Superonasal vs Inferonasal Subconjunctival Gel Stent Placement in Patients with Glaucoma

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ABSTRACT

Aim and background: To compare the safety and efficacy of subconjunctival gel stent implantation in the superonasal (SN) vs inferonasal (IN) quadrants in the treatment of glaucoma.

Materials and methods: Patients with a history of IN (n = 29) or SN, (n = 96) gel stent placement with ≥ 3 months of follow-up were included. Intraocular pressure (IOP) and the number of glaucoma medications were collected preoperatively and postoperatively at months 1, 3, 6, and 12. Safety measures included the number of bleb needlings, complication rate, and additional surgeries.

Results: Mean baseline IOP was 32.4 ± 11.7 mm Hg in the IN group and 21.6 ± 9.2 mm Hg in the SN group (p < 0.01). IOP was similar between groups at 3 months (IN = 15.8, SN = 15.6, p = 0.45), 6 months (IN = 17.4, SN = 15, p = 0.13), and 12 months (IN = 17.9, SN = 14.7, p = 0.15) follow-up. The number of glaucoma medications was also similar at 3 months (p = 0.31), 6 months (p = 0.24), and 12 months (p = 0.39) follow-up. Bleb needling rates were similar with 51.7% (15/29) in the IN group vs 42.7% (41/96) in the SN group (p = 0.39) and subjects requiring further surgery were 17.2% (5/29) in the IN group vs 24.0% (23/96) in the SN group (p = 0.45).

Conclusion: Both IN and SN subconjunctival gel stent placements provide favorable safety and efficacy when treating open-angle glaucoma, with a meaningful decrease in medication use and IOP.

Clinical significance: Implantation of the subconjunctival gel stent in the IN quadrant is an effective and safe alternative to superior implantation in refractory glaucoma.

Keywords: Glaucoma, Inferonasal, Safety profile glaucoma drainage device, Subconjunctival gel stent, Superonasal. *Journal of Current Glaucoma Practice* (2024): 10.5005/jp-journals-10078-1441

INTRODUCTION

Glaucoma remains a leading cause of irreversible blindness across the globe.¹ Currently, intraocular pressure (IOP) remains the single proven predisposing factor associated with the development and progression of the disease. The past decade has welcomed the emergence of minimally invasive glaucoma surgery (MIGS). MIGS is a growing category of minimally invasive procedures aimed at IOP reduction while achieving a more favorable safety profile compared to conventional filtering procedures.^{2,3} These procedures have contributed to a shift in the surgical algorithm and altered the practice patterns of glaucoma specialists.

The most aggressive or least minimally invasive form of MIGS is currently represented by the XEN gel stent (Allergan), a subconjunctival gel stent that channels aqueous into the subconjunctival space in a bleb-forming fashion comparable to traditional filtering procedures. The tube was designed using the Hagen–Poiseuille equation, aimed at preventing hypotony with physiological aqueous production.⁴ The most common implantation technique for the subconjunctival gel stent is superonasal (SN) *via* an ab interno insertion, but an ab externo approach may also be utilized, with or without conjunctival gel stent are well established by a number of prior studies, with complication rates similar to or better than trabeculectomy procedures.^{6–10}

The more common placement of subconjunctival gel stents superiorly is based on experience with other bleb-forming procedures, such as trabeculectomy. The upper eyelids are thought to better protect the bleb surface superiorly, as the inferior ¹Department of Ophthalmology and Visual Sciences, University of Nebraska Medical Center, Nebraska, United States

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conjunctival fornix has a decreased surface area compared to the superior fornix.¹¹ Additionally, the frequency of bleb-associated endophthalmitis is reportedly increased with filtering blebs inferiorly compared to superior blebs.¹² Bleb formation with subconjunctival gel stents is usually more low-lying and diffuse than with other procedures, and the ability to place a stent inferonasal (IN) would spare the superior conjunctiva for trabeculectomy or tube shunts, if needed.

This present study aims to evaluate the safety and efficacy of the subconjunctival gel stent placed IN compared to SN implantation. We hypothesized that IN implantation would be similar to SN

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implantation regarding IOP reduction, glaucoma medication reduction, needling rates, and complications.

MATERIALS AND METHODS

This study was approved by the University of South Dakota Institutional Review Board, which rendered this research exempt (IRB approval number 21-230). Charts were retrospectively evaluated at our institution for patients who had undergone subconjunctival gel stent implantation for refractory glaucoma from 2020 to 2021. Patients must have had a minimum of 3 months of postoperative follow-up at the point of data analysis to be included in this study. Preoperative and postoperative IOP (1, 3, 6, and 12 months of follow-up when available), visual acuity, amount of glaucoma medications, needling events, days from stent implantation to first needling, intraoperative and postoperative complications, and the need for additional surgeries were documented. Needling events were performed at each surgeon's discretion to control the patients' IOP targeted to their individual IOP goal. IOP reduction of ≥20% plus IOP below 18 mm Hg with or without medication was defined as a "qualified success." IOP reduction of ≥20% with IOP below 18 mm Hg without medication was determined to be a "complete success." Patients included in this study had moderate to severe disease, and disease severity staging was based on American Academy of Ophthalmology (AAO) preferred practice pattern guidelines.¹³

Subconjunctival Gel Stent Implantation Procedure

The XEN45 gel stent (Allergan) was placed using both ab externo and ab interno surgical approaches, consistent with methods previously described in the literature.⁵ In both techniques, 0.3 mg/mL mitomycin C was instilled within the subconjunctival bleb. If bleb failure resulted due to conjunctival scarring, the bleb needling technique was performed under topical anesthesia using a slit-lamp biomicroscope. Subconjunctival adhesions were lysed using a 27-gauge needle, and bleb patency was confirmed. Mitomycin C 0.3 mg/mL was instilled in the bleb space.

Statistical Analysis

Data were analyzed using Excel's data analysis tool. Unpaired, onetailed *t*-tests were utilized to determine differences in preoperative and postoperative data between groups. Chi-square analysis was used to compare the significance of complications, needling rates, and further surgery between IN and SN groups. Mann–Whitney *U* tests were performed to assess the normality of the data compared to one-tailed *t*-tests. Mean IOP before surgery was the mean of the two most recent IOP measurements prior to subconjunctival gel stent implantation. The mean preoperative medication use represented the number of glaucoma medications the patient was using immediately before surgery (combination drops = 2 medications). Postoperative medication data were collected at 3, 6, and 12 months of follow-up (when available). Transient numerical hypotony was characterized as an IOP of <6 mm Hg for <1 week following surgery in a patient with no signs or symptoms of hypotony.

RESULTS

Charts were reviewed for 95 eligible patients (125 eyes) who received a subconjunctival gel stent for glaucoma at our institution between 2020 and 2021. The IN group had an average follow-up of 10.7 months compared to 12.7 months in the SN group. There were 29 eyes with stents implanted within the IN quadrant and 96 eyes with stents placed in the SN quadrant during this period. Of these,

4/29 (13.8%) IN stents and 64/96 (67%) SN stents were inserted with the ab externo approach, the rest being placed *via* an ab interno approach. Of note, eyes in the IN group experienced a significantly increased number (1.56 vs 0.94, range: 0–4 surgeries) of previous glaucoma procedures compared to the SN cases (p < 0.01). Based on AAO preferred practice pattern guidelines, 26/29 (89.7%) eyes in the IN group and 86/96 (89.6%) eyes in the SN group had severe disease (p = 0.99), with the rest being moderate (Table 1).

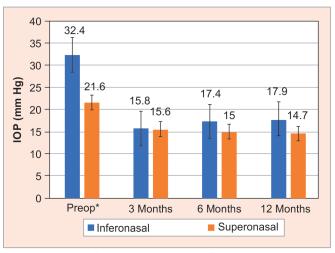
At baseline, the average IOP was significantly elevated in the IN group (32.4 ± 11.8) compared to the SN group (21.6 ± 9.2 , p < 0.01), as shown in Figure 1. Both groups had similar mean IOP at 3 months (IN = 15.8, SN = 15.6, p = 0.45), 6 months (IN = 17.4, SN = 15, p = 0.13), and 12 months (IN = 17.9, SN = 14.7, p = 0.15), postoperatively (Table 2).

At 6 months, the average IOP reduction was 46.3% (15.0 \pm 11.9 mm Hg) in the IN group and 30.5% (6.6 \pm 9.6 mm Hg) within the SN cohort (p < 0.01). Change in IOP from preoperative values was also significant at 3 months (IN = 15.4, SN = 5.9, p < 0.01) and 12 months (IN = 15.4, SN = 6.2, p = 0.01), postoperatively.

 Table 1: Demographics of patients receiving subconjunctival gel stents

 for refractory glaucoma

	IN	SN	p-value
Number of eyes	29	96	***
6 months	24	80	0.98
12 months	16	55	0.92
Mean age	74.6	77.9	0.11
Women	21 (72%)	55 (57%)	0.14
Men	8 (28%)	41 (43%)	0.14
Ab externo	4 (14%)	64 (67%)	<0.00001
Ab interno	25 (86%)	32 (33%)	<0.00001
Prior glaucoma surgeries	1.56	0.94	0.003
Moderate glaucoma	3	10	0.99
Severe glaucoma	26	86	0.99
Mean length of f/u	10.7 months	12.7 months	0.04



* Statistically significant difference

Fig. 1: Mean IOP values before and after subconjunctival gel stent implantation at 3, 6, and 12 months of follow-up. Error bars represent the SD for the mean. For the IN group, N = 29 for preoperative and 3 months, N = 24 at 6 months, and N = 16 at 12 months. For the SN group, N = 96 for preoperative and 3 months, N = 80 at 6 months, and N = 55 at 12 months



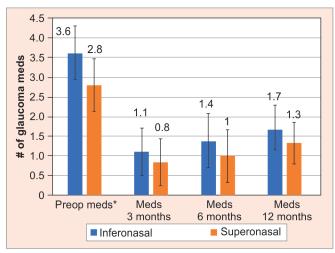
To account for variability in follow-up data and outliers, an additional analysis evaluating IOP was conducted, including only eyes with available 12-month follow-up data and excluding outliers [>standard deviation (SD) from the mean], resulting in a subset of 15 patients from the IN group and 52 patients from the SN group. The data remained statistically significant when comparing the preoperative IOP (IN = 29.6, SN = 20.2, p < 0.001). Similar to the full study cohort, the IOP between groups remained nonsignificant when comparing IOP at 3 months (IN = 13.1, SN = 14.5, p = 0.11), at 6 months (IN = 15.3, SN = 14.0, p = 0.21), and 12 months (IN = 14.7, SN = 13.5, p = 0.27), postoperatively.

A significant variation was observed when comparing preoperative glaucoma medications, with more medications being used in the IN group (3.6 ± 1.6) compared to the SN group $(2.8 \pm 1.1, p < 0.05)$. No significant difference was observed in the number of medications for glaucoma at 3 months (IN = 1.1, SN = 0.8, p = 0.31), 6 months (IN = 1.4, SN = 1, p = 0.24), and 12 months (IN = 1.7, SN = 1.3, p = 0.29) postsurgical follow-up (Fig. 2). At 6 months of follow-up, 16/29 (55%) eyes in the IN group received ≤ 1 glaucoma medication compared to 65/96 (68%) in the SN group. In the IN cohort, qualified success was achieved in 18/29 (62%) cases and complete success in 10/29 (34%) cases. In the SN cohort, qualified success was achieved in 49/96 (51%) cases and complete success in 30/96 (31%) cases. Qualified success (p = 0.35) and complete success (p = 0.83) did not show significant differences between the groups.

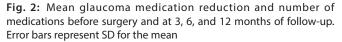
Postoperatively, 15/29 (51.7%) eyes in the IN category and 41/96 (42.7%) eyes in the SN category needed at least one needling

Table 2: Mean preoperative and postoperative IOP at 1, 3, 6, and 12 months of follow-up. Parentheses represent IOP reduction from preoperative values

Mean IOP (mm Hg)	IN	SN	p-value
Preoperative	32.4	21.6	<0.01
1 month	15.8 (–16.6)	13.3 (–8.3)	0.10
3 months	15.8 (–16.6)	15.6 (–6)	0.45
6 months	17.4 (–15)	15.0 (–6.6)	0.13
12 months	17.9 (–14.5)	14.7 (-6.9)	0.15



* Statistically significant difference



procedure due to IOP elevation, which was not significantly different (p = 0.39) (Table 3). Of those requiring needling, 10/29 (34.5%) IN patients and 7/96 (7.3%) SN patients required multiple needlings (p < 0.01). The average days to first needling were similar in the IN (88.2 days) and SN (134.1 days) groups (p = 0.19). Following the primary subconjunctival gel stent surgery, 5/29 (17.2%) patients in the IN and 23/96 (24%) patients in the SN group required further surgery to reach target IOP (p = 0.45), including subconjunctival gel stent revision or replacement (but not including needling). Among these additional surgeries were two Ahmed tube shunts, two endocyclophotocoagulation and canaloplasties, one goniotomy, and two selective laser trabeculoplasties. All other surgical interventions were subconjunctival gel stent revisions and/or replacements.

To reduce confounding data between ab externo and ab interno surgical techniques, data was compared within each group between these approaches (Table 4). In the IN group, the ab externo and ab interno categories had similar effects on IOP lowering (16.5 vs 12.4, p = 0.63) and glaucoma medication reduction (2.2 vs 2.0, p = 0.74), respectively. Similarly, within the SN group, the ab interno and ab externo groups had comparable effects on IOP lowering (5.4 vs 7.9, p = 0.17) and medication reduction (1.8 vs 1.8, p = 0.93), respectively. Regardless of stent location, stents placed *via* an ab interno approach had a mean IOP reduction of 10.3 compared to 8.2 in the ab externo cohort (p = 0.29).

Overall, complication rates were low and not significantly different between both groups. The most frequent complication included brief numerical hypotony (IOP <6 mm Hg) measured during the 1st postoperative week, occurring in 6/29 (21%) eyes in the IN category and 23/96 (24%) eyes in the SN category (p = 0.71). Nearly all of these cases were self-resolved by month 1, and there

 Table 3:
 Needling rates, days until first needling (if required), and complication rates following subconjunctival gel stent implantation

	IN (n = 29)	SN (n = 96)	p-value
%Stents requiring needling	51.7% (15)	42.7% (41)	0.39
%Stents requiring >1 needling	34.5% (10)	7.3% (7)	<0.01
Mean days to needling	88.2	134.1	0.19
%Requiring further surgery	17.2% (5)	24% (23)	0.45
Transient numerical hypotony	21% (6)	24% (23)	0.71

Table 4: Mean IOP and glaucoma medication reduction for ab interno and ab externo approach in each group at 6 months of follow-up

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	Ab interno	Ab externo	p-value
SN			
IOP reduction	5.4	7.9	0.17
Medication reduction	1.8	1.8	0.93
Transient hypotony	8	15	0.71
%Requiring further surgery	9	14	0.39
%Stents requiring needling	13	28	0.82
IN			
IOP reduction	16.5	12.4	0.63
Medication reduction	2.2	2.0	0.74
Transient hypotony	5	1	0.87
%Requiring further surgery	12% (3)	50% (2)	0.25
%Stents requiring needling	48% (12)	75% (3)	0.41

were no reported visual complications as a result of the hypotony. There was one case of postoperative hypotony that persisted beyond 1 month in each group but self-resolved without the need for further surgery. The second most common complication was subconjunctival gel stent failure requiring another operation to remove and/or replace the stent (IN = 5/29, SN = 17/96, p = 0.92). No events of endophthalmitis, bleb-related infections, persistent clinical hypotony, bleb dysesthesia, choroidal effusions, or loss of vision were documented in this study set. A Mann–Whitney *U* test was used to evaluate the normality of all categories and found no statistically significant differences.

DISCUSSION

This research reports on the efficacy and safety of subconjunctival gel stents placed in the SN and IN guadrants in patients with refractory glaucoma. Traditionally, these devices have been placed in the SN quadrant, as this area relatively spares the superior and superotemporal guadrants of the conjunctiva for future trabeculectomies or tube shunts if needed.⁶ In addition, many patients referred for glaucoma surgery have had prior trabeculectomy surgeries in the superior region, causing scarring and changes to the superior conjunctiva and Tenons. The subconjunctival gel stent has successfully controlled IOP while limiting complications when placed SN in patients following previous trabeculectomies,^{14,15} but this often poses additional surgical difficulties. Operating near an area of previous conjunctival manipulation comes with a risk of increased stent exposure and bleb leaks, ^{16,17} so an alternative location is beneficial in this patient population.

Prior work has found that glaucoma filtering surgeries performed at the inferior limbus due to superior conjunctival scarring remain a safe and effective option for treating glaucoma. Rachmiel et al. reported no significant difference in IOP-lowering and success rates when investigating inferior and superior placements of Ahmed glaucoma drainage devices (GDD).¹⁸ Martino et al. reported no significant difference in the average number of glaucoma medications and IOP reduction between superior and inferior glaucoma filtering surgery groups for 2 years following surgery. During the 3rd year of follow-up, the inferior GDD cohort had a significantly greater mean IOP and reoperation rate relative to the superior GDD group.¹⁹

In our study, we found that IN stents provided a significant 15.0 mm Hg (46.3%) reduction in IOP compared to a 6.6 mm Hg (30.5%) reduction in the SN group at 6 months. Postoperative IOPs were similar at 1, 3, 6, and 12 months of follow-up when comparing both groups. Qualified success was achieved in 18/29 (62%) cases and complete success in 10/29 (34%) cases in the IN group, while qualified success was attained in 49/96 (51%) cases and complete success in 30/96 (31%) cases in the SN group. Glaucoma medication reduction, change in visual acuity, number of stents requiring needling, days to first needling, and need for further surgery did not vary significantly between the groups. However, a significantly higher proportion of patients in the IN group required multiple needlings.

Düzgün et al. evaluated the effectiveness of subconjunctival gel stents placed IN in 14 patients following failed trabeculectomies. At 12 months of follow-up, they found a 61% reduction in glaucoma medications and an average IOP reduction of 49.3%, with 50% of patients achieving target IOP without glaucoma medications.¹⁵ Their 42.8% (6/14) needling

rate was similar to our reported rate and comparable to other rates reported within the literature.^{9,15}

Hengerer et al. retrospectively compared IN and SN subconjunctival gel stent implantations. They found no significant difference in gualified success rates (IOP <18 mm Hg and a \ge 20% reduction in IOP with or without medications), IOP reduction, and medication reduction at 12 months after surgery. Interestingly, the IN group had significantly lower IOP at the 3-month mark and an overall significantly lower needling percentage compared to the SN group (27 vs 45%). This led the authors to propose that the reduced tension of the lower eyelid may cause less postoperative fibrosis and allow for reduced impedance to aqueous humor outflow in the months following surgery.²⁰ Although we did not observe the same significant difference in IOP lowering effects at 3 months, this theory could partly explain our more substantial IOP reduction in the IN group. In contrast, we did not find a significantly reduced need for needling in the IN cohort but observed a significantly higher frequency of re-needlings (≥ 2 needlings) in the IN group, despite a similar total number of patients requiring needling between both groups.

The difference in preoperative baseline characteristics between the two groups should also be highlighted. The IN group had significantly higher preoperative IOP, preoperative medication use, and a greater number of previous glaucoma procedures compared to the SN group, despite similar glaucoma severity between the groups (p = 0.99).

There is research showing that blebs located more superiorly have a lower incidence of bleb-related dysesthesia, as has been reported for trabeculectomies.²¹ Budenz et al. discovered a negative correlation between the amount of bleb enclosed under the lid and bleb dysesthesia, indicating that SN blebs had more discomfort compared to superior blebs.²² There is also concern about a higher risk of bleb-related infection and endophthalmitis with inferiorly located blebs.^{12,23,24} Overall, most of these studies evaluated these complications following trabeculectomies and may not directly apply to blebs produced by the subconjunctival stent device studied herein.

Although there was a limited sample size in the IN group, there were no reported cases of bleb dysesthesia, bleb-related infections, or endophthalmitis in either cohort. This is consistent with previous research evaluating the safety of IN subconjunctival gel implants.^{15,20} These findings may be related to the fact that blebs following subconjunctival gel stent implantation have a different morphology and healing process compared to traditional blebs, as measured with anterior chamber optical coherence tomography.²⁵ Bleb morphology and function play a crucial role in the success of these surgeries and are related to the incidence of bleb-related complications.²⁶⁻²⁸ These results, although limited to a single study, suggest that minimally invasive IN implantation may not be associated with an increased risk of endophthalmitis due to their altered bleb morphology. However, further study is certainly needed to confirm these findings.

This study is not without limitations. As a retrospective study, it has inherent limitations including lack of uniform follow-up, differences in sample size between the two groups, and variability in follow-up duration. To address these discrepancies, a sensitivity analysis was performed, comparing only patients with a full 12 months of follow-up and excluding outliers, which showed no changes in statistical significance when comparing IOP at different time points. Additionally, the IN group appeared to have more advanced glaucoma, with higher baseline IOP, more glaucoma



medications, and more previous glaucoma surgeries, which could impact the comparison between the groups. However, a large, prospective, randomized controlled trial would be the optimal approach to assess the safety and efficacy between these two subconjunctival stent locations.

CONCLUSION

This study demonstrates that IN subconjunctival gel stent implantation provides a comparable IOP-lowering benefit compared to SN stents, with a trend toward enhanced IOP reduction in the IN group. Additionally, qualified and complete success rates, medication reduction, needling rates, complications, and the need for further surgery were similar in the two groups. More studies are needed to confirm these findings and improve our understanding of how bleb location influences glaucoma treatment.

Clinical Significance

This article compares the efficacy and safety between SN and IN subconjunctival gel stents for treating refractory glaucoma. Our research, despite its limited sample size, demonstrates that IN placement of subconjunctival stents provides a comparable IOP and glaucoma medication lowering effect compared to the traditional superior approach. Overall, the results of this study suggest that IN quadrant placement is an acceptable approach and may be a strategy to avoid previous scarring or spare the superior conjunctiva, potentially enabling more patients to receive subconjunctival gel stents for the treatment of refractory glaucoma.

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