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BRUNA MARIA MOTA ANTUNES DA CUNHA

NEW METHODOLOGY TO EVALUATE AESTHETICS AND FUNCTIONAL RESULTS AFTER PTOSIS SURGERY

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Trabalho realizado sob a orientação de:
DOUTOR RUI GUILHERME PEREIRA LEITE CASTELA
PROFESSOR DOUTOR JOAQUIM CARLOS NETO MURTA

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NEW METHODOLOGY TO EVALUATE AESTHETICS AND FUNCTIONAL RESULTS AFTER PTOSIS SURGERY

NOVA METODOLOGIA DE AVALIAÇÃO DOS RESULTADOS ESTÉTICOS E FUNCIONAIS APÓS CIRURGIA DE PTOSE

Authors: Bruna Maria Mota Antunes da Cunha[1], Rui Guilherme Pereira Leite Castela[2], Joaquim Carlos Neto Murta[3]

1 - Faculty of Medicine, University of Coimbra, Portugal (medical student)
brunacunha@outlook.pt

2 - Faculty of Medicine, University of Coimbra, Portugal
Ophthalmology Department, *Centro Hospitalar e Universitário de Coimbra*
gcastela@hotmail.com

3 - Faculty of Medicine, University of Coimbra, Portugal
Ophthalmology Department, *Centro Hospitalar e Universitário de Coimbra*
jnmurta@netcabo.pt

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List of abbreviations

CI – confidence interval

ICC – intra-class correlation coefficient

JPEG – joint photographic experts group

MRD_1 – marginal reflex distance 1

MRD_2 – marginal reflex distance 2

PDF – portable document format

PF – palpebral fissure

SD – standard deviation

TX – Texas

USA – United States of America

Abstract

Introduction: An extremely precise measurement of the margin reflex distance 1 (MRD_1), margin reflex distance 2 (MRD_2) and the palpebral fissure (PF) are crucial for a proper ptosis assessment, its surgical repair planning and follow-up. Facial photographs integrated with automated measurements of the eyelid position could represent an objective, accurate and reproducible means of documentation of these parameters.

Purpose: To compare the agreement of eyelid position measurements between a novel device that automatically derives measurements from a digital photograph and the standard manual approach.

Methods: A total of 16 eyes from 8 patients referred for blepharoptosis repair to the ophthalmology department of *Centro Hospitalar e Universitário de Coimbra* were assessed for MRD_1, MRD_2 and PF at the pre-operative and post-operative appointment. The measurements were obtained using two techniques: the standard manual approach, with the use of a ruler; and an automated digital approach, through which facial photographs captured using the Volk Eye Check oculoplastic device. Systematic differences were evaluated by paired t-tests, agreement by construction of Bland-Altman plots and consistency by deriving intra-class correlation coefficients (ICC).

Results: Both manual and digital techniques succeeded in reporting after surgery increases: significantly for MRD_1 manual ($p<0.001$) and digital ($p=0.003$), manual MRD_2 ($p=0.004$) and PF ($p<0.001$); not significantly for digital MRD_2 ($p=0.398$) and PF ($p=0.689$). There was no significant systematic difference between the manual and digital methodologies regarding the MRD_1 (+0.01±1.37 mm, $p=0.961$); and a significant +0.91±1.20 mm ($p=0.002$) for MRD_2 and +1.33±1.68 mm ($p=0.001$) for PF. The derived 95% confidence interval (CI) of [-2.675, +2.704] for MRD_1, [-1.442, +3.267] for MRD_2 and [-1.956, +4.621] for PF exceeded the acceptable clinical limits of ±0.5 mm for MRD_1 and MRD_2, and ±1.00 mm for PF. The calculated ICC was 0.54 for MRD_1, 0.33 for MRD_2 and 0.55 for PF, representing moderate, poor and moderate consistency, respectively.

Conclusion: Our data supports that the digital measurements using the present version of this technology should not be used interchangeably with manual eyelid measurements, the gold standard, as a poor agreement between the methods was found.

Keywords: Blepharoptosis; Surgery; Eyelid; Measurements; Photography.

Resumo

Introdução: Para uma correta avaliação de uma ptose palpebral, planeamento cirúrgico e *follow-up* são necessárias medições palpebrais extremamente precisas. O recurso a uma metodologia que através de fotografias faciais mede automaticamente as distâncias margem-reflexo 1 e 2 (MRD_1 e MRD_2) e abertura palpebral (PF) poderá ser a resposta para uma abordagem objetiva, exata e reprodutível.

Objetivo: Apresentar uma nova metodologia digital de medições palpebrais para a avaliação estética e funcional da ptose palpebral, e comparar a sua concordância com o método manual clássico.

Métodos: Um total de 16 olhos de 8 pacientes referenciados por ptose palpebral ao serviço de Oftalmologia do Centro Hospitalar e Universitário de Coimbra, foram avaliados na consulta pré e pós-operatória, tendo sido medidos o MRD_1, MRD_2 e PF. As medições foram feitas manualmente com uma régua, e digitalmente utilizando a máquina fotográfica Volk Eye Check. Desvios sistemáticos foram avaliados recorrendo a testes t para dados emparelhados, concordância através da construção de gráficos Bland-Altman, e consistência pelo cálculo de coeficientes de correlação intra-classe (ICC).

Resultados: As duas metodologias avaliaram eficazmente os aumentos dos parâmetros após a intervenção cirúrgica, sendo significativos os do MRD_1 manual ($p<0.001$) e digital ($p=0.003$), MRD_2 ($p=0.004$) e PF ($p<0.001$) manuais; e não significativos os do MRD_2 ($p=0.398$) e PF ($p=0.689$) digitais. Não houve desvio sistemático significativo entre as medições manuais e digitais relativamente ao MRD_1 (+0.01±1.37 mm, $p=0.961$) e houve um desvio significativo de +0.91±1.20 mm ($p=0.002$) no MRD_2 e +1.33±1.68 mm ($p=0.001$) na PF. O intervalo de confiança de 95% de [-2.675, +2.704] para o MRD_1, [-1.442, +3.267] para o MRD_2 e [-1.956, +4.621] para a PF excederam os limites clinicamente aceitáveis de ±0.5 mm para o MRD_1 e MRD_2, e ±1.00 mm para a PF. O ICC calculado foi de 0.54 para o MRD_1, 0.33 para o MRD_2 e 0.55 para a PF, representando consistência moderada, fraca e moderada, respetivamente.

Conclusão: Dada a fraca concordância observada entre as metodologias, os nossos dados sustentam que as medições digitais palpebrais recorrendo à versão atual desta tecnologia, não devem substituir o *gold standard* das medições manuais.

Palavras-chave: Ptose palpebral; Cirurgia; Pálpebra; Medições; Fotografia.

I. Introduction

Blepharoptosis is defined as the abnormal lowering or drooping of the upper eyelid, and can have different possible aetiologies. The most common ones are aponeurotic, myogenic, neurogenic and traumatic.[1-3] The ptosis can also be classified by the age of onset: congenital or acquired. It is a very common condition in the oculoplastic practice with significant functional and aesthetics implications. It may cause reduction of the visual field, ocular fatigue, feeling of a heavy lid and amblyopia. Aesthetics wise it has a considerable impact on self-esteem and can lead to depression and isolation.

Blepharoptosis surgery aims to elevate the eyelid margin, taking into consideration not only the functional results, but also the cosmetic: usually harder to obtain and evaluate. It is very important to achieve a smooth curvature, a symmetric height, symmetry of the soft tissues of the eyelid and eyebrow (such as the tarsal platform show), and to meet patients' expectations.[4] Even minor post-operative inaccuracy is significant and seen by the patient, the surgeon and others. Therefore, an accurate measurement of the eyelid parameters is fundamental to achieve the expected results.

The standard clinical assessment of each ptosis patient involves a clinical history and a physical exam performed by the oculoplastic surgeon, typically using solely a ruler and a source of light. The parameters usually taken into consideration are the Margin-reflex distance 1 (MRD_1) – vertical distance between the upper eyelid margin and the corneal light reflex; Margin-reflex distance 2 (MRD_2) – vertical distance between the lower eyelid margin and the corneal light reflex; and palpebral fissure (PF) – the vertical height between the eyelids.

Despite representing the current gold standard of care, the manual assessment has shown to have limited precision (0.50 mm), to be operator dependent, affected by the patient's movement, subjective and not consistent,[5,6] problems that limit the utility of this method.

As an extremely precise assessment is required to select the optimal surgical technique and obtain a favourable functional and aesthetic outcome, a more objective, accurate and reproducible methodology of measurement is needed. Indeed, some authors have already recognized the need for a new approach, and there have thus been a number of studies regarding semi-automated techniques. While some included measurement techniques based on the evaluation of solely one picture and relied heavily on user and computer interaction following picture acquisition,[7-10] others required complex mathematical equations limiting their applicability.[11] There have also been a few fully-automated studies, although they have involved other devices and evaluated only subjects with normal eyelid positions.[12] To our knowledge, no study has proven the clinical benefit of the Volk Eye Check oculoplastic software itself – or any fully automated methodology – in the context of ptosis surgery.

Our belief is that facial photographs with automated measurements could fill this existing gap and mitigate the above-mentioned limitations of manual measurements. Thus, our main purpose is to evaluate a digital methodology that assesses eyelid position in patients undergoing ptosis surgery, and to compare its agreement with the standard manual assessment.

II. Methods

This observational study was performed at the Ophthalmology Department of the *Centro Hospitalar e Universitário de Coimbra* following the work of two oculoplastic surgeons. All the referred patients from November 2017 until January 2019 for uni or bilateral blepharoptosis repair were prospectively observed, before and after surgery. Written informed consent was obtained from all the participants.

The protocol consisted of a manual and digital assessment, in the pre-operative and post-operative appointments (approximately one month after the surgical repair). All the digital pictures were taken by one observer, and the manual measurements were made by one experienced oculoplastic surgeon.

Clinical photographs were obtained using a commercially available camera system: the Volk Eye Check (Fig. 1). It is a handheld 16-million-pixel medical camera device with Xenox flash that captures images, in real time analyses and displays a PDF data sheet with ocular measurements. The device's algorithm uses shape, colour and surroundings of the ocular structures to determine the location of the corneal reflex (by pixel classification), to identify the main eyelid landmarks and then calculates the distances between them. It has been shown to obtain accurate objective measurements in subjects with normal lid position, highly reproducible by other examiners.(13,14)

Figure 1. Volk Eye Check device.

The camera was calibrated using 10 pictures. The patient was observed in a well-lit room, seated in front of the surgeon by approximately 50 centimetres. A calibration rectangular sticker was placed in the middle line of the forehead (Fig. 2), producing a claimed accuracy of ±1% of the measured structures. Relevant patient data, such as birthdate and gender, should be noted.

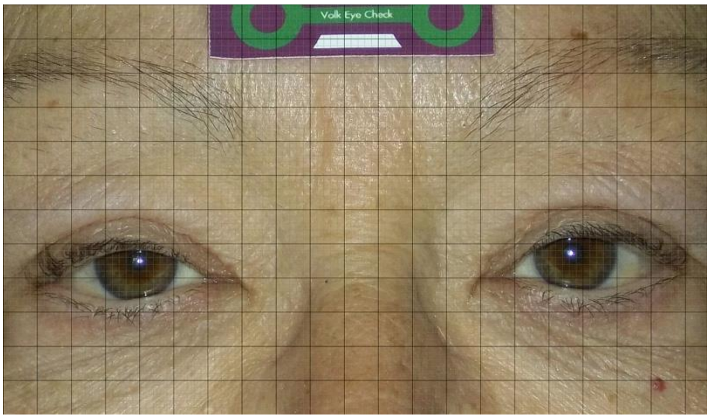


Figure 2. Gridded picture with the calibration sticker.

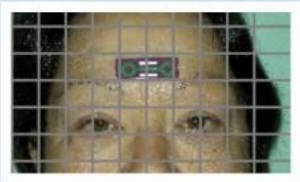
The camera should be aligned at the patient's eye level, and the subject should unequivocally maintain his gaze direction at the primary position, focusing on the centre of the camera lens. The software relies on the reflection of the flash as a basis for the measurements.

The camera indicates any errors that may arise while capturing each photo and alerts the operator to correct them (Appendix I). A sequence of 3 initial pictures were taken and if they were approved by the camera software (green check shown in the screen), no additional pictures were needed. If any of the 3 photos were rejected (red cross shown in the screen), 7 more photos would need to be taken. In the end, the camera presented a report with all the measurements (Fig. 3) of each eye, and attached the gridded pictures (Fig. 2). They were immediately transferred and stored to a Macintosh by email or by cable, and the data was converted into an Excel data sheet.

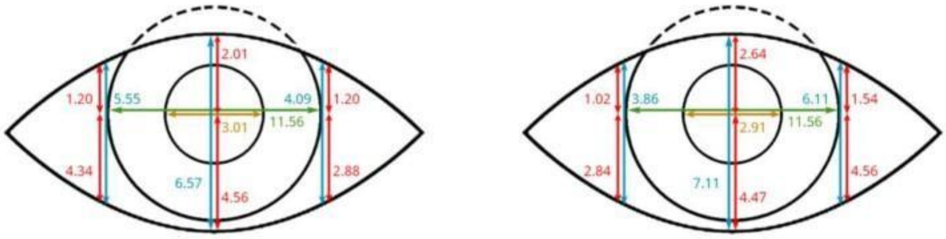
From all the morphologic data the software provided (Fig. 3), we analysed the MRD_1, MRD_2 and the palpebral fissure (palpebral aperture) measurements.

Patient Report Oculoplastics

VOLK eye check



Patient ID [redacted]
Age 64
Gender Female
Session date [redacted]



Right Eye			Left Eye	
3.01	mm	Pupil Diameter	2.91	mm
2.01	mm	MRD 1	2.64	mm
1.20 / 1.20	mm	Upper Lid at Limbus	1.02 / 1.54	mm
4.56	mm	MRD 2	4.47	mm
4.34 / 2.88	mm	Lower Lid at Limbus	2.84 / 4.56	mm
11.56	mm	Horizontal Visible Iris Diameter	11.56	mm
0.43	mm	Horizontal Pupil Eccentricity	0.32	mm
0.26	mm	Vertical Pupil Eccentricity	0.21	mm
6.57	mm	Palpebral Aperture	7.11	mm
5.55 / 4.09	mm	Aperture at Limbus	3.86 / 6.11	mm

Pupil Diameter Difference	0.10 mm
Palpebral Aperture Difference	0.54 mm
MRD 1 Difference	0.62 mm
MRD 2 Difference	0.08 mm
Light Level	67

865256009608938 Version 4.5.0

Figure 3. Volk Eye Check Oculoplastic Patient Report.

In severe ptosis patients, the Purkinje image was occluded by the lid (Fig. 4) not allowing the automated session to be completed. However, the associated JPEG image with a scale grid was stored to the computer. In those cases, we semi-automatically determined the MRD_1 value, quantifying the grid count in the digital photography (1 grid = 1 mm). These semi-automatic measurements were only used for post-operative comparisons of the MRD_1 and not for the purpose of agreement or consistency analysis, as that would add subjectivity to what should be a fully-automated measurement technique.

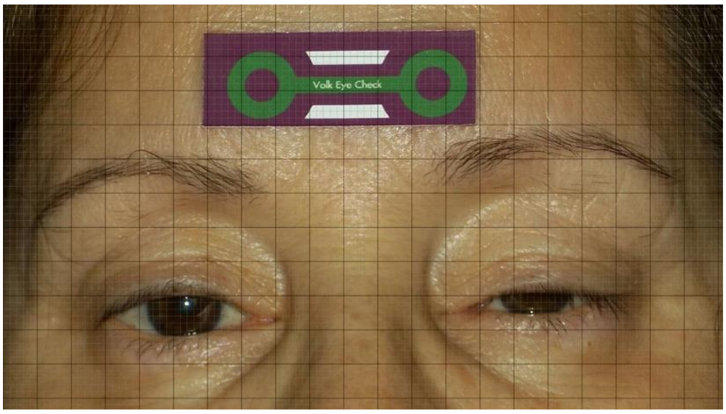


Figure 4. Gridded image of a patient with the visual axis occluded by the lid.

At the same appointment, the surgeon manually measured the MRD_1, MRD_2 and PF using a ruler.

Statistical Analysis

All analyses were performed using STATA version 14 (StataCorp, College Station, TX, USA). Continuous variables were described by mean and standard deviation (SD), if normally distributed. Categorical values were described by absolute frequencies and percentages. A paired t-test was used to compare pre-operative and post-operative measurements, as well as systematic differences between measurement methods. A p-value <0.05 was considered statistically significant and all tests were two-sided. Agreement analysis included the construction of Bland-Altman plots and the determination of the 95% confidence intervals (CI) of agreement. These were compared to pre-specified clinically acceptable limits of agreement. Finally, the intra-class correlation coefficients (ICC) estimates and their 95% confidence intervals were calculated based on a mean-rating (k=3), consistency of agreement, 2-way mixed-effects model. ICC estimate values less than 0.50, between 0.50 and 0.75, between 0.75 and 0.90, and greater than 0.90 are indicative of poor, moderate, good and excellent agreement consistency, respectively.

III. Results

From the 10 referred patients within our study period, we analysed 8 subjects (2 did not undergo surgery), performing on a total of 16 eyes. 37.5% were male and 62.5% were female. The average age was 62±9.08 years (with a range of 43-72 years). Of those 16, 13 eyes had ptosis (8 aponeurotic, 4 myogenic and 1 neurogenic) and underwent repair surgery. The most appropriate technique for each individual was performed: 3 anterior approaches (2 combined with blepharoplasty and 1 with brow lift), 2 posterior approaches combined with blepharoplasty and 5 frontalis muscle suspensions.

1. Measuring the effects of ptosis surgery

Table I. Effects of ptosis surgery in the palpebral measurements.

	Pre-operative		Post-operative		Difference	
	Manual	Digital	Manual	Digital	Manual	Digital
MRD_1	0.69 ±0.85	0.89 ±1.27	3.35 ±0.63	3.11 ±1.46	+2.65 ±0.80 (p<0.001)*	+2.22 ±2.15 (p=0.003)*
MRD_2	3.17 ±1.75	4.00 ±1.41	4.54 ±0.95	4.49 ±0.61	+1.37 ±1.40 (p=0.004)*	+0.50 ±1.01 (p=0.398)
PF	4.13 ±2.67	6.53 ±1.64	8.42 ±0.95	6.81 ±0.97	+4.29 ±2.25 (p<0.001)*	+0.28 ±1.28 (p=0.689)

(* statistically significant = p<0.05)

Following ptosis surgery, MRD_1 improved significantly, as seen in both the manual (+2.65±0.80 mm, p<0.001) and photographic evaluation (+2.22±2.15 mm, p=0.003). MRD_2 improved significantly in the manual assessment (+1.37±1.40 mm, p=0.004), and non-significantly in the photographic assessment (+0.50±1.01 mm, p=0.398). Palpebral fissure improved significantly in the manual assessment (+4.29±2.25 mm, p<0.001), and non-significantly in the photographic assessment (+0.28±1.28 mm, p=0.689) (Table 1).

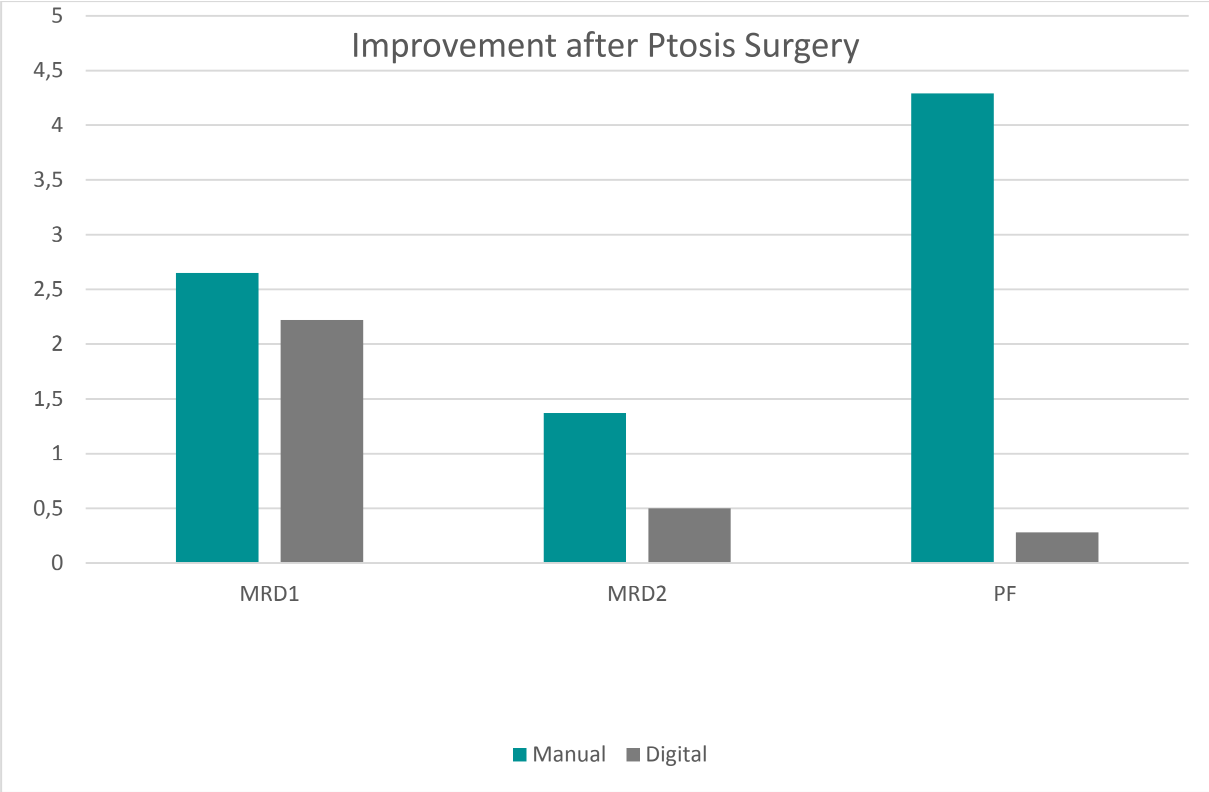


Figure 5. Improvement of the palpebral measurements after ptosis surgery.

2. Agreement analysis between manual and photographic measurements

2.1. MRD_1

The observed systematic difference between the manual and photographic measurements was non-significant (+0.01±1.37 mm, p=0.961).

We have pre-specified a clinical acceptable level of agreement of ±0.5 mm. Following Bland-Altman analysis, the 95% CI for agreement was [-2.675, +2.704] which exceeds this limit (Fig. 6).

The calculated ICC was 0.54, which corresponds to a moderate agreement consistency.

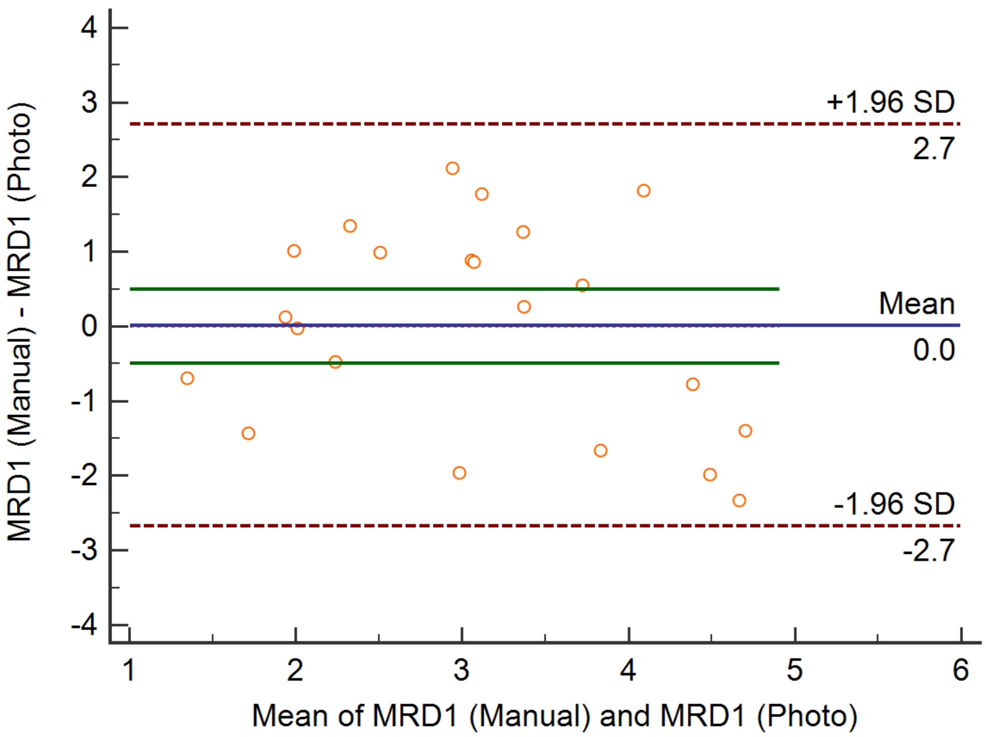


Figure 6. Bland-Altman agreement analysis between manual and digital MRD_1 measurements.

2.2. MRD_2

The systematic differences between the manual and photographic measurements were +0.91±1.20 mm ($p=0.002$), presenting the manual method with higher values than the digital method.

We have pre-specified a clinical acceptable level of agreement of ±0.5 mm. Following Bland-Altman analysis, the 95% CI for agreement was [-1.442, +3.267] which exceeds this limit (Fig. 7).

The calculated ICC was 0.33, which corresponds to a poor agreement consistency.

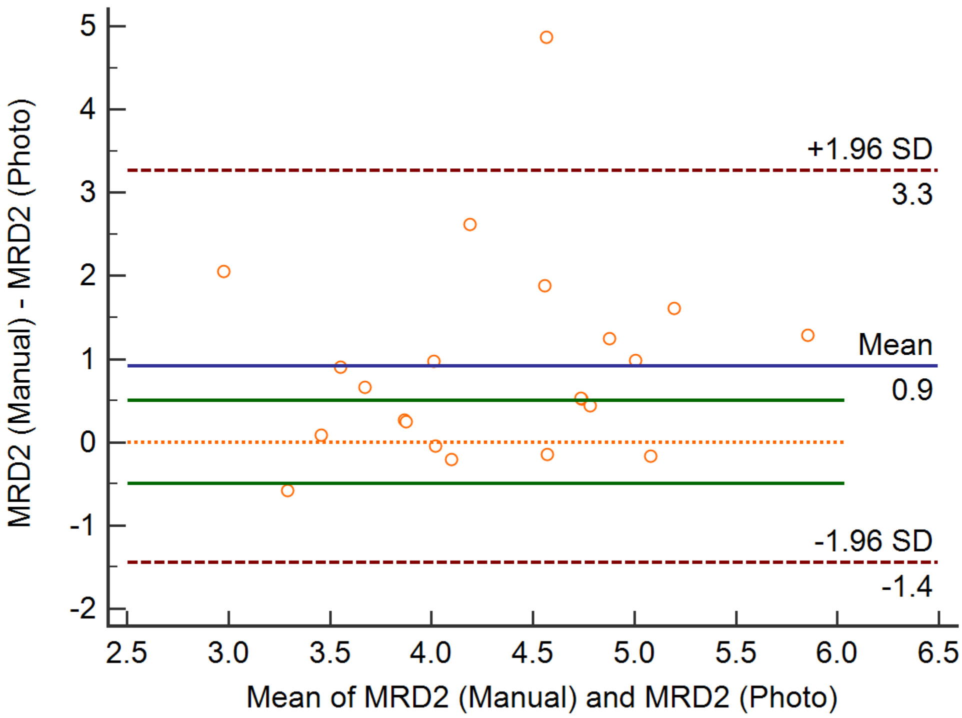


Figure 7. Bland-Altman agreement analysis between manual and digital MRD_2 measurements.

2.3. Palpebral Fissure

The systematic differences between the manual and photographic measurements were +1.33±1.68 mm (p=0.001), presenting the manual method with higher values than the digital method.

We have pre-specified a clinical acceptable level of agreement of ±1.00 mm. Following Bland-Altman analysis, the 95% CI for agreement was [-1.956, +4.621] which exceeds this limit (Fig. 8).

The calculated ICC was 0.55, which corresponds to a moderate agreement consistency.

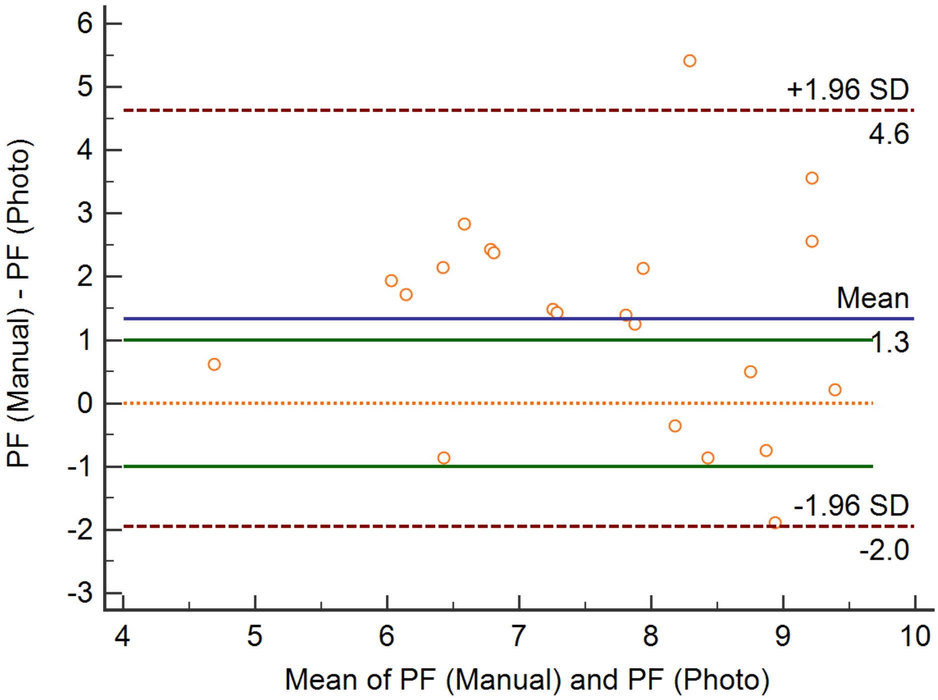


Figure 8. Bland-Altman agreement analysis between manual and digital PF measurements.

Table II. Agreement analysis between manual and photographic measurements.

	Systematic Difference (manual – digital)		**Bland-Altman Analysis**		**ICC**
	Difference	p-value	Pre-Specified	95% CI	
MDR_1	+0.01±1.37	0.961	[-0.5, +0.5]	[-2.675, +2.704]	0.54 (moderate)
MDR_2	+0.91±1.20	0.002	[-0.5, +0.5]	[-1.442, +3.267]	0.33 (poor)
PF	+1.33±1.68	0.001	[-1.0, +1.0]	[-1.956, +4.621]	0.55 (moderate)

IV. Discussion

Regarding the effects of ptosis surgery, both the manual and digital methodology were able to measure its results and efficacy, with the MRD_1 having increased significantly using the two techniques. Attending to the fact that the ptosis surgery was performed in the upper eyelid only, the MRD_2 was not expected to change significantly. That was found with the manual methodology and not with the digital, which may suggest a relative supremacy of the digital measurements. However, the non-significance of the increase of the digital MRD_2 (and also the PF) may as well result from the sample's small number, since in severe ptosis cases (5 patients – 10 eyes), the automated assay could not be run and we did not quantify the grid counts in the attached image, as we did for the MRD_1. The difference in the PF rise (significant for the manual and non-significant for the digital) may additionally be influenced by those differences encountered in the MRD_2 measurements.

We have found that the digital measurements for the MRD_2 and PF were systematically lower than when measured manually: our gold standard. Furthermore, the agreement between the two methods was not clinically acceptable for interchangeable use regarding all the three parameters, since they exceeded the margin of error that is clinically-relevant for ptosis (0.50 mm for MRD_1 and MRD_2, and 1.00 mm for PF, as more than that is already noticeable)[(5,6)]. The agreement consistency of the measurements was only poor to moderate, thus lacking reliability. Hence, the Volk Eye Check digital methodology in its current version does not seem to be able to replace the standard manual assessment.

Photography begins to play an important role in the oculoplastic pre-operative and post-operative assessment and follow-up, particularly in the context of the increased use of electronic patient records. Strong points supporting the use of a fully-automated digital methodology are the fact that it is mostly operator-independent and is easily stored in digital electronic records for future reference. It provides a considerably higher magnification compared to the manual method (0.01 mm versus 0.50 mm). It has been previously proved to be an accurate and objective methodology in individuals without eyelid pathology[(13,14)]. Additionally, the same hardware device used in this study provides other compelling data concerning contact lens' fitting, which expands its potential utility to other areas in ophthalmology.

The main limitation of the digital methodology is that it can only be used in mild-to-moderate ptosis, so long as the flash reflects on both pupils. In a public hospital setting, many patients exhibit severe ptosis, where the upper eyelid obstructs the corneal light reflex, thus inhibiting the camera software to run any check (Fig. 4). Besides, the software needs to identify the Purkinje images in both eyes, so even if only one lid covers the visual axis, the device will not run the analysis. Strabismus may be an additional limitation by displacing the corneal light reflex. Another practical drawback is the time consumed in each digital assessment, as in most cases 10 pictures were required (sometimes 20 if the first 10 were rejected). In daily clinical practises, this methodology would take around 5 to 10 minutes, instead of the 1 minute typically needed for the classical manual assessment.

Some disagreements may as well result from how to place the scale-marker on the patient's forehead, as two observers may place it differently, and as it is hard when the two eyebrows are not at the same horizontal plan. However, this problem can be overcome by selecting the software option of "no sticker placed" when filling the patient data, and manually filling in the inter-pupillary distance (distance between the centre of the right and left corneas in primary gaze).

The main constraint of our study lies in the small sample size. Further work involving a larger pool of patients would be vital to re-evaluate our hypotheses in a more expansive and diverse cohort.

The measurements in our study were made in two visits, and in each visit, the patients went through only one assessment. If a larger sample was present, it would be interesting to compare the digital and manual reports in the non-operated eyes at the two different times, or to run two or more assays in each visit. This way it would be possible to analyse the methods' reproducibility (the intra and inter-observer variability of the successive measurements): a crucial parameter to take into consideration before expanding the methodologies into clinical practice.

V. Conclusion

Manual measurements of the MRD_1, MRD_2 and PF by means of a ruler and a source of light, are currently the gold standard in the clinical assessment of ptosis and its surgical repair planning. Yet, low precision, inter-observer variability, low reproducibility and patient movement present considerable challenges that limit the value of this methodology.

We have demonstrated a proof of concept for a new, potentially-useful digital approach to ptosis evaluation, based on facial photographs. However, the digital measurements with the Volk Eye Check device did not compare favourably with the manual measurements in our analysis.

Given the limitations of our study, further work is necessary to prove Volk Eye Check oculoplastic software to be the solution in the clinical setting, that will fill the existing gap. Therefore, we do not expect our results to change the clinical practice in the near future, and despite all the referred restraints of the manual measurements of the eyelid parameters, it should remain the standard of care.

VI. Acknowledgments

I thank Dr. Guilherme Castela and Dr. Joaquim Murta for the continuous orientation and availability. I thank Dr. Miguel Raimundo for the statistical analysis assistance.

VII. Appendix I – Volk Eye Check instructions for use

Table III. Possible errors while taking the pictures. (Adapted from [15])

Error message	**Suggestion**
Zoom on face. Include both eyes.	Correct zoom setting already pre-set (Z5). Move to correct distance (50-60 cm) from patient to take photo and include both eyes.
Picture not quite in focus.	Lift finger from dual action shutter button. Re-frame patient. Half press shutter button to achieve green focus lock. Repeat half press process if red focus lock appears to achieve a green focus lock.
Face may be tilted.	Readjust patient head position until straight in primary position.
Subject too bright or too far away.	Reduce lighting or move closer to patient.
Too close, move away.	Move further away from patient and retake photo.
Too far, move closer.	Move closer toward patient and retake photo.
Subject not looking at target.	Retake photo and encourage patient to focus on fixation target.
Room too bright.	Reduce room illumination.
Eyes closed or unwanted reflections.	Encourage patient to keep eyes open or relocate patient to an area free from mirrors, large windows and extra reflections.

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