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ORIGINAL RESEARCH

Ocular Sticks for Routine Ophthalmic Surgery: A Randomized Controlled Monocentric Trial

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ABSTRACT

***Introduction*:** Ocular sticks are used to absorb fluids during ophthalmic surgeries. Hence, this prospective study was conducted to evaluate the clinical performance, safety, and usability of Pro-optha® Ocular Sticks in comparison to an alternative device under the conditions of routine ophthalmic surgeries.

***Methods*:** Patients requiring eye surgery were randomly allocated into two equal groups, with the investigational device, Pro-ophta® Ocular Sticks, as the intervention group (IG) and the alternative stick as the comparator group (CG). Two types of surgery were performed. The study is also registered on the German Clinical Trials Register with ID DRKS00025690.

***Results*:** 106 patients were included in the analyses. In both treatment groups, the investigator's/surgeon's general user satisfaction was rated as either "good" or "very good." The non-inferiority hypothesis that the Pro-ophta® Ocular Stick is not rated worse in satisfaction than the alternative device was confirmed with statistical significance ($p=0.0005$). At least 98.12% were rated as "good" and "very good" in both treatment groups for the additional endpoints. Pro-ophta® Ocular Stick was rated better for almost all the additional endpoints and within the surgery subgroups. The mean number of sticks and surgery duration were 3.5 ± 2.74 and 11.5 (± 8.88) min, respectively, with a positive correlation ($r=0.580$) for the Pro-ophta® Ocular Stick and 3.9 ± 2.45 and 9.5 (± 5.90) min, respectively, with a positive correlation ($r=0.025$) for the alternative device. No device-related adverse events occurred.

***Conclusions*:** Effective ocular sticks play an instrumental role in the outcome of ophthalmic surgeries. The investigational device demonstrated efficiency, yielding good surgical results, usability, and an exceptionally good safety profile.

Keywords: Ocular sticks; Or sponges; Ophthalmology; Ophthalmic surgery; Surgical consumables

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Key Summary Points

Ophthalmic surgical consumables, particularly ocular sticks, are indispensable for ophthalmic surgical procedures with the potential to influence surgical outcomes. The evidence to support the efficacy of these sticks is limited.

The study was conducted on a non-inferiority basis to gather real-world data on clinical performance, safety, and usability of the investigational device, an important regulatory requirement for every medical device.

The non-inferiority hypothesis was established; findings for both secondary and additional endpoints were consistent with the use of ocular sticks, confirming their support for ophthalmic procedures and good safety profile.

Notably, the investigational device demonstrated efficiency, as fewer sticks were used despite longer mean surgery time. Cost-effectiveness analysis has several short- and long-term economic implications in different healthcare settings, and future work in this area is recommended.

INTRODUCTION

Ophthalmic surgery is one of the most prevalent therapeutic procedures in the world due to its efficacy, safety, and demand (such as cataract removal) [1]. In modern clinical practice, surgeries for cataract, glaucoma, and vitreoretinal diseases are the most frequently performed ocular procedures [2]. As in all surgeries, complications are inevitable. Regardless, complications such as hemorrhage or infections may occur during these procedures. Potential risk factors that may influence intraoperative bleeding include, but are not limited to, systemic disorders, concomitant diseases, the type of anesthesia, the type of surgical procedure, intraoperative blood pressure, and the use of or change in various systemic medications, such as antiplatelet (AP) and anticoagulant (AC) agents [3]. To reduce these complications, novel minimally invasive techniques using keyhole techniques are employed to especially minimize anatomical disruption between the muscle and the surrounding tissue, thus leading to better preservation of muscle function, less swelling and pain, and more ease in performing reoperations [4].

However, regardless of whether the 'standard' technique or the minimally invasive technique has been used, the regularly used instruments and consumables such as ocular swabs, sponges or sticks are similar for the procedures [5, 6]. Cellulose- and/or viscose-based sponges or swabs have been widely used in ophthalmological procedures for decades [7, 8]. These ocular sticks are sterile compressed gauzes that are typically used in ocular surgery or microsurgery to clean the operating field of blood [9]. Important for the use of ocular swabs is the non-linting property, since contact with external particles could, in rare cases, induce a foreign body reaction in the eye [8, 10]. Hence, it is crucial to use swabs that will not release any particles inside the eye during intraocular surgery [11]. Besides liquid handling in the surgery area, ocular swabs are also used for the application of pharmacological substances such as anesthetics to the eye [8, 12], or the collection of samples for microbiological and/or biochemical analysis [13]. Another fundamental characteristic of the ocular stick is its stability, which allows for the removal of liquids and foreign bodies but does not impact the patient's tissue because intraoperative bleeding can adversely affect the ophthalmic surgical result.

In 2013, Farace and colleagues described the use of ocular sticks as a postoperative dressing for lower eyelid reconstruction. The ocular stick was fixed by knotting and could be removed five days after surgery. Farace and colleagues stated that the ocular sticks guarantee adequate hemostasis and fluid drainage and reduce postoperative hematomas with a uniformly distributed compression over the transposed tissues [9]. In an in vitro study, ocular sticks were used to remove fluids as well as the endothelial cells, which were then transferred onto a human corneal button [14]. Another study established the ideal time for skin incision in oculoplastic

surgery. Blood was collected from the excision site using ocular sticks. No adverse events were recorded, and the surgical results were good [15].

Therefore, this prospective, controlled, randomized, monocentric study was conducted with the aim of confirming the clinical performance, usability, and safety of Pro-ophta® Ocular Sticks in comparison to the alternative device under the conditions of routine ophthalmic surgeries, due to the limited-to-lack of real-world clinical data.

METHODS

Ethical Conduct of the Study

The study, EC number: Eth-57/21, was approved with a positive vote on September 28, 2021, by the Ethics Committee at the Berlin Medical Association, Germany, before starting. The research was performed according to the tenets of the Declaration of Helsinki. All the study participants were thoroughly informed about the study and the voluntary nature of their participation. All study participants signed and gave their fully informed consent. The study is also registered on the German Clinical Trials Register with ID DRKS00025690.

Participants

Patients participated in the study for the time of their one ophthalmic surgery at the Augentagesklinik Spreebogen Berlin. Exclusion criteria were inability to provide informed consent, known intolerability to the products, and participation in other clinical studies within 30 days of study entry and during the study. One hundred and eight patients with various eye pathologies were planned at the investigation site with two investigators.

Design

For this prospective, controlled, randomized, monocentric study, the performance, safety, and usability of the investigational device, Pro-ophta® Ocular Sticks from Lohmann & Rauscher GmbH & Co. KG (intervention group: IG), and the alternative device, BVI Visitec® Absorbent Stick from Beaver-Visitec International (comparator group: CG), were evaluated and compared. Patients only took part in the study for the time of their one ophthalmic surgery. The patients' demographics, type of ophthalmic surgery, and localization of the eye operation were documented after the informed consent form procedure. They were randomly assigned to the intervention and comparator groups. After the surgery, the surgeon recorded the name of the medical device used, the duration of the surgery, and their assessment of the performance and usability of the medical device used, including possible remarks. Upon this, the participation of the patient in the study was completed. No follow-up was foreseen for the study. Further treatment of the patient, if necessary, was to be performed according to the national and institutional standards of care.

Outcomes

The primary outcome of the study assessed the non-inferiority of the investigational device, Pro-ophta® Ocular Stick compared to the alternative device, measured as the level of investigator's/surgeon's general satisfaction on a six-point Likert scale (1 = very good, 2 = good, 3 = rather good/satisfactory, 4 = rather bad/sufficient, 5 = bad/deficient and 6 = very bad/unsatisfactory) directly after the eye surgery. Lower values represented better/higher judgments/satisfaction. It is assumed that the average satisfaction is not worse for Pro-ophta® Ocular Stick than for the alternative device. Secondary outcomes comprised the device-related safety of Pro-ophta® Ocular Stick compared to the alternative device. Any device-related adverse events and device-related serious adverse events served as assessments.

Additional outcomes included performance and usability parameters such as absorption capacity, capillary effect, suction rate, low/absence of linting, atraumatic/tissue conserving, form stability, usage convenience (for tissue hold/fixation, removal of foreign matter and dissecting out), and the mean number of sticks

of Pro-ophta® Ocular Stick also compared to the alternative device. The additional parameters except the mean number of sticks were assessed on a six-point Likert scale (very good, good, rather good/satisfactory, rather bad/sufficient, bad/deficient, very bad/unsatisfactory). The number of sticks per procedure was calculated separately for the study product and comparator, using the data for the number of sticks utilized at each procedure.

Sample Size Calculation

The primary objective of the study was to confirm the non-inferiority of the investigational device, Pro-ophta® Ocular Stick compared to the alternative device, measured as the level of investigator's/surgeon's general satisfaction on a six-point Likert scale (1 = very good, 2 = good, 3 = rather good/satisfactory, 4 = rather bad/sufficient, 5 = bad/deficient and 6 = very bad/unsatisfactory) directly after the surgery. With a power of 80%, an alpha of 5%, and a common standard deviation of 3 units, the threshold up to which the difference was not considered inferior (non-inferiority margin) was set to 1.5 units and using a one-sided two-sample Student's *t* test, it was estimated a total sample size of 102 subjects (51 per group) (SAS 9.4, Proc Power). Assuming a drop-out rate of 5%, 108 patients, 54 per group were planned to be enrolled.

Randomization and Blinding

Patients were randomized in a 1:1 ratio to each treatment arm and also equally stratified by the two surgeons. The block randomization procedure with a block size of 6 was used.

A randomization list was generated by the biostatistician using a validated random number generator, yielding reproducible and non-predictable results. The data management team prepared randomization envelopes, which contained the randomization results for one patient ID. For each patient number, there was a sealed envelope, which was binding for the patient with this patient number. Once a patient was included in the study and a patient ID has been permanently assigned to the patient, the randomization envelope may be opened by personnel who have been briefed on the study and the process. The surgeons were not blinded to the type of stick used.

Statistical Analysis

All variables were calculated using appropriate descriptive statistics (continuous data: sample size, missing values, mean, standard deviation (SD), minimum, median, and maximum; categorical data: sample size, absolute and relative frequency). The primary endpoint was analyzed using a generalized linear model (GLM) assuming a normal distribution and identity link function with surgeons, and the kind of treatment served as fixed effects.

The secondary endpoints, incidence of device-related adverse events and serious adverse events, were summarized by means of absolute and relative frequencies. To achieve a *p* value for the differences between the treatments, a chi-square test was applied.

The categorical additional endpoints were summarized by means of absolute and relative frequencies, and the continuous by means of N, missing values, mean, SD, minimum, median, and maximum, respectively. To achieve *p* values for the differences between the treatments, a (GLM) assuming a normal distribution and identity link function was used with surgeons, and the kind of treatment served as fixed effects.

The level of significance was set to 0.05. The missing data was not replaced. The number of patients with missing values was reported. A subgroup analysis was performed according to the type of ophthalmologic procedure. The Pearson correlation coefficient was used to determine the correlation between the duration of surgery (in minutes) and the number of sticks used during the surgery. Calculations and statistical analysis were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

A total of 106 out of 108 patients were eligible for inclusion in the analyses. Two patients were

excluded due to screening failures. Fifty-three patients each were randomized into the intervention group treated with the investigational device, Pro-ophta® Ocular Stick and the comparator/control group treated with the alternative device. There were no protocol deviations during the conduct of the study, and all patients received the study treatment between February 2022 and March 2023. No patient terminated the study prematurely. Figure 1 shows the patient flow chart. Patient characteristics, type, and eye localization of surgery by treatment group were summarized in Table 1. Two types of surgery—cataract and eyelid surgery—were performed during the study. No patient underwent glaucoma, eye muscle, corneal transplantation, and iris surgeries.

Primary Endpoint

The level of investigator's general satisfaction, measured directly after the surgery on a six-point Likert scale was used as the primary performance endpoint for the study. In both treatment groups (Fig. 2), the investigator's general satisfaction was rated as either "good" or "very good" [IG: good 19 (35.85%), very good 34 (64.15%); CG: good 36 (67.92%), very good 17 (32.08%)]. The mean level of general

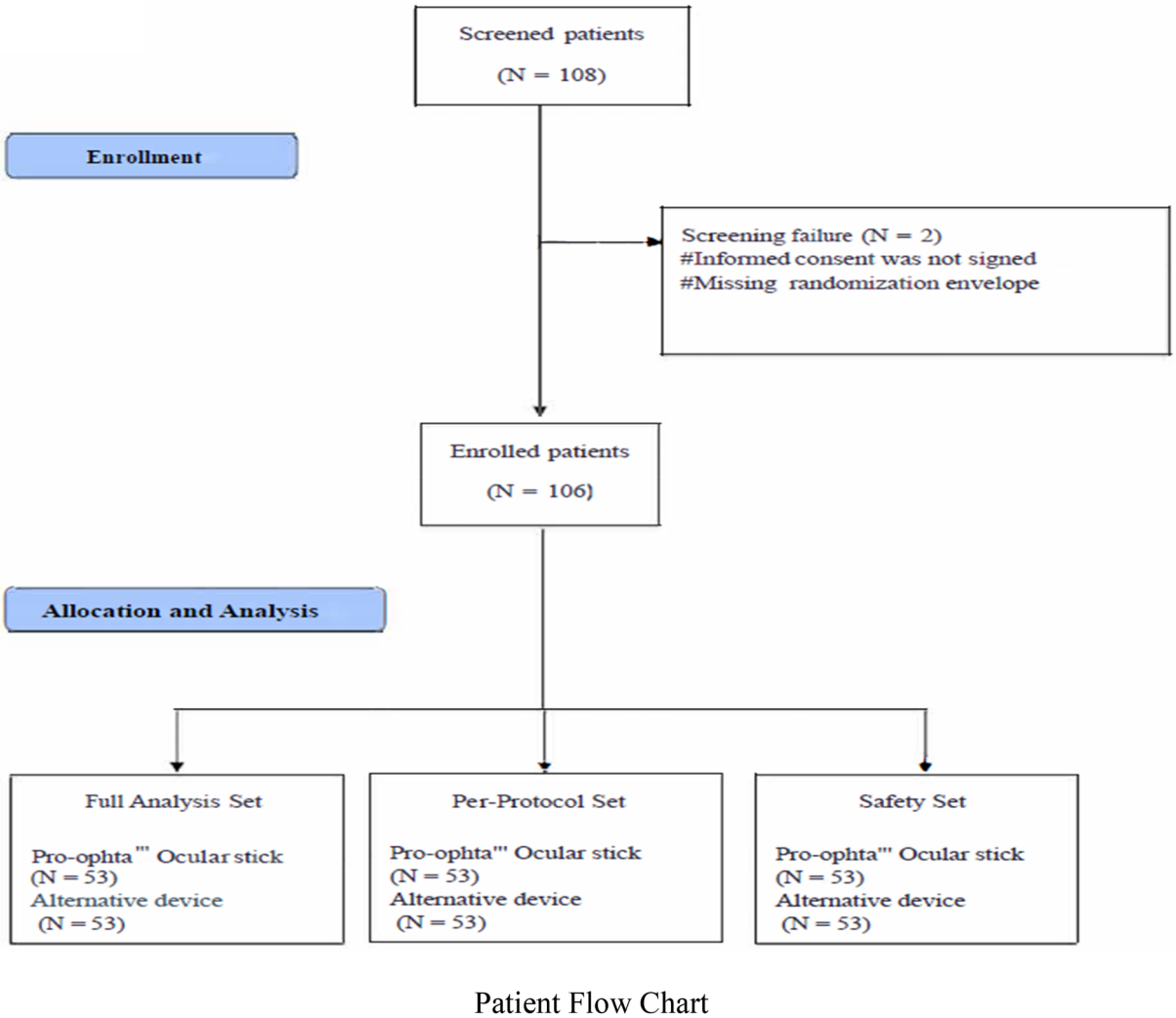

Fig. 1 Patient flow chart

Table 1 Patient characteristics, type, and eye localization of surgery

Patient characteristics		Pro-ophta® Ocular Stick ($N=53$)	Alternative device ($N=53$)
Age (mean ± SD)	Years	61.8 ± 18.94	57.6 ± 17.68
Gender	Male (%)	19 (35.85)	29 (54.72)
	Female (%)	34 (64.15)	24 (45.28)
Height (mean ± SD)	cm	168.9 ± 9.71	173.6 ± 10.77
Weight (mean ± SD)	kg	74.3 ± 16.40	74.4 ± 14.27
Pathology	Eye disorders	43 (81.13%)	46 (86.79%)
	Neoplasms	8 (15.09%)	3 (5.66%)
	Skin and subcutaneous tissue disorders	–	2 (3.77%)
	General disorders and administration site conditions	1 (1.89%)	1 (1.89%)
	Surgical and medical procedures	1 (1.89%)	1 (1.89%)
Surgery localization	One eye (left or right)	52 (98.11%)	52 (98.11%)
	Both eyes	1 (1.89%)	1 (1.89%)
Surgery type	Eyelid surgery	34 (64.15%)	33 (62.26%)
	Cataract surgery	19 (35.85%)	19 (35.85%)
	Refractive surgery	–	1 (1.89%)

SD standard deviation

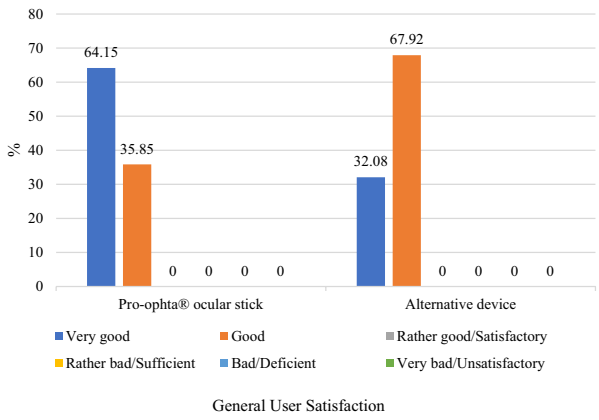

Fig. 2 General user satisfaction

user satisfaction was 1.4 ± 0.48 and 1.7 ± 0.47 scale points for the IG and CG, respectively. Compared to the CG, general user satisfaction, adjusted for the effect of individual assessments of satisfaction by the two surgeons, decreased (lower values represent better/higher judgment/satisfaction) when using the Pro-ophta® Ocular Stick. The satisfaction with the use of Pro-ophta® Ocular Stick was better by −0.31 scale points than when using the alternative device. This effect with Pro-ophta® Ocular Stick was statistically significant ($p=0.0005$).

Compared to the 2nd surgeon (Table 2), the 1st surgeon tended to express slightly lower scale values, namely −0.16 scale points, independent of which device was used. This effect was not statistically significant ($N=106$, beta = −0.16, 95% CI [−0.34, −0.01], $p=0.0711$).

The primary endpoint was also analyzed based on the two types of surgery conducted: cataract and eyelid.

Table 2 General user satisfaction results using GLM analysis

Parameter	Mean difference (beta)	95% lower confidence limit	95% upper confidence limit	*p* value
Intercept	1.7596087	1.6127791	1.9064383	< 0.0001
Pro-ophta® Ocular Stick	− 0.317664	− 0.495533	− 0.139795	0.0005
Surgeon 1	− 0.163818	− 0.341687	0.0140516	0.0711

Reference categories: alternative device, surgeon 2

p value: probability associated with a particular *z* value

In the cataract surgery subgroup, the investigator's general satisfaction was rated as "good" and "very good" in both treatment groups. The mean level of general user satisfaction was 1.4 ± 0.51 and 1.6 ± 0.50 scale points for the IG and CG, respectively. Compared to the CG, general user satisfaction, adjusted for the effect of individual assessments of satisfaction by the two surgeons, decreased when using the Pro-ophta® Ocular Stick. The satisfaction with the use of Pro-ophta® Ocular Stick was better by − 0.22 scale points than when using the alternative device. This effect with Pro-ophta® Ocular Stick was not statistically significant ($N = 38$, beta = − 0.22, 95% CI [− 0.53, 0.07], $p = 0.1464$). Compared to the 2nd surgeon, the 1st surgeon tended to express slightly lower scale values, independent of which device was used, namely -0.34 scale points. This effect was not statistically significant ($N = 38$, beta = − 0.34, 95% CI [− 0.79, − 0.11], $p = 0.1440$).

In the eyelid surgery subgroup, the investigator's general satisfaction was rated as "good" and "very good" in both treatment groups. The mean level of general user satisfaction was 1.3 ± 0.47 and 1.7 ± 0.47 scale points for the IG and CG, respectively. Compared to the CG, general user satisfaction, adjusted for the effect of individual assessments of satisfaction by the two surgeons, decreased when using the Pro-ophta® Ocular Stick. The satisfaction with the use of Pro-ophta® Ocular Stick was better by − 0.35 scale points than when using the alternative device. This effect with Pro-ophta® Ocular Stick was statistically significant ($N = 67$, beta = − 0.35, 95% CI [− 0.57, − 0.13], $p = 0.0016$). Compared to the 2nd surgeon, the 1st surgeon tended to express slightly lower scale values, independent of which device was used, namely − 0.34 scale points. This effect was not statistically significant ($N = 67$, beta = − 0.23, 95% CI [− 0.47, − 0.008], $p = 0.0583$).

Safety

Throughout the study, neither device-related adverse events nor device-related serious adverse events were observed with both ocular sticks. Thus, no complications, particularly significant intraoperative bleeding that would have resulted in severe consequences, occurred.

Additional Endpoints

All additional endpoints were evaluated on a six-point Likert scale, except for the number of sticks per procedure. Illustrated in Fig. 3, the capillary effect, atraumatic/tissue conserving, and usage convenience (for tissue hold/fixation) endpoints were rated in both treatment groups as "good" and "very good." However, surgeons rated one in each treatment group as "rather good/satisfactory" for the absorption capacity, suction rate, and form stability endpoints. Also, one as "rather good/satisfactory" for low/absence of linting endpoint in the CG, and one in the IG for usage convenience (removal of foreign matter or dissecting out) endpoint. Otherwise, the rest were rated as either "good" or "very good." Compared to the CG (Table 3), the assessment of all the additional endpoints except usage convenience (removal of foreign matter/dissecting out), adjusted for the effect of individual assessment of satisfaction by the two surgeons, decreased when using the Pro-ophta®

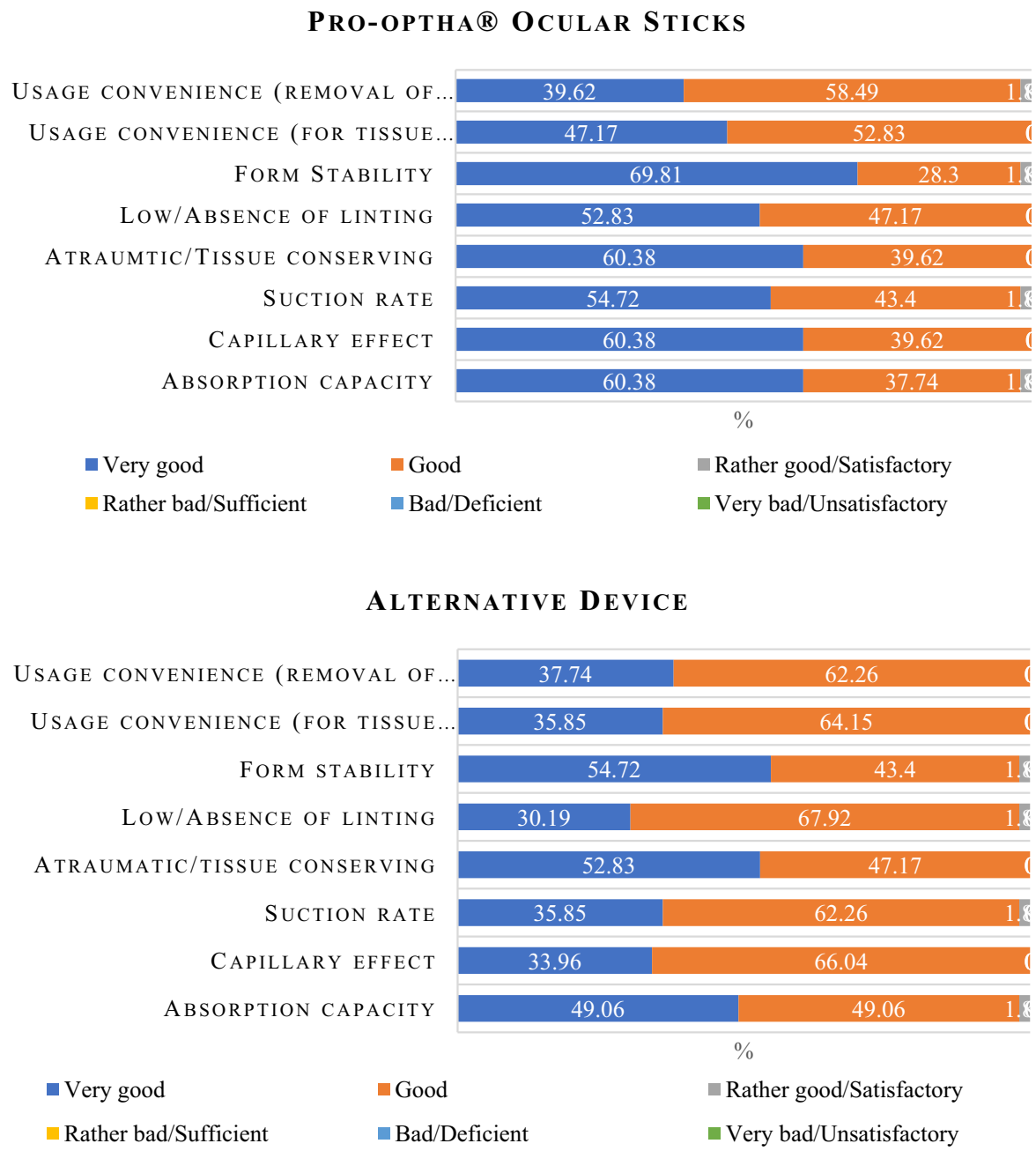

Fig. 3 Performance and usability parameters

Ocular Stick. The assessment with the use of Pro-ophta® Ocular Stick was better, characterized by negative scale points, than when using the alternative device. The usage convenience (removal of foreign matter/dissecting out) endpoint had comparable evaluation in both treatment groups. For the additional parameters, capillary effect, and low/absence of linting, the effect of the use of Pro-ophta® Ocular Stick was statistically significant (capillary effect: $N=106$, beta $=-0.26$, $p=0.0048$; low/absence of linting: $N=106$, beta $=-0.24$, $p=0.0096$). The mean number of sticks was 3.5 ± 2.74 and 3.9 ± 2.45 for the IG and CG, respectively. Fewer Pro-ophta®

Table 3 Additional endpoints results using GLM analysis

Endpoint	Parameter	Mean difference (beta)	95% lower confidence limit	95% upper confidence limit	*p* value
Absorption capacity	Intercept	1.6013277	1.4345298	1.7681257	< 0.0001
	Pro-ophta®	− 0.110399	− 0.311921	0.0911236	0.2830
	Surgeon 1	− 0.14886	− 0.350383	0.052662	0.1477
Capillary effect	Intercept	1.7320056	1.5841794	1.8798318	< 0.0001
	Pro-ophta®	− 0.261396	− 0.442895	− 0.079897	0.0048
	Surgeon 1	− 0.146011	− 0.32751	0.0354877	0.1149
Suction rate	Intercept	1.7512229	1.5861313	1.9163145	< 0.0001
	Pro-ophta®	− 0.185185	− 0.381849	0.0114788	0.0650
	Surgeon 1	− 0.185185	− 0.381849	0.0114788	0.0650
Atraumatic/tissue conserving	Intercept	1.5265549	1.3632471	1.6898626	< 0.0001
	Pro-ophta®	− 0.073362	− 0.260489	1.6898626	0.4423
	Surgeon 1	− 0.111823	− 0.298951	0.0753041	0.2415
Low/absence of linting	Intercept	1.8535989	1.7158445	1.9913533	< 0.0001
	Pro-ophta®	− 0.240028	− 0.421561	− 0.058496	0.0096
	Surgeon 1	− 0.27849	− 0.460023	− 0.096957	0.0026
Form stability	Intercept	1.451782	1.2710312	1.6325327	< 0.0001
	Pro-ophta®	− 0.151709	− 0.349363	0.045944	0.1325
	Surgeon 1	0.0405983	− 0.157055	0.2382517	0.6873
Usage convenience (for tissue hold/fixation)	Intercept	1.6774983	1.5152595	1.839737	< 0.0001
	Pro-ophta®	− 0.111823	− 0.297538	0.0738916	0.2379
	Surgeon 1	− 0.073362	− 0.259077	0.1123532	0.4388
Usage convenience (removal of foreign matter)	Intercept	1.6967156	1.5358104	1.8576208	< 0.0001
	Pro-ophta®	0.002849	− 0.186872	0.19257	0.9765
	Surgeon 1	− 0.150997	− 0.340718	0.0387238	0.1188
Number of sticks	Intercept	5.0681342	4.2892216	5.8470468	< 0.0001
	Pro-ophta®	− 0.369658	− 1.239535	0.5002187	0.4049
	Surgeon 1	− 2.40812	− 3.277996	− 1.538243	< 0.0001

Reference categories: Alternative device, surgeon 2 *p* value: probability associated with a particular *z* value

Ocular Sticks were used, but this difference was not statistically significant ($N = 106$, beta = − 0.36, 95% CI [− 1.23, 0.50], $p = 0.4049$).

For all additional endpoints except the assessment of form stability, compared to the 2nd surgeon (also see Table 3), the 1st surgeon

tended to express slightly lower (scale) values, independent of which device was used. Only for low/absence of linting and the number of sticks was the effect statistically significant (low/absence of linting: $N=106$, beta = −0.27, 95% CI [−0.46, −0.09], $p=0.0026$, number of sticks: $N=106$, beta = −2.40, 95% CI [−3.27, −1.53], $p \leq 0.0001$).

The additional endpoints were also analyzed based on the two types of surgery conducted: cataract and eyelid.

In the cataract surgery subgroup, capillary effect, suction rate, atraumatic/tissue conserving, form stability, and usage convenience (for tissue hold/fixation) endpoints were rated in both treatment groups as "good" and "very good." However, surgeons rated one in either one or both treatment groups as "rather good/satisfactory" for the absorption capacity, low/absence of linting and usage convenience (removal of foreign matter and dissecting out) endpoints. Compared to the CG, all additional endpoints except usage convenience (removal of foreign matter/dissecting out), adjusted for the effect of individual assessments of satisfaction by the two surgeons, decreased when using the Pro-ophta® Ocular Stick. The assessment with the use of Pro-ophta® Ocular Stick was better, characterized by negative scale points, than when using the alternative device. None of these effects with Pro-ophta® Ocular Stick was statistically significant. The mean number of sticks was 1.5 ± 0.84 and 1.8 ± 1.17 for the IG and CG, respectively. This difference was not statistically significant ($N=38$, beta = −0.39, 95% CI [−1.07, 0.29], $p=0.2593$). For all additional endpoints except the capillary effect, compared to the 2nd surgeon, the 1st surgeon tended to express slightly lower (scale) values, independent of which device was used. The effect was statistically not significant for all.

In the eyelid surgery subgroup, capillary effect, atraumatic/tissue conserving, low/absence of linting, usage convenience (for tissue hold/fixation) and usage convenience (removal of foreign matter and dissecting out) endpoints were rated in both treatment groups as "good" and "very good." However, surgeons rated one in either one or both treatment groups as "rather good/satisfactory" for the absorption capacity, suction rate, and form stability endpoints. Compared to the CG, all additional endpoints except usage convenience (removal of foreign matter/dissecting out), adjusted for the effect of individual assessments of satisfaction by the two surgeons, decreased when using the Pro-ophta® Ocular Stick. The assessment with the use of Pro-ophta® Ocular Stick was better, characterized by negative scale points, than when using the alternative device. Statistical significance was evident in only capillary effect ($N=67$, beta = −0.28, $p=0.0169$) and low/absence of linting ($N=67$, beta = −0.33, $p=0.0023$) endpoints. The mean number of sticks was 4.6 ± 2.81 and 5.1 ± 2.19 for the IG and CG, respectively. This difference was not statistically significant ($N=67$, beta = −0.44, 95% CI [−1.62, 0.74], $p=0.4654$). For all additional endpoints, compared to the 2nd surgeon, the 1st surgeon tended to express slightly lower (scale) values, independent of which device was used. Only for atraumatic/tissue conserving, low/absence of linting, usage convenience (removal of foreign matter /dissecting out) and the number of sticks the effect was statistically significant (atraumatic/tissue conserving: $N=67$, beta = −0.29, 95% CI [−0.51, −0.07], $p=0.0084$; low/absence of linting: $N=67$, beta = −0.27, 95% CI [−0.50, −0.04], $p=0.0194$; usage convenience (removal of foreign matter/dissecting out): $N=67$, beta = −0.35, 95% CI [−0.60, −0.10], $p=0.0057$; number of sticks: $N=67$, beta = −1.14, 95% CI [−2.12, −0.16], $p=0.0222$).

Correlation Analysis

The mean duration of surgery was 11.5 (±8.88) min and 9.5 (±5.90) min for the IG and CG, respectively. The Pearson's correlation analysis between the number of sticks and the surgery duration showed a significantly moderate positive correlation for the IG ($N=53$, $r=0.580$, $p<0.0001$) and a not significantly very weak positive correlation for the CG ($N=53$, $r=0.025$, $p=0.8593$). Overall, the number of sticks and surgery duration showed a significantly weak positive correlation ($N=106$, $r=0.354$, $p=0.0002$).

In the cataract surgery subgroup, the mean duration of surgery was 10.7 (±5.39) min and

10.3 (±4.60) min for the IG and CG, respectively. The Pearson's correlation analysis between the number of sticks and the surgery duration showed a significantly strong positive correlation for the IG ($N=19$, $r=0.630$, $p=0.0039$) and a not significantly weak negative correlation for the CG ($N=19$, $r=-0.197$, $p=0.4181$). Overall, the number of sticks and the surgery duration showed a not significantly weak positive correlation ($N=38$, $r=0.165$, $p=0.3220$).

In the eyelid surgery subgroup, the mean duration of surgery was 11.9 (±10.38) min for the IG and 8.9 (±6.63) min for the CG. The Pearson's correlation analysis between the number of sticks and the surgery duration showed a significantly strong positive correlation for the IG ($N=34$, $r=0.662$, $p<0.0001$) and a not significantly weak positive correlation for the CG ($N=33$, $r=0.201$, $p=0.2627$). Overall, the number of sticks and the surgery duration showed a significantly moderate positive correlation ($N=67$, $r=0.481$, $p<0.0001$).

DISCUSSION

This prospective, controlled, randomized, monocentric study compared the clinical performance, usability, and safety of using Pro-ophta® Ocular Sticks to an alternative device. Both medical products consist of non-woven materials and are mainly used for absorbing fluids during ophthalmic surgical procedures. Both products look remarkably similar and have a "cigarette filter" shape. The surgeries were performed at one study site by two surgeons, one with about a decade of expertise and the other with over three decades of expertise in ophthalmology. There was a tendency for different outcomes based on their experience, specialties, or preferences; however, the findings revealed that the difference did not reach statistical significance ($p=0.0711$) between their assessments of general user satisfaction for both devices. This was also evident within the two types of surgery subgroups, cataract ($p=0.1440$) and eyelid ($p=0.0583$). Therefore, the general investigator's satisfaction, which served as the non-inferiority hypothesis evaluation, demonstrated significance ($p=0.0005$) when using the Pro-ophta® Ocular Stick. This outcome proved that the Pro-ophta® Ocular Stick was not rated worse in satisfaction but even significantly better than the alternative device. Higher user satisfaction was achieved when using Pro-ophta® Ocular Stick. The same effect was also noticeable in the two types of surgery conducted, with statistical significance recorded within the eyelid surgery subgroup but not in the cataract surgery subgroup. The good surgical results confirmed the clinical performance and efficacy of Pro-ophta® Ocular Sticks for ophthalmic surgeries and in ophthalmology, consistent with results in vitro and in vivo studies [14–16]. Clinical evidence regarding the safe application of ocular sticks was gathered in a study that used Pro-ophta® Ocular Sticks during upper eyelid blepharoplasty. There were no adverse events, and the surgical results were good, confirming the safe use of Pro-Ophta® Ocular Sticks [15]. Their outcome is consistent with this prospective, controlled, randomized, monocentric study, as no adverse events, for example, the potential release of fibers from the stick inducing a foreign body reaction in the eye or significant intraoperative bleeding, occurred, also confirming the good safety profile of Pro-ophta® Ocular Sticks. The safety of these devices was also confirmed in these studies [12, 16].

Hanson et al. showed that Pro-ophta® Ocular Sticks were successfully used in an in vitro experiment to remove fluids and endothelial cells [14]. Also, Farace and colleagues described ocular sticks as a postoperative dressing which guaranteed adequate hemostasis and fluid drainage [9]. These studies, amongst others [15, 16], also correspond to our study, as all additional endpoints were rated mainly in both treatment groups as "good" and "very good."

Even though Pro-ophta® Ocular Stick was rated better for almost all endpoints, a comparable evaluation was observed with the usage convenience (removal of foreign matter/dissecting out) outcome. This was also evident in the two types of surgery conducted: cataract and eyelid. For important parameters for ocular sticks, such as the capillary effect and low/absence of linting, the use of the Pro-ophta® Ocular Stick was rated not only better but also statistically significant.

This result correlates with the absorptive and non-linting properties that are important for the use of ocular sticks in ophthalmology [8–11]. Furthermore, clinical performance and safety of ophthalmic absorption sponge were further demonstrated when used to dislodge, mobilize, and aspirate emulsified silicon oil (SO) droplets that were adherent to the anterior surface of the iris, thereby reducing the risk of future SO-related complications [17], consistent with this studies' good form stability, absorption capacity and suction rate findings. A study found the sponge as a better choice for the tear-lipid collection in comparison to the other method used [18]. Additionally, several studies have also utilized ocular sponges for fluid collection [13, 19–22], correlating to the clinical performance and usability of ocular consumables and our findings. They have successfully been shown as good drug delivery agents [8, 12, 23–26]. The results from a study that evaluated sponges' biological safety and stability found that they did not affect the viability of conjunctival epithelial cells, and more than 90% of the cells were viable after the treatment [16], consistent with our atraumatic and tissue conserving study findings. The findings on the form stability, absorption capacity, and usage convenience (for tissue hold/fixation) outcomes were further confirmed when ocular sticks were used as a post-operative wound dressing in another study [9].

A correlation was observed between the duration of surgery and the number of sticks used, both overall and within specific surgery subgroups. Surgery duration and the number of sticks used were higher in eyelid surgeries than in cataract surgeries, likely due to the greater complexity of the former. Notably, the use of Pro-ophta® Ocular Sticks was more efficient, as fewer sticks were used compared to the alternative device, despite longer mean surgery durations. This was evident overall and within the specific surgery subgroups. This affirms the reliable performance and usability of Pro-ophta® Ocular Sticks. Additionally, a statistically significant difference was noted in the quantity of sticks used by each surgeon, both generally ($p<0.0001$) and within the eyelid surgery group ($p=0.0222$). This could be due to a variety of factors, including the type and complexity of the surgery, whether both eyes were operated on, and surgeon-dependent factors. A cost analysis of medical devices and the impact of reducing their usage have significant economic implications across various healthcare settings. A further and detailed cost-effectiveness analysis of our findings could potentially reveal relevant information and serve as a guide for researchers studying the benefits of cost-saving measures and the short- and long-term economic implications on the patients, medical staff, and healthcare institutions. This was evident from findings presented in this comprehensive systematic review [27]. Farace and colleagues presented the ocular sticks as an alternative and cheap wound dressing in lower-lid reconstructive surgery [9]. Nonetheless, a number of factors influence cost-effectiveness analysis [28–31].

In general, ocular surgeries are one of the most often performed surgeries worldwide that do not have a high-risk profile, although complications like intra- or post-operative bleeding or infection are possible. None of the previously mentioned complications is usually connected with the use of consumables such as ocular swabs or sponges, as also observed in this prospective, controlled, randomized, monocentric study, indicating their safe use and reliable performance in ophthalmology.

There were some limitations to our study. Firstly, there were only two surgeons in a single center, which may not be representative of a larger, more diverse group of surgeons or multiple centers. Even though the sample size was calculated, the number of patients is small compared to the total number of patients who undergo eye surgeries each year. The generalizability could be enhanced by including a larger sample of patients, surgeons, and centers to ensure more representative and robust results in the future. Secondly, even though the surgeons were not blinded to the type of stick used, the randomization process effectively reduced the possibility of selection bias depending on the patient population, the type of surgery performed, and between the two surgeons who

carried it out. Thirdly, despite the absence of significant intraoperative bleeding complications, the study did not document patient-related or risk factors that could influence intraoperative bleeding and overall surgical outcomes. All national and institutional standards of care were, however, strictly observed for each participant.

The necessity for ocular consumables is further supported by the fact that this is a real-world study with a prospective design that demonstrates the convincing performance, usability, and safety of ocular sticks during ophthalmic procedures. Therefore, the findings' generalizability and broader applicability cannot be ruled out, and the results are consistent with recent investigations identified within the literature.

CONCLUSIONS

Effective ocular sticks play an instrumental role in the outcome of ophthalmic surgeries. This prospective, controlled, randomized, monocentric trial reports the first comparative clinical evidence of the non-inferiority of the investigational device, Pro-ophta® Ocular Stick compared to an alternative device regarding general user satisfaction. The good surgical results and better assessments recorded for the investigational device confirmed its exceptionally good safety profile, efficiency, and clinical performance in ophthalmology. Further research is recommended to investigate the cost-effectiveness analysis of the medical device's economic impact on all stakeholders involved.

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Data Availability. The datasets generated during and/or analyzed during the current study are not available for sharing. All data relevant to the study are included in the article.

Declarations

Conflict of Interest. Isaak Fischinger and Manfred Tetz, the investigators from Augentagesklinik Spreebogen Berlin, have no conflict of interest to report. H. Kulas, an employee of IGES Institut GmbH, served as the statistician on behalf of Clinische Studiengesellschaft mbH (CSG). Martin Abel and Angela Odame are employees of Lohmann & Rauscher GmbH & Co. KG. The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval. The study was performed according to the tenets of the Declaration of Helsinki. Approval was granted by the Ethics Committee at the Berlin Medical Association, Germany (September 28, 2021/EC number: Eth-57/21). All the study participants were thoroughly informed about the study and the voluntary nature of their participation. All study participants signed and gave their fully informed consent. The study is also registered on the German Clinical Trials Register with ID DRKS00025690.

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