Effect of high intensity laser therapy on the range of motion of facial muscles in patients with Chronic Bell’s Palsy

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ABSTRACT

Background: Bell's palsy is a disease involving the seventh cranial nerve, which regulates facial muscle action. Facial muscles get paralyzed when this nerve is damaged. Objective: The primary objective of this researcher is to find out the effect of High Intensity Laser Therapy (HILT) on facial muscle function in patients with chronic bell’s palsy. Subjects and Methods: Twenty patients diagnosed with chronic Bell’s palsy and twenty healthy individuals of both sexes were recruited, falling within the age group of 20-40 years. Participants were assigned into two groups. Group A (Healthy individuals) and Group B (Bell’s palsy patients). Group A participants were intervened with Nd: YAG High intensity LASER, one session/week for total of 4 sessions. Facial angle measurement was done in resting state and in contracted positions of the respective muscles on both the sides of face. These angles were analyzed using the Auto-CAD program. Results: A significant increase in facial angle was observed in raising eye brow, light eye closing, smiling, kissing, and blowing on the non-affected side and a significant decrease of these angles on the affected side following treatment (p<0.05). Comparison between non-affected sides versus affected side showed significant differences in measured angles except for smiling and kissing angles. Conclusion: High-Intensity Laser Therapy (HILT) improved the function of the facial muscles in patients with chronic Bell's palsy.

KEYWORDS

High Intensity LASER Therapy; Bell’s palsy; Facial Palsy
1. INTRODUCTION

The facial expressions convey innermost feelings. They are an important aspect of human communication. This is accomplished through the facial nerve’s exquisite control over voluntary and involuntary face muscle contractions (Mohamed, Kamel, EL-Sayyed & Abd EL-Latif, 2016). Bell’s palsy is a type of lower motor neuron palsy having acute onset. Its clinical manifestations are: unilateral facial weakness with a rapid onset, post-auricular ache, subjective changes in face sensation and hyperacusia. The severity of bell’s palsy greatly depend upon number of factors like the period of facial dysfunction, the level of actual healing, duration of onset etc. (Eviston, Croxson, Kennedy, Hadlock, & Krishnan, 2015).

Bell’s palsy impacts 11–40 persons every 100,000 in the United States each year. It is more prevalent in the persons falling with in the age group of 15 to 50 years. Over 60,000 instances are diagnosed each year, with similar occurrence rates reported among men and women (Loukas, 2014).

Variety of physiotherapy intervention models coexist for rapid return of facial function to normal level. Different treatment models include: treatment with electrotherapeutic approaches such as faradic current, Biofeedback, ultrasound therapy, short wave diathermy, LASER therapy etc. (Teixeira, Valbuza & Prado, 2011). Variety of exercise therapy models also help in improving physical and social indexes of the facial impairment. Exercise therapy approaches include relaxation exercises, suppression of synkinesis, coordinating exercises, and emotional expression exercises (in front of a mirror) (Ordahan & Karahan, 2017).

Individuals with Bell’s palsy also get benefit from low-level laser therapy (LLLT). LLLT is a painless, non-invasive treatment option for any patient, including diabetics and hypertensives, in whom, corticosteroid therapy is contraindicated (Ramova, Ramov & Angelovska, 2016). The Food and Drug Administration (FDA) has approved high-intensity laser treatment (HILT) in 2004 and it was recently brought to the field of physiotherapy. HILT is a non-invasive treatment. It differs from the traditional LASER in terms of greater depth of reach to the deeper tissues. Recent investigations have revealed that the Nd:YAG LASER has anti-inflammatory, anti-oedemigenic, as well as antalgic properties (Pekyavas & Baltaci, 2016; Viliani, Ricci, Mangone, Graziani & Pasquetti, 2009; Zati & Valent, 2006).

To the best of researcher’s knowledge, there is huge gap in the literature regarding impact of HILT on patients with bell’s palsy. Hence the present study is focused to find out the HILT on facial function in patients with bell’s palsy.
2. METHODS

2.1. Study design

The present study is an experimental design, conducted at the outpatient clinic of Cleopatra Hospital, Cairo, Egypt. Ethical approval was obtained from the Cairo University Faculty of Physical Therapy's institutional Review Board (NO.P.T.REC/012/002326). The study was carried out between June 2020 and June 2021, following the guidelines set out by the Helsinki Declaration on Human Subjects.

2.2. Participants and sample size

A total of 20 healthy individuals and 20 patients diagnosed with chronic bell’s palsy, falling within the age group of 20-40 years were recruited for the present study. Inclusion criteria of present study was: patients having unilateral idiopathic facial nerve palsy (Bell’s palsy) from past 6 months. Exclusion criteria for the present study were: 1) facial palsy secondary to stroke, central nervous system (CNS) infection, sarcoidosis, middle ear infection, trauma or upper motor neuron types of facial palsy; 2) bilateral Bell’s palsy; 3) Patients suffering from facial ulceration or undergone a surgical procedure to repair any facial deformities; 4) Pregnant women (Grewal, 2018).

Power test showed sample size is needed for the study (95%). For this investigation, the sample size was estimated for a one-tailed test using the G*power software 3.1.9 (G power software version 3.1, Heinrich-Heine-University, Düsseldorf, Germany). For the results of five main variables using two independent group comparisons, sampling size was calculated using F tests (ANOVA: fixed effects, special effects, main effects, and interaction), Type I error (α) = 0.05, power (1-β error probabilities) = 0.80, and impact size f = 0.6236096. This study required a minimum sample size of 39 patients (a minimum of 20 patients in every group).

Written informed consent was signed by each participant prior to the start of the study. All data was digitized to protect anonymity. There were no dropouts among the participants throughout the study.

2.3. Procedure

2.3.1. Initial assessment

Normal subjects in Group A (control): were assessed one time by measuring 5 facial angles on both sides of the face, 3 times in a static position and 3 times in a muscle contraction, these angles were smiling, kissing, closing, raising, and blowing angles. The Auto-CAD program was used to
calculate and analyze the angles. Patients in Group B (study): were assessed pre and post intervention in the same manner.

2.3.2. Camera

Nikon, D3200 24MP camera, 4 FS camera was used to capture front-view facial images of the participants in a well lifted room. The camera was mounted on a robust tripod 1.5 m away from the participants measured by tape measurement. Each participant was asked to raise his/her chin while looking straight into the camera. (Anping, Guoliang, Xuehai, Jiaxin, Gang & Wu, 2017).

2.3.3. Markers

Skin marker and double face adhesive plaster was used. Twenty-two passive Speed-mark™ radiology skin markers were used as face surface markers. The markers were attached bilaterally to both side of the face of each participant, with well-defined anatomical landmarks, using double-sided adhesive tape to assure a perfect facial fit (Mishima & Sugahara, 2009; Hontanilla & Aubá, 2008; Tomat & Manktelow, 2005). The adhesive plaster was used to ensure good contact of the dots to the skin. Facial movements were demonstrated by researcher to each participant, followed by which they were asked to do the same movements. Landmarks for upper face were: right frontal, left frontal, right external eyebrow, left external eyebrow, right middle eyebrow, left middle eyebrow, nasium point, right external canthus, left external canthus, right internal canthus, left internal canthus, right upper eyelid, left upper eyelid, right lower eyelid, left lower eyelid. Landmarks for lower face were middle nasal point, right zygomaticus, left zygomaticus, right nasogenian, left nasogenian, right commissure, left commissure as shown in (Figure 1) (Tomat & Manktelow, 2005; Hontanilla & Aubá, 2008).

![Figure 1. Facial Landmarks.](image)

All the participants were asked to sit quietly while performing facial movements. They were directed to perform facial movements on verbal command of examiner (“go”). Upper facial expressions were recorded
by asking the participant to “open” and “close eyes” (with no blinking) as well as elevate and relax their brows (Nevein, Sahar & Nirmeen, 2011). Facial expressions of lower face were recorded by asking the participant to “smile while showing their teeth”. They were then requested to draw the mouth angle straight upward and relax (kissing). All the movements were performed in 3 sets.

Facial muscles evaluated were: Frontalis, Orbicularis oculi, Orbicularis oris, Zygomaticus major, Buccinator. The amplitude of the specified facial angles was investigated on both sides of the face, which included: Raising angle, closing angle, smiling, kissing and blowing angles during static position and after contraction (Figure 2). The five angles were measured and analyzed using the Auto CAD 2017 program, which is a precise computer program used in architecture and engineering for calculations and design (Mohamed, Kamel, EL-Sayyed & Abd EL-Latif 2016; Mohammed, El Sayyad, Latif & Kamel, 2016).

![Figure 2. Facial Angles – Static Position: 1, 3, 5 Raising angle (RE) - 12, 8, 14 Closing angle (LE) - 17, 21, 22 Smiling angle(S) - 16, 19, 21 kissing angle (K) - 19, 17, 21 Blowing angle (B).](image_url)

**2.4. Intervention**

**2.4.1. High Intensity Laser Therapy (HILT)**

Pulsed Nd:YAG LASER, developed by Hilterapia® HIRO® 3.0 (ASA laser, Arcugnano, Vicenza, Italy) was used in the present study. LASER was given by keeping the LASER pointer perpendicular to the targeted surface. Three phases of treatment were used to deliver a total energy dose of 1,808.4 J. The initial phase consisted of quick manual scanning for a whole of 873 J, and the LASER frequency was set to 3 successive sub phases of 510, 610, and 710 mJ/cm² for a whole of 873 J. In intermediate phase, LASER was given to total 8 points as shown in the Figure 3. (Bernal, 1993), with 7.8 J, with fluency of 360 mJ/cm², and a time of 7 s per point for a total energy of 62.4 J. The final phase was similar to initial one. It took about 15 minutes to complete all the phases. For each session, the HILT device calculated the number of pulses and energy received during treatment. HILT was used for a total of four treatment sessions over the course of four consecutive weeks (one session per week).
2.4.2. Exercise therapy

Exercises were performed by all the participants in the form of voluntary facial movements like brow raise, eye closure, snarl, smile and pucker in front of the mirror for visual feedback (Cederwall, Fagevik, Hanner & Fogdestam, 2006). Participants were asked to complete the exercise session post application of HILT. All the participants were provided with the home instructions, which included (i) maintenance of eye hygiene, (ii) Home exercises in front of mirror as told by the examiner (10 Repetitions/ facial movement). Family member or care givers were directed to ensure the successful completion of home exercise protocol of participant.

2.5. Data analysis

The data was examined for normality assumptions tests and variance homogeneity. Following removal of outliers, discovered by box and whiskers plots, the data was normalized using the Shapiro-Wilk test, which indicated that the data was normally distributed (P>0.05). Additionally, Levene’s test for determining variance homogeneity indicated no significant difference (P>0.05). The data was therefore normally distributed, and parametric analysis was performed. The statistical analysis was carried out with the statistical SPSS Package software for Windows version 25 (SPSS, Inc., Chicago, IL). Quantitative data was taken in mean and standard deviation. Qualitative data was expressed as number (percentage) for gender and compared between normal and study groups by Chi-square test. Between group comparison was done using independent t-test. Within group comparison was done using paired t-test.

To compare the three sides, the analysis of variance (ANOVA) test has been utilized (non-affected side, affected side, and normal side) and Bonferroni correction test has been employed to evaluate pairwise sides of the tested angles whose F was significant based on the ANOVA results. At a level of probability less than equal to 0.05 (P ≤ 0.05), all statistical analyses were significant.
3. RESULTS

Table 1 shows the general characteristics of both groups of participants (normal group and study group).

Table 1. Baseline characteristics of participants

<table>
<thead>
<tr>
<th>Variables</th>
<th>Groups</th>
<th>Normal group (n=20)</th>
<th>Study group (n=20)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year)</td>
<td></td>
<td>\overline{X} ±SD 31.75 ±7.12</td>
<td>\overline{X} ±SD 30.75 ±7.20</td>
<td>0.861</td>
</tr>
<tr>
<td>Gender (Males : Females)</td>
<td></td>
<td>13 (65.00%) : 7 (35.00%)</td>
<td>4 (20.00%) : 16 (80.00%)</td>
<td>0.288</td>
</tr>
<tr>
<td>Sound side (Right : Left)</td>
<td></td>
<td>----</td>
<td>22 (55.00%) : 18 (45.00%)</td>
<td>----</td>
</tr>
<tr>
<td>Affected side (Right : Left)</td>
<td></td>
<td>----</td>
<td>22 (55.00%) : 18 (45.00%)</td>
<td>----</td>
</tr>
</tbody>
</table>

*\overline{X} : Mean, SD: Standard deviation, p value: Probability value

There was significant increase of facial movement angles (raising eye brow, light eye closing, smiling, kissing, and blowing) on the non-affected side after treatment with improvement percentages 31.08, 26.04, 32.02, 41.52, and 18.54%, respectively. Moreover, there was significant decrease of the same facial angles on the affected side after treatment with improvement percentage 29.41, 19.46, 30.84, 35.00, and 32.05%, respectively as in (Table 2).

Table 2. Comparison of facial movement angles for non-affected and affected sides in the study group

<table>
<thead>
<tr>
<th>Items</th>
<th>Variables</th>
<th>Study group (Mean ±SD)</th>
<th>Change</th>
<th>Improvement %</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Before treatment (n=20)</td>
<td>After treatment (n=20)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-affected side</td>
<td>Raising Eye Brow</td>
<td>4.73 ±2.44</td>
<td>6.20 ±2.53</td>
<td>1.47</td>
<td>31.08%</td>
</tr>
<tr>
<td></td>
<td>Light Eye Closing</td>
<td>15.63 ±6.48</td>
<td>19.70 ±6.67</td>
<td>4.07</td>
<td>26.04%</td>
</tr>
<tr>
<td></td>
<td>Smiling</td>
<td>3.81 ±2.27</td>
<td>5.03 ±2.67</td>
<td>1.22</td>
<td>32.02%</td>
</tr>
<tr>
<td></td>
<td>Kissing</td>
<td>3.30 ±1.52</td>
<td>4.67 ±1.52</td>
<td>1.37</td>
<td>41.52%</td>
</tr>
<tr>
<td></td>
<td>Blowing</td>
<td>4.53 ±2.05</td>
<td>5.37 ±2.38</td>
<td>0.84</td>
<td>18.54%</td>
</tr>
<tr>
<td>Affected side</td>
<td>Raising Eye Brow</td>
<td>2.72 ±1.65</td>
<td>1.92 ±1.34</td>
<td>0.80</td>
<td>29.41%</td>
</tr>
<tr>
<td></td>
<td>Light Eye Closing</td>
<td>16.96 ±7.93</td>
<td>13.66 ±7.24</td>
<td>3.30</td>
<td>19.46%</td>
</tr>
<tr>
<td></td>
<td>Smiling</td>
<td>3.08 ±2.23</td>
<td>2.13 ±1.34</td>
<td>0.95</td>
<td>30.84%</td>
</tr>
<tr>
<td></td>
<td>Kissing</td>
<td>3.80 ±1.70</td>
<td>2.47 ±1.58</td>
<td>1.33</td>
<td>35.00%</td>
</tr>
<tr>
<td></td>
<td>Blowing</td>
<td>3.12 ±1.25</td>
<td>2.12 ±0.80</td>
<td>1.00</td>
<td>32.05%</td>
</tr>
</tbody>
</table>

* Significant (P<0.05), SD: Standard deviation, p value: Probability value.

Comparison of facial movement angles between non-affected side, affected side, and normal control before and after treatment showed significant differences before therapy (P<0.05) and after
therapy (P<0.05) for raising eye brow, light eye closing, smiling, kissing, and blowing angles as in (Table 3).

**Table 3.** Comparison of facial movement angles between non-affected side, affected side, and normal groups pre–post intervention

<table>
<thead>
<tr>
<th>Items</th>
<th>Variables</th>
<th>Groups (Mean ±SD)</th>
<th>F-value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Non-affected side (n=20)</td>
<td>Affected side (n=20)</td>
<td>Normal (n=20)</td>
</tr>
<tr>
<td>Before treatment</td>
<td>Raising Eye Brow</td>
<td>4.73 ±2.44</td>
<td>2.72 ±1.65</td>
<td>8.59 ±0.84</td>
</tr>
<tr>
<td></td>
<td>Light Eye Closing</td>
<td>15.63 ±6.48</td>
<td>16.96 ±7.93</td>
<td>13.25 ±1.50</td>
</tr>
<tr>
<td></td>
<td>Smiling</td>
<td>3.81 ±2.27</td>
<td>3.08 ±2.23</td>
<td>12.17 ±0.94</td>
</tr>
<tr>
<td></td>
<td>Kissing</td>
<td>3.30 ±1.52</td>
<td>3.80 ±1.70</td>
<td>12.35 ±1.60</td>
</tr>
<tr>
<td></td>
<td>Blowing</td>
<td>4.53 ±2.05</td>
<td>3.12 ±1.25</td>
<td>13.21 ±1.39</td>
</tr>
<tr>
<td>After treatment</td>
<td>Raising Eye Brow</td>
<td>6.20 ±2.53</td>
<td>1.92 ±1.34</td>
<td>8.59 ±0.84</td>
</tr>
<tr>
<td></td>
<td>Light Eye Closing</td>
<td>19.70 ±6.67</td>
<td>13.66 ±7.24</td>
<td>13.25 ±1.50</td>
</tr>
<tr>
<td></td>
<td>Smiling</td>
<td>5.03 ±2.67</td>
<td>3.12 ±1.25</td>
<td>13.21 ±1.39</td>
</tr>
<tr>
<td></td>
<td>Kissing</td>
<td>4.67 ±1.52</td>
<td>2.47 ±1.58</td>
<td>12.35 ±1.60</td>
</tr>
<tr>
<td></td>
<td>Blowing</td>
<td>5.37 ±2.38</td>
<td>2.12 ±0.80</td>
<td>13.21 ±1.39</td>
</tr>
</tbody>
</table>

* Significant (P<0.05), SD: Standard deviation, p value: Probability value.

Bonferroni test (Post-hoc test) indicated that there was a significant difference (P<0.05) in raising eye brow, light eye closing, smiling, kissing, and blowing angles between the non-affected side vs. normal and the affected side vs. normal. A comparison between the non-affected side and the affected side showed significant differences (P<0.05) in raising the eyebrow, light eye closing, and blowing angles, and non-significant differences (P>0.05) in smiling and kissing angles, as in (Table 4).

**Table 4.** Post-Hoc analysis between pairwise groups before and after treatment

<table>
<thead>
<tr>
<th>Items</th>
<th>Variables</th>
<th>P-values of Post-hoc (Bonferroni test)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Non-affected side vs. Affected side</td>
</tr>
<tr>
<td>Before treatment</td>
<td>Raising Eye Brow</td>
<td>0.002*</td>
</tr>
<tr>
<td></td>
<td>Light Eye Closing</td>
<td>0.037*</td>
</tr>
<tr>
<td></td>
<td>Smiling</td>
<td>0.689</td>
</tr>
<tr>
<td></td>
<td>Kissing</td>
<td>1.000</td>
</tr>
</tbody>
</table>
4. DISCUSSION

Bell's palsy occurs due to involvement of facial nerve with no identified cause. It may result in an inability to close the eyelid and drop of the mouth corner. Multiple treatment options coexist for management of bell’s palsy which include medical management, surgical decompression of facial nerve, physiotherapy intervention combining exercise therapy and electrotherapy (Baugh, Basura, Ishii, Schwartz, Drumheller, Burkholder et al., 2013; Marques, Soares, Nascimento, Neto, Marques & Pinheiro, 2010).

Statistical findings of the present study revealed, a significant increase in the facial movement angles for raising eyebrow, light eye closing, smiling, kissing, and blowing on the non-affected side post-treatment versus pre-treatment. Furthermore, comparison between non-affected side, affected side, and normal groups revealed post-treatment significant differences for five angles. Also, Comparison between non-affected and affected sides showed significant differences in measured facial angles except for smiling and kissing angles.

The results of this research are in agreement with a study conducted by Alayat, Elsodany & El Fiky in the year 2014, who examined the impact of high-intensity laser therapy (HILT) and low-level laser therapy (LLLT) on patients with bell's palsy patients. The results of their study showed better improvement with HILT in comparison to LLLT.

Similarly, Kumar, 2019, also examined the usage of high-intensity laser therapy (HILT) in the treatment of Bells’ palsy in five participants. The program of treatment included seven days of physiotherapy intervention in the form of (HILT) for three sessions alternatively and four sessions of conservative physiotherapy based on history and clinical examination. The results of their study revealed that participants with bell’s palsy responded very well to HILT along with medical management.
Venosa, Romanini, Padua & Cerciello (2019) also compared the effect of (HILT) with training versus a pairing of ultrasound (US) application and (TENS) with exercise on aches and functional mobility in patients having cervical spondylosis (CS) and revealed that HILT with exercise was more beneficial than US/TENS with exercise, indicating that HILT could be a recommended treatment in rehabilitation programs in CS.

Ezzati, Laakso, Saberi, Chabok, Nasiri & Eghbali (2020) also evaluated the dosage exposure of (LLLT) and (HILT) on electrophysiological evaluation of patients with Carpal Tunnel Syndrome (CTS), finding that HILT was preferable in pain reduction and management of the median motor nerve electrophysiological investigations when contrasted to low-level laser therapy and strength training in the control group.

The short-term efficacy of (HILT) was investigated by (Karaca, 2016) as a retrospective case series. HILT has been shown to be beneficial in managing pain and dysfunction in the short term in 42 individuals having subacromial impingement syndrome (SAIS) who were assessed before and 8 weeks after treatment.

The current study was in line with a systematic review conducted by (Song, Seo, Lee & Kim, 2018). They examined the efficiency of HILT in patients having musculoskeletal disorders (MSD). As per their findings, the HILT procedure for neck and back pain considerably reduced pain and impairment scores. Another study was done by (Abdel-Aal, Ali & Eladl, 2020). They evaluated the therapeutic effects of HILT on patients suffering from systemic lupus erythematosus-related hand arthropathy. They revealed that combining HILT with the routine treatment approach could be more beneficial than a conventional physiotherapy program alone in enhancing grip strength, reducing rate of joint swelling, joint tenderness, and discomfort.

Ordahan, Karahan, & Kaydok (2018) compared the efficacy of (LLLT) versus (HILT) in the therapy of plantar fasciitis (PF) and revealed that HILT group outperformed the LLLT group in all criteria. Both interventions, however, enhanced pain levels, activity, and living standards in PF sufferers, but HILT showed more impact than LLLT. Another study done by (Akkurtt, Akkurtt, Yilmaz, Olgun & Sen, 2018) evaluated 52 patients suffered from (PF) managed with HILT plus insole in one group and only silicone insole in the other group backdated, the study concluded that in terms of pain control and improve living standards, HILT with insole therapy more efficient than just silicone insole.

Another study by Ebid, Ibrahim, Omar, Mohamed & El Baky (2017), analyzed the long-term influence of pulsed (HILT) on the intervention of post-burn pruritus in 49 adult burn patients. The active laser group (ALG) provided HILT, while the placebo laser group (PLG) obtained placebo
HILT and daily cetirizine. They concluded that HILT paired with cetirizine seemed to be more beneficial than a placebo laser technique with cetirizine in individuals with post-burn pruritus.

The impact of (LLLT) and (HILT) were compared by Kheshie, Alayat, & Ali (2014) on pain alleviation and functional recovery in knee osteoarthritis (KOA). HILT and exercise (HILT+EX), LLLT and exercise (LLLT+EX) and placebo laser plus exercise (PL+EX) were used to cure three groups. This study found that HILT paired with exercises was more successful than LLLT paired with exercises in treating patients with KOA, and that both therapeutic methods were more efficient than exercises alone.

5. LIMITATIONS

First: Small sample size, fewer Bell’s palsy cases in relation to exclusion and inclusion criteria, especially after the emergence of COVID-19. Second: The gliding of the markers was considered one of the limitations with study as they could be gliding from some faces according to the nature of the skin of the subjects during the measurement and they need to be relocated again at the same place. Third: The skin markers and camera need to be recalibrate several times during sessions.

6. CONCLUSION

High Intensity Laser Therapy has proved to be an effective and safe rehabilitation modality, and it may be successfully applied in the physical therapy program in treating patients with chronic Bell's palsy.

7. REFERENCES


**AUTHOR CONTRIBUTIONS**

All authors listed have made a substantial, direct and intellectual contribution to the work, and approved it for publication.

**CONFLICTS OF INTEREST**

The authors declare no conflict of interest.

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