SPOTLIGHT
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Patients' Perspectives of Pain, Time, and Hope When Living with Venous Leg Ulcers and Using the geko™ Device: A Qualitative Descriptive Inquiry.

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Abstract

Introduction: Venous leg ulcers have an impact on individuals' perspectives of pain, time, and hope. Community nurses seek to provide person-centred care to patients living with venous leg ulcers. There is a paucity of research exploring individuals' experiences while living with leg ulcers, specifically their insights into the role of a neuromuscular electrostimulation medical device (geko™).

Methods: Using a qualitative descriptive approach and telephone interviews, seven participants shared their experiences living with venous leg ulcers and when using a geko™ device. Research ethics was approved, and informed client consent obtained. Thematic analysis method was utilized to analyze the data. Interviews were typed verbatim and analysis focused on a data-driven approach, leading themes emerged.

Results: Participants described regular use of pain medications. They described the concept of 'time' from the onset of the venous leg ulcer, through wound reoccurrences, and treatments. Participants described feeling hopeful the geko™ device would support wound healing and assist the wound to become smaller and heal faster.

Conclusions: This small qualitative study adds to a growing body of literature focused on the role of the geko™ adjunctive therapy in venous leg ulcer healing. More research is needed to understand the role of adjunctive therapies as they may offer patients' hope and create optimism toward wound healing as part of multi-modal treatment approach.

Keywords: geko™, individual perspectives, qualitative descriptive, pain, time, hope

Introduction

Lower leg ulcer management is a burden to the health care system (Canadian Institute Health Information, 2013). Chronic venous leg ulcers (VLUs) comprise approximately 70 to 80% of all lower limb wounds and occur as a result of chronic venous insufficiency (Evans et al., 2019; Harris et al., 2017; Viva et al., 2016). Most VLUs occur in a population where 30% already have three or more comorbidities; most (85%) live with leg ulcer pain, 53% have issues with mobility, 24% have problems washing or dressing, 58% have difficulty performing usual activities; of these, one-third report moderate anxiety or depression (Harrison et al., 2013). Community nurses spend up to 50% of their time providing person-centered care to persons with VLUs, including offering emotional supports (Simon et al., 2004).

For patients living with VLUs, the emotional and socioeconomic burden is significant to the individual and the health care system (O'Donnell et al., 2014; Phillips et al., 2017). Xhu and Ryan (2017) discuss VLU and pain, and how in combination they contribute to psychosocial issues including suicide risk, relationship distress, and emotional crisis. Vandenkerfhof and colleagues (2015) state pain is one of the leading issues nurses attend to when clients are admitted for chronic wound care and report 58% of patients living with VLUs experienced moderate to severe pain and did not regularly take pain medication(s).

Compression therapy is the 'gold standard' for VLU healing, yet, compression may not be fully maximized due to health care system, clinician, and patient factors (Harding et al., 2015). Patients with VLUs require effective therapies to support leg ulcer healing, and it is important that care options including adjunctive therapies be considered (Harris et al., 2017). Phillips et al. (2000), recommend "'ulcers that are large, of long duration, and slow to heal after three to four weeks of optimal therapy, might benefit from alternative therapeutic measures" (p. 627). Aziz and colleagues (2017), reported there is a wide range of clinician' approaches used to select therapies.

The Geko™ Device and Patient' Perspectives

Broadly speaking, "electrical stimulation devices fall into three categories: neuromuscular electrical stimulation (NMES), transcutaneous electrical nerve stimulation (TENS) and functional electrical stimulation (FES)" (Orsted et al., 2016, p. 3).This study attends to the use of geko™ wound therapy device powered on OnPulse™ neuromuscular electrostimulation technology (Firstkind Ltd., 2021) (See Image: Geko™ device). Health Canada (2017), has licensed the geko™ for clinical indications including: increasing blood flow, treating oedema, and promoting wound healing (Harris et al., 2017, p. 1101).

Geko™ device

There are limited studies exploring the patients' perspectives when utilizing the geko™ device as part of a VLU plan of care. Williams and Davies (2014), in a case study series, reported one client experienced increased motivation to leave their home when trialing the geko™ device. Williams (2017a), in a mixed methods study (n=9) explored geko™ device use with patients living with diabetic peripheral neuropathy; these participants reported increased generic quality of life scores. Williams (2017b), in a study with patients living with chronic venous insufficiency (n=30), reported improvement in some disease specific and generic quality of life questionnaire scores. Harris and colleagues (2017), reported patients (n=12) with 18 non-healing, recalcitrant wounds who did not adhere to the geko™ device as part of wound treatment, reasons included "underuse, overuse and tampering with the device" (p. 1104). The research team identified the need for clinician education, reminders of instructions for use, and conducting interviews to ask why the geko™ device was not adhered to by care providers or clients. Jones et al. (2018), reported 100% patient satisfaction (n=30) with the device. Further work by Harris and colleagues (2019), described residents of long-term care as more 'engaged' in their leg ulcer wound care plan when using the geko™ device.

Therefore, this qualitative study sought to understand individuals' perspectives while utilizing the geko™ device in the community setting. This qualitive descriptive interview study is part of a larger study "*The geko™ Wound Therapy Device as First Line Therapy for New Venous Leg Ulcers" conducted in partnership with* the Mississauga Halton Local Health Integration Network (LIHN) Home and Community Care Program and Perfuse Medtec Inc.

Study Aim

This qualitative descriptive interview study sought to explore the individuals' perspectives while living with VLUs ulcers and while utilizing the geko™ device.

Methods

We utilized a qualitative descriptive interview method (Sandelowksi, 2000). The descriptive approach aims to convey the rich, thick data accurately, and to present the findings in practical everyday language. This supports the understanding of individuals' lived experience while using an adjunctive therapy in their home setting. The authors regularly met to listen to, discuss the data, and field notes were kept by the authors (Braun & Clarke, 2013). Reflexivity practice, including journaling and sketching were created by the authors as part of understanding researchers' responses to the participants' accounts (Finlay, 2002, 2012). Reflexivity practice is a disciplined, critical self-reflection employed during a research study and supports examining the researchers influences in the study (Finlay, 2012).

Framework guiding the study

The researchers utilized a naturalistic inquiry approach to guide this study. Findings from the data emerged through analysis and were not given "a priori" (Lincoln & Guba, 1985, p. 224). As well, the Registered Nurses' Association of Ontario (2015), person-centered care, framed the qualitative questions and focused on the whole person "as a unique individual and [is] not just focused on their illness or disease" (para. 4).

Participants and Recruitment

Participants were English-speaking, living with a venous or mixed leg ulcer, and willing to answer, open-ended interview questions on the phone (see Appendix A). Names were randomly assigned to each participant to protect their identity. Through purposive sampling, seven participants were recruited (Braun & Clarke, 2013). Community nurses aided in recruiting participants who were interested in sharing their experiences with the geko™ device. In this study, interviews were conducted at the beginning the COVID-19 pandemic (World Health Organization, 2020), therefore, the interviewers acknowledged the COVID-19 pandemic at the beginning of the interview and reminded participants they did not have to complete the interview, could stop, or withdraw at any time. Informed consent was obtained. Participants who engaged in an interview determined the time (35-40 minutes) (Sandelowksi, 2000).

Data Thematic Analysis

Qualitative presentation of the data emphasized participants' voice and perspectives (Sandelowksi, 1998, 2000). Data was typed verbatim by a transcriptionist; analysis was open-ended and inductive (Creswell, 2014). We used QRS International NVivo11 software to sort and code the data. Thematic analysis (TA) was conducted by two researchers who read, discussed and became familiar with the data (Lambert & Lambert, 2012). We generated codes, examined words and phrases that resonated toward common themes. We sought themes that related to how participants felt while utilizing the geko™ device as part of their VLU care plan. Researchers kept field notes and reflexivity journals and sketches as part of critical self-reflection recommended while conducting research (Finlay, 2012). In conclusion, we produced an analytic narrative with direct participant quotes embedded.

Ethical Considerations

Ethical approval was sought and granted from Homewood Health Centre, Research Ethics Board and the Mississauga-Halton LIHN, Ontario, and Cape Breton University, Research Ethics Board, Sydney, Nova Scotia.

Results

Participants (n=7) in this study, were introduced to and offered use of the geko™ device as part this research study. The research letter of information (risk, benefits of the device) outlined detailed information on the geko™ device and how it could assist in the healing of their VLU. Participants average age was 70.1 years (range 56-78 years). Four participants were male and three were female. Participants stated they lived with VLU(s) for 1-2 months to 20 years (two participants could not identify the length of time). For six of the participants this was a recurrent ulceration. Two participants worked full-time (35-40 hours/weekly and one worked part-time (20 hours/weekly. Three participants stated they were fully retired, and one actively volunteered four to five hours/weekly.

From the data the following themes emerged: 1) participants describe use of pain medications when living with VLU; 2) participants describe ‘loss of time’ or ‘time passing’ in relation to their lives, including employment, social, travel, or volunteer activities; and 3) participants described hope and were optimistic the device would help the wound become smaller and heal faster.

Theme 1: Pain, “I live with this everyday”

Participants[1] in this study all reported living with various levels of pain. Six of the participants, identified the pain as returning when the VLUs reoccurred. Pain was described as fluctuating and persistent, and over-the counter medications were regularly consumed to control pain; pain was complicated by wound drainage and odour and leg edema. Betty described needing to take her pain medications “all the time” (*Research conversation*, March 2020). Peter described a deep reluctance to ask his physician for stronger pain medications though he regularly experienced leg and wound pain. Peter described taking over-the-counter non-opioid, anti-pyretic medications to try to cope with pain. He stated the following:

> I took these pain and narcotic meds all the time, before using the geko™ device, and then during the time the geko™ was on my leg, I slowly stopped taking those meds, I was getting healed by the device working, and now after I stopped the device, I am great, I am feeling good. (*Research conversation*, March 2020)

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[1] Participants' were assigned anonymous names and narratives were edited for clarity.

Carrie was similar in her use of both prescribed and over-the-counter pain medications. Her description of pain reflects the complex journey of lower leg ulcerations. She stated:

> I first started on two types of strong and prescribed medications acetaminophen with codeine. Then I went to using acetaminophen that I bought over-the-counter. Now I am in pain, and I am not taking any meds because a couple of weeks ago they found a blood clot in my leg. I am now on blood thinners, so they advised me to not take anything for pain with the blood thinners. Now I am really in pain! I am just managing it; I am just dealing-with-it! I mean, it's not that bad, it is just that I am always aware of it, then my foot starts feeling sore, like, not unbearable, it is just there. (*Research conversation*, March 2020)

Richard described how pain interfered in his private and social life.

> Well, I could not do much. Even when I was sitting down, my leg was in so much pain, and it was swollen, so I couldn't do much. I was not socializing or going out or anything. Well I was going out with my friend to visit a few family members, only on the weekends. And, ah, we went there for a few hours. My leg was swollen, and I was in so much pain! It was terrible, and unbearable. I ended up stopping the device and endured the pain. (*Research conversation*, March 2020)

Theme 2: The 'Time' it Takes for me to Live with Leg Ulcers

In this theme, participants described that living with a VLU engaged much of their time throughout the day. Time, was dominated by activities such as scheduling appointments, going to and from community wound clinics, arranging and maintaining social engagements, and planning or changing home care nurse and physician appointments.

Arlene, normally a very social person, stated: "I adapted my life to the ulcer, you have to, and I stay positive over time. This is not my first leg ulcer" (*Research conversation*, March 2020). In addition, Carrie shared the following insights:

> Originally, I was in the hospital for a week. I normally work 30 plus hours a week, I went 'stir crazy' when I got home, and I had to get back to work. I did not change the geko™ device, I go to the nurse led wound clinic, three times a week, where they change my compression bandages. Whether I was wearing the device or not I still went three times a week…I just want the wounds to close. (*Research conversation*, March 2020)

Carrie stated further about the changes in her life and ability to travel:

> I try to keep it [the wound] clean, I don't want to get any dirt, sand, whatever in it, right... like bacteria or anything? This wound coming back is putting off our March vacation time. This is - it is so affecting us. My husband says he is going to go on his own! I don't want him to go without me, I want him to wait so I can be there with him. (*Research conversation*, March 2020)

Peter stated that he was young to have ulcers:

> I normally stand up when I work and it really affected the length of my shift, I could only work part of a day. I had a good supervisor that let me go home early if I needed to because of the pain and infections. [As well] visiting with my family was very short and this was stressful as I miss them. (*Research conversation*, March 2020)

Theme 3: Hope and Optimism that Healing would Occur Faster

In this study, participants described the offering of the geko™ device to have provided some emotional reassurance and to have evoked optimism from within. Carrie stated the following about her feelings: "yes it has made me feel better, oh man, when the geko™ device was offered to me I felt optimistic, that maybe this thing [wound] would heal" (*Research conversation*, March 2020). Richard stated the following about his emotional reaction:

> Well, there was, like an optimism level, ah, in me. I wanted to hope it would help the ulcer close. But then, I am not sure if it actually did help me...because at the same time the doctor put me on a water pill, maybe a couple of months back, whatever it is to help my leg swelling. These events overlapped with the ulcer and the geko™ device being used, either way I wanted this "thing" [my wound] closed. (*Research conversation*, March 2020)

Participants described feeling hopeful that the geko™ device would contribute to heal their new or recurrent wound(s). Peter stated the following about his healing journey:

> At first, I thought it wasn't going to work, but, ah, then I learned how to use it, and, I put it on every time I was instructed to, and I realized it was really working! Every time I went to the clinic, and the nurses opened the dressing, and they said you know….and how it was much better every time; it was very good to hear those words...I found searching the device on the internet [was] the best, it helped me understand the purpose of the device. (*Research conversation*, March 2020)

Arlene shared the following about her journey:

> I have a venous leg ulcer, and I used the device for the required weeks. Though my ulcer is not yet fully healed, it has gotten smaller, it is not as open and not seeping and weeping drainage so much. I am happy about using the device and am glad I tried it as this wound is healing faster than my first ulcer. Overall, I am positive these days and hopeful it will continue to heal, it has been a long time. (*Research conversation*, March 2020)

Betty stated the following about her long-term journey trying to heal her wounds. She stated:

> I have had these ulcers, six, maybe five, or eight years. This is not my 'first time at this show', I have had these ulcers before. I am retired and live at home. But the wounds slow me down, I am getting slower and slower. When I got the geko™ device, my legs were

> flooded with water, soaked…now the wound is getting smaller, better, it is dryer – the nurse told me I was getting new skin like a snake. (*Research conversation*, March 2020)

Darlene shared that she had a strong faith and volunteered weekly with her spiritual group. She stated that because this was not her first ulcer, she was:

> ...happy to try the device when it was offered. The community home care nurses were excellent, they helped me learn where to place the device in the correct spot on my leg. Now I am so pleased that the wound has closed far enough that I can return to my volunteer role in the ministry, I feel needed there. (*Research conversation*, March 2020)

Discussion

This small qualitative descriptive study focused on the experiences of seven participants who utilized the geko™ device as part of their VLU care plan.

Similar to the literature, participants in this study described the presence of pain, and attempts to manage pain, whether it was associated their first VLU, or an ulcer recurrence (Harrison et al., 2013; Vandenkerkhof et al., 2014). Participants described modifying their employment hours, reducing time at work, cancelling social activities, and limiting volunteer hours while waiting for the ulcer to improve, heal, or for the swelling (edema) to lessen. Pain experienced when living with a VLU negatively affects one's quality of life including social, employment, and volunteer roles in the community (Phillips et al., 2017; Upton & Upton, 2015). Jones et al. (2014), in a study (n=30) of patients with mixed wound etiology, reported a 52% reduced pain levels when the geko™ device; edema reduction was not clear due to the use of compression. Moreover, Evans and colleagues (2019), outline the importance of clinicians assessing pain using validated pain assessment tools. Pain assessment should be conducted regularly as part of a wound plan of care.

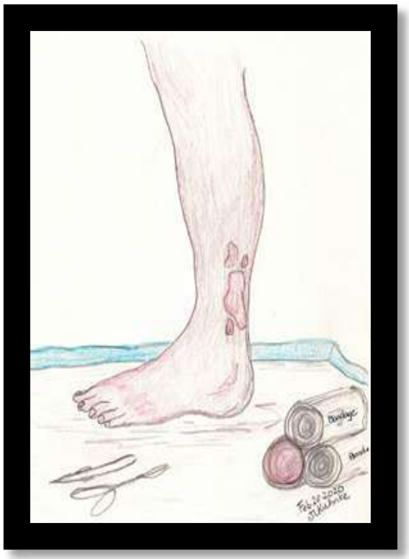

Figure 1: "Pain lives alongside me, in me, all around me"

Orsted et al. (2016), stated in relation to pain, the effects of low frequency nerve stimulation to support the healing of VLUs may lead to the "release of endogenous opiates and hormones within the body, thereby activating the body's own pain-relief mechanisms. This tends to have longer-lasting effects whole-body effect compared with other methods of electrical stimulation used for pain relief…and to improve mobility (p. 8).

Participants valued their relationship with their community nurse and nurses are in a key position to regularly assess pain and anxiety and depression related to living with VLUs (Harrison et al., 2013). Upton and Upton (2015), emphasize the importance of the nurse – patient relationship when assessing pain. Patients benefit from consistent communication that supports them being able to express their concerns. In this study, participants gained emotional support from community nurses (clinic) who moved past the dominant activity of applying lower leg compression, to exploring the whole person, using person-centered approaches (RNAO, 2015) (see Figure 1).

Time

In this study, participants organized their time with VLU clinic and home care appointments being the priority. Participants described the time needed to get to and from appointments, organizing time away from work and obtaining ‘sick-notes’ from physicians. As well, participants described the time they experience waiting for the wound(s) to show some evidence of improvement; this weighed heavily on their minds (see Figure 2). Participants described time in hours, days, weeks, months and years. Descriptions of time were consistent between the participants, whether they were experiencing their first ulcer or if it was an ulcer reoccurrence.

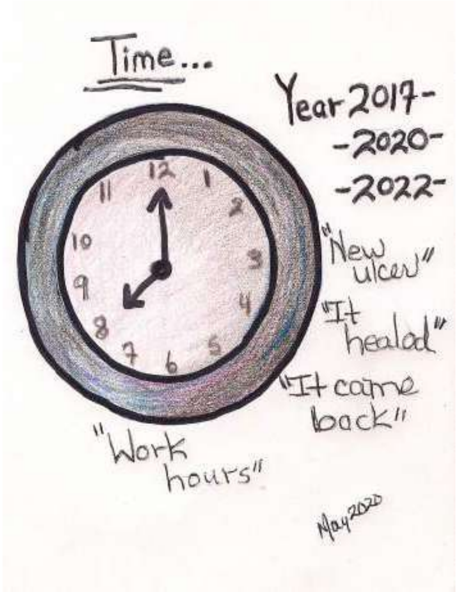

Figure 2: “Time Weighs Heavily”

Time was described as being ‘less-long’, eased, or alleviated when the participant had established a working, trust-filled relationship with the nurses. Participants described feeling ‘less stressed’ when nurses spent time speaking with them to offer emotional care alongside clinical wound care (Upton & Upton, 2015). Nurses need time to teach and educate about the complexity of VLUs, including changes to the patients’ activities of daily living (Zulec et al., 2019). Upton and Upton (2015), identify “the patient-health care professional relationship is often very positive for people with wounds, and these interactions may protect and promote their well-being” (p. 227).

Hope

Hope is defined as part of one’s spirituality, and lack of hope may lead to feeling discouraged, hopeless, and feeling dis-spirited. Hope is an integral part of life and an essential part of living (Giddens, 2019), though in the health care literature the definition of hope varies (Ogom, 2015). Hope is often studied in persons experiencing acute, chronic, or terminal illnesses and for persons with VLUs, offering hope may contribute to a yearning for a life free from wounds (Ebbeskog & Ekman, 2001; Faria et al., 2020).

Participants in this study described ‘agency’ and a deep desire to want to feel hopeful while living with a new, or recurring ulcer. Agency is the “perceived capacity to use one’ pathways to reach desired goals” (Snyder, 2002, p. 251). Though they describe the emotional and physical burdens related to the venous disease process (pain, odour, fatigue, wound drainage) (Stewart et al., 2017), being offered the geko™ device drew forward deep, positive emotional responses. Words such as: “there is hope”, “finally, I feel optimistic”, “I educated myself”, and “I feel hopeful with this device” contribute to this understanding.

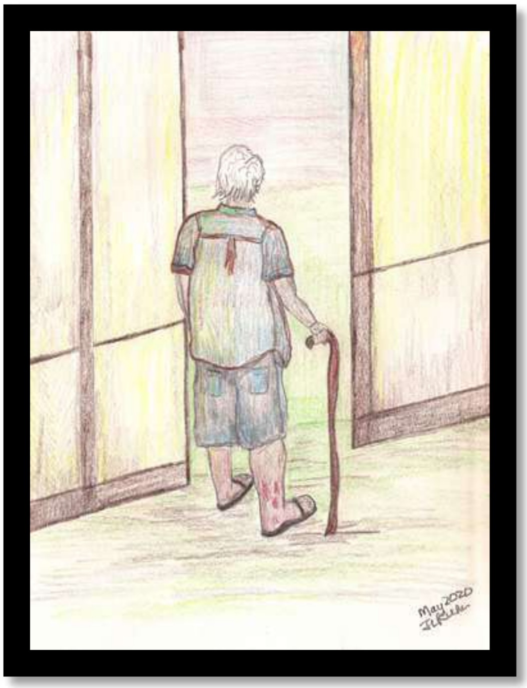

Figure 3: “I would rather be at work or volunteering; I spend too much time in the wound clinic”.

In this study, participants yearned for wound healing or improvement in their ulcer. They identified this as possible, when offered the geko™ device to aid wound healing. Participants hoped that the wound or ulcer would never come back again or recur (see Image 3).

Participants were engaged in the opportunity to use an adjunctive therapy to help close their first, or recurring venous leg ulcer. Harris et al. (2017), notes patients seemed more engaged in their care when using the geko™ device.

The participants lived with daily changes to their social, employment and volunteer selves, as a result of the lower leg ulceration. Some had lost hope or a sense that the wound(s) would “never close”. Salome and colleagues (2013), describe this sense of powerlessness and loss of hope in clients (n=40) with lower leg ulcers. Living with lower leg ulcers “has a negative impact on patients and their family members; they are associated with pain,...decreased functional status, which affects activities of daily living (dressing & walking), [and] intensifying the dependency of these patients” (p. 303).

Through offering the geko™ device, it generated in participants a sense of agency; in turn they described feeling valued. This was similar to study findings by Tallow and Odden, (2016), where participants (n=11) when offered surgical management for their venous leg ulcers, described a sense of hope and investment in the individual. In a recent study, Faria and colleagues (2020), reported patients (n=60) experienced increased rates of subjective hope, well-being, and spirituality when advanced wound care support was offered.

In our study, the human impact of VLU was recognized as being much more than a medical issue. The participants spoke about the direct and often unforeseen consequences ulcers had on their lives (Upton & Upton, 2015). They spoke of their mental health and well-being as being affected by pain and wound odour, embarrassment, shifting work hours, the need to rely on others, feelings of depression, isolation, and loneliness. Some were social excluded and were not able to fully participate in family gatherings and faith-based activities (Upton & Upton, 2015). Participants remained consistently, hopeful. They hoped the geko™ device would bring healing, in any form. They hoped for less pain, less time in clinics or planning life around the demands of a VLU, to produce a level of livability allowing them to return to their lives.

Conclusion

Hope was described by participants as growing when offered the geko™ device to support wound healing. Pain and hope, when living with a venous leg ulcer, should be routinely assessed using validated assessment tools.

Future Research & Study Limitations

We see this study as an important contribution to the role of adjunctive therapies in VLUs. The participants stories remind us that health care professionals have to opportunity to contribute to holistic care; not just VLU care, but mental health and emotional well-being (RNAO, 2015). In this study, interviews were conducted at the beginning the COVID-19 pandemic; participant responses may have been affected by trying to adapt to the first weeks of the COVID-19 pandemic (WHO, 2020). Alongside future geko™ device studies could be more qualitative studies to further explore the participants' perspectives.

Conflict of Interest to Declare

The authors have no conflicts of interest to disclose.

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Appendix A:

Qualitative Interview Questions	
1. What is your age?	Years/months
2. How long have you lived with venous leg ulcer(s)?	Years/months
3. Is this your first experience with a leg ulcer?	Yes/No (circle)
4. Are you employed full-time, part time, casual, or in a volunteer role (circle) 5. How many hours per week? __________ (#)	
6. How has the wound affected your ability to work or volunteer?	
7. How has the wound affected your ability to be involved in spiritual and leisure activities such as walking, sports, spiritual care, or going out socially?	
8. Can you describe what it felt like when the geko™ device was introduced to you? Did if affect your level of hope or optimism that the ulcer would heal?	
9. What have you been able to do now while using geko™ that you could not do before?	
10. What have you done for pain management before, during and after using the geko™?	
11. Were there any changes to your wound visiting schedule when using geko™?	
12. What additional information would you like to share with the researchers?	