Clinical Research

Clinical study on evaluation of anti-cataract effect of *Triphaladi Ghana Vati* and *Elaneer Kuzhambu Anjana* in *Timira* (immature cataract)

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Abstract

Introduction: Senile cataract is the leading cause of blindness according to the World Health Report, 1998. Till date no accepted medical treatment is available for cataract. In Ayurveda visual disturbances are described in the context of Timira, Kacha and Linganasha. Timira is an early stage characterized by blurring of vision and Linganasha is end stage where complete loss of vision occurs. Ancient scholars have advocated different Anjana application and oral medications in the Timira and Kacha stage. Aim: To study the efficacy of test drugs Triphaladi Ghana Vati and Elaneer Kuzhambu Anjana in immature cataract. Materials and Methods: In this trial patients having Senile Immature Cataract were randomized with equal probability to one of the two treatment Groups A and B (n = 20 each). In Group A Triphaladi Ghana Vati 500 mg internally for 3 months and in Group B Triphaladi Ghana Vati 500 mg internally and Elaneer Kuzhambu Anjana for local application were given. Assessment was done on the basis of blurring of vision, visualization of nonexisting things, difficulty in bright light and dim light or night vision, distant visual acuity, pinhole vision, best corrected visual acuity and cataract grading on slit lamp. Results: Both groups showed statistically significant changes in blurring of vision, difficulty in glare, daytime and bright light, distant visual activity, pinhole vision, and best-corrected visual acuity. Group B also showed significant changes in difficulty in night time, visualization of nonexisting things and in nuclear cataract. Conclusion: The study establishes that test drugs can reduce and control the progress of immature cataract, and combined therapy was found more effective. Chakshushya Rasayana, early diagnosis and proper management on Doshic lines can prevent arrest or delay senile cataract.

Key words: Cataract, Elaneer Kuzhambu Anjana, Timira, Triphaladi Ghana Vati

Introduction

In the West, the incidence of cataract in people over 50 years is 15%, while in developing countries it is about 40%.^[1] In the developing world, the prevalence is believed to be greater and the onset at earlier ages, making the social and medical costs of blindness from cataract highly disproportional in areas of the world that can ill afford them.^[2] Thus, senile cataract is a common and obvious ocular condition associated with dramatic effects upon vision. The World Health Report published in

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The similarity between *Timira* and Cataract starts from the word meaning itself. *Timira* is derived from word *Tim* which

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means *Kledane* that is imbibing of moisture, increase of watery substance in the eye.^[5] *Timira*/cataract denotes a shade of darkness which makes the view of the patients affected by this disease as if looking through water, moisture, waterfall, glazed paper, waxed paper etc.

Till date no accepted medical treatment is available for cataract, surgery is the only available treatment for cataract. Though the prevalence of cataract blindness would decrease due to increase in cataract surgery rate, the absolute number of cataract-blind would increase from 7.75 million in 2001 to 8.25 million in 2020 due to the substantial increase in the population above 50 years in India over this period.^[6] Data available in India show that all cataract surgeries are not sight-restoring.^[7] Surgical treatment of cataract imposes great economic burden on the society, and the backlog is perhaps too big to be handled by surgery alone at the same time surgical approach have its own complications. If such a factor is identified which simply delays the onset of cataract by a period of 10 years, the number of cataract surgeries would drastically decrease by 45% or more.^[8]

Therefore, the entire world is looking at the other systems of medicine to tackle the situation and looking upon preventive ophthalmology for improving and maintaining vision. In such a scenario, a study on Immature Cataract management gains much importance. Among many anti-cataract medicines *Elaneer Kuzhambu Anjana*^[9] is extensively used clinically since centuries in Kerala by local physicians, however, clinical and experimental data on the efficacy are not available on this formulation. Hence, this formulation was selected for the present study. As senile cataract can be taken as *Swabhava Balapravritta Vyadhi* which occurs as an aging change in the body. According to Ayurveda, a *Rasayana* drug which contains rejuvenating properties is the best drugs to avoid senile changes, so *Triphaladi Ghana Vati* was selected for this trial. This drug contains 11 Ayurvedic drugs; maximum among them were having *Rasayana* (rejuvenating) properties.

Therefore, this study was planned with the aim to assess the efficacy of *Triphaladi Ghana Vati* and *Elaneer Kuzhambu Anjana* as anti-cataract agents.

Materials and Methods

Total forty patients, from the outpatient department of Shalakya Tantra Department, Institute of Postgraduate Teaching and Research in Ayurveda Hospital, Jamnagar, Gujarat, were registered in this Randomised Parallel Group Clinical Trial. A prior written informed consent was taken from each and every patient. Clinical study was started after getting clearance from Institutional Ethics Committee (No. PGT/7/-A/ Ethics/2013–2014/1767) and study was also registered under Clinical Trial Registry of India (CTRI/2014/01/004357).

Inclusion criteria

Patients of both sexes who met the diagnostic standards of *Timira*/immature cataract aged 30–60 years were included in this study. Participants were included on the basis symptoms like blurring of vision, visualization of nonexisting things, difficulty in bright light and dim light or night vision and signs like distant visual acuity, pinhole vision, best corrected visual acuity and cataract grading on slit lamp biomicroscopy according to Lenticular Opacity Classification System II.^[10]

Exclusion criteria

Patients who are suffering from congenital cataract, mature and hyper mature cataract, glaucoma, diabetic retinopathy, macular degeneration, retinitis pigmentosa, whose random blood sugar level and blood pressure are not within normal limits, who are under steroid treatment and or any kind of immunosuppressive therapy or under any cataract-inducing medication are excluded.

Grouping and posology

All the registered patients were randomly assigned to two groups Group A and Group B (n = 20 each). Lottery method was adopted for randomization.

- Group A: *Triphaladi Ghana Vati* (500 mg) orally administered twice daily for 3 months
- Group B: Elaneer Kuzhambu Anjana used as Anjana, 60 mg in both eyes for topical use and Triphaladi Ghana Vati (500 mg) orally administered twice daily for 3 months.

Follow-up period was fixed as 1 month for both the groups.

The ingredients of *Triphaladi Ghana Vati* [Table 1] were procured from the Pharmacy, Gujarat Ayurved University, Jamnagar and *Ghana-Vati* was prepared. *Elaneer Kuzhambu Anjana* was procured from Arya Vaidya Shala, Kottakkal, Kerala (Batch no. 164292; Mfg. Jan 2014).

Name of ingredients	Botanical name	Parts used	Quantity (parts)
Haritaki	Terminalia chebula Retz.	Pericarp	1
Vibheetaki	Terminalia bellirica Roxb.	Pericarp	1
Amalaki	Emblica officinalis Linn.	Pericarp	1
Yashtimadhu	<i>Glycyrrhiza glabra</i> Linn.	Roots and stolons	1
Gokshura	Tribulus terrestris Linn.	Fruits	1
Guduchi	<i>Tinospora cordifolia</i> Miers.	Stem	1
Haridra	Curcuma longa Linn.	Rhizomes	1
Daruharidra	Berberis aristata DC.	Stem	1
Tulasi	Ocimum sanctum Linn.	Whole plant	1
Punarnava	<i>Boerhavia diffusa</i> Linn.	Whole plant	1
Shunthi	Zingiber officinale Rosc.	Rhizomes	1

Table 1: Ingredients of Triphaladi Ghana Vati

Criteria for assessment

- 1. Subjective parameters visual disturbances were assessed by Snellen's chart and Jaeger's chart reading. Blurring of vision, polyopia, nyctalopia, hamarlopia, glaring of light, colored halos, visualization of nonexisting things^[11] were assessed with the help of grading pattern
- 2. Objective parameters were obtained by retinoscopy, slit lamp bio microscopic examination in tangentional sectioning of lens and retro-illumination technique for grading of cataract, according to Lenticular Opacity Classification System II [Figure 1] and direct and indirect ophthalmoscopic examinations were used to obtain values of objective parameters.

Blurred vision:

- 0 Absent
- l Mild
- 2 Moderate
- 3 Severe disturbing day to day life



Figure 1: The Lens Opacity Classification System II photographic grading standards. N: Nuclear photographs, C: Cortical photographs, P: Posterior subcapsular photographs

Visualization of nonexisting things like dots, lines, threads,

etc:

- 0 Absent
- 1 Occasional perception
- 2 Perception without disturbing routine work
- 3 Severe disturbing day to day work.

Difficulty in day vision or vision in light, glare etc:

- 0 No difficulty in light/day time
- 1 Slight difficulty in light/day time
- 2 Moderate difficulty in light/day time
- 3 Severe difficulty in light/day time.

Difficult in night vision or dim light:

- 0 No difficulty in night time
- 1 Slight difficulty in night time
- 2 Moderate difficulty in night time
- 3 Severe difficulty in night time.

Unaided distant visual acuity, pinhole vision best corrected distant visual acuity (Snellen's distant vision chart)

6/6-0 6/9-1 6/12-2 6/18-3 6/24-4 6/36-5 6/60-6.

Nuclear cataract Lenticular Opacity Classification System II [Figure 1].

Statistical analysis

Wilcoxon matched-pair signed-rank test and paired *t*-test were used to assess results for individual groups. Unpaired *t*-test and Fisher's exact test were used to calculate the comparison of results between the groups using GraphPad Instat 3.1 software (GraphPad Software Inc., California, USA).

Observations and Results

Total 36 patients completed the treatment course. Three dropouts were there in Group A and one in Group B. In Group A, three patients discontinued the treatment, two patients thought that eye diseases have to be treated with eye drops. When this group did not receive any eye drops, they dropped out and one patient was transferred to other state. In Group B, one patient dropped out the treatment as he had to undergo cataract surgery.

There was statistically significant improvement in blurring of vision and in difficulty in light, day vision, glare was found in both the groups. In addition to that Group B showed statistically significant change in visualization of nonexisting things like dots, lines, threads, etc., and difficulty in night vision or dim vision was observed [Table 2].

Statistically significant improvement in unaided distant visual acuity, pinhole vision, and in best-corrected vision was found in both the groups. Groups B also showed statistically significant reduction in nuclear cataract [Table 3].

Comparison between Group A and B

Statistically insignificant change assessed on comparison of difference between Group A and B with Fisher's exact test on symptoms such as blurred vision, visualization of nonexisting things and difficulty in light, day vision, glare, etc., Statistically significant change assessed on comparison between Group A and B with Fisher's exact test for difficulty in night vision or dim light [Table 4].

Statistically insignificant change was assessed on comparison between Group A and Group B with unpaired *t*-test on signs such as unaided distant visual acuity, pinhole vision and best-corrected vision. Statistically significant change was observed on comparison between Group A and B with unpaired *t*-test for nuclear cataract [Table 5].

Group	Ν	Mean		Difference	SD	SE	%	W	T+	T-	Р
		BT	AT	of mean							
Effect of treatment on blurring vision											
A	34	1.912	1.647	0.2647	0.6424	0.1102	13.85	108	149	-41	<0.05
В	38	1.921	1.105	0.8158	0.4565	0.07405	42.46	465	465	0	<0.0001
Effect of treatment on visualization of nonexisting things											
A	6	1.833	1.167	0.667	0.5164	0.2108	36.36	10	10	0	>0.05
В	9	1.444	0.8899	0.5556	0.4640	0.1547	38.46	21	21	0	<0.05
Effect of treatment on glare, poor day vision											
A	8	2.500	1.375	1.125	0.6409	0.2266	45.00	28	28	0	<0.05
В	16	1.875	0.8750	1.000	0.3651	0.09129	53.33	120	120	0	<0.0001
Effect of treatment on difficulty in night											
A	6	1.833	1.167	0.667	0.5164	0.2108	36.36	10	10	0	>0.05
В	12	1.750	0.4167	1.333	0.4924	0.1421	76.19	78	78	0	<0.001

SD: Standard deviation, SE: Standard error, AT: After treatment, BT: Before treatment

Table 3: Effect of treatment on signs of cataract (paired' t-test)										
Group	N Me		ean	Difference	%	Paired <i>t</i> -test				
		BT	AT	of mean		SD	SE	df	t	Р
Effect of treatment on unaided distant visual acuity										
A	34	3.794	3.176	0.6176	16.28	1.045	0.1792	33	3.447	<0.01
В	38	3.500	3.026	0.4737	13.53	0.9792	0.1588	37	2.987	<0.01
Effect of treatment on pinhole vision										
A	34	2.235	1.735	0.500	22.37	0.7487	0.1284	33	3.894	<0.001
В	38	2.132	1.447	0.6842	32.10	0.7391	0.1199	37	5.707	< 0.0001
Effect of treatment on best corrected visual acuity										
A	34	1.618	1.206	0.4118	25.45	0.7014	0.1203	33	3.423	<0.001
В	38	1.395	0,7895	0.6053	43.40	0.6794	0.1102	37	5.492	< 0.0001
Effect of treatment on nuclear cataract										
A	25	1.340	1.300	0.040	2.99	0.1384	0.0277	24	1.445	>0.05
В	30	1.300	1.067	0.2333	17.95	0.4097	0.0748	29	3.120	<0.01

SD: Standard deviation, SE: Standard error, AT: After treatment; BT: Before treatment

Table 4: Comparison of difference of symptoms between Group A and B (Fisher's exact test)									
Symptom	Group	n	<50%	>50%	Р				
Blurring of vision	А	34	32 (44)	2 (3)	>0.05				
	В	38	34 (47)	4 (6)					

	В	38	34 (47)	4 (6)	
Visualization of	А	6	6 (40)	0 (0)	>0.05
nonexisting things	В	9	7 (47)	1 (13)	
Difficulty in light,	А	8	7 (25)	0 (8)	>0.05
day vision, glare	В	16	12 (46)	4 (21)	
Difficulty in night	А	6	6 (33)	0 (0)	<0.05
or dim light	В	12	5 (28)	7 (39)	

n: Number of eyes having given symptom of cataract

Out of 36 patients in Group A 52.94% patients showed mild improvement, 23.53% remained unchanged, moderate improvements was found in 17.65% and 5.88% showed marked improvement and no patient was cured 0%. In Group B 47.36% patients showed moderate improvement, 26.32% showed marked and mild improvement, respectively, and no patient was cured or remained unchanged [Figure 2].

Discussion

Findings of both the groups suggest that selected drugs are effective, but better results were observed in Group B where both the drugs were administered to the patients. This can be because administration of oral drug alone is not sufficient to reverse the biochemical changes happening in the whole body and to attain sufficient quantity of drug to ocular tissues. Hence, a combination of oral and local administration is a must. *Anjana* type of ocular drug administration keeps the drug in contact with the eye surface longer. This *Kriya Kalpa* was an everyday routine to Indians which prevented refractive errors and cataract. *Anjana* is an excellent *Kalpana* which gives excellent systemic results, is evident from experimental and clinical study. In this way, *Elaneer Kuzhambu Anjana* can arrest, delay or reverse progression of cataract.^[12]

In the present study, test drug contained the ingredients suspended in tender coconut water, which is akin to plasma concentrate thus facilitating drug absorption by ocular tissue which also enters the systemic circulation. Also, the nutritive Bhati and Manjusha: Anti-cataract effect of Triphaladi Ghana Vati and Elaneer Kuzhambu Anjana in immature cataract

Table 5: Comparison of difference of signs between Group A and B (unpaired <i>t</i> -test)										
Signs	Group	n	Mean	SD	SE	df	Р	t		
Unaided distant visual acuity	А	34	0.6176	1.045	0.1792	70	>0.05	0.6034		
	В	38	0.4737	0.9792	0.1588					
Pinhole vision	А	34	0.5000	0.7487	0.1284	70	>0.05	1.049		
	В	38	0.6842	0.7391	0.1199					
Best corrected vision	А	34	0.4118	0.7014	0.1203	70	>0.05	1.188		
	В	38	0.6053	0.6794	0.1102					
Nuclear cataract	А	25	0.0400	0.1384	0.02769	53	<0.05	2.252		
	В	30	0.2333	0.4097	0.07479					

SD: Standard deviation, SE: Standard error



Figure 2: Overall effect of therapy

elements in coconut water media can nourish the lens, arresting degenerative changes and promoting lens nutrition, thus reversing nuclear cataract.

This drug is having all the 6 Rasas viz. Madhura (sweet), Amla (sour), Lavana (salty), Katu (pungent), Tikta (bitter) and Kashaya (astringent); Laghu (light), Ruksha (dry), Sheeta (cold), Snigdha (unctous) and Teekshna Gunas (properties); Ushna and Sheeta Veerya Dravya; Lekhana (scrapping), Chhedaniya, Shodhana (purifying), Rasayana, Chakshushya and Tridosha Shamaka properties. Katu Rasa is having Ushna, Pachana (digestive), Kaphahara properties. Kledopashoshana (dries up moisture), Shlesmopashoshana properties are possessed by Tikta Rasa. Kashaya Rasa shows its Shoshana (absorbing), more particularly Kledashoshana and Shleshma Prashamana properties. Laghu Guna has Kaphahara properties, Lekhana property is being possessed by Tikta and Kashaya Rasa and Laghu Guna. Tikta Rasa shows its Chhedaniya property, Katu Rasa is Teekshna and possessing Marga Vivarana (expand/dilate channels) action. Because of the above said inherent properties of drug, after getting absorbed, it may scrap away the vitiated Kapha, Ama and Meda already lodged in the Patalas, Rupavaha Sira as well as in Drishti. Their Shuddha Srotasa (opened channels) allows free movement of Vata, Pitta and Pitta performs its normal function of visual perception which was previously experiencing hindrance due to vitiated Kapha. The specific activity like Kaphahara and Pittavardhaka make an overall attempt to enhance the qualities of Tarpaka Kapha and Alochaka Pitta by alleviating the disturbances related to them.[8]

Senile cataract or *Timira* is a *Swabhava Balapravritta Vyadhi* which occurs by natural ageing process. Taking *Rasayana* is helpful to increase the immunity of person to keep him away from diseases which influence the fundamental aspect of body

viz. Dhatus, Agni and Srotamsi and Ojas etc., Characteristic properties of polyherbal formulation *Triphaladi Ghana Vati* which can help in preventing, delaying and reversal of senile cataract are as follows-

Triphala that is Amalaki (Emblica officinalis Linn.), Haritaki (Terminalia chebula Retz.), and Vibheetaki (Terminalia bellirica Roxb.) is having adaptogenic, antioxidant, anti-cataract, immunomodulatory, anti-diabetic, anti-hypercholesterolemic,^[13] free radical scavenger and rejuvenation properties.^[14] Tulasi (Ocimum sanctum Linn.) is having adaptogenic, antioxidant, anti-cataract, immunomodulatory, anti-diabetic, anti-hypercholesterolemic, free radical scavenger^[15] and advanced glycation end products-inhibitor properties.^[16] Guduchi (Tinospora cordifolia Miers.) is a adaptogenic,^[17] anti-oxidant,^[18] free radical scavenger, anti-cataract,^[19] immunomodulatory, anti-diabetic, anti-hypercholesterolemic and rejuvenating drug.^[20] Haridra (Curcuma longa Linn.) is having anti-oxidant,^[21] free radical scavenger,^[22] anti-diabetic, anti-age^[23] hypercholesterolemic,^[24] anti adaptogenic^[25] characteristics. Daruharidra (Berberis aristata DC.) is having anti-diabetic, anti-hyperlipidemia, anti-oxidant, [26] anti-inflammatory specially in ocular infections, eye infections,^[27] adaptogenic,[28] immunomodulatory,^[29] anti-cataract^[30] effect. Shunthi (Zingiber officinale Rosc.) is having advanced glycation end products-inhibitor,^[17] immunomodulatory,^[29] anti-diabetic, anti-hyperlipidemia, anti-oxidant,^[31] anti-ageing,^[32] immunomodulatory, anti-cataract, free radical scavenger^[33] properties. Yashtimadhu (Glycyrrhiza glabra Linn.) is having antioxidant,^[32] immunomodulatory activity,^[34] anti-diabetic, Rasayana,[35] anti-hypercholesterolemic,[36] enhancer of the bio-availability of drugs^[37] like actions. Punarnava (Boerhavia diffusa Linn.) is having immunomodulatory,^[29] antioxidant,^[38] antihypercholesterolemic, potential nutrients source, [39] adaptogenic, immunopotentiating,^[40] Rasayana^[41] like actions. Gokshura (Tribulus terrestris Linn.) is having immunomodulatory, anti-diabetic, hypolipidemic,^[42] adaptogenic, Rasayana,^[43] antioxidant^[44] and anti-cataract^[45] properties. Maximum numbers of ingredients of Triphaladi Ghana Vati are having Rasayana or rejuvenating, adaptogenic, immunomodulatory, anti-diabetic and anti-cataract effect. These properties are beneficial in senile cataract.

In Ayurvedic classical texts administration of potent psycho-physical rejuvenator formulations come under *Rasayana Chikitsa* which frees one off the diseases, improves quality of life and delays senile degenerative changes and have *Chakshushya* properties that is beneficial to eye.^[46] Cataract is also an ageing disorder and possible move to delay/arrest these senile changes is to start *Rasayana Chikitsa* as early as possible. *Chakshushya Rasayana* is the best choice to delay cataract changes. Hence, *Triphaladi Ghana Vati* can arrest, delay, or reverse progression of cataract.

Multicentric studies with larger sample size on same drugs should be carried out to bring authenticity of results. Photo documented studies are a must so that we can demonstrate the improvement in signs. Protocol of treatment for different types of cataract with choice of drugs based on *Doshas* must be tried. Effect of test drugs on different morphological cataracts needs to be done.

As, till date no medical treatment is available for cataract if the test drugs prove to have anti-cataract effect, then this can reduce a lot of financial burden on patients and can be a milestone in improving healthcare system. For better recording of cataract grading a good quality photographic attachment on slit lamp biomicroscope will add great value to the objectivity and reproducibility of the result as in this study researcher found this as a limitation of the study.

Conclusion

Internal use of *Triphaladi Ghana Vati* along with *Anjana* with *Elaneer Kuzhambu Anjana* that is combined therapy in Group B showed better results. This can be concluded that both systemic and topical administration is required for better management of *Timira* (senile cataract). *Chakshushya Rasayana, Chakshushya Ahara Vihara*, early diagnosis and proper management on *Doshic* lines can prevent arrest or delay senile cataract. The clinical study establishes both the test drugs can reduce and control the progress of *Timira*/cataract.

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Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

त्रिफलादि घन वटी तथा एलानीर कुजम्बु अंजन के मोतियाबिंद विरोधी प्रभाव का आंकलन करने के लिए तिमिर (अपक्व मोतियाबिंद) पर चिकित्सीय अध्ययन

हितेश भाटी, मंजुषा आर.

9९९८ में प्रकाशित विश्व स्वास्थ्य रिपोर्ट के अनुसार जराजन्य मोतियाबिंद से 90,३४०,००० व्यक्ति द्रिपक्षीय अंध हैं। वर्तमान अध्ययन में मोतियाबिंद विरोधी एजेंट के रूप में परीक्षण दवाओं त्रिफलादी घन वटी तथा एलानीर कुजम्बु की प्रभावकारिता का आंकलन करने के लिए चिकित्सीय परीक्षण की योजना बनाई गई थी। मोतियाबिंद से पीड़ित आधारभूत पात्र रोगियों को दो चिकित्सीय समूहों में बराबर संभावना के साथ यादृच्छिक रूप में विभाजित किया गया। परिणाम में दोनो समूहों में धुंधली दृष्टि, दिन के समय और चमकदार रोशनी में कठिनाई, दूर दृष्टि क्षमता, पिन होल दृष्टि, अधिकतम संशोधित दृष्टि क्षमता में सांख्यिकीय दृष्टि से महत्वपूर्ण परिवर्तन पाया गया। साथ ही समूह बी में रात के समय में कठिनाई, अस्तित्वहीन वस्तुओं को देखना तथा केंद्रीय मोतियाबिंद जैसे लक्षणों में भी सांख्यिकीय दृष्टि से सार्थक परिणाम मिले। चिकित्सीय परीक्षण यह निष्कर्ष स्थापित करता है कि मोतियाबिंद विरोधी एजेंट के रूप में परीक्षण दवाँए त्रिफलादि घन वटी तथा एलानीर कुजम्बु दोनों तिमिर (मोतियाबिंद) की प्रगति को नियंत्रित करने और कम कर सकने में सक्षम हैं। संयुक्त चिकित्सा समूह यानी समूह–बी में मोतियाबिंद की प्रगति को नियंत्रित करने में अधिक प्रभावी परिणाम मिले हैं। चक्षुष्य रसायन, शीघ्र निदान और दोषित अवस्था अनुसार उचित प्रबंधन जराजन्य मोतियाबिंद को रोकने या इसकी प्रगति देरी कर सकने में सक्षम हैं।