HAAG-STREIT INTERNATIONAL

White Paper

Compliance of Tonosafe® disposable prisms for Goldmann Applanation Tonometry (GAT) with the relevant ISO Norm and with Haag-Streit internal quality standards.

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Abstract:

Tonosafe® was tested by Haag-Streit and is recommended for use with all Haag-Streit Goldmann and Perkins applanation tonometers.

The parameters correlate closely to the HAAG-STREIT quality standard and meet the ISO 8612 standard. The optical and mechanical quality of Tonosafe® is acceptable but not as good as the Haag-Streit reusable prism. An angle scale on the prism holder would significantly facilitate the horizontal adjustment and the angular IOP measurement on astigmatic corneas.

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1 Purpose

To assess the quality of Tonosafe® disposable prims according to ISO 8612 and Haag- Streit quality standards for reusable Goldmann measuring prisms.

2 Methods

Tonosafe® (Haag-Streit UK, Harlow, UK) from two different LOT numbers (A27336 - 08 (1), B28702-12 (2)) has been tested internally with Haag-Streit standard test methods.
The front surface flatness was measured by an accredited test laboratory using a HeNe-Laser at a wavelength of λ = 633nm. The interference fringes were recorded on video and analyzed with computer systems.
The images of the applanation semicircles were taken during the IOP measuring process in the University Eye Clinic in Basel, using a Haag-Streit Imaging Module IM 900 on a Slit Lamp BQ 900.

3 Results

Table 1: Dimensions of mechanical parts

	Haag-Streit reusable prism	***Tonosafe®***	***ISO 8612 Norm (for comparison)***
Weight (g)	1.60 – 1.70	1.65 – 1.67 (1) 1.64 – 1.65 (2)	Reverse span 0.49 mN
Diameter front surface (mm)	7.00 +/- 0.05	6.50 – 6.65 (1) 6.50 – 6.70 (2)	At least 6.0
Diameter of applanation circle (doubling prism) (mm)	3.06 +/- 0.02	n/a	3.06 +/- 0.02
Length of prism inside which influences the diameter of the applanation circle (doubling prism)	To the middle: 8.31 To the edge: 9.93	8.26 – 8.56 (1) 8.36 – 8.40 (2) 9.81 – 10.21 (1) 9.98 (2)	

(1) (2) different LOT of Tonosafe

Table 2: Mechanical and optical quality of doubling prism and holder

	Haag-Streit reusable prism	***Tonosafe®***	***ISO 8612 Norm (for comparison)***
Doubling prism	Transparent. Front surface smooth. Outer edge smoothed.	Outer edge smoothed. Front surface smooth but with slight inclusions and scratches. Also slightly opaque. Breakpoint from	Surface smooth of touch. Free from surface imperfections (fissures, cracks,

		casting poorly finished.	dents). Outer edge smoothed.
Holder (prism body)	Nicely and smoothly finished. Angle scale (0–180°).	Finish OK but sometimes fringed edges. No angle scale.	
Flatness front surface Mean peak to valley deviation (P-V) (µm) and min/max P-V over a central area of 4 mm	n = 30 Mean P-V = 0.33 Min/Max P-V = 0.12 / 0.46	n = 10 Mean P-V = 1.07 Min/Max P-V = 0.7 / 1.6	Mean peak to valley deviation over a central area of min. 4 mm P-V < 3.0

Figure 1: Image quality of applanation semicircles during IOP measuring

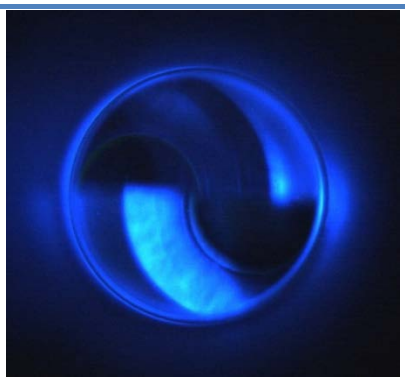
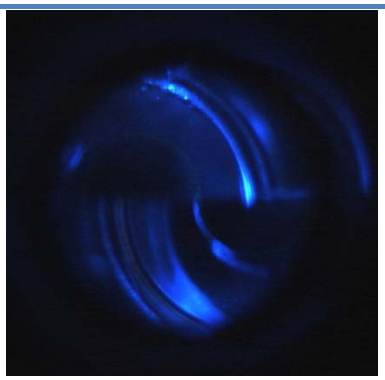
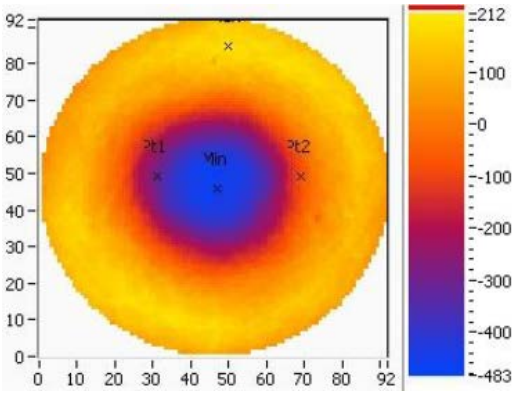
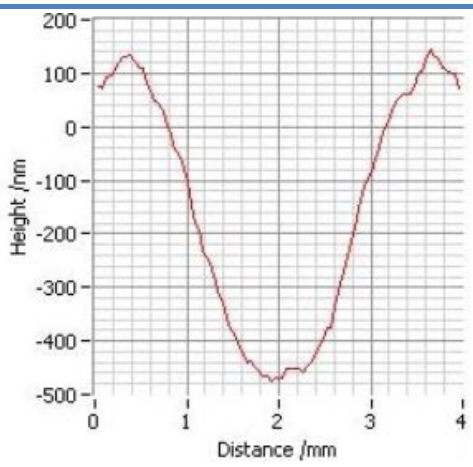
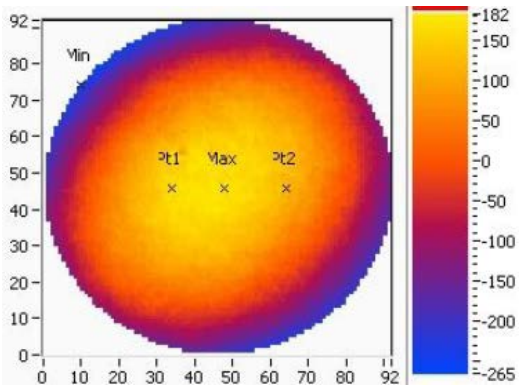
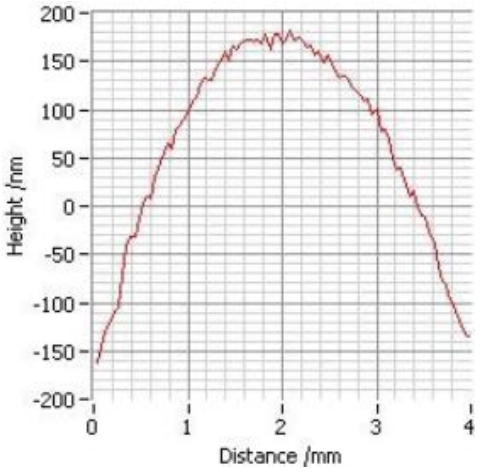
Haag-Streit reusable prism	***Tonosafe®***
	

Table 3: Visualization and analysis of interference fringes and horizontal cross section calculation

	Interference fringes / Scale in nm	**Calculation of horizontal cross section Pt1 to Pt1 in nm**
Tonosafe®		

Haag-Streit reusable prism		

4 Discussion

4.1 Tonosafe

Tonosafe® is designed as a disposable prism to eliminate the risk of cross infection. Tonosafe® is precision moulded and is intended for use with Goldmann and Perkins applanation tonometers. It fits to the workflow in daily clinical practice and avoids the necessity of cleaning and disinfecting of reusable applanation measuring prism [3].

Before each IOP measurement a prism, which is packed in a blister, must be placed precisely on the prism holder.

4.2 Haag-Streit reusable measuring prisms

The original Haag-Streit reusable measuring prisms is a precision made reusable accessory to the Goldmann applanation tonometer with remarkable optical and mechanical quality.

This allows for fast and reliable IOP measurements. The prisms are largely handmade (PMMA) by experienced workers and checked for low tolerances in weight, optical quality, durability and for consistent measurement results. To reduce the risk of cross infection, the measuring prims must be disinfected after each measurement.

4.3 Optical and mechanical quality of Tonosafe®

The optical and mechanical quality of Tonosafe® is not as good as the high quality of the Haag-Streit reusable measuring prisms. Nevertheless, the quality of Tonosafe® is sufficient to get a comparable reproducibility in IOP measurement as with the original Haag-Streit measuring prisms[1][2][3].

4.3.1 Tolerance of the weight

The tolerance of the weight is defined by the reverse span, which means the change of force required to move the tonometer head of a calibrated tonometer in the opposite direction. Both Tonosafe® and Haag-Streit reusable prisms meet the ISO 8612 standard.

4.3.2 Diameter of the applanation circle

The diameter of the applanation circle is critical, as during the IOP measurement, a diameter of 3.06 mm is to be applanated. On the Haag-Streit measuring prims, the diameter of the applanation circle is precisely controlled using an image processing system. Due to optical distortion and different shape of the Tonosafe® prism, the diameter of the applanation circle could not be accurately determined with the available test methods like gauge and vision system.
Therefore the parameters of the Tonosafe® prism (length), which influence the diameter of the applanation circle, had to be measured. The variance of the measured values of the length of the Tonosafe prism could possibly be a reason for the slight deviation of the accuracy as compared to the GAT, using the Haag-Streit reusable measuring prisms[1][2].

4.3.3 Flatness of the front surface

The flatness of the front surface of Tonosafe® is very precise and well below the limits required by the ISO 8612 standard. The mean peak to valley deviation is only 1/3 of the ISO standard value. Even the maximum measured deviation is 50% below the standard.
Due to the polished surface of the Haag-Streit reusable prism, the flatness of the front surface is more accurate than with Tonosafe®.

4.3.4 Image quality

The image quality of the semicircles of Tonosafe® is not as good as with the original Haag-Streit measuring prism but acceptable for reproducible IOP measurement. The reduced image quality may lead to impaired usability and speed in daily practice.

4.4 Angle scale

According to the Haag-Streit Instructions For Use for the Goldmann applanation tonometer[4], IOP measurement on the horizontal meridian is most accurate if the cornea astigmatism is less than 3 diopters. On corneas with astigmatism higher than 3 diopters, the diameter of 3.06 mm is to be applanated when the measuring prism is at an angle of 43° to the flattest meridian. It has been shown in routine clinical practice that the engraved and white painted angle scale on the Haag-Streit reusable measuring prism allows for fast and accurate horizontal and angular alignment. Because of the missing angle scale on Tonosafe® the exact horizontal and angle alignment is not possible.

References

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