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IMPROVED COMFORT AND MOBILITY WITH NOVEL COMPRESSION SYSTEM

Highlights:

- Device comfort, usability, and impact on sleep should be considered to improve patient compliance
- The RF-MAC was subjectively rated as more comfortable and less noisy, as compared to the SCD.
- Objective sleep measures show marginal evidence for longer total sleep time when using the RF-MAC

Maintaining Sleep while Improving Overnight Mobility and Comfort with a Novel Lower Limb External Mechanical Compression System

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IMPROVED COMFORT AND MOBILITY WITH NOVEL COMPRESSION SYSTEM

Abstract

Background: Venous thromboembolism is prevalent, associated with a high degree of morbidity and mortality, and largely preventable. External mechanical compression is a standard of care for prevention, but compliance with traditional external mechanical compression devices is low due to patient reported issues with comfort, mobility, usability, noise, and sleep disturbances. The purpose of this study was to compare user-rated comfort, mobility, usability, noise, perceived sleep disturbance, and objective sleep disturbance for a novel external lower limb mechanical compression device as compared to a standard sequential compression device.

Method: Using a 2-day counterbalanced, within-subject repeated-measures design, 16 participants wore two mechanical compression devices, the commonly-used Kendall SCD Express 9525 (SCD) and the novel Recovery Force Movement and Compressions Device (RF-MAC) for 1 night each in their home while sleep was recorded with polysomnography. For each device, participants also completed questionnaires to assess usability, mobility, perceived noise disturbance, and perceived sleep disturbance.

Results: The novel RF-MAC device was significantly more comfortable and less noisy than the Kendall SCD. There was marginal evidence that participants sleep longer when wearing the RF-MAC compared to the SCD. User-rated usability, perceived sleep disturbance, and other objective sleep disturbance measures did not differ significantly between the two devices.

Conclusion: Patients and clinicians should consider the impact of external mechanical compression devices on user comfort and sleep to improve patient compliance.

Keywords: Venous thromboembolism, external mechanical compression, sleep quality, device usability, mobility, user-centered design

Abbreviations: RF-MAC = Recovery Force Health Movement and Compressions System, SCD = Kendall SCD Express 9525, CRS = Comfort Rating Scale, ECS = Environmental Comfort Scale, SUS = System Usability Scale, TLX = NASA Task Load Index, PROMIS = Patient-Reported Outcomes Measurement System, DVT = Deep Vein Thrombosis, REDCap = Research Electronic Data Capture, TST = Total Sleep Time, WASO = Wake After Sleep Onset, SE = Sleep Efficiency.

1. INTRODUCTION

Venous thromboembolism, consisting of both deep vein thrombosis (DVT) and pulmonary embolism, affects up to 900,000 patients annually in the United States, with an estimated 60,000-100,000 deaths (Centers for Disease Control and Prevention [CDC], 2022). Sudden death occurs in approximately 25% of people with DVT. Thirty-three to fifty percent of people with DVT will have long-term complications, and thirty-three percent will have a recurrence within ten years. Furthermore, both the prevalence and impact of venous thromboembolism has increased in the face of COVID-19 (Hasan et al., 2020; Hippensteel et al., 2020). Venous thromboembolism is the leading cause of preventable death within hospitals (Cayley, 2007; Cohen et al., 2008; Deitelzweig et al., 2011; Mejilla et al., 2017).

Multiple medical societies, including the American Academy of Orthopedic Surgeons and the American College of Chest Physicians, recommend the use of external mechanical compression due to its effectiveness in reducing the incidence of venous thrombosis (Falck-Ytter et al., 2012; Jacobs et al., 2011). Data support that external mechanical compression is an effective therapy and is comparable to anticoagulation in the inpatient setting (Nelson et al., 2015; Shahi et al., 2017). In a 2005 systematic review, it was found that the use of external mechanical compression reduced the risk of venous thrombosis by 60% (Roderick et al., 2005). The efficacy of external mechanical compression as a monotherapy makes it especially useful in patients where the use of anticoagulants is contraindicated due to bleeding risk (Colwell et al., 2010; Falck-Ytter et al., 2012; Jacobs et al., 2011). This includes patients with clotting disorders, actively bleeding patients, or those in fulminant liver failure. A recent study evaluating the cost-effectiveness of postoperative orthopedic venous thrombosis prevention found external mechanical compression

to be the most cost-effective therapy when used as either monotherapy or in combination with heparin (Saunders et al., 2018).

There are numerous compliance issues associated with currently available external mechanical compression devices (Elpern et al., 2013; Gould et al., 2012; Muramato, 2017; Reinhard et al., 2022). A direct-observational study of inpatients found a noncompliance rate of almost 50% (Elpern et al., 2013). A meta-analysis by Craigie et al. (2015) found similar results, with the mean external mechanical compression device compliance among post-operative patients at 75%. The most commonly reported reasons for patient non-compliance include lack of comfort, restricted movement, sweating and overheating, excessive noise during operation, sleep disturbances, the inconvenience of putting on and taking off the device, and poor usability design (Craigie et al., 2015; Reinhard et al., 2022). The inhibition of mobility is a notable barrier because, according to American Academy of Orthopedic Surgeons exercise guidelines, early ambulation is the most important intervention to enhance postoperative recovery after total joint replacement (Sheth & Foran, 2022).

Therefore, external mechanical compression devices that improve comfort and mobility, decrease disturbances related to noise, and decrease sleep disturbances during therapies may help increase patient compliance and improve thrombosis prevention outcomes. The Recovery Force Movement and Compressions System (RF-MAC) is a novel, mobile, external mechanical compression device that was designed to improve venous thromboembolism prevention compliance, But there is limited research comparing user experience between the RF-MAC and other external mechanical compression devices.

2. PROBLEM STATEMENT

There is a need for improved guidance for providers selecting external mechanical compression devices (Pavon et al., 2016; Zhao et al., 2014). The purpose of this study was to compare the comfort, mobility, noise, usability, and sleep disturbances related to overnight use of the novel RF-MAC device versus the most used device for external mechanical compression in acute care, the Kendall SCD Express 9525. Specifically, we addressed two aims. First, we sought to compare the impact of two mechanical compression devices, the RF-MAC and the SCD, on user-rated comfort, noise, usability, mobility, and perceived sleep disturbance. Second, we sought to compare the impact of two mechanical compression devices, the RF-MAC and the SCD, on overall sleep quality as measured by overnight polysomnography.

3. MATERIALS AND METHODS

3.1. Sample Demographics

In total, 16 participants were enrolled in the study; 13 participants were female and 3 were male. Participants were 60.38 ± 6.49 years old. Exclusion criteria were: age below 50 or above 75 years; body mass index below 18 or above 39; self-report to be stomach-sleepers; uncontrolled asthma; and surgery within the past 6 weeks. Participants were also excluded for abnormalities of the lower extremities including: edema (which does not allow for proper fit of the devices), skin breakdown of any kind, severe peripheral neuropathy, skin grafting within the last 3 months, cellulitis or dermatitis, or a previous history of deep vein thrombosis. Additionally, prior to beginning the study protocol, all consented participants were screened in their homes for

undetected DVT using mobile doppler ultrasound (TridentCare LLC, USA) while following all CDC COVID-19 guidelines.

3.2. Questionnaires

To measure device-related changes in comfort and mobility, participants completed the Comfort Rating Scale (CRS; Range (10-50), higher score = more discomfort) (Knight & Baber, 2005). The Environmental Comfort Scale (ECS; Range 6-30, higher score = more comfortable) (Guo et al., 2017) was used to examine self-reported differences in perceived comfort and noise of the study environment. The System Usability Scale (SUS; Range (0-100), $\geq$ 68 = "Above Average", higher = more useable) (Usability.gov) was used to provide a reliable measure of device usability. For information about the cognitive workload associated with each device, participants completed the NASA Task Load Index (TLX; Range (0-100), higher score = increased cognitive workload) (Cao et al., 2009; Hart, 2006; Hart & Staveland, 1988). Finally, the Sleep Disturbance Form of the Patient-Reported Outcomes Measurement System (PROMIS; T-Score Range (32-73.3), higher = more sleep disturbance) (HealthMeasures; Yu et al., 2012) was used to assess self-reported perceptions of sleep disturbance.

3.3. Devices

The Recovery Force Movement and Compressions System (Recovery Force Health, USA) is a wireless, portable, and wearable non-pneumatic compression device intended to reduce the risk of DVT through compression-related increased venous blood flow. The RF-MAC consists of a battery-powered controller mounted to a disposable fabric leg strap through a securement ring, and a small direct current motor that retracts the strap for compression. To apply the RF-MAC,

the leg strap is first wrapped around a participant's calf. After, the controller is attached to both the strap mounts and securement ring. The motor inside of the controller moves the securement ring in and out, contracting and releasing the attached strap. During use, the strap is contracted and released once per minute, creating a mechanical force of compression to increase venous blood flow.

The Kendall SCD Express 9525 (Cardinal Health, USA) is an automatized pneumatic compression device established to reduce the risk of DVT through increased venous blood flow. The SCD consists of a plug-in, bed-mounted controller containing an air pump, tubing, and a disposable leg sleeve. To apply the SCD, the controller is first mounted on the end of the participant's bed. Connectors at the end of each side of the tubing are secured to their corresponding plugs on the controller and leg sleeves. Next, the air pump inside of the controller pumps pressurizes air through the tubing into the leg sleeve, applying compression to the leg. During use, the controller provides each patient with an automated compression cycle to increase venous blood flow.

The Sleep Profiler (Advanced Brain Monitoring Inc, USA) is an ambulatory, self-application sleep monitoring headband used to record overnight sleep physiology. The Sleep Profiler consists of 3 frontal EEG channels, a pulse oximeter, and an accelerometer. The EEG electrodes were placed on the forehead and acquired data at a sampling rate of 256 Hz. Head movement and position were acquired through a triaxial accelerometer. Further technical details regarding the dynamic ranges, sampling, resolution, processing, and filtering are publicly available on the

company's website (https://cportal.b-alert.com/sleep-profiler/documentshelp).

3.4. Procedures

All procedures and materials were approved by the Institutional Review Board at the University of Massachusetts, Amherst. Healthy volunteer subjects were recruited from the geographic area surrounding Amherst, MA using fliers, online publications, and advertising on social media. Interested participants were contacted and sent an electronic link to complete pre-screening. Each participant received $100 as compensation for each of the two nights of data collection.

After providing consent electronically via REDCap, participants were emailed instructions to schedule an in-person ultrasound screening, arrange equipment delivery, complete a remote videoconference orientation meeting, and conduct two in-home self-applied overnight experimental sessions. A summary of the study procedures is provided in Figure 1.

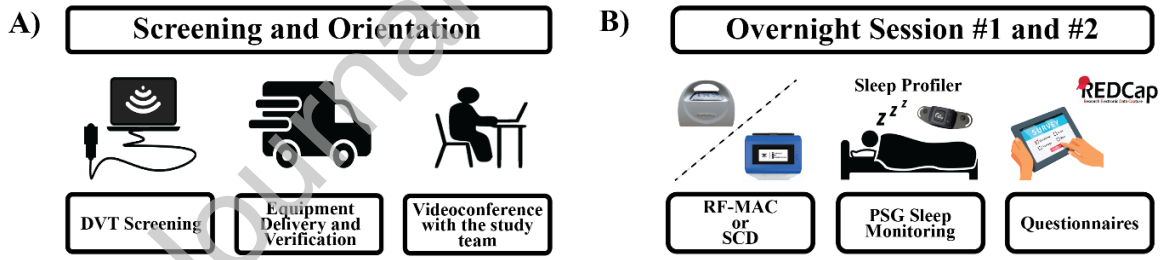

Figure 1: Summary of Study Procedures

On their first scheduled day of data collection and prior to equipment delivery, an ultrasound technician visited participants' homes to conduct a non-invasive ultrasound screening for undiagnosed lower-leg blood clots. Following successful screening, all equipment and materials were delivered to participants' homes. Each delivery contained: a participant manual containing

written instructions, a measuring tape, the RF-MAC controller, 4 MAC leg sleeves (2 medium, 2 large), the SCD controller and tubing, 4 SCD leg sleeves (2 medium, 2 large), the Sleep Profiler (including charging cable, 6 alcohol wipes, 8 EEG electrodes, and 4 3M EMG electrodes).

After equipment delivery, participants attended a videoconference with a member of the study team. During the videoconference, participants were given detailed instructions regarding the self-application of the Sleep Profiler, SCD, and the RF-MAC device. For each device, the study team gave participants thorough verbal instructions, live demonstrations, and real-time feedback while participants executed the procedures. Once participants reported clearly understanding how to apply each device, the study team reviewed how and when to complete the CRS, ECS, SUS, TLX, and PROMIS. Each survey was completed electronically via a browser-based REDCap link following both experimental nights. Additionally, all corresponding data was stored in a de-identified manner through REDCap.

Participants then completed 2 experimental overnight sessions (separated by at least 24 hours) that consisted of concurrent overnight use of the Sleep Profiler, one of the leg compression devices, and electronic questionnaires which were completed in the morning. During the first experimental night, participants self-applied the Sleep Profiler and either the RF-MAC or SCD according to the instructions provided during the videoconference. After sleeping with the devices overnight, participants were asked to complete all 5 questionnaires contained within a browser-based REDCap link. At least 24 hours later, participants completed the second experimental night by self-applying the Sleep Profiler, wearing the remaining compression device (SCD or RF-MAC) overnight (order counter-balanced across participants), and completed

the same questionnaires again in the morning for the second device.

4. MEASURES AND TOOLS

CRS measures were scored on a 50-point scale by finding the sum of the agreement values (ranging from “Strongly Disagree” = 1 to “Strongly Agree” = 5) for all 10 questions. ECS measures were scored on a 30-point scale by finding the sum of the agreement values for statements about the temperature and each source of noise. To calculate a standardized SUS score according to established guidelines, score contributions ranging from 0 to 4 were first calculated for all 10 items. For odd numbered items, score contributions were determined by subtracting 1 from the user responses, while for even numbered were subtracted from 5. Next, all 10 converted responses for each participant were subsequently summed and multiplied by 2.5 to produce one standardized SUS score per participant ranging from 0 to 100. To calculate overall TLX scores, raw responses for each subscale were summed to produce one score per participant.

Standardized PROMIS measures were scored using item-level calibration where raw scores were calculated by finding the sum of the values of the response to each question. Then, for each total raw score, an applicable conversion table was used to translate a standardized T-score that rescaled raw scores with a mean of 50 and standard deviation of 10 for each participant (Buysse et al., 2010; Yu et al., 2012). Device related changes in self-reported discomfort and mobility (CRS), perceived comfort and noise (ESC), device usability (SUS), cognitive workload (TLX), and perceptions of sleep quality (PROMIS) were examined using Bonferroni corrected paired t-

tests.

Sleep records were first uploaded onto the Sleep Profiler Portal, an internet-based software application with an interface for sleep scoring. Each uploaded record was preliminarily automatically staged by the Sleep Profiler automatic scoring algorithm. Subsequently, each epoch was visually inspected for adherence to American Academy of Sleep Medicine sleep staging rules (Iber et al., 2007) by a trained experimenter. The experimenter manually corrected any stage that was inconsistent with staging rules.

Of particular interest in this study were differences in polysomnographic parameters of sleep disturbance and sleep continuity related to overnight use of the RF-MAC and SCD. Primary measures of interest were the total sleep time (TST), wake after sleep onset (WASO), and sleep efficiency (SE) for each overnight session. TST indicated the duration of sleep-in hours. WASO indicated the total duration in minutes of all awakenings and sleep disturbances following sleep onset. Lastly, SE captured the percentage of total hours asleep from the total hours spent in bed. Given potential confounds from established “first night effects” (Ding et al., 2022), paired t-tests examined changes across the 2 nights for each variable (TST, WASO, and SE) irrespective of device. "First night effect” describe the phenomenon of poorer sleep quality during the first night of polysomnography measurement as compared to subsequent nights (Ding et al., 2022). Paired t-tests were used to compare differences in each sleep variable (TST, WASO, and SE) due to overnight RF-MAC versus SCD use. Paired t-tests were calculated using the base ‘stats’ R package (Version 4.04; R Core Team, 2021).

5. RESULTS

5.1. Compression device-related differences in perceptions of comfort and sleep

Table 1 summarizes device-related differences in perceptions of comfort, usability and sleep. The RF-MAC was rated as significantly more physically comfortable than the SCD using the comfort rating scale (CRS, higher = more discomfort). Perceived noise was rated as significantly more comfortable for the RF-MAC as compared to the SCD using the environmental comfort scale (ECS, higher = more comfortable). System usability was average for both the RF-MAC and SCD and did not significantly differ between devices (SUS, higher = more useable). For both devices, cognitive demand was rated as low and did not significantly differ between the devices as rated by the NASA-TLX (TLX = NASA Task Load Index, higher = increased cognitive workload). Lastly, no significant device-related differences were found in self-reported sleep-disturbances (PROMIS = Patient-Reported Outcome Measurement System, higher = more sleep disturbance).

	RF-MAC Mean (SD)	**SCD** Mean (SD)	**Differences** t (15)	p
CRS	26.19 (6.72)	30.25 (5.89)	-2.16	.047*
ECS	22.19 (4.02)	17.19 (4.93)	3.20	.006*
SUS	64.53 (16.33)	66.56 (18.79)	-0.37	.712
TLX	57.31 (4.87)	54.63 (5.57)	0.56	.581
PROMIS	53.17 (7.27)	55.74 (6.98)	-1.15	.269

Table 1. Group means and standard deviations (SD) for device evaluations
*indicates significance $p < .05$.

5.2. Compression device-related differences in objectively-measured sleep

For the objectively measured sleep data, two subjects had incomplete data due to disconnected electrodes. As a result, analyses were completed for the records available (n=14). There was no

difference in total sleep time (TST), wake after sleep onset (WASO) or sleep efficiency (SE)) for the first versus second experimental night. Furthermore, there were no significant device-related differences in sleep (Table 2). However, there was some marginal evidence of greater total sleep time (TST) when using the RF-MAC compared to the SCD.

	RF-MAC M (SD)	**SCD** M (SD)	**Differences** t (13)	p
TST	6.01 (0.36)	5.55 (0.36)	1.98	.069
WASO	66.93 (37.36)	59.29 (68.04)	0.64	.531
SE	78.83 (3.52)	77.97 (4.73)	0.36	.722

Table 2. Group means and standard deviations for device related changes for each sleep variable.

6. STRENGTHS AND LIMITATIONS OF REAL-WORLD USABILITY TESTING

Real-world usability testing is a fundamentally important method for evaluating the performance and usefulness of medical products during actual clinical use by end-users. Usability testing is focused on having real people use the product in the setting and the manner for which it was designed, to better understand how well a product is able to meet its intended use. Thus, the collection of sleep data in the participant's home setting using a validated, portable sleep monitoring device (the Sleep Profiler), was a study strength.

The two major limitations of real-world data collection in healthcare that we encountered in this study included a reduced ability to control data quality, which resulted in incomplete data

collection for two participants; and COVID restrictions, which required the research team to provide all participant training for device applications remotely. This method of training did not allow us to fully assess training comprehension or device application and use, potentially impacting the results.

With regard to sample size, usability research has found that a group size of 10-12 participants is generally accepted as a good baseline range. Additionally, FDA guidance recommends 15 as the practical minimum number of participants (FDA, 2016). We enrolled 16 participants, but since we had incomplete data on two participants, our final analyses were based on data from 14 participants.

Although validated tools to measure comfort are widely available, our choice of tools to measure comfort for this study were limited. Comfort measurement in this usability study required tools that were designed for measuring comfort associated with a device, and we also required tools with items that specifically addressed known limitations of the current SCD technology. The Comfort Rating Scale (CRS) was used because it was specifically designed to measure device comfort. The Environment Comfort Scale (ECS) was used because it was the only scale we could locate that specifically measured temperature and noise, both of which have been identified as significant dissatisfiers of the current SCD technology.

DISCUSSION

External mechanical compression devices that are comfortable, easy to use, and promote mobility are essential to improve compliance and prevent venous thrombosis. However, there is

a lack of evidence to help patients and clinicians make informed choices regarding the effectiveness of external mechanical compression devices for venous thromboembolism prevention (Pavon et al., 2016; Zhao et al., 2014).

Here, we demonstrate that compared to the SCD express, the most commonly used external mechanical compression device in hospital settings, the RF-MAC is more comfortable and the noises it made were less disturbing to participants. These findings are clinically important because discomfort, excessive noise, and sleep disturbances are among the most commonly reported barriers associated with pneumatic compression therapy compliance (Craigie et al., 2015; Reinhard et al., 2022). In a recent study, patients also identified wireless capability and increased ease of putting on and taking of the devices as among the most important factors to increase compliance (Reinhard et al., 2022). While not directly measured in this study, the wireless and portable capabilities of the RF-MAC may have influenced the findings and may also be considered by providers concerned with improving patient compliance and treatment options and outcomes.

Additionally, there was some marginal evidence that participants slept longer when using the RF-MAC compared to the SCD, a finding that may have been limited by the small usability study sample size. Data support that sleep is a crucial part of the postoperative recovery process, with numerous studies reporting that sleep disturbance has a negative impact on postoperative recovery (Aurell & Elmqvist, 1985; Dette et al., 2013; Fernandes et al., 2014; Kjølhede et al., 2012; Knill et al., 1990). Post-operative sleep disturbances have been associated with increased pain perception and impairment of endogenous pain-inhibitory functions (Manning et al., 2017;

Onen, 2001; Redeker, 2000; Roehrs, 2006; Smith, 2007; Su & Wang, 2018). Postoperative sleep disturbances are also increased for up to 3 months and have been shown to negatively affect postoperative recovery (Chen et al., 2016). In a sample of 105 patients who underwent primary total joint replacement, postoperative sleep disturbance was common, particularly in the early postoperative period (Manning et al., 2017). Since the highest risk for venous thrombosis is also in the early postoperative period (Cayley, 2007), prevention using methods that do not interfere with sleep are important for supporting the self-management of sleep. Unfortunately, while data continue to support the importance of sleep for hospitalized patients, both the quality and quantity of sleep in the hospital is negatively impacted from a number of modifiable factors, including medical devices. (Wesselius, et al, 2018). Providers should consider the risk of sleep disturbance when selecting an appropriate external mechanical compression device.

This study adds to other recent work evaluating external mechanical compression devices. Compared to four popular pneumatic compression devices including the SCD, the RF-MAC better remains in place during ambulation and provides improved external mechanical compression overall (Labropoulos et al., 2021).

As a usability study, these findings are limited by the small sample size and replications with larger sample sizes are clearly needed. Additionally, sex differences and sex steroid related changes in sleep-dependent memory consolidation have been demonstrated (Baker et al., 2019; Genzel et al., 2012; McDevitt et al., 2014). Given that the majority of participants in this study were female, the generalizability of these results is also limited. Finally, this study was conducted in a home setting and may not be generalizable to a hospital setting. Since the use of

external mechanical compression is such a widely used therapeutic intervention for DVT prevention, future studies are required to future test these findings and to provide more robust evidence to continue to guide product development in this important area of patient safety.

7. CONCLUSIONS

Though pharmacological alternatives exist, external mechanical compression devices significantly reduce the risk of bleeding compared to pharmacological approaches and are a cost-effective treatment option. Improved guidance is needed to help patients and clinicians select external mechanical compression devices and improve compliance with optimal use. Here we provide comparative within-subject evidence for improved comfort and perceived noise disturbance for the Recovery Force Movement and Compression Device as compared to the Kendall SCD Express 9525.

8. IMPLICATIONS AND APPLICATIONS

External mechanical compression devices with improved mobility and comfort that can be used in home and in the hospital represent a promising opportunity to improve compliance with optima use, prevent venous thrombosis related morbidity and mortality, and improve treatment outcomes. Future development and treatment plans for the prevention of venous thrombosis should prioritize mobility, decreasing noise related disturbances, and should consider how design aspects related to comfort in turn affect sleep as well as overall compliance with optimal use.

Ergonomics is concerned with the way humans interact with product design, including a product's safety, comfort, and impact on human well-being. This study examines the comfort,

usability, cognitive demands, and sleep interference of two external mechanical compression devices. Results suggest that the RF-MAC may be better-suited to meet patient needs than the standard SCD. Because product application is also impacted by the surrounding environment, future studies should compare usage of the RF-MAC and SCD in hospital settings.

Sleep, venous thrombosis prevention, and early mobility are all important aspects of postoperative patient care. The need to improve the patient experience of commonly used medical devices to improve compliance with recommended therapy and promote the sleep required for illness recovery represents an important opportunity for researchers, device manufacturers, and clinicians alike.

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Declaration of interests

☐The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☒The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Karen K. Giuliano reports financial support and equipment, drugs, or supplies were provided by RF Health. Karen K. Giuliano reports a relationship with RF Health that includes: consulting or advisory, non-financial support, and travel reimbursement.