Comparisons of Amplitude Reduction of Pattern Visual Evoked Potential (VEP) and Flash VEP between Using Srinagarind Eye Patch and Commercial Eye Patch in Normal Subjects

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Objective: *To compare the difference of amplitude reduction of pattern VEP and flash VEP between occluding eye with Srinagarind eye patches and commercial eye patches in normal subjects.*
Material and Method: *Fifteen subjects (7 males and 8 females) who had normal eye examinations were enrolled. Amplitude of pattern VEP was recorded for each individual subject as baseline data. Right eyes were occluded with Srinagarind eye patches and fellow eyes with commercial eye patches (3M) and then the VEP were retested (pattern and flash VEP). The reduction of amplitude in pattern and flash VEP was recorded.*
Results: *The commercial eye patch significantly reduced the amplitude of retinal stimulation by pattern reversal stimuli on pattern VEP better than the Srinagarind eye patch 1.68 μV (95% CI 0.48-2.87). The commercial eye patch group had amplitude of retinal stimulation by light stimulation on flash VEP greater than the Srinagarind eye patch 3.92 μV (95% CI -9.25-1.41), but not statistically significant. There was also no report of any serious side effects in either group.*
Conclusion: *This is the first study aiming to demonstrate the ability of the Srinagarind eye patch to reduce the retinal stimulation compared with the commercial eye patch by using the VEP test. Further study is needed to test the effectiveness of the Srinagarind eye patch.*

Keywords: *Eye patch, Occlusion, Srinagarind eye patch, Commercial eye patch, 3M eye patch, Amplitude of VEP reduction*

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Amblyopia is a vision deficiency in the eye, in which the abnormalities cannot be found by physical examination. Strabismus is the most common cause of amblyopia, followed by refractive errors and ocular media opacity[1–4]. Treating the causes of amblyopia requires specific management, in which most of the cases need occlusion of the sound eye to incorporate with the specific treatment. The purpose of occlusion is to decrease the light stimulation of the sound eye and give a chance to the amblyopic eye to receive more stimulation by light or objects[1,2].

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For occlusion therapy, some institutes prescribe commercially available eye patches and patients have to pay by themselves because the eye patch is not covered by the current Thai health insurance system.

The Srinagarind strabismus clinic uses microporemedical tape to occlude normal eye that is known as the "Srinagarind eye patch" in order to reduce the patients' expenditure. Therefore, this study aimed to compare the Srinagarind eye patch with the commercially available eye patch in reducing the light stimulation to the sound eye. The authors used a pattern and flash VEP (Visual Evoked Potential) to measure the amount of light stimulation to the eye followed by conducting a pilot study on normal subjects before investigating amblyopic patients. The objective of this study is to compare the amplitude reduction of pattern VEP and flash VEP between the Srinagarind

eye patch and commercial eye patch in normal subjects.

Material and Method

A pilot study was conducted with 15 participants who had normal eye function and the best-corrected visual acuity of 20/30 or better. Exclusion criteria were those who: (1) had a history of allergy to microporemedical tape or an eye patch; (2) had underlying ocular diseases, such as glaucoma, cataracts, diabetic retinopathy; (3) had a history of ocular trauma; (4) were not willing to enroll in a VEP test; (5) were younger than 18 years or older than 40; (6) had an abnormal refractive error: myopia greater than -6.00 diopters, astigmatism greater than +2.00 diopters or hyperopia greater than +2.00 diopter; (7) were pregnant; and (8) had cerebrovascular diseases. This study was reviewed and approved by Khon Kaen University Ethic Committee. All participants gave their informed consent before participating.

All participating subjects were examined by slit lamp biomicroscopy, intraocular pressure (IOP) measuring by Goldmann applanation tonometry, fundus examination by indirect ophthalmoscopy and Goldmann visual field test. Best-corrected visual acuity was also recorded.

After the eye examination, all participants were tested or the pattern VEP in each eye to demonstrate the baseline amplitude. RETI scan®, Roland instrument (Germany) was used to evaluate the VEP. The protocol of VEP testing conformed to the ISCEV guideline[5]. Pattern-reversal stimulus was used to measure the amplitude of P100 from the preceding N75 peak in pattern VEP[5]. Assuming no difference of amplitude of the VEP between right and left eyes in normal subjects, the right eye was closed by the Srinagarind eye patch and underwent the pattern and flash VEP test to determine the amplitude of the tests. The same individual was tested with his/her left eye closed with commercial available eye patch (3M®) and was then retested to obtain the amplitude of the pattern and flash VEP. The differences of amplitude reduction in Srinagarind eye patch group and commercial eye patch group were calculated used R program (R Development Core Team (2011). R:A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0,URL http://www.R-project.org/) and epical program (Virasakdi Chongsuvivatwong<cvirasak @medicine.psu.ac.th> (2011). Epicalc: Epidemiological calculator. R package version 2.13.2.1.http://CRAN.R-project.org/package=epicalc).

A protocol for preparation method of Srinagarind eye patch

A micropore medical tape, one inch in size, is cut into three pieces. The first one is cut in the same length of the patient's lids. The other two pieces are cut longer than the first one. The length of the small piece is approximately two-thirds the length of the other two pieces (Fig. 1)). The longer two pieces were put together, the one piece overlapping the other. Then sticking the small one onto the center of the jointed two pieces in upside down manner. The sticky aspect of the small piece and the jointed two longer pieces will be attached (Fig. 2A, 2B and 3))

Results

There were 15 participants: seven males and eight females. The mean age was 28.33 years (ranged 25-36 years). The mean amplitude of the pattern VEP of participants before and after occluding the right eye with Srinagarind eye patch and the left eye with commercial eye patch is demonstrated in Table 1. The mean amplitude of the flash VEP after occluding the eyes is shown in Table 2. The reduction of amplitude

Fig. 1 Three pieces of micropore medical tape to produce the Srinagarind eye patch.

Fig. 2A The method of attaching two longer pieces of micropore medical tape together.

and their differences before and after the occlusions are demonstrated in Table 3.

The commercial eye patch significantly reduced the amplitude of retinal stimulation by pattern reversal stimuli on the pattern VEP better than the Srinagarind eye patch 1.68 μV (95% CI 0.48-2.87) when compared to the baseline pattern VEP amplitude. The commercial eye patch group had higher amplitude of retinal stimulation by light stimulation on the flash VEP than the Srinagarind eye patch group, 3.92 μV (95% CI -9.25-1.41), but not statistically significant. There was no any serious side effect in either group.

Discussion

The treatment of amblyopia requires occlusion of the sound eye. The time for full accomplishment depends on the severity of amblyopia and the patient's compliance. The duration of occlusion, described in the literatures by Pediatric Eye Disease Investigator Group (PEDIG), depends on the severity and type of amblyopia[1,2,6–8]. The eye patch is an important weapon to battle with this condition. Though there are numerous commercially, available eye patches in the market, cost and affordability could be an issue especially for parents in developing countries. The Srinagarind strabismus clinic, Department of Ophthalmology, Khon Kaen University uses micropore medical tape to occlude the sound eye instead of the commercial eye patch known as the "Srinagarind eye patch". However, there is no evidence to prove the efficacy of Srinagarind eye patch. This present study, therefore, was the first clinical trial aiming to

Fig. 2B The method of attaching the small piece micropore medical tape onto the center of two jointed longer pieces in upside down manner.

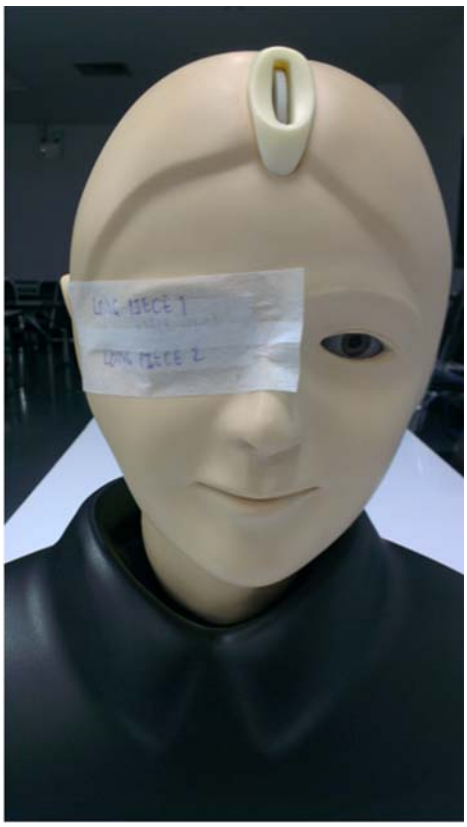

Fig. 3 The Srinagarind eye patch.

Table 1. The mean amplitude of the pattern VEP of the right and the left eye before occluding with the eye patch (baseline amplitude of pattern VEP) and the amplitude of the pattern VEP after occluding the right eye with the Srinagarind eye patch and the left eye with the commercial eye patch

	Baseline P-VEP RE (μV)	Baseline P-VEP LE (μV)	Amplitude of P-VEP in the Srinagarind eye patch (RE) (μV)	Amplitude of P-VEP in the commercial eye patch (LE) (μV)
Mean	11.1	10.02	3.16	3.76
SD	3.70	3.71	2.18	2.21
SE	0.96	0.96	0.56	0.57
95% CI	9.05-13.15	7.97-12.08	1.95-4.36	2.54-4.98

demonstrate the ability of the Srinagarind eye patch to reduce retinal stimulation compare with the commercial eye patch by using the VEP. There is no strong scientific evidence to show the extent of the reduction of VEP amplitude that can be effective in amblyopic treatment. However, an earlier study mentioned that pharmacologic penalization was comparable to occlusion in amblyopic treatment[9]. This finding could imply that occlusion of the better eye in preventing the normal image falling on the retina is sufficient to treat amblyopia. It is not necessary to shut down the visual stimulation of the better eye completely.

In addition, this study was performed on normal people before experimenting on the target amblyopic patients. The results in this present study showed a statistically significant reduction in amplitude in the commercial eye patch as compared to the Srinagarind eye patch group for the pattern VEP. However, the variation of baseline amplitude may affect the results because the baseline amplitude of each type of eye patch was obtained from different eyes. Furthermore, as pervious mentioned, there was no information as to what extent of the VEP reduction was required for amblyopic treatment. Therefore, the cutoff point is not known in order to judge the clinical significance. With regard to the flash VEP, the amplitude of the VEP in the commercial eye patch group was not statistically significant or greater than Srinagarind eye patch group. This could be explained by the fact that the Sringarind eye patch can reduce the amount of light's stimulation at the retina, similar as with the commercial eye patch. Nevertheless, for the pattern stimulation, the Srinagarind eye patch cannot reduce the stimulation as well as the commercial eye patch.

Finally, further study with a large sample size and well control of variation is needed to prove the efficacy of Srinagarind eye patch.

Limitations of the study were composed of a small sample size and the age of the participants who may not represent the age of the general population who used the Srinagarind eye patch. In addition, the use of the baseline VEP amplitude from the different eyes in different types of eye patch within the assumption of no difference in the VEP amplitude of both eyes in the same individual produced variations in the baseline data.

Table 2. The mean amplitude of the flash VEP of the right and the left eye after occluding the right eye with the Srinagarind eye patch and the left eye with the commercial eye patch

	Amplitude of F-VEP in the Srinagarind eye patch (RE) (μV)	Amplitude of F-VEP in the commercial eye patch (LE) (μV)
Mean	26.39	22.47
SD	15.05	13.41
SE	3.89	3.46
95% CI	18.06-34.72	15.04-29.89

Conclusion

This is the first study attempted to demonstrate the ability of the Srinagarind eye patch to reduce the retinal stimulation compared with the commercial eye patch by using the VEP test. Further

Table 3. The amplitude reduction and difference of the amplitude between two eye patches

	Amplitude reduction of P-VEP in the Srinagarind eye patch RE from baseline (μV)	Amplitude reduction of P-VEP in the commercial eye patch LE from baseline (μV)	Difference of amplitude reduction of P-VEP between 2 patches* (μV)	Difference of F-VEP amplitude between 2 patches** (μV)
Mean	7.94	6.26	1.68	3.92
SD	4.13	3.65	2.16	9.63
SE	1.07	0.94	0.56	2.49
95% CI	5.65-10.23	4.24-8.28	0.48-2.87	-9.25-1.41

* Difference of amplitude reduction of P-VEP = {(P-VEP amplitude reduction in the commercial eye patch)-(P-VEP amplitude reduction in the Srinagarind eye patch)}

** Difference of amplitude of F-VEP = {(F-VEP amplitude in the commercial eye patch)-(F-VEP amplitude in the Srinagarind eye patch)}

large-scale study is needed to prove the efficacy of Srinagarind eye patch.

What is already known on this topic ?

There was no information on the use of materials for patching.

What does this study adds ?

There are some possible benefits of using medical tape to patch the eye for treatment of amblyopia but the results from this present study were inconclusive because of a small number of study samples. Despite the inconclusive results regarding the efficacy of the Srinagarind eye patch, we will continue to use this eye patch in our practice and examine further its effectiveness.

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Potential conflicts of interest

None.

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การลดลงของ amplitude ในการทดสอบ pattern VEP และ flash VEP เปรียบเทียบระหว่างการปิดตาด้วยที่ปิดตาศรีนครินทร์และที่ปิดตาที่มีวางจำหน่ายทั่วไปในห้องตลาดในอาสาสมัครปกติ

พรรณทิพา ว่องไว, กนกพรรณ บำรังราชหิรัญ, สิรินยา สุวรรณราช, สมเกียรติ อัศวภูรีกรณ์, สุพัฒน์ แก้วพรรณา

วัตถุประสงค์: เพื่อเปรียบเทียบความแตกต่างของการลดลงของ amplitude ในการทดสอบ pattern VEP และ flash VEP ระหว่างการปิดตาด้วยที่ปิดตาศรีนครินทร์และที่ปิดตาที่มีวางจำหน่ายทั่วไปในห้องตลาดในอาสาสมัครปกติ

วัสดุและวิธีการ: ทำการศึกษาในอาสาสมัครทั้งหมด 15 คน (ชาย 7 คน หญิง 8 คน) ซึ่งทุกคนมีผลการตรวจตาที่ปกติ รวมทั้งมีการบันทึกค่า amplitude พื้นฐานในการทดสอบ pattern VEP หลังจากนั้นจะปิดตาขวาของอาสาสมัครด้วยที่ปิดตาศรีนครินทร์ ตาข้างซ้ายถูกปิดด้วยที่ปิดตาที่มีวางจำหน่ายทั่วไปในห้องตลาดเครื่องหมายการค้า 3M และดำเนินการทดสอบทั้ง pattern VEP และ flash VEP แล้วดูค่าความแตกต่างของการลดลงของค่า amplitude ทั้งในการปิดตาทั้ง 2 วิธีและทดสอบทั้ง pattern VEP และ flash VEP

ผลการศึกษา: ตาที่ถูกปิดด้วยที่ปิดตาที่มีวางจำหน่ายทั่วไปในห้องตลาดพบว่ามีค่าเฉลี่ยของการลดลงของ amplitude ในการทดสอบ pattern VEP ลดลงมากกว่าตาที่ถูกปิดด้วยที่ปิดตาศรีนครินทร์ 1.68 μV (95% CI 0.48-2.87) อย่างมีนัยสำคัญทางสถิติ สำหรับการทดสอบ flash VEP ตาที่ถูกปิดด้วยที่ปิดตาที่มีวางจำหน่ายทั่วไปในห้องตลาดพบว่ามีค่า amplitude มากกว่าตาที่ถูกปิดด้วยที่ปิดตาศรีนครินทร์เฉลี่ยเท่ากับ 3.92 μV (95% CI -9.25-1.41) แต่ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติและไม่พบภาวะแทรกซ้อนที่รุนแรงในทั้งการปิดตาทั้งสองชนิด

สรุป: การศึกษานี้เป็นการศึกษาแรกที่พยายามจะศึกษาความสามารถในการลดการกระตุ้นของจอตาของที่ปิดตาศรีนครินทร์โดยใช้การทดสอบ VEP เป็นเครื่องมือในการประเมินผล แต่เนื่องจากข้อจำกัดของการศึกษานี้ทำให้ยังไม่สามารถสรุปผลได้ ดังนั้นควรจะมีการศึกษาเพิ่มเติมในอนาคตเพื่อตอบปัญหานี้