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**What outcomes are important to burns patients during scar management and how do they compare to the concepts captured in burn-specific patient reported outcome measures?**

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## **Abstract**

### **Background**

Pressure garment therapy (PGT) is an established treatment for the prevention and treatment of hypertrophic scarring; however, there is limited evidence for its effectiveness. Burn survivors often experience multiple issues many of which are not adequately captured in current PGT trial measures. To assess the effectiveness of PGT it is important to understand what outcomes matter to patients and to consider whether patient-reported outcome measures (PROMs) can be used to ascertain the effect of treatments on patients' health-related quality of life. This study aimed to (a) understand the priorities and perspectives of adult burns patients and the parents of burns patients who have experienced PGT via in-depth qualitative data, and (b) compare these with the concepts captured within burn-specific PROMs.

### **Methods**

We undertook 40 semi-structured interviews with adults and parents of paediatric and adolescent burns patients who had experienced PGT to explore their priorities and perspectives on scar management. Interviews were audio-recorded, transcribed and thematically analysed. The outcomes interpreted within the interview data were then mapped against the concepts captured within burn-specific PROMs currently in the literature.

### **Results**

Eight core outcome domains were identified as important to adult patients and parents: (1) scar characteristics and appearance, (2) movement and function, (3) scar sensation, (4) psychological distress, adjustments and a sense of normality, (5) body image and confidence, (6) engagement in activities, (7) impact on relationships, and (8) treatment burden.

## Conclusions

The outcome domains presented reflect a complex holistic patient experience of scar management and treatments such as PGT. Some currently available PROMs do capture the concepts described here, although none assess psychological adjustments and attainment of a sense of normality following burn injury. The routine use of PROMs that represent patient experience and their relative contribution to trial outcome assessment versus clinical measures is now a matter for further research and debate.

**Keywords:** Burn scar management; patient-reported outcomes; qualitative research; interviews.

## Introduction

Pressure garment therapy (PGT) is an established and widely used treatment for the prevention and treatment of hypertrophic scarring in burns [1-3]; however, at present there is limited evidence of its effectiveness and cost-effectiveness. Systematic reviews demonstrate a small but statistically significant effect of PGT on scar height, compared to no PGT, but no significant effect on global scar scales or other measures of scar characteristics such as pigmentation, vascularity, pliability and colour [4,5]. Survivors of burn injuries often experience a range of problems including: scar cosmesis; reduced function; psychological and social issues, and reduced overall quality of life (QoL) [6]. These multi-factorial problems can reportedly impact appearance; interpersonal relationships; emotional, social, sexual, and physical functioning of burns patients [7,8]. Whilst the evidence for PGT is limited, measures that feature in systematic reviews and underlying studies do not necessarily reflect these multifactorial issues, and may not adequately represent the views and priorities of patients. To appropriately assess the effectiveness of PGT it is therefore necessary to i) understand what outcomes matter to patients and ii) to consider whether patient-reported outcome measures (PROMs) such as measures of health-related quality of life (HRQoL) and symptoms may be used to ascertain the effect of treatments on patients' multifactorial concerns. Brédart et al. [9] highlight the importance of using qualitative data collection methods in the development of PROMs to help elicit items that reflect the experience of the specific population of interest. Griffiths et al. [10] have stressed the need for PROMs in burns to represent the key outcome domains that are important to patients' specific and unique experiences of burn injury. Our aims were therefore to (a) understand the priorities and perspectives of adult burns patients and the parents of paediatric and adolescent burns patients who have experience of PGT via in-depth qualitative data, and (b) compare these with the concepts captured within burn-specific PROMs.

## **Materials and Methods**

### **Study design**

This qualitative research, informed by interpretive description [11], formed part of a wider mixed-methods feasibility study of PGT for the prevention of abnormal scarring after burn injury in adults and children (the PEGASUS study) [12,13]. The overall aim of the PEGASUS study was to assess the feasibility of a full-scale randomised controlled trial (RCT) on the effectiveness and cost-effectiveness of PGT. Whilst the qualitative research nested within PEGASUS was broad-ranging, one key objective was to reflect on the conceptual content of outcome measures that might be used in a future RCT of PGT.

### **Eligibility, sampling and recruitment**

Potential participants were deemed eligible for interview if they were i) adults or ii) parents/carers (referred to as parents from this point) of paediatric (0-8 years) and adolescent (9-15 years) burns patients who had had at least six months' experience of PGT and had finished PGT no more than two years prior to data collection. We recruited a diverse range of participants according to their sex, age, ethnicity, type and severity of burn to facilitate a maximum variation sample. Participants were recruited by occupational therapists (OTs) and/ or research nurses (RNs) in four of the PEGASUS pilot trial sites across England: Queen Elizabeth Hospital, Birmingham (adults only); Birmingham Children's Hospital (parents only); St Andrews Centre for Plastic Surgery and Burns, Broomfield Hospital, Essex (adults only); and Queen Victoria Hospital, East Grinstead (adults and parents). Clinical staff provided information sheets to potential interviewees and took written consent to pass contact details on to the PEGASUS qualitative research team. A member of the qualitative research team then contacted potential interviewees, provided further information and answered questions as necessary, before arranging a suitable time, date and venue for the interview. Written informed consent was provided by all participants prior to the start of data collection.

## **Ethics**

A favourable opinion for the PEGASUS study was received from the West Midlands: Coventry and Warwickshire Research Ethics Committee (14/WM/0160).

## **Data collection**

Semi-structured interviews were identified as an appropriate data collection method given that they facilitate an in-depth exploration of participant views [14] and are particularly useful in discussions of sensitive or traumatic experiences. Interviews were conducted by a trained non-clinical qualitative researcher who was independent of the participant's/ their child's clinical care team. Interviews were mainly conducted in the patient's home, which was the preferred venue; although a small number took place via telephone. A semi-structured discussion guide informed by the literature, discussions with our patient and public involvement (PPI) group, and the wider PEGASUS research team guided data collection. The interviews were conducted in a participant-focused manner allowing issues and perspectives important to participants to emerge naturally [15]. Topics discussed included: accounts of the accident and injury (where participants were happy to talk about these in order to provide context for the remainder of the data); accounts of subsequent treatment; the experience of PGT and other scar management techniques; hopes and expectations for treatment, recovery and scar management; perspectives on a trial of PGT, and patient-centred outcomes. The topic guide and interview process was refined after reflection on a small sample of initial interviews. Following this, data collection and analysis took place iteratively [14] and continued until the research team judged that the data and sample had sufficient depth and breadth to address the research questions [16]. At the end of each interview, participants were asked to complete a short demographic questionnaire to facilitate maximum variation sampling and a description of the sample characteristics.

## **Data analysis**

Interviews were digitally audio-recorded and transcribed clean verbatim by an external specialist transcription company, and subsequently checked for quality and anonymised by the interviewer. Data were analysed using an inductive thematic approach, following the six steps proposed by Braun and Clarke [17]. Initially, transcripts were read repeatedly to aid familiarisation and allow for data immersion. This facilitated the generation of preliminary codes and themes supported by the use of NVivo software, which eventually progressed into a developed coding frame. Two of the most concept-rich transcripts were independently double-coded by two authors (LLJ and JM) and additional interpretations were incorporated into the coding frame. These early analytic findings were then discussed amongst the trial management group, and shared for discussion and feedback at PEGASUS investigator meetings, where clinical staff delivering the pilot trial and at least one patient representative were present. Following agreement of the final themes, exemplar quotes were identified from each data source. Divergent cases were also explored and reported in the findings where appropriate. Quotes in the following results section are identified using the participant's unique study identification code, and indicate whether the quote was from an adult patient or a parent of a paediatric or adolescent patient.

## **Outcomes mapping exercise**

Griffiths et al. have published systematic reviews of PROMs used in adult and child and adolescent burn research [10,17]. These reviews identify five burn-specific PROMs that have English language versions and validation evidence - (Burn Specific Pain Anxiety Scale (BSPAS)[18]; Burn Specific Health Scale Brief (BSHS-B)[19]; Burn Specific Health Scale Abbreviated (BSHS-A)[20]; Young Adult Burn Outcome Questionnaire (YABOQ)[21]; Children Burn Outcome Questionnaire (CBOQ)[22]) (Table 2). To assess whether the concepts identified via our qualitative research are included in these PROMs



we have mapped the concepts interpreted within our analysis against the content of these measures. In addition, we have included the Brisbane Burn Scar Impact Profile (BBSIP) in this mapping exercise. The BBSIP is a scar-specific HRQoL measure that has recently been developed and has been subject to validation [23]. Whilst not included in the Griffiths et al. systematic reviews [10,17] we felt this was a highly relevant PROM to include in the mapping exercise.

## **Results**

### **Sample characteristics**

A total of 40 interviews: adults (n=24) and parents (n=16); were undertaken across four burns services. Interviews lasted between 19 and 108 minutes (average 51 minutes), with 33 conducted face to face and seven via telephone. Table 1 provides a description and tabular summary of respondent sample characteristics and is supplemented with information about the burn injury, gender and age of the paediatric/adolescent patients whose parents were interviewed. The sample was approximately evenly split between males (53%) and females, across a range of ages. Most participants were white (78%), with the type of burn predominantly reported as flame (45% total; 54% for adults and 31% for paediatric/ adolescent patients) or scald (38% total; 29% for adults and 50% for paediatric/ adolescent patients).

### **Identification of outcome categories and core outcome domains**

Thirteen outcome categories were interpreted within the mapping exercise: (a) scar characteristics, (b) scar appearance, (c) movement, (d) function, (e) itch, (f) pain and sensitivity, (g) body image and confidence, (h) psychological distress and adjustments (i) sense of normality, (j) social activities, (k) work/education participation, (l) relationships, and (m) treatment burden. These 13 categories were combined within eight core outcome domains: (1) scar characteristics and appearance, (2)

movement and function, (3) scar sensation, (4) psychological distress, adjustments and a sense of normality, (5) body image and confidence, (6) engagement in activities, (7) impact on relationships, and (8) treatment burden.

## Scar characteristics and appearance

Patients and parents identified a wide range of scar characteristics as being important outcomes including: height, texture, colour, size and shape, and tightness/ pliability. See [Box 1](#) for a summary of the language used by participants to describe their own scars/ children’s scars and the associated descriptive scar characteristic:

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*“Probably the colour, the texture of the scar, how raised it is and swollen, and that’s about it really, that’s all I can think of. I think the size of the scar, how big it is depends on how much has been damaged, and tends to stay that size, but the thickness I’ve noticed that has changed a lot from when I first got it, and the texture has changed, very firm and almost like a callous when I first had it, to now it’s soft and back to feeling like skin again.” (CA06 Adult)*

Scar characteristic	Language used by interview participants
Height	Thinness, thin, thickness, thick, swelling, swollen, raised, flatness, flat, level, settle, height, bubbles up, skin held down/in, expanding, protuberance, solid, squashed down, bulky.
Texture	Feels like normal skin, smoothness, dryness, firm, smooth, lumps, bumps, callous, soft, ridges, supple, scabby, shiny, softness, shine, sheen wrinkled, ridges.
Colour	Colour, names of colours, pigment, blotchy, like steak, skin colour, flesh coloured.

**Box 1: Language used by interview participants to describe scars with associated descriptive scar characteristic allocated by PEGASUS analysis team**

The language used by patients and parents to describe scars, the impact of treatment (e.g. PGT) on scars, and perceived outcomes relating to scars, varied within the interviews depending on the context of the discussion at that point in time. For example, when describing the perceived impact of PGT on scarring and related outcomes, participants used terms such as “flatter”, “smoother”, and “paler”. As such, they identified changes to specific scar characteristics which they perceived as being easy to measure. This may reflect the narratives and objective markers (outcomes) of scar maturation used by clinicians/ therapists rather than the natural language of patients and parents:

*“It [scar] is a lot flatter as they [clinician] said. I thought it wouldn’t really go down much but it actually has gone really flat, and it is a lot less noticeable.” (ECO6 Parent)*

When talking in more general terms about scarring and treatment, patients and parents, as part of broader more discursive narratives, reflected on general appearance around the ‘look of the scar’, often without reference to specific scar characteristics. This may indicate that patients and parents may value a more subjective judgement of general scar appearance, over measures of singular specific scar characteristics, such as height. Importantly, participants were able to identify and articulate the fact that outcomes around scar appearance need to reflect both the clinical and patient opinion as they may differ:

*“How somebody feels their healing is coming, and how somebody [clinician] in the scar clinic or burns unit feels it is, because obviously they could be two very different things couldn’t they? But it’s got to be down to the...it’s got to be both of those things, so it’s got to be a medical opinion, but the patient’s opinion as well, managing expectations.” (EG08 Adult)*

There were also differences in the perceived importance of appearance based on factors such as the gender and age of the child, differences in the personality traits of adults, and the location of the scarring:

*"It's [appearance] not going to be an issue I don't think, he's a boy...if he was a girl it would be an issue, but he's a boy, it's on his thigh, it's 95% of the time it's out of view, it's only when he's at the swimming you're going to see it. And we're hoping as he grows it will just get smaller and smaller, so that's what we're hoping for anyway, by the time he's a teenager it should just be a small scar on his leg, hopefully." (BC03 Parent)*

*"If it was my face or maybe my chest or neck or something like that, it might be more important to me, but I don't think I'm a particularly narcissistic person, wrong word but you understand what I mean? I'm not particularly a vain person I don't think I am, but it's difficult, but no they don't worry me. It's something that's happened, it's a war wound, it's a thing that everyone has a scar somewhere to a greater or lesser degree." (CA03 Adult)*

## **Movement and function**

Movement and function were perceived by participants as being important. The priorities of movement and function were also compared with appearance; for some, appearance was perceived as more important than movement and function, whilst for others it was the opposite:

*"Well I want to first 100% be assured in the future she will have no movement restriction, is the first thing. After that I will like to know as much as she can get help to make that look better, any help, and then after that any psychological way she can get help to be perfectly fine how she look...the look comes after, if she has perfectly fine then I will focus on her look, but if she is not or if she is restricted it's more important." (BC04 Parent)*

*“I’ll be honest, the mere fact that I didn’t have to have skin grafts, and it was healing, I could cope with the look, that was not paramount in my thoughts to be honest. It was getting the use back; I can live with the scar.” (CA02 Adult)*

However, those who were more focused on appearance, did report that function was relatively good and so it might be that their views on appearance might have been different if they had more limited function:

*“I’m going to say both really, yes, I’m pretty fortunate that I have got pretty much full mobility apart from like I said the tightness in my legs at times, and I can live with that, but for me it’s probably the appearance, if the appearance is a little bit better I would be a bit more confident and probably wear shorts and go swimming with the children.” (CA09 Adult)*

~~*“Appearance is very important but injury and treatment has never stopped [child] doing anything and didn’t affect function in any way.” (EC04 Parent)*~~

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One parent also highlighted that outcomes are likely to vary depending on the child:

*“The trouble there is you’ve also got people are different, he’s not been bothered, but another child who has had a burn could be very bothered by it. It would be... I suppose you would have to take the personality of the child a bit as well, or the person, not necessarily just a child, it wouldn’t just be children would it?” (EC03 Parent)*

Few participants made an active distinction between range of movement (ROM) and function with these terms being used interchangeably by patients and parents. Our interpretation of these data is that function, in terms of being able to do things, including activities that the patient was doing prior to the burn injury, was perceived as more important than movement per se:

*"I think the most important was his arm, I think it was his arm, because my thing was even though you had these burns I want you to be able to do everything that a normal child could do that never had a burn, and without the range of his arm he couldn't. He couldn't reach for things, he couldn't hold a lot of stuff, there's a lot of stuff that he couldn't do because of that arm, and he started to teach himself how to write with the left hand and use the left hand, but it was never the same. So my thing was I really wanted to get this arm back. Once he got that back I didn't... that was my most important thing, seeing him do everything again, and I think for him it probably was the most important thing, because he seemed a lot more happier when he could play with other kids and use both arms than when he was just using the one." (BC02 Parent)*

*"The range of movement was the most important for me...because at the end of the day I am right handed, all of the jobs I've ever had have been manual work jobs which involve your hands, so to me being able to use it again was the most important thing." (CA06 Adult)*

## **Scar sensation**

Itch and pain were commonly highlighted as important scar sensory outcomes by participants:

*"[The best outcome would be to]...get rid of the pain and the uncomfortableness, yes." (EG07 Adult)*

Some parents reported that they found it difficult to estimate their child's pain and so this may have made it challenging to assess as an outcome. Whereas other parent's reported that they had a good understanding of their child's discomfort and highlighted their perception that pressure garments had made a difference:

*"I think they [pressure garments] do help with the itch because he can't get to it, because he does cut himself occasionally doesn't he when he scratches so hard. So I think they help him with protecting it so he can't get to it. I don't know so much about the pain or the itch, because it's hard to say. I don't think he's had any pain with it as such. Since it's healed he's not actually had pain, it's just itching."* (BC03 Parent)

Adult patients also reported that pressure garments helped with pain management, even for smaller burns:

*"I wore the pressure garment as much as I could tolerate it, and finding as I said the pain... that it helped with the pain. As I say I don't... and even when I was just showing you that, it's very tiny, but the pain it's very difficult to describe the pain, even... and I can't begin to imagine a whole body burn, how someone copes with the pain, and if these go... if the pressure garments go any way to helping with the pain for me that would... yes, I just can't imagine what it would have been like without having one."*  
(EG02 Adult)

Other sensory factors, such as scar tenderness and sensitivity were also identified as outcomes, but less commonly than itch and pain:

*"Yes, it's not an ache as in muscle ache, it was an ache as though the... I don't know how to describe it really, but it was as though the skin was very sensitive and being stretched to its limit."* (CA06 Adult)

## **Psychological distress, adjustments and a sense of normality**

The psychological impact of burn injury was obviously significant and discussed in a lot of the interviews. Related to this many participants, in particular adults, discussed various aspects of their perceived sense of normality and a desire to *"return to normal"*:

*“Exactly, normality yes, you just want to do the things you done before...just basically want to get back to normal, I only go twice a year now for my check ups and everything, so far it’s been okay, so yes just get back to normality and lead a normal life.” (CA04 Adult)*

This included the impact that burn injuries can have on relationships with partners, family and friends. To attain some sense of normality there may be a need for psychological adjustment which helps to facilitate acceptance of the injury and required treatment regime:

*“I never thought I’d get back to normal ever. So I resigned myself to the fact that that’s it now, I’m just going to be like this, until the one they can do for me... all the future hospital operations which I know I’ll be having. So I just resign myself to it’s going to be a good few years of having treatment without thinking about...” (QA02 Adult)*

Parents also reported a desire for a sense of normality for their children and the family. Whilst difficult, psychological adjustment, not only to the accident but also to treatment was seen as key to moving forward:

*“Just about [coping]. It’s taken a while but we’ve just had to tell ourselves that we’re doing everything for him. I always look at it in the perspective of if I can’t move on he won’t move on, so I try... even when sometimes I think back about it [the accident] I still try to push myself and do what I need to do for him, because if you don’t who will?” (BC02 Parent)*

## **Body image and confidence**

As highlighted above in the scar characteristics and appearance section the appearance of the scar can impact emotional well-being, body image and confidence. Patients and parents reported how other people, “react[ing]”, “staring” or “making comments” about the way they or their child looked



could have a negative impact on well-being and confidence and that burns patients often try to keep their scarring and/or their pressure garment “hidden”:

*Patient: “For people who wear the pressure garments I think there’s some sort of psychological aspect in it as well, it’s not just a physical thing. I struggled immensely with keeping the thing hidden, and it’s not easy.” (CA07 Adult)*

*“Right, there’s the scarring, then you’ve got to see somewhere that disappearing, seeing how people react to people as well who have more facial burns and that sort of thing, asking them if there was any way of making life easier for them, because that’s a big one because I was with... well I always seemed to be in the waiting room with two other girls who both had looks like they had a fight actually, everywhere and things, and then they obviously had a hard time because they were... that’s just well how do you cover up something like that? You can’t can you? Not really.” (EG04 Adult)*

In contrast, for others, wearing pressure garments acted as a physical and emotional barrier and offered perceived “protection” and “security” helping to boost confidence and self-esteem. This linked with engagement in activities, and to some extent, psychological adjustment:

*“It gave you a feeling of security...yes, a feeling of protection maybe, now whether that’s psychological or actual I don’t know...” (CA03 Adult)*

## **Engagement in activities**

Experiencing a burn injury and the resultant scarring influenced some patients’ ability to engage in activities including, for example, going to work or school and participation in social events. There were emotional, social and physical aspects to this and patients reported impacts differently, with some more inhibited than others. This was inherently linked with body image and confidence:

*"It's affected him a lot, he doesn't really go out much anymore, he used to go, I wouldn't say he would go out all the time, but he was quite often out with his friends, and now he's more in. He's got a very good group of friends who throughout were very supportive, but him himself it has affected him a lot. Like I say now it's more he's on his Xbox, he'll be with his... you know how they have these headphones, they play live and talk to one another, but he certainly doesn't go out to the extent that he did." (BC09 Parent)*

*"I don't go swimming with the children, like we used to. We used to do family Sundays, go up the swimming pool for an hour or so, I don't do that now because I'm a bit conscious about my scars, my scars they still look quite red and angry, even though they're probably not, it's just the colouration in the scars." (CA09 Adult)*

This was also linked with a participant's "sense of normality" and the burden of treatment where there was a perception that it is not always possible to return to work for example:

*"You get to a point where you feel like you're just getting back to normal, and then another op will come up, but the ops that you need to have they're not the sort of ops where you can say to your employer I need to take a day off of work or a week off of work because I've got to have this op, because these ops can affect your life for weeks down the line." (CA01 Adult)*

When patients' and/ or their parents perceived that they were able to engage in activities and had "returned to routine", such as going back to employment or education or participating in social activities following their burn injury, was identified by patients and parents as being important:

*"I pretty much do most things for myself now, but I don't need mum to care for me, she's gone back to work. She's only gone back part time, because obviously I still need quite a*

*lot of hospital appointments and stuff like that, but no I can do pretty much everything for myself now, it's just the ops and that, if I have an op done to my hand I might not have the mobility to be able to do things myself for just like a week or so." (CA01 Adult)*

## **Impact on relationships**

Participants reflected on the impact of the burn injury and subsequent treatment on their relationships. This impact was often different for each of the participants depending on their familial and social networks and to some extent on the nature of the accident. When compared to adult patients, parents appeared to report more significant impacts, particularly on their relationships with the child's other parent and their other children. For example, one parent reflected on the strain of being separated from her husband and daughter whilst she stayed in the hospital for an extended period to look after her injured son:

*"I stayed [at the hospital] all the time. My husband came up the weekends, but myself and my mum stayed all the time, but my husband came home because we've got a daughter. Well separation for me [biggest impact], I didn't see my daughter for five and a half weeks. I did speak to her obviously...I only came home twice just to pick other stuff up, so I only saw her briefly, I spoke to her every single day. It was a long time for both myself and my husband to spend time apart, and I was with [son] all the time so it was easy for me because I could see exactly what was going on. But it was very difficult for my husband when he was at work, and I explained to him over the phone what's going on." (BC09 Parent)*

Another parent reflected that guilt from the accident and the subsequent burden on the family almost led to divorce:

*“Exactly, so that was... yes it had a big impact on the family and almost had a divorce at the time to be honest, so we managed to work out our issues but it really bad... I was very angry to be honest, such a known thing with the iron that... So anyway we worked out our problems fortunately enough, but it had really a big impact on the family, and obviously my wife felt devastated too. She still feels guilty for what happened basically.”*  
(EC01 Parent)

Adult patients typically reflected on the “strain” that it put on the person who was having to care for them rather than the strain on their relationship with the carer:

*“Yes, it also put a lot of strain on mum because there’s an awful lot to do, and with the plasters and bit that is an awful... days were taken up basically just doing all the bits and pieces, having to put cream on three times a day and all that sort of thing, but yes it’s a lot to do but you manage, you get by, it sorts itself out.”* (CA04 Adult)

## **Treatment burden**

Much of the narrative within the interviews for patients and parents was constructed around the burden of care required for burn injuries and longer term scar management, in particular, the use of PGT. Given the emphasis placed on this in the interviews, it has been interpreted as being an important outcome domain. This domain is multi-faceted. Experience of treatment had positive and negative elements depending on the unique context and experience of each individual patient. For example, and as per body image, self-esteem and confidence, some patients reported positive experiences of wearing pressure garments whilst others articulated a much more negative perception of PGT:

*“It [PGT] was quite easy, I made it into a little game. She enjoyed... it sounds wrong but she enjoyed having the attention brought to her. Like if I forgot to do it she would come up to me and be like, “Mummy you’ve got to do my hand,” so I’d do her hand and*

*everything. So it just became a day to day thing really, so it's never affected her or anything, which I was quite happy for." (BC07 Parent)*

*"I vaguely felt relieved not to wear them because of the effort and the time spent in putting them on I think. So oh goodness I haven't got to worry about that anymore sort of thing. I can remember vaguely feeling like that, relief really in not having to wear them. But it wasn't anything to do with them being uncomfortable or anything like that, it's more the difficulty in putting them on and the time and effort, and things like that, I think." (CA03 Adult)*

Participants identified a significant burden of care for scar management including, for example, the number of follow up appointments required, the cost to the patient and the NHS, and the impact on family, such as parents having to give up work to care for their children following a burn injury:

*~~"Yes, that's it, you're constantly hospital, in and out all the time, in and out. You was thinking I'll get this, get back to work, and then something else you've got to have done, and just never bothered. I'm on incapacity benefit now, I'm not on disability, just incapacity, and income support, that's what I'm on." (QA02 Adult)~~*

*"Besides that whether the hand is functioning normally, and they can stretch their fingers. One thing you could potentially check whether the benefit on the scar and how this impacts the family as well in terms of the restrictions. But again I think any reasonable parents would do anything, and if it means to stop working, and it means sacrificing holidays and whatever and going out..." (EC01 Parent)*

## Outcomes mapping

Table 2 charts the outcome domains and categories interpreted from our qualitative research with those covered within the burns specific PROs identified in recent systematic reviews [10,17] (BSPAS; BSHS-B; BSHS-A; YABQ; CABOQ) and the BBSIP. Only one of these measures, the BBSIP, is available for patients of all ages, with four age-specific versions. Other measures are available for adults (BSPAS; BSHS-B; BSHS-A), young adults aged 19-30 (YABQ) and children aged 5-18 years (CBOQ). The BSPAS was developed to focus exclusively on pain and the anxiety associated with pain. It therefore only covers one element of our scar sensory domain and will not be considered further in these comparisons.

Although the BBSIP, which is scar-specific, is the only measure to include items related to individual scar characteristics, items covering scar appearance feature in all of the measures. Similarly, body image, functional abilities, psychological distress and work/ educational participation are included in each measure, although the detail of specific items does vary. Pain and itch do not feature in the BSHS-B or BSHS-A, although scar sensitivity is a domain in the BSHS-B. The latter does not include items related to social activities and relationships. Treatment burden, which was a significant and varied feature in our qualitative data is only covered by more than one item within the BSHS-B, in a domain termed 'treatment regimens'. The BBSIP has a single item focused on the perceived impact of scar treatments. The other measures do not consider treatment burden for the patient and their families, although the CBOQ is the only measure to include items related to treatment compliance. None of the measures directly address patients' sense of normality and psychological adjustments to burns and scarring, which again was a prominent feature of our data. Some items that were less prominent in our data are featured in the measures, particularly sexuality/ sexual activity and family function/ concern.

## Discussion

This study has identified outcome domains that are likely to be central to any patient-centred assessment of the impact of burn scar management regimes. These findings also have broader relevance to the assessment of burn and scar related quality of life during the period of recovery and rehabilitation that patients undergo following initial acute treatment. Our findings show that the patient experience of PGT, and therefore any assessment of health-related quality of life, is complex and multi-faceted. We have proposed eight outcome domains that are applicable to the assessment of relevant interventions; (1) scar characteristics and appearance, (2) movement and function, (3) scar sensation, (4) psychological distress, adjustments and a sense of normality, (5) body image and confidence, (6) engagement in activities, (7) impact on relationships, and (8) treatment burden.

To our knowledge this is the first published work with a UK burns population that has specifically focused on the outcome domains and concepts that are relevant to patient-centred outcome assessment in burn scar management. It is also derived from one of the largest in-depth qualitative datasets to be constructed with adult patients and parents of paediatric and adolescent patients. We have achieved a broad purposive sample with diversity in demographic characteristics, burn severity and type of burn. [Whilst our sampling was focused upon participants who had direct experience of PGT there is also a need to consider the range of outcomes relevant to other scar management interventions, including for example, laser and light therapy \[24\]. We would however suggest that our findings are likely to have some transferability to other scar management modalities.](#) One limitation to our study is that we did not collect the perspectives of older paediatric patients directly, and are therefore reliant on the views of their parent. The fact that many burn injuries occur in the youngest paediatric populations means that research will always be reliant on the input of parents and carers. However, further work to establish that the findings presented here fully represent the views of children who would be old enough to participate in qualitative research may be warranted.

To date there has been very little published qualitative research with patients examining their experiences of burns scar management that might be used to inform outcome selection or design. Notable exceptions to this include a qualitative study with 8 adult burns patients in the UK focusing on their experience of PGT [7], a qualitative study with German patients examining adherence to PGT [25], and the qualitative study that underpins the conceptual development of the BBSIP [26]. Each of these studies present data that resonate with the outcome domains provided here. The conceptual model established from the qualitative work underpinning the development of the BBSIP recognises that burn scar related quality of life is multi-faceted, including for example physical symptoms and functioning, as well as emotional and social functioning [26]. The work by Ripper et al. [25] focusing on adherence to PGT presents data describing patients' experiences that is concordant with several of the domains identified, for example: scar characteristics and appearance, treatment burden, and scar sensation.

The qualitative study by Martin and colleagues [7] used a phenomenological analysis of adult patients' experiences of scar management to help illustrate how treatments such as PGT might facilitate or hinder adaptation to burn injury, regardless of the physical effects on scarring. One of the outcome domains we have identified concerns patients' psychological adjustments and related adaptation to burn injury. This is clearly important as patients' views on the physical features of scarring cannot and arguably should not be disaggregated from broader requirements to adapt and adjust to life post burn injury. We have conceptualised this psychological adjustment and adaptation as a 'sense of normality'. We have used this term for two reasons: firstly, the patients and parents we spoke to often referred to this component of their experience in reflecting on the overarching impact of the burn injury and treatments using the terms 'normal' or 'normality' and secondly, 'normality' has been used as a conceptual tool to understand the patient experience of other health conditions, particularly chronic conditions, and the adaptations that patients undergo in



order to accommodate the condition and its impact on life [27-30]. Our mapping shows that whilst existing burn PROs do include items that would cohere with elements of what we have termed psychological distress, that they do not directly address adaptation and attainment of a sense of normality. It may be that features such as this are less obviously outcome focused, and hence less likely to be identified as items relevant to health-related quality of life assessment. However, our data, along with insights from studies such as Martin et al. [7] suggest that this domain and related items may be crucial in understanding the overarching meaning of burns scar management for patients and parents.

At present there is a limited range of burn-specific PROs available and only one that is scar-specific (BBSIP). Only two of these measures were developed using qualitative data collected from patients (BBSIP, BSPAS) and the BSPAS is focused exclusively on pain and anxiety related to pain. The BBSIP is also currently the only measure with versions available for all ages, with, for example, the YABOQ being specifically developed for young adults. We are aware that a further set of burns PROMs are in development at the Centre for Appearance Research (Bristol, UK), but these were not available to the research team for the mapping exercise we have presented (personal communication).

[Similarly, the life impact burn recovery evaluation \(LIBRE\) profile has recently been developed to assess the impact of burn injury on social participation, and resonates with some of the outcome domains presented here, particularly 'engagement in activities' and 'impact on relationships' \[31\].](#)

With regards to conceptual content, the BBSIP also covers the broadest range of concepts that cohere with our analysis, although the YABOQ is also relatively comprehensive. The latter does not provide any focus on treatment burden, perspectives on which are integral to the experience of scar management. This is addressed by a single item in the BBSIP. The most comprehensive coverage of this is found in the BSHS-B, but this tool does not focus on other key domains such as scar sensation.

Our work demonstrates that the impact of burn scar management regimes such as PGT are multi-faceted and reach far beyond the intended clinical effect on scarring and the individual scar characteristics that have often been the focus of outcome assessment in clinical research. Systematic review of the effectiveness of PGT has focused on global scar assessments and the scar characteristics (height, pigmentation, vascularity, pliability, colour) that have been the focus of outcome assessment in trials to date [4]. We would suggest that more broadly conceptualised health-related quality of life is central to patient-centred outcome assessment of the effectiveness of scar management and other burn interventions. Outcome selection is a crucial component of trial design, and there have been recent attempts to rationalise the selection of outcomes via the construction of Core Outcome Sets (COS). These are a minimum set of outcomes to be collected in all trials within a specified clinical setting [32]. A protocol for the development of a COS for use in burn care has recently been published [33]. This details plans to conduct preliminary qualitative research with patients to help inform items that will go forward to a consensus process including a range of relevant stakeholders. We would suggest that the patient-centred analysis presented here is likely to have relevance to the development of this COS. [It also starts to respond to a recent call made by Schneider to establish burn rehabilitation research themes and priorities, one of which was ensuring that we measure the right things in rehabilitation research](#) [34].

## **Conclusions**

Using in-depth qualitative data collected with adult burn patients and parents of paediatric and adolescent patients we have suggested eight outcome domains relevant to patient-centred outcome assessment in burn scar management. We have mapped these against available burn-specific PROs. Further research is required to validate relevant measures, including the BBSIP, in different clinical populations. The routine use of measures that represent patient experience and their relative contribution to trial outcome assessment versus clinical measures, for example those of scar characteristics, is now a matter for further research and debate.

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