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Patients' perspectives on systemic sclerosis-related Raynaud's phenomenon in the feet: A qualitative study from the OMERACT Foot and Ankle Working Group

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ABSTRACT

Objective: To explore, from patients' perspectives, the symptoms and impact of Raynaud's phenomenon (RP) on the feet of patients with systemic sclerosis (SSc-RP), and to identify which foot-related domains are important to patients.

Methods: Forty participants (34 women) with SSc-RP took part in one of six focus groups held in the United Kingdom or United States. Participants were purposively sampled to ensure diversity in disease type, duration, and ethnicity. The topic guide included questions on RP impact, self-management, and treatment expectations. Qualitative content analysis was employed to identify key concepts in the data relating to foot-specific symptoms and their impact. Themes were organized by corresponding domains of potential importance.

Results: Twenty-eight participants (70 %) reported experiencing RP in their feet. Five themes were identified corresponding to domains of potential importance: temperature changes, pain, cramping and stiffness, numbness, and color changes. These issues negatively affected participants' lives, impairing walking, driving, and socializing, and causing issues with footwear and hosiery.

Conclusions: This large qualitative study exploring the experiences of patients with SSc-RP in the feet identified several key domains of high importance to patients. SSc-RP is common in the feet, presents in several patterns, and impacts multiple aspects of patients' lives. These findings indicate where future foot-specific interventions for RP could be targeted. Findings from this study improve understanding of what domains are important to patients with SSc-RP affecting the feet and will contribute to the development of a core outcome set for foot and ankle disorders in rheumatic and musculoskeletal diseases.

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Background

Core outcome sets (COS) are agreed, standardized sets of domains and instruments that should be measured and reported in all clinical trials in specific areas of health [1–3]. They are developed with all key stakeholders to ensure clinically relevant outcomes and enhanced transferability of study findings to clinical practice [1,2]. In addition, COS reduce outcome heterogeneity and facilitate meta-analyses. The OMERACT Foot and Ankle Working Group is developing a COS for foot and ankle disorders in rheumatic and musculoskeletal diseases (RMDs) [4,5].

One RMD within the proposed scope of this COS for foot and ankle disorders is systemic sclerosis (SSc), a complex disease with an estimated global prevalence of 18.87 per 100,000 [6]. The condition is characterized by three key features: vasculopathy, immune activation with production of autoantibodies and alteration in immune cells, and fibroblast dysfunction with excessive matrix deposition and subsequent fibrosis of the skin and internal organs [7]. Raynaud's phenomenon (RP), characterized by episodic vasospasm causing discoloration and pain in the digits, is a hallmark feature of SSc, affecting ~96 % of patients [8]. RP is typically triggered by exposure to changes in ambient temperature or emotional stress [9]. RP is part of SSc-related vasculopathy, resulting in digital ischaemia. When severe, this ischaemia can lead to ulceration, necrosis, and digit auto-amputation [10].

Qualitative research is an important step in identifying potential domains for inclusion in a COS [1,2,11,12]. A recent systematic review and thematic synthesis from the OMERACT Foot and Ankle Working Group included data from 34 existing qualitative studies involving patients with foot and ankle problems in RMDs, and identified seven common themes relating to the symptoms and impact of these problems: pain, change in appearance, activity limitations, social isolation, work disruption, financial burden and emotional distress [13]. However, this review did not identify any existing qualitative studies involving patients with foot problems in SSc-related RP (SSc-RP) in the feet.

Qualitative research involving patients with SSc-RP in the hands demonstrated impact and highlighted potential domains of importance for this aspect of SSc [14]. It is possible however, that SSc-RP impacts patients differently based on the specific location of the RP. For example, given the weightbearing activity of the foot and issues associated with wearing footwear, the impact of SSc-RP in the feet is likely different from the impact of SSc-RP in the hands; these issues are well established among patients with other RMDs [15–17]. It is not known what domains are important to patients with SSc-RP in the feet, or which domains should be measured in future interventional trials. Moreover, it is currently unclear whether domains of importance to these patients are similar enough to those in other RMDs to plausibly include SSc-RP trials in the scope of the proposed COS.

Although foot problems in SSc are well recognized [18,19], with up to 67 % of patients with SSc reporting having had foot involvement during the course of their disease [20], clinical trials investigating treatments for patients with SSc-related RP (SSc-RP) tend to focus on measuring RP domains in the hands [21,22], thus overlooking RP-related foot involvement [20,23]. This lack of focus on RP in the feet could be because the incidence of SSc-RP affecting the foot is under-reported or the problem is underappreciated by clinicians and investigators. The study of RP in the feet has not been explored in depth; the lack of outcome measures in this area likely contributes to this reduced depth of research.

This study aimed to explore, from patients' perspectives, the symptoms and impact of Raynaud's phenomenon (RP) on the feet of patients with systemic sclerosis (SSc-RP), and to identify which foot-related domains are important to patients.

Methods

A secondary analysis of an existing qualitative dataset was

conducted. The original study aimed to explore the domains that form the patient perspective of SSc-RP, through understanding of the patient experience, to inform patient-reported outcome instruments assessing the severity and impact of SSc-RP. Full details of the original methods are published elsewhere [14] and the full data set from the original study was analysed.

Participants and data collection

Forty participants (34 women, mean (SD) age 56.6 (13.4) years, mean (SD) disease duration (10.5 (9.1) years) with SSc-RP took part in one of six face-to-face focus groups: two in Bath, United Kingdom, one in Pittsburgh, United States of America, and three in New Orleans, United States of America. Participants were purposively sampled to ensure diversity in disease type (limited cutaneous SSc and diffuse cutaneous SSc), disease duration, and ethnicity, with White, African American and Hispanic representation. The number of participants per focus group ranged from six to nine, and each focus group lasted approximately 60 min. The topic guide included questions on SSc-RP impact, self-management, and expectations from treatments [14].

Data analysis

A directed approach to qualitative content analysis was employed to identify key concepts in the data relating to foot-specific symptoms and impact, aligning to the research aim of identifying potential domains of importance. This method of analysis was selected as it generates descriptive knowledge and understanding of the phenomenon under study, using relevant research findings as guidance [24]. Each anonymized transcript was read multiple times by the lead researcher (LSC), who then extracted data relating specifically to feet into Microsoft Excel (Microsoft, 2022), coded this data, and grouped similar codes into themes. Codes were subsequently independently checked by a senior qualitative researcher (CAF). Finally, an expert in SSc (BAP) independently read 50 % of the transcripts to ensure all foot-related data were captured by the secondary analysis. The analysis team (LSC, CAF, PR, BAP, and HJS) discussed the names of the themes until consensus was reached. Each theme directly related to foot-specific domains of potential importance.

Results

Twenty-eight participants (70 %) self-reported RP in their feet. Five themes were identified from the focus group data: temperature changes, pain, cramping and stiffness, numbness, and color changes. A thematic map, portraying the relationship between themes (domains of potential importance) and their impact, is presented in Fig. 1.

Theme 1 – temperature changes

Most participants with SSc-RP experienced extreme temperature changes in their feet, particularly when in bed:

“About a year ago it started with the feet, and so my feet are frozen my hands are cold ... I love cold weather, but it just attacked my hands and my feet, and when I'm laying down in the bed, my temperature and my body is warm, extremely hot, but my hands and my feet are like ice.” – Grace, focus group (FG) 4

Participants described the life impact of these temperature changes, and how medication had helped:

“Basically, what Raynaud's means to me is it's ... it's debilitating at times. Temperature plays a big part in it. If I go outside, man, before I was given ... prescribed a certain medication ... 50 to 60° [Fahrenheit] was my cut off. If I would go outside and the temperature ... it would affect my hands and my feet very, very quickly, very rapidly to where it was almost

debilitating. It's not as bad as it was; medication has helped immensely, but yes, it can be downright debilitating." – Frank, FG4

In contrast, one participant expressed that temperature changes did not improve with medication.

Participants discussed various strategies to deal with temperature changes, including foot warmers and hot water bottles. Temperature changes also impacted on hosiery and footwear choice:

"If I go into a restaurant, I have to put on my Ugg boots whether it's in the summer or not because [of] my feet." – Jan, FG5

"I've been buying boots and they're lined with like a fur and they're great. If on a bad day I can't get them on I just keep my slippers on and stay home but if I can go out, I put these on and it does help, yes." – Pam, FG3.

"And I pre-empt it, so I don't go out of the house if it's particularly damp without a pair of gloves, or without thick socks on to keep my body temperature up." Clive, FG1

Theme 2 – pain

Most participants with SSC-RP in their feet experienced pain. In some cases, this theme linked to Theme 1; pain was directly related to change in temperature during an episode of RP:

"My feet get cold. I can't ... it's like needles in my toes. You can't walk." Jan, FG5

In other cases, participants described residual pain following RP episodes:

"And my feet, and now, it's gotten so bad 'til I wear two to three pair of socks now, because I can't deal with the cold. It used to happen mostly at night, but now it happens all during the day while I'm working and everything, so I finally just started putting extra socks on, and I get comfort. Now at night, when it's time to get into bed, I somehow can't sleep with socks, so I just pretty much wiggle my feet until I go to sleep, but the pain is just there." – Grace, FG4

Residual pain after recurrent RP attacks also influenced patients' choices in hosiery and footwear:

"I'll put socks on, slippers on indoors and then it starts so I think I just want to walk up and down the hallway. I can't go out in the garden because it hurts too much to put shoes on ... I bought silk socks, they're not very thick but I tell you what when I wear them, and I put a pair of ordinary socks over the top I don't get so much pain in my toes. I have to put them on first, but they were really expensive for a pair of socks ... I think when my feet were pushing in and got holes in them, and I didn't dare

stitch them because the edging would cause more pain. Any pressure on anything makes it worse." – Pam, FG3

"I can go to bed, and I can put socks on like [another participant] used to say, and I can wake up in the middle of the night or most of the night and my feet are cold and my hands. Or I can go the other way that my feet are hot but I'm tight and I get a warm feeling coming up, and I've got to take the socks off. And I've got to throw the duvet off my leg because I can't stand the pressure on it." – Julie, FG1

One participant feared getting ulcers on her toes after having them on her fingers:

"That's my fear of getting ulcers back, and on my toes as well, yes." Pam FG3

Foot pain impacted on participants' daily lives, particularly affecting the ability to walk:

"Sometimes I can't get out the chair to walk because it's, you know, it's painful." – Emily, FG1

"My feet, I can hardly walk about indoors with my feet they hurt so much." – Pam, FG3

Foot pain could also be related to skin lesions, potentially as a result of the overall systemic condition rather than RP specifically:

"On my heels, and I've got a deep one [a crack] at the moment, my right heel has split open ... it's cracks and it bleeds ... I know my scleroderma has been flared up lately and I have had Raynaud's and I do get numbness here, even if they haven't gone white, they've been hurting on the sides. But that one I got a deep cut in my foot, it's split open, and it's painful." – Julia, FG1

Theme 3 – cramping and stiffness

Some participants with SSC-RP in the feet described cramping and stiffness:

"Cramp doesn't do my thumbs either, it's just my fingers and my toes." – Emily, FG1

"Funnily enough I don't get it during the winter, mine starts when it starts to get warmer. That's when my muscles start going into spasm and I get the cramp." – Laura, FG3

Cramping and stiffness in the feet was often directly linked to temperature change:

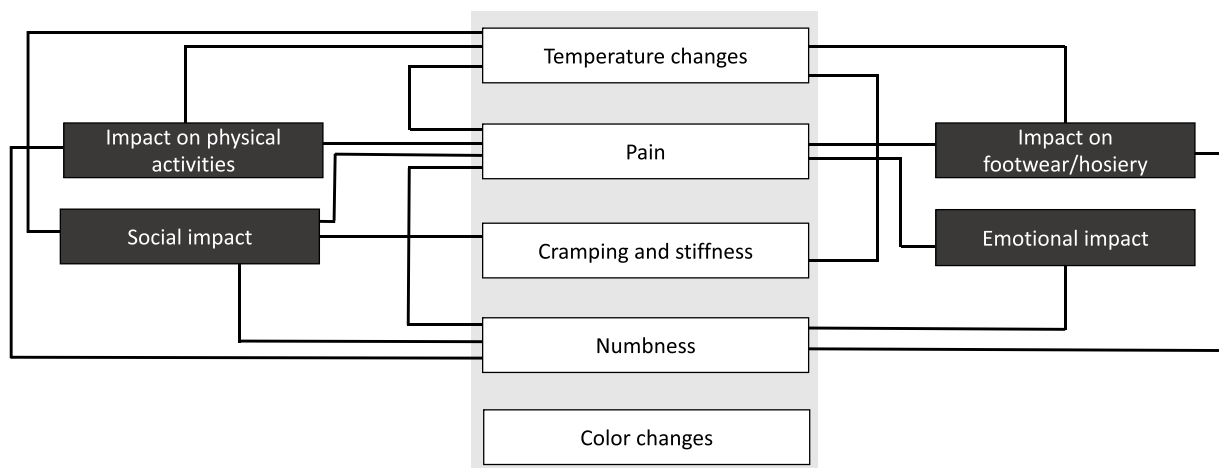


Fig. 1. Thematic map.

“When my toes get really cold, if I’m lying in a bed or something, my toes will stay in this surface place, like it’ll get stuck.” – Betty, FG5

“My toes do that. If I’m very cold they will lock up, like, stiff.” – Jan, FG5

Consistent with Theme 2, cramping also led to foot pain. In some cases, cramping could occur when the feet were warm, independently of a RP episode:

“Cramp in my toes at night usually ... [when my feet] are quite warm ... you have to get out of bed and walk about to get the pain to go away.” – Ali, FG5

Theme 4 – numbness

Many participants with SSc-RP in their feet described numbness, which caused discomfort and irritation:

“They get very numb. It’s not exactly pain, it’s like that really, really deep numbness, like it almost hurts, but to me it’s not exactly the same as pain. And then as it comes back it is uncomfortable. But like joyfully so, because you know it’s getting better.” – Michelle, FG2

“I’m constantly feeling tingling and numbness in my feet ... It’s there right now, you know? I’ll be wiggling my toes, you know, because the numbness, it’s just really aggravating so I kind of try to tune it out ... I just kind of deal with it and pray on it and, and just ignore it ‘cause it’s I been tried so many things and nothing really helps the, the toes, you know. Maybe a little less but it always be, you know, really... And then when I try to ... when I have a tight sock on, I always have to loosen it up or take it off or something like that.” – Dawn, FG5

“The left foot stays numb most of the time. It’s really bad at night ... the foot, it’s like, it goes to sleep as soon as you lay down and ... it don’t seem to be getting better.” – Carl, FG4

Numbness in the feet also affected daily tasks such as walking and driving, causing fear for some participants:

“I think the pain would be bad enough, but my feet do go numb and it’s frightening sometimes if you’re trying to stand up and there’s no feeling in the bottom of your foot. I’ve had that quite a few times, even in the night when I’ve got up and you go to put your foot down and you can’t even feel your foot.” – Julia, FG1

“I was driving, and my foot literally slipped off the pedal driving and [I] didn’t know. That made me say, you know what, something is going on. I need to go and get this checked but it was fingers and toes completely numb and I felt like my entire body was going numb.” – Jan, FG5

“It got to where I couldn’t ... I couldn’t walk. I could only move maybe 20, 30 feet.” – Carl, FG4

Numbness and temperature changes in the feet could lead to a stinging sensation:

“My foot when it gets cold and numb, it stings a whole lot. So I just rub it until ... trying to relieve it, you know.” – Ella, FG4

One participant described needing to use crutches due to numbness in the feet:

“At night my feet can get absolutely numb, and it is that recovery when I get into bed or put a thing over them, it’s that I don’t like, is the feeling of coming back. And then I do struggle to put my weight on them. Whereas when they’re completely numb I use my crutches though.” – Ann, FG1

Theme 5 – color changes

Participants described color changes in their feet. Presentations in the toes included white, purple and black, although the phases were not always clearly defined:

“They start out purple and white. I’ve noticed my toes more white. I didn’t think my toes did that before, but I’ve noticed that more now.” – Heidi, FG2

“I find with myself if I get cold, I get purple lips, my hands, my toes and even my knees go purple.” – Mag, FG3

“Mine go black ...very, very dark.” – Liz, FG1

Discussion

This large, international qualitative study explored the experiences of patients with SSc-RP in the feet. Consistent with previous research exploring hand involvement in SSc-RP [14], pain, numbness and temperature changes in the feet have significant impact on the daily lives of participants. Findings also highlight the impact of cramping and stiffness in the feet on patients with SSc-RP, symptoms that have not been reported in previous work. Whilst color changes in the feet were described by participants in this study, this issue appears to have limited impact. In contrast, color changes and digital ulceration in the fingers can cause unwanted attention and embarrassment, particularly at work and in public, and in some cases lead to dissatisfaction with body image [14]. Change in appearance of the feet and ankles is an important symptom to patients with other RMDs [13]. As discoloration of the toes due to RP is temporary, and feet are often hidden by socks and shoes, change in appearance of the feet may not be as important to patients with SSc-RP as it is to patients with rheumatoid arthritis and osteoarthritis, where foot deformities can be extensive, permanent, and may lead to drastic changes in choices of footwear and clothing.

The experiences and impact of pain in the feet as a result of SSc-RP, a key finding from this study, is congruent with the experiences of patients with foot and ankle problems in other RMDs, including rheumatoid arthritis, psoriatic arthritis, osteoarthritis, gout, and systemic lupus erythematosus [13]. Foot pain is the dominant symptom across these conditions and an important domain to measure in future research. Similar to other RMDs, the scope of this domain in SSc-RP included pain with weightbearing, at rest and at night. Findings also indicate that pain can be transient, occurring during an episode of RP, or can be residual. Residual pain after recurrent RP episodes is associated with nerve sensitivity and chronic allodynia, e.g., not being able to tolerate the pressure of the duvet at night. Whilst participants with SSc-RP were typically able to discriminate between different types of foot pain, measuring pain in clinical trials is challenging and ongoing work by OMERACT aims to standardize pain assessment so that estimates on the effectiveness of interventions can be made [25].

Consistent with findings from the current study, stiffness has been identified as a potential domain of importance to patients with foot and ankle problems in other RMDs, including rheumatoid arthritis, psoriatic arthritis, and osteoarthritis. In contrast, temperature changes and numbness were not identified as prominent symptoms/potential domains of importance in most existing qualitative studies of other RMDs [13], although these domains did overlap with pain among participants with SSc-RP.

This study has implications for clinical practice; findings indicate that RP is common in the feet, similar to other studies reporting prevalence [18–20], and that RP in the feet can have differing manifestations and impacts multiple areas of patients’ lives. Foot involvement should be addressed within the overall rheumatological management of patients with SSc, with footwear and hosiery advice provided as necessary. The importance of establishing patients’ priorities and subsequently the outcomes to target with treatments is always a critical aspect of medical care.

This study has limitations to consider. Firstly, this was a secondary analysis of an existing dataset addressing a research aim relating to the development of outcome measurement instruments for SSc-RP; therefore, none of the questions in the topic guide related specifically to feet.

Previous research showed that patients with foot problems may not be forthcoming in talking about their feet, sometimes viewing them as a separate issue to the rest of their condition and reporting that they are ignored during routine consultations [26,27]. Therefore, not all aspects of living with foot problems in SSc-RP may have been discussed in depth. Additionally, in the context of developing a core outcome set for foot and ankle disorders in RMDs, this study was limited to RP, which is only one aspect of disease in SSc. Some symptoms described by participants may have been due to impaired circulation, skin, musculoskeletal or peripheral nerve involvement in SSc rather than specifically due to RP (e.g., cramping, stiffness and pain). Further work is needed to understand the full breadth and depth of foot-specific domains that are important to patients with SSc. Primary qualitative interviews with patients with SSc who have experienced digital ulcers and musculoskeletal problems in the feet are currently underway in the United Kingdom, to address gaps in existing qualitative research through exploration of patients' experiences of living with this condition. Finally, the potential for researcher bias during data analysis in this study must be acknowledged, as three podiatrists were involved in interpreting the data. Offsetting this, the analysis team also included an experienced qualitative researcher with limited experience of foot and ankle disorders, who independently checked all coding decisions.

Overall, this study indicates that there are some common domains of importance in SSc-RP and other RMDs, suggesting that the scope of a COS for foot and ankle disorders in RMDs should give some consideration to SSc-RP. Domains within a core set are intended to be measured in all trials [1,2]. However, use of the COS in future clinical trials would not preclude measurement of additional domains of interest to researchers. The use of additional domains is expected and will depend on the specific RMD, study question, or intervention being tested.

Conclusion

Findings from this study improve understanding of what domains are important to patients with SSc-RP in the feet, helping to inform the development of a COS for foot and ankle disorders in RMDs (including consensus on core domains and outcome measurement instrument selection). Regardless of their relationship to the domain work, these findings indicate that clinically, SSc-RP commonly affects the feet and feet should be considered within the rheumatological management of patients with this condition. Future research is needed to assess the effectiveness of foot-specific and disease-specific interventions for SSc-RP affecting the feet.

CRediT authorship contribution statement

Lara S. Chapman: Conceptualization, Formal analysis, Writing – original draft, Writing – review & editing. **Begonya Alcaccer-Pitarch:** Formal analysis, Writing – review & editing. **John D. Pauling:** Investigation, Writing – review & editing. **Caroline A. Flurey:** Formal analysis, Supervision, Writing – review & editing. **Anthony C. Redmond:** Supervision, Writing – review & editing. **Pamela Richards:** Writing – review & editing. **Ariane L. Herrick:** Investigation, Writing – review & editing. **Peter A. Merkel:** Writing – review & editing. **Susanna Proudman:** Writing – review & editing. **Hylton B. Menz:** Writing – review & editing. **Philip S. Helliwell:** Writing – review & editing. **Marian T. Hannan:** Writing – review & editing. **Robyn T. Domsic:** Investigation, Writing – review & editing. **Lesley A. Saketkoo:** Investigation, Writing – review & editing. **Beverley Shea:** Writing – review & editing. **Heidi J. Siddle:** Conceptualization, Supervision, Writing – review & editing.

Declaration of competing interest

The authors have no competing interests to declare.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.semarthrit.2024.152372](https://doi.org/10.1016/j.semarthrit.2024.152372).

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