



# Aesthetic and Functional Outcomes of Open Carpal Tunnel Release and Thread Carpal Tunnel Release: A Randomized Clinical Trial

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## Abstract

**Background and Objectives** Surgical techniques for carpal tunnel release (CTR) have gradually become less invasive. No substantial evidence supports replacing the open carpal tunnel release (OCTR) with novel minimally invasive approaches. Thread carpal tunnel release (TCTR) is a new minimally invasive CTR method associated with promising results. This study aimed to compare the aesthetic and functional outcomes of OCTR with TCTR.

**Materials and Methods** This study was a randomized clinical trial conducted in a hospital in Tehran, Iran, in 2022. Patients were randomized to OCTR and TCTR groups through simple randomization. Data such as demographics, nerve conduction study, electromyography, pain, and sensory evaluation by monofilament test were recorded in patients at baseline and after 3 months. Aesthetic evaluation was conducted by assessing the scar length and patients' satisfaction 3 months after the surgery.

**Results** Twenty patients (10 in each group) entered the final analysis. Nerve conduction study, electromyography, and sensory evaluation were similar between groups 3 months after the operation. The TCTR group had lower postsurgical pain ( $p < 0.001$ ) and lower scar length ( $p < 0.001$ ) compared to the OCTR group. Overall satisfaction was not statistically different between TCTR and OCTR.

**Conclusion** The TCTR method is safe in patients with CTS, and its efficacy is similar to OCTR. It can be a good alternative for OCTR, with a better aesthetic outcome.

## Keywords

- carpal tunnel syndrome
- carpal tunnel release
- minimally invasive surgery
- randomized clinical trial
- therapeutic
- level 2

## Introduction

Carpal tunnel syndrome (CTS) is the most common peripheral nerve disorder, occurring in median nerve entrapment and characterized by numbness and pain in the hand and

forearm.<sup>1</sup> CTS is more common in females and can be seen in almost 5% of the general population.<sup>2,3</sup> This phenomenon can be diagnosed through a history of present illness, physical examination, ultrasound study, nerve conduction study,

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and electromyography.<sup>4</sup> In addition, several nonsurgical options, including physical therapy, immobilization, and medications such as nonsteroidal anti-inflammatory drugs (NSAIDs) or local corticosteroid injections, effectively treat this condition.<sup>5</sup> However, surgery is necessary in some severe cases and those who do not respond to the nonsurgical treatment.<sup>6</sup>

Surgical management of CTS can be done through open and minimally invasive approaches.<sup>7</sup> Minimally invasive techniques have promising advantages compared to the available approaches. Endoscopic carpal tunnel release (ECTR) and ultrasound-guided carpal tunnel release (USCTR) are some of the minimally invasive procedures.<sup>8</sup> Thread carpal tunnel release (TCTR) is a novel minimally invasive technique introduced by Guo et al in 2015.<sup>9</sup> This technique has several advantages compared to the conventional treatment, but the evidence related to this technique is still being determined.

In this study, we compared the functional and aesthetic outcome of TCTR to the open carpal tunnel release (OCTR) in a referral center in Tehran, the capital of Iran.

## Materials and Methods

### Study Design

This randomized clinical trial was conducted on patients referred to a hospital in Tehran, Iran, from January 2022 until the end of March 2022. Patients were included in the study based on convenience sampling. The inclusion criteria were assumed to be age between 18 and 65 years, positive Phalen test, mild cases of CTS with sensory action potential (SNAP) of more than 3.6 milliseconds, moderate cases of CTS with SNAP of more than 3.6 milliseconds, compound muscle action potential (CMAP) of more than 4.2 milliseconds, and lack of response to nonsurgical treatments. Patients who had thenar atrophy, severe cases of carpal tunnel syndrome (lack of SNAP and CMAP and nerve conduction velocity [NCV] less than 40 meter per second across the wrist), those with neurodegenerative or demyelinating diseases, patients with a history of surgical treatment for carpal tunnel syndrome in the last 6 months, and patients with lack of consent were excluded from the study.

### Randomization and Blinding

By simple randomization method, patients were divided into two groups in a 1:1 allocation: OCTR and TCTR. Random allocation software (version 2) was used as the randomization tool. Allocation concealment was used for hiding the identity of the participants until they were assigned to a group to prevent selection bias. Each random sequence was recorded on a card, and the cards were placed in envelopes. The envelopes were numbered in the same way on the outer surface. Finally, the lids of the envelopes were glued and placed in a box. At the beginning of the registration of patients, based on the order of entry, one of the envelopes was opened, and the assigned group was revealed.

### Surgical Intervention

A 6-cm incision would be applied at the inter-thenar groove in the open surgery group, with a 5-mm distance from the ulnar side. After opening the palmar fascia and carpal ligament by sharp incision, the median nerve was explored, and in the context of nerve compression, internal neurolysis was conducted. After hemostasis, the palmar skin was closed by Nylon thread (no. 4). In the thread group, a 1.5-cm incision was made at the distal wrist crease. After opening the palmar fascia, the carpal tunnel was passed by a tiny surgical mosquito. At the tip of the surgical mosquito, a small incision was applied in the palmar region, and a Vicryl thread (no. 2) was passed through its groove—the entire carpal retinaculum was released by reciprocating and friction motion of the line (►Fig. 1).

### Follow-Up and Endpoint

Demographics and operation data were recorded in both groups. The endpoints in this study were assumed to be pain relief and improvement of the neurosensory and electrodiagnostic indices. The pain was assessed 1 day after the surgery by visual analog scale (VAS), and the electrodiagnostic index was recorded at baseline and after 1 month of the intervention. In addition, the monofilament test and 2-point discriminations in the thumb and index fingers were used for neurosensory assessment. Furthermore, scar length in centimeters was assessed at baseline and 3 months after the operation as the secondary endpoint. The Mayo modified wrist score assessed the patient's satisfaction, which evaluates pain, pleasure, range of motion (ROM), and grip strength.<sup>10</sup>

### Statistical Analysis

Data were entered into version 25 of SPSS software for statistical analysis. First, we explore the normality of data with the Kolmogorov–Smirnov test. The quantitative variables were reported as mean  $\pm$  standard deviation (SD) or median (Q1, Q3) based on data distribution. The qualitative variables were declared as numerical (percentage) data. We used the Mann–Whitney *U* test or paired sample *t*-test based on the data distribution for bivariate analysis. The chi-squared test was used for the study of nominal variables.

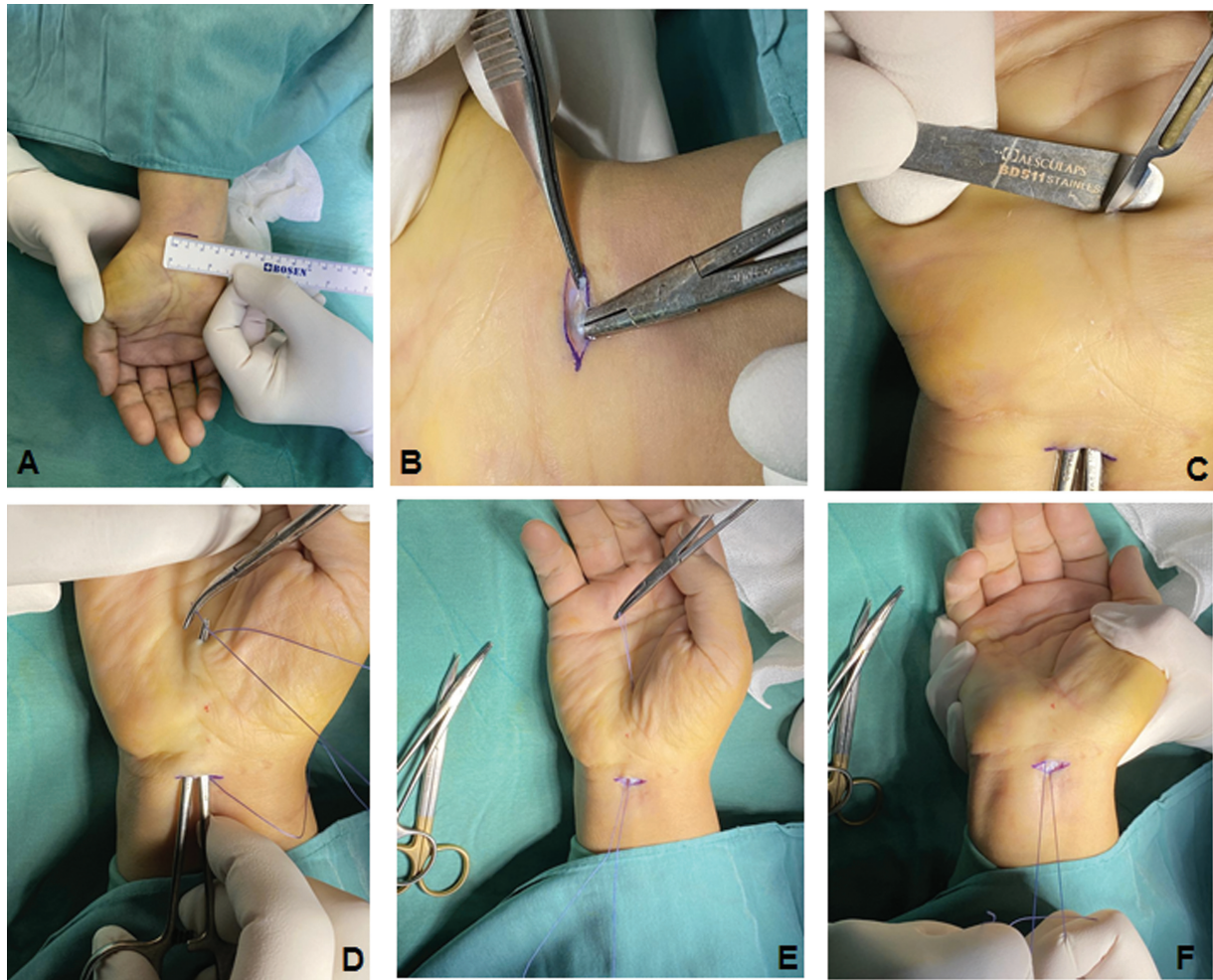
### Ethical Consideration

The ethics committee approved this study, with the registration number IR.IUMS.FMD.REC.1398.194. In addition, this study was registered in the Iranian Registry for Clinical Trials, with the registration number IRCT20211225053519N2.

## Result

### Nerve Conduction Study and Electromyography

Twenty patients were included in the final analysis (►Fig. 2). Nineteen patients were females (95%), and the mean age of the patients was  $48.45 \pm 9.64$  years. There were no significant differences in age, right/left hand, Phalen's test result, or paresthesia between the two groups. In the assessment of nerve conduction study and electromyography, there were



**Fig. 1** (A–F) Thread carpal tunnel release.

no significant differences before and 3 months after the surgery between the studied group (►Table 1).

### Sensory Evaluation

The 2-point discrimination test before the operation was fair (between 7 and 10 mm) in both groups and after 3 months, it was normal (<6 mm) in both groups. ►Table 2 shows no differences in terms of the 2-point discrimination in the thumb and index fingers between both groups before and after the operation. In terms of the monofilament test, the evaluation of the thumb and index finger before and 3 months after the surgery is presented in ►Table 2. As can be seen, the status of monofilament in both groups at baseline was blue (diminished light touch) and purple (decreased protective sensation) with no significant differences, while after the surgery, nine patients were green (average) for monofilament test in the thumb (six in the OCTR group and three in the TCTR group). In addition, 16 patients had a standard monofilament test on the index finger (eight in each group) after surgery. As shown in ►Table 2, there were no significant differences in the monofilament test between the two groups after the surgery.

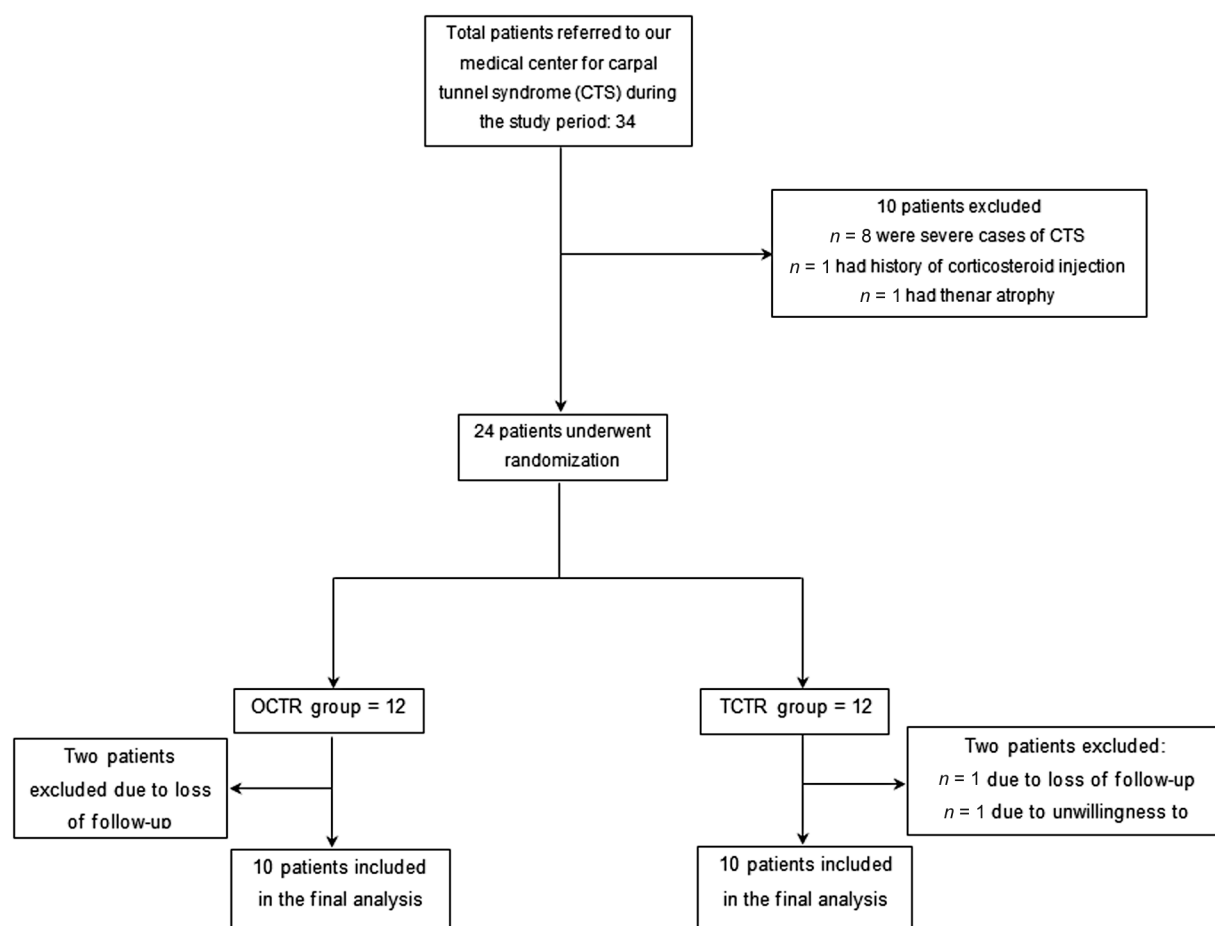
### Operation-Related Data

The operation-related data are presented in ►Table 3. The scar length and operation time were significantly lower in the TCTR group compared to the OCTR group. Furthermore, patients in the TCTR group had less pain postoperatively based on the VAS score than the OCTR group. However, there was no significant difference in pain after 3 months in the two groups. The modified Mayo wrist score was excellent (>90) in both groups, with no significant differences.

### Discussion

The present study compares the functional and aesthetic outcomes of two CTR techniques: TCTR and OCTR. The results of the current study suggest that the practical results between these two techniques were similar. The pain score in the TCTR group was significantly lower in the postoperative period. In addition, the duration of the operation was lesser in the TCTR group. Regarding aesthetic outcomes, TCTR was better than OCTR, with shorter surgery scar lengths.

Pillar pain is the most common complication after CTR, which refers to the pain between the thenar and hypothenar regions of the hand.<sup>11</sup>



**Fig. 2** Flowchart of the study. OCTR, open carpal tunnel release; TCTR, thread carpal tunnel release.

Pillar pain is about 41% in the first month after CTR, 25% in the third month after surgery, and 6% in the sixth month after CTR.<sup>12</sup> Pillar pain has no known etiologies, and it was assumed that most pillar pains would subside after 6 months.<sup>13</sup> However, there are some hypothetical etiologies, such as anatomical changes of the carpal arch, neurogenic cause, edematous changes, and loss of biomechanical and neuroprotective properties of the retinaculum flexor.<sup>14,15</sup> In the present study, postoperative pain in the TCTR group was less than that in the OCTR group. A clinical trial in 2020 observed that minimally invasive methods for CTR are associated with lower pillar pain than OCTR.<sup>16</sup> Similar to the present study, Guo et al observed that the TCTR method effectively reduces pillar pain compared to the conventional method.<sup>17</sup>

OCTR requires a relatively large incision and can cause damage to nerves and ligaments.<sup>18</sup> ECTR was developed to reduce the complications of OCTR. Still, this technique may cause an iatrogenic injury to the median nerve and its surrounding ligaments by inserting the cannula into the carpal tunnel.<sup>19</sup> In contrast, TCTR is a less invasive method associated with lower complications and better aesthetic outcomes.<sup>20</sup> It is associated with lower rates of iatrogenic injury to nerves and ligaments compared to OCTR and ECTR.<sup>21</sup>

The TCTR technique can also preserve the superficial palmar aponeurosis (SupPA). SupPA maintenance is essential because several cutaneous nerve branches of the median and ulnar nerves pass through this aponeurosis.<sup>22</sup> Therefore, maintaining the SupPA can prevent possible damage to the cutaneous branches of the median and ulnar palms. This technique can be performed under local anesthesia, in an outpatient manner or in a private clinic. This issue enables the surgeon to monitor the patients during the operation. In addition, patients can return to their daily routine in a shorter time than OCTR.<sup>23</sup> Moreover, our result shows that this method is associated with no severe surgical complications, and patients are satisfied with this technique. This result is consistent with that of previous studies. Burnham et al observed significant improvement on the Boston Questionnaire scores for pain and nerve conducting study parameters, and they stated that this procedure is safe.<sup>24</sup> Schrier et al also approved the safety and efficacy of this technique.<sup>25</sup>

This study has some positive points. First, we conducted this study as a randomized controlled trial to compare TCTR with the conventional technique, OCTR. To our knowledge, only one study in 2022 compared TCTR with OCTR in a controlled trial.<sup>23</sup> In addition, assessing the sensorimotor properties, electromyography, and overall outcome based on the Mayo score to show

**Table 1** Characteristics of nerve–muscle study between the studied group

Variable		OCTR group	TCTR group	p value
Age (y)		53.5 (25–41.56)	48.5 (37.5–54.25)	0.436 <sup>a</sup>
Dominant hand	Right	7 (53.8%)	6 (46.2%)	0.999 <sup>b</sup>
	Left	3 (42.9%)	4 (57.1%)	
Phalen test	Negative	2 (50%)	2 (50%)	0.999 <sup>b</sup>
	Positive	8 (50%)	8 (50%)	
Paresthesia	Negative	1 (50%)	1 (50%)	0.999 <sup>b</sup>
	Positive	9 (50%)	9 (50%)	
Nerve conduction study	Nerve motor latency (milliseconds)	7.6 (4.5–52.9)	5.4 (4.5–52.91)	0.910 <sup>a</sup>
		4.57 (4.4–42.62)	4.6 (4.4–50.92)	0.316 <sup>a</sup>
	Nerve sensory latency (milliseconds)	5.3 (4.6–34.01)	5 (4.6–33.12)	0.999 <sup>a</sup>
		4.25 (3.4–85.4)	4.2 (4.436)	0.909 <sup>a</sup>
	Nerve motor velocity (meter per second)	33 (29.34–70.25)	33 (29.35–75)	0.788 <sup>a</sup>
		40 (40.42–50.25)	42 (41.43–50.50)	0.092 <sup>a</sup>
	Nerve sensory velocity (meter per second)	25 (22.34–75.75)	25.5 (24.35–75.25)	0.544 <sup>a</sup>
		41.5 (39.42–75)	40 (39.42–75)	0.525 <sup>a</sup>
Electromyography	Baseline (n)	–	–	–
	Mild dysfunction	3 (42.9%)	4 (57.1%)	0.999 <sup>b</sup>
	Moderate dysfunction	7 (53.8%)	6 (46.2%)	
	Severe dysfunction	5 (55.6%)	4 (44.4%)	0.484 <sup>b</sup>
	Mild dysfunction	3 (37.5%)	5 (62.5%)	
	Severe dysfunction	2 (66.7%)	1 (33.3%)	

Abbreviations: OCTR, open carpal tunnel release; TCTR, thread carpal tunnel release.  
Note: Data presented as median (minimum–maximum) or number (%).  
<sup>a</sup>Mann–Whitney *U* test.  
<sup>b</sup>Chi-squared test.



**Table 2** Sensory evaluation of the studied group before and after the intervention

Variable				OCTR group	TCTR group	p value
Two-point discrimination (mm)	Static	Thumb	Baseline	7.75 (7.1–10.5)	7.75 (7–10.7)	0.878 <sup>a</sup>
			After 3 mo	5 (4–6.5)	5 (4–6.4)	0.810 <sup>a</sup>
		Index	Baseline	8 (7.8–10)	8 (7.8–10.5)	0.514 <sup>a</sup>
			After 3 mo	5 (4–5.5)	5 (4–5.6)	0.243 <sup>a</sup>
	Dynamic	Thumb	Baseline	5 (4.7–10)	5 (4.6–10)	0.511 <sup>a</sup>
			After 3 mo	3 (2–3.4)	3 (2–4.3)	0.064 <sup>a</sup>
		Index	Baseline	6 (5–10)	6 (5.6–10)	0.099 <sup>a</sup>
			After 3 mo	3 (2–3.3)	3 (2–3.3)	0.914 <sup>a</sup>
Monofilament test	Thumb	Baseline	Blue	3 (42.9)	4 (57.1)	0.999 <sup>b</sup>
			Purple	7 (53.8)	6 (46.2)	
		After 3 mo	Blue	3 (37.5)	5 (62.5)	0.484 <sup>b</sup>
			Green	6 (66.7)	3 (33.3)	
		Purple	1 (33.3)	2 (66.7)		
	Index	Baseline	Blue	8 (50)	8 (50)	0.999 <sup>b</sup>
			Purple	2 (50)	2 (50)	
		After 3 mo	Blue	2 (50)	2 (50)	
			Green	8 (50)	8 (50)	

Abbreviations: OCTR, open carpal tunnel release; TCTR, thread carpal tunnel release.

Note: data presented as median (minimum–maximum) or number (%).

<sup>a</sup>Mann–Whitney *U* test.

<sup>b</sup>Chi-squared test. Monofilament test definition: blue = diminished light touch; purple = diminished protective sensation; green = normal.

**Table 3** Operation-related data between two studies

Variable		OCTR group	TCTR group	p value
Operation time (min)		13 ± 1.15	5.9 ± 1.14	<0.001 <sup>a</sup>
Surgical scar length (cm)		5.6 (5.25–10)	1.5 (1.1–5.5)	<0.001 <sup>a</sup>
Pain	Postoperation	4.5 (4–10)	2.3 (2–10)	<0.001 <sup>a</sup>
	After 3 mo	1 (0–2)	0 (0–1)	0.255 <sup>a</sup>
	Mayo modified wrist score (after 3 mo)	90 (90–100)	90 (90–100)	0.890

Abbreviations: OCTR, open carpal tunnel release; TCTR, thread carpal tunnel release.

Note: Data presented as mean ± standard deviation (SD) or median (minimum–maximum).

<sup>a</sup>Mann–Whitney *U* test.

the noninferiority of TCTR was another positive point of this study. However, this study had some limitations. First, we did not use a subjective questionnaire like the Levine–Katz Questionnaire<sup>9</sup> or the Boston Carpal Tunnel Questionnaire.<sup>17</sup> These subjective assessments are not necessary, but they are easily accessible, and using them can improve the power of this study. Second, the sample size was small, and a larger sample size may affect the result of functional outcomes. This issue should be considered in future studies.

## Conclusion

TCTR is a safe technique that can be used instead of OCTR. The functional outcome in both groups is similar; however,

the aesthetic result in TCTR is better. Using the TCTR method instead of the OCRT method can decrease the need for hospitalization and prevent iatrogenic injuries. Further studies are needed to approve and confirm the current evidence.

## Ethical Approval

All the procedures were performed in accordance with the principles outlined in the Declaration of Helsinki. Appropriate institutional review board approval has been obtained.

## Conflict of Interest

None declared.

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