JAOA BRIEF REPORT

Effect of Osteopathy in the Cranial Field on Visual Function—A Pilot Study

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Context: The effects of osteopathy in the cranial field on visual function—particularly on changes in the visual field and on the binocular alignment of the eyes—have been poorly characterized in the literature. The authors examined whether osteopathy in the cranial field resulted in an immediate, measurable change in visual function among a sample of adults with cranial asymmetry.

Study design: Randomized controlled double-blinded pilot clinical trial.

Subjects: Adult volunteers between ages 18 and 35 years who were free of strabismus or active ocular or systemic disease were recruited. Inclusion criteria were refractive error ranging between six diopters of myopia and five diopters of hyperopia, regular astigmatism of any amount, and cranial somatic dysfunction.

Intervention: All subjects were randomly assigned to the treatment or control group. The treatment group received a single intervention of osteopathy in the cranial field to correct cranial dysfunction. The control group received light pressure of a few ounces of force applied to the cranium without osteopathic manipulative treatment.

Measurements: Preintervention and postintervention optometric examinations consisted of distant visual acuity testing, Donder push-up (ie, accommodative system) testing, local stereoacuity testing, pupillary size measurements, and vergence system (ie, cover test with prism neutralization, near point of convergence) testing. Global stereoacuity testing and retinoscopy were performed only in preintervention to determine whether subjects met inclusion criteria. Analysis of variance (ANOVA) was performed for all ocular measures.

Results: Twenty-nine subjects completed the trial—15 in the treatment group and 14 in the control group. A hierarchical ANOVA revealed statistically significant effects within the treatment group and within the control group ($P<.05$) in distance visual acuity of the right eye (OD) and left eye (OS), local stereoacuity, pupillary size measured under dim illumination OD and OS, and near point of convergence break and recovery. For the treatment group vs the control group, a statistically significant effect was observed in pupillary size measured under bright illumination OS ($P<.05$).

Conclusions: The present study suggests that osteopathy in the cranial field may result in beneficial effects on visual function in adults with cranial asymmetry. However, this finding requires additional investigation with a larger sample size and longer intervention and follow-up periods. (ClinicalTrials.gov number NCT00510562)

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Anecdotal evidence suggests that patients who undergo osteopathic manipulative treatment (OMT) using osteopathy in the cranial field have improvements in visual function. Although a number of studies have described the effects of osteopathy in the cranial field on intraocular pressure, extent of the visual field, and binocular alignment of the eyes, few studies[1-4] have described changes in visual function resulting from osteopathy in the cranial field—other than in cases of visual perception deficit or closed head trauma.

In the present pilot study, we examine whether there is evidence of an immediate, measurable change in visual function in a small group of adults after a single session of osteopathy in the cranial field.

Methods

Design

The present study was designed as a randomized, double-blinded, sham therapy–controlled clinical trial of the application of osteopathy in the cranial field in volunteer subjects.

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Participants were recruited via flyers and word of mouth at the Health Professions Division of Nova Southeastern University (NSU) in Fort Lauderdale, Florida. The study assessed all outcomes using a repeated measures design.

The Institutional Review Board of NSU approved all procedures and interventions used in the present study. The study was registered on August 1, 2007, with the United States National Institutes of Health's ClinicalTrials.gov registry and assigned ID number NCT00510562.

Study Population

All prospective subjects completed a screening questionnaire and were admitted to the study if they met the following inclusion and exclusion criteria: (1) a refractive error between six diopters of myopia and five diopters of hyperopia with regular astigmatism of any amount; (2) normal best-corrected visual acuity to 20/40 or better; (3) age between 18 and 35 years; (4) free of active ocular or systemic disease; (5) no history of previous closed head trauma or brain injury; (6) no history of treatment with osteopathy in the cranial field; and (7) not pregnant at the time of the study. In addition, students from the colleges of osteopathic medicine and optometry in the NSU Health Professions Division were excluded from the study to prevent bias based on previous knowledge of the OMT procedures used in the study.

A predoctoral fellow in osteopathic principles and practice (OPP) reviewed the returned screening questionnaires to confirm study eligibility of each participant and also obtained written informed consent from each participant. Each subject who completed the study received a $25 gift certificate for the NSU bookstore.

Randomization and Interventions

All subjects were evaluated for cranial strain patterns of the sphenobasilar synchondrosis. Subjects were then randomly assigned to either the treatment or control group by use of a randomization table generated with Microsoft Office Excel 2003 software (Microsoft Corp, Redmond, Washington). Subjects were blinded to group assignment.

Subjects in both groups underwent an initial optometric examination consisting of best-corrected distance visual acuity testing, Donder push-up (accommodative system) testing, local and global stereoacuity testing, pupillary size measurements in both bright and dim illumination, retinoscopy, and vergence system (cover test with prism neutralization, near point of convergence) testing. All procedures are noninvasive optometric tests that required no installation of eye drops. Thus, there was minimal risk to study participants. The tests used to measure optometric parameters were as follows:

- **Distance visual acuity testing**—Determines the subject's ability to distinguish fine detail at a distance. A distance contrast sensitivity (Early Treatment of Diabetic Retinopathy Study [ETDRS]) chart was used. The subject was asked to read the letters from the chart with each eye individually. The subject read from the top of the chart down until he or she reached a line where a minimum of 3 letters could not be read. The subject was scored on the number of letters that he or she read correctly (out of a total of 70).
- **Donder push-up (accommodative system) testing**—Determines the subject's ability to focus on near objects. This examination consisted of accommodative amplitude testing using a Donder push-up card. The subject was required to read a small letter (or number) from a card with one eye while covering the other eye. The card was moved closer to the subject until the first sustained blur point was reached. The accommodative amplitude (in diopters) was recorded as the reciprocal of the distance (in m) from the card to the subject at the first sustained blur.
- **Local stereoacuity testing**—Determines the subject's ability to appreciate depth. A Random Dot E test was used, with the test booklet placed at a distance of 40 cm. This test can identify the smallest target separation needed in order for the subject to perceive depth. The subject was required to wear polarized glasses and identify shapes in the booklet. The test was continued until the subject made two consecutive errors in a row. The last correct response was recorded as the subject's local stereopsis in seconds of arc. This test can measure stereoacuity up to 20 seconds of arc. (Global stereoacuity testing was performed only on the first visit to make sure that the subject met inclusion criteria.)
- **Pupillary testing**—Provides information regarding the neurologic system. Measurement of pupil size in bright illumination (pupil bright) was performed with all room lights turned on and a stand lamp set behind the subject. The subject was asked to fixate at a distant target. The size of each pupil was measured by placing a pupillary (hemisphere) scale against the subject's face and sliding the gauge until the semicircle under the eye was the same size as the pupil being measured. Measurement in dim light (pupil dim) was performed in the same manner, but the overhead lights were turned off and a stand lamp was used as a backlight.
- **Retinoscopy**—Assesses the subject's spectacle prescription. The subject was asked to look straight ahead while viewing a distant target. A streak of light was shined in the subject's eye. Lenses were used to change the appearance of the reflex until the examiner saw a bright flash of light. After compensating for the examiner's working distance, the subject's prescription was obtained. This procedure was performed only on the first visit to make sure that the subject was eligible for the study and to see if the current prescription was appropriate for testing.
- **Vergence system testing**—Determines the subject's ability to use both eyes (fusion). The following tests were used:

  - **Cover test with prism neutralization (CT near)**—An objective measurement of alignment of the eyes. First, the unilateral cover test was performed by placing the cover paddle over the left eye while viewing the right eye for movement. This procedure was repeated for the other eye. If movement was present, the subject had a strabismus and was excluded from the study. Next, the alternating cover test was performed. The cover paddle was placed over the left eye, and some time was allowed to help break fusion. The cover paddle was then rapidly placed over the other eye without giving the subject time to regain fusion. If a movement was seen, the patient was said to have a phoria. The magnitude of this deviation was measured with prism during the alternating cover test. The appropriate prism was placed in front of the subject's eye until no movement was seen. Additional prism was added until the movement reversed direction. The midpoint of the interval of prism in which no movement was seen was recorded as the value.

- **Near point of convergence (NPC)**—Subjective measurement of the maximum ability to cross the eyes (converge) on a near target. The subject was required to view a small letter as it was moved toward him or her. The target was slowly moved toward the subject until the subject reported doubling, until one eye deviated, or until the target reached the patient's nose. The distance (in cm) was recorded as the NPC break. The target was then moved away from the patient until the target again appeared single to the subject or until the subject's eyes regained fixation on the target. The distance (in cm) was recorded as the NPC recovery.

Subjects with strabismus or a refractive error outside the inclusion criteria were excluded from the present study. Subjects were also excluded if they had no cranial somatic dysfunction.

Subjects in the treatment group each received a single session of osteopathy in the cranial field to correct cranial dysfunction. The specific OMT technique performed was balanced membranous tension, which was applied by gentle exaggeration of the dysfunctions toward a point of membranous balance and holding until a tissue release was felt. Subjects in the control group each received a single session of sham therapy, which consisted of light pressure of a few ounces of force applied to the cranium without OMT. Subjects in both groups received intervention while supine on the treatment table for approximately 5 minutes.

After either the treatment or control protocol, subjects were reassessed for the presence of cranial dysfunction and, subsequently, underwent a repeated optometric examination. The osteopathic physician (M.E.S.) evaluating the subjects for cranial asymmetry was unaware of the optometric findings, and the optometrists (D.S., R.S.) were unaware of the results of the cranial assessments or the group to which the subjects had been assigned.

To eliminate concerns regarding interexaminer reliability, the same osteopathic physician (M.E.S.) examined and applied OMT or sham therapy to all subjects. This osteopathic physician was trained by The Cranial Academy and had been in practice for more than 12 years at the time of the study. The preintervention and postintervention optometric examination was also performed by the same optometric physician (D.S. or R.S.). A record keeper (J.L.D.) was used to maintain all information and to perform the randomization procedures.

Statistical Analysis

Descriptive statistics using SPSS statistical software (version 15.0 for Windows; SPSS Inc, Chicago, Illinois) were calculated for all study variables. A *t* test for paired samples was performed to assess equality of means in terms of participant age for both treatment and control groups. A 2-way (repeated measures) analysis of variance (ANOVA) was performed for data from each of the measured variables (α=.05).

Results

Twenty-nine subjects completed the present pilot study—15 in the treatment group and 14 in the control group. The mean (SD) age of the subjects was 24.38 (3.03) years. Twenty-five subjects (86%) were women. There was no statistically significant difference in age or gender distribution between the treatment and control groups.

The means and standard deviations for each of the measured variables are shown in *Table 1*. Statistically significant differences were observed in within-group preintervention vs postintervention main effects in both treatment and control groups ($P<.05$) in distance visual acuity of the right eye (OD) and left eye (OS), local stereoacuity, pupillary size measured under dim illumination OD and OS, and near point of convergence (NPC) break and recovery (*Table 2*).

In addition, a statistically significant difference was observed in preintervention vs postintervention effects for the treatment group vs control group in right pupillary size measured under bright illumination OD ($P<.05$)

Comment

The results of the present pilot study suggest that osteopathy in the cranial field had an interesting treatment effect—subjects who received OMT showed increased pupil size under bright illumination OD after treatment, but sham therapy subjects showed decreased pupil size OD after intervention.

In addition, several main effects were observed in both treated and sham therapy subjects after intervention. Subjects in both groups showed an increase in distance visual acuity, with each eye capable of reading more letters on the Early Treatment of Diabetic Retinopathy Study (ETDRS) visual acuity chart after intervention than before intervention. Subjects in both groups also showed a postintervention decrease in pupillary size measured under dim illumination in both eyes. Furthermore, subjects in both groups showed a post-

Table 1
Optometric Variables Measured in Pilot Study of Osteopathy in the Cranial Field, Mean (SD) (N=29)*

	Treatment Group		Control Group	
Variable	**Preintervention**	**Postintervention**	**Preintervention**	**Postintervention**
■ **Distance VA†**				
□ OD	55.20 (6.38)	57.67 (6.53)	51.93 (6.01)	54.43 (4.97)
□ OS	53.87 (7.98)	56.33 (6.44)	52.64 (5.09)	54.14 (5.35)
■ **Donder Push-Up, diopters**				
□ OD	12.16 (2.53)	12.20 (2.57)	11.38 (2.86)	11.11 (3.34)
□ OS	13.43 (2.84)	13.45 (2.48)	12.09 (2.89)	12.51 (3.38)
■ **Local Stereoacuity, s arc**	39.67 (22.48)	31.67 (15.31)	39.64 (21.61)	34.29 (20.83)
■ **Pupil Size, mm**				
□ Bright light OD	3.27 (0.68)	3.40 (0.60)	3.79 (1.14)	3.39 (0.81)
□ Bright light OS	3.60 (0.95)	3.50 (0.71)	3.79 (0.91)	3.57 (0.78)
□ Dim light OD	6.40 (1.56)	6.03 (1.25)	6.64 (1.79)	5.93 (1.57)
□ Dim light OS	6.43 (1.53)	6.17 (1.26)	6.71 (1.67)	6.00 (1.52)
■ **Vergence**				
□ CT near, prism diopters	-1.37 (4.55)	-1.33 (4.50)	-3.71 (6.32)	-4.61 (7.86)
□ NPC break, cm	3.78 (1.92)	4.53 (1.65)	4.89 (3.15)	5.89 (3.40)
□ NPC recovery, cm	6.36 (2.79)	7.31 (2.43)	10.46 (10.07)	9.80 (4.99)

* Study included 15 subjects in the treatment (ie, balanced membranous tension) group and 14 subjects in the control (sham therapy) group.
† Each subject was scored on the number of letters that he or she read correctly, out of a total of 70.

Abbreviations: CT, cover test with prism neutralization; NPC, near point of convergence; OD, right eye; OS, left eye; VA, visual acuity.

intervention decrease in local stereoacuity indicated by a decrease in seconds of arc; altered NPC break indicated by an increase in target distance at first report of double vision; and improved NPC recovery indicated by an increase in target distance at first report of recovery of single vision.

Although these results can be considered only suggestive because of the small sample size (N=29), they do show the potential of a single session of osteopathy in the cranial field having effects on visual function. Moreover, the fact that postintervention functional effects were observed in both the treatment and control groups implies that a single cranial intervention—regardless of type—may cause changes affecting visual function.

It is entirely possible that these functional effects could rapidly wear off with repeated sham interventions, while remaining intact with repeated OMT interventions. It is also possible that some systematic effect of the present study's protocol caused the observed changes, such as an effect from simply examining the subject's cranium. Two potential mechanisms for these changes are alterations in the shape of the eyes affecting axial length and alterations to autonomic innervation of the eyes.

Regarding the first potential mechanism, the extraocular muscles are attached to both the eyeball and the bones of the orbit, with most of the muscles attaching directly or indirectly (via a tendinous ring) to the sphenoid bone.[5] It is therefore logical to postulate that if the bones attached to the extraocular muscles change position (from cranial manipulation), the eyeball will change shape—thereby altering the axial length and extraocular mobility. In the present study, distance visual acuity, local stereoacuity, and NPC break and recovery were variables affected by changes in axial length and extraocular mobility that demonstrated statistically significant changes within both the treatment and control groups.

Regarding the second potential mechanism, parasympathetic innervation of the eye via both the oculomotor nerve and the ophthalmic branch of the trigeminal nerve is through the superior oblique fissure of the sphenoid bone.[6] Manipulation of the sphenoid bone that releases bony or fascial restrictions placed on these nerves could restore proper function of the autonomic innervation of the eyes by decreasing afferent activity in the nerves.

The sympathetic and parasympathetic innervations to the eyes control constriction and dilation of the pupil, as well as adjustment of the crystalline lens for accommodation. According to Pottenger,[6] "when the excitability of the motor cells in the oculomotor nerve is very high, it may result in an accommodation spasm." Variables affected by changes in autonomic innervation that demonstrated statistically significant changes within groups in the present study were local

Table 2
Within-Group Data for Optometric Variables Measured in Pilot Study of Osteopathy in the Cranial Field (N=29)*

Variable	*df*	F Ratio†	*P* Value	1-β
■ **Distance VA**				
□ OD	1,27	10.50	.01‡	0.88
□ OS	1,26	7.48	.01‡	0.75
■ **Donder Push-Up**				
□ OD	1,24	0.06	.80	0.06
□ OS	1,25	0.84	.37	0.14
■ **Local Stereoacuity**	1,27	5.27	.03‡	0.60
■ **Pupil Size**				
□ Bright light OD	1,25	0.64	.43	0.12
□ Bright light OS	1,26	1.43	.24	0.21
□ Dim light OD	1,27	14.65	.01‡	0.96
□ Dim light OS	1,27	12.72	.01‡	0.93
■ **Vergence**				
□ CT near	1,23	0.42	.52	0.10
□ NPC break	1,26	8.92	.01‡	0.82
□ NPC recovery	1,23	9.02	.01‡	0.82

* Study included 15 subjects in the treatment (ie, balanced membranous tension) group and 14 subjects in the control (sham therapy) group.
† F ratio based on preintervention measurement vs postintervention measurement.
‡ Difference between preintervention and postintervention main effects within treatment and control groups is statistically significant ($P<.05$).

Abbreviations: CT, cover test with prism neutralization; NPC, near point of convergence; OD, right eye; OS, left eye; VA, visual acuity.

stereoacuity, pupillary size measured under dim illumination, and NPC break and recovery.

The only variable that demonstrated a statistically significant change between treatment and control groups in the present study was pupillary size measured under bright illumination OD. The mechanism for this result is unclear.

Conclusion

Several variables in the present study demonstrated statistically significant postintervention effects within both the treatment (ie, osteopathy in the cranial field) group and the control group. Postintervention pupillary size in bright illumination OD showed a statistically significant effect in the treatment group vs the control group.

Further investigation using a larger sample size and longer study period is warranted to explore the effects observed in the present study, to examine the effects of additional treatment sessions using osteopathy in the cranial field, and to ascertain the duration of those effects after the intervention is stopped.

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Editor's Note: In this article, the authors use the term *osteopathy in the cranial field* to describe the palpatory techniques and osteopathic manipulative treatment used to assess cranial dysfunction and to treat patients for such dysfunction.

The authors use *osteopathy in the cranial field* because it is a more universally used term than *cranial osteopathic manipulative medicine* and *osteopathic medicine in the cranial field*, which are the terms preferred by the style guidelines of *JAOA—The Journal of the American Osteopathic Association*.