produce garments that deliver a more consistent pressure with a small range of variance and can support fine adjustments in pressure delivery where necessary. The evidence from other studies shows that bespoke garments are rarely checked to monitor actual pressure delivery [1,2]. The Pressure Garment Design tool takes into consideration the fabric properties, the limb dimensions, and the required pressure, to provide measurements for the finished pattern dimensions that will provide the pressure required within an accepted variance (+/- 1mmHg), whereas the reduction method has a wide range of variances from 9mmHg to 55mmHg [3,4,10].
The Pressure Garment Design tool has not been used in-house due to the challenges of working in NHS teams that vary in their practices. Although the PGD tool has been discussed with the technicians at the National pressure therapy support group, it is the Therapists who are responsible for implementing new practice. The PGD tool requires application in practice to be appreciated and the time constraints on practitioners has some influence on implementing new practices, no matter how important.

Due to the range of pressure garments being made and the variation in pressure therapy there is very little data available regarding pressure delivery to the conclude what the levels of effective pressure are. Without a standard specified application of a known pressure by in-house teams, using the same procedures in all clinical situations useful supportive information cannot be collected. The Pressure Garment Design tool provides a way to produce garments capable of delivering a known pressure or providing predicted pressures for reduction methods. Producing garments with a known pressure would enable the therapist to collect information regarding effective healing using specific pressures. This study is the first to examine the use of the Pressure Garment Design tool in clinical practise supported by pressure readings taken directly on the patient and on a cylinder.

Chapter 3: Methods

To conduct the research study all the required protocol had to be completed for the hospital and the local and regional health and ethics committees, which was a long and thorough process which could not be pre-empted as the research was unique and therefore no format was available to follow.

3.1 Research Application

A proposal outlined the aims and objectives of the study and how the research could support developments in the treatment of patients with scar damage supported by a literature review and audit information was drafted and submitted to the research department at Sheffield Children's Hospital. As this document needed to provide a basis for the application to the Regional Ethics Service and local Health Research Authority it was reviewed and updated several times to produce a document that clearly described the proposed research shown in *Appendix* 4.

3.1.1 Ethics requirements

After a favourable response from the research department at the hospital an application to the Regional Ethics Service was started using an online Integrated Research Application System (IRAS). This standardised process ensures that all relevant processes are completed within the Health Service when applying for ethics approval. This process is very time consuming and precise, for obvious reasons, and took over six months to complete as documents must be reviewed and had to be signed off by more than one person in different locations. At the same time documents were reviewed for the hospital and the local Health Research Authority (HRA) who require slightly different information. The research folder provided by the hospital must contain all the relevant paperwork to be used when conducting the study and these must have the same version numbers and approved by the hospital and the HRA in advance. See *Appendix* 5 for examples of the forms. When approval was received from the Regional Ethics Service the hospital research department put forward the research to be approved by the research committee, this took another 4 months. See *Appendix 6 and 7* for a copy of the approvals. When all approval was in place it was possible to organise the study process with the therapists and complete necessary documentation to adhere to ethics protocol.

Management and consultants were informed of the start date of the research being conducted and how it would impact on normal practice.

3.1.2 Good Clinical Practice

To support the ethics required to conduct research within the hospital two levels of E-leaning were required in Good Clinical Practice. This was conducted online using the website outlined by the hospital research department. This training relates to the collection, use and protection of patient information and is an essential part of conducting research in a clinical setting. See *Appendix 1* for a copy of the certificate.

Training was completed to use The EDGE system which is a web-based accrual reporting system that enables tracking of participant recruitment on a centrally held database. The dates of participant approach and recruitment were entered using initials only and no personally identifiable information was used.

3.2 Sample Testing

For the study and audit of current practice, Pressure Garment Design tools were created at Heriot Watt University by Dr. Lisa Macintyre using data taken from the relevant cotton Lycra sleeknit fabrics. One batch of fabric which had been used to produce the garments made just prior to the audit and two new batches of fabric to be used in the research, one beige and one black were tested.

3.2.1 Fabric sample preparation

Three one metre fabric pieces of cotton Lycra purchased from Spentex Ltd were delivered to the lab and left to rest in a conditioned testing laboratory 20+/- deg Celsius +/- 5% Relative humidity which was 65 % 19.5 deg. The first sample was from a beige batch used to produce garments over the past 3 months. The other samples were FM0227 beige 23514 and FM0227 black 18789 from new stock that were to be used to make garments for the research project.

Test specimens were cut: 5 samples of each fabric, were cut to 50mm wide and 220 mm long, the usable section being 100mm. The lines of cut are crucial for the correct resistance and a true reading of the fabrics' tensile stretch. Any fraying would compromise the results and lead to distortions in the data. The samples were numbered

individually and labelled with the batch number for future reference when using the Pressure Garment Design tool. See Fig. 6 for examples of fabric test pieces.

Figure 6. Fabric strips cut and labelled for testing

3.2.2 INSTRON test method

The samples were placed precisely, without stretching, in the jaws of an INSTRON tensile testing machine which were set at 100mm apart as seen in Fig 7. The machine was set to stretch the samples to 100% extension at a rate of 60mm/min using the 5kN load cell. This extension highlights how the fabrics performance alters as the stretch is increased. The INSTRON is linked to a computer which records the results of each test under the relevant batch code. The load in N was recorded in a spreadsheet which was then transferred to an Excel spread sheet for analysis and processing.

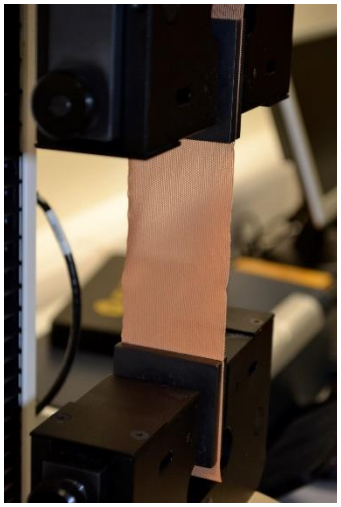


Figure 7. Fabric placed between the clamps of the INSTRON machine

3.2.3 Predictive equations and PGD tool

Fabrics were prepared for test and tested by the researcher but generation, evaluation and selection of the equations and building the PGD tools was done by Lisa Macintyre as explained in the paper on the design tool [14]. The data obtained was then entered onto an Excel spreadsheet which uses equations for predicting extension at any given tension and equations for predicting tension at a given extension. The equations and relevant formulas are built into a further Excel spreadsheet, as they do not need to be seen by the user, which outlines the instructions for use and blank areas for data to be added from the patient's measurement chart. The Excel spreadsheet is known as the Pressure Garment Design tool, the formulas built into the spreadsheet facilitate the precise dimensions required to produce the pressure garments using the inputted data. An example of the tool can be seen in Fig. 5. [14].

3.3 Audit of existing practice

Pressure garments made in Sheffield Children's Hospital are all made using a 20% reduction factor and with the initial garment made of beige sleeknit cotton Lycra fabric. The first stage of this research was to audit previously made garments to establish the pressure that our garments have exerted on patients until now. Patients who had been issued with pressure garments made from beige sleeknit fabric to treat scars on their arms and/or legs were identified. The circumferential measurements from 8 existing patients were copied from their records (anonymously) and entered in the Pressure Garment Design tool created using the Tension profile of the batch of sleeknit fabric that has been used in our department for 1 year. The 20% reduction factor manually used by the therapists was applied to the Pressure Garment Design Tool in this instance to indicate the possible pressures applied to the patients using the original garment. The pressures calculated by the tool were noted and the range of pressures exerted was calculated.

An audit conducted at Sheffield Children's Hospital prior to the research, highlighted the difference in pressure exerted by a range of garments. This was done by entering historical data from patient measurements for garments into a computer programme called The Pressure Garment Design Tool that uses the Laplace law to factor in the values of fabric tension and limb dimensions, to create measurement charts that reflect the pressure

outcomes for specific fabrics. The audit showed that current methods applying a 20% reduction factor to produce pressure garments could exert between 15mmHg and 54mmHg of pressure on patient's limbs. The pressure levels indicated by this information were not 20mmHg as the therapists understood to be delivered using the reduction factor. A study by Macintyre and Baird (2005) confirms that the pressure levels delivered by reduction factors were not known or confirmed by any evidence and the practice was applied due to general acceptance of the procedure rather than confirmation of effectiveness [2].

3.4 Equipment

Cylinders

Prior to the start of the study a selection of cylinders was collected to be used in the taking of pressure readings that each garment delivered on a solid shape. The cylinders acquired ranged from cosmetic bottles to a drain pipe, the smaller circumferences presenting a challenge. The circumference closest in size to the limb were used if actual size was not available, examples of the cylinders can be seen in Fig. 8. The cylinders were measured in centimetres and marked accordingly.

Figure 8. Cylinders used to measure pressure under the garments

Pressure monitor

There is no pressure reading equipment available in the hospital so to support the collection of this important information a Pico-press monitor, as seen in Fig. 9 was on loan from Heriot-Watt university to facilitate pressure reading for the duration of the research.

The Pico-press is compact and easy to carry making it suitable for use in clinics. It consists of a pressure monitor that needs to be charged but does not need to be plugged in when taking readings. The pressure sensor is a 50mm plastic balloon connected to the monitor by a very fine tube. Each time the monitor is switched on an inbuilt syringe is pulled out until 0 pressure is reached, the plunger of the syringe is then pushed back in. To test the balloon was registering pressure from the same base level an 8oz kitchen weight, see Fig. 10, was placed on the balloon giving a reading of 10mmHg. The monitor was calibrated at each use to ensure accuracy.

Figure 9. Pico-press monitor bag and contents

Figure 10. weight used to confirm pressure sensor accuracy

PC/Laptop

A PC and a laptop were used to convert the participants' measurements into the suggested garment size using the Pressure Garment Design tool. The Pressure Garment Design tools were those created from the fabric analysis, for the reduction factor of 20% and for applying the required pressure of 15mmHg and 25mmHg. The spreadsheets used to produce garments for each participant were saved showing the limb circumferences and

the required pattern size without seam allowance. The participants' individual measurement spreadsheets were stored on an encrypted memory stick with no personally identifiable information.

Fabric

The fabric tested was sleeknit cotton Lycra FM0227 r23514 supplied by Spentex Ltd. A piece of fabric from the same test batch was kept for use in the study. The fabric was used to produce the initial garments and repeat garments selected by the participants.

3.5 Research Procedure

The literature review had highlighted the fact that although pressure has been recognised as a positive therapy for scars no actual pressure values have been outlined as the best for purpose. It is acknowledged by some research authors however that 10mmHg can offer positive results and that 25mmHg is the safest upper level recommended. It was therefore decided to provide three garments to each participant, one garment using 20% reduction and one each of 15mmHg and 25mmHg of pressure.

The therapist caring for the patient assessed the scar for healing as suitable for treatment with a garment. Those wounds nearly healed without any signs of potential breakdown are measured for garments at the Sheffield Children's Hospital.

Due to the unpredictability of scar healing all the patients requiring garments in the age range were approached to take part in the study. The possibility that some scars would present to an extreme of expectations, either positively or negatively was considered in the analysis. In the initial assessment, the level of healing was noted with a description of colour, size, and depth of area to be treated. The POCAS scoring system was used to assess the patients view of their scar as well as the therapist's observations. For an example of the form see *Appendix* 4.

The patient and carer were approached at this point to see if they would be prepared to take part in the study. If they were interested a formal introduction to the study was made by the researcher and information sheets were given to the carer and child. The child's information sheet was relevant to their age, examples can be seen in *Appendix 5* .

At the first garment fitting clinic the research information was reviewed and if carer and patient were happy to proceed formal consent was obtained from both. Copies of the

documents were kept in the hospital notes and the research file and a copy sent to the carer, examples can be seen in *Appendix* 5.

The patient was allocated a participant number which was then used on all research documents and to identify their participation on hospital files. A pink copy of continuing consent form was attached to the hospital notes and a pink copy of garment issue form kept in the pattern file in the sewing room which helped to identify the participants notes easily. See *Appendix* 4 for a copy of this form.

All the relevant documents in the research file were completed and the approach and recruitment dates entered onto the EDGE system.

Only 4 participants were recruited in the time allocated for the research due to the small numbers of patients coming through the department at the time of the study. It was possible to collect enough useful data to produce some interesting results that provide a useful indication of pressure delivery. Importantly, the number of participants did not affect the ability to understand the implications of using the PGD tool in a clinical environment. A larger number of participants would be preferred to obtain data representative of the population, but this would require a long-term study or cooperation with other in-house garment providers.

3.5.1 Garment design

The measurements taken by the therapist were sent to the sewing room for processing. Garment dimensions were prepared using the Pressure Garment Design tool on the computer to produce charts which gave the finished pattern size, without seam allowance. The Pressure Garment Design tool outlines the instructions for entering the participants measurements, with boxes to also enter the spacing between measurement points. The Pressure Garment Design tool requires either a reduction factor or a required pressure to be entered in the applicable boxes to complete the process.

The pattern for half the garment were drawn up, garments are usually cut with the fabric folded. The pattern has one straight side which is placed on the fold, this is then pinned to the fabric and the piece cut. This process requires accuracy so that extra fabric is not added at the fold. The garment measurements at each point were recorded on the pattern with a line to indicate their location for reference later, an example can be seen in Fig.11. The pattern was then labelled with the Pressure Garment Design tool used, 20% reduction, 15mmHg or 25mmHg, and the participant number.

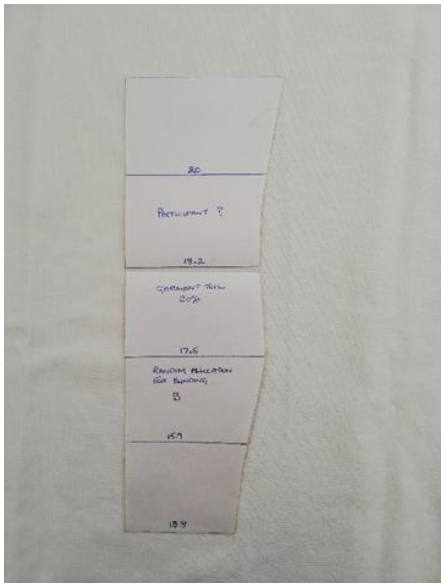


Figure 11. Paper pattern sample with Measurement lines marked

Figure 12. Pressure garment with measurement lines marked with dots for placement of sensors

The garments were cut from the tested sleeknit fabric. Markers were transferred onto garments for each measurement point e.g. 4 dots on each line using a laundry marker which will not wash out. The single seam was sewn using a 1mm zig-zag seam, reverse stitched at each end Placing the raw edge against the inner edge of the machine foot gives a good guide to obtain seam consistency. A sample garment can be seen in Fig 12.

3.5.2 Garment specification

Laundry labels with the letters A, B or C were used to record the random allocation of garment identification for the study as seen in Fig. 13. The labels were placed upside down and shuffled around, picked at random and sewn onto the garment. The garment was then identified through comparing it to the pattern and then the relevant letter could be marked on the pattern.

Figure 13. Research garment with label marked for identification

3.5.3 Cutting check

To record as much useful information as possible a check was done on each garment cut to record the accuracy of cutting. This is important as lack of consistency in cutting can affect the pressure outcomes even though the discrepancies may be small. As the measurement points were marked on the garment it was possible to check the finished cut size with the stated measurement on the pattern. The predicted measurements from the Pressure Garment Design tool were recorded alongside the actual measurements on the cutting chart. This process was also carried out after wash and wear to record differences in dimensions after the fabric had been stretched during use.

3.5.4 Cylinder Pressure readings

A selection of cylinders had been collected to represent the arm circumferences of the participants. The size of the cylinder dictated where the pressure measurement point would be on the garment. The relevant point on the garment related to the arm/cylinder circumference was marked using the laundry pen. This would enable the identification of the placement on the participant during pressure reading at garment fitting clinic. The cylinder size and description and the pressure readings were recorded on the relevant chart, using the garment identification A, B and C. An example of the chart can be seen in *Appendix* 4. As the garments were different lengths either two or three points were used to obtain readings, the measurement point 1-9 was noted on the chart. The circumference of the garment also dictated the number of readings it was useful to take at each point around the limb. It would have been ideal to take 4 readings, but the small circumferences made these many placements difficult. Initially the same measurement point was going to be used on the participant, but this was not always possible due to difficulties placing the sensor at the correct level due to the length of the garment. The cylinder used had to be changed in this situation to obtain comparative pressure measurements and the pressure readings taken again.

3.5.5 Garment fitting

During clinic the research process was discussed with the researcher and after agreeing to take part signed consent was obtained. At the first garment fitting willingness to take part in the study was confirmed. The garments were assessed by the therapist to ensure

that they were a suitable fit and did not give any cause for concern applying standard clinical practise and expertise. After confirmation that the therapist was satisfied that the garments were suitable for pressure therapy pressure readings were taken by the researcher and recorded on the chart for A, B and C garments already used to record the pressures on the cylinder.

3.5.6 Garment use

Once the pressure readings were taken their wearing and use of the garments was explained again. Although covered in the introduction to the study until the garment are tried it might not seem clear. The participant was instructed to wear the garments for the 23.7-hour period as usual but to use each garment in turn as they changed them after bathing or applying moisturiser. The three garments were labelled clearly, A, B or C so that they could be identified by the participant and the researcher. They were asked to keep rotating for a couple of weeks and to fill in a questionnaire regarding their experience *see Appendix* 4. They were asked to choose the garment they preferred from A, B or C, so that this design could be used for the duration of the study if the therapist was satisfied with the scars' progress.

There was an 8-week gap between clinics, giving the participant the opportunity to have worn and washed all garments several times.

Before the second follow up clinic the participant was contacted to establish if a selection had been made of the preferred garment, either A, B or C. If the participant could confirm a choice, 3 more garments were prepared of that design, so they could continue wearing the chosen garment without delay. If there was no clear choice another set of initial garment designs, A, B AND C, were made so that they were available if the therapist needed to reassure the participant if there were any concerns due to fit and comfort. Each garment made was measured at the same levels on the pattern to check correct cutting and the pressure readings were taken on the cylinders relevant to the participants limb size.

At the follow up clinic the scar was assessed to ensure healing was good and there were no issues raised for concern. Where possible pressure readings were taken of the new garments on the participant. The parent/carer was asked to return the used garments to clinic or in the stamp addressed envelope provided, this reminder had to be repeated in some cases.

The third follow up clinic enabled pressure readings to be taken after the wash and wear of the initial garments and the chosen design. The pressure readings were taken on the participant and on the cylinders at the marked points and the readings recorded on the relevant form an example of which can be seen in *Appendix* 4. In some instances, this follow up pressure readings could not be completed at the third clinic as the initial garments were not returned by the participant until later. The dimensions of the washed and worn garments were measured at the marked points and recorded to compare with the original information .

3.6 Data collation

The pressure data collected for each participant's garments was double checked and entered on to Excel spread sheets so that it was ready to be analysed. Although there were only 4 participants there was enough information to analyse the application of the Pressure Garment Design tool and to compare the predicted pressure with that delivered on the garment and the participant.

3.6.1 Pressure readings

The pressure readings from the measurement points of each garment worn by the participant were collated on an Excel spreadsheet. The formula in Excel was used to work out the mean for each measurement point on the cylinder and the participant. The mean from the cylinder and the participant were compared to each other and the predicted measurements. The results of these comparisons were then tabulated and can be seen in *Appendix* 3.

With the help of Dr. Macintyre to obtain the fabric performance values for the tensile stretch from the fabric test results and using the collated data confidence intervals were produced for the pressure readings and the predicted pressures for garments using the 20% reduction factor.

Chapter 4: Results

4.1 Ethics procedure

A research proposal was submitted to the Sheffield Children's Hospital research department and after being accepted for consideration the process of application through the Regional Health Authority electronic system was started as well as submitting to the hospital for sponsorship.

The process of applying for ethics approval is essential for conducting research within a hospital and required quality time, focus and energy before the project was started which was beneficial to putting together a quality research plan. The detail required for ethics approval involves rewriting specific areas to clear up any ambiguity that could lead to unethical practice especially in the way children are recruited as they must make the choice to take part and must not be led. The hospital research department play a crucial role in filling out the IRAS form as they have knowledge of the clinical language and as sponsors were qualified to answer the legal and protection sections, regarding confidentiality and insurance safeguards required to conduct research at the hospital. All alterations to the documents were then counter signed by the Principal Investigator the Chief Investigator and the hospital research department before the final documents are submitted. The research project has specific documents and consent forms for each age group and carer that must be edited to fit the needs of the research to be conducted *See Appendix* 5. Each document then had to be checked and authorised, and date approved. The request to do the research was presented to the hospital in June 2017 and the process of putting together the research proposal and the IRAS forms started in July 2017. By March 2018 the hospital had confirmed approval for the research to start. The first participant could be recruited in April 2018.

This whole process took a year to complete and therefore left a short period of time to complete the actual study to be able to submit within the time restraint of the part-time Masters which is two years. The research was limited to a 6-month period to enable enough time to write up the dissertation, but the data has produced valuable information regarding pressure delivery using the three garment designs .

4.2 Fabric testing and analysis

Only the beige sleeknit fabric data was used for the study as the results of the sample testing showed that the black sleeknit was too variable even when a second sample of 5 specimens was tested and analysed as shown in Table 1. The data used to predict the pressure needs to have as small a variation as possible for the Pressure Garment Design tool to be reliable.

Black 18789 samples 1-5			Black 18789 samples 6-10			Beige 23514 samples 1-5		
mean	SD	%CV	mean	SD	%CV	mean	SD	%CV
5dp	2dp	3dp	5dp	2dp	3dp	5dp	2dp	3dp
1.133	0.868	76.553	1.243	0.392	31.542	0.877	0.391	44.542
9.396	1.072	11.405	9.575	0.888	9.275	7.440	0.642	8.624
15.176	1.232	8.117	16.062	1.355	8.433	12.535	0.719	5.737
20.805	1.468	7.058	22.063	2.124	9.625	18.150	0.608	3.350
26.093	2.790	10.694	28.154	3.032	10.770	23.464	0.781	3.327
31.411	3.654	11.632	33.733	4.215	12.495	28.244	0.378	1.339
36.911	4.336	11.746	39.469	4.824	12.223	33.421	0.703	2.105
42.449	5.451	12.842	45.334	5.812	12.821	38.739	0.686	1.771
47.939	5.919	12.346	51.024	6.427	12.596	43.406	0.903	2.081
53.095	6.632	12.491	56.890	6.846	12.033	48.119	0.642	1.334
58.364	7.351	12.595	62.410	7.301	11.699	52.789	0.523	0.990
63.528	7.815	12.302	67.607	7.261	10.740	57.162	1.013	1.772
68.408	8.360	12.220	73.076	6.949	9.509	62.032	0.987	1.591
73.472	8.101	11.026	78.387	6.513	8.309	66.192	0.485	0.733
77.948	9.106	11.683	83.392	6.555	7.860	70.205	1.127	1.606

Table 1. Data from the fabric samples tested of FM0227 Black and Beige

The data analysis highlighted some big variations (high %CV) for the black fabric samples, therefore a second batch of 5 strips were tested. The results from the second test indicated that the fabric was variable across the piece and could not produce consistent readings suitable for analysis and it was not the sample cutting that was at fault. Table 1 shows a section of the results.

The coefficient of variation (%CV) of the black samples show a high variance in the range of extensions between samples of above 5% which is much higher than would normally be used as it deliver a less consistent pressure. The %CV of the beige shows a much lower variability of just below 3% which is within a range that will deliver a more consistent pressure. This high deviation of the black fabric would give big differences between calculated average pressure delivery and any given garment which would not be reliable for application with the Pressure Garment Design tool. *See Appendix* 2 for longer

fabric extension readings of all three sample sets, FMO227 , Black 18789 and Beige 23514

4.3 Audit outcomes

The measurements used were from legs and arms of a total of 8 girls and boys aged between 2 and 14 between September 2015 and September 2016. All available circumferential measurements were entered in to the Pressure Garment Design tool. This meant that the number of measurements were different for different patients. Results were tabulated for each patient/pressure garment and given a number e.g. PGN1 was Pressure Garment Number 1. All measurements along the limb were recorded and will be presented where REF POINT 1 was the most distal measurement of the garment.

Table 2. Audit of pressure predictions for historical garments using Pressure Garment Design tool for 20% reduction factor.

AUDIT OF LEG AND ARM SLEEVES	made using 20% reduction factor									
		DISTAL								PROXIMAL
		PRESSURE READINGS MMHG AND PARTICIPANT MEASUREMENTS IN CENTIMETRES								
PG NUMBER	output measure	REF POINT 1	REF POINT 2	REF POINT 3	REF POINT 4	REF POINT 5	REF POINT 6	REF POINT 7	REF POINT 8	REF POINT 9
PG A1	pressure	52 mmHg	52 mmHg	43 mmHg	36 mmHg	34 mmHg	34 mmHg			
	circumference	10.8 cm	10.9 cm	13 cm	15.5 cm	16.7 cm	16.7 cm			
PG A2	pressure	41 mmHg	36 mmHg	32 mmHg	28 mmHg	28 mmHg				
	circumference	13.8 cm	15.9 cm	17.5 cm	18.2 cm	20 cm				
PG A3	pressure	51 mmHg	46 mmHg	40 mmHg	35 mmHg	38 mmHg	35 mmHg			
	circumference	11 cm	12.2 cm	14.3 cm	16 cm	15 cm	16 cm			
PG A4	pressure	38 mmHg	33 mmHg	32 mmHg	33 mmHg	33 mmHg	32mmHg	31mmHg		
	circumference	14.9 cm	17.2 cm	17.5 cm	17.3 cm	17.2 cm	17.9 cm	18.1 cm		
PG L1	pressure	39 mmHg	36 mmHg	31 mmHg	27 mmHg	27 mmHg	26 mmHg			
	circumference	14.4 cm	15.7 cm	18.3 cm	20.8 cm	21.2 cm	21.7 cm			
PG L2	pressure	35 mmHg	31 mmHg	28 mmHg	24 mmHg	24 mmHg	24 mmHg	21 mmHg	23 mmHg	
	circumference	15.6 cm	18.2 cm	20 cm	23.2 cm	23.1 cm	24 cm	26.1 cm	25.3 cm	
PG L3	pressure	28 mmHg	25 mmHg	21 mmHg	19 mmHg	19 mmHg	20 mmHg	18 mmHg	16 mmHg	15 mmHg
	circumference	20.5 cm	23 cm	26.5 cm	29.5 cm	29.6 cm	28.6 cm	31.5 cm	34.7 cm	37.2 cm
PG L4	pressure	22 mmHg	21 mmHg	19 mmHg	18 mmHg	17 mmHg				
	circumference	26.2 cm	27.5 cm	29.6 cm	31.8 cm	33.5 cm				

PGA=pressure garment arm. PGL=pressure garment leg.

Table 2 shows that a wide range of pressures that were exerted on our young patients. Pressures exerted by pressure garments constructed using a standard 20% reduction factor varied from 15 mmHg to 52 mmHg with the higher pressure being exerted on the smallest circumference. Arm garments ranged from 28-52mmHg and leg garments ranged from 15-39mmHg, as the patient's legs were bigger than the arms.

The variations in pressure being applied even in one garment shows how variable the fabric stretch can be due to the finished size of the garment piece. As the Pressure Garment design tool gives dimensions for the garment size it was possible to cross check the patterns already produced against the new information. This confirmed that the Pressure Garment Design tool for 20% reduction factor was reliable and that the pressures indicated were realistic.

According to the literature pressure delivered by garments should ideally be around levels of capillary pressure, i.e. 24 or 25 mmHg. For garments on limbs we might want a slightly graduated pressure, with highest pressure at the most distal part, reducing slightly as the garment approaches the torso, but the target pressure of 25mmHg should be applied to the scar site.

4.4 Equipment

Pressure reading equipment was not available at the Sheffield Children's Hospital and application for funding was unsuccessful.

As pressure readings were an essential support for the study a Picopress monitor was loaned to the researcher from Heriot-Watt University.

4.5 Research Procedure

It was estimated that recruitment would be approximately 20 in the under 16's based on historical patient numbers from the previous year 2016-17 . This number was limited due to the age group restrictions that were stipulated for the ethics requirements, to that of children between 6-16. The possible recruitment numbers were further restricted by time constraints. Due to the lengthy process of ethics application and the time restraints of completing the Masters by research the time left for recruitment was 6 months which limited the opportunities to recruit. It is also difficult to judge the number of patients who will require treatment as accidents are an unwanted event.

All those approached agreed to take part or no longer required garments. However, this only resulted in 4 participants in the pilot study. This was unfortunate for us but good for the children of Sheffield

4.5.1 Participant overview

The participants were two boys and two girls between the ages of 11 and 15. They were all able to put on and remove their pressure garments independently.

Participant 1 was issued with a garment 20cm long to cover a scar to the lower arm on the dorsal side, up toward the elbow crease.

Participant 2 was issued with a garment 36cm long to cover a scar to the lower arm on the palmar side, midway up the arm to the elbow.

Participant 3 was issued with a garment 21.4cm long to cover a scar to the lower arm on the dorsal side, from the wrist to mid arm.

Participant 4 was issued with a garment 16cm long to cover a scar to the elbow, over the rear of the joint.

GARMENT	Participant 1		Participant 2		Participant 3		Participant 4	
ARM SLEEVE	Length	circumference	Length	circumference	Length	circumference	Length	circumference
WRIST	20cm	13.2 cm	36cm	Not used	21.4	15.1 cm	16	Not used
		13 cm		Not used		15.3 cm		Not used
		13.5 cm		16.5 cm		16.1 cm		Not used
		16 cm		17.6 cm		18 cm		20.5 cm
		17.8 cm		21.2 cm		19.8 cm		22.5 cm
Elbow		19 cm		23.3 cm		22 cm		24.5 cm
Above		19.3 cm		23.5 cm		22.2 cm		23 cm
elbow		Not used		23.9 cm		Not used		22.5 cm
		Not used		26 cm		Not used		Not used

TABLE 3. Participant limb dimensions. This table shows the circumferential measurements taken from the wrist towards the elbow. Two of the garments started above the wrist.

4.5.2 Blinding

The study was double blind as the garments were identified by labelling A, B or C which meant that the participant and the therapist were not aware of the method of garment dimension calculation or target pressure delivery being applied by each garment. This method was effective and easy to put into practice which may have been due to the small number of participants.

4.5.3 Cutting charts

Cutting charts were used for each participants' garments to check for precise cutting by the researcher, as even the smallest variations in size can have a big impact on pressure delivery. To confirm that the garments being used were suitable for purpose this information was considered useful as a cross check that garments were an accurate to size. The initial measurements of the garments could also be compared the garment size after wash and wear to compare changes in performance.

Table 4. cutting chart example

Participant 1						
	A 20% red		B 15mmHg		C 25mmHg	
	Predicted	Actual	Predicted	Actual	Predicted	Actual
1	5.7 cm	5.8 cm	6.3 cm	6.3 cm	6.0 cm	6.0 cm
2	5.6 cm	5.6 cm	6.3 cm	6.3 cm	5.9 cm	5.9 cm
3	5.8 cm	5.8 cm	6.6 cm	6.6 cm	6.1 cm	6.1 cm
4	6.8 cm	6.8 cm	7.5 cm	7.5 cm	7.0 cm	7.0 cm
5	7.5 cm	7.5 cm	8.2 cm	8.2 cm	7.6 cm	7.6 cm
6	7.9 cm	7.9 cm	8.7 cm	8.7 cm	8.0 cm	8.0 cm
7	8.1 cm	8.1 cm	8.8 cm	8.8 cm	8.0 cm	8.0 cm

Table 4 is an example of the cutting chart which shows the predicted size of the garment and the cut size. The tolerance for error is =/- 1mm. Working with precision is essential for good fitting garments, errors of more than 1mm can change the pressure being delivered. Any errors in cutting would have required replacement garments but there were no errors above or below the tolerance level. .

4.5.4 Fabric changes during testing

There is concern that the performance of the fabric is greatly compromised after stretching and manipulation caused by putting on and removing even in a short time, for this reason garment size and pressure readings were double checked against the first cylinder reading taken under a garment and the cutting chart measurements to highlight any notable changes. No notable changes +/- 1mmHg were seen in the pressure when checked on the cylinder using the same cylinder size and sensor placement as previously, or changes in garment size when measured at the marked points used previously.

4.5.5 Garment use

The questionnaire provided to the participants at garment fitting provided feedback regarding their use of the garments and reasons for preferences. There was total compliance as all participants tried all garments. Figures 14 and 15 show a selection of garments used in the research.

Figure 14. A,B and C trial garments

Figure 15. A selection of well-worn garments

Table 5. collated data from questionnaires

Questionnaire responses collated	Number of responses for :-				
	20% reduction	15mmHg	25mmHg	All garments	
Question ?					
Which did you wear for the longest time		3		1	
Which garment did you wear most		3		1	
Which garment felt the best to wear	1	3			
Which garment was the easiest to put on/off		4			
Which garment did you like best	1	2	1		
Which garment was most difficult to put on/off	3		1		
Which garment felt the worst to wear	1	1	2		

Table 5 shows the outcomes of the questionnaires for compliance and preferences. Each participant filled in and returned their questionnaire for which they were required to circle the letter of the garment in response to the question. The collated responses can be seen in table 3 under the relevant pressure garment design. All had a different and valid reason for preferences or non-use of a garment. The responses to the questionnaire are useful to appreciate that individuals need an individual approach to their therapy needs one product will not suit all. Although the indications are that the 15mmHg of pressure is the easiest

to pull on and off and felt the nicest to wear and was worn the longest not all chose this garment to continue therapy. The participant number was too small to use as a clear indication that 15mmHg is the preferred garment design although 2 out of 4 opted to use it for continued therapy. Although it is possible to see that 15mmHg offers a more comfortable fit due to the responses given. It is interesting that no one chose 25mmHg as the best to wear but someone did choose the 20% reduction (24-30mmHg). Using this type of qualitative data is limiting and can be interpreted wrongly without comments from the individuals.

The participant who chose the 20% reduction factor garment had recognised it delivered more pressure and assumed that this was therefore the best therapy.

The participant who chose the 25mmHg design felt that the 15mmHg was not enough but that the 20% reduction caused discomfort.

One of the participants who chose the 15mmHg garment design had to wear it over the elbow which caused discomfort with the other two designs even though they were very close in size due to the circumferences in that area.

Two participants stated that they suffered swelling to the hand with the tighter garments initially but that stopped as they got used to the garment and stretched whilst in use .

All four participants were very different in build and had very different garments and for this reason the pressure readings cover a range of measurements on the arm from 13cm to 22.5 cm relevant to children seen at the hospital. The range of circumferences seen in this small number of participants highlighted the variations in garments sizes and the pressure delivered applying the 20% reduction factor in each case which is standard practice with in-house garments.

There were no causes for concern during the research and healing outcomes were positive. All the participants who agreed to take part in the study were happy to continue when asked at each clinic. They were also happy to carry on using chosen therapy garment after the study ended. Although a record of healing progress was recorded using the POSAS scale the study did not look at the effectiveness of each garment for best pressure for healing due to the time scale of the project.

4.6 Collation of pressure data, predicted, cylinder and participant

The limited number of participants did not provide the amount of data as expected but there was enough information from each participants' pressure readings and the cylinder

pressure readings to compare with the predicted pressure readings. The pressure readings were taken from the three garment designs 20% reduction factor, 15mmHg and 25mmHg. Using Excel spread sheets the mean values of the pressure readings from the predicted, cylinder and participant pressure were used to create tables and charts to analyse the information available.

4.6.1 Mean values of predicted, cylinder and participant pressure readings

The mean pressure for all participants were entered onto the same Excel spreadsheet to create a table listing them in increasing limb circumference. Tables were created for each PGD tool used which also show the limb circumference, garment size and predicted pressures.

Table 6. Mean outcomes for all 20% reduction factor garments

circumference in cm		pressure in mmHg			predicted pressure minus:		pressure on cylinder minus on participant
of patient limb	garment at 20% RF	predicted	exerted on cylinder	exerted on participant	exerted on cylinder	exerted on participant	
(P1) 13	10.8	42	31	23.5	11	18.5	7.5
(P1) 16	13.2	35	26	20	9	15	6
(P3) 16.1	13.3	35	29	23	6	12	6
(P2) 17.6	14.5	32	30	21	2	11	9
(P1) 19	15.6	30	24	20	6	10	4
(P2) 21.2	17	27	26	15.3	1	11.7	10.7
(P3) 22	18	26	29.3	17	-3.3	9	12.3
(P4) 22.5	18.4	25	25	23.5	0	1.5	1.5
(P4) 23	18.8	25	25	13	0	12	12
(P2) 23.5	19.2	24	24	15	0	9	9

Using the mean results from predicted, cylinder and participant pressure outcomes it was possible to calculate the differences between each set of results. In Table 6 the outcomes for 20% reduction factor results can be seen. The range of predicted pressures decreases as the circumference of the limb increases. The pressures exerted by the garment on the cylinder did show a trend to decrease apart from one anomaly which could be due to user error when taking the pressure readings. The pressures exerted by the garment on the participant are much lower according to the information. This information could be influenced by the structure of the limb and may account for the high differences in pressures from17mmHg to 23mmHg for example as seen for the readings for P3 at the circumference of 22cm and 16.1cm. When comparing the participant with the cylinder or the predicted the differences are large this could be due to the limb structure and that the pressure readings are much lower over fleshy areas or because the garments had already been stretched for cylinder measurements and due to

the difficulties getting garments onto the patient at first fit. The smallest dimension gives the highest differences but the high figures across all three right hand columns raise questions about how variable 20% reduction factor can be in pressure delivery.

Table 7. Mean outcomes for all 15mmHg pressure garments

circumference in cm		pressure in mmHg			predicted pressure minus:		pressure on cylinder minus on participant
of patient limb	garment at 15mmHg	predicted	exerted on cylinder	exerted on participant	exerted on cylinder	exerted on participant	
(P1) 13	15	15	14	17	1	-3	-2
(P1) 16	15	15	15	10	0	5	5
(P3) 16.1	15.1	15	16	12.6	-1	3.4	2.4
(P2) 17.6	16.4	15	16	15.3	-1	0.7	-0.3
(P1) 19	17.5	15	15	19	0	-4	-4
(P2) 21.2	19.1	15	16	12.3	-1	3.7	2.7
(P3) 22	19.7	15	16	12.6	-1	3.4	2.4
(P4) 22.5	20.1	15	15	14	0	1	1
(P4) 23	20.4	15	15	14	0	1	1
(P2) 23.5	20.8	15	16	11.6	-1	4.4	3.4

In contrast Table 7 shows lower differences between the pressure means for 15mmHg garments on the cylinder and on the participant. The differences between the predicted and the cylinder are within the accepted tolerance of +/- 1mmHg indicating that Pressure Garment Design tool was accurate in the prediction of pressure for the garments applying 15mmHg of pressure. The differences between the participant and the predicted and cylinder do show bigger differences. As the predicted and cylinder are so close it would suggest that pressure delivered on the limb performs in a way that is difficult to monitor just using a pressure sensor pad. It is also worth considering that the pressure sensors do not give effective readings if placed on a curved area which is more than likely on small circumferences. The tolerances for the pressure sensor are +/- 3mmHg which is significant when testing on small circumferences.

Table 8. Mean outcomes for all 25mmHg pressure garments

circumference in cm		pressure in mmHg			predicted pressure minus:		pressure on cylinder minus on participant
of patient limb	garment at 25mmHg	predicted	exerted on cylinder	exerted on participant	exerted on cylinder	exerted on participant	
(P1) 13	11.8	25	25.5	25	-0.5	0.5	0
(P1) 16	14	25	23	20	2	3	5
(P3) 16.1	14.1	25	25.3	16.3	-0.3	9	8.7
(P2) 17.6	15.1	25	24	20.3	1	3.7	4.7
(P1) 19	16	25	26	20	-1	6	5
(P2) 21.2	17.4	25	25	14.3	0	10.7	10.7
(P3) 22	17.9	25	25.6	18.3	-0.6	7.3	6.7
(P4) 22.5	18.2	25	26	21.5	-1	4.5	3.5
(P4) 23	18.5	25	26	18	-1	8	7
(P2) 23.5	18.8	25	24.3	17.6	0.7	6.7	7.4

Table 8 shows again the small differences between the predicted and the cylinder readings supporting the effectiveness of the PGD tool to be used to provide 25mmHg of pressure. The differences between the cylinder and the predicted are +/- 1mmHg, which are within the acceptable tolerances. There are, however higher difference between the cylinder and participant and the predicted and the participant. This is unlikely to be an error as the same pattern of larger differences can be seen in the 20% reduction factor results. As there are notable differences between the predicted and the participant readings for the delivery of 25mmHg and the 20% reduction factor it is possible to account for this in the way that pressure is exerted on the limb and that mean pressure readings are influenced by two or more readings taken from significantly higher or lower pressure values. The smaller differences between predicted pressures and the cylinder pressures support the effectiveness of predicted pressure values at 15mmHg and 25mmHg.

4.6.2 Correlations of pressure at 20% reduction

The predicted pressure was correlated to the limb circumference and the pressure exerted on the cylinder was correlated to the cylinder circumference, which was within 3mm of the limb circumference, and the pressure exerted on the participant was correlated to the limb circumference and was evaluated for significance at the 95% confidence level.

Table 9. Correlations of limb circumference to pressures at 20% reduction

circumference in cm		mean pressures in mmHg for:		
of patient limb	garment at 20%RF	predicted	cylinder	participant
13	10.8	42	31	23.5
16	13.2	35	26	20
16.1	13.3	35	29	23
17.6	14.5	32	30	21
19	15.6	30	24	20
21.2	17	27	26	15.3
22	18	26	29.3	17
22.5	18.4	25	25	23.5
23	18.8	25	25	13
23.5	19.2	24	24	15
correlation of results of limb,predicted,cylinder and participant		-0.99124	-0.64120	-0.68870

The results in table 9 show a minus figure for the correlations between limb circumference and predicted pressure, pressure exerted on the cylinder and pressure exerted on the participant indicating that as the limb size increased the pressure decreased. All these

correlations were significant at 95% confidence and indicates that as the measurement or circumference gets bigger the pressure gets lower.

4.6.3 Comparisons between pressure delivery for each garment design

The information in tables 6-8 was used to create combination bar and line charts which highlight the levels of pressure delivery at the range of circumference from the four participants. (Figures 13-18)

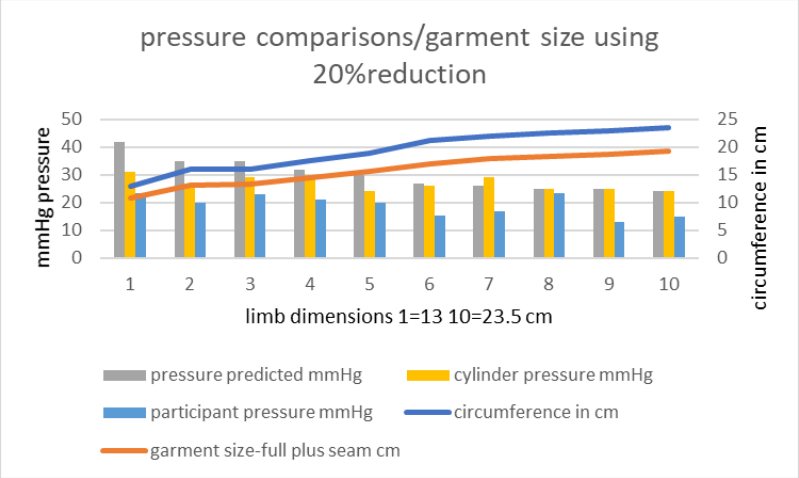
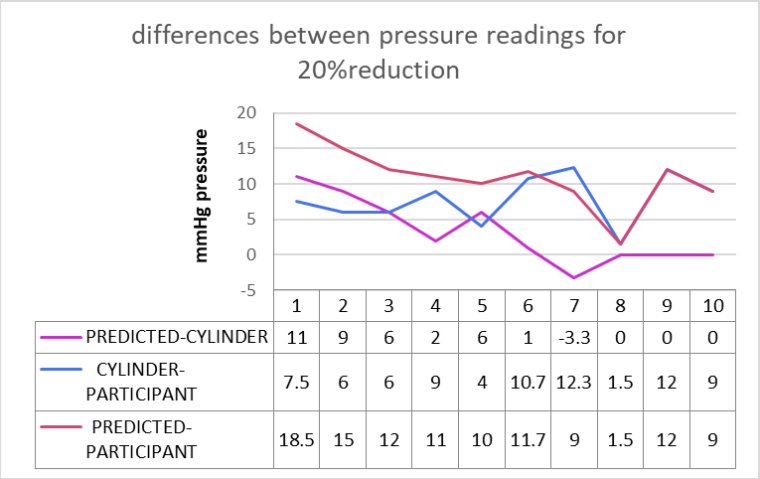


Figure 13. 20% reduction factor pressure comparisons/limb circumference

Figure 13 and Table 6 shows that the smaller the circumference of the limb the higher the pressure delivered when using a reduction factor. The opposite is also true, that the greater the limb circumference the lower the pressure delivered when using a reduction factor. The difference in the pressure delivery is due to the fabric properties not being considered when working out the finished dimensions for the pressure garment which allows for changes in pressure delivery over different limb dimensions.



	1	2	3	4	5	6	7	8	9	10
PREDICTED-CYLINDER	11	9	6	2	6	1	-3.3	0	0	0
CYLINDER-PARTICIPANT	7.5	6	6	9	4	10.7	12.3	1.5	12	9
PREDICTED-PARTICIPANT	18.5	15	12	11	10	11.7	9	1.5	12	9

Figure 14. Differences between mean pressures for 20% reduction factor

Figure 14 shows how variable the readings can be between the predicted and the solid cylinder form especially at small dimensions. This highlights how challenging it can be to obtain pressure readings on small dimensions. The difficulty is not only due to the size of the limb but also the need for the pressure sensor to be flat to obtain accurate readings which is very difficult on small dimensions. The variation in the data indicates that there is a lack of consistency across all circumferences.

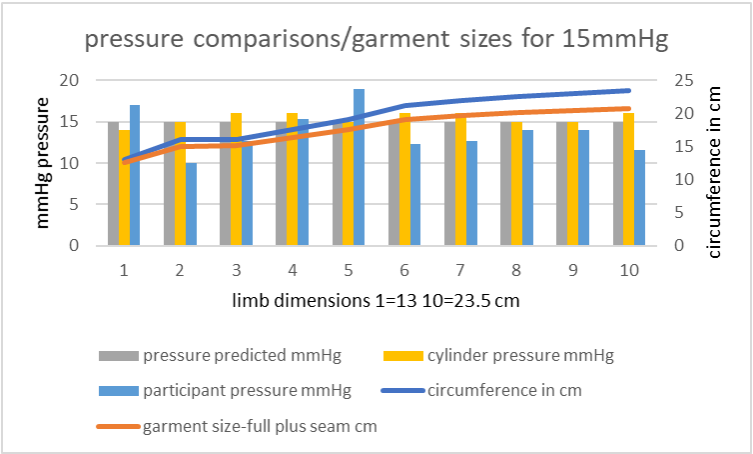
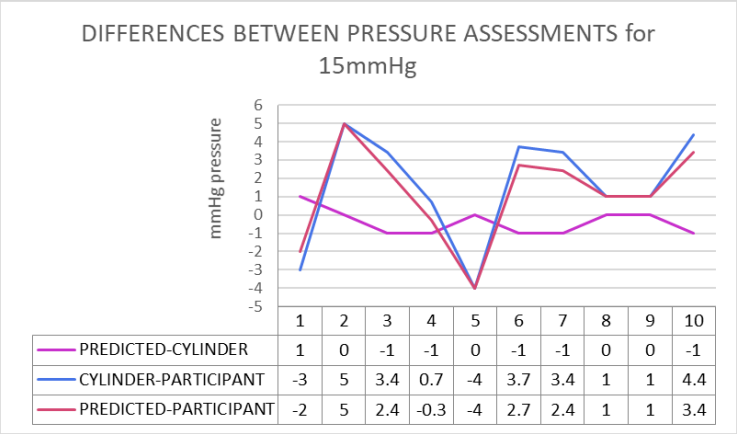


Figure 15. 15mmHg pressure comparisons/limb circumference

Figure 15 shows a more consistent pressure delivery with the predicted and cylinder reading confirming that the PGD tool is effective in producing a known pressure. The participant readings 15mmHg are very close to the predicted and the cylinder but never the same. The participant readings for the 20% reduction factor were noticeably lower than the cylinder and predicted.



	1	2	3	4	5	6	7	8	9	10
PREDICTED-CYLINDER	1	0	-1	-1	0	-1	-1	0	0	-1
CYLINDER-PARTICIPANT	-3	5	3.4	0.7	-4	3.7	3.4	1	1	4.4
PREDICTED-PARTICIPANT	-2	5	2.4	-0.3	-4	2.7	2.4	1	1	3.4

Figure 16. differences between mean pressures differences for 15mmHg pressure

Figure 16 shows the differences between predicted pressure of 15mmHg and the readings on the cylinder and the participant. There is a small variation in the predicted and the cylinder reading but it is within the tolerance level of +/-1mmHg. The differences between the cylinder and predicted are very close to each other, suggesting that the PGD tool has provided a consistent pressure. The readings from the participant when compared to the cylinder and the predicted also highlight very small differences of between 0.3 and 5mmHg, which confirms confidence in the delivery of pressure at this level using the PGD tool.

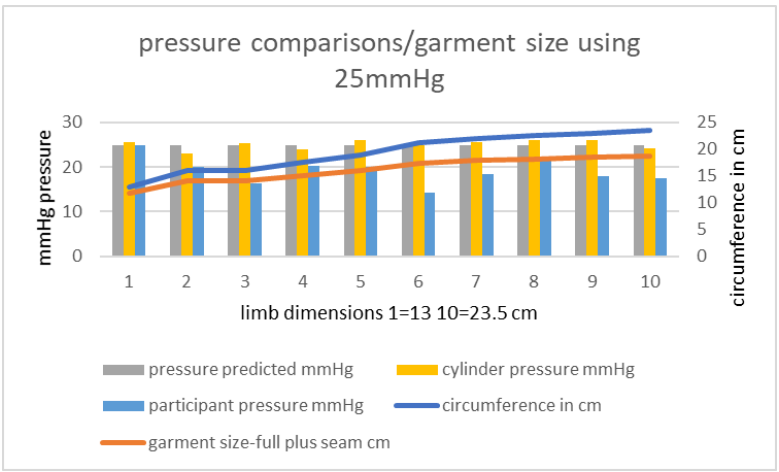
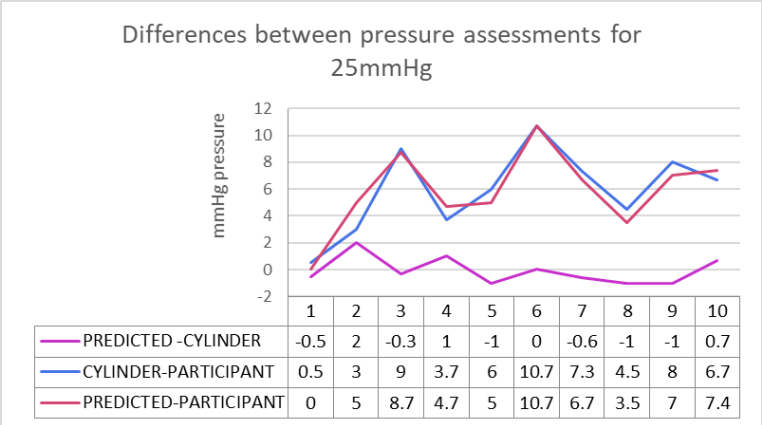


Figure 17. 25mmHg pressure comparisons/limb circumference

Figure 17 shows a balanced delivery of pressure with the predicted and the cylinder showing little variation. This chart shows that the PGD tool can be used to produce consistent pressure delivery at a higher level of 25mmHg.



	1	2	3	4	5	6	7	8	9	10
PREDICTED -CYLINDER	-0.5	2	-0.3	1	-1	0	-0.6	-1	-1	0.7
CYLINDER-PARTICIPANT	0.5	3	9	3.7	6	10.7	7.3	4.5	8	6.7
PREDICTED-PARTICIPANT	0	5	8.7	4.7	5	10.7	6.7	3.5	7	7.4

Figure 18. Differences between mean pressures for 25mmHg pressure

Figure 18 shows the differences between predicted pressure of 25mmHg and the readings on the cylinder and the participant. The differences between the predicted and cylinder is within the accepted tolerance of +/-1mmHg apart from point 2 which may be due to small dimensions and difficulty placing the pressure sensor especially when the garment is smaller. The difference between participant and the predicted and cylinder readings, which are between 0.5 and 10.7 suggests that the pressure readings are not accurate on the participant due to sensor distortion, or they are affected by the substance of the limb at higher pressures. The fleshy parts may disperse the pressure into the body whereas the bony part may provide a more solid base for pressure to be read and shows lower difference between the pressures being delivered. Macintyre (2006) and Atiyeh (2103) highlighted that the amount of subderminal pressure is not known and how it affects the veins close to the surface of the skin [2,9]. The differences shown between the cylinder and the participant in these results give an indication of the levels of pressure dispersed over different areas of the limb.

4.6.4 Individual participant pressures

The following charts show data for the individual corresponding to the measurements as they were taken up the arm and showing the pressures applied in each garment. This data highlights the variations of limb size that influence applied pressure that can be considered when tailoring treatment for each situation and specific scar needs.

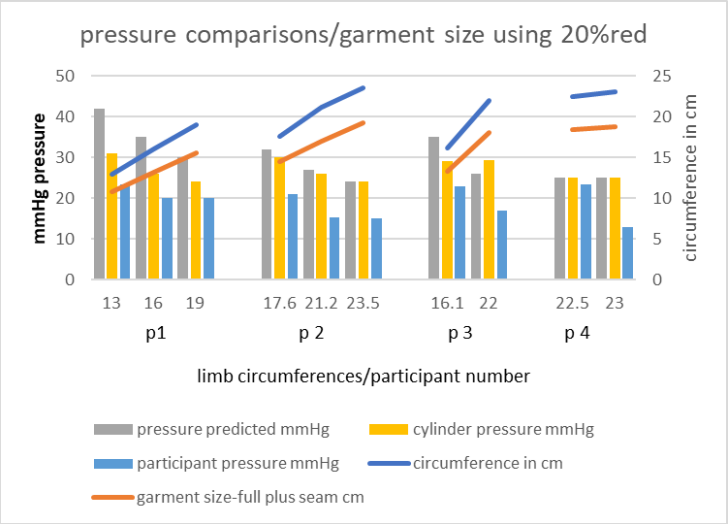
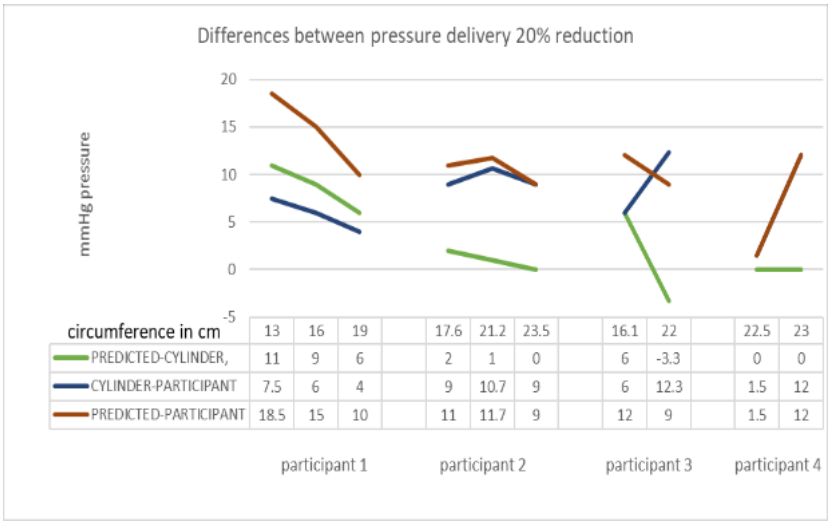


Figure 19. 20% reduction factor pressure comparisons/ limb circumference

Figure 19 highlights how variable pressure delivery is for individuals when using the reduction factor. The chart shows that as circumference increases pressure decreases. It can also be seen how as circumference decreases, the pressure increases, to a level that can be above 25mmHg which is the recommended safe level of pressure.



circumference in cm	13	16	19		17.6	21.2	23.5		16.1	22		22.5	23
PREDICTED-CYLINDER,	11	9	6		2	1	0		6	-3.3		0	0
CYLINDER-PARTICIPANT	7.5	6	4		9	10.7	9		6	12.3		1.5	12
PREDICTED-PARTICIPANT	18.5	15	10		11	11.7	9		12	9		1.5	12

Figure 20. Differences between mean pressures for 20% reduction factor

Figure 20 highlights the difference between the pressure outcomes for the individual using 20% reduction. There are only a couple of instances where any conformity can be seen in the data and this is at the larger circumferences.

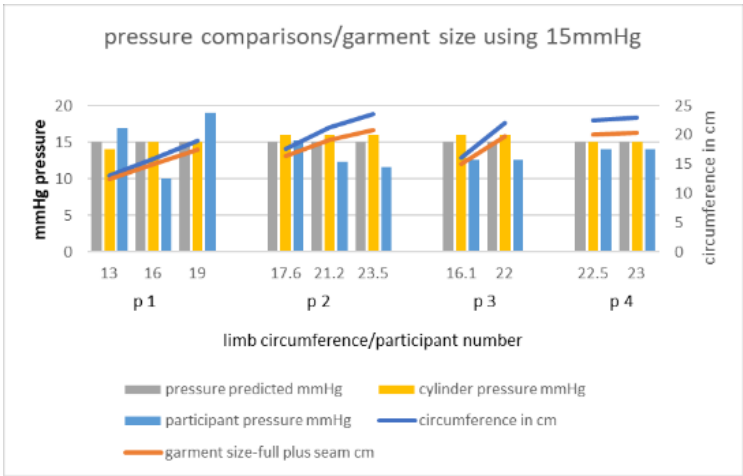
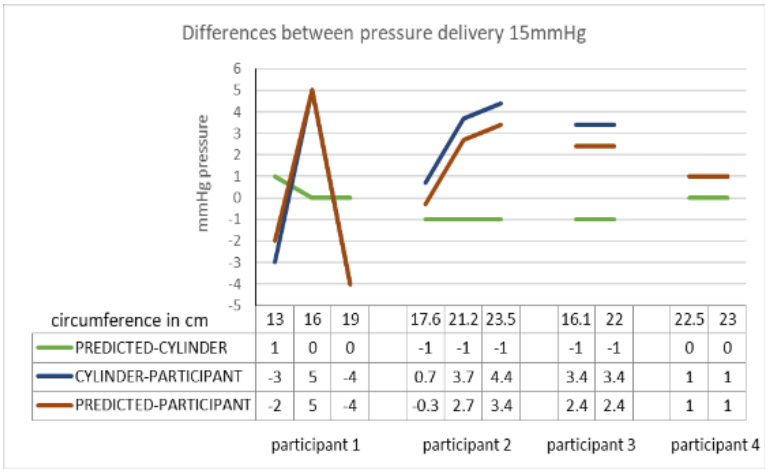


Figure 21. 15mmHg pressure comparisons/limb circumference

Figure 21 shows the changes in garment dimension, which gradually decrease with the increase in circumference to provide an even pressure along the garment. Compare these to the outcomes for the 20% reduction factor and the garment dimensions remain consistent along the length which affects the pressure delivery. The pressure measured on the cylinder support the use of the PGD tool to produce a garment with consistent pressure. The greater variations in the participant readings are seen at the smaller circumferences.



circumference in cm	13	16	19	17.6	21.2	23.5	16.1	22	22.5	23
PREDICTED-CYLINDER	1	0	0	-1	-1	-1	-1	-1	0	0
CYLINDER-PARTICIPANT	-3	5	-4	0.7	3.7	4.4	3.4	3.4	1	1
PREDICTED-PARTICIPANT	-2	5	-4	-0.3	2.7	3.4	2.4	2.4	1	1
	participant 1			participant 2			participant 3		participant 4	

Figure 22. Pressure differences for 15mmHg pressure

Figure 22 shows the predicted pressure of 15mmHg and the pressure readings on the cylinder are very close which confirms the effectiveness of the PGD tool. This can be seen to be true for the individual as the results are within the tolerance of +/- 1mmHg.

The small differences between the predicted or cylinder and participant support the effective delivery of the predicted pressure of 15mmHg.

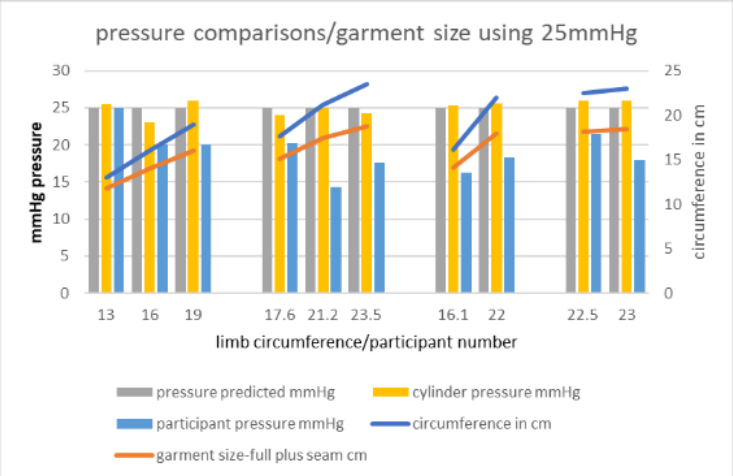
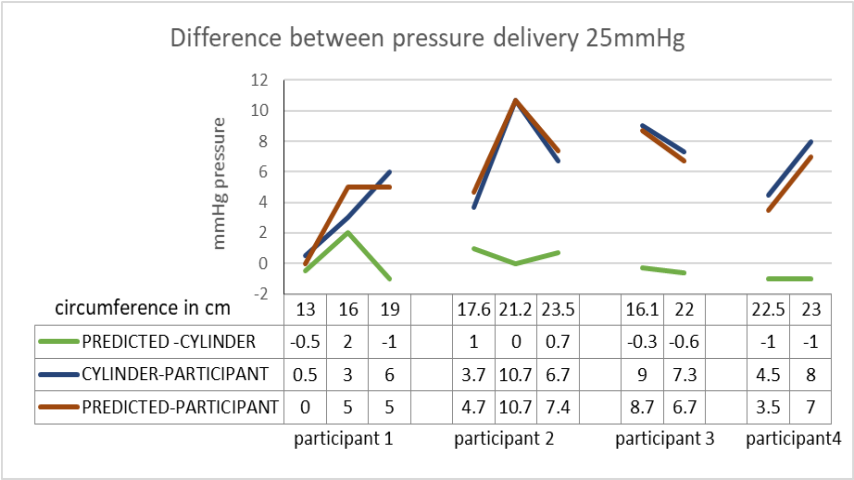


Figure 23. 25mmHg pressure comparisons/limb circumference

Figure 23 shows a consistency in the pressure registered on the cylinder and the predicted at a higher mmHg for the individuals and this highlights the close relationship between the predicted and cylinder readings at 25mmHg using the PGD tool. The variations in the participant readings are across all garment data which could indicate that the measurement of pressure on the individual is affected by the body mass and or the sensitivity of the sensor.



circumference in cm	13	16	19		17.6	21.2	23.5		16.1	22		22.5	23
PREDICTED -CYLINDER	-0.5	2	-1		1	0	0.7		-0.3	-0.6		-1	-1
CYLINDER-PARTICIPANT	0.5	3	6		3.7	10.7	6.7		9	7.3		4.5	8
PREDICTED-PARTICIPANT	0	5	5		4.7	10.7	7.4		8.7	6.7		3.5	7
	participant 1				participant 2				participant 3			participant4	

Figure 24. Differences between mean pressure readings for 25mmHg pressure

Figure 24 shows the effectiveness of the PGD tool in delivering a consistent pressure on the cylinder but there are some difference between the participant and predicted or cylinder readings. Looking at the variations in pressures on the individual at 25mmHg of pressure it is possible to see how important it is to be aware of the sensitivity of the sensor. Even with a known pressure delivery the variation on the participant between the

15mmHg and the 25mmHg shows some high variations. The extremes for participants may be due to pressure sensor problems over smaller dimensions and under smaller garments or taking readings on more fleshy areas of the limb.

Chapter 5: Discussion of results

In the process of planning for the research and putting in place the crucial elements to get it going there have been many challenges. The logistics of completing the necessary paperwork and ethics forms is difficult in the work environment as keeping track of paperwork and email gets more difficult as things progress especially when things cannot be kept in one place. Preparation for work away from the hospital had to adhere to patient confidentiality guidelines and therefore cross referencing on notes and garment records were put in place. This was important as the sewing room is on a different site to the main hospital, so it was necessary to keep items safely and carefully filed after doing any research work.

The hospital environment is challenging due to the work load and quick turnaround of patients so fitting research in to a clinic schedule needs good planning. The small number of participants made this easier and the research fitted into normal therapy sessions well. This would have been more difficult to manage had there been more participants and no specific treatment room assigned.

5.1 Suitable work space

The rooms where clinics are held vary depending on the location in the hospital and some have no suitable desk space which made using the equipment a problem even though it is very small. Most clinical rooms have a high volume of use and setting aside space for research was challenging at times as restricting access was not possible especially in treatment rooms. Treatment rooms are very difficult spaces to work in as no desk space is available only high work benches which over stretched the monitor tube that links to the sensor which is delicate, but also meant there was a high risk of dropping the monitor. The availability of seating was also an issue as chairs were needed to be able sit close to the work space, but treatment rooms need to be hazard free. Using the same work place for using sensor equipment would be ideal but busy hospitals cannot always provide this due to demands on space.

The placement of the monitor on a safe work space is essential if one person is placing the sensor. It is not possible to hold on to the monitor and work on the participant. The placement of the monitor on a desk top means less fluctuation in the readings as it is

possible to note variations due to movement or difficult posture. It is essential to ensure the participant is sat comfortably and safely.

5.2 Participant Pressure readings

Pressure reading equipment was not available at the Sheffield Children's Hospital and application for funding was unsuccessful. When the initial protocol was submitted to the research department there was no funding available for research projects. Application was made later but the need for the equipment was not seen a justified by the Reviewing body for research support. The difficulty in the purchase of equipment highlights the need for other ways to assess therapy and looking at new approaches to methods used.

The process of taking pressure readings is fiddly and frustrating. Although plenty of practice was undertaken in the use of the pressure monitor and taking readings on the cylinders this does not prepare for use in clinic with participants. Placing the soft balloon sensor between garment and limb is challenging as the sensor easily folds or pleats as the small area for placement and the fabric create a conflict of surfaces. The fabric squeezes as it is released from being raised to place the sensor which is placed flat on the skin. Trying to align the sensor to the measurement point and get it flat presented difficulties which could be overcome with the tolerance of the participant. When you get to know the individual, this task is much easier as you are both more relaxed and able to work together.

However, these difficulties will have impacted on the accuracy of the pressure measurements made on the participants. Therefore, measurements were made on cylinders before fitting the garments and these measurements are likely to be more accurate indications of the garment compression than the measurements taken on children's limbs. The number and location of measurements made on the limbs will also have impacted on the mean pressure exerted and accounts for some of the variability in measurements.

5.2.1 Participant sensitivity

There is a marked difference in taking pressure readings on an adult and a child as not only the physiology has an impact on the ease of taking pressure readings, but the behaviour does too. The pressure sensor is very sensitive, and it gave very different readings if the limb was not held still or if the child tensed up due to apprehension regarding someone touching the scar site. The comfort and wellbeing of the participant was important when gathering information. In some instances, it became obvious that

pursuing further sensor placement was causing discomfort and would cause distress due to the length of time taken to get correct placement especially in the more restricted areas. For this reason, some pressure readings were not available after the initial fitting but were taken using new garments at a later clinic. If time allowed extra readings were taken.

5.2.2 Garment fitting

The age group of the participants made the fitting of the garments and the compliance less challenging. Younger children find this more difficult and do not appreciate being restricted by people trying to treat them or cause them extra anxiety.

The challenge for our participants was having three garments fitted and reviewed by the therapist and then having to repeat the process for pressure readings to be taken by the researcher. In one instance the participant found this difficult to cope with so pressure measurements were limited. A second set of initial garments were used at a later clinic to confirm pressure measurements. This was possible as the participant had become more settled and familiar with the process.

The trauma of being injured is difficult enough for young people so trying to carry out pressure readings during normal clinic would generally be frowned upon. This therefore restricts the collection of important data to assess the best pressure levels for healing of scar sites. The difficulties of collecting pressure information would therefore be eased if there was a way to produce garments with a known pressure, such as the use of the PGD tool in garment design. Even in this small study the monitoring of pressure was challenging, and it would be unrealistic to expect pressure readings to be collected at regular intervals.

This small study has provided some interesting insight into the pressures being delivered on patients using three different designs, 20% reduction factor, 15mmHg and 25mmHG. The 20% reduction factor is standard practice at Sheffield children's Hospital, but it is done manually. The Pressure Garment Design tool can be provided to produce reduction factor measurements as well as those for known pressure which makes it a very versatile method which can also be designed to produce garments with graduated compression. This study set out to look at the effective use of the Pressure Garment Design tool to deliver a known pressure. The collated information shows that the pressure measurements on the cylinder were very close to the predicted pressure measurements and support the effectiveness of the Pressure Garment Design tool. As collecting pressure readings is so challenging, especially on children, being able to produce

garments delivering a known pressure would make the collecting of effective pressure therapy information much easier. The delivery of a known pressure on children would be more ethical and could be supported by pressures testing on adults to confirm accuracy of the Pressure Garment Design Tool.

The information has also highlighted the big differences between the pressure deliveries on the participant and the cylinder. The big differences that occur are seen in all the charts which would suggest that it was not a fault with the researcher. The pressure readings on the cylinder are within the +/- 1mmHg tolerance and this suggests the pressure being delivered is an effective use of the Pressure Garment Design tool to deliver a known pressure.

The pressure Garment Design tool has proved to be easy to use for the reduction factor to check on pressure delivery and to produce garment dimensions to deliver a known pressure applying the Pressure Garment Design tool based on the Laplace law.

Chapter 6: Conclusions

The objectives were;

1.To build a Pressure Garment Design Tool for sleeknit fabric used at Sheffield Children's Hospital.
This was done and used successfully in the study.

2.To establish the pressure used historically at Sheffield Children's Hospital for pressure therapy.

Pressures exerted in 8 garments made between January 2016 and October 2016 for children's arms, ranged from 28mmHg-52 mmHg and for children's legs ranged from 15mmHg-39mmHg mmHg. This confirms that using a 20% reduction factor (the standard method) results in a wide range of different pressures being exerted on different people.

3. To establish how easy it is to use the PGD tool in a hospital environment and compare this to the traditional, manual, method of calculating pressure garment dimensions.

The pressure Garment Design tool is easy to use and is recommended for clinical use. The patient information is easily entered in the applicable boxes and once a required pressure is applied the garment dimension are calculated by the tool. The garment information can be managed and adjusted if required and new data sheets saved for future reference and printed off to keep in the patient notes if required. Using the Pressure Garment Design tool, it will be possible to support the training of staff in the effective application of pressure therapy as during garment fitting they will be able to understand and see the effects of applying a known pressure. It is a useful tool to have at hand and if used in conjunction with the tested fabric offers the option to produce graduated compression which would be useful.

4. The research set out to compare the pressure exerted by a reduction factor of 20% used at Sheffield Children's Hospital and predicted pressures of 15mmHg and 25mmHg.

The data collated from garments designed to deliver 15mmHg and 25mmHg of pressure indicated the Pressure Garment Design Tool was reliable and accurate in the outcomes for garment size and pressure. The 20% reduction factor tool over predicted high pressures on small limbs according to the cylinder pressures. In all three garment designs the pressures on the participant were much lower than expected. This supports findings of other researchers experience when taking pressure readings on the patient which has led to questioning the accuracy of the pressure sensor. The differences between the predicted and the participant pressure readings were greatest on the smaller circumferences which could be due to the difficulties of sensor distortion and accuracy over small circumferences. There is also the suggestion that pressures applied over fleshy areas are dispersed sub dermally which may also account for the differences seen between the cylinder and participant readings with the higher pressures. The accuracy of the Pressure Garment Design Tool and its ease of use could help to analyse the differences in pressure delivery on the patient and predicted pressures especially when looking at soft tissue areas.

5.To establish whether the consideration of fabric stretch and patient dimensions using the Laplace Law offers a more effective therapy garment.

Due to the limited number of participants it was not possible to draw any conclusions regarding the effectiveness of the therapy garments. It was possible to see that the requirements and comfort of the individual are important in the use of pressure therapy and that the Pressure Garment design tool could establish the base level pressures to work from when producing garments that present fit challenges. Some of the participants chose a garment as it felt the best and caused less swelling to the hand. One chose a garment they identified as delivering the greatest pressure as they believed that was good for treating the scar. During the initial fitting which is always a challenge, all the participants were concerned about the way all the pressure garments felt and were apprehensive about being able to tolerate even the lowest pressure. Being able to trial the three garments was an opportunity for them to come to terms with pressure therapy and select a garment that suited them which may be worth considering as compliance is one of the challenges of pressure therapy.

6.1 Limitations

It was only possible to recruit 4 participants during the period we had ethics approval for. This was disappointing in terms of the amount of data that could be generated.

The small number of participants and the 6 months' time scale of the project did not generate enough information to draw any conclusion regarding therapy effectiveness. The questionnaires did give an indication that not all participants would necessarily favour one garment design. It is probably safer to say that individuals would prefer to be able to have some input to achieve the most comfortable fit and most effective pressure for their needs.

Chapter 7: Recommendations

This research project has been able to apply the Pressure Garment Design tool in a practical setting and to look at its effectiveness in delivering a known pressure. The pressure readings on the cylinder confirm the pressures were within the acceptable tolerance of +/- 1mmHg. It was not possible in such a small study however to explain the larger anomalies seen in the participant pressure readings compared to those of the predicted and cylinder. Further studies into the delivery of a known pressure on the participant with garments produced using the Pressure Garment Design tool would help to confirm whether lower pressure readings on a participant of a certain size, shape and build are to be expected.

The Pressure Garment Design Tool has only been used to produce arm and leg sleeves so far as other parts of the body may need a different application or variation to the charts to consider variations in physique, the fleshy and bony areas. Further studies into pressure delivery on participants would help to clarify how pressure garments perform over different areas of the body and the effectiveness of the garments.

The impact of the fleshy and bony part on pressure readings should be investigated further to establish if there is a requirement to adapt garments so that therapy is not ineffective or too aggressive.

Further studies using the Pressure Garment Design tool to deliver a known pressure would ideally collate information regarding healing progress and the final outcomes after scar management and pressure values applied during the therapy.

The pressure Garment Design tool can be used with confidence to deliver known pressures and would eliminate the need for pressure readings to support the effectiveness of pressure therapy. Taking pressure readings in clinical practice is not practical in the limited time available for therapists conducting clinics as the pressure sensor equipment is challenging and time consuming to use and is one reason there is little data available. Information from the Pressure Garment Design Tool would be easy to collate from burns units able to use it and help contribute to the understanding of suitable pressures to be used in therapy.

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Appendix 1. Training certificate

NHS
National Institute for Health Research
Clinical Research Network

CERTIFICATE of ACHIEVEMENT

This is to certify that

DAWN SYRON-JONES

has completed the course

Introduction to Good Clinical Practice eLearning (Primary Care)

July 24, 2017

Modules completed:

Introduction to Research in the NHS
Good Clinical Practice and Standards in Research
Study Set Up and Responsibilities
The Process of Informed Consent
Data Collection and Documentation
Safety Reporting

This course is worth 4 CPD credits

CPD
The CPD Certification Service

National Institute for Health Research
Clinical Research Network

Appendix 2 Fabric sample coefficient of variation percentages

Black samples 1-5
F0227 18789

mean	SD	%CV
5dp	2dp	3dp
1.13340	0.87	76.553
9.39592	1.07	11.405
15.17636	1.23	8.117
20.80484	1.47	7.058
26.09308	2.79	10.694
31.41112	3.65	11.632
36.91080	4.34	11.746
42.44852	5.45	12.842
47.93948	5.92	12.346
53.09528	6.63	12.491
58.36436	7.35	12.595
63.52780	7.82	12.302
68.40844	8.36	12.220
73.47224	8.10	11.026
77.94776	9.11	11.683
82.98620	8.59	10.355
87.91128	8.09	9.199
92.53068	8.31	8.979
97.67888	8.14	8.336
101.70796	7.76	7.633
106.86316	7.81	7.309
111.77036	7.78	6.956
116.74076	7.45	6.382
121.46140	6.97	5.736
126.62048	6.88	5.432
131.40600	6.66	5.069
136.24992	6.31	4.629
141.32328	6.18	4.374
146.05040	5.80	3.970
151.34768	5.53	3.657
156.22564	5.12	3.275
161.39212	5.27	3.265
166.12832	4.93	2.966
171.25232	4.89	2.854
176.29032	4.65	2.640
181.46804	4.95	2.728
186.56480	4.92	2.640
191.63072	5.41	2.824
196.66076	5.67	2.886
201.87380	6.02	2.981
206.84112	6.14	2.970
212.31356	6.45	3.037
217.25680	6.77	3.118
222.70336	6.59	2.960
228.28572	7.27	3.187
233.83336	7.47	3.196
239.48332	7.52	3.139
245.38292	8.10	3.301
251.47964	8.08	3.212
257.22992	8.57	3.333
263.24184	8.75	3.324
269.26804	8.87	3.294
276.03920	9.34	3.384
282.72472	9.62	3.401
289.68200	10.09	3.483
296.88064	10.34	3.484
304.22772	10.80	3.550
311.55816	11.28	3.620
319.31664	11.42	3.576
327.29264	12.14	3.710
336.01304	12.40	3.691
344.96940	13.12	3.803
353.97408	13.32	3.764
363.71020	13.90	3.822
373.74532	14.32	3.832

Black samples 6-10
FM0227 18789

mean	SD	%CV
5dp	2dp	3dp
1.24320	0.39	31.542
9.57460	0.89	9.275
16.06196	1.35	8.433
22.06316	2.12	9.625
28.15352	3.03	10.770
33.73300	4.21	12.495
39.46940	4.82	12.223
45.33380	5.81	12.821
51.02404	6.43	12.596
56.88988	6.85	12.033
62.41044	7.30	11.699
67.60660	7.26	10.740
73.07580	6.95	9.509
78.38672	6.51	8.309
83.39228	6.56	7.860
88.53580	5.98	6.751
93.44180	5.95	6.373
98.37644	5.39	5.474
103.33800	4.96	4.802
107.98168	4.68	4.336
112.89588	4.10	3.631
117.40264	4.07	3.466
122.10624	4.06	3.325
126.64352	3.98	3.145
131.29704	4.00	3.048
135.75300	3.67	2.706
140.04172	3.62	2.583
144.51424	4.07	2.817
149.26312	4.08	2.730
153.36392	3.81	2.484
158.24880	3.97	2.511
162.87476	3.44	2.110
167.45684	4.23	2.527
172.14368	3.97	2.306
176.55344	4.08	2.308
181.57168	3.77	2.079
186.45716	4.13	2.218
190.99836	4.08	2.137
195.85544	4.40	2.248
200.62456	4.45	2.218
205.37884	4.41	2.147
210.72248	4.61	2.189
215.35728	4.52	2.098
220.59960	4.66	2.112
225.97428	4.82	2.135
231.28036	5.17	2.235
236.67748	4.89	2.067
242.07432	5.39	2.227
247.97116	5.34	2.154
253.63992	5.38	2.122
259.60308	5.52	2.127
265.89032	5.54	2.085
271.87256	5.82	2.139
278.12008	5.88	2.115
284.88316	6.19	2.174
291.55552	6.10	2.094
298.61044	6.76	2.264
306.05492	6.89	2.252
313.48980	7.00	2.232
321.10636	7.18	2.238
329.46660	7.40	2.245
338.32620	7.95	2.350
346.86644	8.16	2.354
355.66156	8.75	2.461
365.10132	8.51	2.332

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mean	SD	%CV
5dp	2dp	3dp
0.87704	0.39	44.542
7.43988	0.64	8.624
12.53488	0.72	5.737
18.14960	0.61	3.350
23.46440	0.78	3.327
28.24380	0.38	1.339
33.42108	0.70	2.105
38.73940	0.69	1.771
43.40568	0.90	2.081
48.11856	0.64	1.334
52.78880	0.52	0.990
57.16176	1.01	1.772
62.03156	0.99	1.591
66.19208	0.49	0.733
70.20532	1.13	1.606
74.20600	0.87	1.167
78.46668	0.78	0.991
82.38184	0.59	0.720
86.36684	0.73	0.846
90.65148	0.65	0.721
94.31296	0.85	0.904
98.27556	0.57	0.581
102.14316	0.91	0.891
106.04188	0.59	0.560
109.77624	1.02	0.929
113.47936	1.12	0.987
117.52844	1.39	1.183
121.32384	1.21	0.998
125.03368	1.37	1.093
128.97288	1.53	1.184
132.99032	1.42	1.066
136.73164	1.68	1.228
140.94228	1.74	1.233
144.50720	1.92	1.328
148.69488	1.67	1.121
152.37972	2.19	1.437
156.84604	2.17	1.381
160.97736	2.09	1.300
165.20940	2.22	1.346
169.25200	2.34	1.382
173.65156	2.61	1.501
178.01004	2.33	1.308
182.23528	2.41	1.324
186.36008	2.69	1.442
190.82484	2.25	1.180
195.58048	3.04	1.553
199.91672	2.88	1.442
204.72504	3.20	1.562
209.84824	2.95	1.408
214.57936	3.36	1.568
219.41552	3.52	1.603
224.77400	3.60	1.603
229.83308	3.66	1.594
235.38776	4.13	1.754
241.03324	3.98	1.653
246.50716	4.44	1.799
252.40484	4.50	1.782
258.18440	4.94	1.914
264.40052	5.21	1.969
270.92396	5.20	1.919
277.22368	5.18	1.870
283.95112	5.72	2.016
291.02812	6.03	2.071
298.29636	6.38	2.139
306.00008	6.66	2.175

Appendix 3 . Individual participant pressure readings showing confidence intervals.

PARTICIPANT 1			sensor placement							CONFIDENCE INTERVALS	
			point2					1.4142 SQRT			
PGD tool		mmHg	mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI		
25mmHg	cylinder		25	26	25.50	0.71	0.50	24.50	26.50		
	participant		25	25	25.00	0.00	0.00	25.00	25.00		
15mmHg	cylinder		14	14	14.00	0.00	0.00	14.00	14.00		
	participant		15	19	17.00	2.83	2.00	13.00	21.00		
20%red	cylinder		31	31	31.00	0.00	0.00	31.00	31.00		
	participant		24	23	23.50	0.71	0.50	22.50	24.50		
			sensor placement								
PARTICIPANT 1			point 4	point 4			1.732 SQRT				
PGD tool		mmHg	mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI		
25mmHg	cylinder	22	23	23	22.67	0.58	0.33	22.00	23.33		
	participant	20	20	20	20.00	0.00	0.00	20.00	20.00		
15mmHg	cylinder	15	15	15	15.00	0.00	0.00	15.00	15.00		
	participant	10	10	10	10.00	0.00	0.00	10.00	10.00		
20%red	cylinder	26	25	26	25.67	0.58	0.33	25.00	26.33		
	participant	20	20	20	20.00	0.00	0.00	20.00	20.00		
		sensor placement									
PARTICIPANT 1			point 6	point 6			1.4142 SQRT				
PGD tool		mmHg	mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI		
25mmHg	cylinder		26	26	26.00	0.00	0.00	26.00	26.00		
	participant		20	20	20.00	0.00	0.00	20.00	20.00		
15mmHg	cylinder		15	15	15.00	0.00	0.00	15.00	15.00		
	participant		12	12	12.00	0.00	0.00	12.00	12.00		
20%red	cylinder		25	23	24.00	1.41	1.00	22.00	26.00		
	participant		22	18	20.00	2.83	2.00	16.00	24.00		
PARTICIPANT 2			sensor placement								
			point 2	point 2	Point 2					CONFIDENCE	INTERVALS
PGD tool		mmHg	mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI		
25mmHg	cylinder	24	24	24	24.00	0.00	0.00	24.00	24.00		
	participant	23	19	19	20.33	2.31	1.33	17.67	23.00		
15mmHg	cylinder	16	16	16	16.00	0.00	0.00	16.00	16.00		
	participant	15	12	19	15.33	3.51	2.03	11.28	19.39		
20%red	cylinder	29	31	29	29.67	1.15	0.67	28.33	31.00		
	participant	25	18	19	20.67	3.79	2.19	16.29	25.04		
			sensor placement								
PARTICIPANT 2			point 3	point 3			1.4142 SQRT			CONFIDENCE INTERVALS	
PGD tool			mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI		
25mmHg	cylinder		24	26	25.00	1.00	0.71	23.59	26.41		
	participant		16	14	15.00	0.71	0.50	14.00	16.00		
15mmHg	cylinder		16	15	15.50	0.35	0.25	15.00	16.00		
	participant		14	12	13.00	0.71	0.50	12.00	14.00		
20%red	cylinder		26	26	26.00	0.00	0.00	26.00	26.00		
	participant		15	16	15.50	0.35	0.25	15.00	16.00		

	participant			15	16	15.50	0.55	0.25	15.00	16.00
PARTICIPANT 2			sensor placement							
			point 5	point 5	point 5			1.732 SQRT	CONFIDENCE INTERVALS	
PGD tool			mmHg	mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI
25mmHg	cylinder		25	24	24	24.33	0.58	0.33	23.67	25.00
	particpant		16	19	18	17.67	1.53	0.88	15.90	19.43
15mmHg	cylinder		17	16	15	16.00	1.00	0.58	14.85	17.15
	particpant		10	13	12	11.67	1.53	0.88	9.90	13.43
20%red	cylinder		23	25	24	24.00	1.00	0.58	22.85	25.15
	particpant		15	15	15	15.00	0.00	0.00	15.00	15.00
PARTICIPANT 3			sensor placement							
			point 3	point 3	point 3			1.732 SQRT	CONFIDENCE INTERVALS	
PGD tool			mmHg	mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI
25mmHg	cylinder		26	25	25	25.33	0.58	0.33	#REF!	26.00
	particpant		17	16	16	16.33	0.58	0.33	15.67	17.00
15mmHg	cylinder		16	16	15	15.67	0.58	0.33	15.00	16.33
	particpant		13	13	12	12.67	0.58	0.33	12.00	13.33
20%red	cylinder		28	30	29	29.00	1.00	0.58	27.85	30.15
	particpant		23	23	23	23.00	0.00	0.00	23.00	23.00
PARTICIPANT 3			sensor placement							
			point 6	point 6	point 6			1.732 SQRT	CONFIDENCE INTERVALS	
PGD tool			mmHg	mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI
25mmHg	cylinder		27	25	25	25.67	1.15	0.67	24.33	27.00
	particpant		21	19	15	18.33	3.06	1.76	14.81	21.86
15mmHg	cylinder		16	16	16	16.00	0.00	0.00	16.00	16.00
	particpant		12	13	13	12.67	0.58	0.33	12.00	13.33
20%red	cylinder		30	30	28	29.33	1.15	0.67	28.00	30.67
	particpant		16	20	20	18.67	2.31	1.33	16.00	21.33
PARTICIPANT 4				sensor placement						
				point 2	point2			1.4142 SQRT	CONFIDENCE INTERVALS	
PGD tool				mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI
25mmHg	cylinder			26	26	26.00	0.00	0.00	26.00	26.00
	particpant			22	21	21.50	0.71	0.50	20.50	22.50
15mmHg	cylinder			15	15	15.00	0.00	0.00	15.00	15.00
	particpant			14	14	14.00	0.00	0.00	14.00	14.00
20%red	cylinder			25	25	25.00	0.00	0.00	25.00	25.00
	particpant			25	22	23.50	2.12	1.50	20.50	26.50
				sensor placement						
PARTICIPANT 4				point 4	point 4				CONFIDENCE INTERVALS	
PGD tool				mmHg	mmHg	mean mmHg	SD	SE	LCI	UCI
25mmHg	cylinder			26	26	26.00	0.00	0.00	26.00	26.00
	particpant			21	15	18.00	4.24	3.00	12.00	24.00
15mmHg	cylinder			15	15	15.00	0.00	0.00	15.00	15.00
	particpant			12	16	14.00	2.83	2.00	10.00	18.00
20%red	cylinder			25	25	25.00	0.00	0.00	25.00	25.00
	particpant			13	13	13.00	0.00	0.00	13.00	13.00

Sheffield Children's NHS
NHS Foundation Trust

FULL STUDY TITLE Evaluating standardised pressure for garments used in scar management. A feasibility study of pressure garment therapy for children between 6 and 16 at the burns clinic at Sheffield Children's Hospital.

SHORT STUDY TITLE Pressure for burns scar therapy

STUDY NUMBER SCH 2224

DATE AND VERSION NUMBER 07/12/2017 V2

Sponsor's Representative DR. PAUL DIMITRI Dated ……..

Principal Investigator Dawn Syron-Jones Dated …07/12/2017……..

LAY SUMMARY (max 300 words)

Pressure garments are used to treat scars after major trauma such as burns. Some hospitals have in house teams that make bespoke pressure garments for patients. These garments are made using body measurements taken in clinic and manually applying a reduction factor to create tight fitting garments from lycra fabric. The reduction factor is used to apply pressure, which varies depending on the size of the limb and the fabric. Producing garments manually means there is little evidence of the pressure being delivered. Pressure sensor equipment is difficult to use in clinic to measure pressure and very little work has been done in the collating such information. The manual method of design for garments does not consider the impact that limb size or fabric stretch has on pressure being delivered. A pilot study highlighted the difference in pressure exerted by a range of garments by entering historical data into a computer programme that uses the La Place law to factor in the values of fabric stretch and limb dimensions. The pilot study showed that current methods exert between 15mmHg and 54mmHg on patient's limbs.

This study will compare the reduction factor which applies an unknown pressure, with a data programme that applies a known pressure. Three garments will be produced for the participant to trial, one using the reduction method currently used and two using different levels of known pressure. One of which will be selected by the participant for the continuation of the study. All garments will be assessed by the therapist to ensure that they are suitable for use by the Participant. During the study the pressure will be measured using pressure sensors and the scars assessed for healing progress. The data collected will confirm the pressure applied and which garments provide the desired fit and performance preferred by the participant.

GENERAL INFORMATION

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GLOSSARY

La Place Law- physical law that describes the relationship between pressure (in this case garment pressure on the body), tension (in this case fabric tension) and circumference (in this case limb circumference)

Cotton Lycra- fabric used in garments for pressure therapy

Reduction factor- manual method using a percentage reduction to achieve pressure

Sleeknit- the fabric construction

2.0 BACKGROUND (max 600 words))

The study will evaluate the participants preference for a pressure garment which will deliver either a standard graduated pressure or an unknown pressure.

There is very little supporting research for the effective outcomes of pressure therapy [1 2, 3, 4, 5,6,7] due to the individual approach to garment making, variation in pressures achieved using the normal reduction factor method and lack of pressure monitoring in hospitals. It is the purpose of this research to apply this new tool already used commercially to evaluate the pressures exerted on our patients and to establish the benefits and limitations of using limb circumference and fabric stretch/Tension to assess the outcomes of standardised pressure delivery.

Macintyre [4] has developed a computer programme that makes the Laplace Law method of pattern size calculation accessible to therapists [4]. First the fabric to be used is tested and then equations describing the Tension profile of the fabric are built into a pressure garment design tool to enable the pressure at any given body circumference and fabric Tension to be calculated. Using the data from fabric testing and entering patient measurements into the Pressure Garment Design (PGD) Tool it is possible to simultaneously calculate garment/pattern dimensions and produce a record of garment size and pressure achieved on each body part [4].

An audit of current practice was carried out to ascertain the pressures being delivered with arm and leg sleeves using a 20% reduction factor which has been standard practice in many burns units in UK [3] and at Sheffield Children's hospital for over 10 years. The current fabric used at the Sheffield Children's Hospital was tested to obtain performance data and the results were entered in to the Pressure Garment Design (PGD) Tool (based on our fabric performance) using historical measurements. The results of this audit showed pressures between 15mmHg and 54mmHg had been delivered to children's limbs, which shows a large variation in the pressures delivered within the patient group audited. Research has suggested that the ideal pressure is 25mmHg [6] and this is not possible to achieve using our current method of calculating garment dimensions.

This proposed study will use a computerised data programme titled PGD tool [1]. The PGD tool combines the properties of physical stretch, tension of fabric and the circumference of the limb to deliver known pressures. The delivery of standard therapeutic pressure applied to the production of pressure garments used to treat burn scars for children will be assessed by comparing the Manual Reduction method currently used to design and produce pressure garments and the computerised PGD tool method.

The manual reduction method reduces the measurements of the patient by a standard 10-20% on all body parts regardless of the body size, this is used to produce in-house pressure garments which are then smaller than the body they are to fit and thereby to apply pressure. The pressure applied is greatly variable and can be between 19 to 52mmHg [2] depending on the size of the limb and the fabric used. Macintyre (2013) highlights that the pressures delivered can be ineffective or dangerous, potentially compromising vascular function, especially when used on children [2,3].

The PGD tool calculates the required garment's size freeing up therapists' clinical time for patients as we envisage fewer garment alterations being required. Using exact measurement techniques to ensure consistency will mean that all burns units will be able to provide information for use in outcome audits.

STUDY OBJECTIVES AND PURPOSE (max 300 words)

This study is part of a Research Masters and will try to establish if patients prefer the pressure garment exerting a standardised graduated pressure profile or the pressure garment made using the traditional method utilised in Sheffield Children's Hospital. The data collected using the Picopress pressure sensor will show which garment delivers pressure closest to 25mmHg (accepted in the literature as the ideal pressure for treatment). By combining the feedback from participants and clinical observations supported by pressure data it is the purpose of the study to support the use of the PGD tool which produces garments with a known pressure that is safer for the therapy of patients.

Aim

To compare garments produced using the Garment design tool and the manual method to establish the most effective delivery of 'ideal' pressure and fit for burns therapy.

Objectives

6. To develop and evaluate a more user friendly measuring format for recording patient dimensions and garment needs.
7. To develop children's measurement charts that support effective measuring techniques.
8. To build a pressure garment design tool for the sleek knit fabric used at Sheffield Children's Hospital.
9. To establish the pressure used historically at Sheffield Children's Hospital for pressure garment therapy.
10. To compare the pressures exerted by garments made using reduction factor and Laplace Law using the pressure garment design tool method for production of final pattern.
11. To establish whether the consideration of fabric stretch and patient dimensions using the Laplace Law offers a more effective therapy garment.

Using the combined information of pressure readings and the feedback forms, the performance of each garment will be recorded, providing evidence for the levels of pressure for beneficial therapy.

3.0 STUDY DESIGN (max 600 words)

The proposed research will be a double-blind feasibility study conducted in the Burns unit at Sheffield Children's Hospital. Scar management is undertaken with inpatients and in outpatient's clinics. The provision for pressure therapy will not be compromised and patients will receive burns care complying with accepted clinical practice. The study will look at the provision of garments for arms and legs for children aged between 6 and 16 years.

using sleeknit (cotton and elastane) fabrics as is standard in burns therapy.

Prior to healing the therapist discusses options for treatment with the parents/carers and patients. It is appropriate for the research project to be introduced at this point. If the patient and carer show an interest in opting in the researcher will discuss the study and what it involves and provide the relevant information sheets. The researcher will discuss with parents informed consent, and the child informed assent as appropriate. After healing and when the patient is ready to be fitted for a garment a member of the therapy team will

enquire if they wish to take part in the study. If they still wish to take part the researcher will discuss the study again to reinforce understanding of what is involved and the relevant consent/assent forms will be signed by the patient, carer and researcher as appropriate. Originals will be given to the patient/carer, and copies kept in the study file at the hospital. Those happy to take part will be given a copy of the research outline and supporting information and asked to sign the informed consent form and given a copy.

The patient will be given 3 garments to trial, 1st = 20% reduction method (current practice), 2nd =15mmHg and 3rd =25mmHg both using the Pressure Garment Design Tool method, at the start of therapy. The garments will be made up by hospital technicians using the standard methods which will ensure consistency in the garment performance. All three garments deliver pressure within the range of normal practice and are being compared to identify the actual pressure delivered and performance differences to support good clinical practice.

At the initial fitting, the therapist will assess all three garments using normal clinical practice to ensure that there are no risks to the patients care and that all provide acceptable pressure for therapy. The relevant notes will be made at first fit regarding suitability and any need for changes. A questionnaire is to be filled out by the therapist at the initial fitting regarding observations on
garment fit. The patient will be reviewed within 3 weeks and provide feedback regarding comfort and ease of use of each garment. The participant will be asked to select the garment, that they feel is most suitable, and which is to be used for the duration of the project. The therapist will assess the scar to confirm that the healing process is not hindered and that the garment is suitable for therapy. For the purpose of the study at garment fitting the pressures being delivered by the garments will be measured using a pressure monitor. The readings will be recorded.

The research is to be conducted over 6 months and at the start of the therapy patient details, including measurements, will be documented along with pictures of the burned/scarred area to be treated and the level of healing. It is not standard practice to use any technical equipment to assess for developments during or after pressure therapy.

The patient will be supplied with 2-3 of the preferred garments at a time to ensure consistency and enable laundering as the garments need to be worn 23 hours a day.
The patient will attend the normal pattern of clinics although more time may be required at each clinic, to support the consistency required for research and the additional paperwork required for research feedback. At the end of the study there will need to be longer review appointment.

The study is to be conducted in normal clinics with the co-operation of the therapists. If the support of the therapist is withdrawn for any reason the study will have to be stopped as their experience and expertise is vital for the assessment of scar healing and ensuring the care of the participant is not compromised.

Primary and Secondary Endpoints

The primary end point of the study is to compare the pressures delivered by the garments produced using the reduction method and the PGD tool.
The secondary endpoint is the fit and comfort of the garments and the compliance of the participant to wear the garments 23/7.

General Information

The study will use garments that conform to normal clinical practice. There should be no risk to the participant as their scar will be mature. There is always a risk that the scar may break down but that is present under normal therapy and if this occurs the participant will not continue in the study as their therapy will be changed.
Effective pressure therapy is very beneficial for scar management and the study will deliver an acceptable therapy using all the garments provided.

Use within the study

The treatment will be offered during normal clinic by the burns therapists. The therapist will assess and measure the participants following normal procedure and they will fit and assess the pressure garments when ready.

The therapy treatment falls within normal clinical provision and will be monitored by the therapists to ensure the patient is not at risk and that treatment is sufficient for scar management. The fabrics used are not harmful and are used world-wide for pressure garments.
The treatment is not invasive and does not use radioactive substances.

The therapy delivered during the study will carry on until the patient is discharged as the it forms part of normal clinical practice.

4.0 SELECTION OF PARTICIPANTS (max 300 words)

Participants will be recruited from the burns clinics at Sheffield Children's Hospital who are to be provided with arm or leg sleeve pressure garments as we are able to predict pressure on limbs more accurately than other parts of the body.
Sheffield Children's Hospital is the only centre being used for the study.
Historical information indicates that about 20 eligible participants may be available per year and a high proportion of these are expected to agree to the study as it fits in with normal clinical treatment of scars provided by the hospital. Numbers of suitable participants vary greatly depending on seasonal activities that potentially cause injuries.

Inclusion Criteria

Patients aged between 6 and 16 are eligible for the study. All participants will be using arm or leg sleeves as these garments have a simple structure which causes less interference with pressure delivery. The participants will be assessed by the therapist to ensure that the scar is matured sufficiently and shows no signs for concern. All participants giving consent will be included.

Exclusion Criteria

Patients who have suffered severe trauma or who present with scars that do not mature well and break down will not be involved in the research as their therapy programme may

be interrupted. Patients with scars not requiring pressure therapy will be excluded from the study. Those participants who do not give consent will not be part of the study.

5.0 PARTICIPANT RECRUITMENT (max 300 words)

Participants will be recruited from the burns department at Sheffield Children's Hospital. Posters will be used to promote the study within the burns department and clinical areas to encourage interest and participation. As this study is taking place in normal clinical practice for therapy no payment incentive will be used.

During burns therapy assessment carried out prior to full healing a qualified therapist will assess the patient's suitability for the study, taking into consideration the effect of the trauma and possible compliance issues. If the therapist is happy that the patient is suitable, and will be using leg or arm sleeves for pressure therapy, the option to take part in the study will be discussed with the patient and the parent/carer.

If the patient and the parent/carer show an interest in taking part they will be introduced to the researcher, who will discuss the study process and what it involves. The discussion will be conducted in a separate room from the therapy sessions and not in the presence of the therapist. After a full introduction to the research project the researcher will ask if there are any questions and address any queries that may be raised. The researcher will ask again if they are still interested in taking part, and if so, information sheets relevant to the participants and parents/carers needs, based on the template provided by the Sheffield Children's Hospital, will be provided outlining the research project and questions that may be raised. The researcher will ensure that the patient and the parent/carer understand that the decision to take part should be made after considering the information provided, during the two weeks before the next clinic. It will be made clear that at any point they can opt out of the study process and that normal therapy will be provided.

Where necessary, the hospital provides interpreters to support the patient in understanding treatment and care procedures. All children will be supported by an adult in making the decision to take part.

At the first garment fitting clinic, which is usually within two weeks of being measured for garments, those patients who expressed and interest in taking part in the study will be seen by the researcher to discuss their decision the take part. The outline of the study will be discussed again with the patient/carer to ensure they understand the requirements of the therapy and how the research is to be conducted. If they are still happy to be involved informed consent/assent will be obtained as required, a copy will be given to the participant and a copy kept in the research file.

Participants will have a unique number, used as a cross reference for data collection on the patients notes and garment file. The data collection file will not have any personal information references.

The sensor equipment will be introduced at the first fitting clinic and time taken to ensure the participant is comfortable having the readings taken. This is not an invasive procedure, and should not cause any discomfort, but involves the use of pressure pads around a sensitive area and therefore some initial anxiety is expected.

At enrolment into the study the participant will be given an information sheet that discusses the research and questions they may have and provide contact details should they encounter any problems.

Randomisation

The study will be randomised by the participant making a garment selection after trialling all three garments (standard method plus one designed to deliver the recommended target pressure and a third to deliver a lower pressure believed to be effective). The study is double blind and neither the therapist nor the participant will know which design method has been used for the garment they have chosen. The participant will make the choice between garments labelled A, B or C after trialling all three for a short while, up to two weeks. The principal investigator will allocate the garment to the label A B or C (randomly) when they are constructed to prevent the therapists guessing which garment is which.

Blinding and other measures taken to avoid bias

The study will look closely at the fit and comfort of the garment as well as the delivery of suitable pressure. As the therapist may have some bias towards the method already in place it is preferable to blind them to which garment is which. The participants will make a choice through comfort and dressing preferences.

Three garments will be made and each labelled with a letter A, B or C. The letters will be allocated randomly to different patient's garments, so that garment A will not consistently be a particular method of construction for different patients. Only the principal investigator will know the measurement system used for each garment unless the therapist can guess through experience.

Bias should not be an issue as the participant will make the choice of garment and will be able to identify from the labels the choice made.

Participant compliance

During follow up clinics the participants' scar will be reviewed by the therapist. Any deterioration in the healing of the scar will be noted as this could potentially indicate non-compliance or a problem with the garment. The POSAS score chart will also be used to assess for any issues regarding compliance with the therapy. The initial data collected can still be useful even if the participant cannot continue in the research if they consent to this.

Non-compliance with burns is an issue that must be addressed regularly. The therapist will always endeavour to encourage the use of the garments even after a short break. The study can continue if the participant does have some laps in compliance.

Withdrawal of participants

Participants will be withdrawn from the study if it is obvious that it is causing any distress as children and carers will already find the trauma enough to cope with. If participants wish to withdraw, their consent to use the data recorded will be obtained if possible. It is hoped that any issues will be identified prior to healing. New participants will be added to the study after healing, as they will be recruited through burns clinic not by any other means.

All participants (including those that withdraw) will continue with therapy through normal burns clinic after taking part for a short while or for the duration of the study.

Data collection

Data will be collected by use of questionnaires completed by both the participant (or carer) and the therapist. The Therapist will be asked to fill out a questionnaire at the initial garment fitting. The participant will be asked to fill out a questionnaire at home after trialling the garments (a duplicate will be supplied for the follow up clinic in case this is forgotten). The therapist will collect the questionnaires for the principal investigator.
Data will also be collected using a paper measurement chart for pressure sensor readings. Readings will be taken at the initial fit of garments and at follow up clinics at varying intervals to monitor changes in fabric performance. Pressure measurements will be taken and recorded by the principal investigator.
Both the questionnaires and the sensor readings will be kept by the principal investigator. The information will be identified by a unique number and no personal identifying information will be used.
The POSAS scores taken by the therapist are kept in the patient's files as this is normal clinical practice. If this information is used to support findings regarding healing of the scars it will be transferred to the research file by the principal investigator with no personal information collected or retained.

Quantitative data from the pressure sensor readings will be used to compare the pressures being applied by each garment. This will be shown in a table format so that readings can be compared, and differences identified to verify the effectiveness of the design procedure and quality of the fabric used (research has shown that the pressure deteriorates over time and with use). Questionnaires will be used to evaluate patient's choices and their feelings about the comfort of pressure garments to enable treatment to be improved and reported on in literature.
Quantitative data from the feedback forms will be shown in a table that will show which garment was preferred and whether there are preferences of fit and difficulties using each garment. Qualitative data in the form of patient or therapist comments will enrich the discussion of the quantitative data provided. The POSAS form will also be a source of information regarding effectiveness and will be shown in a table.

6.0 DATA HANDLING AND RECORD KEEPING (max 300 words)

Pressure measurement data and therapist questionnaires will be collected by the principal investigator. The therapist will collect the patient questionnaires in the first instance and then hand to the principal investigator. All data will be collected and retained in accordance with the Data Protection Act 1998.

Trial documents (paper and electronic Microsoft word and excel files) will be retained in a secure location during and after the trial has finished. All source documents will be retained for a period of 5 years following the end of the trial. Where trial related information is documented in the medical records – those records will be retained for 5 years after the last patient last visit.

The principal investigator is responsible for collecting the data and ensuring the consistency and recording of all relevant information. Data collected will be in paper format such as questionnaires and feedback forms, these will be scanned to retain an electronic copy, paper tables of pressure measurement data will be copied into excel files and double checked by the principal investigator. Paper documents will be stored in the research file kept at the hospital. Electronic copies of questionnaires, pressure measurement data and pressure garment design tool files will be stored on encrypted memory sticks which will be kept at the hospital. A copy of the raw data (without any patient identifying information) will also be given to the C-I, Lisa Macintyre at Heriot-Watt University, this will be stored on their University server. The measurements and patterns for each participant are stored in the patient file box as is normal practice in the sewing room. All data used in the research study will be stored without personal information.

7.0 ACCESS TO SOURCE DATA (max 300 words)

The sponsor will permit monitoring and audits by the relevant authorities, including the Health Research Authority and Research Ethics Committee. The investigator will also allow monitoring and audits by these bodies and the sponsor, and they will provide direct access to source data and documents.

8.0 STATISTICAL ANALYSIS (max 300 words)

The study will evaluate the pressures delivered by the three individual garments (A B C) at different locations on the garment/body and also at initial fitting and subsequent visits to the clinic. The mean pressure, standard deviation, coefficient of variation, standard error and 95% confidence intervals will all be calculated for each set of pressure data. The measured pressure data will then be compared to the predicted pressure (from the pressure garment design tool), it will be compared between patients for different sized limbs, leg and arm and links, if any, will be sought between pressures exerted and patient and therapist opinion from the questionnaires. The quantitative data will be presented in tables and figures to best communicate the results of the study and enable variations to be compared. Comparisons will be made between the reduction factor and the PGD tool designs.

Given the small numbers of patients anticipated in this study there will be limited use of sophisticated statistics as the numbers are unlikely to support this.

If patients withdraw or do not comply (or data is missing for any other reason) then it will not be included in the data analysis for that stage of analysis. Data will be considered in blocks and only if all data is complete for the block will it be included. If a patient withdraws from the study but is happy for earlier data to be used, then it will be included in all blocks that are possible/complete. It will not be necessary for all blocks to have the same number of patients included (although this would be desirable). Blocks will be:

1. Initial fitting: measured pressures, predicted pressures and therapist questionnaire
2. First follow-up clinic: measured pressures, participant's choice of garment, patient questionnaire and therapist/Patient POSAS form
3. Second follow-up clinic: measured pressures, participant's choice of garment,
4. Third follow-up clinic: measured pressures, patient/therapist POSAS forms.
5. Fourth follow-up clinic: measured pressures, participant's choice of garment,

As this is a six-month study there are no criteria for early termination of the study and interim analysis will not be undertaken (although data will be processed as it is received).

Sample size calculation

Using historical information as a guide to the possible sample size it is hoped that 20 participants will be recruited. Participants will be recruited as soon as they are healed enough to take part (at the normal point for pressure garments to be issued) with the full support of the parent/carer.

This is a convenience study to gather pilot data to indicate patient preference, there is no power calculation as we do not have opportunity within this study to recruit sufficient patients for it. There is an assumption of normality but also recognition that patients are individuals and will make individual choices for a wide range of reasons (we will try to capture these reasons in the questionnaire). Statistics will be calculated to 95% significance. The study will not be terminated for statistical reasons (due to the scale of the study undertaken). Missing data (from any block) or suspected counterfeit data would result in all data for that participant being removed from the analysis undertaken fro that block. If the statistical plan were to change the ethics committee would be consulted to request the proposed alteration. Data from all participants will be included in the statistical analysis.

The study is to be carried out over 6 months and participants will be recruited for the first 4 months as after that there will not be enough time to obtain useful data.

9.0 SAFETY ASSESSMENTS (max 300 words)

The study will be conducted in a clinical setting with qualified staff under normal clinical procedures. There should be no safety issues as all aspects of the study comply to acceptable clinical practice and all participants will be assessed by the therapist to ensure they are suitable.

Any participant who suffers any adverse reaction during therapy will be identified and supported by the therapist. It is very unlikely as those vulnerable patients will not be recruited to the study.

Any adverse events will be reported by the researcher to all relevant contacts as outlined by GCP guidelines.

The pressure sensor equipment will be tested to comply with the SCH regulations for electrical items.

Stopping/discontinuation rules and breaking of randomisation code

The main reason for stopping the study is if therapy support is withdrawn. Under these circumstances the participants would be signed off from the study and debriefed, but the data collected would still be used to finish the Masters Dissertation.

Monitoring

The study will be monitored and audited in accordance with the Monitoring Standard Operating Procedures of the Directorate of Research & Innovation at Sheffield Children's NHS Foundation Trust. All study related documents will be made available on request for monitoring and audits by the Sponsor, the Health Research Authority and the relevant Research Ethics Committee.

10.0 ETHICAL CONSIDERATIONS (max 300 words)

Ethics and R&D approval

The study will be conducted in compliance with a Research Ethics Committee favourable opinion, Health Research Authority approval and Confirmation of Capacity & Capability at all participating sites.
The study will also be conducted in accordance with the International Conference for Harmonisation of Good Clinical Practice (ICH GCP), and the Research Governance Framework for Health and Social Care (2nd Edition).

11.0 FINANCE AND INDEMNITY (max 300 words)

This is an NHS sponsored study. For NHS sponsored research HSG (96) 48 reference no. 2 refers. If there is negligent harm during the study when the NHS body owes a duty of care to the person harmed, NHS Indemnity will cover NHS staff, medical academic staff with honorary contracts and those conducting the study. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim

12.0 JUSTIFICATION OF FINANCE (max 300 words)

There no requirements in this section.

13.0 JUSTIFICATION OF RESOURCES

Picopress pressure sensor equipment will be borrowed from Heriot-Watt university.

Fabrics will be supplied as for normal clinical use.

14.0 REPORTING AND DISSEMINATION (max 300 words)

The study will form part of a Masters by research dissertation.
The final research paper will be submitted to the relevant Burns Journals for publication (target is 'Burns' published by Elsevier). An over view of the outcomes and the benefits of the study will be submitted to the Sheffield Children's Hospital communications department for publication on the web page and in the Theo Burns Newsletter and will also be disseminated to the Pressure Garment Interest Group following publication.

It is intended that this short study will support the benefits of doing larger studies into the effects of pressure therapy and the benefits/difficulties of applying known levels of pressure to patient's scars. With the support of the therapists and Burns department interest in conducting a long-term study into effective pressure, will be investigated and suitable funding streams identified.

15.0 IMPACT (max 400 words)

By identifying the pressures being applied using the different design methods it is hoped that the best clinical therapy can be developed. The audit already undertaken highlighted the large variations in pressures being used at present, this is not necessary using the computer based Pressure Garment Design tool, which will provide more suitable sized garments with less risk of harm to the scar site and the well-being of the patient. The Pressure Garment Design tool calculates the required garment's size to deliver any clinically appropriate pressure, which will enable therapists to free up clinical time for patients especially if they are involved in pattern making as we envisage fewer alterations being required.

Using exact measurement techniques to ensure consistency will mean that all burns units will be able to provide information for use in outcome audits. At present, there is no consistency in the way pressure is delivered when garments are produced using the reduction method of calculation and no measurement of the pressure exerted by the garment. By putting PGD tool method into practice and using the results it is hoped to confirm the benefits of its application and provide guidance for ideal pressure delivery especially for children.

The study will focus on the patterns for limbs but once the PGD tool has been evaluated in practice at Sheffield Children's Hospital the programme will be adapted to provide

patterns for other parts of the body. This development will be carried out with the support of the work in the School of Textiles and Design at Heriot-Watt University.

The Pressure Garment Design tool has been tested with measurement data to establish how easy it is to enter the information and apply the output measurements to patterns. The pressure garment design tool is already used commercially by 3 different companies providing pressure garments in the UK, Australia and Israel who find it very useful. This will be the first time it has been evaluated in a hospital setting and since it is freely available (supplied with the fabrics we use) it has the potential to significantly improve the efficacy of hospital treatment.

16.0 OUTCOMES (max 400 words)

Information about how the outcomes from your research will feed into future national applications to charitable and national funding bodies (including NIHR/MRC/Wellcome).

There is very little research carried out into the in-house provision of pressure therapy garments. The results from the feasibility study will help to support the use of a computer programme that can provide better fitting garments with an easy to use format. This design enables the monitoring of pressure delivered which is not possible with the manual method and opens the door to research into best effective pressure studies for scar management.

17.0 Authorisations

Finance Department Representative:

Finance Department Signature: **Date:**

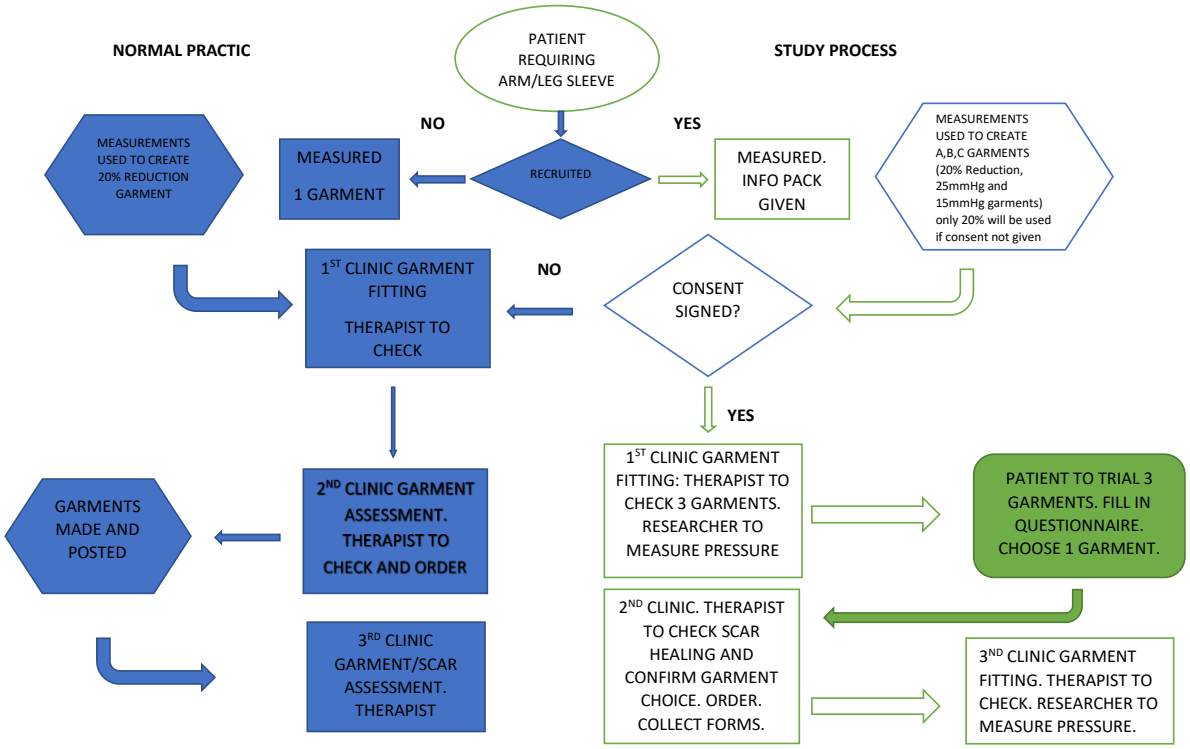
Applicant's Manager:

Applicant Manager's Signature: **Date:**

TABLES, FIGURES AND REFERENCES

APPENDICES

Normal Practice and Study Process Flow Chart



PARTICIPANT	CONSENT CONFIRMED	GARMENT FITTED	POSAS	QUESTIONNAIRES	INFORMATION PACK	PRESSURE READINGS	PRESSURE READINGS
CLINIC 1							
CLINIC 2							
CLINIC 4							
CLINIC 5							
CLINIC 6							
CLINIC 7							
CLINIC 8							
CLINIC 9							
CLINIC 10							

RESEARCH PROTOCOL

This form is to be used at each clinic to ensure procedure is followed correctly to support the study viability.

Record chart for pressure sensor reading

Single participant -paper format

GARMENTS INITIAL FITTING	SENSOR PAD 1	SENSOR PAD 2	SENSOR PAD 3	SENSOR PAD 4	SENSOR PAD 5	COMMENTS
A						
B						
C						

N.B. The garment design will be added in after clinic to protect blinding. Placement of sensor pads will depend on limb, scar and size. Position will be marked on garment with a special pen. (A drawing of the limb and placement of sensors will be used to support this)

SELECTED GARMENT FITTING. (circle) **A B C**	SENSOR PAD 1	SENSOR PAD 2	SENSOR PAD 3	SENSOR PAD 4	SENSOR PAD 5	COMMENTS
NEW						
NEW/WORN						
NEW/WORN						
NEW/WORN						
NEW/WORN						
NEW/WORN						

This chart will look at consistency in pressure delivery and long-term variance after selection of garment to be used in the study. Sensor readings will be taken for first garment and after wear as required. This will enable the deterioration in pressure exerted by garments to be monitored (pressure will reduce during wear – this is an inevitable part of all treatment using compression textiles but is not normally captured clinically).

Data collation

Record chart for initial garments and comparative pressure readings- this is an example of part of the records that will be kept in Microsoft Excel

RESULTS		PARTICIPANT.1					PARTICIPANT.2					PARTICIPANT.3			
GARMENT ARM/LEG															
SENSOR	Design method	1	2	3	4	Design method	1	2	3	4	Design method	1	2	3	4
Garment A															
Garment B															
Garment C															

This will enable comparison of differences in pressure delivery between garment designs and methods.

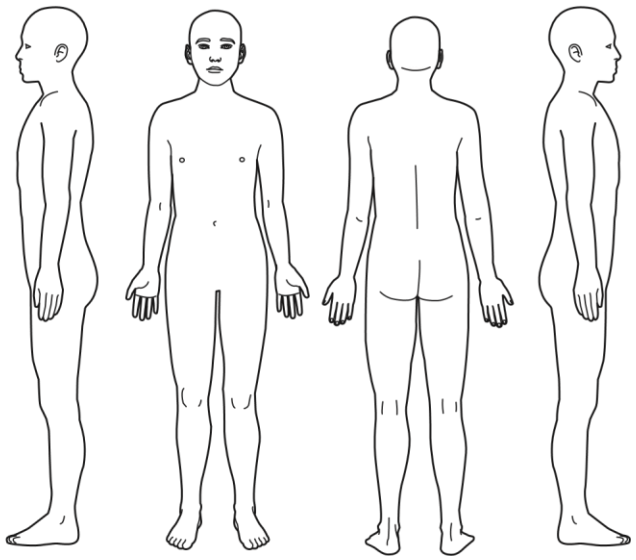
The Patient and Observer Scar Assessment Scale v2.0 / EN

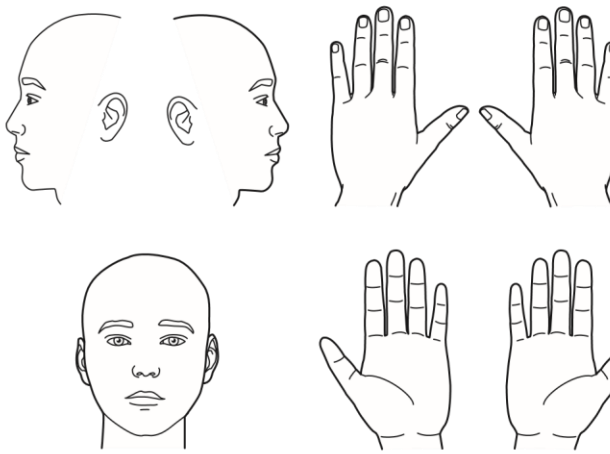
Date of examination: | **Name of patient:**

Observer:

Location: | **Date of birth:**

Research / study: | **Identification number:**





	1 = normal skin								worst scar imaginable = 10	
PARAMETER	1	2	3	4	5	6	7	8	9	10
VASCULARITY	○	○	○	○	○	○	○	○	○	○
PIGMENTATION	○	○	○	○	○	○	○	○	○	○
THICKNESS	○	○	○	○	○	○	○	○	○	○
RELIEF	○	○	○	○	○	○	○	○	○	○
PLIABILITY	○	○	○	○	○	○	○	○	○	○
SURFACE AREA	○	○	○	○	○	○	○	○	○	○
OVERALL OPINION	○	○	○	○	○	○	○	○	○	○

CATEGORY
PALE | PINK | RED | PURPLE | MIX
HYPO | HYPER | MIX
THICKER | THINNER
MORE | LESS | MIX
SUPPLE | STIFF | MIX
EXPANSION | CONTRACTION | MIX

Explanation

The observer scale of the POSAS consists of six items (vascularity, pigmentation, thickness, relief, pliability and surface area). All items are scored on a scale ranging from 1 ('like normal skin') to 10 ('worst scar imaginable').
The sum of the six items results in a total score of the POSAS observer scale. Categories boxes are added for each item. Furthermore, an overall opinion is scored on a scale ranging from 1 to 10. All parameters should preferably be compared to normal skin on a comparable anatomic location.

Explanatory notes on the items:

- **vascularity** Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas
- **pigmentation** Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity
- **thickness** Average distance between the subcutical-dermal border and the epidermal surface of the scar
- **relief** The extent to which surface irregularities are present (preferably compared with adjacent normal skin)
- **pliability** Suppleness of the scar tested by wrinkling the scar between the thumb and index finger
- **surface area** Surface area of the scar in relation to the original wound area

POSAS Patient scale

The Patient and Observer Scar Assessment Scale v2.0 / EN

Date of examination:

Name of patient:

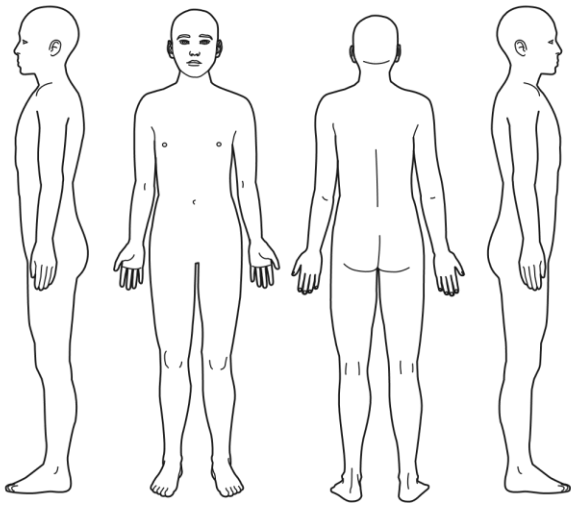
Observer:

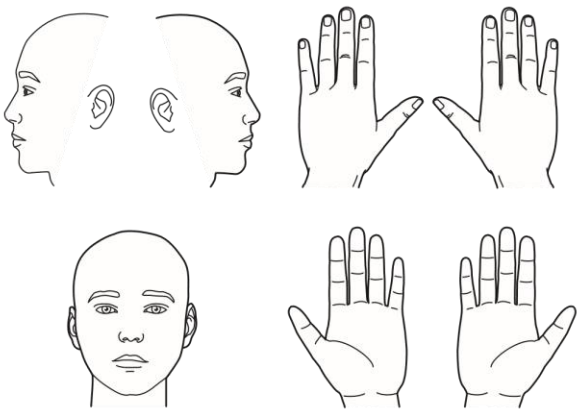
Location:

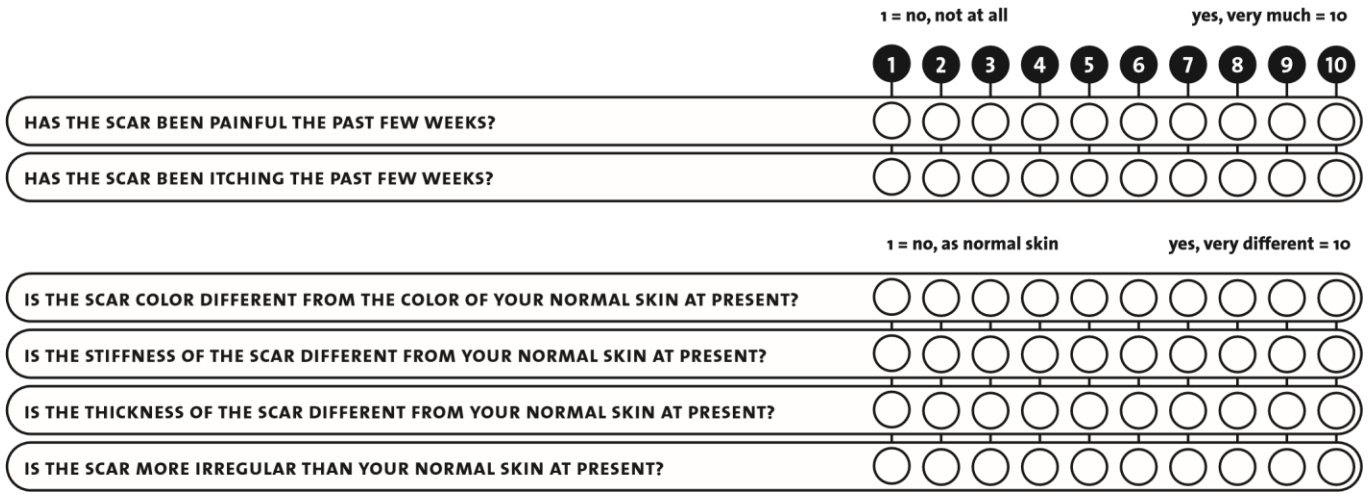
Date of birth:

Research / study:

Identification number:






1 = no, not at all
yes, very much = 10
1 2 3 4 5 6 7 8 9 10
HAS THE SCAR BEEN PAINFUL THE PAST FEW WEEKS?
HAS THE SCAR BEEN ITCHING THE PAST FEW WEEKS?
1 = no, as normal skin
yes, very different = 10
IS THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT?
IS THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?
IS THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?
IS THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT?

Questionnaire
Patient

1. Which garment did you wear for the longest time? (please circle)

   A B C
2. Which garment did you wear most? (please circle)

   A B C
3. Which garment felt the best to wear? (please circle)

   A B C
4. Which garment felt the worst? (please circle)

   A B C
5. Which garments was easiest to get on/off? (please circle)

   A B C
6. Which garment was the most difficult to get on/off? (please circle)

   A B C
7. Which garment did you like best? (please circle)

   A B C

If you have any comments please write them here, particularly if you experienced any specific problems with any of the garments:

_____

_____

_____

_____

_____

_____

Therapist
Questionnaire

Which garment gave best fit for purpose? (please circle)

A **B** **C**

Comments
_____
_____
_____

Which garment gave worst fit for purpose? (please circle)

A **B** **C**

Comments
_____
_____
_____

Which garment was easiest to put on/off? (please circle)

A **B** **C**

Comments
_____
_____
_____

Which garment was the most difficult to put on/off? (please circle)

A **B** **C**
Comments
_____
_____
_____

Indicate your preference of 'best garment' and the patient's (please circle)
A **B** **C** patient

A **B** **C** therapist
Comments
_____
_____
_____

References

[1] Macintyre, L., 2007. Designing pressure garments capable of exerting specific pressures on limbs. *Burns*, *33*(5), pp.579-586.

[2] Subcommittee, S., Subcommittee, A. and ISBI Practice Guidelines Committee, 2016. ISBI Practice Guidelines for Burn Care. *Burns*, *42*(5), pp.953-1021.

[3] Macintyre, L. and Baird, M., 2005. Pressure garments for use in the treatment of hypertrophic scars–an evaluation of current construction techniques in NHS hospitals. *Burns*, *31*(1), pp.11-14.

[4] Macintyre, L. and Ferguson, R., 2013. Pressure garment design tool to monitor exerted pressures. *Burns*, *39*(6), pp.1073-1082.

[5] Anzarut, A., Olson, J., Singh, P., Rowe, B.H. and Tredget, E.E., 2009. The effectiveness of pressure garment therapy for the prevention of abnormal scarring after burn injury: a meta-analysis. *Journal of Plastic, Reconstructive & Aesthetic Surgery*, *62*(1), pp.77-84.

[6] Van den Kerckhove, E., Stappaerts, K., Fieuws, S., Laperre, J., Massage, P., Flour, M. and Boeckx, W., 2005. The assessment of erythema and thickness on burn related scars during pressure garment therapy as a preventive measure for hypertrophic scarring. *Burns*, *31*(6), pp.696-702.

[7] Williams, F., Knapp, D. and Wallen, M., 1998. Comparison of the characteristics and features of pressure garments used in the management of burn scars. *Burns*, *24*(4), pp.329-335.

Appendix 5. information sheets

PARENT/LEGAL GUARDIAN INFORMATION SHEET

Study title

Pressure for Burns scars using computer analysed fabric data.

We would like to invite you and your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve. The researcher**will go through the information sheet with you and answer any questions you have.** Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you and your child if you take part.
Part 2 gives you more detailed information about the conduct of the study.

As us if there is anything that is not clear.

Part 1 – **to give you first thoughts about the project**

What is the purpose of the study?

Pressure therapy to treat burns has been used for a long time but we need to look at how much pressure is being achieved using three different garments.The study is being conducted for 6 months as part of a Masters project.

Why have we been invited?
Your child has been invited because he/she has burns scar on their leg/arm and will be using a pressure garment to help it to heal. We hope to have 20 children in this study.

Do we have to take part?
No it is up to you and your child (wherever possible) to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an assent form with you, if they want to.

You will be given a copy of the information sheets and the signed consent and assent forms to keep for your records. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care your child receive.

What will happen to my child if we agree take part?

How long will they be involved in the research?
Your child will be involved for the duration of the six month study or until they are healed which ever comes first.
How often will they need to visit a clinic/met a researcher?
Your child will attend clinic every two weeks to start off with and at the advice of the therapist once healing settles down.
How long will the visits be?
The clinic will last between 15-30 minutes.
Will they need to visit the clinic more often than for their usual treatment?
No the research will not require extra visits.

The research will involve taking pressure readings for each new garment. This is done using little sensor pads in between the garment and the skin. It is not painful or harmful.
Your child will be asked to make a choice between three garments and to answer some simple questions.
During all the research and clinical sessions you will be with your child and will be involved in all aspects of the therapy.

Blind trial
In a blind trial you will not know which treatment your child is receiving. If the trial is a double blind trial, neither you nor your child's therapist will know in which treatment group your child is in (although if your child's therapist needs to find out he/she can do so). Your child will be given three garments to wear for a short while labelled A,B and C. We would like you to choose one garment out of A, B or C. One garment will provide standard pressure therapy having a 20% reduction and variable pressures, one will provide 15mmHg of pressure which is the lowest known to provide results
and the third will provide 25mmHg of pressure which is an ideal upper pressure. The selected garment style will then be used for treatment. Your child will be asked to choose which one they want to wear for continuing treatment.

What will we have to do?

As part of normal therapy treatment your child will be given garments to wear that apply pressure to the scar. It is important that the garment is worn 23 hours a day. The first time you receive garments if you opt-in to the study, there will be three different styles. You will be asked to help your child wear a different one each time they change it. It may be that one is preferred to another. We will ask you to fill in a questionnaire that tells us about any likes and dislikes and the good and bad things you may want to say.
We would like your child to choose one garment out of A,B or C. This garment style will then be used for treatment.
The clinics are very important to help us give your child the best care and make sure the garments are doing their job well. The garments need to be washed regularly and will therefore lose their stretch so we need to make new ones very often to make sure they fit well.
Every time we make new ones we will want to take some pressure readings for the research. This is a very important part of the study and can only be done in clinic.

There will be a questionnaire for you to take home when you first get some garments. This will take 5 minutes to complete. Sometimes in clinic you and your child will be asked some questions about the scar and the answers will be put on a form called a Patient and Observer Scar Assessment Scale. This is the same for everybody but these answers will also be used in the research.

What are the alternatives for diagnosis or treatment?

Sometimes gel and cream can be used instead of garments, but the therapist will decide which is the best method to use.

What are the possible disadvantages and risks of taking part?

You may need to spend a little extra time in clinic but the research fits in with your treatment schedule and should not require any additional visits.
In trialling different garments which apply different pressures there may be variable progress to the healing process, it may be quicker or slower or as expected. Individuals heal in different ways. Every care will be taken to ensure

that positive results are achieved. If it is observed that healing is compromised the participation in the study will be stopped and standard therapy used.

What are the side effects of any treatment received when taking part?

The therapy treatment is safe and is used regularly across the NHS and at the Sheffield Children's Hospital. The therapist will check the scar sight regularly for any breakdown of the healing process. If you notice anything to worry about you should notify the burns team straight away.

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Name:Lena Plaskitt/Kayleigh O'Mahoney
Title:OCCUPATIONAL THERAPIST
Hospital/Department:BURNS
Tel: 0114 2667890

OR

Name:Dawn Syron-Jones
Title:OCCUPTIONAL THERAPY TECHNICIAN/RESEARCHER
Hospital/Department:RYEGATE
Tel: 0114 3053087

What are the possible benefits of taking part?

Pressure therapy helps the scar to heal better. It will not take it away completely. The garments can make you feel safer by protecting the burn area. The therapy will offer the similarbenefits as normal, but will also provide better fitting garments and with your help we can use the information to provide a more efficient and

effective service. The study will enable us to understand the best way to make pressure garments to treat scars.

What happens when the research study stops?
The research is for 6 months and your child may need therapy support for longer. After the research is finished the therapy will be the same as long as it is needed. The same team will look after you and make your garments and the clincs will be in the same place.
After all the information is put together we will send you a letter to explain what we have found. The information will also be available through the hospital website and burns club newsletter.

What if there is a problem?
Any complaint about the way you or you child have been dealt with during the study or any possible harm you or your child might suffer will be addressed. The detailed information on this is given in Part 2.

Will my child's taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence. The details are included in Part 2.

This completes Part 1.

If the information in Part 1 has interested you and you are considering your child's participation, please read the additional information in Part 2 before making any decision.

Part 2 of the information sheet

What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, someone from the research team will tell you and your child and discuss with you whether you want your child to continue in the study. If you decide not to carry on, arrangements will be made for your child's care to continue. If you decide to continue in the study you may be asked to sign an agreement outlining the discussion.

If the study is stopped for any other reason, we will tell you and arrange your continuing care.

What will happen if we don't want to carry on with the study?

You can withdraw from the study any time you wish but we would appreciate being able to use the information we have collected with your help. All the information we have collected will be anonymous.

What if there is a problem?

Complaints

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

Name: Dawn Syron-Jones
Title: OCCUPATIONAL THERAPY TECHNICIAN
Hospital/Department: RYEGATE
Tel: 01143053087

If you remain unhappy and wish to complain formally, you can do this by contacting:

Patient Advice & Liaison Co-ordinator
Sheffield Children's NHS Foundation Trust
Tel: 0114 271 7594

Harm

In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All information which is collected about your child during the course of the research will be kept strictly confidential. Any information about your child which leaves the hospital will have their name and address removed so that they cannot be recognised from it. Once the study is complete all information will kept for the amount of time specified on the REC Application form or kept in their confidential notes.

Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 1998.

All data and questionnaires used for the research will be kept for 5 years but will be anonymised.
The researcher as therapy technician, will have access to identifiable data.

Your child's medical notes may also be looked at by other people within the hospital involved in the running and supervision of the study to check that it is being carried out correctly.

What will happen to the results of the research study?

The results of the research will be used as part of a Masters research project. The information will be used to discuss the levels of pressures achieved with different garment designs.
The results will be submitted for publication but it is not possible to say if or when. Any publications will be promoted through the hospital web page and the burns club newsletter.

When the study has finished we will present our findings to other researchers, and we will put the results in medical magazines and websites that researchers read. We would also like to put a brief summary on the hospital research website so that you will be able to read about our results too. This will be available at the end of the study, in January 2019, on www.sheffieldchildrens.nhs.uk/research-and-innovation.htm. The results will also be included as part of the investigator's educational qualification. They will be anonymous, which means that your child will not be able to be identified from them.

Who is organising and funding the research?

Researchers at Children's NHS Foundation Trust are organising this study. They will not get any extra money for doing this research.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Health Research Authority and the West of Scotland Research Ethics Committee 3.
It has also been given approval by the Research Department to run at this hospital.

How can I find out more?

If you would like to find know more about research in general, the Clinical Research Facility at this hospital has an **Information for families** section on its

website www.sheffieldchildrens.nhs.uk/research-and-innovation.htm or you could contact the hospital Clinical Research Facility:

Dr Gillian Gatenby
R&D Manager
Sheffield Children's NHS Foundation Trust
Tel: 0114 3053478

If you would like to know more specific information about this research project, please contact the project co-ordinator:

Name: Dawn Syron-Jones
Title: OCCUPATIONAL THERAPY TECHNICIAN
Hospital/Department: RYEGATE
Tel: 0114 3053087

If you would like advice as to whether your child should participate you could contact the project team, or one of your child's health care professionals.

If you have any concerns during the study, you should contact the project team.

If you and your child decide to take part in this study, you will be given this information sheet and signed consent and assent forms to keep.

Thank you for taking the time to read this information sheet.

PARTICIPANT INFORMATION SHEET

FOR CHILDREN AGED 6-10 YEARS

To be shown and read by parent/carer if required

ME and My Special Garments

What is research?
Research is a way we try to find out the answers to questions.

Why is this project being done?
We want to try and find out if one is nicer than the others to wear and how much you like it.

Why have I been asked to take part?
You have been invited because you have a poorly mark that needs our help and you can help us find some answers that will help us make you better.

We are asking 20 children all together.

Did anyone else check the study is OK to do?
Before any research is allowed to happen, it has to be checked by a group of people called a Research Ethics Committee. They make sure that the research is fair.

Your project has been checked by the West of Scotland Research Ethics Committee 3.

Do I have to take part?

No, you do not! It is up to you. We would like you to read this information sheet. If you agree to take part, we would like you to write your name, if you can, on two forms. We will also ask your mum, dad or carer to write their name on the forms and give one back to us. You can still change your mind later. If you don't want to take part, just say no!

What will happen to me if I take part in the research?

Then we would like to do a special test.

This is:

- A Pressure sensor test to see how stretchy the special garment is. We will put little pads in between the garment and your arm/leg. This will not hurt, and you won't feel anything.

We will also ask you some questions.

These will be about:

- How easy the garment was to put on
- If the garment fit nicely
- How comfortable it is

How long will they be involved in the research?

6 months or until the end of their therapy

How often will they need to visit a clinic/meet a researcher?

You will need to be at clinic every 2-3 weeks which is normal. You will see the researcher every time there is a new garment to be fitted.

How long will the visits be?

The visit will usually be about 30 minutes.

Will they need to visit the clinic more often than for their usual treatment?

The number of visits will be the same as normal clinics.

The researcher will take pressure sensor readings for each new garment but there will be no other tests.

There will be one questionnaire for you to fill in which is very simple to do.

You will always be with the parent/carer during clinic.

The special garment is made of a stretchy fabric a bit like a thick stocking. It may feel a bit strange to start off with, but it will help you get better. It is a very boring colour, so we like to make it special by putting a lovely picture on it for you.

Might anything else about the research upset me?

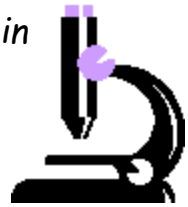
I hope not but please let me know if it does.

If we find out something that we think is important about your therapy, we will talk to your mum, dad or carer and ask them if they want to come back and have you checked again at the hospital.

Will joining in help me?

We cannot promise the study will help you but the information we get might help treat children and young people with burns scars with better garments in the future.

What happens when the research stops?



When the research stops the pressure therapy will carry on in the same way and the people helping you will be the same.

We will collect all the information together and we will decide if it is useful in telling us if the therapist can manage pressure therapy better in the future.

What if something goes wrong during the project?

Your mum, dad or carer will be able to talk to someone who will be able to tell them what they need to do about it.

Will my medical details be kept private if I take part? Will anyone else know I'm doing this?

The people in our research team will know you are taking part. The doctor looking after you while you are in hospital will also know. No

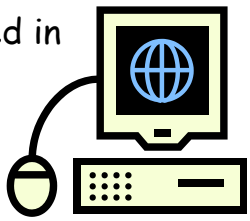
one else will know because we will not use your name or address. You will get a number which will be used instead.

What happens if a better medicine comes along?
If better, proven treatment is developed, taking part in this study will not stop you getting it.

What if I don't want to do the research anymore?
If at any time you don't want to do the research any more, just tell your parents or therapist. They will not be cross with you. Your therapist will help you decide which medicine is best to use afterwards.

What if something goes wrong?
If you want to complain you or your mum, dad or carer can talk to Dawn Syron-Jones or Mrs Linda Towers at this hospital.

What happens to what the researchers find out?
When we collect your information, we will make sure it is stored in a safe place and only the people doing the research study can look at it.



We will use the information to teach doctors and therapists about how to treat burns scars and put it in medical magazines and on websites that doctors and therapists read.

A short summary will also be on the hospital's research website. No-one will know you were in the study.

How can I find out more about this study?

Your mum, dad, carer or other grownup you trust may be able to answer your questions. The therapists looking after you can also help you find out more about the study.

Thank you for taking the time to read this – please ask any questions if you need to.

ASSENT FORM FOR CHILDREN & YOUNG PEOPLE

(To be completed by the child/young person and their parent/carer)

ME and My Special Garments

Participant study number:

Child (or if unable, parent on their behalf)/young person to circle all they agree with:

Has somebody else explained this project to you?

Yes / No

Do you understand what this project is about?

Yes / No

Have you asked all the questions you want?

Yes / No

Have you had your questions answered in a way you understand?

Yes / No

Do you understand it's OK to stop taking part at any time?

Yes / No

Are you happy to take part?

Yes / No

If any answers are 'no' or you don't want to take part, don't sign your name!

If you do want to take part, you can write your name below

Your name _____ Date _____

The person who explained this project to you needs to sign too:

_____ _____ _____

Name of Researcher Signature Date

Thank you for your help.

1 for participant; 1 for researcher site file; 1 to be kept with hospital notes

Participant study number:

PARENT CONSENT FORM

Title of project: *Pressure for Burns scars using computer analysed fabric data.*

Name of researcher: Dawn Syron-Jones

Please initial box

1. I confirm that I have read and understand the information sheet dated 28.11.17 (version 2) for the above study. I have had the opportunity to consider the information ask questions and have had these answered satisfactorily.

2. I understand that my child's participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of any of my child's medical notes and data collected during the study, may be looked at by researchers and those involved in the running and supervision of the study from Sheffield Children's NHS Foundation Trust or from regulatory authorities, where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

4. I agree to my child taking part in the above study.

_____ _____

_____

Name of Parent/ Guardian Signature Date

_____ _____

Name of Child Relationship to Child

_____ _____

_____

Name of Person taking consent Signature Date

When completed: 1 for participant; 1 (original) for researcher site file; 1 to be kept with hospital notes

Participant study number:

PARTICIPANT CONSENT FORM

Title of project: *Pressure for Burns scars using computer analysed fabric data.*

Name of researcher: Dawn Syron-Jones

Please initial box

1. I confirm that I have read and understand the information sheet dated 28.11.17 (version 2) for the above study. I have had the opportunity to consider the information ask questions and have had these answered satisfactorily. ☐

4. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

5. I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by researchers and those involved in the running and supervision of the study from Sheffield Children's NHS Foundation Trust or from regulatory authorities, where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

_____	_____	
Name of Participant	Signature	Date
_____	_____	
Name of Person taking consent	Signature	Date

When completed: 1 for participant; 1 (original) for researcher site file; 1 to be kept with hospital notes

PARTICIPANT INFORMATION SHEET

FOR CHILDREN/YOUNG PEOPLE AGED 11 TO 15

Study title

Pressure for Burns scars using computer analysed fabric data.

We are asking if you would join in a research project to find the answer to the question 'Can the consideration of fabric stretch offer a more effective pressure therapy garment?' Before you decide if you want to join in, it's important to understand why the research is being done and what it will involve for you. So please consider this leaflet carefully. Talk to your family, friends, doctor or nurse if you want to.

Part 1 – to give you first thoughts about the project

Why are we doing this research?

We want to try and find out if considering the fabric stretch offers a more effective pressure therapy garment.

This research is being done by Dawn Syron-Jones as part of their educational course and is being supervised by Dr Lisa Macintyre.

What is the medicine, device or procedure that is being tested?

The research will be looking at the pressure garments you will be wearing to treat your burns scar. We are interested in how it feels and if one design is more suitable than the others for you.

Why have I been invited to take part?

You have been invited because you have a burns scar on your arm/leg and require pressure therapy to help it heal. This project will involve about 20 other children from this hospital.

Do I have to take part?

No! It is up to you. We will ask you for your assent and then ask if you would sign a form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.

What will happen to me if I take part?

How long will you be involved in the research?

Your will be involved for the duration of the six months study or until you are healed whichever comes first.

How often will you need to visit a clinic/meet a researcher?

You will attend clinic every two weeks to start off with and at the advice of the therapist once healing settles down.

How long will the visits be?

The clinic will last between 15-30 minutes.

Will you need to visit the clinic more often than for your usual treatment?

No, the research will not require extra visits.

The research will involve taking pressure readings for each new garment. This is done using little sensor pads in between the garment and the skin. It is not painful or harmful.

You will be asked to make a choice between three garments and to answer some simple questions.

During all the research and clinical sessions, you will be with your parent/carer and they will be involved in all aspects of the therapy.

Blind trial

In a blind trial you will not know which treatment you are receiving. If the trial is a double-blind trial, neither you nor your therapist will know which treatment group you are in (although if your therapist needs to find out he/she can do so). You will be given three garments to wear for a short while labelled A, B and C. You will be asked to choose which one you want to wear for continuing treatment.

What will I be asked to do?

As part of normal therapy treatment, you will be given garments to wear that apply pressure to the scar. It is important that the garment is worn 23 hours a day. The first time you receive garments if you opt-in to the study, there will be three different styles. You will be asked to wear a different one each time you change it. It may be that one is preferred to another. We will ask you to fill in a questionnaire that tells us about any likes and dislikes and the good and bad things you may want to say.

We would like you to choose one garment out of A, B or C. One garment will provide standard pressure therapy having a 20% reduction and variable pressures, one will provide 15mmHg of pressure which is the lowest known to provide results and the third will provide 25mmHg of pressure which is an ideal upper pressure. The selected garment style will then be used for treatment.

The clinics are very important to help us give you the best care and make sure the garments are doing their job well. The garments need to be washed regularly and will therefore lose their stretch, so we need to make new ones very often to make sure they fit well.

Every time we make new ones we will want to take some pressure readings for the research. This is a very important part of the study and can only be done in clinic.

There will be a questionnaire for you to take home when you first get some garments. This will take 5 minutes to complete. Sometimes in clinic you and your parent/carer will be asked some questions about the scar and the answers will be put on a form called a Patient and Observer Scar Assessment Scale. This is the same for everybody, but these answers will also be used in the research.

What other medicines could I have instead?

Sometimes gel and cream can be used instead of garments, but the therapist will decide which is the best method to use.

What are the possible side effects of the medicines?

The therapy treatment is safe and is used regularly across the NHS and at the Sheffield Children's Hospital. In trialling different garments which apply different pressures there may be variable progress to the healing process, it may be quicker or slower or as expected. Individuals heal in different ways. Every care will be taken to ensure that positive results are achieved. If it is observed that healing is compromised the participation in the study will be stopped and standard therapy used.

The therapist will check the scar sight regularly for any breakdown of the healing process. If you notice anything to worry about you should notify the burns team straight away.

Name: Lena Plaskitt/Kayleigh O'Mahoney
Title: OCCUPATIONAL THERAPIST
Hospital/Department: BURNS
Tel: 0114 2667890

OR

Name: Dawn Syron-Jones
Title: OCCUPTIONAL THERAPY TECHNICIAN/RESEARCHER
Hospital/Department: RYEGATE
Tel: 0114 3053087

Is there anything else to be worried about if I take part?

The therapy will offer the same benefits as normal as the lower pressure is still effective, but with your help we can use the information to provide a more efficient and effective service. The study will enable us to understand the best way to make pressure garments to treat scars.

If we find out something that we think is important about your pressure therapy we will talk to your mum, dad or carer and ask them if they want to come back and have you checked again at the hospital.

What are the possible benefits of taking part?

Pressure therapy helps the scar to heal better. It will not take it away completely. The garments can make you feel safer by protecting the burn area. The therapy will offer the similar benefits as normal, but will also provide better fitting garments and with your help we can use the information to provide a more efficient and effective service. The study will enable us to understand the best way to make pressure garments to treat scars.

Contact for further information

If you would like any further information about this study, you could contact:

Name: Dawn Syron-Jones
Title: OCCUPATIONAL THERAPY
TECHNICIAN
Hospital/Department: RYEGATE
Tel: 01143053087

Thank you for reading so far - if you are still interested, please go to Part 2:

Part 2 - more detail – information you need to know if you want to take part.

What happens when the research project stops?
The research is for 6 months and you may need therapy support for longer. After the research is finished the therapy will be the same, as long as it is needed. The same team will look after you and make your garments and the clinic will be in the same place.

What happens if new information about the research medicine comes along?

Sometimes we get new information about the treatment being studied. If this happens, someone from the research team will tell you and discuss with you whether you want to continue in the study. If you decide not to carry on, arrangements will be made for your care to continue. If you decide to continue in the study, you may be asked to sign an agreement outlining the discussion.

If the study is stopped for any other reason, we will tell you and arrange your continuing care.

What if there is a problem or something goes wrong?
Tell us if there is a problem and we will try and sort it out straight away. You and your mum, dad or carer can either contact the project co-ordinator:

Name: Dawn Syron-Jones
Designation: Occupational Therapy Technician
Hospital/Department: Ryegate
Tel:01143053087

or the hospital complaints co-ordinator:

Patient Advice & Liaison Co-ordinator
Sheffield Children's NHS Foundation Trust
Tel: 0114 271 7594

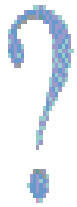
Will anyone else know I'm doing this?
We will keep your information in confidence. This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address removed.

Who is organising and funding the research?
Researchers at Children's NHS Foundation Trust are organising this study. They will not get any extra money for doing this research.

Who has reviewed the study?
Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This study has been checked by West of Scotland Research Ethics Committee 3.

It has also been checked by the Research Department at this hospital.

Thank you for reading this – please ask any questions if you need to.



PARTICIPANT INFORMATION SHEET

ADULT (16+)

Study title

Pressure for Burns scars using computer analysed fabric data.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. **The researcher will go through the information sheet with you and answer any questions you have.** Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

As us if there is anything that is not clear.

Part 1 – to give you first thoughts about the project

What is the purpose of the study?
Pressure therapy to treat burns has been used for a long time but we need to look at how much pressure is being achieved using three different garments. The study is being conducted for 6 months as part of a Masters project.

Why have I been invited?
You have been invited because you have a burns scar on your leg/arm and will be using a pressure garment to help it to heal. We hope to have 20 children in this study.

Do I have to take part?
No, it is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You will be given a copy of the information sheet and the signed consent form to keep for your records. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I agree take part?

How long will I be involved in the research?

You will be involved for the duration of the six-month study or until you are healed whichever comes first.

How often will they need to visit a clinic/met a researcher?

You will attend clinic every two weeks to start off with and at the advice of the therapist once healing settles down.

How long will the visits be?

The clinic will last between 15-30 minutes.

Will you need to visit the clinic more often than for their usual treatment?

No, the research will not require extra visits.

The research will involve taking pressure readings for each new garment. This is done using little sensor pads in between the garment and the skin. It is not painful or harmful.

You will be asked to make a choice between three garments and to answer some simple questions.

During all the research and clinical sessions, you will be with your parent/carer and they will be involved in all aspects of the therapy.

Blind trial

In a blind trial you will not know which treatment you are receiving. If the trial is a double-blind trial, neither you nor your therapist will know in which treatment group you are in (although if your therapist needs to find out he/she can do so). You will be given three garments to wear for a short while labelled A, B and C. We would like you to choose one garment out of A, B or C. One garment will provide standard pressure therapy having a 20% reduction and variable pressures, one will provide 15mmHg of pressure which is the lowest known to provide results and the third will provide 25mmHg of pressure which is safest upper pressure. The selected garment style will then be used for treatment.

What will I have to do?

As part of normal therapy treatment, you will be given garments to wear that apply pressure to your scar. It is important that the garment is worn 23 hours a day. The first time you receive garments, if you opt in to the study, there will be three different styles. You will be asked to wear a different one each time you change it. It may be that one is preferred to another. We will ask you to fill in a questionnaire that tells us about any likes and dislikes and the good and bad things you may want to say.

We would like you to choose one garment out of A, B or C. This garment style will then be used for treatment.

The clinics are very important to help us give you the best care and make sure the garments are doing their job well. The garments need to be washed regularly and will therefore lose their stretch, so we need to make new ones very often to make sure they fit well.

Every time we make new ones we will want to take some pressure readings for the research. This is a very important part of the study and can only be done in clinic.

There will be a questionnaire for you to take home when you first get some garments. This will take 5 minutes to complete. Sometimes in clinic you will be asked some questions about the scar and the answers will be put on a form called a Patient and Observer Scar Assessment Scale. This is the same for everybody, but these answers will also be used in the research.

What are the alternatives for diagnosis or treatment?

Sometimes gel and cream can be used instead of garments, but the therapist will decide which is the best method to use.

What are the possible disadvantages and risks of taking part?

You may need to spend a little extra time in clinic, but the research fits in with your treatment schedule and should not require any additional visits. There are no risks in taking part in the study as all procedures conform to normal clinical practice. In trailing different garments which apply different pressures there may be variable progress to the healing process, it may be quicker or slower or as expected. Individuals heal in different ways. Every care will be taken to ensure that positive results are achieved. If it is observed that healing is compromised the participation in the study will be stopped and standard therapy used.

What are the possible benefits of taking part?

Pressure therapy helps the scar to heal better. It will not take it away completely. The garments can make you feel safer by protecting the burn area. The therapy will offer the similar benefits as normal, but will also provide better fitting garments and with your help we can use the information to provide a more efficient and effective service. The study will enable us to understand the best way to make pressure garments to treat scars.

What happens when the research study stops?

The research is for 6 months and you may need therapy support for longer. After the research is finished the therapy will be the same as long as it is needed. The same team will look after you and make your garments and the clinics will be in the same place.

After all the information is put together we will send you a letter to explain what we have found. The information will also be available through the hospital website and burns club newsletter.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 of the information sheet

What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, someone from the research team will tell you and discuss whether you should continue in the study. If you decide not to carry on, arrangements will be made for your care to continue. If you decide to continue in the study, you may be asked to sign an agreement outlining the discussion.
If the study is stopped for any other reason, we will tell you and arrange your continuing care.

What will happen if I don't want to carry on with the study?

You can withdraw from the study any time you wish but we would appreciate being able to use the information we have collected with your help. All the information we have collected will be anonymous.

What if there is a problem?

Complaints
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.
Name: Dawn Syron-Jones
Title: OCCUPATIONAL THERAPY TECHNICIAN
Hospital/Department: RYEGATE
Tel: 01143053087

If you remain unhappy and wish to complain formally, you can do this by contacting:

Patient Advice & Liaison Co-ordinator
Sheffield Children's NHS Foundation Trust
Tel: 0114 271 7594

Harm

In the event that something does go wrong, and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. Once the study is complete all anonymous information will be kept for 5 years and all personal data kept in your confidential notes.
Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 1998.

Your medical notes may also be looked at by other people within the hospital involved in the running and supervision of the study to check that it is being carried out correctly.

What will happen to the results of the research study?

The results of the research will be used as part of a Masters research project. The information will be used to discuss the levels of pressures achieved with different garment designs.
The results will be submitted for publication, but it is not possible to say if or when. Any publications will be promoted through the hospital web page and the burns club newsletter.

When the study has finished we will present our findings to other researchers, and we will put the results in medical magazines and websites that researchers

read. We would also like to put a brief summary on the hospital research website so that you will be able to read about our results too. This will be available at the end of the study, in January 2019, on www.sheffieldchildrens.nhs.uk/research-and-innovation.htm. The results will also be included as part of the investigator's educational qualification. They will be anonymous, which means that you will not be able to be identified from them.

Who is organising and funding the research?
Researchers at Children's NHS Foundation Trust are organising this study. They will not get any extra money for doing this research.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by West of Scotland Research Ethics Committee 3.
It has also been given approval by the Research Department to run at this hospital.

How can I find out more?
If you would like to find know more about research in general, the Clinical Research Facility at this hospital has an **Information for families** section on its website www.sheffieldchildrens.nhs.uk/research-and-innovation.htm or you could contact the hospital Clinical Research Facility:

Dr Gillian Gatenby
R&D Manager
Sheffield Children's NHS Foundation Trust
Tel: 0114 3053478

If you would like to know more specific information about this research project, please contact the project co-ordinator:

Name: Dawn Syron-Jones
Title: OCCUPATIONAL THERAPY TECHNICIAN
Hospital/Department: RYEGATE
Tel: 0114 3053807

If you would like advice as to whether you should participate you could contact the project team, or one of your health care professionals.

If you have any concerns during the study, you should contact the project team.

If you decide to take part in this study, you will be given this information sheet and signed consent form to keep.

Thank you for taking the time to read this information sheet.

Appendix 6. Health research authority approval

NHS
Health Research Authority

Dr Lisa M. Macintyre
School of Textiles and Design
Heriot-Watt University
Netherdale, Galashiels
TD1 3HF

Email: hra.approval@nhs.net

13 December 2017

Dear Dr Macintyre

Letter of HRA Approval

Study title:	**Evaluating standardised pressure for garments used in scar management**
IRAS project ID:	**227861**
REC reference:	**17/WS/0246**
Sponsor	**Sheffield Children's NHS Foundation Trust**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

and further information about working with the research management function for each organisation can be accessed from the HRA website.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through IRAS.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the HRA website.

Your IRAS project ID is **227861**. Please quote this on all correspondence.

Yours sincerely

Simon Connolly

Senior Assessor

Email: hra.approval@nhs.net

Copy to: Ms Dawn Syron-Jones, Heriot-Watt University & Sheffield Children's NHS Foundation Trust

Dr Gillian Gatenby, Sheffield Children's NHS Foundation Trust

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
IRAS Application Form [IRAS_Form_14112017]		14 November 2017
Other [pressure therapy study poster]	1	20 November 2017
Participant consent form [Assent form]	2	28 November 2017
Participant consent form [Parent]	2	28 November 2017
Participant consent form [16+]	2	28 November 2017
Participant information sheet (PIS) [Parent]	2	28 November 2017
Participant information sheet (PIS) [6-10]	2	28 November 2017
Participant information sheet (PIS) [11-15]	2	28 November 2017
Participant information sheet (PIS) [16+]	2	28 November 2017
Research protocol or project proposal [Clean]	2.0	07 December 2017
Summary CV for Chief Investigator (CI)		23 October 2017
Summary CV for student		23 October 2017
Summary CV for supervisor (student research)		02 October 2017

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in

England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Dr Gillian Gatenby

Email: gillian.gatenby@sch.nhs.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	Minor amendment made to study documents to add IRAS number subsequent to REC approval. Version numbers and dates revised.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	Sponsor is single participating NHS organisation. No requirement for statement of activities or schedule of events.

4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	Study undertaken towards Masters qualification. No external funding applications.
Section	**HRA Assessment Criteria**	**Compliant with Standards**	**Comments**
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There will be a single participating NHS organisation where research activities will take place.

If this study is subsequently extended to other NHS organisation(s) in England, an amendment should be submitted to the HRA, with a Statement of Activities and Schedule of Events for the newly participating NHS organisation(s) in England.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
This is a single site study sponsored by the site. The R&D office will confirm to the CI when the study can start.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A principal investigator will be in place at the participating NHS organisation. GCP training is not a generic training expectation, in line with the HRA/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Research will be completed by local staff with existing contractual arrangements.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 7. Regional ethics approval

WoSRES

West of Scotland Research Ethics Service

Ms Dawn Syron-Jones
Therapy Technician
Sheffield Children's NHS Trust
Rygate Therapy Centre
TaptonVille Road
SHEFFIELD
S11 5DD

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

West of Scotland REC 3
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
(former Royal Hospital for Sick Children Yorkhill)
Dalnair Street
Glasgow G3 8SJ
www.nhsggc.org.uk

Date 8th December 2017
Your Ref Our Ref
Direct line 0141 232 1805
E-mail WOSREC3@ggc.scot.nhs.uk

NHS
Greater Glasgow and Clyde

Dear Ms Syron-Jones

Study title:	**Evaluating standardised pressure for garments used in scar management**
REC reference:	**17/WS/0246**
IRAS project ID:	**227861**

Thank you for your responding to the Proportionate Review Sub-Committee's request for further information and changes to the documentation for the above study.

The further information and revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Covering letter on headed paper		06 November 2017
Covering letter on headed paper		14 November 2017
IRAS Application Form [IRAS_Form_14112017]		14 November 2017
Other [pressure therapy study poster]	1	20 November 2017
Participant consent form [227861 Parent Consent Form]	1	03 November 2017
Participant consent form [227861 Participant Consent Form]	1	03 November 2017
Participant consent form [227861 Assent Form]	1	03 November 2017
Participant information sheet (PIS) [227861 Parent Information Sheet]	2	20 November 2017
Participant information sheet (PIS) [227861 Participant Information Sheet 16+]	2	20 November 2017
Participant information sheet (PIS) [227861 Information sheet 6-10]	2	20 November 2017
Participant information sheet (PIS) [227861 Participant Information Sheet ages 11-15 years]	2	20 November 2017
Research protocol or project proposal [Tracked]	2.0	07 December 2017
Research protocol or project proposal [Clean]	2.0	07 December 2017
Summary CV for Chief Investigator (CI)		23 October 2017
Summary CV for student		23 October 2017
Summary CV for supervisor (student research)		02 October 2017

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

17/WS/0246	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Liz Jamieson
REC Manager – Proportionate Review

On behalf of Mrs Rosie Rutherford, Vice Chair

Enclosures: "After ethical review – Guidance for Researchers"

Copy to: Dr Lisa M Macintyre, Heriot Watt University

Dr Gillian Gatenby, Sheffield Children's NHS Foundation Trust