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Effect of cold laser versus laser puncture on post cervical Laminoplasty syndrome

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Abstract
Background: Determining appropriate cold laser (CL) parameters in post cervical laminoplasty syndrome (PCLS) is a key challenge in physical therapy practice facing conflicting results.
Purpose: The purposes of this study was to compare CL with laser puncture (LP) effect on chronic neck pain using pain intensity numerical rating scale (PI-NRS), cervical kinematics using C2-C7 cobb angle, gold method for cervical sagittal lordotic angle and cervical sagittal range of motion (ROM) and neck disability level using neck pain and disability scale (NPDS) in patients suffering from PCLS.
Methods: Sixty participants suffering from PCLS randomly allocated into three groups. Group (A) received conventional physical therapy (isometric strengthening and stabilization) exercises, plus CL (632.8 nm, 24 J/cm^2 within tender areas); group (B) received conventional physical therapy exercises, plus LP (632.8 nm, 24 J/cm^2 over selected acupoints and control group (C) received conventional physical therapy exercises. All groups received fourteen sessions, twice weekly for seven consecutive weeks. All participants underwent three evaluations of outcomes measures using PI-NRS, NPDS and Cobb angle, at the beginning and the end of the study, as well after twelve weeks as a follow up. SPSS was used for statistical analysis.
Results: There were no significant differences at the baseline of the study (P-values > 0.5). Statistical analysis shown high significant differences (P-values < 0.005) at 7th week. There was high statistical significant in pain intensity (P-values < 0.005), and significant differences in neck disability (P-values < 0.05), while there were no significances for cervical kinematics measures (P-values > 0.05) at follow up. Only pain intensity showed significant differences (P-values < 0.05) in all groups and other outcome measures have no statistical significant differences (P-values > 0.05) at follow up. The study showed that both CL and LP have extended mild analgesic effect and gained moderate improvement of neck disability.
Conclusion: It was concluded that CL and LP (632.8 nm, 24 J/cm^2) per tender areas/ selected acupoints were recommended as a physical therapy modality in treating patients with PCLS.

Keywords: cold laser, laser puncture, post cervical laminoplasty syndrome, chronic neck pain

Introduction
Recently, medical literatures have shown a high subaxial affection incidence with unclear management practical guidelines, as well PCLS is marked by progressive kyphosis and persistent, chronic neck pain. Evidence gap still prove a specific and standard care for PCLS, which is marked by chronic neck pain and cervical malalignment, as well considered the second largest cause of time-off work (Machino *et al*., 2012) [21].
Recently, it has been stated tha6+t pain based treatment are most likely to succeed. Laser therapies; selectively had better results than a wait-and-see policy, but laser therapy results were not significant (Kumar and Saha, 2011) [18]. Over and above, CL was efficacious for such patients (Chow *et al*., 2006) [8]. Furthermore, LP is defined as correct tradition acupuncture point's site stimulation using laser. In the same context, LP elicits a direct electro-biosignal response that modulates pain intensity and improves life quality (Sprague and Chang, 2011) [11].
Therefore, the study purpose was comparing the CL with LP effect on chronic neck pain, cervical kinematics (cervical sagittal lordotic angle and cervical sagittal ROM) and disability level in patients suffering from PCLS.

Methods
Subjects
A total of 60 participants were referred from orthopedic, neurosurgery and spinal unit surgeons with confirmed diagnosis of PCLS. The eligible participants were fluent in English, where 23 (60%) male and 24 (40) female, as well their age ranging from 35 to 45 years. The participants had chronic persistence neck pain for at least more than three month after underwent cervical laminoplasty. Participants were excluded if they had any abnormal neurological signs relating to nerve entrapment or impingement from cervical spine, any systemic rheumatologic diseases or suffer from complications of sever systematic diseases, as well open wounds or cellulites over cervical spine, with known photosensitivity or dermatological lesions, plus patients who require regular analgesic, steroid or anti-inflammatory

medications, as well underwent any form of physical therapy or acupressure within the three months prior to study entry and finally pregnant or lactating women.

After approval of the ethical committee of Faculty of Physical Therapy, Cairo University- Egypt, with respect to single blind study design, the procedures of the present study were discussed thoroughly and all the participants were asked to sign a written informed consent. All participants were randomly allocated in three groups, twenty participants in each. As a single-blinded randomized controlled study, outcome measure assessment done was the researcher was blinded to the participant's treatment allocation. Group A received conventional physical therapy exercises, plus CL, group B received conventional physical therapy exercises, plus LP and control group C received conventional physical therapy exercises.

Instruments

Measurement instrument and tools

1. **Digital radiography (axiom Artis dtA):** The Axiom Artis dtA (Siemens) model was used with digital imaging and communication in medicine (DICOM) system, imaging software (Image J 1.46r Java 1.6.0_20 [32-bit] http://imagej.nih.gov/ij), is standard software exchanging medical images in digital format that designed to analyze, save, copy and paste the image of the digital radiography evaluation using C2-C7; Cobb angle considered a simple, fundamental, gold standard for precise evaluating of (Machino *et al*., 2012) [21].
2. **Pain intensity-Numerical rating scale (PI-NRS):** The pain intensity level assessed using PI-NRS that considered the most practical index provides a precise assessment of pain sensation that enhances practical usage, validity and comparability (Krebs *et al*., 2007) [17].
3. **Neck pain and disability scale (NPDS):** Neck pain and disability scale was used as a comprehensive measure for neck pain and related disability, and it has a high level of reliability, sensitivity and construct validity that deal specifically with neck pain. Furthermore, its visual analogue scale structure provides immediate information, it is simple to use and it is sensitive to varying pain intensities (Blozik *et al*., 2011) [3].

Treatment instrument

Laser therapy (APP 915-MEDILASER)

Laser therapy device produces combined irradiation of He-Ne 632.8 nm/1mW with the frequency varied from 1 to 10000Hz and infrared lasers; BF/ IIB risk group class. As well, it has one interlock (safety key) and 2 X 603 A-T fuses. The device gave out two laser probes; MLAI and two AC 938 laser safety goggles for patient and the therapist. Routine device calibration done. The laser parameters selected were based programmatically on 632.8 nm, 2.4 J/cm^2 throughout the present study using grip technique for group A and scanning technique for group B (Saliba and Saliba, 2009) [25].

Procedures

Each participant was subjected to a detailed demographic data collection and a complete medical examination at the baseline of the study, plus repeated measurement for study parameters chronic neck pain intensity level using PINRS, cervical kinematic by digital radiographic Cobb angle method for (cervical sagittal lordotic angle and cervical sagittal ROM) and neck disability level using NPDS, were repeated at the end of the treatment program by 7th week, in addition as follow up evaluation after 12th week of the treatment course.

Measurement procedures

1. Pain intensity levels using PI-NRS the verbal questions were as follows; "on average over yesterday, how could you numerically evaluate pain has been?" As well, PI-NRS scores were determined by measuring in millimeters from the left hand end of the scale to the point that the patient marked (Hjermstad *et al*., 2011) [14].
2. Cervical kinematics measurement by two lines drawn at second and seventh cervical inferior vertebrae bodies' margin on a radiograph done includes sagittal lordotic angle and sagittal range of motion both were evaluated by digital radiographic evaluation using Cobb angle method.
   1) Cervical sagittal lordotic angle measurement C2-C7`Cobb angle measured at the neutral posture, its value is in degrees. Every participant's done films were analyzed by expert certified radiologist (Tang *et al*., 2012) [29].

Fig 1: PCLS- Cobb angle, neutral position.

   2) Cervical sagittal ROM measurement was calculated using the Cobb method (Figure 2), by sum both Cobb angle value in maximal flexion plus its value in maximal extension; these values are in degrees (Yukawa *et al*., 2012) [21, 31].

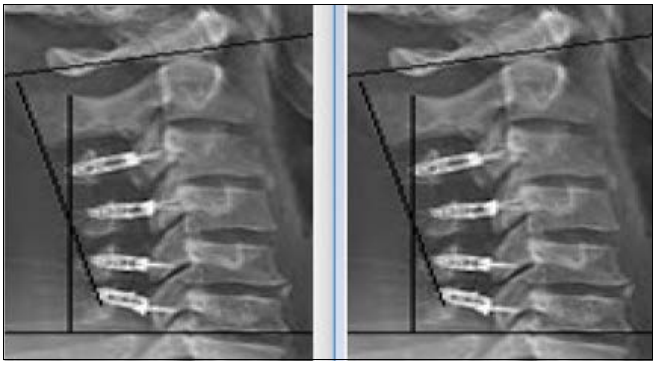

Fig 2: PCLS- Cobb angle, Flexion and Extension positions.

3. Neck Disability using NPDS participants responded to a

multi-visual scales; as a template by making along visual analogue scale ten centimeters with zero expressing no pain, while ten presenting the worse pain. Therefore, maximum total score equal 100 points by dividing the total score (200 by 2) that was indicating maximum neck pain and disability. A score of 10-29% is considered mild disability, 30-49% is moderate, 50-69% is sever and 70% or more is complete disability (Wheeler *et al*., 1999) [30].

Treatment procedures

1. **Conventional physical therapy exercise:** All sixty participants received conventional physical therapy exercises in form of cervical isometric strengthening (the task was ten repetitions of isometric strengthening exercises that were divided into double sets for; flexors, extensors, bilateral side bending and bilateral rotators) and stabilization exercises (were divided into double sets; chin tuck, chin tuck into a towel, extension, bilateral shoulder shrugs, bilateral shoulder rolls and finally bilateral scapular retraction), all exercises were done under supervision throughout the study course of 14 treatment sessions twice weekly over 7 consecutive weeks (Chiu *et al*., 2005) [7].
2. **Cold laser- group A:** All twenty allocated participants in group A received a course of 14 treatment sessions twice weekly over 7 consecutive weeks. Before CL application, routine laser therapy device calibration done then each participant comfortably seated, after that participants underwent systematic cervical palpation every session to precise identification of tender areas using firm finger pressure (Bogduk and McGuirk, 2006) [4]. Finally, safety goggles used then laser beam of continuous He-Ne, 632.8 nm, 1 and 3mW (average and peak; respectively), 24 J/cm^2 within each tender area applied in gridding technique for thirty-eight seconds per each tender area, typically 4- 6 areas of irradiation were the total time taken was 2-4 minutes (Chow *et al*., 2006 and Saliba and Saliba, 2009) [8, 25].
3. **Laser puncture- group B:** All twenty allocated participants in group B received a course of 14 treatment sessions twice weekly over 7 consecutive weeks. After precise identification of all selected acupoints (cervical acupoints; Jianjing [GB 21], Jianwaishu [SI 14] and Jianzhongshu [SI 15] over cervical spine, plus the distal three acupoints (Hegu [LI 4], Shousanli [LI 10] and Quchi [LI 11]), (ensured by patient felt of de qi sensation (de qi) while treatment. Finally, safety goggles used then laser beam of continuous He-Ne, 632.8 nm, 1 and 3mW (average and peak; respectively), 24 J/cm^2 within all identified acupoints applied safety goggles used then laser beam applied in scanning technique with the tip of the laser probe held at a distance of 5-10 mm, in angle of 30° to all identified acupoints for thirty-eight seconds per each (Saliba and Saliba, 2009 and Matsubara *et al*., 2011) [25, 22].

Statistical analysis

All data were collected, coded then tabulated. All statistical measures were performed using SPSS version 23 for the windows (SPSS Institute, Inc., Chicago, IL, USA). Descriptive statistics of mean, standard deviation and minimal-maximal values presented participants` age and percentage for participants` gender. Inferential statistical; paired t-test, one-way ANOVA and LSD/ Post Hoc test were used for outcome measures of the current study. P-value > 0.05=nonsignificant, < 0.05=significant and < 0.01=highly significant.

Results

The study 60 participants` demographics analysis shown that the overall mean age was 39.38 ± 2.69 years (Table 1), and there were no significant differences (P > 0.5; 0.806) between groups, where male participants are 36 (60 %) and female participants 24 (40 %) of the study populations. Furthermore, gained improvements (Table 2) along the study on all outcome measures within each study group revealed high significant differences (P-values < 0.001).

Table 1: Demographic analysis of patients` age in all groups.

Groups	Mean± SD	Min-Max Values	F-value	Sig.
A – CL	39.7±3.045	35----45	0.217	0.806NS
B – LP	39.15±2.46	35----43		
C-Control	39.3±2.66	35----44		
Total	39.38±2.69	35----45		

*__SD:__ standard deviation, **Sig.**: Significance; **P- value** ≥0.05; Non-significant.
Min-Max Values: Minimal and maximal values.

Table 2: Separated group, comparative analysis of outcome measures along the study timeline.

		Group A/ CL		Group B/ LP		Group C/ Control	
		Mean ±SD	Sig.	Mean ±SD	Sig.	Mean ±SD	Sig.
PINRS	Before	5.65±1.09	.000***	5.7±1.17	.000***	5.8±1.19	.000***
	At end	2.3 ±1.03		2.4 ±1.09		3.85 ±1.14	
	Follow up	1.75 ±0.79		1.75 ±0.79		2.2 ±0.83	
NPDS	Before	62 ±12.06	.000***	63.05 ±12.77	.000***	62.25 ±11.76	.000***
	At end	29.65 ±9.34		30.15 ±9.68		37.3 ±12.14	
	Follow up	18.45 ±6.89		18.7 ±6.67		23.5 ±7.09	
Cobb Angle	Before	10.9 ±1.02	.000***	10.65 ±0.88	.000***	10.85 ±0.93	.000***
	At end	10.4 ±1.05		10.45 ±0.89		10.2 ±1.01	
	Follow up	9.4 ±0.94		9.5 ±0.89		9.45 ±1.05	
ROM	Before	26.2 ±2.86	.000***	27.7 ±1.8	.000***	27.85 ±2.21	.000***
	At end	29.4 ±2.96		29.8 ±1.6		29.85 ±2.3	
	Follow up	31.9 ±3.18		32 ±1.5		32.75 ±2.45	

SD: standard deviation, Sig.: Significance; P-value< 0.001: high significant.

Moreover, inferential analysis revealed no significant differences between all groups (Table 3), while, there was high statistical significant for pain intensity using PINRS, at the end of treatment by 7th week (P-values < 0.001), and significant differences for neck disability using NPDS, at the end of treatment, 7th week (P-values < 0.05), as well other outcome measures had no significances [cervical sagittal lordotic angle and cervical sagittal ROM, (P-values > 0.05). On the other hand, only pain intensity using PINRS has significant differences (P-values < 0.05) in all groups and other outcome measures have no statistical significant differences after follow up period by 12th weeks (P-values > 0.05).

Table 3: Comparative analysis of outcome measures between study groups

	Time	**Before**		**7th week- end of treatment**		**Follow up-12th week**	
		Mean ±SD	Sig.	Mean ±SD	Sig.	Mean ± SD	Sig.
PINRS	A- CL	5.65 ±1.09	.916^{NS}	2.3 ±1.03	.000***	1.75 ±0.79	.040*
	B- LP	5.7 ±1.17		2.45 ±1.09		1.75 ±0.79	
	Control	5.8 ±1.196		3.85 ±1.137		2.2 ±0.83	
NPDS	A- CL	62 ±12.06	.960^{NS}	29.65 ±9.34	.042*	18.45 ±6.89	.947^{NS}
	B- LP	63.05 ±12.77		30.15 ±9.68		18.7 ±6.67	
	Control	62.25 ±11.76		37.3 ±12.14		23.5 ±7.09	
Cobb Angle	A- CL	10.9 ±1.02	.678^{NS}	10.4 ±1.05	.697^{NS}	9.4 ±0.94	.439^{NS}
	B- LP	10.65 ±0.88		10.45 ±0.89		9.5 ±0.89	
	control	10.85 ±0.93		10.2 ±1.01		9.45 ±1.05	
ROM	A- CL	26.2 ±2.86	.056^{NS}	29.4 ±2.96	.804^{NS}	31.9 ±3.18	.132^{NS}
	B- LP	27.7 ±1.84		29.8 ±1.61		32.8 ±1.51	
	control	27.85 ±2.2		29.85 ±2.3		32.75 ±2.45	

SD: standard deviation, **Sig.**: Significance; **P-value**> 0.1: not significant. **P-value**< 0.05: significant. **P-value**< 0.001: high significant.

Finally, repeated measurement LSD statistical evaluation revealed before treatment no significant differences between all groups, Table 4. While, there was high statistical significant (P-values < 0.001) at groups (A and B) for pain intensity using PINRS at the end of treatment by the 7th week, and significant differences at groups (A and B) for neck disability using NPDS (P-values < 0.05) with the end of treatment by 7th week, as well other secondary outcome measures; (cervical sagittal lordotic angle and cervical sagittal ROM) had no significances. On the other hand, only pain intensity using PINRS has significant differences (P-values < 0.05) at groups (A and B) for PINRS at 12th weeks of follow up period, and moderate significant differences at groups (A and B) for neck disability using NPDS (P-values < 0.01) with same period of follow up, other outcome measures have no statistical significant differences.

Table 4: LSD/ Post Hoc analysis of outcome measures between groups.

LSD- Post Hoc		**Before**	**Sig.**	**7th week**	**S**	**Follow Up**	**S**
PINRS	A- CL	5.65^{a}	NS	2.30^{b}	S***	1.75^{b}	S*
	B- LP	5.70^{a}	NS	2.45^{b}	S***	1.75^{b}	S*
	control	5.80^{a}	NS	3.85^{c}	NS	2.20^{c}	NS
NPDS	A- CL	62.00^{a}	NS	29.65^{b}	S**	18.45^{b}	S**
	B- LP	63.05^{a}	NS	30.15^{b}	S**	18.70^{b}	S**
	control	62.25^{a}	NS	37.30^{c}	NS	23.50^{c}	NS
Cobb Angle	A- CL	10.90^{a}	NS	10.40^{a}	NS	9.40^{a}	NS
	B- LP	10.65^{a}	NS	10.45^{a}	NS	9.50^{a}	NS
	control	10.85^{a}	NS	10.20^{a}	NS	9.45^{a}	NS
ROM	A- CL	26.20^{a}	NS	29.40^{a}	NS	31.90^{a}	NS
	B- LP	27.70^{a}	NS	29.80^{a}	NS	32.80^{a}	NS
	control	27.85^{a}	NS	29.85^{a}	NS	32.75^{a}	NS

a-c Means with different letters superscripts in the same raw denote significance at (P < 0.05), while similar superscript letters denote non-significance. S: significance, NS: no significant, S: low significance, S**: moderate significance, S***: high significance. LSD: least significant differences.

Discussion

To our knowledge, the present study is the first to examine the effects of two clinical CL parameters on PCLS. Despite CL has a fast efficient antalgic effect, unless PCLS` patients suffered from resultant axial pain that initiated due to disrupted posterior subaxial structures. Therefore, subaxial kinematic changes considered the prime factor PCLS (Heshiguchi *et al*., 2018) [13], which will define CL benefits' that accelerating active physical therapy interventions on the long term on such progressive neck disability (Ma *et al*., 2018) [20].

According to previous medical literature, before commencement of the present study, an independent person further randomized allocation that ensured single blind designing value. In addition, the chronic nature of PCLS experience fluctuating pain which was faced by usage of

NPDS, plus secondary objective measure (C2-C7 Cobb angle) for strengthening the gained evidence.

The study results shown that there were no statistical significance differences between study participants in their demographic features (P> 0.05), that deny any prior effect and strengthened this study. Furthermore, study results revealed no statistical significant differences were found at the baseline (P> 0.05) for chronic neck pain and disability measures, as well other objective cervical kinematics measures. Moreover, the results of present study proved that by the end of the fourteen treatment sessions, high significant differences (P-values < 0.001) for chronic pain intensity and neck disability, as well cervical kinematic measures for neck alignment and sagittal mobility. Such findings came in context with medical literature that recommending, even early physical therapy intervention for PCLS (De Pauw *et al*., 2016 and Cao *et al*., 2017) [11, 6].

Previous documented results were conflicted by the unclear evidence for effectiveness of CL or LP if considered the control group (active exercise) intervention in form of conventional cervical isometric and stabilizing exercising (Antúnez Sánchez *et al*., 2017 and Bridges *et al*., 2018) [2, 5]. In addition, specific cervical and core stabilizing exercise was recommended intervention aiming to overcome cervical disability, even with radiculopathy, that was documented by Akkan and Gelecek, (2018) [1].

After the 7th consecutive treatment weeks, the results of current study proved that there was high statistical significant for pain intensity and low significant differences for neck disability (P-values < 0.001 and 0.01, respectively). That could explained by previous stated CL therapeutic potential mechanism, which advocated laser effectiveness to reverses persistent or chronic pain and accompanied disabilities as agreed by de Andrade *et al*., (2016) [9], who stated the positive efficacy of CL; analgesia even for neuropathic pain. Earlier studies as reported by Glazov, (2010) [12] advised acupuncture in form of LP after applied to one hundred patients suffering of chronic spinal pain and documented accelerated improvement specific with chronic nature of underling axial disorder pathophysiology.

On the other hand, recent recommendations reported by Pour *et al*., (2017) [24], who studied thirty-nine patients suffering from sub-acute and chronic neck pain, and documented multidisciplinary management approaches specific in chronic neck disorders. Furthermore, Kadhim-Saleh *et al*., (2013) [16] found inconclusive evidence for CL in various chronic neck disorders, over and above lowering clinical laser efficacy. While, Schomacher and Falla, (2013) [26], who ensured the kinematic origin of PCLS that orient management mainly for exercise therapy, which came in context with Lee *et al*., (2017) [19], who focused on low intensity strengthening and stretching training for chronic post-operative cervical management.

The substantial difference that clearly was turns out throughout the current study was that only pain intensity using PINRS, has low significant differences (P-values < 0.05) at groups (A and B) at follow up (12th weeks) period, and moderate significant differences at groups (A and B) for neck disability (P-values < 0.01) with same period of follow up, unless cervical kinematics` measures (cervical alignment and sagittal ROM) shown no statistical significant differences.

The present study results came with agree with numerous recent studies, those recommended CL (>20 J/cm^2) for prolonged relief by altering the chronic inflammatory process according to de Andrade *et al*., (2017) [10], which also strengthened by Holanda *et al*., (2017) [15].

Over and above, Takahashi *et al*., (2012) [28], who conducted a long term (3 years) study for (15 male and 11 female) patients using 19.5J/cm^2 [0.620λ ×30 S = 19.5] demonstrated that an eight session laser therapy is an effective treatment maneuver for neck pain, especially if reinforced by postural training. Furthermore, Oliveira *et al*., (2017) [23] provided that CL advocated the therapeutic potential mechanism (reverse chronic constriction injury), which accelerated valuable exercise therapies in a precise physical management of chronic axial pain as agreed by De Pauw *et al*., (2016) [11] after review 395papers and accept only fourteen and confirmed that deep cervical extensors loss their cross section as well deep flexors with chronic neck pain.

Conclusion

Early physical therapy is recommended post cervical laminoplasty. With precise concordance drawn for rehabilitation modalities, we advised CL has significant efficacy on chronic pain intensity and neck disability with other active therapy interventions that based on individual evaluation will maximize the gain of physical therapy management of PCLS.

Limitations

The current study had some limitations, which should be addressed in future research that are the small sample size, restricted decade of life, as well the present study did not investigate the long term effect.

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Conflict of interest

The authors confirm that this article content has no conflict of interest.

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