Evaluation of a disposable prism for applanation tonometry

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CLINICAL STUDY

Abstract

Background **Recently the Medical Devices Agency recommended that 'ophthalmic devices that touch the surface of the eye should be restricted to single use'.**

Aim **To evaluate one such device: a disposable tonometer prism for routine applanation tonometry.**

Methods **The intraocular pressure (IOP) of 100 consecutive patients from a general eye clinic (197 eyes) was measured with both a disposable and the standard Goldmann tonometer (Goldmann). The level of agreement between the two methods of clinical measurement was assessed and the sensitivity and specificity of the disposable prism in detecting clinically significant raised IOP estimated.**

Results **The mean difference in IOP measured by the two different prisms was 0.44 mmHg with a standard deviation (SD) of 1.54. The mean IOP for the disposable prism was 19.51 mmHg (SD 6.53 mmHg). The mean IOP for the standard Goldmann tonometer prism was 19.07 mmHg (SD 6.64 mmHg). The sensitivity to detect IOP > 21 mmHg was 95.9% (95% confidence interval (CI): 86.0–99.5%) and the specificity of 93.9% (95% CI: 88.8–97.2%). It gave a positive predictive value of 83.9% (95% CI: 71.7–92.4%).**

Conclusion **There was close agreement between the IOP measurements obtained by the disposable tonometer prism and the Goldmann device for high and low pressures. If replicated, the high sensitivity and specificity would justify its use in screening.**

Key words Cross-infection, Disinfection, Intraocular pressure, Tonometry

The risk of cross-infection, especially of viral infections, from one patient to another is always a concern to both ophthalmologists and optometrists. Previous reports of spread of infection through ophthalmic devices have been of adenovirus,[1,2] but theoretically hepatitis C, human immunodeficiency virus, variant Creutzfeldt–Jakob Disease (vCJD) and *Acanthamoeba* can spread through contact instruments. A variety of disinfecting methods exist, but none of them eliminates the risk totally.[3] In October 1999 the Medical Devices Agency (MDA), an executive body of the Department of Health in the UK, sent out a notice that 'components of ophthalmic devices that touch the surface of the eye should be restricted to single patient use wherever practicable and where this does not compromise clinical outcome'.[4] This prompted a debate on the risk of cross-infection and the feasibility of implementation of that recommendation. Are such devices available? Are they reliable? In this study we attempted to validate a single-use disposable Goldman-style tonometer prism recently made available.

Materials and methods

Patients

Intraocular pressure (IOP) of 197 eyes of 100 consecutive patients who attended the general ophthalmic clinic was checked with both the Goldmann applanation tonometer (Goldmann) and a disposable tonometer prism by two experienced examiners after obtaining informed consent. No adult patient was excluded because of age, sex or race except by the exclusion criteria (see below). The study was performed over a 2 week period.

The disposable prism

The device (Tonosafe, Clement Clarke) consists of two parts: (1) a precision-moulded holder, into which is slotted (2) the disposable applanating prism (Fig. 1) whose doubling effect is within proposed International Standards. The combined mass of the holder and the prism is the same as the standard Goldmann prism (1.65 g ± 0.05 g). The holder is made of ABS material (acrylonitric butadiene styrene) and the prism of clear acrylic with Nd(refractive index) = 1.4910. Each tray supplied by the manufacturer contains 20 disposable sterile prisms and one prism holder. To check the IOP the holder is removed from the packing and its narrow end placed over the prism to engage it. The other end is mounted on the vertical arm of the Goldmann apparatus. The applanating surface of the prism, which

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This paper was presented orally in an abridged form at the Eighth Scarborough Eye Symposium, 16 June 2000

Competing interests: None. The authors have no financial or other interests in any of the products mentioned

Received: 15 August 2000
Accepted in revised form: 15 December 2000

Fig. 1. *Disposable prism (Tonosafe) and the holder.*

comes in contact with the tear film, has the same diameter as that of the Goldmann and the prism is for single use, but the holder can be re-used.

Methods

The IOP of the first 50 patients was checked with the Goldmann tonometer prism and then by the disposable prism. For the remaining 50 patients, the order was reversed to eliminate any error introduced by the first instrument. The IOP was checked on the slit-lamp after instilling a drop of proxymetacaine hydrochloride 0.5% and fluorescein sodium 0.25% from a preservative-free single-dose Minims into the eye. Care was taken to avoid errors of repeated tonometry.[5] To eliminate the risk of bias the slit-lamp breath shield was masked[6] so that the observer was unaware of the first reading when taking the second. For each measurement, the first observer adjusted the tonometer dial, and a second observer read the tonometer scale and recorded the IOP. There was no pre-selection of patients in relation to their previous IOP. Children and patients with corneal pathology were excluded from the study.

Table 1. *Comparison chart: disposable prism versus the Goldmann tonometer*

Applanating prism	No. of eyes	Mean IOP (mmHg)	Standard deviation	Range (mmHg)
Disposable	197	19.51	6.53	8–48
Goldmann	197	19.07	6.64	8–50

Results

Table 1 compares the readings produced by the two methods. The mean difference in the IOP between the two prisms was 0.44 mmHg (standard deviation 1.54 mmHg). The data were analysed using the method described by Bland and Altman[7] for assessing agreement between two methods of clinical measurement. Fig. 2 shows the differences between the disposable prism and the Goldmann readings plotted against the average of the two readings. The middle horizontal line represents the mean difference (0.44 mmHg) and the range of 2 standard deviations from the mean is shown by the dotted lines. Ninety-five per cent of the readings fall between the two dotted lines, that is, between –2.6 mmHg and +3.5 mmHg. In other words, the disposable prism read on average 0.44 mmHg higher than the Goldmann and 95% of the time read between

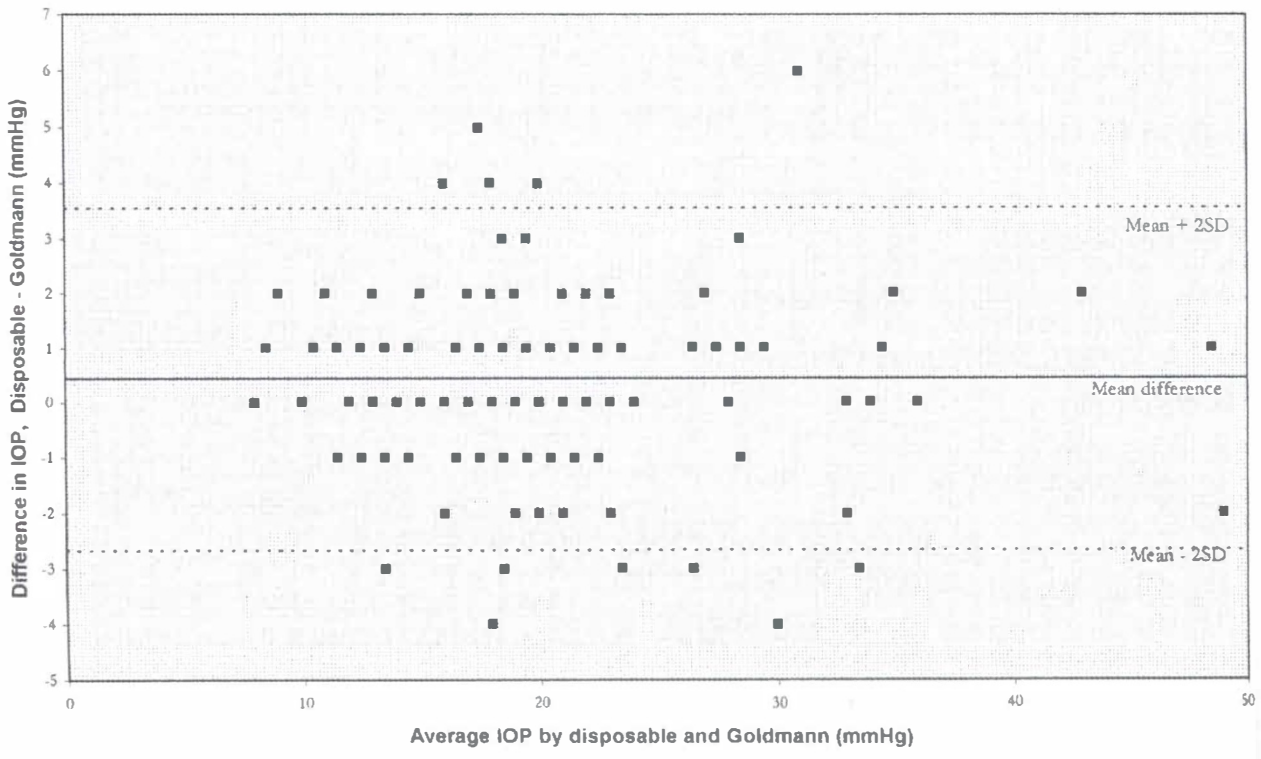

Fig. 2. *The difference between the Tonosafe and Goldmann readings plotted against the average of the two readings (Bland and Altman method[7]). Dotted lines represent 2 standard deviations (SD) on either side of the mean. Some data points represent measurements from two or more eyes.*

Table 2. *Diagnosing IOP > 21 mmHg using the disposable prism versus the Goldmann tonometer*

IOP measured by Goldmann	IOP measured by the disposable prism		
	≤ 21 mmHg	≥ 21 mmHg	Total
≤ 21 mmHg	139	9	148
> 21 mmHg	2	47	49
Total	141	56	197

Values are the number of eyes.
Sensitivity: 95.9% (95% CI: 86.0–99.5%).
Specificity: 93.9% (95% CI: 88.8–97.2%).
Positive predictive value: 83.9% (95% CI: 71.7–92.4%).

2.6 mmHg below and 3.5 mmHg above the Goldmann reading. The largest difference occurred when the disposable prism read 6 mmHg higher than the Goldmann. The figure shows that the differences were scattered consistently; there is no suggestion that readings of very high IOP tend to be subject to any greater error than those of 'normal' IOP levels.

The 'two by two' table (Table 2) shows how the disposable prism performed when compared with the 'gold standard' Goldmann in detecting IOP higher than 21 mmHg. Of 49 eyes with the IOP > 21 mmHg according to the Goldmann tonometer, only 2 were missed by the disposable prism, representing a sensitivity of 95.9%. Of the 148 eyes measured as ≤ 21 mmHg by the Goldmann, 9 were measured as > 21 mmHg by the disposable prism (specificity = 93.9%). The positive predictive value (PPV) was 83.9%, that is of patients identified as having IOP > 21 mmHg by the disposable device, 83.9% had this confirmed by the Goldmann. See Table 2 for the 95% confidence intervals.

Discussion

This study has shown that the recording of IOP by the disposable tonometer prism (Tonosafe) is comparable with that by the standard Goldmann prism across the wide range of IOPs encountered in routine clinical work. Looking at the style, weight and design of the prism assembly one would expect it to give measurements of IOP similar to the Goldmann, but it has to be validated in clinical use. As far as we are aware this has not been done before. The errors of measurement for the disposable prism appear to be very small. On average the readings by the disposable prism were only 0.44 mmHg higher than the Goldmann. In addition, it had 95.9% sensitivity (and 93.9% specificity) in identifying IOPs of higher than 21 mmHg. This, combined with a high PPV of 83.9%, makes it acceptable as a useful measuring device.

To accord with the advice published by the MDA,[4] ophthalmologists should review their clinical practice and take measures to avoid risks of cross-infection. With this in mind, the use of non-contact tonometers, and tonometers with disposable contact devices, should be considered. In a recent review Lueck *et al.*[8] discussed the risk in detail and leant their weight in favour of disposable tonometer heads in routine applanation tonometry. It has been shown that because of the deterioration in the accuracy of the Pulsair tonometers through repeated use, regular recalibration is needed.[9] If applanation is the preferred method of tonometry in one's practice, a thorough disinfection policy has to be adopted. Chemical methods of disinfection of the Goldmann-type tonometer are time- and labour-intensive.[3] Incomplete removal of micro-organisms, damage to the instrument tip and irritation to the skin from handling are other disadvantages of these methods of disinfection.[10] They may even be ineffective.[8] The choice may lie between a sterile, disposable silicone tonometer shield (Tonoshield, Oasis Medical, Glendora, CA) and the disposable tonometer prism. Maldonado *et al.*[10] found that the disposable shield over-read the true IOP by 1.9 mmHg on average which, they claim, was similar to the intraobserver variation of 1.5 mmHg. In another study[11] the inter-observer variation was even higher. In our study, the disposable tonometer over-read the true IOP by 0.44 mmHg. The disposable prism, as shown in this study, detects eyes with an IOP greater than 21 mmHg with a sensitivity of 95.9% and a specificity of 93.9%. In Maldonado's study[10] the sensitivity and specificity were 96.3% and 68.8% respectively.

The disposable prism is more expensive than the silicone shield; just over 70 pence each compared with 33 cents (as quoted by the USA suppliers) for a silicone shield (information supplied to the author (S.P.D.) by the respective companies). Although it adds to the cost of an outpatient consultation, it amounts only to the price of two units of a single-use local anaesthetic eye-drops (*British National Formulary*, 40th edition, September 2000). In the case of the disposable silicone shield, one has to take care not to touch the front surface of the shield whilst it is being applied to the Goldmann prism, a process requiring some skill. Moreover, it adds slightly to the weight of the assembly, which might affect the accuracy of the reading. The disposable prism was very easy to slot into the holder once the cover was peeled off to expose the prism. It was easy to view the fluorescein semi-circles as the prism itself was made of clear acrylic material. Repeated measurements were not required, thereby eliminating an error introduced by repeated tonometry, which can decrease the IOP[5] (the order of the prism used was reversed for half of the subjects to eliminate any bias). The leaflet accompanying the disposable prism states: 'it is not intended that it should replace the standard Goldmann prism for quantitative clinical work, but is suitable for screening and checking'. The present study would suggest that it fulfils the latter aim.

In conclusion, the readings recorded with the disposable prism were marginally higher than those with the standard Goldmann prism. They were consistently reliable for 'normal' as well as high IOPs. This was a pilot study and further studies on larger numbers of patients and by different examiners will be required if routine use of the disposable prism is to be justified on terms of reliability, safety and cost. However, if replicated in the

appropriate setting, the high sensitivity and specificity would validate its use in screening patients at known risk of high IOP.

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