

SELF ENGINEERED ACRY C IMPLANT IN NON-PENETRATING GLAUCOMA SURGERY

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Abstract

Objective: Analysis of safety and efficacy of self engineered polymethylmethacrylate (Acry C) implants in Non-Penetrating Glaucoma surgery (NPGS) for control and maintenance of intraocular pressure in Primary Open Angle Glaucoma (POAG) patients.

Design: A Hospital based Randomized study

Participants: 0 eyes of 50 POAG patients, divided in 3 groups based on preoperative IOP range.

Materials: NPGS was done with polymethylmethacrylate implants made from haptics of intraocular lenses. All patients were followed up after 1 week, 1 month, 3 months, 6 months and 12 months. Post-operative success was defined as IOP <21 mm Hg at 1 month in absence of additional anti glaucoma medication or other treatment.

Results: A significant reduction in intraocular pressure was observed post-surgery in all three groups, changing from a preoperative mean of 25.62 ± 1.72 mm Hg, 34.38 ± 2.27 mm Hg and 41.66 ± 1.15 mm Hg to a postoperative mean of 13.27 ± 2.13 mm Hg, 16.50 ± 2.74 mm Hg and 17.66 ± 1.52 mm Hg respectively ($P < 0.001$) at 12 months. No significant difference was seen with change in position of the implant i.e. convexity facing limbus or fornix. No intraoperative complications were observed. The main postoperative complication was failure of filtration in 1 case (3.44%) from group 1, 5 cases (27.78%) from Group 2 and all 3 cases (100%) from Group 3 at 1 month postoperatively. Thus, 9 eyes (41 %) required postoperative anti glaucoma medications following which the intraocular pressure was controlled.

Conclusion: NPGS with Acry - C implants is a safe and cost effective (less than one U.S. dollar) procedure for control of Intraocular pressure in POAG patients especially those with moderately elevated intraocular pressures.

Keyword: NPGS, POAG, Acry C Implant, self engineered, efficacy.

Introduction –

Glaucoma, a serious sight threatening optic Neuropathy, is marked among ophthalmic

disorders by the variability of its presentations and the variability of the array of treatment options available. Among the

most recent forms of surgical treatment in Glaucoma is the Non-Penetrating Glaucoma Surgery with the use of implants being a further advancement in this safe and efficacious procedure. Our study is a pilot study that unbiased tests whether the economically advantageous self engineered Acry C plants successfully serve the primary aim of controlling Intraocular pressure.

Materials and Methods –

This Hospital based Randomized Prospective study included 50 eyes with Primary Open Angle Glaucoma on who Non-Penetrating Glaucoma Surgery with Acry C plants was performed and patients were followed up.

Inclusion Criteria: Patients with Primary Open Angle Glaucoma who gave consent.

Exclusion Criteria: All patients with any other type of glaucoma

Preoperative data included Ocular complaints, BCVA, Intraocular tensions by Perkins applanation tonometer, Diurnal variation test, Slit lamp examination, gonioscopy, perimetry and fundus examination.

The above parameters were reassessed postoperatively after 1 week, 1 month, 3 months, 6 months and 1 year.

Success of surgery was considered as postoperative intraocular pressure less than 21 mm hg in the absence of antiglaucoma medication or other intervention.

Complications such as hyphaema, flare, hypotony, shallow or flat anterior chamber, bleb leak, blebitis, macular edema, maculopathy, choroidal effusion were also looked for.

Surgical Procedure – (Figures 1 to 9) All surgeries considered in this study were performed by a single experienced senior surgeon. The surgery was preceded by

systematic preoperative preparation and was done under peribulbar anesthesia.

7 mm of limbus based conjunctival flap is made in the upper quadrant. Superficial scleral flap – 5x5 mm square scleral flap of 40% depth is dissected upto clear cornea followed by a second 3x3 mm deep scleral flap of 90 % depth of sclera using a crescent blade. At the level of the scleral spur, the Schlemm's canal is deroofed and a corneoscleral lake is formed to facilitate the diffusion of the aqueous humor. The deep scleral flap is excised along its base 0.5 mm anterior to Schwalbe's line to create the deep sclerectomy space. Scleral pockets are made on both lateral sides of the deep groove.

The Acry C plant: This non-absorbable C shaped implant is made by cutting one of the haptics of the Polymethylmethacrylate Intraocular lens regularly used for cataract surgery. Thus, a 3-4 mm curved inert implant is created and can be directly placed in the scleral pockets for fixation. (Fig 1) Superficial scleral flap and conjunctival flap are sutured using 10 – 0 Nylon sutures.

The purpose of placing this implant in the deep scleral groove is to prevent the common complication of fibrosis to keep the space patent that often follows NPGS resulting in failure of filtration and ineffective control of IOP.

The implant is placed either with its convexity toward the fornix or the limbus, the position remaining constant i.e. in the deep scleral groove. The implant does not need to be sutured to ensure it stays in the scleral pockets of the groove. In our study, 25 (50%) implants were placed with convexity toward the limbus and the rest were placed with convexity toward the fornix and the results compared.

Observation

Table 1: Age wise and sex wise distribution of patients in all three groups along with direction of placement of implants. No statistically significant difference is seen in these preoperative values.

Group	Number	Fornix		Number	Limbus		P - value
		Age(years)	Sex(M/F)		Age(years)	Sex(M/F)	
1	13	54.33 ± 10.12	7/6	16	54.50 ± 8.89	9/7	0.8342
2	12	58.08 ± 6.21	5/7	6	59.00 ± 14.83	4/2	0.5206
3	0	-	-	3	59.33 ± 10.06	0/3	

Table 2: Preoperative and postoperative intraocular pressures in all three groups

Group	Mean ± SD for IOP						
	Pre operative	Post Operative					
		Day 1	Week 1	Week 4	Month 3	Month 6	Month 12
1	25.62 ±1.72	13.38 ± 1.72	13.24 ± 1.55	13.14± 2.19	13.44 ±1.99	13.27 ±1.55	13.27 ± 2.13
2	34.38 ±2.27	18.77 ± 2.39	18.27 ± 3.47	18.05 ± 4.17	17.33 ±2.44	16.94 ±2.23	16.50 ± 2.74
3	41.66 ±1.15	23.33 ± 1.15	23.66 ±3.78	24.00 ±2.00	17.33 ±1.52	17.33 ±0.57	17.66 ± 1.52

Table 3: Failure and success rates in all three groups and p value <0.0001 by Chi square test indicates significance between the baseline IOP and efficacy of procedure.

Group	Failure of Filtration n (%)	No Complications n (%)	Total
1	1 (3.44%)	28 (96.56 %)	29
2	5 (27.78%)	13 (72.22 %)	18
3	3 (100 %)	0	3
Total	9 (18%)	41 (82 %)	50

Results

The above statistics indicate that NPGS is effective in controlling Intraocular pressure independently in cases with mild to moderately elevated IOPs and in combination with antiglaucoma medication in eyes with highly elevated IOPs.

Studies including those by Ates H et al¹, Bonilla R et al², Dahan et al³, Devloo et al⁴, Hamel et al⁵, Sanchez et al⁶ and most others indicate that the preoperative IOP taken for our study falls in the same range as that taken in other similar studies. Also the average age range in our study vs similar

studies and within the three groups in our study are statistically insignificant.

The mean percentage reduction in IOP at 12 months for the three groups is 48.14 ± 7.85 %, 52.00 ± 7.59 % and 57.52 ± 4.72 %

The only significant complication encountered in our study was failure of filtration seen in 9 (18%) cases. Ravinet et al⁷ in their study diagnosed surgery related complication including positive seidel test, hyphema, choroidal detachment and iris incarceration. Ates H et al¹ in their study showed no anterior segment complications and as a complication one case of self

limited shallow choroidal detachment was seen. Bonilla R et al² noted the only intraoperative complication was the microperforation of trabeculodescemet membrane in four patients. Drolsum L⁸ in their study noted that there were no complications related to hypotony or other significant complications. Thus the safety of this procedure as compared to other similar procedures is evident.

Another very important consideration is the cost effectiveness of the Acry C plant. Tan JC and Hitchings RA⁹ state that in deep sclerotomy, the adjunctive implant is priced at approximately £120. Wang NL¹⁰ et al have documented that cost of NPTS remains a serious concern. Guedes RAP et al¹¹ reported that cost of Non penetrating deep sclerotomy cost between US \$305.25 to US \$390.09 depending on the severity of glaucoma.

Thus, in comparison to the above expenses the PMMA implant is considerably inexpensive since it has to be constructed from a PMMA lens which is freely available at low costs. The cost of the implant was estimated to be between Rs. 50 to Rs. 100 i.e \$1 - \$2.

One other aspect the study considered was the position of the implant in the deep scleral groove and no significant difference was seen in post operative results based on whether the convexity of the implant was toward the limbus or the fornix.

Conclusion

Non Penetrating Glaucoma Surgery with implant is an effective modality for control and maintenance of Intraocular pressure in patients with primary open angle glaucoma with its greatest efficacy being in patients with a preoperative IOP between 20 – 30 mm Hg. With the exception of failure of filtration seen in few (9%) cases, no major complications were noted related either to the surgery or the implant. The procedure is thus cost effective without a compromise in safety. However further wider and long term research in this area is required.

Reference

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Figures:



Fig 1: Creating superficial sclera flap

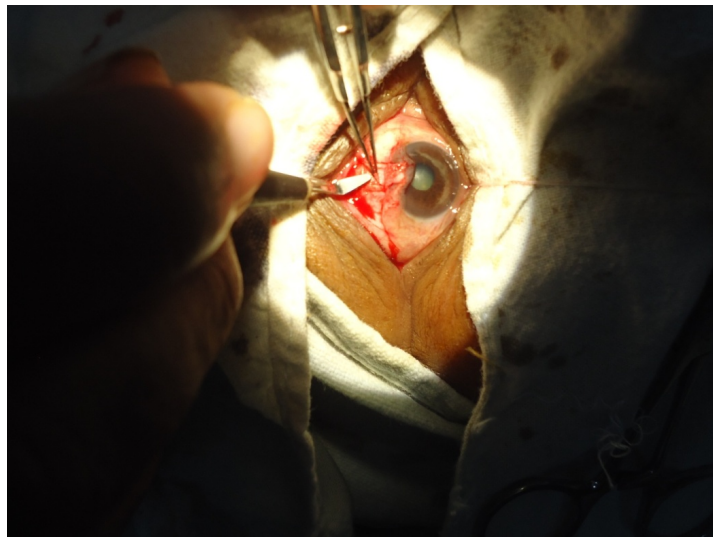


Fig 2: Creating a deep sclera flap

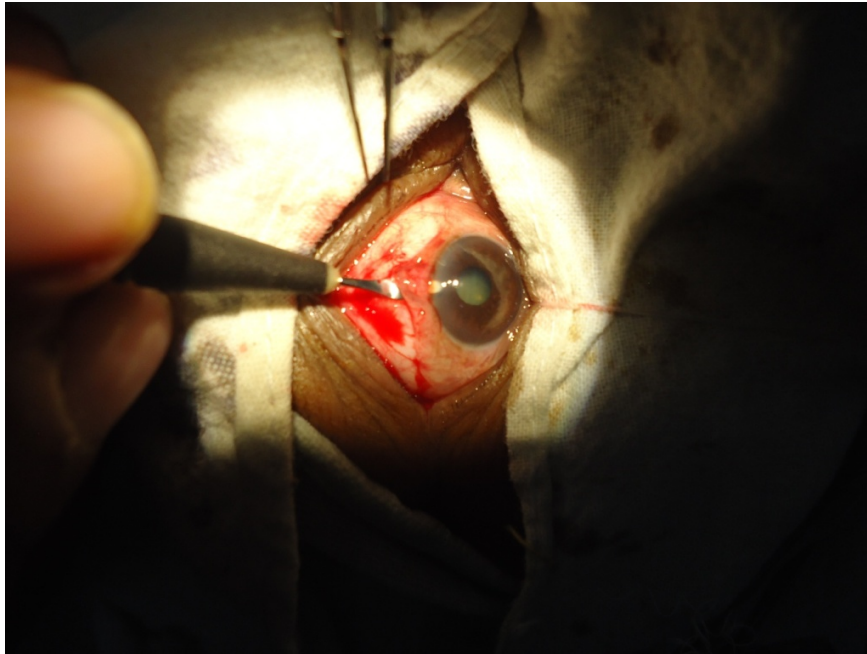


Fig 3: Creating a sclero corneal groove

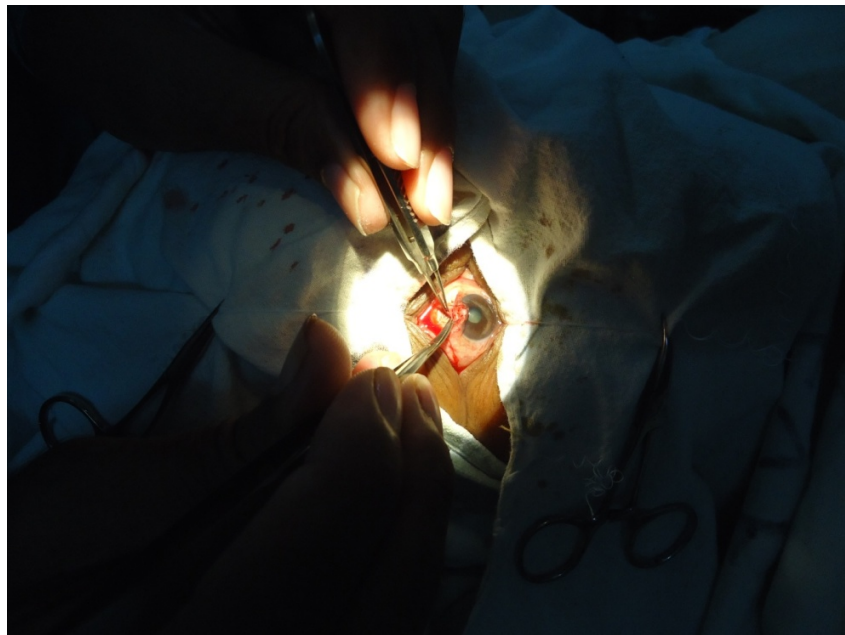


Fig 4: cutting the deep sclera flap

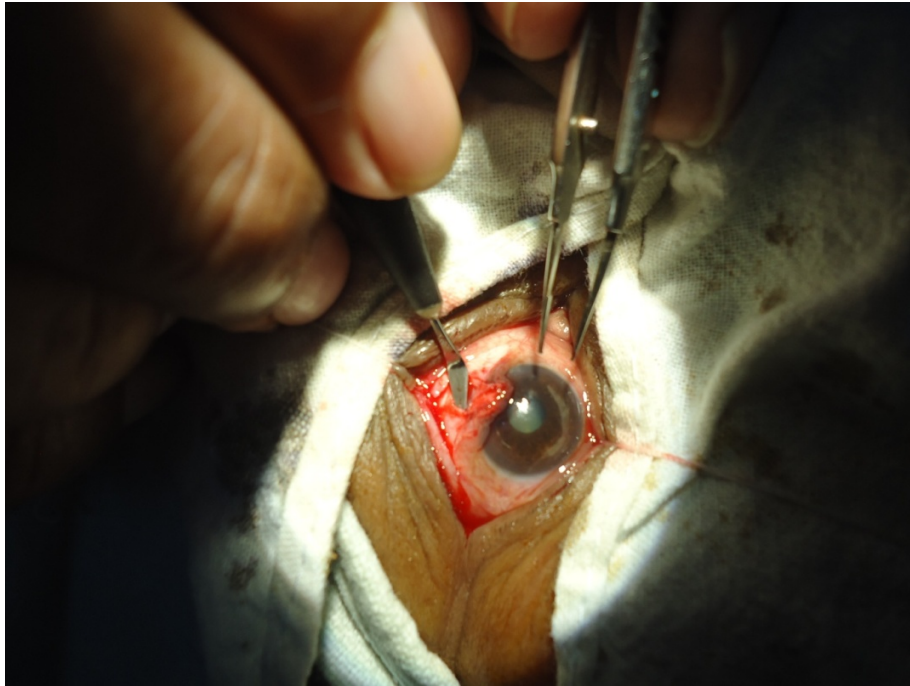


Fig 5: Creating a sclera side pocket to fix the implant



Fig 6: self designedAcry C Implant

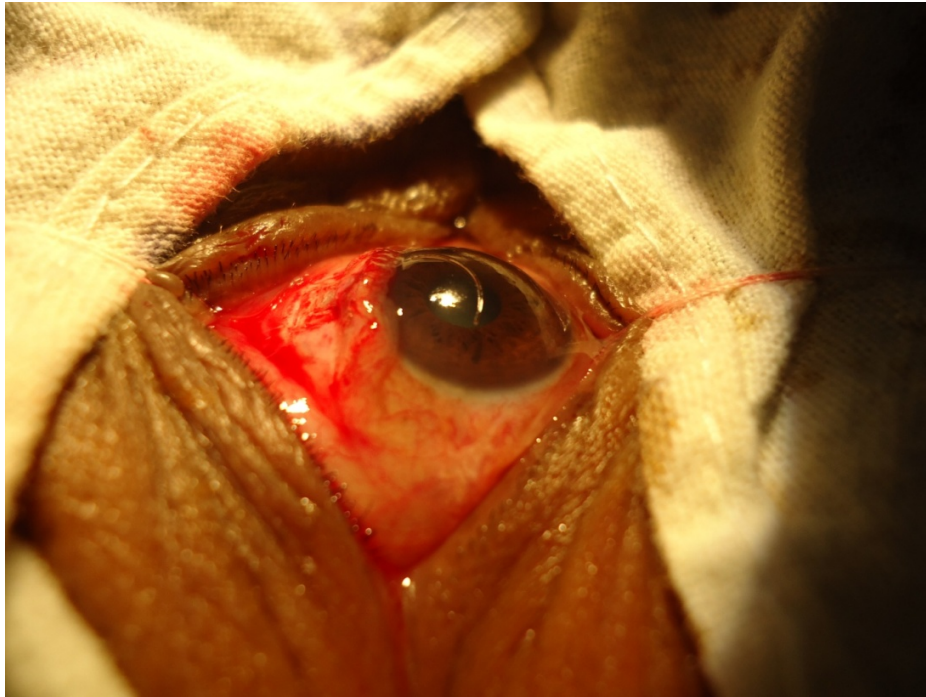


Fig 7: Magnified view of implant

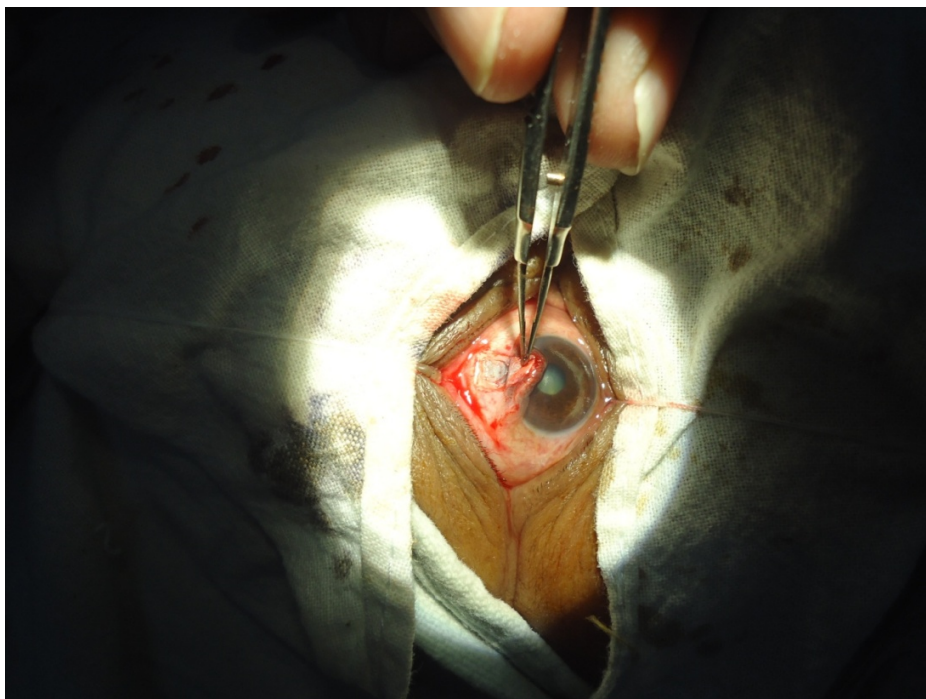


Fig 8. Acy C Implant fixation in side pocket

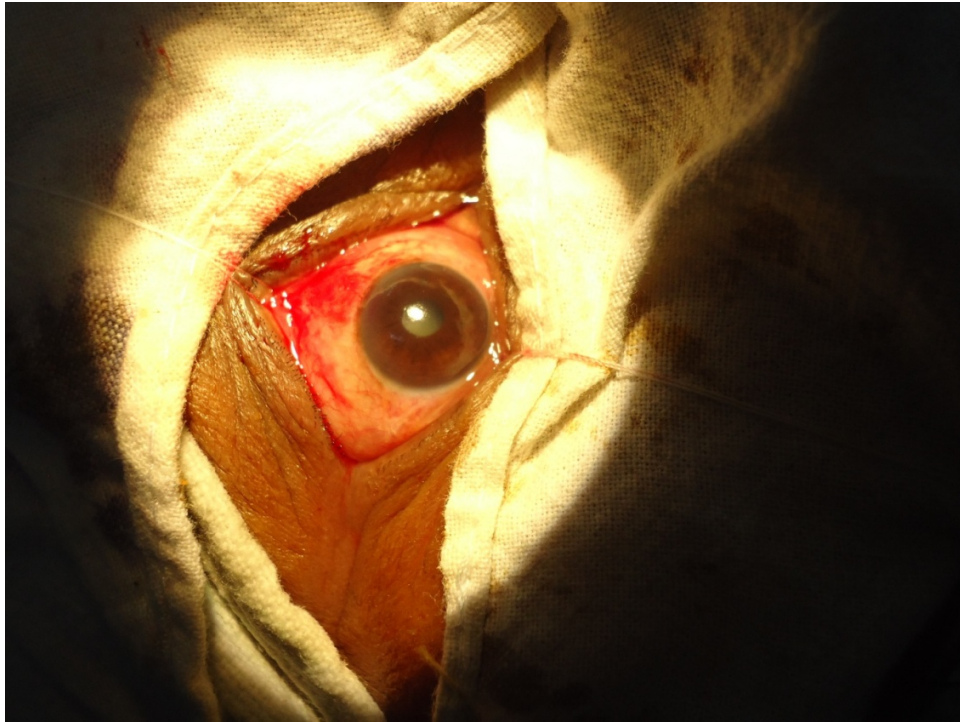


Fig 9: Acry C implant in situ