

SCIENTIFIC REPORT 2

"REPORT of the reference IOP measurements performed with tonometer "Easyton", with the use of a Goldman tonometer as referents standard

The purpose of the study: analysis of the range of indications of intraocular pressure (IOP) in comparison with measurements made by a standard application tonometer, such as Goldman's tonometer according to ANSI Z80.10-2014 standard (with the exception of: within Annex B: (5.3 last paragraph); 5.5; 7.2)

Research method:

Simultaneous measurement of IOP tonometer Easyton No. 00005 and Goldman's reference tonometer Z0009 No. 06112635.

The study was conducted in the IPO "Glaucoma Society" in the period from 11.11.2018 to 30.01.2019 in 156 patients (eyes). For each subject, IOP was measured with Goldman's tonometer and tonometer "EAYTON" only on each subject's right eye.

Total 156 reference IOP measurements were performed in 3 IOP ranges:

1. In the range of 7 up to (and including) 16 mmHg : 46 measurements;;
2. In the range above 17 up to (and including) 23 mmHg : 40 measurements;
3. In the range above 23 mmHg : 40 measurements

Including 30 measurements: 10 highly astigmatic eyes (>3 D of corneal astigmatism) each in the low, medium and high IOP ranges. The result of the measurements were grouped according to the 3 above mentioned ranges and enlisted in the Records below.

Records of the reference IOP measurement performed tonometer "Easyton" with a Goldman tonometer as reference standard (main group)

Under 17 mm Hg					
Nº	Goldman tonometer	EASYTON	Nº	Goldman tonometer	EASYTON
1	14	13	31	13	15
2	16	15	32	13	16
3	16	17	33	12	14
4	14	15	34	13	15
5	16	18	35	15	13
6	13	15	36	14	16
7	16	15	37	14	16
8	16	17	38	14	16
9	16	16	39	14	14
10	16	16	40	8	10
11	16	18	41	13	12
12	16	18	42	13	12
13	16	19	43	14	14
14	14	14	44	15	16
15	15	16	45	10	11
16	14	15	46	16	18
17	16	16			
18	16	18			
19	12	13			
20	15	17			
21	16	17			
22	16	16			
23	16	16			
24	16	18			
25	16	15			
26	16	17			
27	15	14			
28	15	14			
29	14	17			
30	16	14			

Records of the reference IOP measurement performed tonometer "Easyton" with a Goldman tonometer as reference standard (main group)

17-23 mm Hg					
Nº	Goldman tonometer	EASYTON	Nº	Goldman tonometer	EASYTON
1	22	22	31	18	20
2	18	20	32	21	19
3	22	20	33	19	19
4	18	15	34	19	22
5	18	15	35	17	14
6	22	22	36	23	24
7	20	21	37	21	22
8	18	17	38	21	23
9	20	21	39	20	20
10	18	17	40	21	20
11	18	15			
12	18	19			
13	22	24			
14	18	15			
15	22	23			
16	23	24			
17	19	21			
18	22	19			
19	17	17			
20	18	21			
21	23	23			
22	21	20			
23	20	19			
24	17	17			
25	19	19			
26	22	20			
27	21	20			
28	20	22			
29	21	22			
30	23	20			

Records of the reference IOP measurement performed tonometer "Easyton" with a Goldman tonometer as reference standard (main group)

Above 23 mm Hg					
Nº	Goldman tonometer	EASYTON	Nº	Goldman tonometer	EASYTON
1	29	30	31	32	32
2	30	31	32	26	25
3	48	49	33	34	29
4	36	33	34	33	34
5	26	28	35	29	30
6	30	29	36	26	27
7	38	35	37	30	29
8	34	31	38	32	29
9	28	27	39	26	27
10	26	25	40	38	36
11	34	33			
12	28	27			
13	31	29			
14	31	32			
15	34	35			
16	32	33			
17	26	25			
18	28	27			
19	27	30			
20	40	42			
21	42	44			
22	28	33			
23	24	21			
24	30	29			
25	25	22			
26	38	39			
27	27	29			
28	28	33			
29	37	44			
30	40	42			

Records of the reference IOP measurement performed tonometer
 "Easyton" with a Goldman tonometer as reference standard
 (astigmatic group)

Under 17 mm Hg		
Nº	Goldman tonometer	EASYTON
1	15	16
2	10	11
3	13	13
4	12	13
5	15	14
6	13	15
7	13	13
8	15	17
9	14	16
10	15	16

Records of the reference IOP measurement performed tonometer
 "Easyton" with a Goldman tonometer as reference standard
 (astigmatic group)

17 - 23 mm Hg		
Nº	Goldman tonometer	EASYTON
1	20	19
2	16	16
3	19	22
4	20	18
5	19	18
6	21	22
7	24	26
8	20	20
9	23	23
10	17	18

Records of the reference IOP measurement performed tonometer "Easyton" with a Goldman tonometer as reference standard (astigmatic group)

Above 23 mm Hg		
Nº	Goldman tonometer	EASYTON
1	39	43
2	38	37
3	24	23
4	25	24
5	28	29
6	30	32
7	27	29
8	35	39
9	34	33
10	24	27

Analysis of results in accordance with paragraph 5 of the FDA recommendations

The graphical presentation of comparative test results for main group is given in Fig. 1.

The linear regression formula based on the result of the test appears as follows:

$$P_{tvgd} = P_g * 0.978 + 0.739;$$

Where:

P_{tvgd} – IOP according to Easyton;

P_g – IOP according to Goldman tonometer;

Pearson correlation coefficient - 0.97.

Root-mean-square deviation - 1.94.

Slope of the regression line - 0.978.

Displacement of the regression line - 0.25 average for Bland-Altman (Bias), and initially coordinates 0.739.

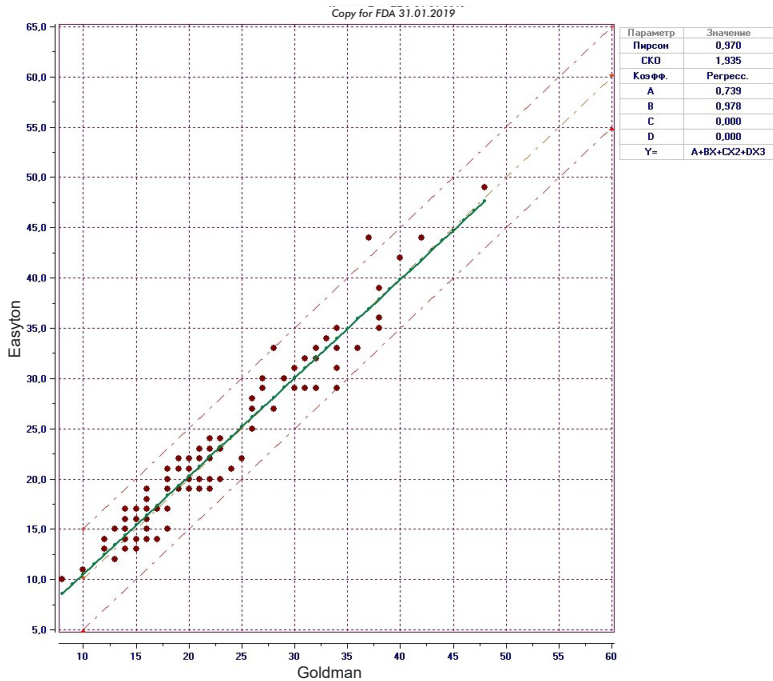


Fig 1. Scatter plot of measured IOP values (main group)

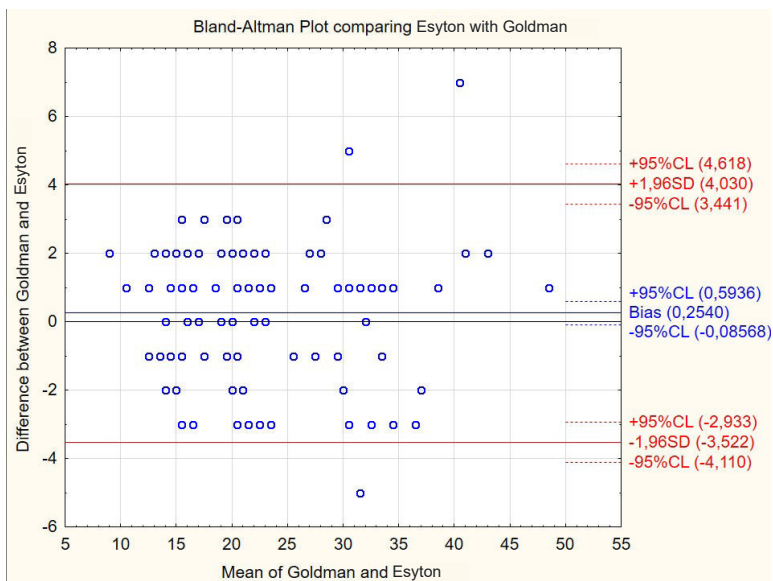


Fig. 2. Bland-Altman type plot (main group))

The graphical presentation of comparative test results astigmatic group is given in Fig. 3.

The linear regression formula based on the result of the test appears as follows:

$$P_{tvgd} = 1.035P_g + 0.06;$$

Where:

P_{tvgd} – IOP according to Easyton;

P_g – IOP according to Goldman tonometer;

Pearson correlation coefficient - 0.982.

Root-mean-square deviation - 1.751.

Slope of the regression line - 1.035.

Displacement of the regression line - 0.83 average for Bland-Altman (Bias), and initially coordinates 0.06.

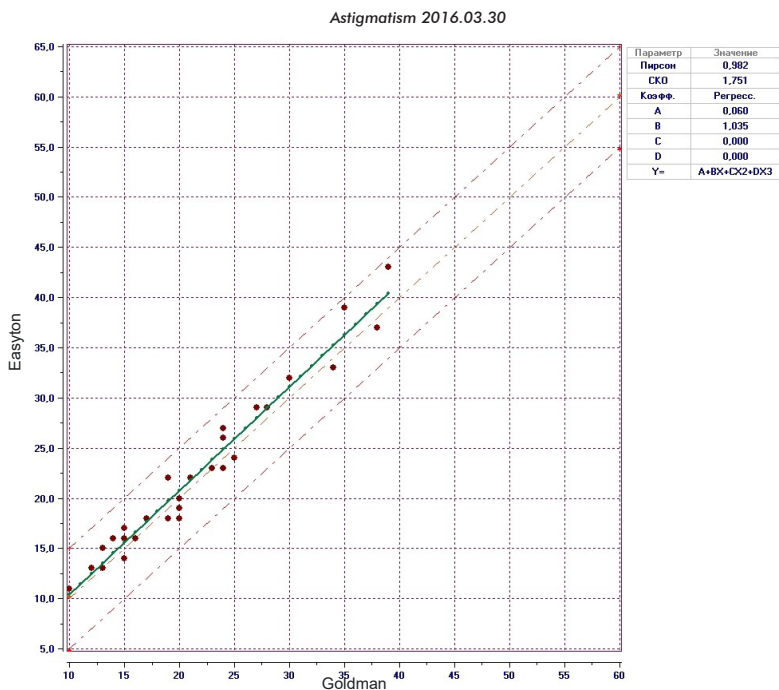


Fig 3. Scatter plot of measured IOP values (astigmatic group)

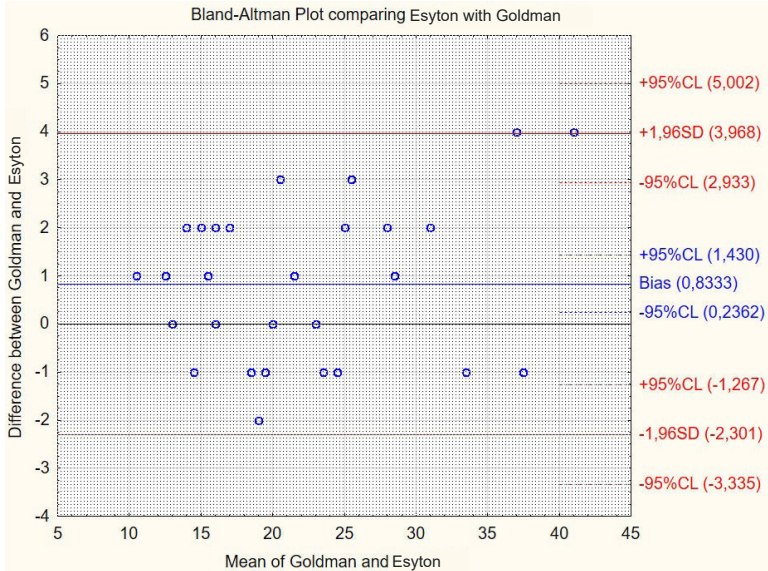


Fig. 4. Bland-Altman type plot (astigmatic group)

Comparability with a Goldman-type tonometer

The measurement results tonometer "Easyton" have a high correlation with the results tonometer Goldman. This indicates a high repeatability and reproducibility of tonometer "Easyton".

Deviations [reference tonometer measurement] - [measurement of Easyton], exceeding the permissible deviations in accordance with ANSI Z80.10-2003, were not revealed.

Conclusion:

The obtained results meet the requirements of the document "Guidance for Industry and FDA Staff. Tonometers – Premarket Notification [510(k) Submissions]"

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