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Understanding the role of stimulation in reflexology: development and testing of a robotic device

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Understanding the role of stimulation in reflexology: development and testing of a robotic device

Reflexology is a common choice of women with breast cancer as supportive care during treatment. It involves stimulation of specific locations of the feet called reflexes using a specialised walking motion with the thumb of the reflexologist. Reflexology has shown potential for the successful management of cancer and treatment-related symptoms and improvement in physical functioning; however to date, the mechanism of action for these improvements is unknown. One confounder to the study of reflexology is the 'human factor'. To study the effects of the stimulation of the reflexes independent of the 'human factor', there is a need for an alternative method for the delivery of reflexology. The objective of this work was to design and create a robotic reflexology device that would deliver a breast cancer-specific reflexology protocol to the feet of patients. A prototype robotic reflexology device was developed and tested for feasibility, safety and acceptability with breast cancer survivors (n = 13), and preliminary efficacy in symptom management and enhanced functional status with a sample of women undergoing chemotherapy for breast cancer (n = 13). Safety, feasibility and acceptability were established, and significant improvements from pre- to post-device-delivered reflexology were seen in symptom severity among women on chemotherapy.

Keywords: reflexology, breast cancer, symptom management, robotic device.

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer among women, with more than 40 000 deaths annually (American Cancer Society 2010). Women with breast cancer are burdened with an array of symptoms from the time of diagnosis, and throughout the treatment process. Chemotherapeutic agents are linked to multiple symptoms including fatigue, weakness and insomnia. If these symptoms are not properly managed, their presence can lead to treatment interruptions and deterioration in functioning, and may affect survival (Miaskowski *et al.* 2006; Chang *et al.* 1998, 2007; Diedrich *et al.* 2007). Most women consider various avenues of support to enhance their health-related quality of life (HRQOL) as they continue through treatment, often turning to complementary and alternative medicine (CAM) therapies (Kosachik *et al.* 2006). Boon *et al.* (2007) reported that 80% of women

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diagnosed with breast cancer turn to CAM for symptom management. Among CAM therapies, reflexology is one of the most commonly used (Eisenberg *et al*. 1998). Lengacher *et al*. (2002) ranked reflexology in the top 10 in frequency of use of traditional and ethnic medicines among women with breast cancer.

Reflexology is a specialised foot therapy that is applied primarily to the sole of the foot by a certified reflexologist. The reflexologist uses a firm thumb-walking pressure over specific regions referred to as reflexes. Reflexology is similar to massage in that it manipulates soft tissue for therapeutic purposes but also differs from massage due to the specific focus on the feet and the use of a firm thumb-walking motion on the reflexes (Snyder & Cheng 1998).

While the use of reflexology is extremely high (Eisenberg *et al*. 1993, 1998; Lengacher *et al*. 2002) and literature on reflexology research is continuously expanding, mixed evidence of its effectiveness is reported (Hodgson 2000; Stephenson *et al*. 2003; Wang *et al*. 2008; Ernst 2009). One systematic review by Ernst (2009) found that in three cancer studies, reflexology resulted in a significant decrease in anxiety among breast and lung cancer patients, a second showed significant improvement in quality of life among patients in palliative care and a third reported no change in depression or anxiety in a sample of palliative care patients. A second systematic review by Wang *et al*. (2008) that did not include cancer studies found a decrease in urinary symptoms among multiple sclerosis patients. A third review (Wilkinson *et al*. 2008) documented an immediate post-intervention reduction in pain.

Apart from the systematic reviews, five randomised control trials (RCTs) focused on a cancer patient population. Among the five studies, sample sizes ranged from 18 to 60 patients per group and provided one to eight sessions of reflexology for the intervention group, with a range of 15–30 min per session. One study reported significantly lower anxiety among multiple types of cancer patients (Quattrin *et al*. 2006); another found lower pain among patients with mixed cancers (Stephenson *et al*. 2003); a third reported decreased pain among digestive cancer patients (Pan *et al*. 2000); a fourth, using a bundled intervention, found eight weekly sessions of reflexology plus self-initiated support to significantly promote relaxation among post-surgical early-stage breast cancer patients (n = 60) (Sharp *et al*. 2010); and a fifth study involved a mixed sample of hospitalised cancer patients (n = 42) and taught a partner to conduct one session, resulting in an immediate decrease in pain intensity and anxiety (Stephenson *et al*. 2007).

While multiple studies have investigated the effect of reflexology on HRQOL of cancer patients, there is no single scientifically established mechanism of action for how reflexology affects HRQOL outcomes including symptoms and function. One theory suggests that the mechanism of action is that the nerve endings in the feet connect with different areas of the body, and the direct pressure on a specific nerve ending of the foot stimulates the corresponding area of the body for symptomatic relief (Hodgson 2000). According to this theory, specific areas of the foot (reflexes) correspond to specific organs or systems of the body (Fig. 1), and thus manipulation of these specific areas can lead to the improvement in symptoms. A protocol that targets reflexes tied to symptoms of breast cancer and its treatment has been developed (Wyatt *et al*. 2005).

In addition to the stimulation of specific reflexes, the 'human factor' is also thought to influence outcomes of reflexology. The human factor includes the experience of the reflexologist in finding and stimulating specific reflexes. The interpersonal style of the reflexologist during the session may also be a confounding human factor. In addition, the human touch by itself may have a therapeutic effect, and the touch produced by different reflexologists may be different (e.g. different motion patterns or methods of force application). This variability in the delivery of reflexology that is due to human factor may explain some of the variable effects on patient outcomes. *Thus, to understand the role of stimulation of the reflexes in reflexology, removing the human factor is necessary.* One of the ways to remove the human factor is to stimulate the reflexes using a mechanical device.

Currently available commercial foot devices that claim to be 'reflexology-based devices' apply a generic vibration over the entire foot, or random stimulation of non-specific reflexes. None of the current devices provide the equivalent of a hands-on reflexology session. Such a device needs to apply and release pressure along specific paths on the sole of the foot, for specific durations, in a consistent fashion with control for force levels. In addition, the device would need to follow a specific protocol associated with select reflexes tailored for breast cancer. Commercial devices do not exist with these attributes; therefore, there was a need to develop a device with these specifications.

The purpose of this work was to begin to uncover the specific components of reflexology which may or may not play a role in symptom management and improvements in physical functioning among cancer patients. Testing against hands-on reflexology is planned in the future, as the device may provide an alternative for some cancer patients who are homebound. The intent of this line of work is not to replace a therapist, but rather to advance the science by isolating the key active ingredients of

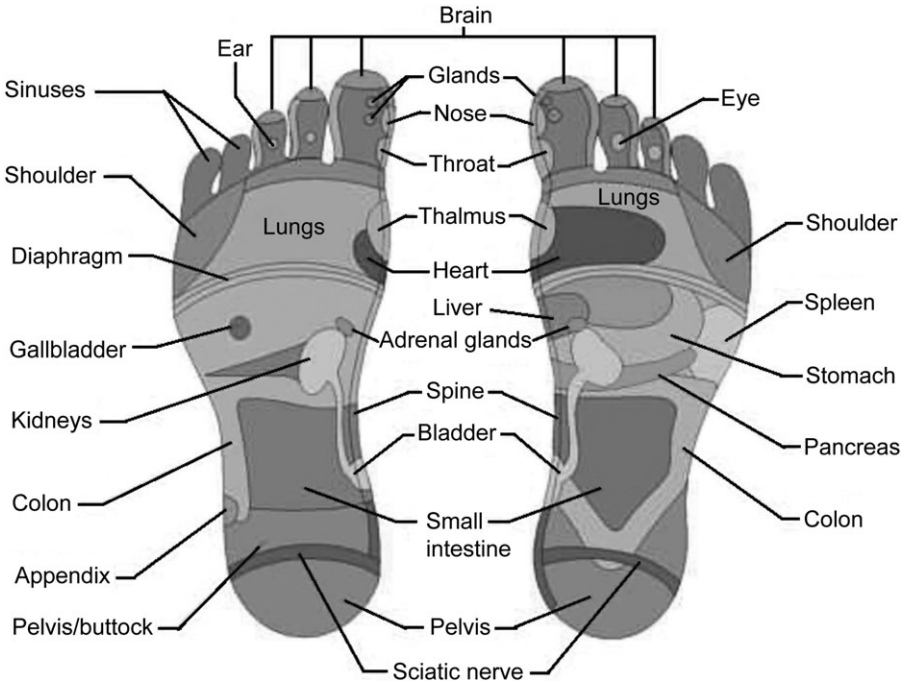

Figure 1. Reflexology chart for the sole of foot – (chart location: http://www.exhalereflexology.com/wp-content/uploads/2008/09/reflexology-chart.jpg).

reflexology, and in the long run possibly offer in-home or in-clinic options for some patients. However, large-scale clinical testing in a randomised trial would be required before the device-delivered reflexology could be offered to patients as supportive care during cancer treatment.

Thus, the goals of this study were to:

Goal 1: Design and create a robotic reflexology device that would provide a breast cancer-specific reflexology protocol;
Goal 2: Test the device for feasibility and acceptability with a sample of breast cancer survivors; and
Goal 3: Conduct a preliminary evaluation of the efficacy of the device for symptom management and improvement in physical function of women with breast cancer undergoing chemotherapy.

MATERIALS AND METHODS

Reflexology protocol

According to a breast cancer-specific reflexology protocol tested in the ongoing RCTs of hands-on reflexology (Wyatt *et al*. 2005), the reflexes associated with symptoms of breast cancer and its treatment are located in three regions: (1) the sole of the foot; (2) around the base of the ankle on the top of the foot; and (3) at the base of the toes on the top of the foot. During stimulation, the mechanical device mimics the thumb-crawling motion of a reflexologist. The total time for the protocol is 15 min per foot. Each region and stimulation of corresponding reflexes by the device is discussed in detail below.

Stimulation of the sole of the foot

Seven reflexes are stimulated as discussed below.

Spine reflex The device begins by applying pressure along the inside arch of the foot, spanning from the base of the big toe to the heel. The robotic device is programmed to identify the starting point and uses a walking motion with pulsing pressure while moving from the heel to the base of the great toe. According to one of the current theories of reflexology, this reflex stimulates the nervous system which is responsible for maintaining homeostasis throughout the body. Homeostasis can be significantly impaired by breast cancer and the associated therapies, and this reflex assists with rebalancing (Watson & Voner 2009) (Fig. 1).

Lung and diaphragm reflexes The robotic reflexology device then locates the region that runs from the base of the toes to approximately the top one-third of the sole of the foot (Figs 1 and 2). The device uses the walking pulsing pressure and moves from the inside (great toe area) to the outside (little toe) and reverses direction. Next, the device automatically locates the diaphragm guideline and stimulates along the line which is the diaphragm reflex. The

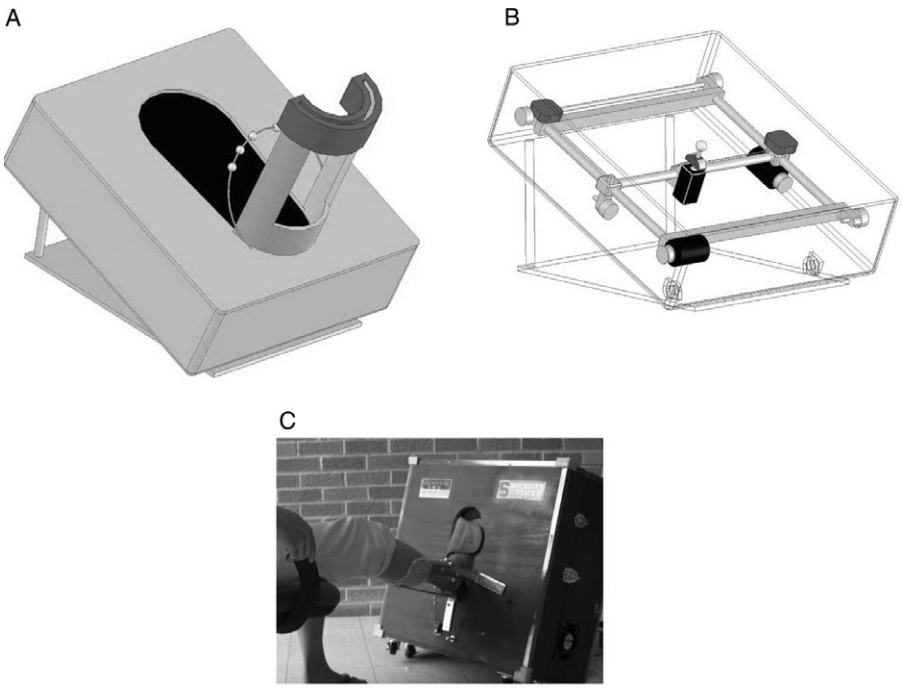

Figure 2. (A) Robotic reflexology device, exterior view. (B) Mechanism for sole stimulation, showing the inside of the robotic reflexology device. (C) Subject using the device.

lung and diaphragm reflexes are included in the protocol since they are believed to support the essential exchange of oxygen and carbon dioxide with the environment (Watson & Voner 2009).

Kidneys and adrenal reflexes The device locates the area that spans the mid third region on the sole of the foot. These reflexes are part of the protocol since the kidneys remove wastes from the body and regulate water, salt and nutrients in the blood. Since the adrenal glands are located on top of the kidneys, this wider combined reflex stimulates both organs. The adrenals are included in the protocol since they function to regulate the hormones in the body that are often affected by cancer treatment (Watson & Voner 2009). In addition to this broad stimulation, a focused stimulation is conducted on an area approximately the size of a kidney bean that is located below the diaphragm line, just lateral to the tendon line. The kidney reflex is specifically stimulated to further support the cleansing functions mentioned above.

Spleen reflex The robotic reflexology device focuses on the stimulation of the region approximately the size of a dime on the outer edge of the foot in the midsection of the sole (Fig. 1). The reflex is stimulated since it contributes to the production of red blood cell and antibodies and may aid in the removal of cells damaged by cancer treatment (Watson & Voner 2009).

Intestinal reflex The sole of the foot is stimulated between the heel line and mid foot. The device moves back and forth several times across this entire area using the walking pulsing motion that mimics the motion of a reflexologist. This reflex addresses the many intestinal symptoms develop due to cancer treatment including both diarrhoea and constipation.

Stimulation on top of foot

Breast and chest reflexes A mechanism, separate from the one used for stimulation of the sole of the foot, is used for stimulation of the region at the base of the toes which encompasses the breast and chest reflexes. The mechanism is positioned in the area that runs across the base of the toes between the second and fifth toe (Fig. 3). It applies a rolling pressure to the soft tissue between all toes simultaneously. The breast/chest reflex stimulation assists in the lymphatic drainage which is often impaired after breast cancer surgery (Byers 1996).

Stimulation of the base of the ankle

Lymphatic reflexes A crawling pulsing pressure horizontally is produced across the ankle region starting from under the lateral ankle bone and continuing across the front of the foot to the medial ankle bone. This movement

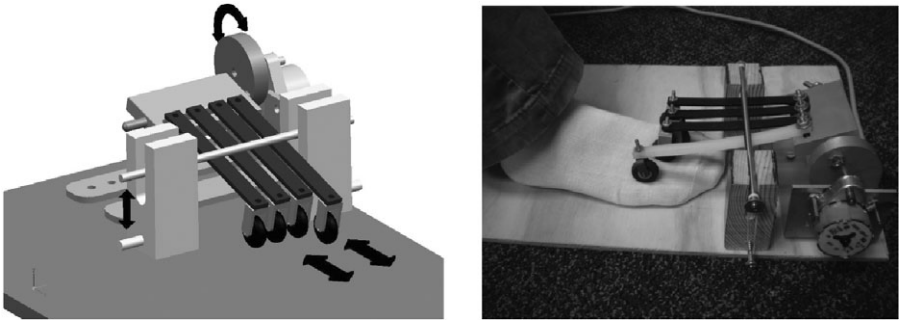

Figure 3. Unit used for stimulation of the top of the foot at the base of the toes.

stimulates the flow of lymph so that it is less likely to become congested in the arm and surrounding tissue after breast surgery (Byers 1996).

Design and development of the robotic device

The device has been designed to follow the breast cancer-specific protocol described above.

Automated foot calibration

Because patients have a wide variety of foot sizes and shapes, a semi-automated procedure was developed for locating the reflexes with the device. By taking a few landmark measurements of the foot, the device is able to automatically identify the locations of the reflexes used in the protocol. This method requires an initial session to non-invasively take measurements of each foot, and enter these measurements into the computer program operating the device. These measurements only need to be entered once and saved in the computer so they can be used for subsequent sessions with the same patient.

Foot calibration begins with a planar view digital picture of the patient's foot. The foot is aligned at approximately the same angle as it would be in the machine, and a scale is placed next to the foot for reference. This digital image is then used to determine landmarks on the bottom of the foot through the use of Didge Image Digitizing Software (2008; Didge, Omaha, NE, USA). This software allows definition of the base of the heel as a reference point. From this reference point, the distances to other foot landmarks are determined. For stimulation of the sole of the foot, six landmarks are necessary. Using the reference image, the positions of the landmarks are selected on the image and entered into the software. From these coordinates the location of each reflex can be identified.

Since the device is programmable, different landmarks or different paths for stimulation could be used to define different reflexology protocols, if desired.

The device also has the ability to collect and store information that includes time of usage, initial force/pressure settings and any user changes made to the force/pressure settings during the application of the reflexology protocol.

Mechanism for stimulation of the sole of the foot

The robotic reflexology device was designed as a rectangular unit with a calf support (Fig. 2). The rectangular unit has a central location for placement of the left or right foot. The central location is an opening that is covered by a thin, opaque, smooth and stretched, flexible fabric. The robotic component/mechanism for stimulation of the sole of the foot (Fig. 2B) is located inside the rectangular device and below the central opening. This component is not visible to the patient. The contact point, which applies the pressures, is comprised of a small sphere mounted on a motorised slide. The sphere applies pressure on the sole of the foot and its movement is controlled by two other slides so the sphere can travel in any direction. The flexible fabric prevents direct contact between the foot and the sphere, keeps friction constant between the two and prevents any pinching between the foot and device.

Once the patient is positioned and her foot dimensions are recorded by the device, the custom computer program is started. The computer is programmed to automatically determine the regions/locations on the sole of the foot to be stimulated and time trajectories following the breast cancer-specific reflexology protocol.

Most importantly, the system has been designed with safeguards so that the patient is not harmed. The force sensor that measures the level of pressure applied is continuously monitored to ensure that desired force levels are never exceeded.

Mechanism for stimulation of the top of the foot

A separate mechanism is used for stimulation of the region at the base of the toes on the top of the foot (i.e. the

area that runs across the base of the toes between the second and fifth toe). This mechanism is placed on the patient's foot by a test assistant or the patient can be shown how to do this herself. This device applies a rolling pressure to the soft tissue between the toes simultaneously for a fixed duration.

The robotic component/mechanism for stimulation on the top of the foot is comprised of a small CAM-driven adjustable arm with multiple wheels (Fig. 3). The arm is rotated and the stimulation wheels are lifted to allow the patient to place her foot under this mechanism. Once the foot has been positioned, the arms are lowered such that the wheels are located on the soft tissue regions between the second and fifth toe. The CAM mechanism causes the wheels to move back and forth to stimulate the reflex. Medial/lateral adjustments in the arms of the device enable it to adapt to different foot sizes. Also, the arms can be repositioned to accommodate either the left or the right foot. Tension adjustments are located on either side of the device and allow for various levels of pressure exerted by the wheels onto the foot. Future plans are to integrate this stimulation unit with the main device so all components operate as one unit.

Stimulation of the base of the ankle

A third mechanism, mounted on the device (Fig. 2), is wrapped around the base of the ankle. The ankle stimulation mechanism consists of a series of small spheres attached to a flexible cord. The woman wraps this system around the base of her ankle. The clasp is a spring/hook system which keeps tension on the spheres while stimulation occurs. Once positioned, the woman initiates stimulation through a remote control device. The remote control turns on a motor that produces a reciprocating motion. This in turn causes the spheres to roll back and forth over the ankle region, stimulating the reflexes. The woman also has the ability to select the frequency of the reciprocating motion based on her level of comfort.

Laboratory testing and oncology clinic testing

This research was approved by the university Human Subjects Institutional Review Board and the participating oncology clinic. Consent was obtained from all participants. This research involves two distinct samples:

- Sample 1: breast cancer survivors (n = 13);
- Sample 2: women undergoing chemotherapy for breast cancer (n = 13).

Sample 1: laboratory testing

To test the device for safety, feasibility and acceptability (goal 2), 13 breast cancer survivors were recruited. The feasibility and acceptability testing were conducted at the College of Engineering in the Biomechanical Design Research Laboratory at Michigan State University.

Sample 2: clinic testing

The preliminary efficacy testing (goal 3) was conducted with a sample of women undergoing chemotherapy for breast cancer (n = 13). The device was located at a community-based oncology clinic where women were receiving chemotherapy for breast cancer.

Neither the laboratory nor the clinic setting provided any special amenities (e.g., special lighting, music or aromas), and women did not receive financial compensation for their participation in the study. Women were told the following during the consent process: 'The purpose of the study is to test a foot device that applies therapeutic pressure to specific areas of the foot. This research will test if the device helps you feel better physically and/or emotionally during cancer therapy'.

Intervention procedures

Women in both samples received four device-delivered reflexology sessions – one per week for 4 weeks. All participants were provided a pair of footie socks so that the interaction with the device would be consistent across all women and all sessions.

Data collection procedures

In sample 1 (breast cancer survivors), the first session was preceded by paper and pencil collection of data including demographics, symptoms and physical function data. This was done while the foot calibration was performed by the technician. After the fourth session with the device, data were again collected via paper and pencil including symptoms, physical function, satisfaction and acceptability. For sample 2 (women undergoing chemotherapy), symptom and physical function data were collected via telephone interviews at baseline and at 5 weeks (following four weekly device sessions). If women adjusted the pressure of the device during the sessions, these pressures were recorded by the onboard computer.

Measures

Demographics

Demographic data included age, race and ethnicity, level of education and employment status.

Acceptability

Acceptability was assessed by a 13-question instrument developed for this project. Women were asked to rate the acceptability of session duration, device size, pleasantness of and relaxation during session, absence of pain, degree of stimulation, comfort of leg and foot positions, the appropriateness of chair height and the use of socks. Each item was rated on the scale from 1 = completely unacceptable to 5 = completely acceptable.

Symptom inventory (Cleeland et al. *2000)*

The M. D. Anderson Symptom Inventory (MDASI) evaluates severity of 13 symptoms experienced by cancer patients (i.e. pain, fatigue, nausea, disturbed sleep, distress, shortness of breath, difficulty remembering, decreased appetite, drowsiness, dry mouth, sadness, numbness/tingling), and the interference of these symptoms with daily life. Both severity and interference are rated on a scale from 0 = absent to 10 = maximum possible. Reliability and validity of the instrument were established (Cleeland 2007). Summed symptom severity and interference scores were computed before and after device sessions. The potential range of scores was 0–130 for severity, and 0–60 for interference with higher scores indicating worse severity and interference.

Medical Outcomes Study Short Form 36 (MOS SF-36) (Ware et al. *1996)*

The physical function subscale of SF-36 has 10 items that are scored using Likert's method of summated ratings (Ware *et al*. 1993). The instrument has established content and construct validity and internal consistency reliability (Ware *et al*. 1993, 1996). The potential range of scores was 0–100 with higher scores reflecting better function.

Force data

The force applied to the sole of the foot was measured using a single-axis force transducer mounted directly under the force applicator. This transducer allowed accurate force measurement when the applicator was pressed into the sole of the foot. The patient-controlled force dial contained numbers from 0 to 10 indicating the level of force. The controller was provided to the patient, so she could increase or decrease the level of force depending on her level of comfort and desired level of stimulation.

Data analysis

For both samples, descriptive statistics for demographic characteristics of the participants, their symptom severity and interference, physical function and responses to acceptability questions were obtained. Mean values of the force at each specific reflex for each foot were determined for the purposes of setting them as defaults in the future, and plotted over time (sessions 1–4) to determine if women's preferred force settings change as time progresses. The trends in force levels over time were analysed for the locations corresponding to the protocol steps on right and left feet separately. Matched paired *t*-tests were used to evaluate the change in symptoms and function from before to after the device sessions. Since the purpose of the study was to evaluate feasibility and acceptability and obtain preliminary efficacy data, the study was not powered for the formal tests of hypotheses. All analyses were performed in SAS 9.1 (SAS Software 2010; SAS Institute Inc., Cary, NC, USA).

RESULTS

Goal 1 and sample demographics

A robotic device for the delivery of a breast cancer-specific reflexology protocol was successfully designed and built. It was tested with both sample 1 and sample 2. In both samples, over one-third of women were employed (part-time or full-time), all had at least some college education, and the majority were married or living with a partner (Table 1). In sample 1, all 10 women completed all four device sessions as prescribed by our study protocol.

Goal 2

In sample 1, the summary of acceptability ratings in Table 2 revealed very high mean levels for: session duration (4.77), pleasantness (4.69), relaxation (4.77), absence of pain during session (4.46), comfort of leg and foot (4.69), comfort of chair height (4.85) and acceptability of socks worn (5.00). Women were also asked to rate the acceptability of three device sizes for home use. Medium and small sizes received the highest ratings and the current size was rated at the mean of 3.08 (neutral).

Furthermore, in sample 1, women were breast cancer survivors who were no longer on treatment and therefore

Table 1. Demographic characteristics of the participants in the study samples

Characteristic	Category	Sample 1, *n* (%)	Sample 2, *n* (%)
Age, mean (SD)		61 (9.5)	56 (11.3)
Education	Completed high school	0 (0)	1 (7.7)
	At least some college	6 (46.2)	6 (46.2)
	Completed college	3 (23.1)	5 (38.5)
	Professional or graduate degree	4 (30.8)	1 (7.7)
Marital status	Never married	3 (23.1)	1 (7.7)
	Married/living with partner	8 (61.5)	8 (61.5)
	Divorced	2 (15.4)	3 (23.1)
	Widowed	0 (0)	1 (7.7)
Employment	Full-time	4 (30.8)	4 (30.8)
	Part-time	1 (7.7)	1 (7.7)
	Not employed	0 (0)	3 (23.1)
	Retired	6 (46.2)	2 (15.4)
	Disabled	1 (7.7)	1 (7.7)
	Homemaker	1 (7.7)	2 (15.4)
Race	Caucasian/White	13 (100)	11 (84.6)
	Black/African American	0 (0)	2 (15.4)

Table 2. Participants' acceptability of the device and device sessions (sample 1)

	Mean (SD) on the scale from 1 = completely unacceptable to 5 = completely acceptable
Acceptability of session duration	4.77 (0.44)
Potential device size: large	3.08 (1.44)
Potential device size: medium	3.23 (1.42)
Potential device size: small	4.61 (1.12)
Pleasantness of the session experience	4.69 (0.75)
Session experience was relaxing	4.77 (0.60)
Absence of pain during session	4.46 (1.71)
Session was not too stimulating	4.46 (1.85)
Leg and foot in a comfortable position	4.69 (0.63)
Comfort for left leg position	4.54 (1.20)
Comfort for right leg position	4.54 (1.20)
Appropriate chair height	4.85 (0.38)
Acceptability of socks	5.00 (0.00)

had few symptoms as reflected by the mean symptom severity score of 0.96 (Table 3). The symptom severity and interference and physical function did not change (improved insignificantly) from pre- to post-device sessions, further supporting feasibility and acceptability of the robotic reflexology device.

Goal 3

In sample 2, the symptom severity significantly decreased ($P = 0.02$) from pre- to post-device sessions, and physical function improved ($P = 0.06$) from pre- to post-device sessions. The effect sizes for these improvements expressed as Cohen's *d* (difference between means in standard deviation units) were 0.86 for symptom severity and 0.70 for physical function. In Cohen's classification (Cohen 1988), the cut-off for the large effect size is 0.80, and our results point to the potential efficacy of the device with respect to symptom management and improvement of physical function during chemotherapy.

Furthermore, in sample 2, three women dropped out after the intake interview, and did not complete the device sessions and post-sessions interview. The other 10 women out of 13 in sample 2 (77%) completed both interviews. Of these 10 women, nine completed all four device sessions, and one woman completed three out four. Thus, feasibility of device sessions held in the clinic was supported.

Additional results: level of force selected by women

Across all reflexes for sample 1, the levels of forces decreased over time with varying magnitude, indicating that women on average dialled back the levels at later sessions compared to the earlier ones. For one of the locations (left ball of foot), the negative slope was significantly different from zero; however, the sample size in this pilot study was small to draw conclusions based on *P*-values alone (Fig. 4).

DISCUSSION

Goal 1

A robotic device that applies a breast cancer-specific reflexology protocol was successfully developed and tested. This device is principally different from existing 'foot massagers' in several ways. The device can identify reflex locations on a patient's foot and can target specific

Table 3. Symptom severity, symptom interference and physical function before and after the device sessions

	Sample 1			Sample 2		
	Before device sessions (n = 12*)	After device sessions (n = 13)	Difference (before–after) (n = 12)	Before device sessions (n = 13)	After device sessions (n = 10)	Difference (before–after) (n = 10)
						Mean (SD)
Outcome	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	P-value
Symptom severity†	0.96 (1.55)	0.89 (1.24)	0.09 (1.00)	46.46 (31.22)	31.10 (23.83)	10.00 (11.59) $P = 0.02$
Symptom interference†	0.58 (1.31)	0.33 (0.66)	0.11 (0.27)	15.77 (13.62)	13.80 (17.47)	0.8 (11.83) $P = 0.84$
Physical function‡	83.35 (26.4)	84.17 (27.1)	–0.83 (6.34)	45.77 (23.97)	61.5 (29.35)	–14.00 (20.11) $P = 0.06$

*One participant in sample 1 did not fill out symptoms and function part of the pre-session assessment.
†Higher values indicate higher severity or interference.
‡Higher values indicate better physical function.

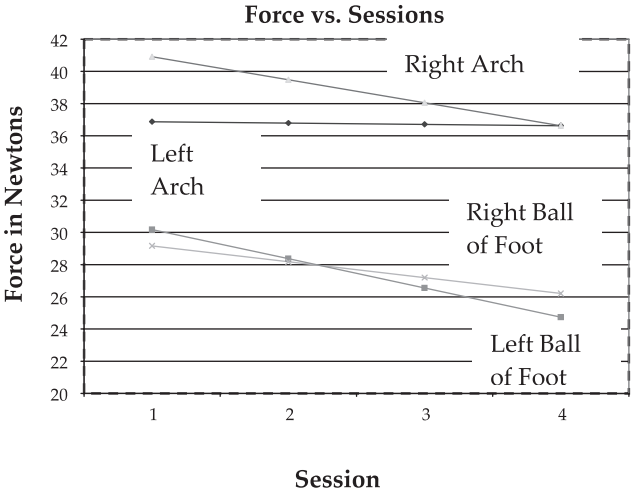

Figure 4. Average force values in newtons for the entire subject pool. The data are plotted over the 4-week session.

reflexes rather than providing a generic stimulation (e.g. a generic vibration or movement). The device is also programmable for time spent in stimulating a specific reflex and the reflexes to be stimulated. Thus, even though the current protocol is specific to symptoms of breast cancer and its treatment, the protocol can be tailored to address the unique concerns of patients with other cancers or other diseases. The device separates the human factor from the stimulation of specific reflexes. Allowing this separation is the beginning to the uncovering of the mechanism of action of reflexology on HRQOL including symptom and function outcomes.

Goals 2 and 3

Data from preliminary testing indicate that the application of reflexology through a robotic device was not only acceptable to laboratory patients, but showed beneficial trends in decreasing symptom severity and increasing physical function among clinic patients receiving chemotherapy. The reduction in symptom severity from pre- to post-device sessions was statistically significant ($P = 0.02$, Table 3). Thus, it is possible that the stimulation of the reflexes alone could be beneficial as supportive care for cancer patients undergoing treatment; however, the efficacy conclusions can not be drawn from the present study. The results obtained in our pilot sample of women undergoing treatment could be used to appropriately power a larger study, which would control for extraneous influences via randomisation, and compare device-delivered reflexology to hands-on reflexology and standard care for symptom management.

Additional results

Level of force selected by women

These force data will be used as input for future device modifications: default values will be set for each region and the device will begin at this level for each session. Thus, in future uses of the device this modification may allow women to have fewer adjustments during sessions.

Limitations

As mentioned earlier, the evidence reported is preliminary. First, the study did not have a sufficiently large sample size to produce reliable estimates of the effect of the robotic device on symptom and function outcomes. Second, this study did not have a control group. However, this limitation is somewhat offset by the fact that studies with cancer patients undergoing chemotherapy have reported very small improvements over time for patients

in the control group. Given *et al*. (2004) observed the effect sizes below 0.20 for the improvements in symptom severity under usual care. In the ongoing RCT of hands-on reflexology, women show no improvements in symptom severity and physical function in the usual care control group (Wyatt *et al*. 2005). Third, it is also possible that the introduction of a new device may create a sense of expectancy for improvement by the patient. Future RCT work would need to compare this device against a device that does not provide the stimulation of reflexes. Clearly, there remains additional testing to be carried out with various comparison groups and with larger samples.

The evidence of feasibility, safety and preliminary efficacy presented here indicates that this approach to supportive care for women with breast cancer during chemotherapy warrants further examination.

Potential benefits

Applying reflexology through an objective means such as a robotic device allows for repeatable and consistent administration of the protocols. By using such a device, the variability encountered across reflexologists and within a reflexologist during a hands-on reflexology session is removed.

In addition to the contribution to the science of reflexology, there are other potential gains from the development of a robotic reflexology device. Hands-on reflexology requires a patient to travel outside the home for weekly reflexology sessions. This places scheduling burdens on patients who already are undergoing breast cancer treatment in addition to meeting their daily needs. A robotic device, such as the one developed for this research, has the potential to offer supportive care to patients through an accessible tool for managing symptoms during chemotherapy. Two usage possibilities were identified. Clinic usage was explored in the current study with sample 2. The advantage of having the device in the clinic would come from the reduction in the number of trips for the patient out of the home, since the sessions can be scheduled in accordance with patient's visits to the oncology setting. The other usage possibility is at home including two possible scenarios. In the first scenario, the patient could purchase a device and keep it permanently in her home for usage at any time. In a second scenario, the patient could rent a device for use in her home for a period of time when symptom management is most needed. These possibilities could be further investigated to expand the pool of evidence-based supportive care interventions during cancer treatment.

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