ORIGINAL ARTICLE

Aqueous Outflow Facility after Periocular Triamcinolone Injection: A Preliminary Evaluation of the Falck Medical Applanation Tonometer

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Abstract

Aim: To evaluate the Falck Medical Applanation Tonometer 1 (FMAT-1) as a device for measuring intraocular pressure (IOP) and outflow facility (OF) in patients with uveitis after periocular triamcinolone injection in one eye.

Materials and methods: Retrospective observational comparison. IOP and OF measurements were recorded and analyzed, comparing Goldmann tonometry and FMAT-1 readings. Records were reviewed for adult patients with uveitis who had undergone recent periocular triamcinolone injection in one eye.

Results: A total of 19 patients' records were evaluated. In treated eyes, median IOPs (in mm Hg) by Goldmann and FMAT-1 were 21 and 21.0, respectively, and mean IOPs were 22.21 and 21.15, respectively. In untreated eyes, median IOPs by Goldmann and FMAT-1 were 15 and 15.7, respectively, and mean IOPs were 15.52 and 15.31, respectively. Median OF (in µL/mm Hg) in treated and untreated eyes was 0.17 and 0.22, respectively, and mean values were 0.17 and 0.23, respectively. Pearson correlation showed an inverse relationship between IOP and OF in treated eyes, and linear regression analysis showed that IOP strongly predicted outflow in this group.

Conclusion: The FMAT-1 generates IOP results substantially similar to Goldmann and OF readings with greater ease than prior tonography devices.

Clinical significance: The mechanism of corticosteroid-induced IOP elevation appears to be a reduction in aqueous OF, and its measurement is tonography. This technique has traditionally been cumbersome. FMAT-1 is a newly launched instrument that measures IOP and OF at the slit lamp simultaneously in a few seconds.

Keywords: Glaucoma, Goldmann, Outflow facility, Tonography, Triamcinolone, Uveitis.

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Introduction

Intraocular pressure (IOP) elevation is the most well-recognized risk factor in glaucoma, and aqueous humor outflow facility (OF) is the principal determinant of IOP.[1] IOP reduction is currently the only effective treatment for all forms of glaucoma.[2] IOP measurement is termed tonometry, and the global standard and probably the most commonly used device is the Goldmann tonometer.[3] The device is slit-lamp mounted and works by pressing against the anesthetized cornea and measuring resistance. Goldmann tonometry appears to be affected by corneal thickness variations in a linear fashion, such that readings may require adjustment based on corneal thickness in order to determine actual IOP.[4]

Most aqueous humor outflow from the eye traverses the trabecular meshwork,[5] the remainder exiting *via* the uveoscleral route.[6] Aqueous humor outflow through the conventional (trabecular) pathway is known as OF, and its measurement is termed tonography.

The significance of OF has remained incompletely understood, and this parameter has not achieved a place in clinical practice, largely because tonography has traditionally been technically cumbersome and, thus, has been limited to the research setting. Tonography was originally developed in the 1940s;[7] the most commonly employed devices being Schiotz, pneumotonography, and the Mackay–Marg tonometer's tonography function. Schiotz tonography involves having the patient lie supine, then placing a plunger on the ocular surface and measuring resistance of the eye against the force of gravity on the plunger; this resistance then forms the basis for calculating aqueous outflow.[8] Pneumotonography involves subjecting the eye to a directed burst of air and then measuring resistance to this burst to achieve a similar basis for calculating OF.[9] The Mackay–Marg tonometer measures OF by electronically calculating resistance over time to a microplunger pressed against the eye. Neither pneumotonography nor Mackay–Marg tonography relies on the force of gravity, so they can be performed with the patient sitting upright.[10] All of these techniques require bulky equipment and are time-consuming and difficult for patients; none lends itself to ready application for clinical purposes.

Therapeutic use of corticosteroids to treat eye disease began in the early 1950s, and within a decade, it was quite clear that

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this therapy resulted in IOP elevation.[11,12] By 1965, Armaly had defined three distinct subgroups of severity of corticosteroid hypertensive response.[13] The term "steroid responder" was coined in the same year and remains in common use.[14] IOP elevation following corticosteroid therapy has been well-documented by all routes of application, including topical, systemic, intravitreous, and periocular injection.[15,16] Younger age and higher baseline IOP have been identified as risk factors for corticosteroid-induced IOP elevation.[17]

The mechanism of corticosteroid-induced IOP elevation appears to be a reduction in OF. Bernstein and Schwartz in 1962 found mean outflow significantly decreased in 48 patients receiving long-term systemic corticosteroids.[18] In 1963, Armaly showed that steroid-induced IOP elevation may be the result of increased aqueous humor outflow resistance, although the exact mechanism remains unknown.[19] Data from animal studies are supportive of this observation.[20,21]

The current study involves the Falck Medical Applanation Tonometer 1 (FMAT-1; Falck Medical, Mystic, Connecticut), which was introduced into the United States market in 2018 after receiving the United States Food and Drug Approval as a medical device for measuring IOP, OF, and ophthalmodynamometry (Fig. 1).[22]

The device is slit-lamp mounted and is operated quite similarly to the Goldmann tonometer. Tonometry is given as the average of approximately 60 IOP measurements made during three cardiac cycles and, thus, includes measurements made at the extremes of ocular pulse amplitude (the difference between IOP during systole and diastole) and multiple points in between. FMAT-1 tonometry measurements do not require adjustment for corneal thickness, as the device automatically measures the mutually countervailing effects of tear film capillary action and cornea resistance and incorporates these measurements into tonometry calculations (FY Falck, 3rd January, 2022. Personal communication).

The theoretical basis for the FMAT-1 tonography function is compelling—the device identifies aqueous humor by capturing the optical signature of an intrinsic compound and measures its egress through the trabecular meshwork (FY Falck, 3rd January, 2022. Personal communication). The identity of the compound in question is proprietary and not disclosed publicly (and the authors

Fig. 1: Falck Medical Applanation Tonometer 1 (FMAT-1) for slit-lamp on the right, wireless display with the different available modalities and results output on the left

Table 1: Intraocular pressure (IOP) measurements by Goldmann and FMAT-1, OF measurements by FMAT-1 after subconjunctival or STTA injection

Study number#	*Gender*	*Age*	*Date of STTA*	*Date of tonography*	*Interval*	*Treated eye*	*pre-STTA IOP*	*post-STTA IOP Goldmann*	*post-STTA IOP FMAT-1*	*Tonography*	*IOP/outflow*	*DEV± (%)*	*TA dose*
1	F	63	05/26/2020	08/10/2020	3	OD	10	11	15	0.24	62.08	7.70	20 mg
2	M	32	02/18/2021	06/24/2021	4	OS	14	20	18.7	0.18	103.9	9.70	20 mg
3	F	22	01/07/2020	08/25/2020	7	OD	12	20	15.4	0.22	70	14.5	20 mg
4	F	68	06/18/2020	07/16/2020	1	OS	14	24	21	0.16	131.25	8.7	20 mg
5	M	54	03/12/2019	07/30/2019	4	OD	18	26	21.3	0.16	133.12	6.6	20 mg
6	F	58	10/15/2019	03/30/2020	5	OS	17	20	18.7	0.19	98.42	0	8 mg
7	F	68	07/16/2019	11/01/2019	4	OS	12	14	15.1	0.23	65.65	14.8	40 mg
8	M	59	12/16/2019	02/15/2021	2	OS	13	18	18.2	0.19	95.1	8.8	40 mg
9	F	43	03/31/2020	05/08/2020	2	OS	19	27	27.2	0.13	209.23	21.1	8 mg
10	F	37	04/10/2020	08/10/2020	4	OS	12	15	15	0.24	62.5	0	20 mg
11	M	31	12/05/2019	04/24/2020	4	OS	16	20	24.8	0.14	177.14	23.2	32 mg
12	M	29	02/01/2021	09/07/2021	7	OS	18	21	21	0.17	123.53	5.6	20 mg
13	M	69	04/19/2019	10/16/2019	6	OS	18	24	17.7	0.2	88.5	10.2	20 mg
14	M	31	12/22/2020	06/25/2021	6	OD	15	36	25.6	0.13	196.92	4.8	20 mg
15	F	51	05/08/2020	06/01/2020	1	OS	12	12	13.8	0.26	53	11.5	12 mg
16	F	64	09/23/2019	01/06/2020	4	OD	14	28	32.1	0.11	291.8	3.9	20 mg
17	M	57	06/07/2019	09/27/2019	3	OS	18	24	23.4	0.17	137.65	0	32 mg
18	F	36	10/04/2019	12/18/2019	2	OD	16	32	30.2	0.12	251.66	11.9	20 mg
19	F	39	11/22/2019	02/28/2020	3	OD	24	30	27.8	0.13	213.85	9.9	20 mg

DEV, FMAT measurement variation percentage; IOP, intraocular pressure in mm Hg; Interval, number of months between treatment and tonography; OD, right eye; OS, left eye; STTA, subconjunctival or subtenon triamcinolone acetonide injection; TA dose, triamcinolone acetonide injection dosage; Tonography, conventional OF in µL/mm Hg

do not know it). Acknowledging this closely held engineering, a user-friendly tonometer could be a very beneficial instrument, and the familiar configuration and technique for operating the FMAT-1 represent a substantial advantage over prior tonography devices; measuring OF is only about as complicated as checking IOP (the two functions are performed simultaneously in a few seconds). An evaluation of the device in the clinical setting is therefore in order, and a reasonable study population would seem to be patients treated with local corticosteroids, a group in whom OF has been studied, and some reference for comparison exists.

The purpose of this study is to describe our findings with the FMAT-1 in patients with uveitis who had recently undergone periocular triamcinolone acetonide injection.

Materials and Methods

Falck Medical Applanation Tonometer 1 (FMAT-1) tonography is routinely performed in patients at Eye Disease Consultants, Limited Liability Company in West Hartford, Connecticut, when there is any question of glaucoma. This practice participates in the Ocular Measurements in Eye Disease (OMED) study, as approved by the Yale University Institutional Review Board (IRB #2000028008), and this project was conducted in accordance with the OMED protocol.

Falck Medical Applanation Tonometer 1 (FMAT-1) testing was performed as described in the device user manual (www.falckmedical.com). As noted above, the device is operated quite similarly to the Goldmann tonometer—patients receive a drop of proparacaine in both eyes and sit at the slit-lamp while a prism is touched to the central cornea. Measurement takes approximately 3 seconds, and centration is imperative. The FMAT-1 stops operating if patient alignment is inadequate and calculates error measurements for each result.

Measurement data are recorded electronically in a small computer integral to the device, and these are transferred automatically to a secure protected database and also copied manually into each patient's electronic medical record. For the current study, records were culled for all patients at least 18 years old who underwent FMAT-1 tonometry and tonography between 1st January 2019 and 31st December 2021, and from this group was selected the subset who had undergone subconjunctival or subtenon triamcinolone acetonide (STTA) injection (herein abbreviated STTA for injection in either layer) in one eye only within the 7 months prior and in whom the medical record showed that repository triamcinolone was visible on the eye. All patients had IOP measurements recorded by Goldmann Applanation not >20 minutes prior to FMAT-1 measurements. Patients' records were excluded from analysis if their fellow eye had a different lens status than the treated eye (phakic vs pseudophakic) or was phthisical. Additional exclusionary criteria included treatment with topical corticosteroids in the prior 3 months, periocular corticosteroid injection in the prior 12 months, a history of treatment with IOP lowering medications in either eye, or a history of scleral buckling, scleritis, or phthisis.

Statistical analysis with R-Studio [RStudio Team (2020). RStudio—Integrated Development for R. RStudio, Primary Biliary Cholangitis, Boston, Massachusetts] and Minitab (Minitab 17 Statistical Software, State College, Pennsylvania, Minitab, Inc) was performed to determine the correlation between IOP measured with FMAT-1 and Goldmann devices and to ascertain the correlation between IOP and OF.

Results

A total of 19 patients' records were included in the analysis; 11 were female. Patient ages ranged from 22 to 69; median age was 51. Results are tabulated in Tables 1 and 2. Median time from STTA to tonography was 4 months. STTA injection doses ranged from 8 to 40 mg. All patients were phakic in both eyes at the time of evaluation, and none had significant nuclear sclerotic cataract.

Table 2: Intraocular pressure (IOP) measurements by Goldmann and FMAT-1, OF measurements by FMAT-1 after subconjunctival or STTA injection in control eyes

Study number#	*Control eye→*	*pre-STTA*	*post-STTA IOP Goldmann*	*post-STTA IOP FMAT-1*	*Tonography*	*IOP/outflow*	*DEV± (%)*
1	OS	10	12	16.5	0.21	78.57	0
2	OD	14	12	16	0.22	73.18	4.5
3	OS	12	18	16.1	0.22	73.18	27.4
4	OD	12	17	19	0.18	105.6	9.6
5	OS	18	18	17	0.21	80.95	9.5
6	OD	15	20	10.9	0.32	34.06	0
7	OD	12	14	14.8	0.23	64.35	3.4
8	OD	12	14	14.1	0.25	56.4	6.60
9	OD	20	19	19	0.18	105.55	24.3
10	OD	10	14	14.3	0.25	57.2	6.6
11	OD	16	13	14	0.25	56	15.9
12	OD	16	18	16.1	0.21	76.67	0
13	OD	18	16	11.3	0.31	36.45	11.3
14	OS	16	15	12.9	0.28	46.07	2.2
15	OD	14	12	11.1	0.3	39	6
16	OS	14	16	15.7	0.22	71.4	13.1
17	OD	12	12	13.9	0.26	53.46	10
18	OS	19	22	16.6	0.21	79.05	12.20
19	OS	17	13	21.6	0.16	135	5.5

DEV, FMAT measurement variation percentage; IOP, intraocular pressure in mm Hg; OD, right eye; OS, left eye; STTA, subconjunctival or subtenon triamcinolone acetonide injection; Tonography, conventional OF in µL/mm Hg

Tonometry

In treated eyes, median IOP by Goldmann was 21 mm Hg [95% confidence interval (CI), 18–27], and this figure by FMAT-1 was 21.0 mm Hg (95% CI, 15.4–25.6). The FMAT-1 mean error rate was 9.1% (95% CI, 6.02–12.17).

Mean figures in treated eyes resembled median figures. Mean IOP by Goldmann was 22.21 mm Hg [95% CI, 18.96–25.45, standard deviation (SD) 6.7], and by FMAT-1, it was 21.15 mm Hg (95% CI, 18.48–23.82, SD 5.5). The Spearman's rank correlation coefficient (r_s) between Goldmann and FMAT-1 for post-STTA IOP was 0.8847, [$r(17) = 0.885$, $p < 0.001$], indicating a positive relationship between these two tonometry modalities.

In untreated eyes, median IOP by Goldmann was 15 mm Hg (95% CI, 13–18), and by FMAT-1, it was 15.7 mm Hg (95% CI, 13.9–16.6). The FMAT-1 mean error rate was 8.8% (95% CI, 5.2–12.48).

Mean IOP in control eyes by Goldmann was 15.52 mm Hg (95% CI, 14.06–16.98, SD 3.02), and by FMAT-1, it was 15.31 mm Hg (95% CI, 13.96–16.65, SD 2.79). Despite these similarities, the Spearman's rank correlation coefficient (r_s) between Goldmann and FMAT-1 IOP in the control group was 0.2516 [$r(17) = 0.252$, $p = 0.299$], indicating that the evident similarity in tonometry measurements by these two modalities did not achieve statistical significance.

The IOP difference between treated and untreated eyes was statistically significant for both devices ($p < 0.05$; Welch's two-sample *t*-test).

Tonography by FMAT-1

Median OF (in µL/mm Hg) was 0.17 (95% CI, 0.13–0.22) in treated eyes and 0.22 (95% CI, 0.21–0.26) in untreated eyes.

Mean OF in treated eyes was 0.17 (95% CI, 0.15–0.19, SD 0.045) and 0.23 (95% CI, 0.21–0.25, SD 0.044) in untreated eyes. The difference in mean and median OF between these two groups was statistically significant ($p < 0.05$ Welch's two-sample *t*-test, $p = 0.0224$ Mood's median test, respectively).

For treated eyes, the Spearman's rank correlation coefficient (r_s) between Goldmann IOP vs OF for post-STTA IOP was $r_s = -0.8897$ [$r(17) = 0.89$, $p < 0.001$), indicating a significant inverse relationship (Fig. 2).

This statistical result was even stronger for FMAT-1 IOP vs OF in this group, $r_s = -0.9877$ [$r(17) = 0.988$, $p < 0.001$] (Fig. 3).

In untreated eyes, the Spearman's rank correlation coefficient (r_s) between FMAT-1 IOP vs OF for post-STTA IOP was $r_s = -0.9876$, [$r(17) = 0.988$, $p < 0.001$], indicating that IOP and OF were inversely correlated even in the lower IOP range (Fig. 4).

Regression analysis in treated eyes showed that post-STTA IOP by Goldmann strongly predicted OF in a linear fashion [R2 = 0.77, F(1,17) = 55.45, $p < 0.001$. $\beta = -0.0059$, $p < 0.001$] (Figs 5 to 7).

This statistical result was even more significant for post-STTA IOP by FMAT-1 vs OF [R2 = 0.92, F(1,17) = 185.5, $p < 0.001$ $\beta = -0.0078$, $p < 0.001$), although this last relationship most closely fit a quadratic—rather than a linear—equation (Figs 8 to 10).

No significant correlation was found between OF measured by FMAT-1 and STTA dose.

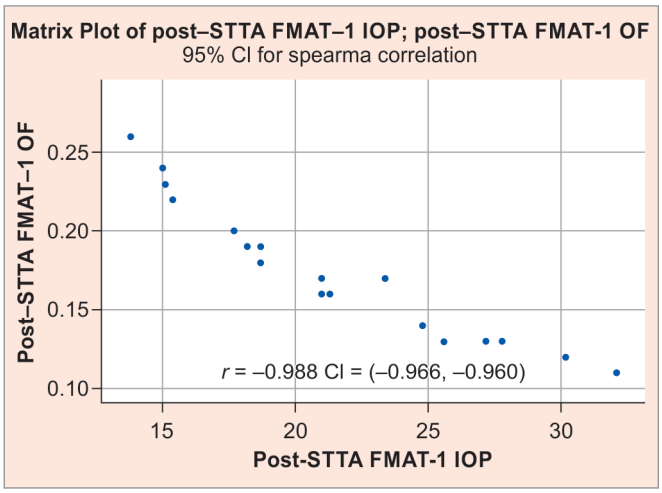


Fig. 3: FMAT-1 IOP compared to FMAT-1 OF in treated eyes. Spearman's rank correlation coefficient (r_s) between post-STTA FMAT-1 IOP (mm Hg) and post-STTA FMAT-1 OF (µL/mm Hg), showing the close linear inverse correlation between these parameters

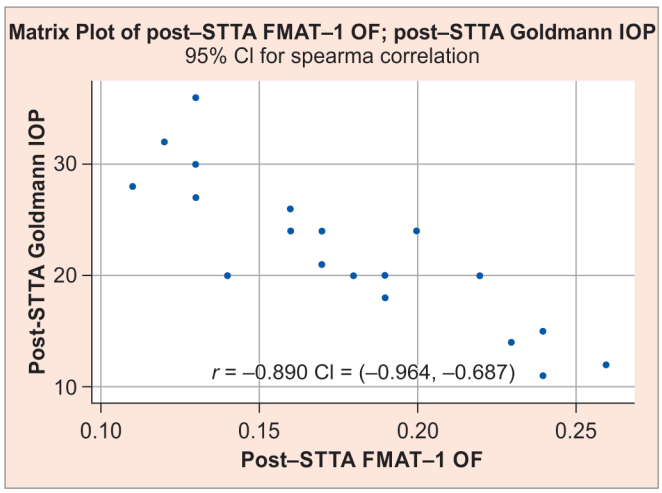


Fig. 2: Goldmann IOP compared to FMAT-1 OF in treated eyes. Spearman's rank correlation coefficient (r_s) between post-STTA Goldmann IOP (mm Hg) and post-STTA FMAT-1 OF (µL/mm Hg), showing the close linear inverse correlation between these parameters

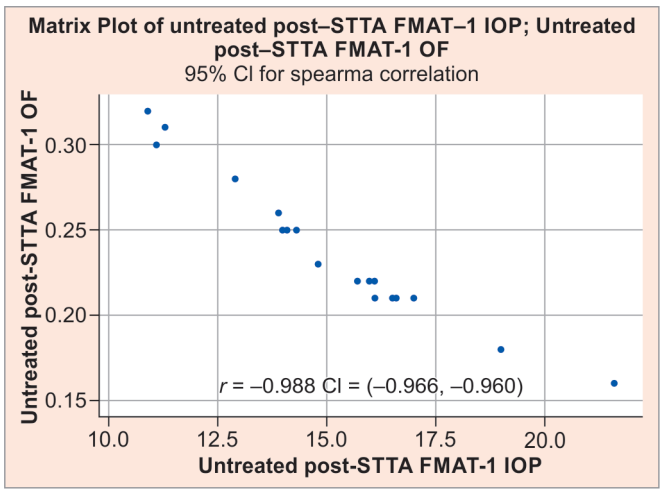


Fig. 4: FMAT-1 IOP compared to FMAT-1 OF in untreated eyes. Spearman's rank correlation coefficient (r_s) between post-STTA FMAT-1 IOP (mm Hg) and post-STTA FMAT-1 OF (µL/mm Hg), showing the close linear inverse correlation between these parameters

Discussion

Our data demonstrate that the FMAT-1 generates IOP results that are substantially similar to the Goldmann tonometer. In addition, FMAT-1 tonography demonstrates markedly reduced OF in patients who had recently undergone periocular triamcinolone injection and had visible triamcinolone on the eye. IOP and OF showed a clear inverse relationship in treated and untreated eyes.

Goldmann IOP served as the reference standard against which we compared FMAT-1 IOP readings. In treated eyes, IOP measurements by both modalities appeared quite

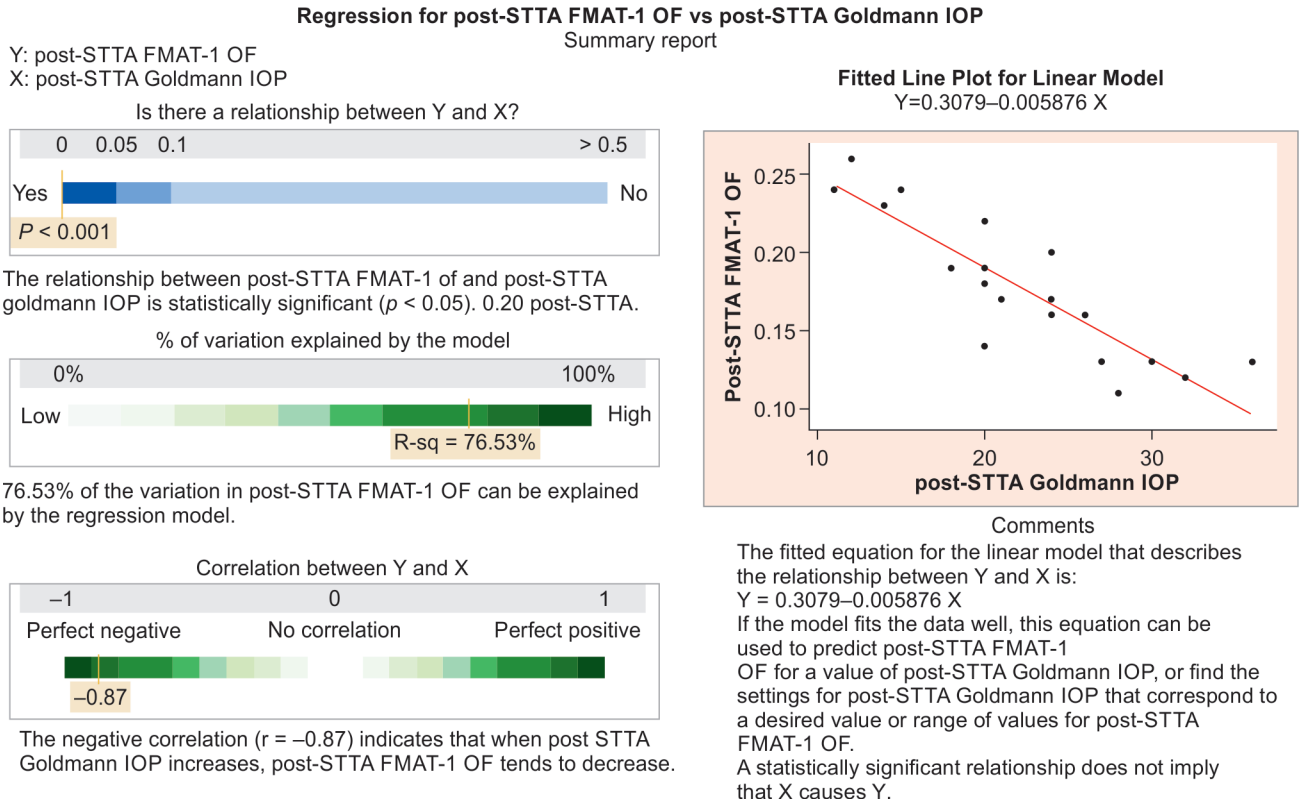
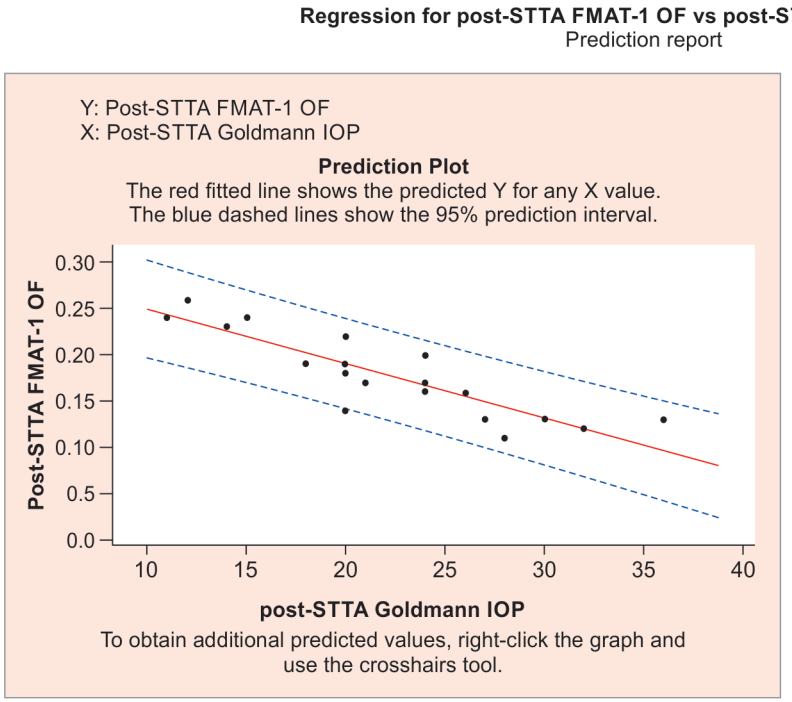


Fig. 5: Linear regression analysis showing that post-STTA Goldmann IOP predicts post-STTA FMAT-1 OF



X	Predicted Y	95% PI
10	0.24911	(0.19628; 0.30194)
11.2	0.24206	(0.18996; 0.29416)
12.4	0.23501	(0.18358; 0.28644)
13.6	0.22796	(0.17713; 0.27879)
14.8	0.22091	(0.17061; 0.27121)
16	0.21386	(0.16401; 0.26371)
17.2	0.20681	(0.15733; 0.25628)
18.4	0.19976	(0.15058; 0.24893)
19.6	0.19271	(0.14375; 0.24166)
20.8	0.18566	(0.13683; 0.23448)
22	0.17861	(0.12984; 0.22737)
23.2	0.17155	(0.12276; 0.22035)
24.4	0.16450	(0.11560; 0.21341)
25.6	0.15745	(0.10836; 0.20654)
26.8	0.15040	(0.10104; 0.19976)
28	0.14335	(0.093644; 0.19306)
29.2	0.13630	(0.086168; 0.18644)
30.4	0.12925	(0.078616; 0.17989)
31.6	0.12220	(0.070991; 0.17341)
32.8	0.11515	(0.063296; 0.16700)
34	0.10810	(0.055533; 0.16067)
35.2	0.10105	(0.047704; 0.15439)
36.4	0.093998	(0.039813; 0.14818)
37.6	0.086947	(0.031862; 0.14203)
38.8	0.079897	(0.023854; 0.13594)

Fig. 6: Prediction plot for post-STTA Goldmann IOP and post-STTA FMAT-1 OF, showing predicted values falling within the 95% CI

similar and were statistically correlated. In untreated eyes, however, tonometry readings by both devices were in the normal range, with very similar medians and means, but the Spearman correlation between modalities, to evaluate for linear similarities throughout the data range, did not achieve statistical significance. In considering explanations for this statistical discrepancy, one possibility is simply an inadequate sample size. Another is corneal thickness variation. As noted above, FMAT-1 tonometry measurements do not require adjustments for corneal thickness, whereas Goldmann IOP readings do. A large review and meta-analysis by Doughty and Zaman in 2000 found that Goldmann IOP measurements are best adjusted approximately 1 mm Hg for every 15 µm corneal thickness from the population normal of 535 µm.[4] The optimal amount of adjustment remains a matter of some debate, but the effect of corneal thickness on Goldmann measurements is generally accepted. One would, therefore, expect slight differences between unadjusted Goldmann readings compared with FMAT-1 readings, and these few mm Hg represent a greater percentage difference at lower IOPs (untreated patients) than at higher ones (treated patients). Our Goldmann tonometry values in the current analysis are unfortunately unadjusted, and we lack pachymetry data on enough patients to perform a meaningful analysis along these lines (since obtaining an FMAT-1 device, our clinic stopped routinely measuring pachymetry), an oversight that we suspect accounts for this observed statistical blemish. Additional possible reasons for this discrepancy are operator error or that one device or the other is simply less accurate in the lower IOP ranges. We are planning further studies that address this question.

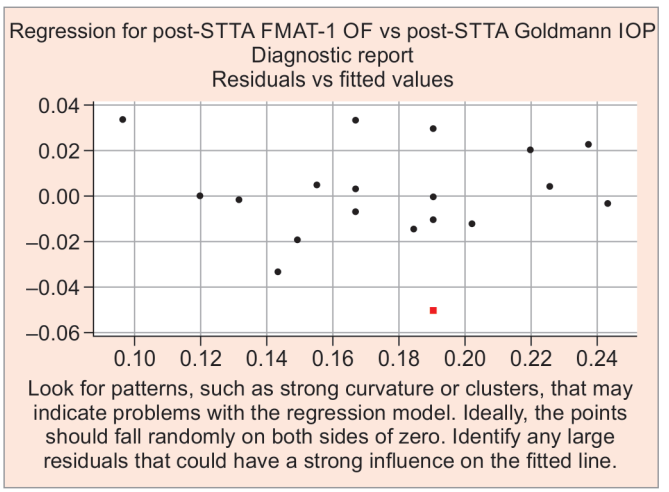


Fig. 7: Residual plot for post-STTA Goldmann IOP and post-STTA FMAT-1 OF, showing random dispersion of the data points around the horizontal axis, supporting the linear regression model

Our finding that corticosteroids cause a decrease in OF with correspondingly elevated IOP aligns with what multiple prior studies have shown.[16,17] Probably the largest study along these lines was conducted by Armaly in 1963 and found moderate IOP elevation with decreased OF after 4 weeks of corticosteroid eyedrop treatment in 90% of glaucoma patients and 30% of glaucoma suspects.[22] The observation that IOP predicted OF along a linear model for Goldmann IOP but a quadratic model–with an R2 closer to 1.0–for FMAT-1 IOP is noteworthy, as it suggests that the FMAT-1 IOP could be the stronger predictor. We look forward to additional studies to shed light on this observation. We are unaware of prior studies evaluating OF specifically following periocular corticosteroid injection in humans, so our findings somewhat expand the repository of evidence-based knowledge in this area.

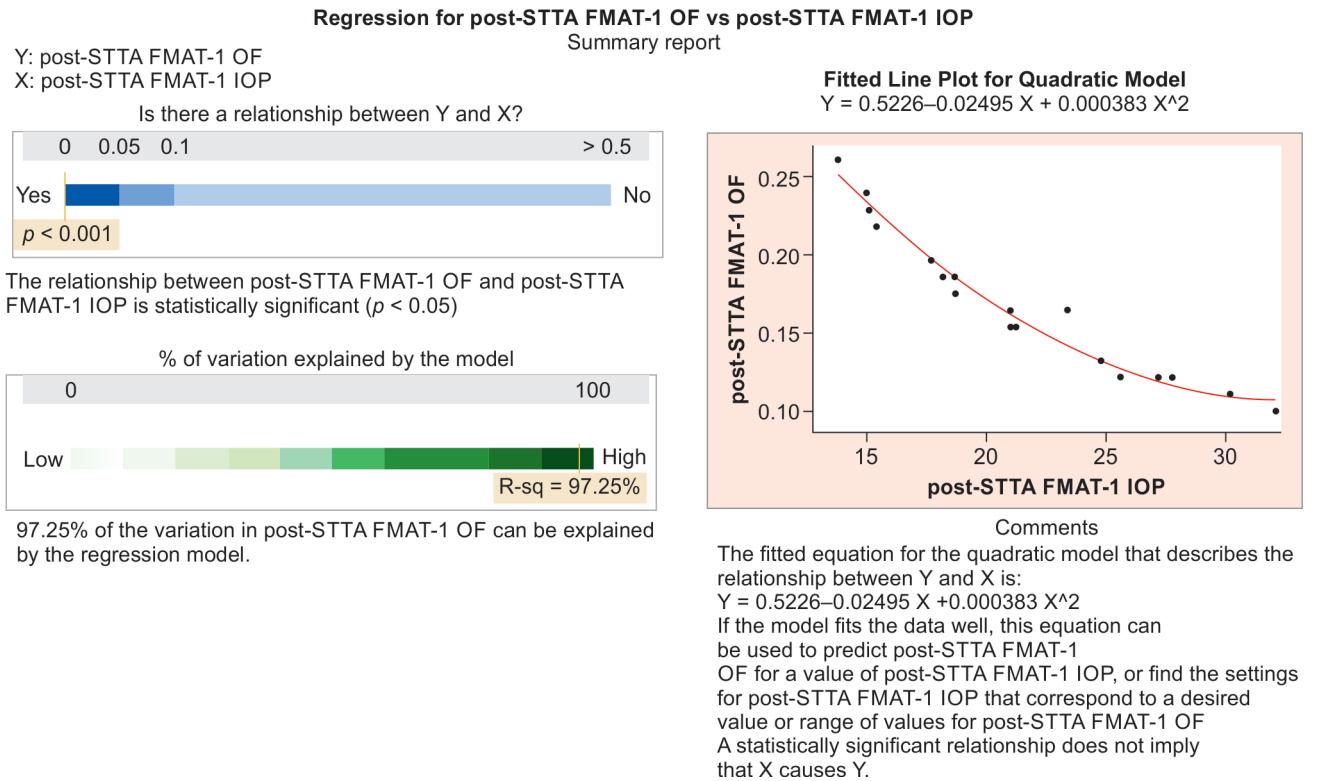
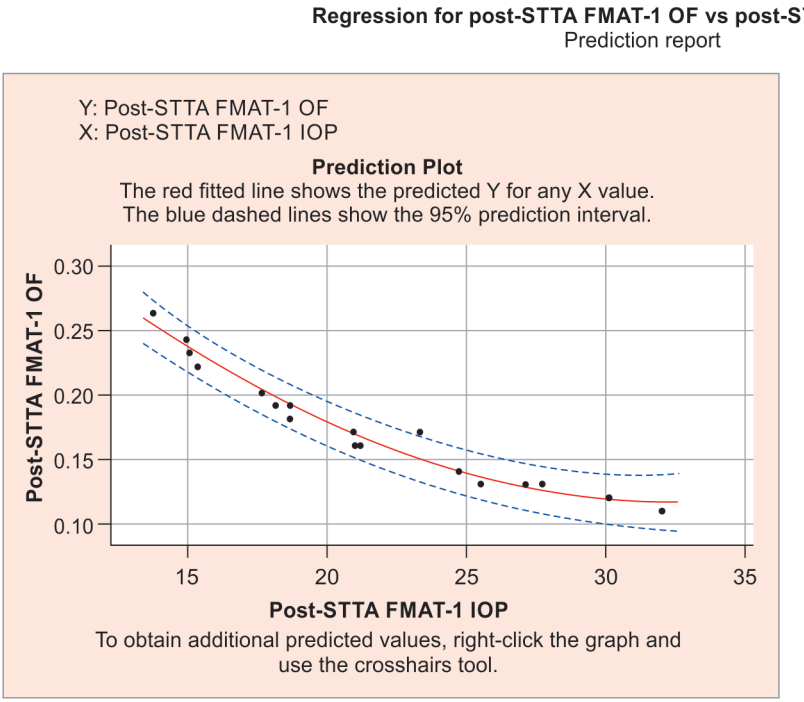


Fig. 8: Regression analysis showing that post-STTA FMAT-1 IOP predicts post-STTA FMAT-1 OF in a quadratic fashion



X	Predicted Y	95% PI
13.4	0.25702	(0.23754; 0.27650)
14.2	0.24552	(0.22682; 0.26423)
15	0.23452	(0.21637; 0.25267)
15.8	0.22400	(0.20621; 0.24179)
16.6	0.21397	(0.19638; 0.23157)
17.4	0.20444	(0.18693; 0.22195)
18.2	0.19539	(0.17788; 0.21291)
19	0.18684	(0.16928; 0.20440)
19.8	0.17878	(0.16114; 0.19642)
20.6	0.17120	(0.15348; 0.18892)
21.4	0.16412	(0.14634; 0.18191)
22.2	0.15753	(0.13970; 0.17536)
23	0.15143	(0.13358; 0.16928)
23.8	0.14582	(0.12797; 0.16367)
24.6	0.14070	(0.12287; 0.15853)
25.4	0.13607	(0.11827; 0.15388)
26.2	0.13194	(0.11414; 0.14974)
27	0.12829	(0.11046; 0.14612)
27.8	0.12513	(0.10721; 0.14306)
28.6	0.12247	(0.10434; 0.14059)
29.4	0.12029	(0.10183; 0.13875)
30.2	0.11861	(0.099644; 0.13758)
31	0.11742	(0.097737; 0.13710)
31.8	0.11672	(0.096088; 0.13734)
32.6	0.11650	(0.094675; 0.13833)

Fig. 9: Prediction plot for post-STTA FMAT-1 IOP and post-STTA FMAT-1 OF, showing predicted values falling within the 95% CI

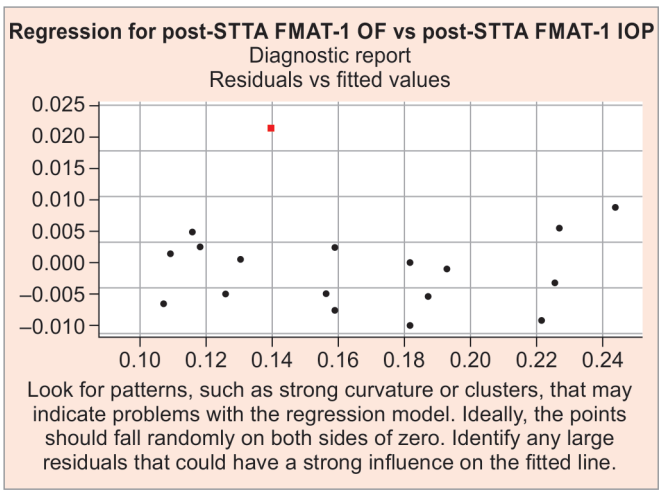


Fig. 10: Residual plot for post-STTA FMAT-1 IOP and post-STTA FMAT-1 OF, showing random dispersion of the data points around the horizontal axis supporting the quadratic model as the best fit

This study has numerous limitations, being small, retrospective, and observing a group of patients with slightly varying clinical histories and possibly different anterior chamber angle morphologies, we did not systematically perform gonioscopy in these study patients during the period in question. Additionally, and perhaps most substantially, in undertaking this study, we made the assumption that the FMAT-1 is actually measures what the manufacturers claim, and we were conscious of a vague uncertainty hovering over the new device (a skepticism presumably common with new biological measuring instruments). Our assumptions are substantially validated by the rather good correlation between FMAT-1 IOP readings and the Goldmann tonometer, which we consider the most credible standard for comparison. We have not performed a direct comparison with other outflow measurement devices in this study, including tonography or fluorophotometry, and while we consider it is encouraging that our OF findings essentially match earlier data, additional studies will be necessary to enable an understanding of the reliability and clinical utility of FMAT-1 OF readings.

Assuming that our OF measurements indeed capture biological reality, the FMAT-1 represents an enormous improvement in tonography technology, being much easier for the operator and the patient, smaller, faster, and storing results in a computerized fashion. By simplifying tonography to the point where it is easily performed in the clinical setting, the FMAT-1 may help incorporate OF as a useful parameter in the management of glaucoma. It may be worth noting that in our experience so far—with the patients in this study and with others—where IOP is markedly elevated, OF measurements are not necessary for clinical decision-making, but we have taken to considering OF data in cases where the IOP is borderline, both as an indicator of the need to start treatment and as an adjunct in evaluating the efficacy of such treatment. We are conducting additional studies to evaluate the validity of this approach.

In summary, our findings suggest that the FMAT-1 generates reliable IOP measurements and OF data that match previous studies and represents a very substantially improved means of determining OF compared with prior tonography instruments. We feel that our findings amount to a preliminary validation of the FMAT-1 as a clinically useful device.

Conclusion

This study is the first clinical evaluation of the FMAT-1 and suggests it is a very promising device. The FMAT-1, a new device, was used to evaluate patients' status post unilateral periocular triamcinolone injection. IOP by Goldmann and FMAT-1 tonometry and aqueous

outflow in treated vs control eyes was then compared. FMAT-1 tonometry readings were quite similar to Goldmann and outflow was markedly reduced in treated eyes. This study is the first clinical evaluation of the FMAT-1 and suggests that it is a very promising device.

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Manufacturer Name

- Falck Medical Applanation Tonometer 1 (FMAT-1; Falck Medical, Mystic, Connecticut, United States of America).
- Food and Drug Administration Report—GUDID 00867009000208.

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