

# Novel surgical procedures in glaucoma: advances in penetrating glaucoma surgery

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## Purpose of review

Despite late modifications and enhancements, traditional penetrating glaucoma surgery is not without complications and is reserved for patients in whom pharmacologic treatment and/or laser trabeculoplasty do not suffice to control the intraocular pressure. This article critically reviews recent advances in penetrating glaucoma surgery with particular attention paid to two novel surgical approaches: ab interno trabeculectomy with the Trabectome and implantation of the Ex-PRESS shunt.

## Recent findings

Ab interno trabeculectomy (Trabectome) achieves a sustained 30% reduction in intraocular pressure by focally ablating and cauterizing the trabecular meshwork/inner wall of Schlemm's canal. It has a remarkable safety profile with respect to early hypotonous or infectious complications as it does not generate a bleb, but it can be associated with early postoperative intraocular pressure spikes that may necessitate additional glaucoma surgery. The Ex-PRESS shunt is more commonly implanted under a partial thickness scleral flap, and appears to have similar efficacy to standard trabeculectomy offering some advantages with respect to the rate of early complications related to hypotony.

## Summary

Penetrating glaucoma surgery will continue to evolve. As prospective randomized clinical trials become available, we will determine the exact role of these surgical techniques in the glaucoma surgical armamentarium.

## Keywords

ab interno trabeculectomy, Ex-PRESS shunt, glaucoma penetrating surgery, goniotomy, miniature glaucoma device, Trabectome

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## Introduction

Since introduced by Sugar and Cairns [1–3], guarded filtration surgery (i.e. trabeculectomy) remains the procedure of choice for the majority of patients with glaucoma requiring operative intervention [4]. Antifibrotic agents, namely 5-fluorouracil and mitomycin C, allowed wound healing modulation and an individualized approach to modify the inflammatory and fibrotic response to the surgical insult, improving surgical outcomes [5–10]. In addition, postoperative filtration titration by removal of releasable sutures [11,12] or postoperative laser suture lysis [13–15] provided an additional safety measure that is commonly employed to avoid early postoperative complications and maximize outcomes [16–18]. As a result of the above, the success rate of modern trabeculectomy in experienced hands is estimated between 60 and 100% depending on patient selection, definition of success and length of follow-up [19–25]. Despite these developments, guarded filtration

surgery remains to a certain extent unpredictable, with a significant rate of early postoperative complications related to hypotony, wound leak, late infectious complications or failure.

Glaucoma drainage devices or aqueous shunts were initially reserved for eyes where trabeculectomy had failed or for eyes with poor visual prognosis or high risk for failure with conventional trabeculectomy [26–28]. This belief has been recently challenged by the early results of the tube versus trabeculectomy study [29,30], and may be reflected in the fact that the number of aqueous shunt surgeries that are performed in the US is steadily rising [4,31,32]. Glaucoma drainage devices have attained success rates ranging between 25 and 94%, most commonly above 60%, depending on the type of shunt used, the definition of success criteria, the length of follow-up and the characteristics of the population studied [28]. Glaucoma drainage devices, however, are certainly not without complications such as early hypotony, choroidal

effusions, shallow anterior chamber, diplopia, tube obstruction, conjunctival erosion, tube migration, corneal decompensation, plate encapsulation and late failure [28,33,34].

As a result, there has been a continuous quest for a more predictable and physiologic glaucoma procedure with rapid recovery and a greater margin of safety. Nonpenetrating glaucoma procedures have emerged as an alternative to standard filtration surgery, and include viscocanalostomy [35–40], deep sclerectomy with or without a collagen implant and with or without subsequent Nd-YAG goniopuncture [41–48], and canaloplasty [49]. Even though encouraging results have been reported with nonpenetrating glaucoma surgical procedures, a review of these is outside the scope of this article. Similarly, surgical procedures or devices not approved by the FDA in the US, with limited enrollment of patients or short follow-up, such as ab interno trabecular bypass shunt implantation into Schlemm's canal [50,51], implantation of a modified aqueous shunt into the suprachoroidal space [52], or procedures with ab interno delivery of laser energy to the trabecular meshwork, such as excimer laser trabeculotomy [53] or endoscopically controlled erbium YAG goniopuncture [54,55], are not discussed in this review. The focus of this review is on two novel surgical procedures approved in the US: ab interno trabeculectomy with the Trabectome (NeoMedix Corp., Tustin, California, USA) and implantation of the Ex-PRESS Glaucoma Miniature Device (Optonol Inc., Kansas City, Kansas, USA). With regards to the Trabectome, we also present an interim analysis of the results of an ongoing multicenter study as of October 2007, evaluating the safety and efficacy of this surgical approach for which recruitment is continued.

### Ab interno trabeculectomy (Trabectome)

Goniotomy and trabeculotomy have attained success rates of up to 90% in cases of congenital glaucoma [56], whereas the long-term results of trabeculotomy in adults have been less promising [57,58]. Ab interno trabeculectomy with the use of a novel device, the Trabectome, has been introduced as an alternative to conventional filtration surgery, with excellent initial results. The theoretical advantages of this procedure are a temporal clear cornea approach, which leaves the conjunctiva available for subsequent conventional filtration surgery as necessary, and the absence of a filtering bleb, which greatly minimizes the risk of late infectious complications. In addition, the Trabectome can be combined with phacoemulsification using the same temporal clear cornea incision.

Briefly, the Trabectome disposable handpiece is introduced through a 1.6-mm to 1.8-mm temporal clear cornea

incision. The handpiece contains a 19-gauge infusion sleeve and a longer coaxial 25-gauge aspiration port coupled to a bipolar electrocautery controlled by a conventional foot pedal [59]. The instrument is bent at the distal end creating a relatively sharp triangular footplate that is used to engage and focally ablate the trabecular meshwork/inner wall of Schlemm's canal [60]. Once in an appropriate position, a strip of trabecular meshwork spanning 30–90° that constitutes the inner wall of Schlemm's canal is ablated and removed in a continuous circular movement under direct gonioscopic visualization. Insulation of the external aspect of the footplate and continuous irrigation of the anterior chamber prevent thermal damage to adjacent intraocular structures. Intraoperative reflux of blood through the trabecular meshwork cleft is the rule in this procedure and confirms appropriate ab interno 'unroofing' of Schlemm's canal. The hyphema transiently affects vision postoperatively as it clears after an average of 6.4 days [59]. In the initial clinical report of the procedure, intraocular pressure (IOP) reduction of about 38% was achieved at the 6-month follow-up ( $n=25$ ) along with a concurrent reduction in the number of medications used [59]. In a subsequent larger series of patients ( $n=101$ ) with follow-up extended up to 30 months, the overall success rate, defined as IOP lower than 21 mmHg with or without medication and no subsequent glaucoma surgery, was determined to be 84% [61]. Furthermore, a very low incidence of early hypotony and loss of vision in excess of two lines was reported with this procedure (<1% for both parameters) [61]. Table 1 summarizes the published studies.

Interim analysis of an ongoing prospective multicenter study evaluating the efficacy and safety of this novel procedure has provided equally encouraging results. Analyzing the clinical outcome of  $n=679$  consecutive patients undergoing ab interno trabeculectomy with the Trabectome with a maximum follow-up of up to 52 months, an average reduction in intraocular pressure of 29% was achieved at 6 months follow-up ( $n=106$ ), 34% at 12 months follow-up ( $n=65$ ) and 30% at 24 months follow-up ( $n=30$ ). This level of pressure reduction (30%) was sustained in the few patients who have reached 48 months follow-up as of October 2007 ( $n=13$ ). In addition, a reduction in the number of glaucoma medications by about two medications was documented, which peaked at 10 months follow-up and remained stable thereafter. The most common indication for surgery in this cohort was primary open angle glaucoma (73%), followed by pseudoexfoliation (9%), pigment dispersion (3%) and uveitic glaucoma (2%). In 30% of the cases, the procedure was combined with cataract extraction. No patient lost more than two lines in visual acuity and there was zero incidence of flat or shallow anterior chamber, sustained hypotony, wound leak, infection, choroidal effusion or

**Table 1 Summary of the pertinent studies describing outcomes of the Trabectome procedure and the Ex-PRESS shunt implanted under a partial thickness scleral flap**

Author	Procedure	n	Proportion of POAG (%)	Combined cases (%)	Preop. IOP	Postop. IOP at 1 year	Incidence of flat A/C or hypotony (%)	Average follow-up	Success rate (%)
Minckler	Trabectome	37	70	0	28.2	16.3 (n = 15)	0	7.3 <sup>b</sup>	97 <sup>c</sup>
Minckler <sup>a</sup>	Trabectome	101	81	0	27.6	16.4 (n = 37)	1	10.8 <sup>b</sup>	84
Current enrolment	Trabectome	679	73	30	23.7	15.7 (n = 65)	0	5.5 <sup>b</sup>	79–92 <sup>d</sup>
Dahan	Ex-PRESS	24	88	0	27.2	14.5 (n = 21)	8.3	16.6	83
Maris	Ex-PRESS	50	74	30	26.2	14.1 (n = 33)	8	10.8	90
Coupin	Ex-PRESS	99	100	28	22.9	14.3 (n = 40)	6	7.5	87

Preop. and postop. intraocular pressure (IOP) at 1 year refer to the average intraocular pressure of the cohorts at the respective time-points, while the number in parentheses indicates the number of patients who reached 1 year of follow-up. The column labeled 'Incidence of flat A/C or hypotony' provides an estimate of the combined rate of significant complications related to hypotony, such as flat anterior chamber requiring reformation, presence of choroidal effusions or sustained hypotony; it does not include transient self-limited hypotony. Average follow-up is expressed in months. Success is defined as intraocular pressure below 21 mmHg with or without medications and without subsequent glaucoma surgery or removal of an implant at least 1 month after the operation. Postoperative bleb manipulation, such as laser suture lysis or bleb needling, anterior chamber washout or tube repositioning, do not constitute subsequent glaucoma surgery.

<sup>a</sup> The follow-up study by Minckler *et al.* includes the initial 37 patients that have been described in the initial report of the Trabectome procedure.

<sup>b</sup> The average follow-up in the Trabectome studies is an estimate calculated from the patients that reached respective time-points.

<sup>c</sup> In the first Trabectome report by Minckler *et al.* failure is based on performance of subsequent glaucoma surgery; as patients were recruited in Tijuana, Mexico, the cohort's utilization of glaucoma medications is very low both before and after the surgery and therefore IOP criteria for success cannot be reliably employed.

<sup>d</sup> In the current Trabectome study, a Kaplan-Meier survival curve is not possible as there is continuous influx of data and a significant portion of patients have not reached sufficient follow-up; therefore we provide the range of patients who had an IOP lower than 21 mmHg and did not require subsequent glaucoma surgery at all data-points past 1 month after surgery.

hemorrhage in the postoperative period. Very few patients (n = 7, 1%) experienced early transient hypotony (IOP < 5 mmHg) on postop day #1. The most common and the only clinically significant complication was a spike in intraocular pressure (IOP > 21 mmHg) in the early postoperative period (19.7%). The cumulative incidence of a subsequent glaucoma surgical procedure was 8% for this cohort with the overwhelming majority (85%) of surgeries being performed within 6 months after the Trabectome procedure, and 67% of the treating physicians preferring trabeculectomy as the second procedure. In conclusion, ab interno trabeculectomy with the Trabectome appears to be a safe alternative to conventional filtration surgery for open-angle glaucoma, with a clinically relevant reduction in intraocular pressure and an excellent safety profile.

### Ex-PRESS miniature glaucoma device

The Ex-PRESS Miniature Glaucoma Device is a small nonvalved stainless-steel implant originally designed to be implanted near the limbus directly under the conjunctiva, allowing drainage of aqueous humor into the subconjunctival space (unguarded implant) [62,63]. The implant is 3 mm long with an external diameter of 400  $\mu$ m and an internal diameter usually of 50  $\mu$ m (R-50), and has an external disc-like flange and an internal spur-like projection to prevent extrusion. Several versions of the Ex-PRESS shunt are commercially available with different internal lumen diameters (30 and 50  $\mu$ m, respectively); only the 50- $\mu$ m implants are currently available in the US. Early experience with this implant using an unguarded technique was associated with significant reduction in intraocular pressure, and acceptable short-term and long-term success [64,65], but also with a high

incidence of postoperative hypotony (up to 90% in the early postoperative period) [66,67], erosion of the conjunctiva over the implant or traumatic extrusion of the implant [68–72]. Dahan and Carmichael [73] modified the surgical technique implanting the Ex-PRESS shunt under a 5  $\times$  5 mm partial thickness scleral flap similar to a standard limbus-based guarded trabeculectomy. In the initial case series of 24 eyes, predominantly in patients with primary open angle glaucoma, mitomycin C 0.05% was applied under the scleral flap in all cases. The modified technique yielded excellent short-term results with an average decrease of 46% in intraocular pressure at 12 months and a significant reduction in the need for postoperative glaucoma medications. With the guarded approach, the rate of transient hypotony was not insignificant (20.8%), but only two patients (8.3%) developed choroidal effusions and only one (4.1%) required anterior chamber reformation. In a retrospective nonrandomized comparative case series between the Ex-PRESS shunt implanted under the scleral flap and standard limbus-based trabeculectomy with mitomycin C, Kaplan-Meier survival curves were not statistically different for the two groups, with success defined as postoperative intraocular pressure between 5 and 21 mmHg with or without medications and no further glaucoma surgery or removal of the implant [74••]. Laser suture lysis, bleb needling and 5FU injections were not considered to be criteria for failure in this report. The success rate was 90% for the Ex-PRESS shunt and 92% for the trabeculectomy group at the last follow-up, on average 11 months after the procedure. In addition, both procedures were comparable with regards to reduction in the need for postoperative glaucoma medications and postoperative visual acuity. Intraocular pressure was, on average, significantly lower in the

trabeculectomy group in the early postoperative period (up to 3 months) despite laser suture lysis being performed more frequently in the Ex-PRESS shunt group. The average intraocular pressure curves converged after that time-point and were not significantly different thereafter. In contrast, there was a significantly higher incidence of early transient hypotony (32% compared with 4%) and choroidal effusions (38% compared with 8%) in the trabeculectomy group. Similar success rates have been reported in a different case series for the Ex-PRESS shunt implanted under a scleral flap: 87% with medication and 63% without medication using a similar definition of success [75]. Table 1 summarizes the pertinent studies. In conclusion, the Ex-PRESS shunt implanted under a partial thickness scleral flap may be a safe alternative or adjunct to standard guarded trabeculectomy, and may provide some additional margin of safety against early postoperative hypotony.

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## Discussion

An ideal glaucoma procedure should be easy to perform, reproducible, with a low incidence of early postoperative hypotony, and long-term adequate IOP control. Furthermore, it should be minimally cataractogenic, allow rapid visual recovery and have the potential to be combined with phacoemulsification without one procedure potentially affecting the outcome of the other.

As reported in the literature, the Trabectome has a favorable safety profile, and allows rapid visual rehabilitation of the patient. The most common (~60%) complication of the Trabectome procedure is transient hyphema/microhyphema as a result of intraoperative or postoperative blood reflux from Schlemm's canal, which almost never persists past 1 week after the procedure [59]. Early complications related to hypotony occur at very low rates with the Trabectome (0–1%), which makes this procedure particularly attractive for patients with poor IOP control despite maximal medical therapy and good visual acuity. There is an approximate 20% incidence of IOP spikes above 21 mmHg with the Trabectome procedure on postop. day one, and a 3% incidence of early (within 1 month) failure of the procedure necessitating subsequent filtration surgery (unpublished data from the ongoing prospective study evaluating the safety and the efficacy of the procedure). In view of the fact that the conjunctiva remains undisturbed during this procedure, conventional incisional glaucoma surgery remains available to the patient who is in need of better IOP control. Furthermore, the incidence of infectious complications as a result of the procedure should be comparable with modern phacoemulsification (0 events so far in 679 cases), whereas attrition of late cases of endophthalmitis is theoretically very unlikely. Compared with trabeculectomy with antimetabolites, the

Trabectome procedure does not generate, on average, as low an intraocular pressure, and therefore it may not be suitable for patients with end-stage optic nerve cupping who are in need of extremely low intraocular pressures. As long-term data become available for this surgical procedure, we will be able to clarify the exact role of the Trabectome in our glaucoma surgical armamentarium, optimize the surgical parameters (i.e. clock hours of trabecular meshwork that need to be ablated), and hopefully spare or delay classic filtration surgery for a significant proportion of our patients.

The Ex-PRESS is now most often implanted under a large partial thickness scleral flap [72]. The surgical procedure is designed to generate a filtering bleb and allows intra-operative and postoperative modulations identical to standard trabeculectomy. Thus, it is subject to the same late complications as standard trabeculectomy, namely bleb encapsulation, blebitis, late endophthalmitis, conjunctival erosion and bleb dysesthesia. Implantation under a trabeculectomy flap has solved many of the problems of direct subconjunctival implantation [73,74<sup>••</sup>,75]. In the retrospective comparative case series by Maris *et al.*, the most significant advantage of the Ex-PRESS shunt over standard trabeculectomy was the lower incidence of early postoperative complications related to hypotony (8% compared with 38%) [74<sup>••</sup>]. A feasible explanation is that the small internal lumen of the device provides some additional resistance to flow, controlling filtration at least in early stages [70]. As a result of the above, the Ex-PRESS group of patients had a higher IOP profile over the first 3 months after surgery and required more postoperative manipulation. The IOP curves of the two groups converged at 6 months of follow-up. The above characteristics may render this procedure attractive for the young myopic patient with good preoperative visual acuity who is in need of the low intraocular pressure profile that trabeculectomy can provide. In addition, there is some evidence in support of less of an inflammatory response in the immediate postoperative period as a result of the fact that the Ex-PRESS shunt is more atraumatic to the iris [63,70,74<sup>••</sup>]. This alone could potentially discourage encapsulation and late failure.

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## Conclusion

Ab interno trabeculectomy (Trabectome) and implantation of the Ex-PRESS shunt under a partial thickness scleral flap constitute reasonable alternatives to classic penetrating filtration surgery, with acceptable short-term results and an attractive safety profile. Ab interno trabeculectomy (Trabectome) may assume a role in early or moderately advanced glaucoma where a percentage reduction in IOP is desired but cannot be achieved with medications alone. Comparative studies to guarded trabeculectomy and to laser trabeculoplasty are warranted

in the near future. On the other hand, the Ex-PRESS shunt may become the procedure of choice for patients with advanced glaucoma in need of low intraocular pressures with a high risk for hypotonous complication. Prospective studies with longer follow-up will hopefully allow us to clarify the exact indications of the Ex-PRESS shunt implanted under a partial thickness scleral flap, providing one additional option in penetrating glaucoma surgery.

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Papers of particular interest, published within the annual period of review, have been highlighted as:

- of special interest
- of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (pp. 163–165).

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