CO₂ laser-assisted sclerectomy surgery compared with trabeculectomy in primary open-angle glaucoma and exfoliative glaucoma. A 1-year follow-up

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ABSTRACT.

**Purpose:** To report on the efficacy and safety of CO₂ laser-assisted sclerectomy surgery (CLASS) compared with trabeculectomy in primary open-angle glaucoma and exfoliative glaucoma.

**Methods:** One hundred and thirty-one patients underwent CLASS (66 patients) or trabeculectomy (65 patients) and were followed up for 12 months. ‘Complete success’ was defined as intraocular pressure (IOP) between 10 and 18 mmHg and reduced by at least 30% from the baseline without medications, while ‘qualified success’ was compliant with the above criteria with or without the medications.

**Results:** Comparing CLASS with trabeculectomy at 1 year, the mean IOP reduction rate was 32.6 ± 10.8% versus 40.6 ± 15.9% (p < 0.001) and the average use of medications was 1.4 ± 1.4 versus 0.7 ± 1.1 (p < 0.05). At 12 months, the complete success rate was 35% for CLASS versus 60% for trabeculectomy (p < 0.01), while the qualified success rate was 74% versus 75%, respectively, with no significant difference in qualified success rate between the groups at any time-point (p > 0.05). Compared with CLASS, patients after trabeculectomy developed a higher rate of early complications (9.1% versus 29.2%, p = 0.004), higher endothelial cell density (ECD) loss (1.4 ± 1.4% versus 6.5 ± 4.8%, p < 0.001), higher astigmatism (0.0 ± 0.1 versus 0.1 ± 0.2, p < 0.001) and significant visual acuity deterioration (0.1 ± 0.1; range 0–2 lines versus 0.4 ± 0.6; range 0–3 lines, p = 0.016).

**Conclusion:** Although CLASS shows a less potent hypotensive effect, it is similar to trabeculectomy in the qualified success rate and offers the reduction in medications up to 12 months. With a more attractive complications profile, CLASS may be an alternative to trabeculectomy, especially at the earlier glaucoma stage and in patients with a low ECD.

Key words: CO₂ laser – exfoliative glaucoma – glaucoma surgery – nonpenetrating deep sclerectomy – primary open-angle glaucoma – trabeculectomy

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**Introduction**

The spectrum of surgical options for Open-angle glaucoma (OAG) includes several techniques, but trabeculectomy has remained the gold standard procedure (Mermoud & Schnyder 2000; Landers et al. 2012) for almost half a century, since it was first proposed by Cairns (1968) and modified by Watson (1970). Over the decades, the conventional trabeculectomy has embraced a range of advancements, driven by the need to minimize the risk of complications and surgical failure. In the traditional model, there was a tendency to develop a sudden intraocular pressure (IOP) fall in the first days following the surgery, which may result in early hypotony and a considerable rate of early vision-threatening complications, with hyphema, anterior chamber (AC) shallowing and choroidal effusion. One year after trabeculectomy, a loss of more than one Snellen line of preoperative visual acuity has been reported in 15–18.8% of patients (Edmunds et al. 2002; Gedde et al. 2007; Landers et al. 2012). Modern strategies called the ‘Moorfields Safer Surgery System’ (Khaw et al. 2012), including the use of perioperative antimetabolites, AC maintainer, adjustable and releasable sutures together with secure conjunctival closure technique, have been proven to result in gradual IOP decrease, reduced risk of complications and improved long-term surgical outcomes (Kirwan et al. 2013). Nowadays, trabeculectomy is widely adopted at an early stage of glaucoma surgery training and is reported to be performed at a similar rate of success and complications by trainees and experienced surgeons (Chan et al. 2007; Sun & Lee 2013; Kwong et al. 2014). Nonetheless, the invasive nature of trabeculectomy carries the risk of late corneal sequelae of surgical trauma, with surgically induced astigmatism.
Acta Ophthalmologica 2000, it has been reported at a rate of
the iridocorneal angle (Dietlein et al. 2007). Although the
risk of intraoperative TDM perforation, which requires conversion to
intrinsically prevents excessive ablation. Subsequently, the risk of intra-
operative TDM perforation is reduced, and the whole procedure is less depend-
ent on the surgeon’s skills (Assia et al. 2007; Klink et al. 2008). CO2 laser-
assisted sclerectomy surgery (CLASS) outcomes, in terms of IOP-lowering
potential, have already been reported as comparable to classic NPDS over a
period of up to 2-year follow-up (Geffen et al. 2012; Skaat et al. 2014; Greifner et al. 2016). Potentially, combi-
going the preoperative and the final
nating the surgical precision and short learning curve, CLASS may enable
patients to benefit from the safety and effectiveness of nonpenetrating surgery.
The following study aims to report
on the safety and efficacy profile of CLASS compared with trabeculectomy in primary open-angle glaucoma
(POAG) and exfoliative glaucoma (XFG).

Materials and Methods

Study design

This was a prospective cohort comparative study, approved by the local
ethics committee (KNW/0022;KB1/132/16) and conducted according to the
tenets of the Declaration of Hel-
sinki. Informed written consent was obtained from all patients. Inclusion
criteria were as follows: adult patients (aged ≥ 18), medically uncontrolled
POAG or XFG, open angles confirmed in gonioscopy (grade 3 or 4 in four
quadrants, according to Shaffer classification), pseudophakia and a history of
uneventful cataract surgery performed >6 months prior to listing for
the glaucoma surgery. Patients with a history of any other eye surgery were
not included in the study. Medically uncontrolled glaucoma was defined as
a progression of glaucomatous optic neuropathy despite the use of maximal
topical treatment, or one in which the topical medications were contraindi-
cated or not tolerated by the patient. One hundred and thirty-one white
patients (131 eyes) were enrolled in the study and randomly divided into
two groups that underwent filtration surgery either by CLASS (group 1: CLASS) or by conventional trabecu-
lecomy (group 2: TRAB). The patients underwent a baseline examination
within 2 days before the surgery and were followed up at 1 week, 1, 3, 6 and
12 months postoperatively. At each visit, we recorded best-corrected Snel-
len visual acuity, IOP as an average of three consecutive measurements with a
calibrated Goldmann applanation tonometer (Haag-Streit AG, Koeniz,
Switzerland), number of antiglaucoma medications (if topical combinations
were used, these were counted according to the number of active drugs) and
dioptric scans using a rotating Scheimpflug tomography (Pentacam, OCULUS
GmbH, Wetzlar, Germany). Comparing the preoperative and the final
measurements of ECD and TCRPA3, respectively, we calculated mean ECD
loss and mean surgically induced cor-
neal astigmatism. The main outcomes were: IOP reduction, use of adjuvant
medications, ECD loss, the magnitude of surgically induced cor-
neal astigmatism, change in the best-
corrected Snellen visual acuity and rates of complications recorded in both
groups. ‘Complete success’ was defined as IOP values measured at each follow-
up visit ranging between 10 and 18 mmHg and reduced by at least
30% from
the baseline without glaucoma medica-
tions and ‘qualified success’ as IOP
measurements within the above criteria with or without glaucoma medications. Intraocular pressure (IOP) <10 mmHg or >18 mmHg despite medications, reduction of <30% from the baseline, reoperation for glaucoma within 12 months or loss of light perception were classified as failure.

**Surgical procedures**

All the procedures were performed under peribulbar anaesthesia (3:1 of bupivacaine 0.5% and lidocaine 2%) and by the same experienced surgeon (EW). There was no application of perioperative antimetabolites. CO₂ laser-assisted sclerectomy surgery (CLASS) was performed in the superior quadrant, following the technique described by Geffen et al. (2012), using a commercially available OT-135 CO₂ laser system (IOPtima Ltd, Ramat Gan, Israel). The procedure involved a corneal traction suture, conjunctival peritomy, opening and dissection of the Tenon’s capsule, catarization of bleeding vessels within the area of exposed sclera and dissection of 50% lamellar scleral flap of dimensions 4 mm × 4 mm at the 12-o’clock position using a feather blade (initial horizontal incision) and a crescent blade (flap dissection). The laser dissection of the deep sclera and Schlemm’s canal towards the TDM was performed to achieve aqueous humour percolation. The scleral flap edges were approximated with two fixed 8.0 nylon intrascleral sutures, applied at the corners of the flap, and conventional conjunctival closure was done with four 9.0 nylon interrupted sutures. Postoperative management in both groups included routine overnight patching, topical levofloxacin 5 mg/ml, which continued for 4 weeks, and dexamethasone 1 mg/ml, which tapered down over 8 weeks.

**Statistical analysis**

Descriptive statistical results were presented as mean ± standard deviation (SD) or median with range. Normality of the data was tested with the Shapiro–Wilk test, and parametric or nonparametric tests have been applied accordingly. Comparisons of quantitative variables between the groups were conducted with the chi-squared test (with Yates’ correction), for normally distributed variables in both groups, or via the Wilcoxon two-sample test, a.k.a. Mann–Whitney test, in other cases. Repeated measurements of quantitative variables were compared with paired t-test (for normally distributed differences in both groups) or paired Wilcoxon tests (otherwise). The cumulative probability of success was illustrated using Kaplan–Meier survival curves. A p value of <0.05 was considered significant. Analysis was performed in R package, version 3.4.1 (R Core Team 2017).

**Results**

**Baseline**

One hundred and thirty-one patients were enrolled in the study, 66 patients underwent CLASS (group 1) and 65 patients underwent TRAB (group 2). There was no significant difference in age, sex, glaucoma type, baseline IOP and number of drugs between the groups (p > 0.05; Table 1).

**IOP**

Patients in both groups achieved a significant IOP decrease from baseline (p < 0.001), with a higher IOP reduction in the TRAB group through the whole follow-up period of the study (p < 0.001). The mean IOP reduction rate at 1 year was 32.6 ± 10.8% in group 1 compared to 40.6 ± 15.9% in group 2, excluding the patients who underwent surgical revision after 6 months. The mean IOP reduction following both procedures over time is illustrated in Table 2 and Fig. 1.

**Medications**

Table 3 and Fig. 2 present the average numbers of IOP-lowering medications which were used up to 12 months postoperatively, in both study groups. The reduction in number of medications was significant in both groups up to 12 months (p < 0.001), but group 1 required significantly more drugs than group 2 after 3, 6 and 12 months following the surgery (p < 0.05). Initially, glaucoma medications were routinely withdrawn after the surgery in all patients. Twelve months after the surgery, the average use of hypotensive drops by patients in CLASS and TRAB groups was 1.4 ± 1.4 versus 0.7 ± 1.1 (p < 0.05), respectively.

In both groups, there were no significant differences in rates of patients who stopped using at least one drug after the surgery (p > 0.05; Table 4).

**Success**

**Complete success**

After a week, CLASS procedure was successful in 55 patients (83%) and TRAB in 60 (92%), p > 0.05. Significant differences in complete success rates between groups were found after a month from baseline and later, with more TRAB patients meeting complete success criteria. A year after the surgery, the complete success rate dropped to 23 patients (35%) for CLASS versus 39 patients (60%) for TRAB (p < 0.01). Table 5 shows the complete success rates over time in both groups.

**Qualified success**

There was no significant difference in qualified success rate between the groups at any time over the follow-up period of the study (p > 0.05). After a year, the qualified success rate was 74% in CLASS group and 75% in TRAB. Table 6 shows the complete success rates over time in both groups.

**Early complications**

The total number of early complications following TRAB was significantly higher than following CLASS (19 patients (29.2%) versus 6 patients (9.1%) p = 0.004).

Choroidal detachment occurred in one patient (1.5%) in the CLASS and in 12 patients (18.5%) in the TRAB
Table 1. Baseline demographic characteristics of study groups.

<table>
<thead>
<tr>
<th>Glaucoma type</th>
<th>CO₂ laser-assisted sclerectomy surgery (N = 66)</th>
<th>Trabeculectomy (N = 65)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>30 (45%)</td>
<td>35 (54%)</td>
<td>0.413*</td>
</tr>
<tr>
<td>Female</td>
<td>36 (55%)</td>
<td>30 (46%)</td>
<td></td>
</tr>
<tr>
<td>Glaucoma type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary open-angle glaucoma</td>
<td>34 (52%)</td>
<td>34 (52%)</td>
<td>1*</td>
</tr>
<tr>
<td>Exfoliative glaucoma</td>
<td>32 (48%)</td>
<td>31 (48%)</td>
<td></td>
</tr>
</tbody>
</table>

Kaplan–Meier cumulative survival curves

Figure 3A,B shows Kaplan–Meier plots of the cumulative probability of complete success and qualified success in both groups up to 12 months, defining failure as IOP >18 mmHg or not reduced by 30% below baseline at any time-point. There were 17 patients (26%) in the CLASS group and 16 patient (25%) in the TRAB group for whom the surgery was considered failed at the end of the follow-up. Among these, seven patients (11%) in CLASS and four (6%) in TRAB groups, respectively, underwent reoperation for IOP reduction within 6–12 months after the initial surgery. Two patients (3.1%) required urgent revision of trabeculectomy after a week due to iris incarceration with IOP spike. In the CLASS group, three patients required the enhancement procedure of Nd:YAG laser GPT due to iris incarceration with peripheral anterior synchiae, which developed within the filtration site of the sclerectomy. The procedures were performed between 1 and 3 months postoperatively and did not result in achievement of the target IOP level despite adjuvant medications.

Endothelial cell density, surgically induced astigmatism and vision loss

Trabeculectomy (TRAB) group developed significantly higher average ECD loss 12 months after the surgery compared to CLASS group (6.5 ± 4.8% versus 1.4 ± 1.4%, respectively, \( p < 0.001 \); Table 8). The magnitude of mean surgically induced astigmatism (change in TCRPA3) 12 months after trabeculectomy was significantly lower in the CLASS than in the TRAB group (0.0 ± 1 versus 0.1 ± 0.2, respectively, \( p < 0.001 \)). Only the astigmatism changes in the TRAB group were statistically significant (\( p < 0.001 \)). Changes in mean TCRPA3 1 year after the surgery are presented in Table 9 and Fig. 4.

The mean Snellen lines loss 12 months after TRAB was higher than after CLASS (0.4 ± 0.6; range 0–3 lines versus 0.1 ± 0.1; range 0–2 lines, respectively, \( p = 0.016 \)). Mean best-corrected visual acuity (BCVA) deterioration was statistically significant only in TRAB group (\( p < 0.001 \)). Table 10 and Fig. 5 illustrate Snellen lines loss at the end of the follow-up period of the study. The loss of at least one line was more common in the TRAB group (29% versus 8%, \( p = 0.017 \); Table 11).

Discussion

To the best of our knowledge, we are the first to have conducted a comparison between CLASS and trabeculectomy, which remains a gold standard technique in OAG.

Table 2. Mean intraocular pressure (IOP) reduction over time for CO₂ laser-assisted sclerectomy surgery (CLASS) and trabeculectomy (TRAB).

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>( N )</th>
<th>IOP (% reduction from baseline)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>After a week</td>
<td>CLASS</td>
<td>66</td>
<td>32.7</td>
</tr>
<tr>
<td></td>
<td>TRAB</td>
<td>65</td>
<td>49.3</td>
</tr>
<tr>
<td>After a month</td>
<td>CLASS</td>
<td>66</td>
<td>23.8</td>
</tr>
<tr>
<td></td>
<td>TRAB</td>
<td>65</td>
<td>42.9</td>
</tr>
<tr>
<td>After 3 months</td>
<td>CLASS</td>
<td>66</td>
<td>26.9</td>
</tr>
<tr>
<td></td>
<td>TRAB</td>
<td>65</td>
<td>38.4</td>
</tr>
<tr>
<td>After 6 months</td>
<td>CLASS</td>
<td>66</td>
<td>24.2</td>
</tr>
<tr>
<td></td>
<td>TRAB</td>
<td>65</td>
<td>37.8</td>
</tr>
<tr>
<td>After 12 months</td>
<td>CLASS</td>
<td>59</td>
<td>32.6</td>
</tr>
<tr>
<td></td>
<td>TRAB</td>
<td>61</td>
<td>40.6</td>
</tr>
</tbody>
</table>

* Intragroups analysis: Wilcoxon paired test (reductions non-normally distributed).

\( p^* \) Intergroups analysis: Wilcoxon two-sample test (reductions non-normally distributed in both groups).
reduced number of medications over the 1-year (Geffen et al. 2012) and the 2-year follow-up period (Greifner et al. 2016). However, as CLASS is a relatively recent procedure, the scientific base on this subject still includes only a small number of research articles. A review of the literature comparing NPDS to trabeculectomy reveals contradictory findings in terms of IOP reduction on a medium-term and long-term basis, with suggestions that NPDS is similar (El Sayyad et al. 2000; Eldaly et al. 2014) or inferior (Chiselita 2001; Hondur et al. 2008) to trabeculectomy. There is a trend to report lower rates of complications following NPDS (Chiselita 2001; Sarodia et al. 2007). The recent paper by Harju et al. (2017) demonstrated that both MMC-augmented and nonaugmented deep sclerectomy can produce a long-term significant IOP reduction in normal tension glaucoma, with a low incidence of sight-threatening complications (Harju et al. 2017).

Through the whole follow-up period of our study, both procedures brought a significant IOP decrease from baseline (p < 0.001), but with a lower mean IOP reduction rate 1 year after CLASS compared with trabeculectomy (32.6 ± 10.8% versus 40.6 ± 15.9%, p < 0.001). In terms of drug reduction, the number of medications has remained significantly lower in both groups up to 12 months (p < 0.001) and CLASS patients, compared with trabeculectomy, required more drugs to maintain the target IOP 3, 6 and 12 months following the surgery (p < 0.05). A month after the baseline and later, complete success was maintained by a higher number of patients in the trabeculectomy group. A year after the surgery, the complete success rate dropped to 35% for CLASS versus 60% for trabeculectomy (p < 0.01). There was no significant difference, however, in the qualified success rate between the groups at any time through the follow-up period of the study (74% versus 75%, p > 0.05). As glaucoma surgery for OAG is still frequently performed in patients with moderate to advanced disease, we

![Fig. 1. Mean intraocular pressure reduction over time for CO2 laser-assisted sclerectomy surgery and trabeculectomy. Boxes indicate quartiles; bars indicate range.](image1)

![Fig. 2. Average number of intraocular pressure-lowering medications postoperatively in CO2 laser-assisted sclerectomy surgery and trabeculectomy. Boxes indicate quartiles; bars indicate range.](image2)

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>Q1</th>
<th>Q3</th>
<th>p*</th>
<th>p†</th>
</tr>
</thead>
<tbody>
<tr>
<td>After a month</td>
<td>CLASS</td>
<td>66</td>
<td>0.3</td>
<td>0.8</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>&lt;0.001</td>
<td>0.596</td>
</tr>
<tr>
<td></td>
<td>TRAB</td>
<td>65</td>
<td>0.2</td>
<td>0.8</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>After 3 months</td>
<td>CLASS</td>
<td>66</td>
<td>0.9</td>
<td>1.1</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>&lt;0.001</td>
<td>0.017</td>
</tr>
<tr>
<td></td>
<td>TRAB</td>
<td>65</td>
<td>0.5</td>
<td>1.1</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>After 6 months</td>
<td>CLASS</td>
<td>66</td>
<td>1.3</td>
<td>1.3</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>&lt;0.001</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>TRAB</td>
<td>65</td>
<td>0.7</td>
<td>1.2</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>After 12 months</td>
<td>CLASS</td>
<td>59</td>
<td>1.4</td>
<td>1.4</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>3</td>
<td>&lt;0.001</td>
<td>0.006</td>
</tr>
<tr>
<td></td>
<td>TRAB</td>
<td>61</td>
<td>0.7</td>
<td>1.1</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

* Intragroups analysis: Wilcoxon paired test (change in number of drugs from baseline non-normally distributed).
† Intergroups analysis: Wilcoxon two-sample test (number of drugs non-normally distributed in both groups).
decided to set ambitious target IOP (≤18 mmHg with a reduction by 30%), following the European Glaucoma Society guidelines (2014). Skaat et al. (2014) reported a complete and qualified success rate for CLASS after 12 months at 45.5% and 90.9%, respectively. However, they used MMC in 76.9% of the subjects and defined their criteria as the IOP between 5 and 21 mmHg with a 20% reduction from baseline. Other authors (Geffen et al. 2012; Greifner et al. 2016) set the target IOP between 5 and 18 mmHg. Greifner et al. (2016) performed CLASS combined with intrascleral space-occupying implants and MMC, achieving complete success rate in 73% and qualified success in 96% of the patients after the mean follow-up of 20.7 ± 6.8 months. Geffen et al. (2012), using MMC in 83.3% of patients, reported a complete success rate for CLASS with and without MMC after 12 months of 68.2% and 42.9%, respectively. Interestingly, the difference between the MMC and non-MMC groups did not show statistical significance. In our group, CLASS without MMC presented a less potent long-term hypotensive effect; however, it was not inferior to trabeculectomy in the qualified success rate at the end of the follow-up period.

Even though the efficacy of glaucoma surgery is mainly reflected by its potential to lower the IOP, the reduction in the number of medications and the lack of visual acuity deterioration following the procedure contribute to the overall success of the surgery (EGS 2014). Among our subjects, five patients lost at least one line following CLASS, which was significantly less frequent than in the trabeculectomy group (8%, versus 29%, p < 0.05), and the mean BCVA change following CLASS was not statistically significant. The main advantages of the nonpene- trating glaucoma surgery compared with trabeculectomy, consistent with our findings, are lower rate of complications (Eldaly et al. 2014) including lower inflammatory response (Chiou et al. 1998), quicker and full visual recovery (Karlen et al. 1999) and lack of significant changes in astigmatism (Corcostegui et al. 2004; Egrilmez et al. 2004). In our study, total rates of early complications and the incidence of choroidal detachment following CLASS were significantly lower compared to trabeculectomy (9.1% versus 29.2% and 1.5% versus 18.5%, respectively). We note, however, that the rate of choroidal detachment in our trabeculectomy group seems to be high compared with the modern literature. Trabeculectomy (TRAB) technique has embraced a range of refinements; there- fore, there was a noticeable decrease in the rate of early postoperative complications reported in the major multicen- ter trabeculectomy surveys carried out in the UK over the last two decades (Edmunds et al. 2002; Gedde et al. 2007; Kirwan et al. 2013). Kirwan et al. (2013) reported lower incidence of shallow AC (0.9%) and choroidal detachment (5%) than those published earlier in the National Survey of Trabeculectomy by Edmunds et al. (2002) (shallow AC 23.9%, choroidal detachment 14.1%) or the TVT study by Gedde et al. (2007) (shallow AC 10%, choroidal detachment 19% in the trabeculectomy group). It has been established that the Moorfields Safer Surgery System results in a reduced rate of hypotony-related early
complications and the outflow control may be improved, especially with the use of releasable and adjustable sutures. Therefore, we conclude that our trabeculectomy technique requires revision.

The list of early complications in the CLASS group included hyphema (one patient), bleb leakage with shallow AC and choroidal detachment requiring bleb suturing (one patient) and postoperative anterior uveitis (one patient). Other authors have reported a similar rate of complications following CLASS, including sporadic cases of microhyphema, choroidal detachment, wound dehiscence and leaks (Geffen et al. 2012; Skaat et al. 2014; Greifner et al. 2016). Microperforations of TDM were suspected in three of our patients who developed peripheral anterior synechia and iris incarceration within the filtration site of the sclerectomy. These patients underwent the enhancement procedure of Nd:YAG laser GPT between one and 3 months postoperatively, and they finally failed to achieve the target IOP despite adjuvant medications. CO₂ laser ablation was introduced to replace and simplify the manual dissection of the deep sclerectomy. Indeed, it has been shown to achieve good percolation and low IOP but still at the risk of perforation of the TDM. Geffen et al. (2012) and Greifner et al. (2016) have reported intraoperative macroperforations requiring conversion to trabeculectomy and postoperative iris incarceration occurring spontaneously or following GPT. We did not notice the intraoperative macroperforation in our study group; however, we had observed this complication in our department twice while performing CLASS prior to this study (unpublished data). We agree that the ablation in the CLASS procedure needs standardization, which was already postulated by the other authors (Greifner et al. 2016). We also strongly support the suggestion that using the laser applications of low energy increases the safety of deep ablation, while high energy applications result in creating deeper ‘bites’ in dry tissue and potentially result in perforation prior to achieving the percolation of fluid.

It has been established that glaucoma surgery can adversely affect the cornea in terms of postoperative astigmatism and accelerated ECD loss. Our

Table 7. List of early complications in CO₂ laser-assisted sclerectomy surgery (CLASS) versus trabeculectomy (TRAB) groups.

<table>
<thead>
<tr>
<th>Complications</th>
<th>CO₂ laser-assisted sclerectomy surgery (N = 66)</th>
<th>Trabeculectomy (N = 65)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early complications</td>
<td>6 (9.1)</td>
<td>19 (29.2)</td>
<td>0.004</td>
</tr>
<tr>
<td>Shallow AC</td>
<td>1 (1.5)</td>
<td>4 (6.2)</td>
<td>0.208 F</td>
</tr>
<tr>
<td>Hyphema</td>
<td>1 (1.5)</td>
<td>4 (6.2)</td>
<td>0.208 F</td>
</tr>
<tr>
<td>Bleb leakage</td>
<td>1 (1.5)</td>
<td>6 (9.2)</td>
<td>0.062 F</td>
</tr>
<tr>
<td>Choroidal detachment</td>
<td>1 (1.5)</td>
<td>12 (18.5)</td>
<td>0.001</td>
</tr>
<tr>
<td>Anterior uveitis</td>
<td>1 (1.5)</td>
<td>1 (1.5)</td>
<td>1 F</td>
</tr>
<tr>
<td>Iris incarceration</td>
<td>3 (4.5)</td>
<td>2 (3.1)</td>
<td>1 F</td>
</tr>
</tbody>
</table>

One patient may have more than one complication.

* Chi-squared test, F = Fisher’s exact test (due to low expected values).
Table 8. Endothelial cell density (ECD) loss 1 year after the surgery in both groups.

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>Q1</th>
<th>Q3</th>
<th>p*</th>
<th>p†</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 12 months</td>
<td>CO₂ laser-assisted sclerectomy surgery</td>
<td>66</td>
<td>1.4</td>
<td>1.4</td>
<td>1.0</td>
<td>-0.4</td>
<td>5.4</td>
<td>0.5</td>
<td>1.8</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Trabeculectomy</td>
<td>65</td>
<td>6.5</td>
<td>4.8</td>
<td>5.0</td>
<td>-0.5</td>
<td>18.3</td>
<td>3.2</td>
<td>9.1</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

* Intragroups analysis: Wilcoxon paired test (reductions non-normally distributed).
† Intergroups analysis: Wilcoxon two-sample test (reductions non-normally distributed in both groups).

Table 9. Change in mean 3-mm-zone total corneal refractive power astigmatism (TCRPA3) 1 year after the surgery in both groups.

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>Q1</th>
<th>Q3</th>
<th>p*</th>
<th>p†</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 12 months</td>
<td>CO₂ laser-assisted sclerectomy surgery</td>
<td>0.0</td>
<td>0.1</td>
<td>0</td>
<td>-0.1</td>
<td>0.2</td>
<td>0</td>
<td>0</td>
<td>0.075</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Trabeculectomy</td>
<td>0.1</td>
<td>0.2</td>
<td>0.1</td>
<td>-0.1</td>
<td>0.6</td>
<td>0</td>
<td>0.2</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

* Intragroups analysis: Wilcoxon paired test (changes non-normally distributed).
† Intergroups analysis: Wilcoxon two-sample test (changes non-normally distributed in both groups).

Fig. 4. Change in mean 3-mm-zone total corneal refractive power astigmatism (TCRPA3) 12 months (12 m) after the surgery in both groups. Boxes indicate quartiles; bars indicate range.

results indicated that CLASS remains astigmatically neutral and is followed by low ECD loss. While ECD loss in the normal cornea is linear and estimated between 0.5% and 0.6% per year during adulthood (Bourne et al. 1997; Moller-Pedersen 1997), glaucoma itself predisposes it to faster endothelial cell loss (Gagnon et al. 1997) and surgical trauma may accelerate this process, resulting in mild ECD loss observed in specular microscopy or even in corneal decompensation due to endothelial failure (Aldave et al. 2000; Hau & Barton 2009; Stewart et al. 2011). A wide range of average central ECD loss after glaucoma surgery was reported, between 1.6% and 54.8%, which was correlated with intraoperative and postoperative AC depth (Smith et al. 1991). The recent study by Tan et al. (2017) reported central ECD loss rates of 4.1% and 6.2%, depending on the tube–cornea distance, 1 year after the Baerveldt tube insertion. Storr-Paulsen et al. (2008) studied the central ECD loss after MMC-augmented trabeculectomy and found an ECD loss of 10% after 12 months. Arnavielle et al. (2007) compared ECD loss after trabeculectomy with deep sclerectomy and found a significant difference (9.6% versus 4.5%) after 1 year. Similarly, our study revealed higher ECD loss 12 months after the surgery in the trabeculectomy group (6.5 ± 4.8% versus 1.4 ± 1.4%, p < 0.001).

Considering the nature of penetrating and nonpenetrating filtration surgery, it seems unlikely that CLASS can be more potent in IOP lowering than trabeculectomy. In contrast to the results published by Yick et al. (2016), we believe that CLASS is not a viable therapeutic option for any patient with angle closure glaucoma, uveitic glaucoma or for patients in whom trabeculectomy had already failed due to fibrosis. It seems unlikely that CLASS, as a nonpenetrating procedure, could be effective in conditions affecting the anatomy of the iridocorneal angle, for example the primary narrow and occludable angles or secondary glaucoma with the presence of peripheral anterior synchia. This technique, however, offers potential gains for the patients in terms of quality of life. In our study, CLASS provided the

Table 10. Snellen lines loss 12 months after the surgery in both groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>Q1</th>
<th>Q3</th>
<th>p*</th>
<th>p†</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO₂ laser-assisted sclerectomy surgery</td>
<td>66</td>
<td>0.1</td>
<td>0.1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0.126</td>
<td>0.016</td>
</tr>
<tr>
<td>Trabeculectomy</td>
<td>65</td>
<td>0.4</td>
<td>0.6</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

* Intragroup analysis: Wilcoxon paired test (changes non-normally distributed).
† Intergroup analysis: Wilcoxon two-sample test (changes non-normally distributed in both groups).
patients with a significant reduction in medications up to 12 months. Moreover, compared to trabeculectomy, it produced a small number of early complications and a low ECD loss. Additionally, CLASS did not induce significant post-surgical astigmatism and vision loss.

In the light of the above results, as surgery in POAG is still frequently reserved for advanced disease when low IOP is required, trabeculectomy will continue to remain the surgery of choice. CO₂ laser-assisted sclerectomy surgery (CLASS) may be an appealing therapeutic option for certain groups of patients, such as a population of elderly patients with moderate glaucoma, in whom a low target pressure is not necessary and for whom a slightly higher target IOP with a potentially lower risk of complications, compared to trabeculectomy, may be justifiable.

As safety concerns are a barrier, CLASS may have a role at an earlier stage of disease, especially in patients with a compromised baseline ECD.

The main limitation of our work was a lack of access to MMC, as at the time of the study the use of MMC in ophthalmology remained uncompliant with Polish state regulations. On the other hand, our study reports on the efficacy of CLASS without antimetabolites, as proposed by Skaat et al. (2014). We conducted our analysis for homogenous groups of patients with POAG and XFG; however, we did not achieve a normal distribution of all the analysed variables, which might have affected the statistical analysis. Nevertheless, as there is still a scarce scientific base in the subject of CLASS, we find our results contributory in terms of providing a comparison between CLASS and trabeculectomy. We believe that the evaluation of the impact of CLASS on corneal astigmatism and ECD is also important.

To conclude, the results of the following study, along with the modern literature on trabeculectomy, indicate that CLASS is certainly a safe surgical procedure; however, it is remarkably less effective than trabeculectomy. Since the complication rates in the trabeculectomy group are high, we note that it may cast a relatively favourable light onto the CLASS results. Surgical precision and safety of CLASS seem to have improved with modifications in the laser operating system (Geffen et al. 2012; Skaat et al. 2014). What remains uncertain is the degree and longevity of IOP control following CLASS compared with modern trabeculectomy. Therefore, we emphasize that the revision of our present trabeculectomy technique is necessary. We suggest that a randomised prospective study with a higher number of participants and a longer follow-up period is required to monitor the safety and the long-term efficacy of MMC-augmented CLASS compared with trabeculectomy technique adherent to the Moorfields Safer Surgery System. Moreover, a cost–benefit analysis evaluating CLASS, microwasive glaucoma surgery (MIGS) techniques and medical treatment in early to moderate glaucoma could be useful to clarify the economic position of CLASS in the armamentarium of current nonpenetrating procedures for glaucoma.

References


Table 11. Rates of best-corrected Snellen visual acuity change, 1 year after the surgery in both groups.

<table>
<thead>
<tr>
<th>Best-corrected Snellen visual acuity change</th>
<th>CO₂ laser-assisted sclerectomy surgery (N = 66)</th>
<th>Trabeculectomy (N = 65)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change</td>
<td>61 (92)</td>
<td>46 (71)</td>
<td>0.017</td>
</tr>
<tr>
<td>At least one line lost</td>
<td>5 (8)</td>
<td>19 (29)</td>
<td></td>
</tr>
</tbody>
</table>

* Chi-squared test.

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