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Original Article

Effects of Far-Infrared Irradiation on Myofascial Neck Pain: A Randomized, Double-Blind, Placebo-Controlled Pilot Study

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Abstract

Objectives: The objective of this study was to determine the relative efficacy of irradiation using a device containing a far-infrared emitting ceramic powder (cFIR) for the management of chronic myofascial neck pain compared with a control treatment.
Design: This was a randomized, double-blind, placebo-controlled pilot study.
Participants: The study comprised 48 patients with chronic, myofascial neck pain.
Intervention: Patients were randomly assigned to the experimental group or the control (sham-treatment) group. The patients in the experimental group wore a cFIR neck device for 1 week, and the control group wore an inert neck device for 1 week.
Main outcome measurement: Quantitative measurements based on a visual analogue scale (VAS) scoring of pain, a sleep quality assessment, pressure-pain threshold (PPT) testing, muscle tone and compliance analysis, and skin temperature analysis were obtained.
Results: Both the experimental and control groups demonstrated significant improvement in pain scores. However, no statistically significant difference in the pain scores was observed between the experimental and control groups. Significant decreases in muscle stiffness in the upper regions of the trapezius muscles were reported in the experimental group after 1 week of treatment.
Conclusions: Short-term treatment using the cFIR neck device partly reduced muscle stiffness. Although the differences in the VAS and PPT scores for the experimental and control groups were not statistically significant, the improvement in muscle stiffness in the experimental group warrants further investigation of the long-term effects of cFIR treatment for pain management.

Introduction

Myofascial pain syndrome (MPS) is one of the most common causes of musculoskeletal pain in clinical practice.[1,2] The MPS is characterized by painful myofascial trigger points, increased stiffness in taut, palpable bands of skeletal muscle, and referred pain.[3] Neck pain is a common musculoskeletal complaint and is a major public health problem, contributing to activity limitations, work disabilities, and health care costs.[4,5] In one study of musculoskeletal pain, 30% of the complaints described continuous pain, and 55% described recurrent pain.[6]

The pain and stiffness of MPS have been treated with local injection,[7] physical therapy (including manual stretch and intermittent cold application),[8] educational programs,[9] acupuncture or dry-needle therapy,[10,11] and *botulinum*-toxin treatments.[12,13] The results of numerous studies of pain management have been conflicting, and evidence-based

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studies have been unable to verify that acupuncture therapy or *botulinum*-toxin treatment was more beneficial than a placebo.[12,14] Therefore, a critical need exists for efficacious therapies for MPS.

Studies have shown that far-infrared irradiation produces nonthermal and thermal effects, including an increase in microvascular dilation, higher blood flow volume, and elevated regional tissue temperature.[15,16] These wavelengths of far-infrared light may influence intracellular processes, affecting heat transfer in subcutaneous tissues and other physiologic processes.[17,18] Far-infrared (FIR) irradiation can be an effective treatment modality for phantom pain, fibromyalgia, postoperative pain, and chronic pain.[19–23] However, there are scan studies of the clinical efficacy of FIR irradiation for the management of chronic neck pain based on subjective and objective parameters. Therefore, the purpose of this study was to explore the effects of irradiation using a device containing a far-infrared-emitting ceramic powder (cFIR) for the management of myofascial neck pain.

Materials and Methods

cFIR material

The cFIR material was obtained from the Department of Radiology, Taipei Medical University Hospital, and was composed of microsized particles containing various elemental components, as described.[24] Figure 1A shows a microscopic view of the ceramic powder granules. The cFIR material emits high levels of saturated wavelengths of FIR light at room temperature that are measurable using a CI SR5000 spectroradiometer with high emissivity,[15,16,24] and can induce numerous biochemical and physiologic effects.[18,24]

cFIR neck device

The neck devices used in the experimental group were composed of thermoplastic urethane (TPU) fibers mixed with 3% SynerTex bioceramic material, which contained the cFIR (Fig. 1B). The control group used an inert neck device made of the TPU fiber without the cFIR material. The inert and cFIR neck devices were identical in appearance (Fig. 1C). The physicochemical properties of the cFIR material used in the neck device have been described elsewhere.[25]

Study design

This study was approved by the Ethics Board of Taipei Medical University Hospital. The potential risks and benefits of participation were explained to each patient. All candidates provided written consent before their participation. Patients who had chronic MPS of the neck and upper back and who were aged 20 years or older were reviewed. The diagnostic criteria for MPS have been described previously.[26,27]

Patients with acute trauma, serious illness, obvious cervical spondylosis, cervical radiculopathy or myelopathy, fibromyalgia, or a history of psychiatric disorders were excluded from our study. Patients who were undergoing or who planned to undergo physical therapy or antidepressant, analgesic, or anti-inflammatory medical treatment during the course of our study were excluded. Women who were pregnant or planned to become pregnant during the study period were also excluded.

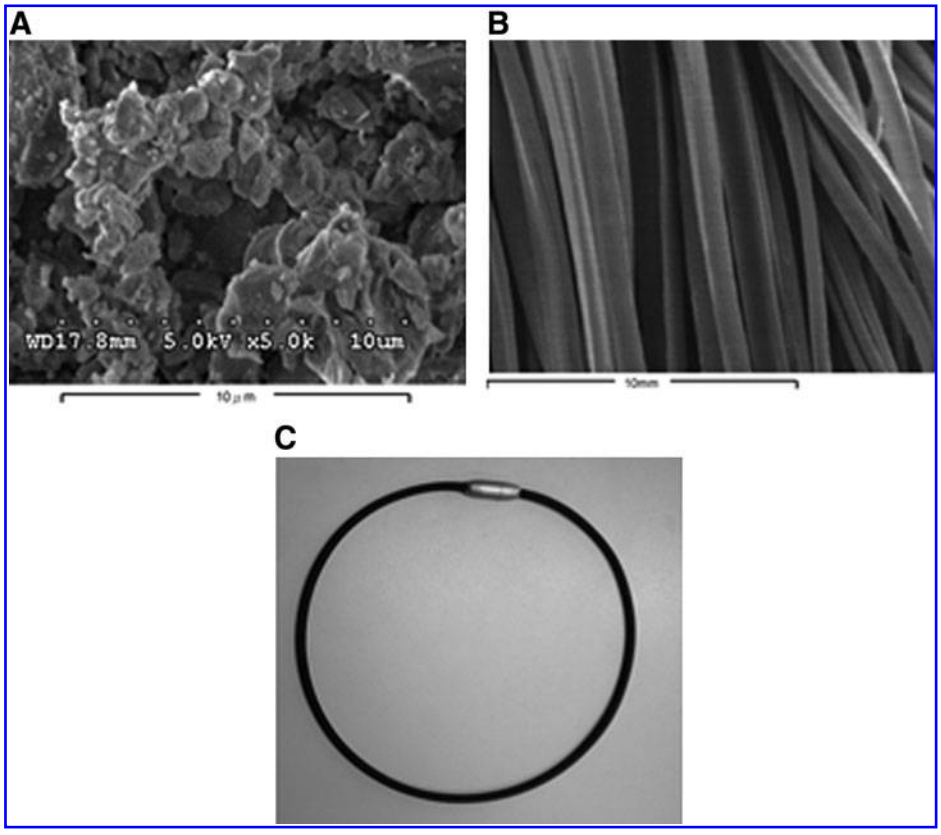

FIG. 1. The neck appliance containing the far-infrared emitting ceramic powder (cFIR). **(A)** The ceramic powder granules are shown in electronic microscope images. **(B)** The ceramic powder granules were embedded in the urethane fibers, as shown under high magnification in the electronic microscope image. **(C)** The appearance of the cFIR and sham neck devices was identical.

We used a randomized, double-blinded, placebo-controlled study design. The patients were randomly assigned to either the experimental (cFIR treatment) or control (sham treatment) group. All the participants and the examiners performing the assessments were blinded to patients' treatment status. All participants in both groups wore the neck device 24 hours per day for 1 week, except during bathing. The assessments of clinical variables were performed before treatment to collect baseline data in both groups. The assessments were performed again after 1 day of treatment and after 1 week of treatment to evaluate the effects of cFIR irradiation.

Assessment of pain severity

The severity of pain was assessed using a visual analogue scale (VAS) analysis. Patients were asked to make a mark on a 10-cm horizontal line to represent their perception of pain, with 0 cm representing no pain and 10 cm representing the severest possible pain.

Sleep-quality analysis

The Epworth Sleepiness Scale (ESS) was used to measure daytime sleepiness based on a self-administered eight-item questionnaire. The ESS is commonly used to quantify sleep disturbances. The retest reliability and internal consistency of the ESS are high.[28]

Measurement of pressure-pain threshold

The patients were comfortably seated in a chair with a low support for the back and arms. The pressure-pain threshold (PPT) recording points were selected, and marked with a pen. The PPT of the upper trapezius and the second tender-point muscles of the neck and upper back were measured three times bilaterally at 30-second intervals with an algometer (Force Dial, Greenwich, CT). Progressively increasing pressure was applied perpendicularly to the skin surface at the marked points at a rate of 1 kg/s until the patient indicated he or she sensed pain, at which point the pressure was released. The PPT value was defined as the lowest pressure at which the patient began to perceive pain. Replicate muscle tests were performed at 2-minute intervals. One examiner performed all of the PPT measurements. Previous studies have shown high reliability and repeatability in similar pressure-based assessments of pain.[29,30]

Measurement of muscle stiffness

A Myotonometer (Neurogenic Technologies, Missoula, MT) tissue-compliance meter was used to measure the muscle stiffness associated with chronic MPS based on muscle tone and tissue compliance.[31] The Myotonometer quantifies tissue displacement per unit of force applied as its probe presses against the skin overlying a muscle. The probe consists of an outer cylinder that contacts the skin surface as an inner cylinder extends to compress the underlying tissue. The displacement of the inner cylinder is equivalent to the tissue displacement.[32]

Computational software was used to construct force-displacement curves based on Myotonometer measurements. The area under the force-displacement curve (AUC) was also calculated, which provides a direct measure of the sum of myofibril stretching that occurred per unit of applied force over the range of force values applied.[32] Thus, a lower level of muscle stiffness will exhibit more displacement per unit of force and a higher AUC over the range of displacement measurements recorded than a muscle with a higher level of stiffness. High validity and reliability have been reported for assessments of muscle stiffness using tissue-compliance meters.[32] The calculation of AUC values based on Myotonometer measurements has been shown to be a reliable method for assessing muscle stiffness, tone, and compliance of both relaxed or contracted muscle[32,33]

For muscle stiffness measurements, each patient was required to sit upright in a chair with their shoulders held horizontally and their palms placed atop their thighs. The muscle stiffness of the upper area of both trapezius muscles and the second tender-point muscles of the neck and upper back were measured using the Myotonometer with the patient at rest. Manual palpation identified the middle of the muscle belly, which served as the site of measurement. The measurement sites were marked. Eight displacement measurements were recorded at 0.25, 0.50, 0.75, 1.0, 1.25, 1.50, 1.75, and 2.00-kg increments of force. Each measurement lasted for 6 seconds, and data were acquired at the first, third, and fifth seconds. Replicate measurements were separated by 2-minute intervals.

Measurement of skin temperature

All patients abstained from using topical agents for at least 1 day before skin temperature testing. Patients were seated with no clothing covering the neck and upper back for 20 minutes at 24°C. A Spectrum 9000MB-500 Digital Infrared Thermal Imaging System (UIS, Taipei, Taiwan) was used to measure the mean temperature at the neck and upper back in both groups. Previous studies of pain assessment have demonstrated high accuracy and repeatability in infrared thermal imaging measurements of skin-surface temperature.[34–36]

Statistical analysis

The mean and the standard deviation of the mean were determined for all outcome measurements. Differences in age and time to development of pain between the experimental and control groups were examined using *t*-tests. A repeated-measures analysis of variance (ANOVA) was conducted to compare triplicate measurements for all outcomes to determine differences between the experimental and control groups. A p-value < 0.05 was considered to indicate a statistically significant difference. Statistically significant ANOVA results were further examined using a Bonferroni post-hoc analysis. All statistical analyses were performed using the SPSS, version 18.0, computer software (IBM, Chicago, IL).

Results

Participant characteristics

Forty-eight (48) patients with chronic neck and upper back pain were included in this study. The experimental group comprised 16 men and 8 women, with a mean age of 53.9 ± 11.2 years. The control group (inert neck-device treatment) comprised 16 men and 8 women with a mean age of 56.9 ± 9.2 years. The time to development of pain was 47.7 ± 13.4 months and 48.5 ± 12.9 months for the cFIR and control groups, respectively. There were no significant intergroup differences in

age and the time to development of pain. No adverse effects of treatment were noted during the study period.

Pain severity

The mean VAS score of pain severity in the experimental group decreased from 5.04 before treatment to 4.38 after 1 day of treatment ($p=0.001$). After 1 week of treatment, the mean VAS score dropped to 4.00 in the experimental group ($p=0.002$; Table 1). The mean VAS score of pain severity in the control group also decreased from 5.04 before treatment to 4.17 after 1 day of treatment ($p=0.019$), dropping further to 3.67 after 1 week of treatment ($p=0.001$; Table 1). Both the experimental and control groups experienced significantly reduced neck and shoulder pain. No statistically significant difference in VAS scores was observed between the experimental and control groups before treatment, after 1 day of treatment, or after 1 week of treatment (Table 1).

Daytime sleepiness

The ESS scores of daytime sleepiness did not demonstrate significant improvement in either the experimental group or the control group before or after treatment (Table 1).

Pain threshold

No significant changes were observed in PPT values for the upper regions of the trapezius muscles and second tender point of the neck and upper back muscles in either study group (Table 1). Significant differences in the PPT values were also not observed between the experimental and control groups (Table 1).

Muscle stiffness

In the experimental group, the AUC values for the force-displacement curves based on the Myotonometer measurements of the upper regions of the left and right trapezius muscles progressively increased after 1 day and after 1 week of cFIR treatment, compared with the intragroup mean values before treatment, with increases after 1 week of cFIR treatment, reaching statistical significance (Table 1). No significant improvements were noted in the muscle stiffness in the upper regions of the left and right trapezius muscles in the control group after 1 day and after 1 week of sham treatment (Table 1).

The difference in AUC values for the upper regions of both the left and right trapezius muscles were significantly greater for the experimental group after 1 week of cFIR treatment, compared with their baseline AUC values (Table 1). The difference in AUC values for the bilateral trapezius was also significantly greater than that of the AUC values for the bilateral trapezius in the control participants. Changes in the AUC values for the second tender point of the neck and upper back were not statistically significant for either the experimental or the control group before or after treatment (Table 1).

Table 1. Area Under the Force-Displacement Curve Values, Surface Temperatures, and the Visual Analogue Scale, Epworth Sleepiness Scale, and Pressure Pain Threshold Scores for the Experimental and Control Groups Before and After Treatment with the Sham or the Far-Infrared-Emitting Neck Device

			Baseline values	*After 1-d treatment*	*After 1-wk treatment*	p *(intragroup)*	p *(intergroup)*
VAS		Experimental	5.04 (1.92)	4.38 (2.16)[a]	4.00 (2.55)[a]	<0.001*	0.72
		Control	5.04 (1.52)	4.17 (1.45)[a]	3.67 (1.83)[a]	0.002	
ESS		Experimental	8.29 (3.75)	8.83 (3.90)	8.71 (3.69)	0.591	0.427
		Control	9.54 (3.61)	9.21 (4.91)	8.88 (4.22)	0.544	
PPT (kg/cm^2)	Left trapezius	Experimental	2.42 (0.78)	2.37 (0.70)	2.40 (0.72)	0.877	0.592
		Control	2.52 (0.66)	2.42 (0.68)	2.37 (0.63)	0.225	
	Left STP	Experimental	2.46 (0.82)	2.37 (0.72)	2.45 (0.62)	0.184	0.744
		Control	2.50 (0.57)	2.48 (0.61)	2.50 (0.77)	0.97	
	Right trapezius	Experimental	2.38 (0.79)	2.47 (0.82)	2.41 (0.76)	0.597	0.396
		Control	2.52 (0.78)	2.42 (0.66)	2.36 (0.50)	0.331	
	Right STP	Experimental	2.44 (0.80)	2.42 (0.75)	2.39 (0.68)	0.939	0.926
		Control	2.48 (0.61)	2.44 (0.70)	2.38 (0.69)	0.933	
AUC (kg·mm)	Left trapezius	Experimental	16.18 (2.47)	16.37 (2.23)	17.62 (2.31)[a,b]	0.001*	0.028*
		Control	16.37 (1.78)	16.46 (1.85)	16.66 (1.97)	0.575	
	Left STP	Experimental	17.62 (2.27)	16.99 (1.86)	17.34 (2.16)	0.218	0.968
		Control	17.46 (2.05)	16.93 (1.95)	17.18 (2.23)	0.176	
	Right trapezius	Experimental	16.15 (1.84)	16.53 (2.21)	17.32 (1.73)[a,b]	0.003*	0.025*
		Control	16.14 (2.36)	16.07 (2.09)	16.29 (2.13)	0.863	
	Right STP	Experimental	17.33 (2.49)	17.18 (2.18)	17.45 (2.62)	0.661	0.929
		Control	16.87 (1.96)	16.74 (2.24)	16.96 (1.78)	0.395	
Skin surface temperature (°C)	Neck	Experimental	33.02 (1.27)	33.28 (0.88)	33.84 (1.18)*	0.018*	0.045
		Control	33.29 (0.74)	33.39 (0.99)	33.32 (1.05)	0.839	
	Upper back	Experimental	33.18 (1.00)	33.34 (1.09)	33.36 (0.96)	0.623	0.947
		Control	33.19 (1.40)	33.42 (1.11)	33.33 (1.13)	0.583	

[a]Significantly different compared with the baseline values as determined by a Bonferroni post hoc test.
[b]Significantly different between the experimental and control groups.
*$p<0.05$, determined by repeated-measures analysis of variance.
VAS, visual analogue scale; ESS, Epworth sleepiness scale; PPT, pressure pain threshold; STP, second pain point; AUC, area under the force-displacement curve.

Skin temperature

The neck skin temperature in the experimental group significantly increased after 1 week of cFIR treatment, compared with measurements before treatment (Table 1). The neck skin temperature in the control group did not significantly increase with treatment (Table 1). However, the differences in neck skin temperature between the experimental and control groups were not statistically significant after 1 week of treatment (Table 1). The upper-back skin temperatures did not differ significantly for either the experimental or the control group with or without treatment (Table 1).

Discussion

Several previous studies have demonstrated that treatment with near-infrared light, a red-colored laser, or irradiation using an equivalent wavelength spectrum reduced muscle and joint pain.[37,38] Another study reported that optically modified fabrics reduced chronic foot pain as a result of the illumination of the tissues by infrared light.[39] In the present study, the VAS scoring of pain severity demonstrated a significant decrease in both the cFIR and sham treatment groups. No significant changes were observed in PPT values for the upper fibers of the trapezius muscles and second tender point of the neck and upper back muscles in either study group. Muscle stiffness of the upper fibers of the left and right trapezius muscles was significantly reduced after 1 week of cFIR treatment, compared with their baseline muscle-stiffness data, and the improvement in the right trapezius muscle was significantly greater than that of the control group.

One of the possible explanations for the contradictory PTT and VAS results is that a placebo effect may have influenced the self-reported VAS values in both study groups. In a similar study conducted by York and Gordon, most of the differences in the questionnaire results were not statistically significant because of a relatively small sample size and cohort heterogeneity.[39] Numerous pain management studies have demonstrated improvements in pain scores following various types of treatments that could be contributed to placebo effects.[39,40] Placebo-mediated mechanisms of pain relief, such as the ratings of expected pain levels, the desire for pain relief, or anxiety levels, may influence pain scores.[41] Therefore, the improvement in the VAS scores in our study may have been the result of a placebo effect. Another possible explanation is that pain thresholds can be assessed across multiple stimulus modalities, including pain thresholds to pressure, heat, cold, or electrical stimuli. However, no single stimulus modality may completely reflect the subjective index of pain sensitivity for patients.

Muscle stiffness is typically defined as the ratio of change in force to change in length along the long axis of a muscle. The change in stiffness to forces applied along the long axis of a muscle is proportional to changes in stiffness to forces applied perpendicular to muscle.[42,43] The Myotonometer measures stiffness by quantifying resistance as millimeters of tissue displacement per unit of a perpendicularly applied force, using a noninvasive probe that applies pressure to the muscle by pressing against the skin surface. Transducers within the probe measure the amount of underlying tissue displacement per unit of force applied to the muscle. Force-displacement curves based on these recordings represent the amount of myofibril stretching per unit of applied force, and the AUC represents the sum of myofibril stretching per unit of applied force over the range of the force values applied.[32,42] Therefore, a muscle displaying a lower level of stiffness will have larger AUC values than a muscle with a higher level of stiffness.

In the experimental group, increasing AUC values reflected bilaterally decreasing muscle stiffness in the upper regions of the trapezius muscles. The reason for this decrease in muscle stiffness remains unclear. However, according to the "ATP energy crisis" theory, loci of spontaneous acetylcholine release at the motor end-plate cause the contraction of the sarcomeres in the end-plate zone nearest the loci of spontaneous membrane depolarization. Sustained sarcomere contraction increases the cellular metabolic rate and decreases local circulation, resulting in reduced oxidative phosphorylation. This type of selective sarcomere shortening occurs in the end-plate zone only, increasing muscle tension in that area.[44–46] The cFIR may affect muscle stiffness by altering the supply of oxygen or ATP by increasing microcirculation through thermal stimulation. Previous investigations have also shown that thermal stimulation of the skin relieves muscle stiffness through the inhibition of sympathetic neuromuscular stimulation and increasing parasympathetic activity.[47] Whether the cFIR treatments reduced muscle stiffness in the trapezius muscles of our participants by increasing microcirculation warrants further investigation.

Cooling of the skin may be secondary to sympathetic overactivity following nociceptor and mechanoreceptor stimulation, leading to a reflex neuropathic state. Increases in sympathetic efferent activity can cause increased painful response rates to afferent stimuli.[48,49] The trend toward increasing neck skin temperatures with cFIR treatment in this study may reflect reduced sympathetic activity and increased regional microcirculation. However, whether skin temperature and pain levels are correlated requires further investigation.

According to previous studies, cFIR treatment induced the production of calcium-dependent intracellular nitric oxide (NO) and calmodulin, and stimulated hydrogen peroxide–scavenging and antioxidant activities.[17,18,24,50] The cFIR treatments have also demonstrated anti-inflammatory and anti-arthritic outcomes, including the inhibition of prostaglandin E2 (PGE2).[17,18,51] The elevation in intracellular NO and calmodulin directly correlated with increased regional microcirculation, and the antioxidant activity and the induction of local anti-inflammatory mechanisms following the cFIR treatment may contribute to reduced pain and muscle stiffness.[17,18,24,50]

A close association has been observed between acute inflammation and pain. Previous research established the role of PGE2 as an inflammatory mediator, and identified a positive correlation between pain and the concentration of PGE2 at the site of local inflammation.[52] This association suggests that the use of cFIR treatment to inhibit PGE2 may be beneficial for pain management.[53] However, improvements in the pain scores in both the experimental and control groups in this pilot study indicate a placebo effect, which may have resulted from the wearing of the neck device. Additional clinical studies of cFIR treatment are necessary to distinguish the effects of cFIR treatment from the associated placebo effect.

There are additional limitations to the findings of this pilot study. It did not clarify whether the reduction in pain

severity in cFIR and sham-treatment groups were the result of a placebo effect or that of some other inadvertent action taken during the neck device treatment or the assessments. Future studies of the cFIR neck device will require additional treatment groups in which a neck device is not worn to clarify the causes of pain relief in all of the study groups. Also, a relationship was not confirmed between decreased muscle stiffness following cFIR treatment and increased microcirculation or reduced sympathetic activity in the experimental group. In addition, the secondary tender points of the neck and upper back varied among the patients in both study groups. Furthermore, the 1-week duration of the cFIR treatment in this study may have been insufficient to produce statistically significant changes in the clinical variables. Further study of the long-term effects of cFIR treatment may allow the clarification of the causes of pain relief observed in both of the study groups in this short-term, pilot study.

Conclusions

Results from this pilot study suggest that the short-term application of the cFIR neck device partly reduced muscle stiffness. However, improvements in the VAS scores for pain in both the cFIR and sham-treatment groups may imply the influence of a placebo effect. Although this study was unable to demonstrate the efficacy of the cFIR treatment based on the VAS and PPT values, the improvement of muscle stiffness between the experimental and control groups warrants further investigation of the long-term effects of cFIR treatment for pain management.

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Disclosure Statement

No competing financial interests exist.

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