A randomized controlled trial of peeling and aspiration of Elschnig pearls and neodymium: yttrium–aluminium–garnet laser capsulotomy

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Abstract

AIM: To compare surgical peeling and aspiration and neodymium yttrium garnet laser capsulotomy for pearl form of posterior capsule opacification (PCO).

METHODS: A prospective, randomized, double blind, study was done at Rotary Eye Hospital, Maranda, Palampur, India, Santosh Medical College Hospital, Ghaziabad, India and Laser Eye Clinic, Noida India. Consecutive patients with pearl form of PCO following surgery, phacoemulsification, manual small incision cataract surgery and conventional extracapsular cataract extraction (ECCE) for age related cataract, were randomized to have peeling and aspiration or neodymium yttrium garnet laser capsulotomy. Corrected distance visual acuity (CDVA), intra-operative and post-operative complications were compared.

RESULTS: A total of 634 patients participated in the study, and 314 (49.5%) patients were randomized to surgical peeling and aspiration group and 320 (50.5%) to the Nd:YAG laser group. The mean pre-procedural logMAR CDVA in peeling and neodymium: yttrium – aluminium–garnet (Nd:YAG) laser group was 0.80 ±0.25 and 0.86 ±0.22, respectively. The mean final CDVA in peeling group (0.22 ±0.23) was comparable to Nd:YAG group (0.24 ±0.28; t-test, P=0.240). There was a significant improvement in vision after both the procedures (P<0.001). A slightly higher percentage of patients in Nd:YAG laser group (283/88.3%) than in peeling group (262/83.4%) had a CDVA of 0.5 (20/63) or better at 9mo (P<0.001). On the contrary, patients having CDVA worse than 1.00 (20/200) was also significantly higher in Nd:YAG laser group as compared to peeling group (25/7.7% vs 15/4.7%, respectively). On application of ANCOVA, there was less than 0.001% risk that PCO thickness and total laser energy had no effect on rate of complications in Nd:YAG laser group and less than 0.001% risk that PCO thickness had no effect on complications in peeling group respectively. Sum of square analysis suggests that in the Nd:YAG laser group, thick PCO had a stronger impact on complications (Fisher test probability, Pr<0.0001) than thin PCO and total laser energy (Fisher test probability, Pr<0.002), respectively; similarly, in peeling group, thick PCO and preoperative vision had a stronger effect on complications than thin PCO, respectively (Fisher test probability, Pr<0.001). The rate of complications like uveitis (P=0.527) and cystoid macular edema (P=0.068), did not differ significantly between both the groups. However, intraocular pressure spikes (P=0.046) and retinal detachment (Pr<0.001) were significantly higher in Nd:YAG laser group as compared to peeling group. Retinal detachment was more common in patients having degenerative myopia (7/87.5%, Pr<0.001). Recurrence of pearls was the most common cause of reduction of vision in the peeling group (24/7.6%, Pr<0.001).

CONCLUSION: There is no alternative to Nd:YAG laser capsulotomy for fibrous subtype of PCO. For pearl form of PCO, both techniques are comparable with regard to visual outcomes. Nd:YAG laser capsulotomy has a higher incidence of IOP spikes and retinal detachment whereas recurrence of pearls may occur after successful peeling and aspiration. When posterior capsulotomy is needed in patients with retinal degenerations, retinopathies and pre-existing retinal breaks, the clinician should be cautious about increased risks of possible complications of Nd:YAG laser capsulotomy.

KEYWORDS: posterior capsule; neodymium; Elschnig pearls; yttrium-aluminium-garnet; capsulotomy

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INTRODUCTION

Elschnig pearls were first described by Hirschberg [1] as a subtype of secondary cataract, caused by proliferation of equatorial lens fibres. Elschnig [1] later characterized these pearls as semi-globular and globular structures located on the posterior capsule to differentiate these from the other subtype of secondary cataract resulting from posterior capsular fibrosis.

Posterior capsule opacification (PCO) was the most common visually disabling complication of modern cataract surgery [2]. However, there has been a gradual and unnoticed decrease in its incidence and subsequent neodymium: yttrium-aluminium-garnet (Nd:YAG) laser capsulotomy rates over the past decade; this has been attributable to advancement in technique of cataract surgery, recognition of importance of thorough cortical clean up, and better intraocular lens (IOL) designs and biomaterials [3]. However, PCO rates may be much higher in countries of the sub-continent, where a sizeable population still has limited access to phacoemulsification and modern IOLs [4-6].

Nd:YAG laser capsulotomy has been the most common modality for treatment of fibrous and pearl form of PCO. However, surgical capsulotomy like pars plana membranectomy combined with vitrectomy may be preferred in eyes with thick PCO in pseudophakic children [7]. Posterior capsular disruption following laser capsulotomy, however, disturbs the lens-vitreous-retina equilibrium. This may predispose to posterior segment complications, which may threaten vision; when posterior capsulotomy is needed in such patient with pre-existing retinal breaks, diabetic retinopathy and glaucoma, the clinician should be careful about increased risks of possible complications of Nd:YAG laser capsulotomy [8,9].

Therefore, a rationale exists for exploration of alternative modalities of PCO treatment [10]. Surgical peeling and aspiration of epithelial pearls preserves posterior capsular integrity and may be promising in conditions having vitreo-retinal degenerations. On the contrary, surgical peeling and aspiration is an invasive procedure involving surgical risks.

The present study compared postoperative outcomes of the two procedures in eyes with pearl form of PCO.

SUBJECTS AND METHODS

A prospective, randomized, double blind study was done between April 2006 and September 2010 at three referral eye hospitals. The institutional review boards and the local ethics committee approved the trial. A written informed consent was obtained from all patients based on Helsinki protocol.

Inclusion and Exclusion Criteria Patients with pearl form of PCO, following cataract surgery for age related cataract, participated in the study. This included eyes with in the bag (both haptics in capsular bag), sulcus-sulcus (one haptic in sulcus and one in the capsule bag) and sulcus-sulcus (both haptics in sulcus) fixation of posterior chamber IOLs with a potential space between IOL optic and continuous curvilinear capsulorhexis margin.

Patients with history of retinal detachment (RD) in fellow eye, vitreo-retinal degenerations associated with RD like lattice, retinal breaks, past history of vitreo-retinal surgery and follow up less than 9mo were excluded.

Patients with fibrous PCO, poor pupillary dilatation (<5.0 mm), posterior synechia and posterior capsule plaques, capsular phimosis and anterior capsule opacification were also excluded.

Randomization, Masking and Sample Size

In order to estimate the sample size, a pilot study was first done on 20 subjects. The mean decrease in logMAR visual acuity in peeling group was from 0.82 to 0.26 (0.56 logMAR units). The mean decrease in logMAR visual acuity in Nd:YAG laser group was from 0.81 to 0.18 (0.63 logMAR units). The common standard deviation was 0.27. Assuming 1:1 randomization, alpha was set at 0.05 and power 90%. The sample size of each group was calculated to be 313. Figure 1 shows the patient flow chart, randomization schedule and follow-up protocol.

The procedures were performed by either of two surgeons, well versed with both the procedures. The allocation codes were generated by a DOS based computer software in Department of Community Ophthalmology. The allocation
was concealed in green coloured numbered envelopes that were opened by health care staff not involved in patient care. Patients were not informed about the type of procedure assigned. The evaluating independent investigators (Manoj Kumar & Ayub Ali), an ophthalmologist (not a study surgeon) and an optometrist who assessed vision, respectively, were masked to the identity of the operating surgeons and the type of procedure.

**Preoperative Evaluation** A thorough preoperative evaluation was performed by the independent investigator (Manoj Kumar). The examination included recording of visual acuity, slit-lamp examination, fundus examination with +90 D lens and indirect ophthalmoscopy.

**Surgical Technique (Peeling and Aspiration)** Peribulbar anaesthesia was delivered. Asepsis was achieved as per the standard norms for an intraocular procedure; this included ciprofloxacin (0.3%) eye drops 6-8 times, 24h prior to the procedures, instillation of 5% povidone-iodine solution in the cul-de-sac prior to surgery and ensuring patency of nasolacrimal duct. In the preoperative holding area, perocular skin was cleansed with povidone-iodine 10% solution. On the operating table, periocular cleansing was repeated and a drop of 5% povidone-iodine solution instilled on the ocular surface. A side port entry was fashioned with a 20 G MVR blade corresponding to the IOL haptic (mostly at 3 o'clock positions). Another side port entry was made at six o clock position for anterior chamber maintainer (ACM). In cases with capsular coverage of IOL optic, a nick was made on the capsulorhexis margin with a 26 gauge needle at 12 o'clock position. The optic edge was slightly lifted out of the bag with a Sinskey hook. An attempt was made to dial the intraocular lens. We previously described that dialing, coupled with the hydrodynamic flow of irrigating fluid through ACM throughout the procedure probably loosens adhesions between IOL haptic and lens fibres in the capsular bag and probably wash out some regenerative equatorial lens epithelial cells.[11]

With a specially designed (Figure 2) 20 G curved, blunt tipped single port (0.3 mm) silicone tubed cannula attached to a 5 mL syringe [Chandra Kanta Bhargava (CKB) cannula], the IOL edge was slightly lifted to create a space for insinuation of cannula. A blunt tip guided peeling of the membrane was initiated from the centre and fashioned towards the periphery by to and fro motion. Peeled pearls were then aspirated by the single port cannula. Each quadrant was dealt with in a similar way. The ACM ensured a constant depth anterior chamber (AC) with minimal fluctuations at the level of posterior capsule.

AC was thoroughly washed with irrigating fluid and IOL was re-positioned. Paracentesis was hydrated at the end of procedure. The procedure time was recorded from side port entry to hydration of paracentesis.

**Figure 2** A specially designed blunt tipped single port (0.3 mm) silicone tubed cannula attached to a 5 mL syringe [Chandra Kanta Bhargava (CKB) cannula].

**Technique (Nd:YAG Laser Capsulotomy)** Topical anaesthesia was achieved with 4% xylocaine drops. Capsulotomy was performed using Abraham's lens with Q-switched Nd:YAG laser. Hydroxypropyl methylcellulose 2.5% was used as coupling media. The optical centre of the IOL was matched with the centre of the opening, not exceeding greater than 50% of optical zone. The starting initial energy and the total summated energy were noted in each patient. A pad and patch was applied to the eye after the procedure. The procedure time was recorded from positioning of Abraham's lens to the last fired Nd:YAG laser shot. To estimate PCO thickness, standardized photographs of the eye were taken using a photo slit lamp and retro-illumination images were analyzed along with pre-procedural vision; mean laser energy for capsulotomy and rate of recurrence of pearls were also noted and compared.

**Postoperative Evaluation** Common postoperative regimen in both groups included topical betamethasone 0.1%, every two hours, tapered over 2-4wk. However, patients in peeling group received additional topical moxifloxacin every 4h for two weeks. Topical apraclonidine 0.5% was given twice daily for IOP spikes following Nd:YAG laser capsulotomy and timolol 0.5% twice daily in Peeling group for two weeks respectively topical ketorolac tromethamine 0.4% was used selectively, 4 times a day in patients who developed cystoid macular edema; these patients also received topical corticosteroids; there was resolution of CME in all eyes after therapy tapered over 6-8wk.

Patients were followed up on day 1, 7, 21, 30, 90 and thereafter at 3mo interval, for a minimum of 9mo. On each visit, recording of CDVA, applanation tonometry, slit lamp examination with 90 D lens, and indirect ophthalmoscopy was done by the independent investigator. Aqueous flare and cells were graded by modified Hogan's technique[12].
Pre and post-procedural corrected distance visual acuity (CDVA), \( P<0.001; \) NA: Not applicable; USD: United States dollar.

Table 2 CDVA 9mo postoperatively

<table>
<thead>
<tr>
<th>Subtype of PCO</th>
<th>Peeling group</th>
<th>Nd:YAG laser group</th>
</tr>
</thead>
<tbody>
<tr>
<td>LogMAR CDVA Pre</td>
<td>0.00-0.25</td>
<td>217 (69.1)</td>
</tr>
<tr>
<td></td>
<td>0.26-0.50</td>
<td>45 (14.3)</td>
</tr>
<tr>
<td></td>
<td>0.51-0.75</td>
<td>37 (11.8)</td>
</tr>
<tr>
<td></td>
<td>0.76-1.00</td>
<td>15 (4.7)</td>
</tr>
<tr>
<td></td>
<td>1.01-1.25</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

CDVA: Corrected distance visual acuity. \( P<0.001. \)

Table 3 Parameters in subtypes of PCO

<table>
<thead>
<tr>
<th>Subtype of PCO</th>
<th>Peeling group</th>
<th>Nd:YAG laser group</th>
</tr>
</thead>
<tbody>
<tr>
<td>LogMAR VA Pre</td>
<td>0.83</td>
<td>0.87</td>
</tr>
<tr>
<td>LogMAR VA(Post)</td>
<td>0.1</td>
<td>0.4</td>
</tr>
<tr>
<td>Mean total energy (mJ)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Recurrence of pearls (%)</td>
<td>2.2</td>
<td>5.4</td>
</tr>
<tr>
<td>IOP spikes (%)</td>
<td>4.1</td>
<td>3.1</td>
</tr>
<tr>
<td>Uveitis (%)</td>
<td>3.4</td>
<td>5.1</td>
</tr>
<tr>
<td>CME (%)</td>
<td>1.7</td>
<td>0.8</td>
</tr>
<tr>
<td>IOL pitting (%)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>RD (%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Thick and thin subtypes of pearl form of PCO: Pre and post-operative logMAR visual acuity; CME: Cystoid macular edema; RD: Retinal detachment; NA: Not applicable. \( P<0.001. \)

Intraoperative and Procedural Observations Based on intraoperative and procedural observations, pearl form of PCO were grouped into two subtypes (thick and thin subtypes, Table 3). In the "thick" subtype, pre-procedural vision was worse, mean laser energy required to create capsulotomy was significantly higher (47.8 mJ) in the Nd:YAG laser group, bloated cells accumulated along capsulotomy margin obscuring vision and of the incidence recurrence of pearls was higher in peeling group (5.4%). On the contrary, in the "thin" subtype, pre-procedural vision was better, mean laser energy for capsulotomy was lower (21.8 mJ) in Nd:YAG laser group and recurrence rate of pearls was lower in peeling group (2.2%), respectively (Table 3). The probability of posterior capsule thickness (thin and thick subtypes of PCO) in having complications or not having complications in Nd:YAG laser group and Peeling
group respectively was investigated by ANCOVA and Pearson Chi-square tests, respectively. On application of ANCOVA, there was less than 0.001% risk that PCO thickness and total laser energy had no effect on rate of complications in Nd:YAG laser group and less than 0.001% risk that PCO thickness had no effect on complications in peeling group respectively. Sum of square analysis suggests that in the Nd:YAG laser group, thick PCO had a stronger impact on complications (Fischer test probability, \(P < 0.0001\)) than thin PCO and total laser energy (Fischer test probability, \(P < 0.002\)), respectively; similarly, in peeling group, thick PCO and preoperative vision had a stronger effect on complications than thin PCO, respectively (Fischer test probability, \(P < 0.001\)). PCO thickness allows us to explain 43% variability of the complications in Nd:YAG laser group and 42% variability in peeling group respectively. The likelihood of thick posterior capsule in having complications was significantly higher as compared to the thin subtype (Chi-square values 55.77 and 25.89, \(P < 0.001\)) in both the groups, respectively. Focal rupture of posterior capsule without vitreous prolapse was seen in 8 (2.5%) eyes after surgical aspiration. Recentration of a de-centered IOL was performed in 9 (2.9%) cases after successful peeling and aspiration of pearls.

**Complications and Follow-up** Both groups were associated with complications. Kaplan-Meier curves adjusted with a Cox model was used to estimate survival probability (Figure 3). Estimated mean survival time in peeling group was 15.57 ±0.19 (95%CI: 15.19–15.95) and 26.93 ±0.483 (95%CI: 24.98–28.88) in Nd:YAG laser group, respectively, estimation limited to largest survival time (censored). On Log Rank (Mantel-Cox) test of equality of survival distributions at different levels, events observed in peeling group were 58 and 83 in the Nd:YAG laser group, respectively. Chi-square value was 27.356 and the probability was \(P > \text{Chi}^2 = 0.001\).

At any point of time, both groups were comparable with regards to complications like uveitis, IOP rise and CME. However, incidence of RD was higher in Nd:YAG laser group.

On first postoperative day, the incidence of uveitis in the peeling group (8.5%) was comparable to the Nd:YAG laser group (10%, \(P = 0.527\)). Likewise, the incidence of IOP spikes in peeling and Nd:YAG laser group was (7.2%) and 12.5% respectively \(P = 0.046\); the mean intraocular pressure in peeling group was 20.73 ±1.10 and 24.97 ±1.75 in ND:YAG group. The incidence of clinically detectable (+90 D lens stereoscopic examination) CME in Nd:YAG laser group was (5.8%) as compared to peeling group (2.5%, \(P = 0.068\)). IOL pitting was seen in (19/5.9%) cases. We did not encounter any case of postoperative endophthalmitis following peeling and aspiration procedure.

![Figure 3 Graph showing Kaplan–Meyer survival curve.](image-url)

The incidence of RD in Nd:YAG laser group was 8/2.5%. We did not encounter any case of RD in peeling group. The 7/87.5% eyes with RD had degenerative myopia \(P > 0.001\). The mean duration of RD after capsulotomy was 9.87 ±2.3mo. Recurrence of pearls was the most common cause of reduction of vision in the peeling group (24/7.64%, \(P < 0.001\)). The 8/2.5% eyes randomized to receive peeling and aspiration required another peeling and 2/0.6% eyes, a tertiary peeling. The mean time of recurrence of pearls after primary peeling was 3.82 ±1.02mo. There was no significant difference in the rate of recurrence of pearls in sulcus, sulcus to bag or in the bag fixated IOLs (ANOVA, \(P = 0.264\)).

**DISCUSSION**

Although there has been an appreciable decrease in the incidence of PCO, it may remain a nagging complication of cataract surgery for long as it seems virtually impossible to totally get rid of regenerative cells in the equatorial lens bow during cortical aspiration by any aspiration method currently known [13].

The results of the present study suggest that both surgical peeling and aspiration and Nd:YAG laser capsulotomy achieved good and comparable visual outcome at 9mo (Table 2). In a retrospective study by Janknecht and Funk[14] on 224 eyes, 95.5% patients had a mean improvement in vision of 0.38 logMAR units (0.54-0.16) following surgical aspiration. Klemen et al. [15] managed 102 eyes with soft after-cataract using a 20G cannula and accomplished successful removal of pearls in 89% of cases.

In another retrospective study, Bhargava et al. [16] found that 94.6% patients achieved a BCVA of 20/40 or better at 3mo following Nd:YAG laser capsulotomy. Although the visual...
outcomes were either comparable or slightly better in these studies, follow-up period was shorter and they were not prospective randomized comparisons and may have been influenced by selection bias.

Prospective studies have found that an uneventful cataract surgery with intact posterior capsule is estimated to have 4-fold less risk for RD as compared to that after Nd:YAG laser capsulotomy with posterior capsular disruption [17]. In a retrospective study on 367 eyes, Trinkmann et al.[18] achieved successful removal of Elschnig pearls without any complications like CME, IOP spikes and endophthalmitis, apart from focal rupture of posterior capsule without vitreous prolapse in two cases following surgical peeling.

Survival analysis suggests that both groups were associated with complications like IOP spikes, CME and uveitis at different levels. However, Nd:YAG laser capsulotomy had a higher incidence of RD (Figure 3). Thus, it appears that retention of posterior capsule does minimize the risk of vision threatening posterior segment complications.

In the present study, there was a significant association (P <0.001) of RD in myopes (7/87.5%). The risks and benefits of Nd:YAG lasers should be considered whenever capsulotomy is performed in patients with retinal degenerations and pre-existing retinal breaks. Surgical aspiration and peeling may be a viable alternative, under such circumstances. In a long term study in a large series of patients, Lin et al. [19] found increased risk of pseudophakic RD in eyes with myopia. A similar observation was made by Janknecht and Funk[20] in patients who were high myopes.

The results of the present study suggest that PCO thickness may well be the crucial determinant for treatment strategy and subsequent visual outcome. This was substantiated by a significant difference in preoperative and postoperative parameters like visual acuity, rates of recurrence of pearls and mean laser energy required to create capsulotomy (47.8 ± 1.76 vs 21.8 ± 2.34 mJ, respectively) in thick and thin subtypes of pearls (Table 3)[20]. Montanes-Moreno et al. [21] measured PCO thickness using optical coherence tomography (OCT) and also found a significant relationship between CDVA and PCO thickness, with thick subtype having worse vision. This necessitates further evaluation and PCO quantification by techniques other than slit lamp retroillumination image analysis[22].

One of the limitations of the present study was that anterior chamber inflammation, quantification of PCO, diagnosis and follow up of postoperative CME was done on slit-lamp or serial slit-lamp stereoscopic examinations, due either to limited availability of high end devices or cost constraints. These complications or PCO quantification could be more precisely done/monitored with laser flare cell meter, OCT or fundus fluorescence angiography respectively [23].

The procedure costs and time for any intraocular procedure like peeling and aspiration are significantly higher in comparison to Nd:YAG laser capsulotomy. On the contrary, Nd:YAG laser machines may put additional financial burden on health care system in sub-continent countries and may affect allocation of health care services.

The main disadvantage of peeling and aspiration technique is reformation of Elschnig pearls after primary peeling and the need for repeated procedures. Secondly, being an invasive procedure, it involves surgical risks and possibility of post-operative endophthalmitis. Having said this, endophthalmitis has also been reported following Nd:YAG laser capsulotomy. Probably, low virulence micro-organisms like *staphylococcus* epidermidis and propionibacterium acnes, sequestered in the capsular bag, may be released into the vitreous cavity following capsulotomy [24,25]. Another advantage of peeling and aspiration is that it allows re-centration of a de-centered IOL in the same sitting.

Our technique of peeling using CKB cannula is simple, effective, and easily reproducible and can be used by other researchers. In conclusion, recurrence of pearls after primary peeling was the main complication of surgical peeling and aspiration procedure whereas RD was a late complication of Nd:YAG laser capsulotomy; intraocular pressure spikes, uveitis and CME may be seen after either of the procedures. We should be cautious in doing capsulotomy in patients with retinal degenerations, retinopathies and pre-existing retinal breaks. Peeling and aspiration of pearls may be a viable alternative under such circumstances.

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REFERENCES


