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CASE REPORT

Amblyopia: Can Laser Acupuncture be an Option?

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Abstract
This paper describes the results of the treatment of amblyopia in young patients using an unconventional laser-acupuncture technique. After obtaining satisfactory results in the treatment of a 14-year-old amblyopic girl, the treatment was applied to 13 amblyopic children aged 3–11 years, with an encouraging outcome. An ultralow-light-intensity laser with a square-wave modulated emission was applied over a sequence of acupuncture points. Each session lasted < 15 minutes, and the treatment was performed once a week in 6-week cycles. Patients were followed for several years to evaluate the long-term results and/or to extend the treatment. All except two of the treated patients showed a rapid increase in visual acuity after several treatment sessions. Some required retreatment for regressions in visual acuity. The need for medium-term treatment cycles seems, however, to suggest that results may not be stable for all individuals. Although acupuncture has already been proved to be effective in the treatment of amblyopia, the results reported in this paper suggest that laser acupuncture at ultra-low-light-intensity levels can provide similar, if not better, results to conventional acupuncture stimulation, but with higher patient compliance.

1. Introduction

Although it is widely accepted that it is very difficult to achieve functional improvement of the visual system at the end of its complete development—age 10/12 years at the latest—a traditional Chinese medicine (TCM) approach was used to treat a teenage (14-year old) girl with reduced visual acuity. As she suffered from a congenital depigmentation of the retina, her visual acuity of 20/40 in both eyes (BE) was considered to be the highest visual acuity possible. Traditional techniques had not provided any significant benefit. It was, therefore, decided to apply unconventional TCM techniques [1].

The girl had best corrected visual acuity (BCVA) BE of 20/40 and after 15 sessions of treatment with a variety of TCM techniques (needle acupuncture, laser acupuncture, and Ma Litang hammer) over a 10-month period, to our

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surprise and enthusiasm, she achieved a BCVA BE of 20/25 with the same slight optical correction.

She was further treated (4 sessions) over 2 months in the autumn of 2008. BCVA BE was 20/25 at the beginning of treatment, and at the end, BCVA was 20/28 in the right eye and 20/22 in the left eye.

Over a further 2-year period (March 2009—May 2011), she was treated 28 times: BCVA BE was 20/25 at the beginning, and by the end it was 20/22.

Without any further treatment after 2011, she was examined again at the end of 2014 when her BCVA BE measured 20/33.

While the deficit was not fully compensated or stable, the observed modifications encouraged us to study and test the possibility of treating amblyopia with protocols derived from acupuncture theory, without any exceptions in the selection of patients and with better results expected in younger ones.

Since then the technique has been simplified, and the most effective and repeatable form investigated, based on a theoretical approach and through the analysis of significant reported experiences.

The use of a novel type of ultralow-light-level laser (ULLLL) was deemed to be particularly interesting, rather than either needle insertions or the Ma Litang hammer, for the purpose of achieving higher compliance by young patients and shortening treatment session length.

The American Academy of Ophthalmology [2] has quite recently (2012) carried out a survey of the pathology and, in the framework of the "Preferred Practice Patterns," proposed "*optical correction, patching, pharmacological penalization, optical penalization, Bangerter filters, surgery to remove the causes of amblyopia, acupuncture, and vision therapy*" for the treatment of amblyopia.

The abovementioned document reports the use of acupuncture for amblyopia treatment in two clinical trials: The first study found acupuncture over a 15-week period to be as effective as occlusion for 88 children aged 7—12 years who had anisometropic amblyopia [3]. In this randomized controlled trial, children had 20/40—20/125 BCVA and no strabismus. The second study examined the effect of adding acupuncture to refractive correction for 83 children aged 3—7 years who had untreated anisometropic amblyopia (20/40—20/200) [4]. At 15 weeks, there was a greater improvement in visual acuity using refractive correction with acupuncture compared with refractive correction alone. In both studies, the acupuncture technique consisted of five acupuncture needles placed and manipulated for 15 minutes 5 times/wk for 15 weeks. In both the above studies, the selected acupoints, needle insertion, manipulation of the needles, and application protocol are indicated.

Five acupoints, unilateral GV20 (baihui), bilateral EX-HN5 (taiyang), bilateral BL2 (cuanzhu), unilateral LI4 (hegu), and bilateral BL59 (fuyang), were selected on the basis of the theory and literature reports of TCM as referenced by the authors. The locations of the acupoints are shown in Table 1 and Fig. 1.

2. Case Presentation

2.1. Materials and methods

2.1.1. Patients

Thirteen young patients (2 males and 11 females), with a mean age of 7 years (range 3—11 years), were recruited into the study after obtaining formal written consent from their parents, and the patients underwent treatment. All patients were amblyopic or had BCVA $<$ 20/20 (Snellen fraction).

Patients with any of the following conditions were excluded from the present study:

- eye diseases
- vision deficits not previously corrected
- use of optimal correction spectacles for $<$6 months
- absence of stabilized BCVA
- patch occlusion of the best eye
- strabismus
- a previous history of conventional treatments

These patients, inhomogeneous for clinical conditions and/or applied treatment, were not included in the present report that deals with patients receiving laser-acupuncture treatment only.

2.1.2. Measurements

Visual acuity was measured via the Snellen fraction, always by the same operator, in the same ward, by the same visual acuity tester, and under identical conditions. All patients wore the prescribed spectacles when needed.

For each participant, visual acuity was tested first in the amblyopic eye and then in the healthy eye. Thirty minutes

Table 1 Acupuncture points in the published trials [3,4].

Acupoint		Location (see Fig. 1)
GV20	Baihui (unilateral)	On top of the head, 7 cun above the occipital hairline and 5 cun behind the frontal hairline
EX-HN5	Taiyang (bilateral)	At the temporal dimple and 1 cun behind the midpoint of a line from the lateral end of the eyebrow to the external canthus
BL2	Cuanzhu (bilateral)	In the supraorbital notch and at the median end of the eyebrow
LI4	Hegu (unilateral)	At the dorsum of the hand, and between the first and second metacarpal bones
BL59	Fuyang (bilateral)	3 cun above the site between the Achilles tendon and the lateral malleolus

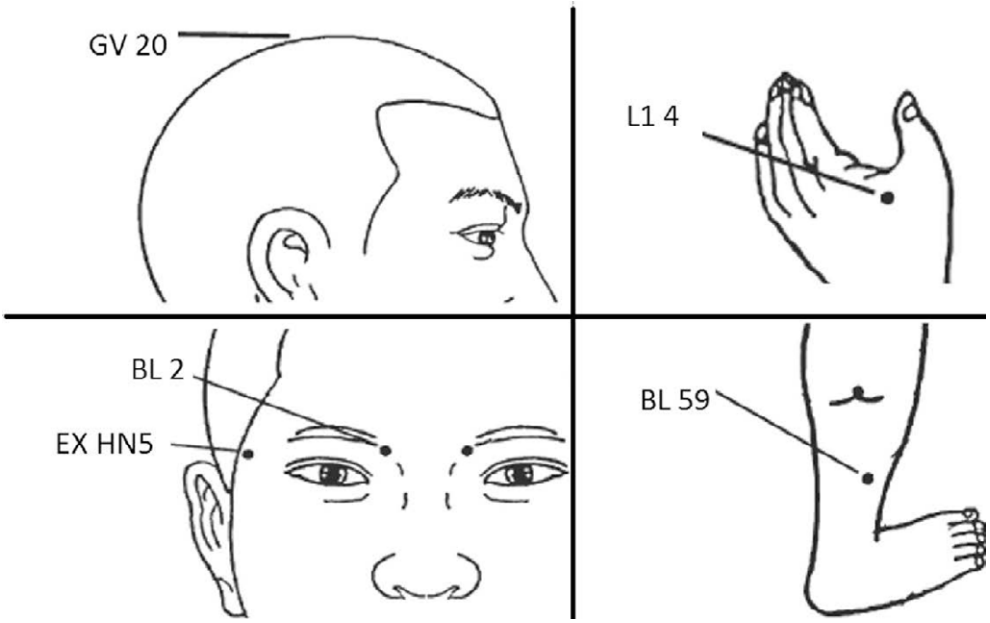

Figure 1 Acupuncture points in the published trials [3,4].

after treatment, the visual acuity was measured in the amblyopic eye.

Anisometropia, astigmatism, and myopia were corrected fully, whereas hyperopia was either fully corrected or symmetrically undercorrected by no more than 1.50 D.

Glasses had to be worn all day. Whenever a change in the visual defect was detected, new glasses were prescribed.

One treatment session was performed weekly by the same operator—a certified acupuncturist ophthalmologist (MD)—until visual acuity was stabilized or could be improved no further.

2.1.3. Laser acupuncture

Based on the above experiences and our first case of a young girl, we have been treating children with amblyopia using acupunctural techniques, using Biolite (RGM SpA, Genoa, Italy), a new internationally patented ULLLL used to perform laser acupuncture. The ULLLL treatment affords

Table 2 Selected acupuncture points.

Acupoint		Location (see Fig. 2)
EX-HN5	Taiyang	At the temporal dimple and 1 cun behind the midpoint of a line from the lateral end of the eyebrow to the external canthus
BL1	Jing Ming	In a depression, 1 cun above the inner canthus of the eye
LI1	Shang Jang	1 cun posterior to the corner of the nail on the radial side of the index finger
LI4	Hegu	At the dorsum of the hand, and between the first and second metacarpal bones
BL59	Fuyang	3 cun above the site between the Achilles tendon and the lateral malleolus
BL64	Jing Gu	Below the tuberosity of the fifth metatarsal bone at the junction of the red and white skin
BL67	Zhi Yin	0.1 cun posterior to the corner of the nail on the lateral side of the little toe
ST1	Chengqi	Below the pupil, between the eyeball and the infraorbital ridge
GB1	Tong Zi Liao	0.5 cun lateral to the outer canthus of the eye in a depression on the lateral side of the orbit
GB20	Fengchi	In a depression between the upper portion of the sternocleidomastoid muscle and the trapezius, level with GV16
TE23	Sizhukong	In a depression at the lateral end of the eyebrow
SP2	Dadu	On the medial side of the big toe, distal and inferior to the first metatarsal digital joint in a depression at the juncture of the red and white skin

much higher compliance than needling, especially in children. Biolite features a modulated red light ($\lambda = 635$ nm) square-wave pulsed emission with an average optical power of approximately 0.02 mW over a 0.13-cm^2 spot [5,6].

The extremely low average power is generated through the combination (logical AND) of two square-wave modulations of the 3-mW laser diode emission: a 100-Hz (duty cycle 1%) and a 1-Hz (duty cycle 50%) modulation. The former modulation (100 Hz) is electronically generated, whereas the latter (1 Hz) is manually generated by the operator (using a push button) emitting a half-second flash every second. A converging/diverging lens, absorbing around 30% of the emitted power, focuses the beam at approximately 30 mm from the probe tip on a 0.13-cm^2 spot.

The resulting values of power (0.015 mW), power density (0.115 mW/cm^2), and energy dosimetry at 20 seconds (0.3 mJ; 2.3 mJ/cm^2) are well below any known effectiveness threshold [7]. Nevertheless, there is sound evidence of acupunctural effectiveness most probably linked to the square-wave modulation of the emission [8], and its capability to propagate seems to depend on mechanical effects induced through the fibroblast within the ubiquitous extracellular matrix, according to patterns that very likely correspond to the acupuncture meridians [9—11]. The choice of the two modulation frequencies is linked to known responses observed in electroacupuncture [12,13].

2.1.4. Acupoint selection and application protocol in our study

The acupoint selections made in the previous studies were modified for the following reasons:

- GV20 was deemed not to be useful as it is located in the scalp and was therefore discarded.
- BL1, in our opinion, is more effective than BL2 and can be safely selected for laser acupuncture, which does not need needle application. Furthermore, BL1 is the interconnecting point of LI, ST, TB, and GB meridians.
- LI1 was added to LI4 (bilateral) owing to its well-known efficacy in improving blood flow in the cerebral [14] and central retinal arteries.
- In addition, BL64 and BL67 were added to BL59 as they are known to activate the cortical regions involved in visual perception [15—17]. Furthermore, BL64 is known to be specific for eye affections deriving from kidney DeQi depletion.
- ST1, GB1, GB20, and TB23 were added as they are known to be specific to eye and vision pathologies [16—21].
- SP2 was added as, according to the TCM, it tonifies the spleen meridian in relation to the macula in the "five-circle" TCM theory.

The corresponding selection is shown in Table 2 and Fig. 2.

The above criteria were derived from specifically referenced documents and from several TCM textbooks [22—31]. Unfortunately, some of the latter are out of print or generally not easy to find. The protocol and preliminary evidence were proposed at the fifth European Congress for Integrative Medicine in Florence, Italy (20—22 September 2012).

The acupoints were stimulated bilaterally. Each of the selected points was stimulated with 20 half-second flashes (flash repetition rate 1/s) using Biolite. The tip of the emitting probe was kept at approximately 30 mm from the skin (spot area 0.13 cm^2) and perpendicular to the selected acupoint.

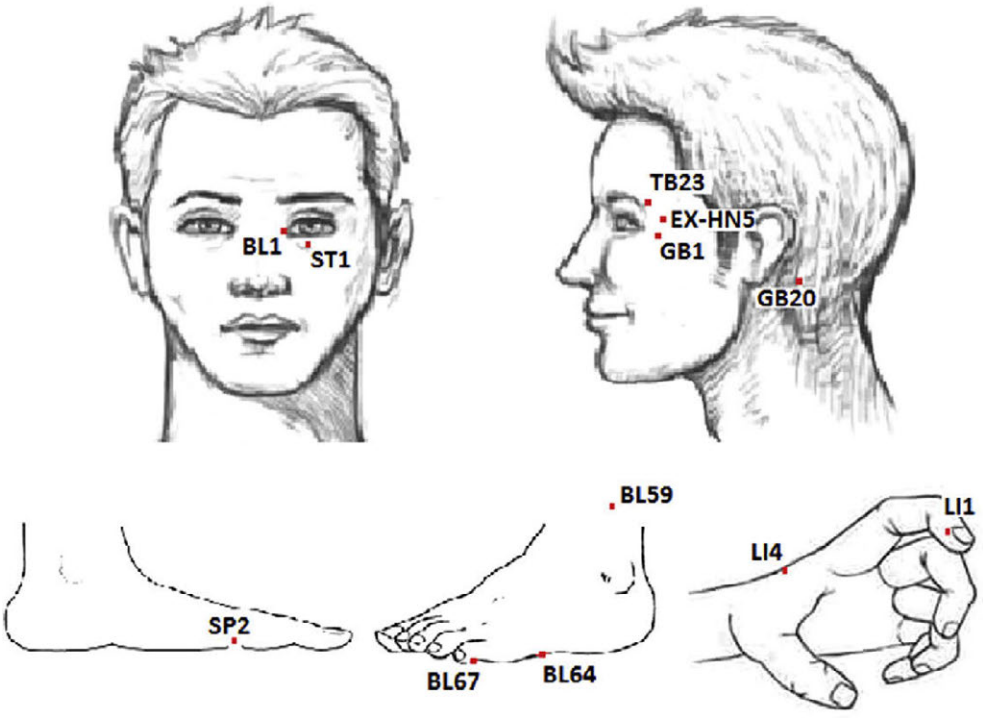

Figure 2 Selected acupoints.

Table 3 Amblyopia patients' main data (Refraction correction can be either Spherical − sph or Cylindrical − cyl).

Name	AL	BA	BY	BM	BS	BA	RS	CF	CG	CA	PA	MG	PD
Age (y)	7	11	5	9	9	6	8	9	3	6	5	8	5
Sex (M/F)	M	F	F	M	F	F	F	F	F	F	F	F	F
Refraction right eye	cyl. +1.50 95°	None	None	sph. +2.50 = cyl. +0.50 20°	None	cyl. +0.50 90°	cyl. +1 90°	sph. −0.50 = cyl. −1 180°	sph. +3.50 = cyl. +0.50 90°	cyl. +2.50 80°	sph. +3.50	sph. +0.50 = cyl. +2 95°	cyl. +2.50 90°
Refraction left eye	cyl. +1 90°	None	sph. + 2	None	None	None	sph. −1 = cyl. +3 90°	sph. −0.50 = cyl. −1 180°	None	cyl. +2.50 90°	sph. +1.50	sph. +0.50 = cyl. +4 90°	cyl. +3 90°
First treatment													
Evaluation in													
Month/year	May/13	Jan/12	Feb/14	Mar/11	Apr/14	Oct/13	Jan/13	Sep/12	May/11	Feb/12	Mar/12	Jun/12	Jun/12
BCVA RE	20/25	20/22	20/20	20/22	20/25	20/33	20/24	20/33	20/40	20/28	20/28	20/30	20/33
BCVA LE	20/20	20/22	20/25	20/13	20/25	20/20	20/25	20/33	20/13	20/28	20/28	20/33	20/33
Number of treatments													
Sessions	7	4	11	8	6	10	8	12	6	9	9	8	5
Evaluation out													
Month/year	Jul/13	Feb/12	Jun/14	May/11	Jun/14	Dec/13	Mar/13	Nov/12	Jun/11	Jun/12	May/12	Jul/12	Jul/12
BCVA RE	20/20	20/20	20/20	20/20	20/25	20/28	20/20	20/20	20/33	20/20	20/22	20/22	20/25
BCVA LE	20/20	20/20	20/20	20/13	20/25	20/20	20/22	20/20	20/13	20/20	20/22	20/30	20/25
Second treatment													
Evaluation in													
Month/year	Sep/13			Nov/11			Jun/13		Sep/11	Jun/13	Oct/14	Jan/13	Mar/13
BCVA RE	20/23			20/22			20/22		20/33	20/22	20/28	20/22	20/28
BCVA LE	20/20			20/13			20/22		20/13	20/22	20/28	20/25	20/25
Number of treatments													
Sessions	8			4					6	4	7	14	4
Evaluation out													
Month/year	Jan/14			Dec/11			Jun/13		Oct/11	Jul/13	Nov/14	Jun/13	Mar/13
BCVA RE	20/20			20/21			20/20		20/33	20/22	20/22	20/20	20/25
BCVA LE	20/20			20/13			20/20		20/13	20/22	20/22	20/20	20/22
Third treatment													
Evaluation in													
Month/year				Oct/12						Jun/14		May/14	
BCVA RE				20/21						20/22		20/20	
BCVA LE				20/13						20/22		20/22	
Number of treatments													
Sessions				7						4		10	
Evaluation out													
Month/year				Dec/12						Jul/14		Nov/14	
BCVA RE				20/21						20/20		20/20	
BCVA LE				20/13						20/20		20/22	
Control visit													
Month/year	Oct/14	Sep/14	Mar/15	Nov/14		Mar/15	Oct/14	Apr/14		Mar/15			Oct/13
BCVA RE	20/20	20/20	20/20	20/21		20/28	20/20	20/20		20/20			20/22
BCVA LE	20/20	20/20	20/20	20/13		20/20	20/20	20/20		20/20			20/22
	P	P	P	N	N	P	P	P	P	P	P	P	P

BCVA = best corrected visual acuity; LE = left eye; N = negative result; P = positive result; RE = right eye.

2.2. Results

As is quite normal for this kind of pathology, the range of deficits was rather wide and the patients were not homogeneous by age, sex, or anthropometrics. Rather than attempting a statistical assessment, it was preferred to present the 13 cases as individual experiences (Table 3).

The case reported in the "Introduction" is not included because the patient was treated with many different techniques that cannot be compared with the ULLLL treatment applied to the 13 young patients.

As can be observed in Table 3, the patients were kept under observation for quite a long period of time. The results obtained—11 remarkable improvements—are also reported in Table 3 and encourage us to proceed further in refining the technique, which, besides being effective and devoid of any known side effects, is readily accepted by the patients, as it is absolutely painless and its application process is fast.

It should be noted, however, that the 13 patients underwent an average of slightly more than 13 sessions each and one of the two nonrespondent patients (Female Id. BS, aged 9 — of Table 3) discontinued the treatment after the first cycle of just six laser-acupuncture sessions. It seems reasonable to suggest that after a longer cycle, she would probably have experienced some benefit.

3. Discussion

3.1. Amblyopia prevalence, its social relevance, and recommended intervention age

The document by the American Academy of Ophthalmology [2] states that "Amblyopia is an important public health problem because of its prevalence among children and because visual impairment from amblyopia is lifelong and can be profound. Both amblyopia and treatment can have a substantial impact on quality of life [32—34]. Prevalence estimates range from 0.8% to 3.3% depending on the population studied and the definition used" [35—44].

Amblyopia, more commonly known as "lazy eye," is defined as a unilateral or, less commonly, a bilateral reduction of BCVA that occurs in the setting of an otherwise normal eye. The causes of amblyopia lie both in the eye and in vision-related cortical activities: whenever the perceived or interpreted visions do not match, the "blurred" perceived vision is discarded, resulting in the "lazy eye" condition. The lazy eye condition also leads to the development of an incorrect visual system. The process of development and integration of visual functions starts at 6—7 months and is completed by the age of 10—12 years.

The first sentence of the same chapter of the above-mentioned document actually states that "Success rates of amblyopia treatment decline with increasing age," clearly stressing the need for treatment suitable for very young children. It is confirmed to some extent that the effects may reside in functional adaptive control in the "plastic phase," although good results were found even at the age of 14 years. The same technique was tested on adults, although no significant results were observed.

3.2. Rapidity and stability of the improvement

The results of treating amblyopic children with laser acupuncture, in our experience, are sometimes obtained very rapidly. Thirty minutes after the treatment, an improvement can often be observed in visual acuity. This benefit may last, with slight decay, into the following week. After a few treatment sessions, usually once a week for 6 weeks (hence, much faster than in the 2 traditional acupuncture trials reported), the improvement is substantial and stabilizes for up to several months. Sometimes, further sessions are required at an interval of several months.

3.3. Side effects and patient compliance

The treatment is devoid of any side effects and is totally painless, and young patient compliance is very high. Compared with optical penalization or patching techniques, this laser-acupuncture treatment is generally accepted much more readily by children and their parents, and, by allowing binocular vision to be retained, it avoids the risk of strabismus.

While acupuncture has been shown to be effective, needling around the eyes certainly does not meet with compliance by young patients; they might more agreeably be treated with ULLLL, which appears to be as effective as classical acupuncture.

3.4. Action mechanisms

As mentioned with reference to the two trials involving acupuncture treatment of amblyopia, "Acupuncture for amblyopia requires further investigation, including an evaluation of cost-effectiveness [45]. The effect of acupuncture on strabismic amblyopia has not been studied. The mechanism of action for acupuncture in the treatment of amblyopia is unknown."

Although far from providing a full explanation of a possible mechanism, as mentioned in the paragraph describing acupoint selection, it is suggested that the increased blood perfusion of the eye [14] and the observed activation of the vision-related cortical areas [15—17] might be a part of the action mechanism.

3.5. Application in current routine and protocol optimization

The encouraging results obtained to date with Biolite and the indications of the American Academy of Ophthalmology for acupuncture, in the absence of any side effects, indeed point to the possible application of this treatment in current therapeutic practice.

We submit that our study can also serve the purpose of ameliorating the applied protocol — selected acupoints and/or number/frequency of sessions — that are different from the ones proposed in the referenced studies [3,4] and need further optimization.

Disclosure statement

The authors declare that they have no conflicts of interest and no financial interests related to the material of this manuscript.

Acknowledgements

M.G. was involved in the design of Biolite and is among the patent inventors. No commercial interest of any sort is, however, involved. All patent rights are owned by RGMD SpA. M.V. is applying Biolite in his private medical activity and declares the absence of any conflict of interests.

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