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Direct Costs of Second Aqueous Shunt Implant versus Transscleral Cyclophotocoagulation (The Assists Trial)

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Abstract

Purpose: To compare the total direct costs of implantation of a second glaucoma drainage device (SGDD) with transscleral cyclophotocoagulation (CPC) for patients with inadequately controlled

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intraocular pressure (IOP) reduction, despite the presence of a preexisting glaucoma drainage device in the ASSISTS clinical trial.

Methods: We compared the total direct cost per patient, including the initial study procedure, medications, additional procedures, and clinic visits during the study period. The relative costs for each procedure during the 90-day global period and the entire study period were compared. The cost of the procedure, including facility fees and anesthesia costs, were determined using the 2021 Medicare fee schedule. Average wholesale prices for self-administered medications were obtained from AmerisourceBergen.com. The Wilcoxon rank sum test was used to compare costs between procedures.

Results: Forty-two eyes of 42 participants were randomized to SGDD (n=22) or CPC (n=20). One CPC eye was lost to follow-up after initial treatment and was excluded. The mean (± standard deviation [SD], median) duration of follow-up was 17.1 (±12.8, 11.7) months and 20.3 (±11.4, 15.1) months for SGDD and CPC, respectively (P=0.42, two sample t-test). The mean total direct costs (± SD, median) per patient during the study period were $8,790 (±$3,421, $6,805 for the SGDD group) and $4,090 (±$1,424, $3,566) for the CPC group, (P<0.001). Similarly, the global period cost was higher in the SGDD group than in the CPC group ($6,173 [±$830, $5,861] vs. $2,569 [±$652, $2,628]; P<0.001). The monthly cost after the 90-day global period was $215 (±$314, $100) for SGDD and $103 (±$74, $86) for CPC, P=0.31). The cost of IOP-lowering medications was not significantly different between groups during the global period (P=0.19) or after the global period (P=0.23).

Conclusion: The total direct cost in the SGDD group was more than double that in the CPC group, driven largely by the cost of the study procedure. The costs of IOP-lowering medications were not significantly different between groups. When considering treatment options for patients with a failed primary GDD, clinicians should be aware of differences in costs between these treatment strategies.

Keywords

glaucoma; aqueous shunt; costs; cyclophotocoagulation; tube shunt; drainage device

INTRODUCTION

The frequency with which glaucoma drainage devices (GDD) are used for glaucoma management has increased over the past decade. It has been reported that 30–50% of these surgeries may fail during the first 5 years.[1] There are several treatment options for patients with glaucoma, including medical therapy, various laser procedures and incisional surgical intervention. The decision to proceed with a specific treatment depends on numerous factors, including patient characteristics, disease etiology, prior ocular surgical history, and patient and surgeon preferences.

Four studies have compared the efficacy and safety of transscleral cyclophotocoagulation (CPC) with second glaucoma drainage device (SGDD)[2–5] in eyes with a preexisting GDD. These studies show that both treatments were efficacious in lowering intraocular pressure (IOP) and reducing the number of ocular hypotensive medications. Schaefer et al. and Wang

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et al. showed that eyes treated with CPC had a higher early failure rate, while those two studies and Levinson et al. showed that eyes treated with SGDD had more complications.[2–4]

The Second Aqueous Shunt Implant versus Transscleral Cyclophotocoagulation Treatment Study (ASSISTS) reported more clinic visits and an increased risk of additional glaucoma surgery with SGDD compared with CPC.[5] However, failure rates were similar between groups.[5] Thus, the combined literature shows both treatments are clinically reasonable options for eyes with inadequately controlled IOP after a single GDD.

An important factor not previously reported is the cost of these surgical interventions. In a health system with limited resources, a cost comparison may inform clinical decision making, given the relatively small differences in safety or efficacy between study groups. The purpose of this study is to compare the costs of glaucoma care and ocular hypotensive medications for patients undergoing SGDD or CPC in ASSISTS.

METHODS

ASSISTS (registered at www.clinicaltrials.gov [NCT02691455]), is a prospective, randomized, stratified, controlled, multicenter clinical trial comparing cumulative success rates between SGDD and CPC for eyes with uncontrolled glaucoma after an initial GDD implant. In all, 23 sites agreed to participate in the study and each received Institutional Review Board approval to conduct the study and informed consent was obtained from each participant before enrollment. The University of Texas Health Science Center and Robert Cizik Eye Clinic served as the headquarters and data-coordinating center. The study was monitored by an independent Data and Safety Monitoring Board. Research adhered to the tenets of the Declaration of Helsinki and was compliant with the Health Insurance Portability and Accountability Act.[5] It was designed to directly compare efficacy and safety of SGDD and CPC in eyes with a preexisting GDD. The detailed methods have been reported elsewhere.[5] A secondary aim of this study was to compare the total direct medical costs of the management of glaucoma in the study eye associated with these two procedures. For this study, data regarding clinic visits and costs related to procedures, devices, medications, and any subsequent procedures after treatment failure were compiled to compare total costs. Procedure costs are inclusive of facility and anesthesia costs.

Sources of Cost Estimations

Costs of study treatments and additional procedures performed during the study period, including both facility and physician fees, were obtained from Medicare rates from the Centers for Medicare and Medicaid Services (https://www.cms.gov/medicare/physician-fee-schedule/search) using the 2021 fee schedule for Houston, Texas. (Table 1) The costs of the GDD, the tissue reinforcement graft, and intraocular lenses (IOL) are included in the surgical facility fee, which was standardized as ambulatory surgery center costs for all operating room cases. The cost of anesthesia was obtained by combining the base units with an additional unit of time (15 minutes) based on the average operative times reported for these types of cases from Memorial Hermann Surgical Center—Texas Medical Center, Houston, Texas, adjusted to the Medicare Houston, Texas, rate ($22.07 per unit).

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The IOP-lowering medications utilized included brimonidine, timolol, latanoprost, dorzolamide, and netarsudil. Postoperative medications included antibiotics, corticosteroids, cycloplegic agents, and non-steroidal anti-inflammatory drugs (NSAID). The cost of topical medications was estimated assuming 100% adherence to the prescribed dosing frequency and no waste. Costs were calculated based on the use of bottles in single-bottle increments. The number of bottles of each medication used was calculated assuming 60 drops were administered per 2.5 mL. Medication costs were calculated using average wholesale prices (AWP) obtained from AmerisourceBergen.com. (Supplemental Table)

Costs of clinic visits that occurred during the global period were defined to have been included as part of the surgical fee. All clinic visits that occurred after the global period were calculated as Evaluation and Management (E&M) level 4 visits (current procedural terminology [CPT]=99214, $134.57) and non-hospital-based clinic visits. “Total direct cost” was defined as the sum of the cost of medical and surgical care and medications during the study period, as described above.

Outcomes and Data Analysis

The main outcome of interest in this study is the total direct cost during the study period. The cost of medical and surgical care and medications was also evaluated in several ways, as summarized in Table 2. Data were summarized by mean (±standard deviation [SD]) and median. Wilcoxon rank sum test (also known as the Wilcoxon-Mann-Whitney U test) was used for comparing the costs between SGDD and CPC groups. All calculations were performed using SAS 9.4 for Window (Cary, NC). A P-value <0.05 is considered statistically significant.

RESULTS

Forty-two eyes of 42 subjects were randomized to SGDD (N=22) or CPC (n=20) in ASSISTS. One CPC subject was lost to follow-up after treatment and was excluded. Thus, 22 SGDD eyes and 19 CPC eyes were included in this study. The mean (±SD, median) duration of follow-up was 17.1 (±12.8, 11.7) months for SGDD and 20.3 (±11.4, 15.1) months for CPC (P=0.42, two sample t-test). Two patients in the SGDD group were lost to follow up on or before 90 days.

The mean total direct cost per patient during the study period was significantly higher in the SGDD group ($8,790 [±$3,421, $6,805]) compared to the CPC group ($4,090 [±$1,424, $3,566], P<0.001). Similarly, the global period cost (<0.001) and the first-year total direct cost (P<0.001) were higher in the SGDD group than in the CPC group. However, despite what appear to be important differences in costs, there are no statistical differences in the total post-global period cost (P=0.46), the monthly post-global period cost (P=0.31), or the post-global period first-year cost (P=0.65, Table 3).

The major contributors for the cost differences between groups are the cost of the initial study procedure and the cost of additional procedures. The study procedure was significantly higher in the SGDD group ($5,585 [±$543], median=$5,469) compared to CPC ($2,151 [± $431], median=$2,367, P<0.001). The cost of additional procedures, including a new global

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period, was $1,317 (±$2,474) with median $0 for SGDD and $250 (±$749) with median $0 for CPC (P=0.15), respectively.

The monthly costs of clinic visits after the global period were $67 (±$85) with median $44 for SGDD and $20 (±$19) with median $20 for CPC, respectively (P=0.023). Similarly, the cost of post-global period first-year clinic visit was significantly higher in SGDD compared to CPC (P=0.038, Table 3).

As detailed in Table 3, except for the cost of antibiotics during the global period, there were no significant differences in the cost of medications between groups during the global period or after the global period.

A total of 8 eyes underwent 13 additional procedures, 6 (27%) SGDD eyes underwent 11 procedures and 2 (10%) CPC eyes underwent 2 procedures. Neither group had more than 50% of patients who underwent additional procedures, resulting in median costs being $0 for all periods even with higher average additional procedure costs in the SGDD group during the global period ($198 [±$645] for SGDD and $0 [±$0] for CPC) and post-global period ($1,099 [±$2,260] for SGDD and $250 [±$749] for CPC). (Table 3)

DISCUSSION

ASSISTS is a prospective, randomized, stratified, controlled multicenter clinical trial comparing SGDD and CPC for eyes with uncontrolled glaucoma after a primary GDD implant. The study shows that the short-term overall success rates were high with either SGDD or CPC. However, SGDD was associated with more clinic visits and an increased risk of additional glaucoma surgery.[5] Both treatments are clinically reasonable options for patients whose glaucoma is inadequately controlled after a single GDD, despite medical therapy. Since there was not an overwhelming benefit of one procedure over the other, the cost may be an important factor in clinical decision making. The aim of this study was to compare the total direct medical cost per patient between SGDD and CPC groups.

We demonstrated that patients in the SGDD group had statistically significantly higher total direct costs, study procedure costs, and monthly clinic visit costs. Overall, the main driver of the cost difference is the cost of the initial surgical procedure. Although not statistically significant, the cost of additional procedures was higher in the SGDD group. There were 6 (27%) patients who underwent 11 additional procedures in the SGDD group compared to 2 (10%) patients in the CPC group. One additional surgical procedure was ectropion repair in one patient. This was included as an additional procedure because it was thought to be potentially related to the surgical procedure.

There was no significant difference in medication costs between groups, except for higher cost of antibiotics in the SGDD group. The ongoing costs of IOP-lowering medications after the global period was also similar between groups. During the global period, while the SGDD group used postoperative antibiotics, the CPC group had more use of topical NSAIDs, particularly bromfenac (Prolensa, Bausch + Lomb, Rochester, New York), which is an expensive medication ($359.56 for 3 mL), offsetting that difference.

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Several studies in the literature have used hypothetical patient models to compare the costs of glaucoma treatments.[6–7] Choi et al. demonstrated that patients who underwent trabeculectomy and laser trabeculoplasty had lower costs compared to patients treated with topical medications using a Markov model.[6] Similarly, using the results from the Tube Versus Trabeculectomy study and comparing patients treated with topical medications, Kaplan et al. found that trabeculectomy and tube shunt surgery were more cost-effective compared with medical treatment alone.[7] Several studies have used prospective data to compare costs. A prospective study among patients with untreated, primary open-angle glaucoma or ocular hypertension found that patients treated with selective laser trabeculoplasty had lower total costs over three years compared to patients treated with topical medications.[8] Another prospective study compared the first-year cost of the Ex-Press shunt (Alcon, Fort Worth, TX) to trabeculectomy and found Ex-Press is associated with greater surgical cost.[9] A strength of the current study is its use of actual events from a prospective randomized trial to calculate cost. This reduces the number of assumptions required to compute expenses.

To our knowledge, this is the first study comparing the cost of SGDD implantation to CPC in eyes with uncontrolled glaucoma after a primary GDD implant. (PubMed search terms: “cyclophotocoagulation; drainage device; tube shunt” on 06/07/2022). No statistically significant differences in IOP reduction, failure rates, or quality of life were observed between SGDD and CPC groups in ASSISTS. Thus, with little difference in clinical outcomes, the cost of the procedures becomes more important in clinical decision making. Based on the total direct costs, CPC is a more cost-effective method to control glaucoma in patients with failed primary GDD.

The study evaluated the total direct costs during the initial 90-day global period and thereafter. Since there were differences in follow-up duration between groups, we evaluated monthly total direct costs after the global period to facilitate comparisons. The global period was evaluated separately from the post-global period due to the differing lengths of follow up and to make projections about future, ongoing changes in the cost differential. We also evaluate the various components of total direct costs (procedures, visits and medications) to determine the drivers of the cost differential. This could be important if, for example, the device was the only difference and a less-expensive alternative device would reduce the difference or, similarly, if the ability to reevaluate the differences in light of changing medication costs, such as generics becoming available.

At a 5% significance level, the sample size of 41 (22 in SGDD and 19 in CPC) in the current study has a power of 82% to detect 75% or more of patients in one group having a cost greater than the other group (P[X>Y]=0.75) based on a Wilcoxon rank sum test.

This study has several limitations. First, the costs of medications were estimated on the basis of several assumptions, as described in the Methods section, rather than having captured the number of bottles actually used. Second, the CPT level assigned to the clinic visits was not captured. Thus, we assigned clinic visit costs at E&M level 4 (CPT=99214) to each visit outside the initial global period, since the patients undergoing the study procedures tend to be more complex with multiple eye diseases and a high-level of medical decision making.

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With the understanding that this assumption may have overestimated the level of service, we recalculated costs after reassigning all visits at E&M level 3 (CPT=99213), and found no difference in the overall results. Therefore, the mix of levels of service used would not likely affect the observed cost differential between groups.

Third, unlike scheduled study visits, the specific dates of additional, non-study visits were not captured. Therefore, it was not possible to classify most visits that took place during the 90-day global period after an additional procedure, as a postoperative global visit. The additional cost for these visits should have been included in the additional procedure costs and would have had its fee bundled with that of the additional procedure, rather than as a separate added visit cost. There were significantly more visits and more additional procedures in the post-global period in the SGDD group compared to the CPC group. Therefore, this limitation could potentially confound the results. As a sensitivity analysis, after excluding patients who underwent additional study procedures (6 in SGDD and 2 in CPC), the difference in the post-global period first-year visit costs did not remain statistically significant (P=0.059). This, on first glance, suggests that the higher clinic visit cost in the SGDD group may have been related to the non-study visits that took place during the global periods and after additional procedures but were classified as E&M level 4 visits. However, this sensitivity analysis also undercounted visits that occurred prior to the additional procedure (not in the global period). These are more frequent because of the issue which required additional intervention. Thus, the worst-case scenario is the trend (P= 0.06) toward significance, which we do not believe invalidates the statistical difference.

Fourth, we did not capture costs of additional clinical testing performed for complications, for example, imaging for macular edema or echography for evaluation of choroidal effusions. There is no reason to believe there would be difference in standard glaucoma follow up testing between groups and that differences would only be related to complications or additional procedures. There were no statistically different rates of complications (P=0.29) and, therefore, the effects likely limited.

CONCLUSION

Our results demonstrated that patients with failed primary GDD who underwent SGDD had significantly higher total direct costs compared to patients who underwent CPC. CPC is a more cost-effective method of treatment for glaucoma in patients with inadequately controlled IOP, despite medical therapy after implantation of a primary GDD.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Conflict of Interest/Disclosures:

Dr. Gross reports personal fees from Aerie during the conduct of the study; membership of Data and Safety Monitoring Board for Glauckos and consultant and stockholder for Intelligent Retinal Imaging Systems, outside the submitted work. Dr. Greenfield reports personal fees (consultant) from Allergan, Alcon, Aerie, and Eyenovia outside the submitted work. Dr. Pasquale reports grants from NIH, The Glaucoma Foundation, and Research to Prevent Blindness, as well as personal fees from Eyenovia, Twenty-Twenty, and Skye Biosciences outside the submitted work. Dr. Mansberger reports a research grant from AbbVie and the National Eye Institute (outside the submitted work); and consulting fees from Nicox and Thea. Dr. Tanna reports grants or contracts from Google and Research to Prevent Blindness (to Northwestern University); consulting fees from Ivantis, Sandoz, and Zeiss; and payment for expert testimony from Ivantis. Dr. Weinreb reports personal fees (consultant) from Abbvie, Allergan, Amydis, Aerie, Equinox, Eyenovia, Iantrek, Implandata, IOPtic, Nicox, Perivision, Topcon Medical. He reports research support from the National Eye Institute, National Institute of Minority Health and Health Disparities, Bausch + Lomb, Heidelberg Engineering, Zeiss-Meditec, Optovue, Centervue, and Topcon, Dr. Feldman reports personal fees from Bausch and Lomb and Catawba; stock in 4DMD; and grants from Santen and Ivantis outside the submitted work. Dr. Blieden reports personal fees (consultant) from Allergan, Abbive and Aerie outside the submitted work.

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Table 1.

Facility and Physician Fees for Procedures performed during the Study Period

Procedure	Physician Fee	Facility Fee
CPC (office)	$484.67	$853.58
CPC (operating room)	$523.94	$1,666.96
Aqueous shunt with tissue reinforcement graft	$1,177.40	$4,049.02
Cataract extraction	$562.45	$1,666.96
Anterior vitrectomy	$488.74	$1,666.96
Anterior chamber washout	$93.29	$1,666.96
Drainage of choroidal effusion	$623.47	$1,666.96
Reposition GDD	$710.71	$1,666.96
Regraft GDD	$877.99	$1,666.96
Ectropion repair	$470.66	$1,369.07

GDD=Glaucoma drainage device; CPC=Cyclophotocoagulation

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Table 2.

Definitions of Outcome Variables

Definition	Study Procedure	Medications			Additional Procedures*			Clinic Visits	
		Global Period	Post Global Period		Global Period	Post Global Period		Post Global Period	
			Post Global 1st year	After 1 year		Post Global 1 year	After 1 year	Post Global 1st year	After 1 year
Total Direct Cost	x	x	x	x	x	x	x	x	x
First Year Total Direct Cost	x	x	x		x	x		x	
Global Period Cost	x	x			x				
Post Global Period Total Cost			x	x		x	x	x	x
Monthly Post Global Period Cost			x	x		x	x	x	x
Post Global Period 1st year Cost			x			x		x	

Medications=IOP-lowering and surgically related ophthalmic drops, such as antibiotics and anti-inflammatory agents.

*Additional procedures are defined as unplanned surgeries for glaucoma or to address a complication related to the study procedure.

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Table 3.

Costs in the SGDD and CPC Groups

Cost	Mean (±SD) [Median]		P
	SGDD (N=22)	CPC (N=19)	
Total Direct Cost	**$8,790 (±$3,421) [$6,805]**	**$4,090 (±$1,424) [$3,566]**	**<0.001**
Study Procedure	$5,585 (±$543) [$5,469]	$2,151 (±$431) [$2,367]	<0.001
All Ophthalmic Medications	$1,179 (±$1,443) [$614]	$1,229 (±$1,054) [$801]	0.24
IOP-lowering Medications	$881 (±$1,438) [296]	$831 (±$904) [551]	0.12
Other Ophthalmic Medications (cycloplegic agents, NSAIDs, antibiotics, corticosteroids, etc.)	$298 (±$115) [$278]	$397 (±$743) [$160]	<0.001
Additional Procedures	$1,317 (±$2,474) [$0]	$250 (±$749) [$0]	0.15
Clinic Visits	710 (±$757) [$538]	460 (±$571) [$269]	0.30
First Year Total Direct Cost	**$7,651 (±$2,678) [$6,678]**	**$3,539 (±$1,277) [$3,178]**	**<0.001**
Study Procedure	$5,585 (±$543) [$5,469]	$2,151 (±$431) [$2,367]	<0.001
All Ophthalmic Medications	$692 (±$377) [$601]	$911 (±$788) [$638]	0.62
IOP-lowering Medications	$394 (±$340) [$297]	$514 (±$788) [$638]	0.23
Other Ophthalmic Medications (cycloplegic agents, NSAIDs, antibiotics, corticosteroids, etc.)	$298 (±$115) [$278]	$397 (±$743) [$160]	<0.001
Additional Procedures	$928 (±$2,200) [$0]	$250 (±$749) [$0]	0.41
Clinic Visits	$447 (±$399) [$404]	$227 (±$211) [$135]	0.11
Global Period Cost	**$6,173 (±$830) [$5,861]**	**$2,569 (±$652) [$2,628]**	**<0.001**
Study Procedure	$5,585 (±$543) [$5,469]	$2,151 (±$431) [$2,367]	<0.001
All Ophthalmic Medications	$390 (±$146) [$369]	$418 (±$363) [$297]	0.41
IOP-lowering Medications	*$114 (±$118) [$84]*	*$162 (±$119) [$137]*	0.19
Ophthalmic Antibiotics	*$99 (±$88) [$72]*	*$0 (±$0) [$0]*	<0.001
Topical Corticosteroids	*$168 (±$26) [$160]*	*$151 (±$37) [$160]*	0.11
Topical NSAIDs	*$10 (±$31) [$0]*	*$114 (±$340) [$0]*	0.82
Other Ophthalmic Medications (Cycloplegic agents, etc.)	*$3 (±$13) [$0]*	*$9 (±$22) [$0]*	0.26
Additional Procedures	$198 (±$645) [$0]	$0 (±$0) [$0]	0.20

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Cost	Mean (±SD) [Median]		P
	SGDD (N=22)	CPC (N=19)	
Total Post=Global Period Cost [2]	**$2,789 (±$3,235) [$1,068]**	**$1,597 (±$1,303) [$1,163]**	**0.46**
All Ophthalmic Medications	$909 (±$1,452) [$339]	$887 (±$962) [$512]	0.22
IOP-lowering Medications	*$876 (±$1,466) [$246]*	*$704 (±$907) [$376]*	0.23
Other Ophthalmic Medications (cycloplegic agents, NSAIDs, etc.)	*$33 (±$71) [$0]*	*$183 (±$512) [$0]*	0.95
Additional Procedures	$1,099 (±$2,260) [$0]	$250 (±$749) [$0]	0.22
Clinic Visits	$781 (±$758) [$606]	$460 (±$571) [$269]	0.14
Monthly Post=Global Period Cost [2]	**$215 (±$314) [$100]**	**$103 (±$74) [$86]**	**0.31**
All Ophthalmic Medications	$50 (±$45) [$47]	$68 (±$68) [$31]	0.50
IOP-Lowering Medication	*$45 (±$46) [$33]*	*$49 (±$45) [$30]*	0.51
Other Ophthalmic Medications (cycloplegic agents, NSAIDs, etc.)	*$5 (±$11) [$0]*	*$20 (±$54) [$0]*	0.92
Additional Procedures	$97 (±$242) [$0]	$14 (±$47) [$0]	0.25
Clinic Visits	$67 (±$85) [$44]	$20 (±$19) [$20]	0.023 [3]
Post Global Period 1st Year Cost [2]	**$1,543 (±$2,325) [$830]**	**$1,041 (±$962) [$683]**	**0.65**
All Ophthalmic Medications	$381 (±$354) [$333]	$564 (±$622) [$285]	0.50
IOP-Lowering Medications	$345 (±$355) [$246]	$382 (±$399) [$285]	0.68
Other Ophthalmic Medications (cycloplegic agents, NSAIDs, etc.)	$33 (±$71) [$0]	$183 (±$512) [$0]	0.95
Additional Procedures	$672 (±$1,954) [$0]	$250 (±$749) [$0]	0.60
Clinic Visits	$491 (±$391) [$404]	$226 (±$211) [$135]	0.038 [3]

[1] P values obtained from Wilcoxon rank sum test

[2] Two patients in the SGDD group were lost to follow-up after global period

[3] No longer significant if patients with additional procedures with additional global periods excluded (P=0.10 for monthly clinic visits and P=0.059 for post global period 1st year)

IOP=Intraocular pressure; NSAID=Non-steroidal anti-inflammatory drugs