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Assessment of Inter Observer Variability in Measurement of Ptosis

Janitha Plackal Ayyappan[1]*, Ravipati Sarath[2], Mohm Zeeshan Uddin[3]

[1] School of Medical Sciences, University of Hyderabad, Andhra Pradesh-500046, India
[2] School of Medical Sciences, University of Hyderabad, Andhra Pradesh-500046, India
[3] Student, BLSO, Hyderabad, Andhra Pradesh-500046, India

ABSTRACT

The aim of the study is to determine the Inter observer variation of the ptosis measurements. 100 eyes of 51 healthy volunteers, which included both eyes of 22 males and 26 females, and right eye of 2 males were assessed for the measurements of ptosis which included: Palpebral Fissure Height (PFH), Margin Reflex Distance (MRD) 1, Margin Reflex Distance (MRD) 2, Lid Crease Distance (LCD), Levator Palpebral superiosis (LPS) action, Lateral limbus to Lateral Canthus (LL to LC), Medial Limbus to Medial Canthus (ML to MC). The volunteers were measured once by each of the 3 investigators. All the volunteers except 1 male were students and trainees of L.V. Prasad Eye Institute. The inter class correlation for the PFH values was 0.816 (0.743- 0.871) p< 0.0001, for MRD1 values was 0.830 (0.752- 0.890) p< 0.0001, for MRD2 was 0.822 (0.693-0.904) p< 0.0001, for LPSA was 0.869 (0.818-0.908) p< 0.0001, for LCD was 0.871 (0.820- 0.910) p< 0.0001, for LL to LC was 0.747 (0.604- 0.810) p< 0.0001, for ML to MC was 0.730 (0.610- 0.804). This shows that 82 to 84% of the times all the measurements except LL to LC and ML to MC correlate between the three observers. The LL to LC and ML to MC values correlate 74% and 73% of the times. The Bland and Altman graphs show that all the values in different sets of measurements fall in 95% class interval. The study suggests that there is good correlation between the sets of measurements and the inter observer variation in the measurement of ptosis when conducted in standardised fashion is modest and clinically acceptable.

Corresponding author
Email: ravi.jani@gmail.com

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INTRODUCTION

Fundamental to the assessment of the patient and the choice of operation in the ophthalmic plastic surgery are the measurements of certain parameters of the eyelids. These include position of eyelids in primary position, level of upper skin crease, function of Levator muscle of upper eyelid and distance between limbus and canthus. Accurate knowledge of the biometric parameters of the anterior eye and adnexae are important in a variety of clinical and research applications [1]. The natural appearance of the palpebral fissure is influenced by various factors, including age, ethnicity, and gender [2]. There was a rapid change in palpebral fissure measurements from birth to 48 months of age, with many measurements reaching close to adult levels within the first 1 to 2 years of life [3]. General increase in the laxity of the eyelids has been found in subjects over the age of 50 [4]. Increased laxity leads to shortening of the horizontal eye lid fissure and sagging of the lower eye lid [5]. In male subjects found wider horizontal eyelid fissure by approximately 0.7 mm than female subject [5]. Subjects of Asian ethnic origin have shown to exhibit smaller vertical palpebral apertures and more angled palpebral fissures than whites. Incorrect values may lead to an incorrect diagnosis or an incorrect surgery. To avoid errors and to be more accurate, multiple times external examination must be conducted. The inter and intra observer variability in assessment of upper lid ptosis using a standard measuring protocol is low and is clinically acceptable when the technique of assessment is standardised , but this study included only PFH, MRD1, LCD and LPS action. In this study we have included other measurements also like MRD2, LL to LC, and ML to MC [6]. Normal subjects i.e., subjects without ptosis were included in the study to avoid the bias findings which may lead to abnormal position of eyelid and variation in positions of upper lid.

MATERIALS AND METHODS

Study protocol was reviewed and approved by Institutional review board of L.V. Prasad Eye Institute, Hyderabad. The methods applied in the study adhered with the tenets of the declaration of Helsinki for the use of human subjects in biomedical research. Informed consent was taken from all the participants after explanation of the nature, procedure and consequences of the study and the subjects were free to withdraw at any time without any obligation. The study included 100 eyes of 51 subjects (both eyes of 49 subjects and right eye of 2 subjects), of which 24 subjects were male and 26 subjects were female. The mean age was 22.43 years and ranged between 20 and 36 years.

Sample size calculation:

A pilot study was done to determine the sample size. 10 subjects were chose for the pilot study and these subjects were not included in the main study. The sample size was calculated by using the following formula = $\frac{2 \times (SD)^2 \times (Z\alpha + Z\beta)}{\Delta^2}$, where N is the sample size, (Zα+Zβ) is the Power index , SD is the standard deviation and **Δ** is minimum difference in the population means that is detected as significant **=** 96 with 99% power and at 0.01 level [7]. Inclusion Criteria of the study falls in the category of age group greater than 18 years. Informed

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consent was taken from all the subjects participated in the study. Exclusion Criteria for the study are any ocular or systemic diseases, contact lens wearers, post ptosis surgery, trauma and any obvious facial asymmetry syndromes. The observers were masked to the other fellow's readings to avoid bias. Once the suitability was confirmed, the subjects underwent the following measurements by three investigators each measurement are, palpebral fissure height **,** margin reflex distance 1and 2, levator palpebrae superioris action, lid crease distance, medial limbus to medial canthus, lateral limbus and the lateral canthus. To measure the palpebral fissure height of the right eye the subject was asked to look straight into the left eye of the observer who was seated right in front of the subject and the same level to avoid parallax error. The distance between the upper lid margin and the lower lid margin was recorded in the primary gaze by a millimetre ruler and the reading was taken. In order to take the measurement of the marginal reflex distance-1, the subject was requested to look at the light source (pen torch-muscle spot light) shown to the subject and the distance from the upper lid margin to the corneal light reflex was recorded in millimetres as margin reflex distance -1 and the same procedure as MRD1 was followed and the distance between the lower lid margin and the corneal reflex was recorded as margin reflex distance -2. To measure the levator palpebrae superioris function the subject's eyebrow was stabilised by pressure exerted by examiner's thumb (to negotiate the action of frontalis), the subject was requested to look fully down and then fully up while the excursion of the eyelid was measured against the ruler. Lid crease distance is the distance between the skin crease and the lid margin, was measured and documented. To measure this, the upper lid skin fold was gently raised if necessary and the distance between skin crease and lid margin was recorded, if there were more than one creases the first one was considered. For taking the measurement of lateral limbus and lateral canthus, the subject was requested to look straight into the opposite eye of the examiner and the distance between the lateral limbus and the lateral canthus was recorded. To evaluate the distance between medial limbus to medial canthus in our study, subject was looking straight into examiner's eye and the measurement was recorded.

RESULTS

Statistical Analysis

Table 1: shows that the measurements lay within the expected ranges of parameters measured.

	Co-investigator1	Co-investigator2	Co-investigator3
PFH	8, 12	8.5, 11.5	8, 12
MRD1	2.5, 5	3, 5	2.5, 5
MRD2	4, 7	5, 7	5, 7
LPSA	13, 18	13, 19	13, 18
LCD	4, 9	4, 9	4, 9
LL to LC	5, 9	5, 9	4, 9
ML to MC	6, 11	6, 11	6, 12

The data was analysed by using inter-class correlation [8]. All the three sets of measurements were analysed at the same time.

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Table 2: shows the interclass correlation values of different measurements with 95% class interval and also found good correlation between the different measurements of all the three investigators.

	Interclass correlation	95% CI	P-value
PFH	0.816	0.743-0.871	<0.0001
MRD1	0.830	0.752-0.890	<0.0001
MRD2	0.822	0.693-0.904	<0.0001
LPSA	0.869	0.818-0.908	<0.0001
LCD	0.871	0.820-0.910	<0.0001
LL to LC	0.747	0.604-0.830	<0.0001
ML to MC	0.730	0.610-0.804	<0.0001

The inter class correlation for the PFH values is 0.816 (0.743- 0.871) p< 0.0001, for MRD1 values is 0.830 (0.752- 0.890) p< 0.0001, for MRD2 is 0.822 (0.693-0.904) p< 0.0001, for LPSA is 0.869 (0.818-0.908) p< 0.0001, for LCD is 0.871 (0.820- 0.910) p< 0.0001, for LL to LC is 0.747 (0.604- 0.810) p< 0.0001, for ML to MC is o.730 (0.610- 0.804). This shows that 82 to 84% of the times all the measurements except LL to LC and ML to MC correlate between the three observers. The LL to LC and ML to MC values correlates 74% and 73% of the times. The data was also analysed by graphical method described by Bland and Altman for method comparison studies [9]. To test the inter observer accuracy the difference between the two sets of measurements recorded by the first two investigators was plotted against the average of the two for each parameter, and similarly between second and third observers and then third and first observers. The Bland and Altman graphs reveal that all the values in different sets of measurements fall in 95% class interval [10].

DISCUSSION

Ptosis is a condition common to many patients and is frequently seen in the clinic. To understand the steps in evaluating a ptosis patient, it is important to have a good grasp of the normal anatomy, terms and measurements as they relate to the upper eyelid and levator muscle. Although there will be variability among normal individuals, in the large majority of patients the upper eyelid margin rests at or just below the superior corneal limbus. The distance from the upper lid margin to the central cornea (visual axis) is known as the marginal reflex distance or MRD1. The MRD1 typically measures 4-5 mm. It is the most accurate method of assessing the degree of ptosis in that it is solely indicative of upper lid position and is not influenced by the position of lower lid. In contrast, measurement of the distance from the upper lid margin to the lower lid margin, known as the palpebral fissure height is always affected by the lower lid position and usually measures about 9mm. MRD2 refers to the position of lower lid margin in relation to the apical light reflex. In some cases of unilateral ptosis, the opposite eyelid may appear to be in normal position while it is actually having ptosis. This opposite eyelid appears “normal” as a result of the action of the frontalis muscle, which is elevating both upper lids. If frontalis is relaxed, then the ptosis of the normal side will be unmasked. This variation of Hering’s law also has an application in regard to levator function. Failure to identify the bilateral nature of such problems prior to surgery may lead to a less than desirable cosmetic result. The upper eyelid skin crease is created by the levator inserted into

the skin. This crease from the central aspect of the lid margin is measured as the lid is positioned in downward gaze. It measures around 7-8 mm in men and 8-10 mm in women. This measurement is of great importance especially in cases of unilateral ptosis, since the surgically created lid crease should match the crease on opposite side. The measurement of all these parameters is fundamental to the assessment of ptosis and the choice of operation in ophthalmic plastic surgery. Incorrect values may lead to an incorrect diagnosis or an inappropriate surgery. A possibility of variation in values is always there when measured by different examiners. So the main aim of this study is to see if this variation between different examiners is significant. Three investigators took part in the study. The first investigator was an Optometry intern; the second was a senior optometrist in occuloplasty department of L.V. Prasad eye institute and the third investigator was the Adjunct Consultant ophthalmologist in the same department. The subjects underwent all the measurements by each investigator. The observers were masked when the other fellow's readings are being taken to avoid bias. These values were analysed by SPSS v.16 software. The PFH values showed interclass correlation of 0.816 (0.743- 0.871) p< 0.0001. This means that almost 81% of the times the values of the three investigators correlated to each other. Similarly the MRD1 readings showed correlation of 0.830 (0.752- 0.890) p< 0.0001. Again 83% of the times the values correlate with each other. MRD2 readings also were 82% of the times correlating with correlation value of 0.822 (0.693-0.904) p< 0.0001. The LPSA and LCD readings also showed good correlation of almost 87% with significant P value. The LL to LC and the ML to MC values showed moderate correlation of 74% and 73% respectively. These values were less when compared to other sets of readings. The data was also analysed by plotting Bland Altman graphs for each set of values between two investigators at a time. The graphs showed good agreement between the measurements with 95% class interval. The study suggests that there is good correlation between the sets of measurements and the inter observer variation in the measurements of ptosis when conducted in standardised fashion is modest and clinically acceptable.

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