LASTING EFFECTS OF ATLANTO-AXIAL MANIPULATION ON EDGE LIGHT PUPIL CYCLE TIME

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ABSTRACT

Background: Edge Light Pupil Cycle Time (ELPCT) is a light reflex of the eye, which is controlled via the autonomic nervous system. Studies have shown ELPCT to be a measurable constant, unaffected by visual acuity, refractive error, eye colour, pupil size or gender. Recent studies have shown that high-velocity manipulation of the upper cervical spine causes an immediate decrease in ELPCT on the same side as the manipulation. This change is presumed to be mediated in part by alterations in the autonomic tone following manipulative intervention, therefore suggesting that unilateral manipulation produces an immediate unilateral change in the autonomic nervous system.

Objective: To investigate the lasting effects (up to 1 hour) of C1-2 high-velocity low amplitude manipulation upon ELPCT.

Design: A two group blind, randomized study, with a control group.

Method: Twenty-five subjects (23.24 ± 3.4yrs) without a history of eye disease, diabetes, central or autonomic nervous system pathology, were randomly allocated into either the intervention (manipulation) group (n=13) or control group (n=12). They then all had their ELPCT of both eyes measured pre-intervention and three times post-intervention (immediately, 20 minutes and 1 hour, respectively). The manipulation involved a high-velocity low amplitude rotatory thrust, localised to the C1-2 joint on the right. The control group underwent the same protocol, including pre-positioning for the manipulation, but without the thrust.

Results: ELPCT measures demonstrated a significant difference for the right-eye after right-sided manipulation between pre-manipulation and post-immediate and post 20-min ($p=0.011$ & $p=0.013$, respectively) but no significant change post one-hour.

Conclusion: This suggests that ELPCT, which is mediated by the autonomic nervous system, can be directly influenced by high-velocity manipulation to the atlanto-axial joint, and these changes occur on the same side as the manipulation (i.e. unilateral manipulation produces unilateral physiological change). Over a one-hour time frame these changes are still significant at 20-minutes post-manipulation but only slightly evident at one-hour post-manipulation.

Key words: Manipulation; Eye; Autonomic Nervous System

INTRODUCTION

Despite recent developments of new manual therapy techniques such as muscle energy, myofascial and craniosacral techniques, high-velocity low amplitude (HVLA) manipulation continues to be one of the most frequently advocated techniques by authors within the field of osteopathy.[1] It specifically involves the application of a high velocity, low amplitude thrust directed at a joint or group of joints that is accompanied by cavitation of underlying facet joints producing a 'popping' or 'cracking' sound. [2,3]

A number of therapeutic benefits from HVLA manipulations have been established through the extensive research conducted on spinal manipulation. The majority of this research has focused on the local effect of HVLA manipulations on range of motion (ROM)[2,4-9] and pain.[4-5,10-16]

Recent studies have documented the potential for neurophysiological changes distant to the site of HVLA manipulation. A study by Harris and Wagnon[17] found that HVLA manipulations to the cervical spine could, via stimulation of the nervous system, affect the skin surface temperature of the fingers. Numerous studies support this concept of neurophysiological changes distant to the site of HVLA manipulation. Vincenzino et al[15] found that cervical mobilisation induced a rapid hypoalogesic effect at the elbow in patients with lateral epicondylitis. Other authors have investigated the effects of spinal manipulation on blood pressure,[18-20] women with primary dysmennorrhea,[11] cardiac arrhythmia[21] and other cardiovascular and respiratory changes.[22-25]

Although there is much conjecture to the mechanism for this distant effect, the research suggests that it is via the stimulation of the autonomic nervous system (ANS), especially the sympathetic nervous system (SNS). Calender et al[18] has shown that manipulation had an effect on the ANS through SNS stimulation, to produce a lowering of blood pressure within hypertensive individuals. Sterling et al[12] examined the effects of cervical mobilisation on pain, sympathetic nervous system and motor activity and discovered that mobilisation had an excitatory effect on the sympathetic nervous system (SNS). In addition to these studies, numerous more support SNS stimulation by means of HVLA thrust techniques.[12,16-19,22,24-25,27-28]

The exact mechanism of these distant changes is unclear, but it has been suggested that these neurophysiological changes occur due to the close anatomical relationship between the cervical spine and sympathetic chain. Harris and Wagnon[17] investigated the effects of chiropractic HVLA manipulation on distal skin temperature and found that manipulation can significantly affect the temperature, presumably by alterations in the sympathetic tone of the subjects. They presumed that "the mere presence of the sympathetic chain ganglion in the neck region may, in itself, explain why manipulation of the neck can influence the SNS."[17] Support for sympathetic influence over the ANS after cervical manipulation is provided by Knutson[20] and McGuiness et al.[25] They postulated that manipulation of the spine can directly stimulate local sympathetic fibers and cervical ganglia, because they have a close anatomical relationship. This anatomical relationship is supported by Kuchera & Kuchera[29] who opine that fascias around the cervical ganglia are closely related to the cervical joints and the facial planes of the neck. They proposed

that treating cervical spinal dysfunctions can alter activity of the cervical ganglia and therefore the structures the ganglia supply (ie. sinus, ear, eye and heart).

Despite research supporting the concept that HVLA manipulation applied to the spinal joints can produce measurable remote neurophysiological effects via the ANS, credible documentation of a direct effect upon the ANS is lacking, and evidence that these effects can be systematically harnessed to produce a definitive therapeutic result is sparse.

Previous researches have examined the effects of cervical HVLA manipulation on the ANS by measuring a reflex called the edge light pupil cycle time (ELPCT).[30,31] The ELPCT is a light induced cyclic pupillary reflex, which can be produced by focusing a small beam or slit of light at the edge of the pupillary margin causing the pupil to constrict. The beam is then held in this position so the constricted pupil will block the light from reaching the retina. The retina is now in total darkness which causes the pupil to dilate again allowing light to reach the retina producing another pupil constriction. This therefore sets up regular, persistent oscillations of the pupil, which can be easily measured and recorded.[32,33] (Fig 1)

Insert Figure 1 here

Studies conducted by Miller and Thompson[33] and Martin and Ewing[32] have shown ELPCT to by a measurable constant, unaffected by gender, eye colour, visual acuity, refractive error and pupil size. Martyn and Ewing[32] state that since the iris is exclusively innervated by the autonomic nervous system, measurement of the ELPCT provides a simple way of quantifying its function.

The results of previous studies found that manipulation of the atlanto-axial joint produce a significant difference between pre and post manipulation ELPCT, with the ELPCT becoming significantly faster post-manipulation in the eye on the same side as the manipulation.[30,31] This shows that ELPCT, which is mediated by the ANS, can be directly influenced by HVLA thrust technique to the upper cervical spine and that ANS changes have the potential to occur on the same side as the manipulation (i.e. unilateral manipulation produce unilateral physiological changes).

Although Gibbons et al[30,31] showed a link does exist between HVLA manipulation and the ANS, through the medium of ELPCT, there have been no further studies to support them. Further research needs to be completed to ascertain the length of time that the change is present, because both of the previous studies only measured the immediate effects on ELPCT after HVLA manipulation. This current study aimed to determine if a cervical HVLA thrust technique produced a lasting effect on the ANS, measured by ELPCT.

MATERIALS AND METHODS

Subjects

Twenty-five subjects aged between 18 and 32 years (23.24 ± 3.4yrs) were recruited through a volunteer list posted on notice boards at Victoria University (VU) and also by word of mouth. Subjects were excluded from the study if they had a previous history of eye disease, such as optic nerve degeneration/neuritis/compression, diabetes mellitus or previous pathology of the autonomic nervous system. All subjects signed a standard consent form, were free to withdraw at any time and the study was approved by the VU Human Research Ethics Committee.

Procedure

Measurement of the Edge Light Pupil Cycle Time (ELPCT)

All subjects had their ELPCT measured in both eyes, using a Hag-Steit Bern slit lamp, based on the method as first outlined by Miller and Thompson[33] and later used by Gibbons et al.[30,31] This involved the subjects being seated comfortably in a dimly lit room with the slit lamp directly in front of them. Subjects then removed any contact lenses or glasses and focused on a distant point while trying not to blink. A moderate intensity (0.5mm thick) horizontal slit beam of light was then directed perpendicular to the plane of the iris at the inferior limbus and just medial to the pupil. The beam was then slowly moved medially until it overlapped the pupil margin causing it to constrict. The beam was then held in this position so the constricted iris will block the light from reaching the retina. This caused the pupil to dilate again, allowing the light to reach the

retina producing another pupil constriction. This set up a persistent oscillation and after evoking 2-3 regular cycles, the time taken to measure five consecutive cycles was measured to the nearest 0.1 seconds with a handheld stopwatch**.** The exact same procedure was then repeated for the other eye.

Subjects were randomised into either the manipulation group (n=13) or control group (n=12) by computer allocation. The subjects that were part of the manipulation group received a HVLA rotatory thrust with the applicator localised to the atlanto-axial joint (C1-2) on the right side as described by Gibbons and Tehan.[3] An experienced osteopathic practitioner delivered the HVLA thrusts to all subjects to limit variability. The practitioner then recorded if a cavitation was achieved. Subjects in the control group were not submitted to the manipulation. They had their cervical spine placed in the position of manipulation but without the thrust.

Immediately after the treatment intervention subjects returned to the ELPCT room and had their ELPCT re-measured by an examiner who was blind to whether the subject was part of the control or treatment group.

Once the first measurement of ELPCT after intervention was completed, the subjects were seated in a quiet waiting room and asked to relax for an hour. During this time the subjects had their ELPCT measured twice again, after 20-minutes and one-hour rest time had elapsed respectively.

Statistical Methods

Means and Standard-Deviations were computed for all ELPCT measures. We quantified the effect of manipulation on ELPCT using a MANCOVA with the pre-measure as the covariate, computed using SPSS for windows (version 12, SPSS Inc.). Four one-way ANOVAs with planned post-Hoc analysis were then carried out for pre and post-manipulation ELPCT's, in both control and experimental groups, to determine if a difference existed within each eye. The significance level was set at $p<0.05$ with a Bonferroni adjustment for the ANOVA analysis, to account for the possibility of a type I error.

RESULTS

There was a significant interaction between ELPCT and Manipulation ($F=7.762$, $p=0.000$ $\eta^2 = 0.744$) with a large effect for this interaction. The data was analysed for each eye in each condition using a one-way ANOVA with planned post-Hoc (Turkey HSD) comparisons, which revealed a significant difference over time ($F=4.611$, $p=0.006$) after manipulation. Post-Hoc analysis indicated a significant difference between right-eye manipulation groups ELPCT when interpreted using a Bonferroni adjustment $(0.05/4)$ $\alpha = 0.0125$.

Table 1 and Figure 2 show the pre-manipulation and post–manipulations (immediate, 20-minute and one-hour) for ELPCT for the right eye after right-sided manipulation. The results show that after right-sided manipulation there was a significant difference between the pre-manipulation and post-immediately ($p=0.011$) and between pre-

manipulation and post-20-min ($p=0.013$), but no significant difference between pre-manipulation and post one-hr ($p=0.111$).

Insert Table 1 here

No significant difference was observed in any other measures for the left eye after right-sided manipulation (Figure 3). The results showed that after a right-sided thrust there was a small change in the left eye between pre-manipulation and post-manipulation ELPCT, but this was not significant.

Insert Figure 2 here

Insert Figure 3 here

DISCUSSION

The results of this study indicate that manipulation of the atlanto-axial joint can produce a significant measurable difference to ELPCT, with the ELPCT becoming significantly faster post-manipulation. This occurred in the right eye ($p=0.011$) immediately after right-sided manipulation, but not in the left eye ($p=0.886$). These findings concur with the results obtained from previous studies, which also showed that the ELPCT becomes significantly faster immediately post-manipulation on the same side. However, one of the papers, Gibbons et al[30] was only a pilot study with small subject numbers, which lead to the larger and more comprehensive follow-up study.[31] The results obtained in the present study also concur with the proposal raised in the comprehensive study, that ANS changes appear to occur on the same side as the manipulation (i.e. unilateral manipulation may produce unilateral physiological changes).

Numerous studies have shown that unilateral manipulation produces effects on the unilateral side to the thrust.[5-6,8-9] Nansel et al[6] found that unilateral cervical manipulation to the restricted side improved asymmetry for at least 30-45 minutes in otherwise asymtomatic subjects exhibiting cervical lateral-flexion asymmetry. Surkitt et al[9] tested the effect of C1-2 HVLA on asymptomatic subjects with atlanto-axial and cervical spine rotation asymmetry and found that unilateral manipulation to the restricted C1-2 joint produced a significant immediate reduction in rotation asymmetry. Although, even though there was still some maintenance of improvement after one-hour, they found the asymmetry had almost returned to pre-manipulation range.

It is interesting to note that this study showed similar time-frame effects of HVLA manipulation as those reported by Surkitt et al.[9] We found that after manipulating the right C1-2 joint, there was a significant difference in ELPCT in the right eye immediately post-manipulation (p= 0.011) and post-20min (p=0.013) but no significant difference post-1hour (p=0.111). However, even though there was still a difference in mean ELPCT between pre-manipulation and post-1hour manipulation, it was slowly returning to pre-manipulation time and this difference was not great enough to be significant.

These effects of manipulation over time do conflict with other research conducted by Howe et al[34] and Nansel et al.[7] Howe et al[34] found that cervical manipulation performed on subjects with neck pain increased cervical spine rotation both immediately and 3-weeks post-manipulation. However, the individual responsible for goniometric assessment was not blinded from treatment categories, and therefore, the results are open to question. Nansel et al[7] examined the effects of manipulation on subjects who had suffered previous neck trauma, had frequent episodes of neck stiffness and who also exhibited significant cervical lateral-flexion passive asymmetry. Their results showed that manipulation to the restricted side significantly reduced asymmetry at 30-minutes and 4 hours post-manipulation, with asymmetry returning to pre-manipulation values within 48 hours. Both Howe et al[34] and Nansel et al[7] studies used subjects with pain (symptomatic) and, along with Surkitt et al[9], they measured the effect of HVLA manipulation on ROM. In contrast, this study measured ELPCT in pain-free (asymptomatic) subjects to determine the effect of HVLA manipulation on the ANS. Therefore, we are unable to make any comment on what the outcome may be in

symptomatic patients, or that ELPCT and ROM changes correlate over time. Future studies may be conducted on symptomatic patients (i.e. whiplash patients with visual disturbances) with outcome measures of both ROM and ELPCT.

Many researches attribute the mechanism for the documented changes in ELPCT as being mediated by branches of the autonomic nervous system, either the parasympathetic[32,35] or sympathetic.[36,37] The extent of interplay between the two divisions of the ANS on the pupillary reflex continues to be disputed. Certain authors have been more assertive as to the possible mechanism when discussing trials using ANS activating or blockading drugs or results from particular medical conditions.[32,35-36,38]

Blumen et al[36] examined ELPCT in patients with Horner's syndrome and their results illustrate that ELPCT in each patient's affected eye to be significantly slower when compared to their normal eye. Horner's syndrome is a condition in which the cervical sympathetic nerves are paralysed, thus slowing the speed of their firing. As these findings show that Horner's syndrome affects ELPCT, it is apparent that sympathetic innervation is necessary for normal ELPCT function. These findings give strong support to the present study, which proposed that HVLA manipulation affects the ANS by stimulation of the SNS. The results of the present study reveal that cervical HVLA manipulation caused ELPCT to become faster, and presumably this is due to SNS stimulation, because Blumen et al[36] demonstrated that SNS inhibition slowed ELPCT.

An earlier study on ELPCT by Miller and Thompson[33] found that there was a significant decrease in the speed of the ELPCT, in people over the age of 50 years. Bitsios et al[37] examined pupillary kinetics in young and old people and discovered that loss of sympathetic innervation to the pupil in the elder population (age range 61 – 79 years) was the cause of the alteration in pupillary kinetics. This helps account for the change in the ELPCT with age that was noted by Miller and Thompson[33] and corresponds well with the findings of Blumen et al[36], in that a decrease in the sympathetic innervation to the pupil can cause a lengthening of the ELPCT.

In contrast, other authors have identified the PNS rather than the SNS as being directly responsible for alteration in the ELPCT. Martyn and Ewing[32] investigated the effects of various parasympathetic and sympathetic drugs on the ELPCT, and found that parasympathetic blockading drugs lengthened the ELPCT within the first few minutes. However, sympathetic blockading and stimulating drugs had no effect on the ELPCT. Martyn and Ewing[32] proposed that the ELPCT was particularly sensitive to dysfunction in the parasympathetic efferent limb of the pupillary light reflex. An additional study by Blumen et al[35] supported this theory with findings of an increased ELPCT in people with occulomotor nerve palsy. The increase in ELPCT was found on the ophthalmoplegic side, indicating a subclinical involvement of the parasympathetic component of the occulomotor nerve. However, Martyn and Ewing[32] administered the sympathetic drugs by means of intra-ocular eyedrops, and therefore, their results most likely indicate the effect of sympathetic drugs on the intra-ocular nerve endings, rather then directly on the ELPCT ANS control.

Despite the conflicting views between researchers in relation to which divisions of the ANS controls the ELPCT, there is agreement that shifts in the ELPCT do represent changes in the ANS. Therefore, results obtained from this study show that HVLA manipulation has an effect on ELPCT, which we can conclude occurs via either the PNS or SNS. Moreover, authors who have conducted research using other mechanisms to determine the state of ANS function following cervical HVLA manipulation also show a lack of consensus.[16-20]

Harris and Wagnon[17] investigated the effects of manipulation on distal skin temperature, and found that cervical and/or lower lumbar HVLA manipulations resulted in an increase in skin temperature (a decrease in SNS function), and the opposite with a thoracic or upper lumber manipulation (increase in SNS function). They determined that HVLA manipulation to the C1-C7 area resulted in SNS inhibition, whereas manipulation to the T1-L2 area caused SNS stimulation, though the mechanism for this occurrence was not clearly understood or explained by Harris and Wagnon.[17] In constrast, Vicenzino et al[16] discovered mobilisation in the cervical region causes sympathoexcitation combined with a hypoalgesic effect. Many other studies also support SNS stimulation as a result of cervical manipulation.[12,16-19,22,24-28]

Atlanto-axial joint manipulation has been shown to have an effect on ELPCT, in that it decreases the time it takes to complete a cycle. The results of the present study demonstrate an association between the side of the HVLA manipulation and effect on the ELPCT in the ipsilateral eye, but not the contralateral eye. This is seen in the results of the manipulation group - which were all right-sided manipulations. The right eye showed significant change in the ELPCT immediately and 20 minutes post-manipulation ($p=0.001$ & $p=0.013$, respectively), while the left eye showed no significant change. This further substantiates the proposal from a previous study[31] that ANS changes occur predominantly on the same side as the manipulation.

This study has confirmed that the use of cervical manipulation directly influences the autonomically mediated ELPCT. The exact neurophysiological mechanism of how this alteration is mediated remains in question although there is distinct evidence of ANS involvement. Even if this study does not distinguish the exact mechanism by which the manipulation effects the ELPCT, the results justify subsequent investigations to attempt to identify which division of the ANS causes these changes.

The results of the present study indicate that HVLA manipulation of the atlanto-axial joint can effect the ANS is asymptomatic subjects, however, a great deal more research is necessary to attain a definitive understanding of when manipulation could be usefully applied in the clinical setting to patients with ANS symptoms.

The effect of only one manipulation technique applied to a single joint in asymptomatic subjects was investigated in this study. This does not emulate a complete clinical approach where more than one therapeutic modality is utilised in the overall treatment of symptomatic patients. There also appeared to be no lasting effect from manipulation on the ANS. Future studies may explore whether the application of other therapeutic techniques following successful manipulation may produce a more prolonged effect upon the ANS.

CONCLUSION

Edge Light Pupil Cycle Time (ELPCT), which is mediated via the autonomic nervous system, can be directly influenced by cervical manipulation of the atlanto-axial joint, and these changes occur on the same side as the manipulation. Examining these alterations over a one-hour time frame showed that the changes are still significant at 20-minutes post-manipulation but only slightly evident one-hour post-manipulation.

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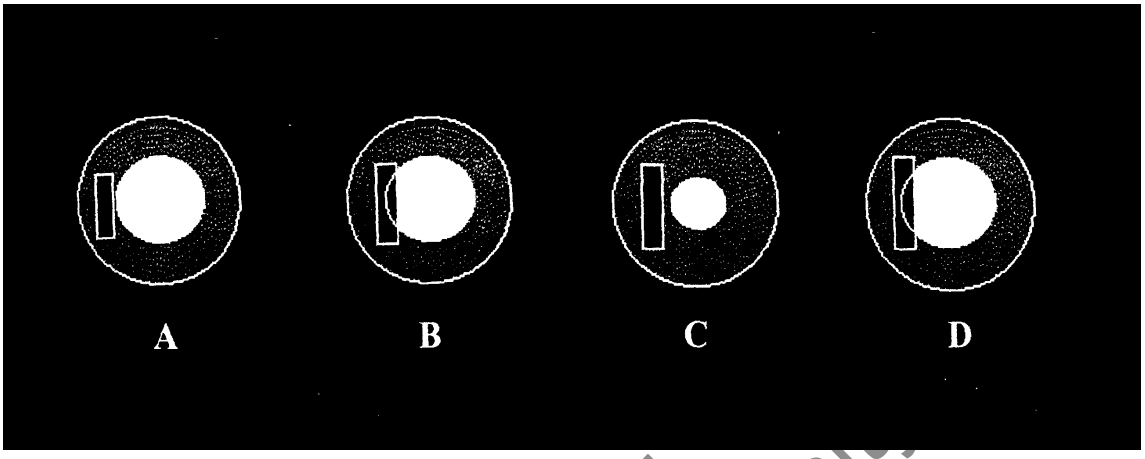


Figure 1. Examination technique. The focused beam is slowly moved medially (**A**) until it overlaps the pupillary margin (**B**). The pupil then constricts vigorously (**C**), and the beam is held in this position so the pupillary margin is out of the beam. The pupil will now be in darkness and will dilate to again overlap the edge of the light beam (**D**) then constrict (**C**), producing a persistent pupillary oscillation.[30]

Table 1 - ELPCT for right eyes pre and post manipulation (immediate, 20-min & one-hour)

Right eye (n=13)	Means (ms)	Standard Deviation	Critical p Value
Pre	890	± 72	
Post Immediate	793	± 75	0.011
Pre	890	± 72	
Post 20min	794	± 76	0.013
Pre	890	± 72	
Post 1hour	821	± 82	0.111

Figure 2. The Effect of Right-Sided Manipulation Vs Control on the Right-Eye ELPCT

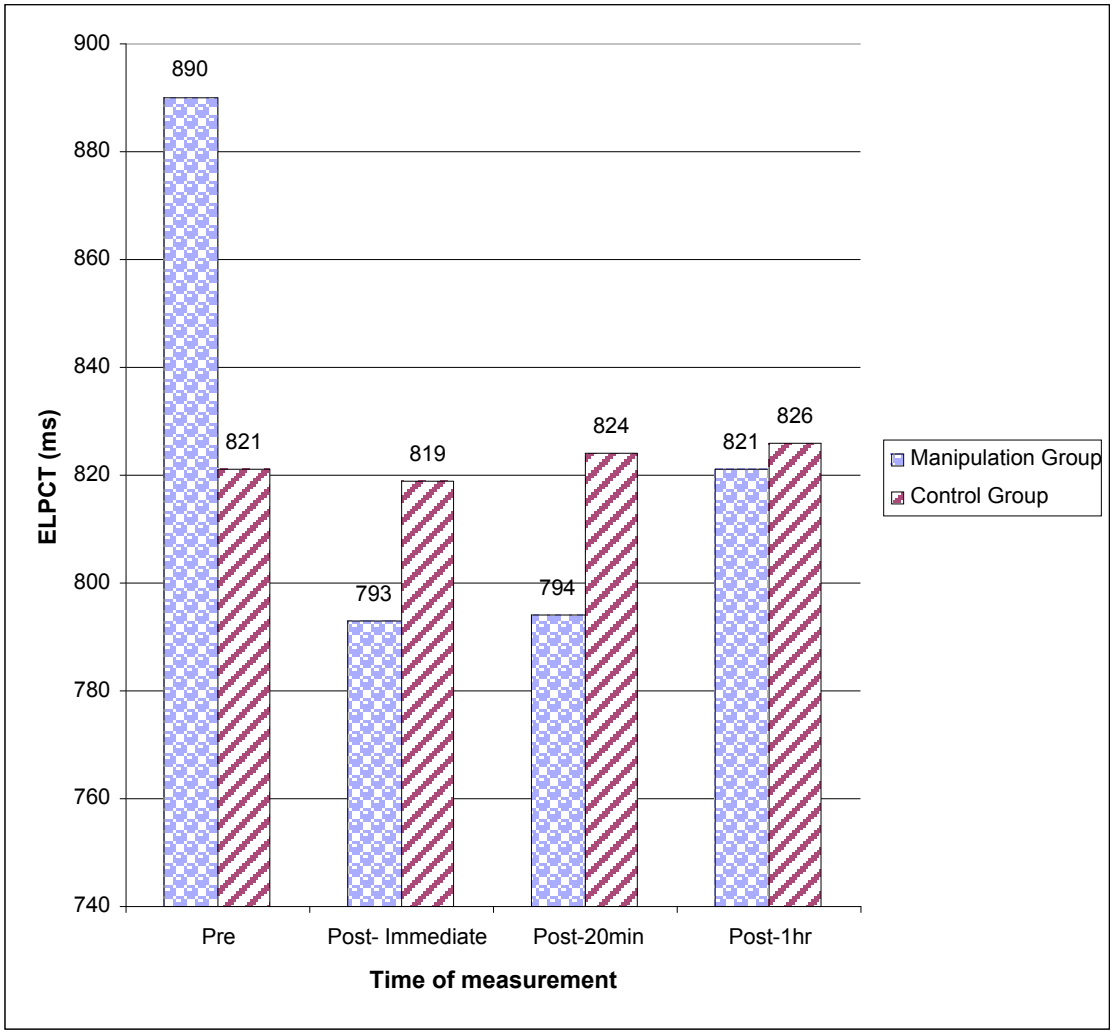
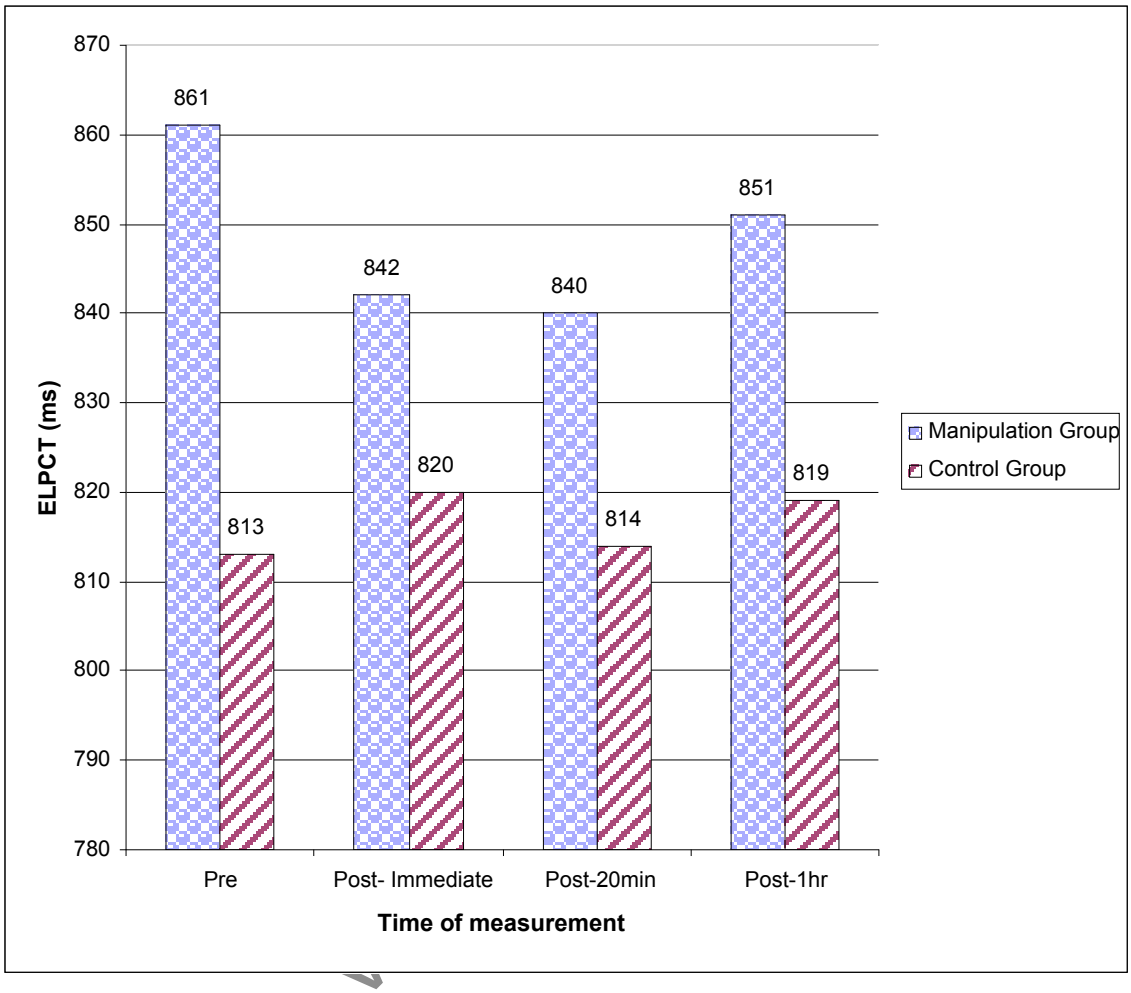


Figure 3. The Effect of Right-Sided Manipulation Vs Control on the Left-Eye ELPCT



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We would like to invite you to be a part of a study that looks into the effects that spinal manipulation has on your nervous system.

The study will be conducted at Victoria University and will involve manipulation of the spine and recording of your eye reflex. The whole procedure will only take approximately 1 hour of your time.

If you are interested in participating in this study, please contact one of the investigators listed below:

- Cameron Gosling

Phone: 9248 1290
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- Adam Olarenshaw (5th yr. student)

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INFORMATION TO PARTICIPANTS

Project
High-Velocity Low Amplitude Manipulation of the Atlanto-Axial Joint: Lasting Effects on the Edge Light Pupil Cycle Time

Investigators
Cameron Gosling, Ass. Prof. Peter Gibbons & Adam Olarenshaw

Location
Victoria University,
Student Union Building Optometry Clinic
Footscray Park Campus,
Ballarat rd., Footscray.

Purpose of this study
You are invited to participate in a study to test the effect of a high velocity low amplitude (HVLA) manipulation on the nervous system. The testing will involve attending the Victoria University Optometry clinic for approximately 1 hour. A time will be arranged before testing begins to have any questions answered and for you to bring in the consent form.

The testing session entails taking a brief medical history, followed by your ELPCT measurement (as described below). You will then be asked to lye on a table on your back where a qualified registered osteopath will perform a manipulative technique to your atlanto-axial joint (see below). Following the manipulation your ELPCT will be measured 3 more times at: 30 seconds, 20 minutes and 1 hour post-manipulation. In between taking these measurements you will be asked to rest on the treatment table.

Procedures and Risks

Edge-light pupil cycle time (ELPCT) measurement: A slit lamp will be used to measure the ELPCT in each eye. This will involve you sitting in a dimly lit room in front of the thin lamp. The lamp will then be shone into the edge of your eye with a beam of moderate intensity. This will cause your pupil to rhythmically constrict and then dilate without any discomfort to you. Someone will then time these constrictions and dilations using a stopwatch. This will then be repeated with the other eye.

Manipulation: An experienced osteopathic clinician will apply a small force localised to your atlanto-axial joint (between the first 2 segments of your neck) to see if this has an effect on the edge-light pupil cycle time in your eye. A clicking or popping sound may be heard at the time of manipulation. It must be emphasised that this is not bones grinding against one another, but is believed to be formation of a gas bubble (cavitation) within the joint that is thrust. Prior to manipulation, you will have the arteries in your neck (which supply the brain) tested to see if they are damaged in any way. If there is no evidence of arterial problems the manipulative procedure will be performed.

There is a small risk of about one in a million that damage may occur to the arteries supplying the head, which may lead to a stroke. To give you a realistic idea of the risks involved, the risk of dying after taking a non-steroidal anti-inflammatory drug, available over the counter at any pharmacy, is 100-400 times more likely than dying following cervical manipulation.

The risk of any damage occurring to the patient is extremely low, and the safety of the subjects is further increased by the preventative measures we will undertake (i.e. full patient history eliciting all appropriate information and VBI{arteries that supply your brain} testing). Also by using an experienced and registered osteopath this will increase the safety and therefore decrease the risk.

Participation and Confidentiality

Participation in this study is entirely voluntary. You can withdraw from the study at any time, for any reason, without prejudice. All results and information collected will remain secure and confidential so that your privacy is protected

Questions

If at any time you have any queries regarding the study, please feel free to contact the investigators on the following numbers.

Cameron Gosling	9248 1290
Adam Olarenshaw	9248 1111

If you have any questions regarding the ethics of the study, or your rights as a participant, please contact the Victoria University Human Research Ethics Secretary on (03) 9688 4710.

Victoria University of Technology

Consent Form for Subjects Involved in Research

INFORMATION TO PARTICIPANTS:

We would like to invite you to be a part of the study "High-Velocity Low Amplitude Manipulation of the Atlanto-Axial Joint: Lasting Effects on the Edge Light Pupil Cycle Time".

All results and information collected will remain secure and confidential so that your privacy is protected.

CERTIFICATION BY SUBJECT

I,……..

of……
……

certify that I am at least 18 years old and that I am voluntarily giving my consent to participate in the experiment entitled:

"High-Velocity Low Amplitude Manipulation of the Atlanto-Axial Joint: Lasting Effects on the Edge Light Pupil Cycle Time"

being conducted at Victoria University of Technology by: Mr. Cameron Gosling, Associate Professor Peter Gibbons and Mr. Adam Olarenshaw.

I certify that the objectives of the experiment, together with any risks and safeguards associated with the procedures listed here under to be carried out in the experiment, have been fully explained to me by Cameron Gosling or Adam Olarenshaw, and that I freely consent to participation involving the use on me of these procedures.

Procedures:

Edge-light pupil cycle time (ELPCT) measurement: A slit lamp will be used to measure the ELPCT in each eye. This will involve you sitting in a dimly lit room in front of the slit lamp. The slit lamp will then be shone into the edge of your eye with a beam of moderate intensity. This will cause your pupil to rhythmically constrict and then dilate without any discomfort to you. Someone will then time these constrictions and dilations using a stopwatch. This will then be repeated with the other eye.

Manipulation: An experienced osteopathic clinician will apply a small force localised to your atlanto-axial joint (between the first 2 segments of your neck) to see if this has an effect on the edge-light pupil cycle time in your eye. A clicking or popping sound may be heard at the time of manipulation. It must be emphasised that this is not bones grinding against one another, but is believed to be formation of a gas bubble (cavitation) within the joint that is thrust. Prior to manipulation, you will have the arteries in your neck (which supply the brain) tested to see if they are damaged in any way. If there is no evidence of arterial problems the manipulative procedure will be performed.

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I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this experiment at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Date: **……**

Signed: **……**

Witness other than the experimenter: **……**

Any queries about your participation in this project may be directed to the researcher (Name: Mr. Cameron Gosling, Ph. (03) 9248 1290, Mr. Adam Olarenshaw Ph. (03) 9248 1111). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MCMC, Melbourne, 8001 (telephone no: 03-9688 4710).