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Effect of low level laser on pelvic floor muscles and fascia in cases of stress urinary incontinence: a randomized controlled trial

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Abstract

Introduction. The aim of the study was to determine the effect of low level laser applied for 3 months, 2 sessions per week, on pelvic floor muscles and fascia compared with a pelvic floor exercise program in patients with stress urinary incontinence.
Methods. The randomized controlled trial involved 30 patients with stress urinary incontinence and with pelvic floor muscle strength not less than grade 1 on the Oxford scale. They were assigned to 2 equal groups. The experimental group received low level laser for 15 minutes and a pelvic floor muscle exercise program for 30 minutes, 2 sessions per week, for 12 weeks; the control group only received the pelvic floor muscle exercise program for 30 minutes, 2 sessions per week, for 12 weeks. The pelvic floor muscles were evaluated before and after treatment with a Neen Peritone perineometer and the Modified Oxford Grading Scale. The Revised Urinary Incontinence Scale served to assess incontinence severity before and after treatment.
Results. The statistical analysis indicated a significant increase in pelvic floor muscle strength ($p < 0.05$), a significant improvement of the grade muscle test of pelvic floor muscles ($p < 0.05$), and a significant reduction of Revised Urinary Incontinence Scale score ($p < 0.05$) after treatment compared with pre-treatment status in both groups. Also, there was a significant improvement in all dependent variables in favour of the experimental group.
Conclusions. Low level laser may be an effective intervention in treating stress urinary incontinence and improving pelvic floor muscle strength and fascia.
Key words: stress urinary incontinence, low level laser, pelvic floor muscles, Neen Peritone, perineometer

Introduction

The International Continence Society and the International Urogynecological Association define stress urinary incontinence as involuntary loss of urine on effort, during physical exertion, or while sneezing or coughing. Women with urinary incontinence have low levels of awareness regarding preventive or treatment methods [1]. Urinary incontinence is an endemic problem associated with considerable costs. Its prevalence increases with age; some degree of involuntary urine loss is experienced by approximately 25% of young women and up to 75% of older women [2, 3]. The disorder may be caused by the weakness of pelvic floor muscles which support the urethra and bladder, and/or urethral sphincter weakness (intrinsic sphincter deficiency). Advancing age, obesity, and vaginal delivery are among the stress urinary incontinence risk factors. These also include vaginal or pelvic surgery, chronic cough, and constipation [4, 5].

Pelvic floor muscle treatment for stress urinary incontinence has become widespread since the 1950s, after Kegel [6] reported that the treatment employing pelvic floor muscle exercises with a pressure biofeedback perineometer was successful. Pelvic floor muscle exercises improve the muscle function and strength through teaching the patient how to properly isolate and recruit the pubococcygeus muscle [7]. A damage within the pelvic floor structures (endopelvic fascia) with its histological composition, the collagen or elastin, nerves, smooth muscles, or blood vessels makes exercises alone of restricted benefit [8].

Low level laser therapy affects various body cells, increasing metabolism, cell migration and proliferation, as well as the secretion and synthesis of various proteins. It also causes vasodilation, with increased local blood flow [9]. There are, however, no studies on the efficacy of low level laser in treating stress urinary incontinence. Previous studies investigating laser in stress urinary incontinence focused mainly on cold laser. Therefore, the aim of this randomized clinical trial was to determine the effect of low level laser applied for 3 months, 2 sessions per week, on pelvic floor muscles and fascia compared with a pelvic floor exercise program in patients with stress urinary incontinence.

Subjects and methods

Design

The study was designed as a randomized, pre-post-test controlled trial. It was conducted in the out-patient clinic of gynaecology and obstetrics at Cairo University Hospitals, Kasr Al Aini, between August 2017 and August 2019. The Consolidated Standards of Reporting Trials have been followed.

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Participants

The study involved a convenient sample of 30 female patients, diagnosed as having stress urinary incontinence. Before inclusion, they were screened by an obstetrician through a full obstetric examination. The purpose and essence of the study were clarified to all the women. The were also informed on the privacy of all the collected data and their right to withdraw at any moment. The subjects were recruited in accordance with the following criteria: age of 30–65 years; mild or moderate grade of stress urinary incontinence, identified by clinical grading (Ingelman-Sundberg) as follows: grade I (mild) – the leakage of urine occurs on straining, grade II (moderate) – the leakage occurs after abrupt movement. Participants were excluded if they had a history of neurologic disorders, systemic diseases, complete denervation of the pelvic floor, urinary tract infection, vaginitis, pelvic pain, painful haemorrhoids, skin breakdown around the perianal region, or rectal or vaginal bleeding.

Randomization

The patients were randomly assigned to 2 groups: the experimental group (n = 15) and the control group (n = 15). The randomization was performed by a blinded and independent research assistant by using computer-generated randomization cards saved in sealed envelopes. No subject dropped out of the study after randomization (Figure 1).

Interventions

In both groups, the intervention involved 2 sessions per week for 12 consecutive weeks. The experimental group received low level laser for 15 minutes and a pelvic floor muscle exercise program for 30 minutes. The control group only received the pelvic floor muscle exercise program for 30 minutes.

The low level laser therapy parameters were as follows: low level laser unit, model LIS 1050, with 1 output, wavelength: 905 nm, density: 2 J/cm^2, area radiated: 10 cm^2, duty cycle: 100%, frequency: 5000 Hz (12 mW), probe: MLA3/75, time: 15 minutes.

Procedure

The perineum area was treated with low level laser, with a wavelength of 905 nm. Immediately before the laser treatment, the woman's perineum was thoroughly washed with a disinfecting solution and carefully dried off. The participant remained in the lithotomy position. Specially designed protective eye glasses were worn by the patient and the therapist. The laser probe was applied perpendicularly on the perineum in the scanning technique; each point was irradiated by laser beams, spot size: 1 cm^2 per each, and the radiation application lasted for half a minute per each point. The whole area was thoroughly covered with laser energy to achieve a sufficient level of thermal impact to the treated areas. No anaesthesia was used before or during the sessions.

The pelvic floor muscle exercise program was divided into muscle re-education (pubococcygeus muscle) and resistive pelvic floor exercises involving a perineometer in addition to a home program performed by the women at home.

The muscle re-education and awareness (pubococcygeus muscle) referred to pelvic floor muscles depending on the different types of muscle fibres: slow-twitch muscle fibres (type 1 muscle fibres) and fast-twitch muscle fibres (type 2 muscle fibres).

The learning of exercising the right muscles involved the following steps: (1) The patient imagined that she was passing urine and was trying to stop the stream. (2) The patient lay on her back with her knees bent and legs comfortably apart, knelt on her hands and knees, sat on a chair with her knees slightly apart, or stood straight. She imagined that she was trying to stop wind escaping from her anus (back

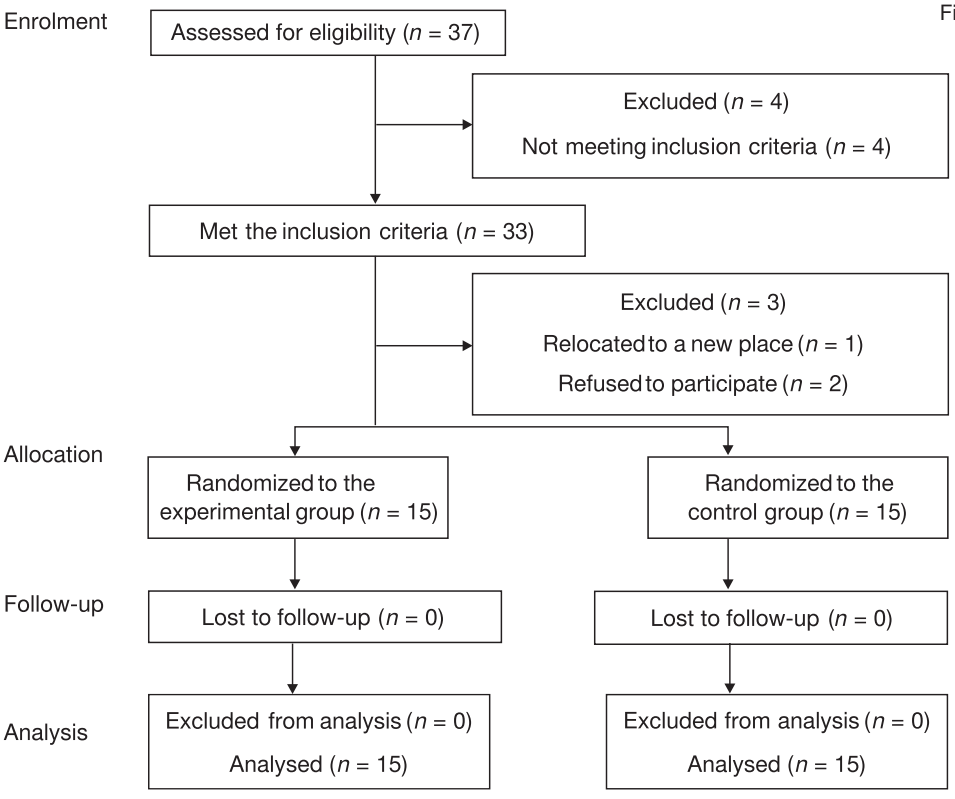

Figure 1. Flow chart of the participants during the trial

passage). She was asked to squeeze the muscle just above the entrance of the anus. She would find herself using slightly different parts of the pelvic floor muscles as compared with the first exercise. She should not move her buttocks or legs (puborectalis). (3) The participant was to tighten the muscles around her front passage, vagina, and back passage as strongly as possible and hold for 3–5 seconds. By doing this, she should feel her pelvic floor muscles 'lift up' inside her and feel a definite 'let go' as the muscles relax. If she was able to hold longer (but not more than a maximum of 8 seconds), she was asked to do so. The squeeze, however, had to stay strong and the patient should have felt a definite 'let go'. The exercise was repeated up to 10 times or until the participant felt her pelvic floor muscles fatigue. A several-second rest was applied between the squeezes (pubococcygeus).

The graduation of pubococcygeus muscle exercises was as follows:

Quick flick: Tighten and relax the muscle as quickly as possible 10–20 times. Relax for a count of 10 and then repeat. Repeat the exercise, increasing by 5 repetitions each week up to a maximum of 50 repetitions.

Slow contraction: Tighten the muscle as hard as you can for a count of 10–20. Relax for a count of 10 and then repeat. Repeat the exercise, increasing by 5 repetitions each week up to a maximum of 50 repetitions.

Sustained contraction: Tighten the muscle 'halfway' (half as hard as you did for the slow contraction) and hold it for 60 seconds. Relax for a count of 20 and then repeat. Repeat the exercise, increasing by 2 repetitions each week up to a maximum of 10 repetitions.

Daily home program

After the first therapy, the women were instructed to practise pelvic floor exercises at home. The exercise program consisted in holding each contraction for 6 seconds and then relaxing the muscles for 6 seconds. Also, the participants were to quickly hold and relax the muscles 10–20 times, relax for a count of 10, and then repeat. Those sequences were repeated continuously for up to 15 minutes. The women were told to do the exercises in lying, sitting, standing, and walking positions. Two training repetitions were performed in the clinic as a practice.

The control group received only a 30-minute program in accordance with the evidence-based treatment for stress urinary incontinence; the same pelvic floor exercise program was applied in the experimental group.

Outcome measures

Pelvic floor muscle strength assessment

This was performed by using a valid device (perineometry) that measures accurately the pelvic floor muscle strength and could be applied for improving the strength of the pelvic floor muscles [10, 11]. All patients were evaluated before and after treatment with a Neen Peritone single channel perineometer, manufactured by Patterson Medical Ltd., UK. The device is supplied with a vaginal sensor, which was used in this study. It measured intravaginal muscle contraction, reflecting the structural force of the perineal musculature; it measured the pubococcygeus muscle contraction, so that changes were provided in by microvolts. Also, it offered powerful sensory, visible, and audible biofeedback throughout the resistive isometric exercises of the pubococcygeus muscle.

Before assessing the pelvic floor muscle strength, the battery of the perineometer was checked out and the vaginal probe was connected to the main unit. Intravaginal muscle contraction was measured by using the vaginal probe of the apparatus before starting the treatment program and at the end of the program. Each woman was trained on the localization of pelvic floor muscle contraction. The participant remained in the crook lying position, with pillows under her head and knees, with slightly abducted legs to avoid substitution by hip adductors. The wires of the vaginal electrode were properly connected to the main unit. The vulva was cleaned with an antiseptic solution; the vaginal electrode was covered with a disposable condom and a layer of sterile lubricant and was inserted into the vagina until 1 cm of the lower margin of the pressure area of the probe remained outside. Next, the woman was asked to contract her pelvic floor muscles to squeeze the vaginal probe and then to relax. The perineometer recorded the changes. The contractions were repeated 5 times; the maximum vaginal contraction was recorded and considered for analysis.

Pelvic floor muscle testing grading scale

The Modified Oxford Grading Scale [12] was used to measure pelvic floor muscle strength, with the following grades: 0 – no contraction, 1 – flicker contraction, 2 – weak contraction, 3 – moderate contraction with lift, 4 – good contraction with lift, and 5 – strong contraction with lift.

Revised Urinary Incontinence Scale

This was used to measure the frequency and amount of urine loss in order to calculate the incontinence severity [13]. The patients were asked if they experienced the following events and to what extent:

1. Urine leakage related to the feeling of urgency: 0 – not at all, 1 – slightly, 2 – moderately, 3 – greatly.
2. Urine leakage related to physical activity, coughing, or sneezing: 0 – not at all, 1 – slightly, 2 – moderately, 3 – greatly.
3. Small amounts of urine leakage (drops): 0 – not at all, 1 – slightly, 2 – moderately, 3 – greatly.
4. How often do you experience urine leakage? 0 – never, 1 – less than once a month, 2 – a few times a month, 3 – a few times a week, 4 – each day and/or night.
5. How much urine do you lose each time? 0 – none, 1 – drops, 2 – small splashes, 3 – more.

Data analysis

The results were expressed as mean ± standard deviation (*SD*) for normally distributed data (pelvic muscle strength), as median (interquartile range) for not normally distributed data (stress urinary incontinence questionnaire), and as frequency distribution (number and percent) for ordinal variable (grade muscle test of pelvic floor muscles). A comparison of different variables between the groups was performed by using the unpaired *t*-test in normally distributed data or the Mann-Whitney *U*-test in not normally distributed data or ordinal variable. A pairwise comparison (pre- vs. post-assessment) within the same group for different variables was performed with the paired *t*-test in normally distributed data or the Wilcoxon signed-rank test in not normally distributed data and ordinal variable. The Statistical Package for the Social Sciences (SPSS) computer program (version 23 for Windows) was applied for the data analysis. The value of $p \leq 0.05$ was considered significant.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the Research Ethics Committee of the Faculty of Physical Therapy, Cairo University (No. P.T.REC/012/001657).

Informed consent

Informed consent has been obtained from all individuals included in this study.

Results

Demographic data

The independent *t*-test revealed that there were no significant differences ($p > 0.05$) in the mean values of age, body mass, height, or body mass index between the tested groups (Table 1).

Pelvic floor muscle strength

The mean ± *SD* values of pelvic floor muscle strength in the pre and post tests are presented in Table 2 for both groups. The paired *t*-test revealed that there was a significant increase of pelvic floor muscle strength ($p < 0.05$) after the treatment in both groups. Considering the effect of the tested group (first independent variable) on pelvic floor muscle strength, the unpaired *t*-test demonstrated that the post-treatment comparison of the groups exhibited a statistically highly significant increase in the pelvic floor muscle strength ($p < 0.05$) in favour of the experimental group as compared with the control group.

Grade muscle test of pelvic floor muscles

The frequency distribution of the grade muscle test of pelvic floor muscles in the pre-treatment and post-treatment tests are presented in Table 3 for both groups. The Wilcoxon signed-rank test revealed that there was a significant im-

Table 1. Demographic characteristics of patients in both groups

Characteristics	Experimental group	Control group	*t*	*p*
Age (years)	43.66 ± 10.34	40.86 ± 9.81	0.761	0.453
Body mass (kg)	76.6 ± 13.69	79.06 ± 12.93	–0.507	0.616
Height (cm)	159.46 ± 5.68	159.93 ± 6.82	–0.203	0.84
Body mass index (kg/m^2)	30.27 ± 6.31	30.78 ± 5.42	–0.233	0.817

Table 2. Descriptive statistics of pelvic floor muscle strength for both groups

Pelvic floor muscle strength	Pre test (mean ± *SD*)	Post test (mean ± *SD*)	Mean difference	% of change	*t*	*p*
Experimental group	22.2 ± 5.29	59.26 ± 8.86	–37.06	166%	–18.589	0.0001^{HS}
Control group	22.13 ± 3.96	47.53 ± 8.55	–25.4	114%	–11.907	0.0001^{HS}
Mean difference	0.07	11.73				
t	0.039	3.687				
p	0.969^{NS}	0.000^{HS}				

^{NS} non-significant ($p > 0.05$), ^{HS} highly significant ($p < 0.01$)

Table 3. Frequency distribution of the grade muscle test of pelvic floor muscles before and after treatment for both groups

Grade muscle test of pelvic floor muscles, frequency distribution [*n* (%)]	Experimental group					Control group				
	Flicker	Weak	Moderate	Good	Strong	Flicker	Weak	Moderate	Good	Strong
Before treatment	12 (80%)	3 (20%)	0 (0%)	0 (0%)	0 (0%)	14 (93.3%)	1 (6.7%)	0 (0%)	0 (0%)	0 (0%)
After treatment	0 (0%)	0 (0%)	1 (6.7%)	3 (20%)	11 (73.3%)	0 (0%)	0 (0%)	3 (20%)	8 (53.3%)	4 (26.7%)
Within groups (Wilcoxon signed-rank test)										
	Z					*p*				
Group A	–3.493					0.0001*				
Group B	–3.499					0.0001*				
Between groups (Mann-Whitney test)										
	Before treatment					After treatment				
U	97.5					59.5				
Z	–1.056					–2.421				
p	0.291					0.026*				

* significant ($p < 0.05$)

Table 4. Descriptive statistics of Revised Urinary Incontinence Scale for both groups

Revised Urinary Incontinence Scale	Pre test [median (IQR)]	Post test [median (IQR)]	*Z*	*p*
Experimental group	13 (4)	0 (0)	–3.455	0.001^{HS}
Control group	13 (4)	0 (5)	–3.44	0.001^{HS}
U	72	75		
Z	–1.758	–1.861		
p	0.098^{NS}	0.03^{S}		

IQR – interquartile range
^{NS} non-significant ($p > 0.05$), ^{S} significant ($p < 0.05$), ^{HS} highly significant ($p < 0.01$)

provement of the grade muscle test of pelvic floor muscles ($p < 0.05$) after treatment in both groups. Considering the effect of the tested group (first independent variable) on the grade muscle test of pelvic floor muscles, the Mann-Whitney *U*-test demonstrated that there was a significant difference in the post-treatment test between the groups ($p < 0.05$) and a significant improvement in favour of the experimental group as compared with the control group.

Revised Urinary Incontinence Scale

The median (interquartile range) values of the Revised Urinary Incontinence Scale in the pre-treatment and post-treatment tests are presented in Table 4 for both groups. The Wilcoxon signed-rank test revealed that there was a significant reduction of the Revised Urinary Incontinence Scale score ($p < 0.05$) after treatment in both groups. Considering the effect of the tested group (first independent variable) on the Revised Urinary Incontinence Scale, the Mann-Whitney *U*-test demonstrated that there was no significant difference ($p > 0.05$) in the pre-treatment test between the groups. However, it showed that there was a significant difference in the post-treatment test between the groups ($p < 0.05$) and a significant reaction in favour of the experimental group as compared with the control group.

Discussion

Stress urinary incontinence is a common problem prevalent in adult women. It has a significant negative impact on the quality of life, attributed to the weakening of the endopelvic supporting tissues. Women with urinary incontinence too seldom seek preventive treatment [1]. Pelvic floor rehabilitation is an effective method for treating stress urinary incontinence. To the authors' knowledge, no studies have examined the effect of low level laser on pelvic floor muscles and fascia in cases of stress urinary incontinence. Therefore, the present work is considered the first study on this point. Its purpose was to determine the effect of low level laser applied for 3 months, 2 sessions per week, on pelvic floor muscles and fascia compared with a pelvic floor exercise program in patients with stress urinary incontinence.

The study revealed a significant increase in pelvic floor muscle strength, a significant improvement of grade muscle test of pelvic floor muscles, and a significant reduction of the Revised Urinary Incontinence Scale score after treatment as compared with the pre-treatment status in both groups. Also, there was a significant improvement in all dependent variables in favour of the experimental group as compared with the control group.

Because of the lack of previous studies investigating the issue, the results cannot be compared or discussed directly with other research outcomes. As for the pelvic floor muscle strength, the scores in the grade muscle test of pelvic floor muscles and the stress urinary incontinence questionnaire improved statistically significantly in favour of the experimental group after therapy. These findings indicate that the low level laser treatment alleviated the patients' symptoms. The results of the current study are in line with those obtained by Braverman et al. [14], who examined the biostimulating effects of helium-neon laser radiation (632.8 nm), pulsed infrared laser radiation (904 nm), and the combination of both on skin wound healing in white rabbits. They found that there was a significant difference in the tensile strength of all laser-treated groups in comparison with the group that received no intervention. There were no differences in the rate of wound healing or collagen area. In the helium-neon-lased area, epidermal growth was greater than in unexposed tissues, but the difference was not significant. The tensile strength increased during the laser wound healing, and the tissue factors released into the systemic circulation improved tensile strength on the opposite side as well.

The results of the present study also corroborate the outcomes of a study conducted by Joensen et al. [15], who examined the skin penetration time-profiles for continuous 810-nm and superpulsed 904-nm lasers in rats. The study investigated the skin penetration abilities of 2 low level laser therapy devices during 150 seconds of irradiation. These abilities turned out significantly different ($p < 0.01$) between the 2 lasers at all points of measurement. The superpulsed 904-nm low level laser light energy penetration through the rat skin barrier was 2–3 times easier than that of the 810-nm continuous wave low level laser, which corresponded well with the results of low level laser therapy dose analyses in systematic reviews of its application in musculoskeletal disorders.

A recent study conducted by Hardy et al. [16] concerned treating female stress urinary incontinence by using laser thermal remodelling of subsurface tissues with an applied surface tissue cooling. Computer simulations of light transport, heat transfer, and thermal damage in tissue allowed a comparison between transvaginal and transurethral approaches. The authors concluded that the more feasible approach was the transvaginal one.

The results of the present study also remain in line with those observed by Assis et al. [17], who evaluated the effects of low level laser therapy application after a protocol of endurance training on biochemical markers and morphology of rats' skeletal muscles. The results suggested that low level laser therapy could be effective for stimulating recovery during a protocol of endurance exercises. Al-ashaikh [18] studied the impact of low level laser therapy involving a diode laser with a wavelength of 790–805 nm on promoting and enhancing episiotomy wound healing and evaluated its analgesic

effect in reducing pain resulting from episiotomy wounds. There was a significant reduction in pain and tenderness after the first exposure to laser, and a rapid healing process occurred within 7 days. It was concluded that low level laser therapy could enhance wound healing after episiotomy and provide an analgesic effect if there were a proper wavelength selection, energy density, and exposure time.

The findings of this study agree with the observations by Enwemeka and Reddy [19], who studied the biological effects of laser therapy and other physical modalities on connective tissue repair. They demonstrated that (1) appropriate doses of early functional activities, ultrasound, and helium-neon and gallium-arsenide laser therapy increased collagen synthesis, modulated the newly synthesized collagen maturation, and improved the biomechanical characteristics of the repaired tendons; (2) the combinations of either of the two lasers with early functional activities and either ultrasound or electrical stimulation further promoted collagen synthesis when compared with functional activities alone.

Limitations

Although the current study reveals objective data with statistically significant differences, there are some limitations. Firstly, there was a difficulty in the histological assessment of pelvic floor muscles and fascia to examine the effect of low level laser on them. Secondly, no follow-up was applied. Future studies should search for new methods of evaluating pelvic floor muscles and fascia.

Conclusions

This study suggests that low level laser improved pelvic floor muscles and fascia in cases of stress urinary incontinence in comparison with pelvic floor exercises only.

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Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

The authors state no conflict of interest.

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