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CLINICAL EVALUATION OF NAYANASUKHA VARTHI ANJANA IN DWITIYA PATALAGATA TIMIRA (SENILE IMMATURE CATARACT)- AN OPEN-LABEL SINGLE-ARM CLINICAL STUDY

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ABSTRACT

Background and Objectives: ***Timira*** is one of the ***Drishtigata Rogas*** described in ***Ayurveda*** and is characterised by the gradual deterioration of vision. Based on its clinical manifestations, ***Timira*** can be correlated with senile immature cataract, a major cause of visual impairment among the ageing population. Cataract remains one of the leading causes of preventable blindness worldwide. Although surgical intervention is the definitive treatment, there is a growing need for safe, economical and effective therapeutic measures that can alleviate symptoms and improve visual function in the early stages of the disease. ***Nayanasukha Varthi Anjana,*** a classical Ayurvedic formulation indicated in ocular disorders, is known for its ***Chakshushya***, ***Lekhana*** and ***Rasayana*** properties. Hence, the present study was undertaken to assess its efficacy in the management of ***Dwitiya Patalagata Timira***. **Aim:** To find a better alternative and cost-effective management for ***Dwitiya Patalagata Timira*** (Senile immature cataract). **Materials and Methods:** An open-label single-arm clinical study was conducted on 40 patients diagnosed with ***Dwitiya Patalagata Timira*** (Senile Immature Cataract). ***Nayanasukha Varthi Anjana*** was administered for the prescribed treatment period. Patients were assessed at baseline, during treatment, after treatment, and at follow-up using subjective symptoms and objective ophthalmic parameters. The collected data were analysed using appropriate statistical methods: RMANOVA, post-hoc analysis using Tukey's test and Wilcoxon signed-rank test. **Results:** Treatment with ***Nayanasukha Varthi Anjana*** resulted in a statistically significant improvement in both subjective symptoms and objective clinical parameters **($p < 0.05$).** The therapeutic benefits observed after treatment were maintained during the follow-up period. **Conclusion:** ***Nayanasukha Varthi Anjana*** was found to be effective in reducing the clinical manifestations of ***Dwitiya Patalagata Timira*** and improving visual function in patients with senile immature cataract. The therapy was safe, well tolerated, and may serve as a supportive ***Ayurvedic*** intervention in the early management of this condition.

KEYWORDS: ***Dwitiya Patalagata Timira***, Senile Immature Cataract, ***Nayanasukha Varthi Anjana***, ***Anjana Karma***.

INTRODUCTION

Timira[1] is one of the ***Drishtigata Rogas***[2] described in ***Ayurveda*** and is characterised by gradual impairment of vision due to the vitiation of ***Doshas*** in the ocular structures. When the pathology is confined to the ***Dwitiya Patala***, the condition is termed ***Dwitiya Patalagata Timira***, which presents with blurred vision, floaters, and difficulty in seeing near objects. If left untreated, it may progress to ***Kacha*** and eventually ***Linganasha,***[3] leading to severe visual loss.

In modern ophthalmology, senile cataract is the most common cause of reversible blindness worldwide. The immature stage of senile cataract is characterised by partial lens opacity and gradual deterioration of vision, which closely resembles the clinical features of ***Dwitiya Patalagata Timira.*** Since cataract surgery is the only definitive treatment, there is a need for safe and effective interventions to improve visual function and delay disease progression in the early stages.

Ayurveda describes several local ocular therapies under ***Netra Kriyakalpa***, among which ***Anjana Karma***[4] is widely indicated for managing eye diseases. ***Nayanasukha Varthi Anjana***, a classical formulation mentioned in ***Ayurvedic*** texts, contains ingredients possessing ***Chakshushya*** (vision-promoting), ***Lekhana*** (scraping), ***Deepana*** (metabolic enhancing), and ***Rasayana*** (rejuvenating) properties. These actions may help improve ocular health and reduce the progression of lens opacity.

Although ***Nayanasukha Varthi***[5] ***Anjana*** has been traditionally used in the management of ocular disorders, scientific clinical evidence supporting its efficacy in ***Dwitiya Patalagata Timira*** (Senile Immature Cataract) is limited. Therefore, the present study was undertaken to evaluate the clinical efficacy of ***Nayanasukha Varthi Anjana*** in patients with ***Dwitiya Patalagata Timira*** using subjective symptoms and objective ophthalmic parameters.

AIM OF THE STUDY

- To find a better alternative and cost-effective management for ***Dwitiya Patalagata Timira*** (Senile immature cataract).

OBJECTIVES OF THE STUDY

1. To evaluate the efficacy of ***Nayanasukha Varthi Anjana*** in ***Dwitiya Patalagata Timira*** (Senile immature cataract).
2. To delay the surgical phase for senile cataract.

Review of literature

According to ***Shabda Kalpa Drumam***[6], ***Timira*** is described as a disease affecting the eyes, characterised by dimness or obscuration of vision. The term also denotes darkness perceived before the eyes, leading to impaired visual perception.

Classical ***Ayurvedic*** texts do not specifically enumerate separate etiological factors for ***Timira***. However, the general causative factors described for ***Netra Rogas*** can also be considered responsible for the development of ***Timira***.

These include sudden immersion in cold water immediately after exposure to excessive heat, prolonged viewing of distant objects, improper sleep habits, psychological stress, trauma, excessive sexual activity, excessive intake of ***Amla Rasa*** (sour substances), and exposure to smoke, heat, and other ***Pitta***-provoking factors that are harmful to the eyes (***Achakshushya***).[8] These factors lead to vitiation of ***Doshas***, particularly ***Pitta***, which then circulate through the ***Siras*** and localise in the eye, eventually resulting in the manifestation of ***Timira.***[7]

Timira is classified into six types based on ***Dosha*** predominance: ***Vataja, Pittaja, Kaphaja, Raktaja, Samsargaja,*** and ***Sannipataja Timira***. The disease progresses through four successive ***Patalas*** of the eye. Disease progression is explained based on the involvement of ***Doshas*** in different ***Patalas*** of the eye.

Dwitiya Patalagata Timira

The vitiated ***Doshas*** progress to the second Patala, which is predominantly composed of ***Mamsa Dhatu.***[9] At this stage, visual blurring becomes persistent because the ***Doshas*** become more firmly lodged and are unable to move easily. The patient may perceive various abnormal visual phenomena such as flies, mosquitoes, hairs, nets, circles, flags, mirage-like appearances, rings, moving stars, rainfall-like images, or darkness. Errors in distance perception may also occur, where distant objects appear near and near objects appear far. Fine objects, such as the eye of a needle, become difficult to visualise.

Management of *Dwitiya Patalagata Timira*[10]

The line of treatment mainly includes therapies possessing strong eliminative and scraping actions. Classical texts recommend procedures such as ***Teekshna Nasya***, ***Teekshna Anjana, Teekshna Shodhana, Putapaka***, and ***Apatarpana*** for the management of this condition. These therapies help in eliminating aggravated ***Kapha Dosha***, clearing obstruction within the ocular channels, and improving visual function. Various treatment modalities are advised in ***Timira*** depending upon the predominance of the involved ***Doshas***.

These include: ***Snehana*** (oleation therapy), ***Raktasrava*** / ***Asravisravana*** (bloodletting procedures), ***Virechana*** (therapeutic purgation), ***Nasya*** (nasal administration of medicines), ***Anjana*** (application of medicated collyrium), ***Moordhavasthi, Vasti*** (medicated enema), ***Tarpana*** (ocular nourishment therapy), ***Lepa*** (external application of medicated paste) and ***Seka*** (ocular irrigation).

Cataract

The term cataract originates from the Latin word “cataracta” and the Greek word “katarraktes,” both of which mean “waterfall.”

Cataract is defined as the development of opacity within the lens or its capsule. In general usage, the term denotes any reduction in the transparency of the lens, particularly when associated with visual impairment.

Lens Opacity: Any loss of transparency involving a part or the whole of the ocular lens without necessarily causing visual impairment or functional disability.

Senile cataract

Also known as age-related cataract, is the most common variety of acquired cataract. It generally affects individuals above 50 years of age and occurs with almost equal frequency in both sexes. Cataract remains one of the major causes of blindness worldwide and contributes significantly to visual impairment, especially in developing countries. It has been estimated that by the

age of 70 years, the majority of the population demonstrates some degree of senile lens opacity. The disease is usually bilateral in nature, although one eye may develop cataract earlier than the other. In certain middle-aged individuals, cataract may progress rapidly, constituting the pre senile type, which often exhibits a hereditary predisposition.

Classification of Senile Cataract

1. Morphological Classification

Based on the location and nature of lens opacity, senile cataract is mainly divided into two forms:

- **Cortical (Soft) Cataract**: This is the commonest variety, accounting for nearly 75-80% of cases. The opacity primarily affects the cortical region of the lens. Cortical cataract may initially appear in the form of wedge-shaped or spoke-like opacities, commonly termed cuneiform cataract. In some cases, it may present as a cupuliform cataract.
- **Nuclear (Hard) Cataract**: Nuclear cataract constitutes approximately 20–25% of cases and involves sclerosis and opacity of the central nucleus of the lens. The coexistence of both cortical and nuclear cataracts in the same eye is relatively uncommon during the initial stages, making the assessment of their exact prevalence difficult. Generally, cuneiform cataract forms the predominant type, followed by nuclear and cupuliform varieties.

2. Anatomical Classification

Anatomically, senile cataract can be categorised into the following types

- **Cortical Cataract**: Involves the cortex of the lens and is characterised by radial or wedge-shaped opacities extending from the periphery towards the center.
- **Nuclear Cataract:** Involves the nucleus of the crystalline lens and is associated with hardening and discolouration of the nucleus.
- **Posterior Subcapsular Cataract:** The opacity is situated immediately anterior to the posterior capsule of the lens. This type often causes significant visual disturbance, particularly during near work and exposure to bright light. Although cataracts may begin as a single anatomical type, they frequently become mixed as the condition advances and matures.

Aetiology

Senile cataract is primarily considered a degenerative change associated with ageing. However, it is considered a multifactorial disorder influenced by systemic, environmental, and metabolic factors. The exact etiopathogenesis remains incompletely understood.

Factors Influencing the Age of Onset, Type, and Maturation of Senile Cataract

- **Age:** Advancing age is the most important risk factor for senile cataract.
- **Heredity:** Genetic predisposition plays a significant role in the occurrence of cataract.
- **Geographical region:** Early onset in tropical countries compared to temperate regions, possibly due to greater exposure to ultraviolet radiation and environmental factors.
- **Dietary factors:** Nutritional deficiencies are considered important contributors to cataractogenesis.
- **Diabetes Mellitus:** Diabetes accelerates the onset and progression of cataract due to metabolic disturbances within the lens.
- **Body Mass Index (BMI):** Increased body mass index has been associated with a higher risk of cataract formation[11].
- **Corticosteroid Use:** Prolonged administration of corticosteroids, especially systemic therapy, is known to increase the risk of posterior subcapsular cataract.
- **Smoking:** Cigarette smoking is strongly associated with an increased risk of nuclear cataract and lens sclerosis.
- **Alcohol Consumption:** Excessive alcohol intake has been associated with an increased risk of all forms of cataract.
- **Diarrhoea and Dehydration:** Severe or recurrent diarrhoea may predispose to cataract development by causing dehydration and osmotic imbalance between the aqueous humour and the lens.

Pathogenesis of Cataract

Biochemically, three major factors are involved in the pathogenesis of cataract formation[12]

1. Hydration
2. Denaturation of lens proteins
3. Slow sclerosis

Effect of cataract on Visual Function

1. Myopia and Astigmatism

Nuclear cataract commonly produces a significant increase in myopia, while cortical cataract may lead to astigmatism or changes in the astigmatic axis.

2. Monocular Diplopia or Polyopia

Monocular diplopia or polyopia is mainly associated with cortical cataract and, less commonly, posterior subcapsular cataract.

3. Reduced Light Transmission

All types of cataracts reduce the amount of light reaching the retina. In slit-lamp examination, this is observed as back-scattered light from the lens opacity.

4. Changes in Colour Vision

Ageing itself causes mild tritanopia (reduced blue colour perception), and cataract further impairs colour discrimination. Increased forward light scatter produces a veiling effect that reduces colour saturation of retinal images. Nuclear cataracts especially absorb blue light, thereby increasing tritanopic colour vision defects.

5. Forward and Backward Light Scatter

Visual impairment in cataract mainly results from increased intraocular light scatter. Light may be scattered backward out of the eye or forward onto the retina.

6. Effect of Pupil Size

Pupil size has a significant influence on vision, particularly in posterior subcapsular cataract (PSC).

7. Coloured Halos

Patients with cataract may perceive coloured halos around lights due to alterations in colour transmission within the lens.

Methods Used for Cataract Evaluation and Documentation

No single test can completely describe the effect of cataract on a patient's visual status or functional ability. Modern clinical cataract grading systems, based on standardised cataract photographs, help clinicians document the progression of cataract more accurately. These grading systems are especially useful in clinical research and publication of scientific reports.[13]

Visual Acuity Testing

Visual acuity is commonly assessed using Snellen's chart and remains the standard clinical method for evaluating vision.

Contrast Sensitivity Testing

Contrast sensitivity measures the minimum contrast required to detect or recognise a target. Cataracts increase intraocular light scatter, thereby reducing retinal image contrast and decreasing contrast sensitivity.

Glare Testing

Glare sensitivity refers to the deterioration of visual function in the presence of a bright light source within the visual field. Glare is broadly classified into: discomfort glare and disability glare.

Ophthalmoscopy

A direct ophthalmoscope with its built-in +10 diopter lens can be used with both direct illumination and retroillumination from the fundus reflex to detect lens opacities, particularly in field examinations.

Slit-Lamp Examination

Slit-lamp biomicroscopy is the most important clinical method for detecting and localising lens opacities. It helps determine the type, extent, density, and progression of cataract over time. It is considered the standard clinical technique for the detailed examination of cataracts.

Slit-Lamp Photography and Cataract Grading

One of the most widely used cataract grading systems is the Lens Opacities Classification System III (LOCS III). This system provides standardised photographic references demonstrating different grades of Cortical cataract, Nuclear cataract and Posterior subcapsular cataract.

MATERIALS AND METHODS

Study Design: Open-label single-arm clinical study with pre- and post-test,

The present study incorporated three study designs: a before-and-after design, a two-eye design, and a worst-eye design.

Sampling technique: Convenient sampling method.

Sample size: A clinical study was performed on a group of 40 patients in the Department of Shalakya Tantra OPD and IPD of Alva's Ayurveda Medical College and Hospital, Moodubidire.

Diagnostic criteria

Subjects presenting with the signs and symptoms of ***Dwitiya Patalagata Timira*** and Senile immature cataract, as mentioned in Ayurvedic literature and contemporary textbooks, respectively, are selected for the study.

- *Vihwal drusti*- Blurred vision
- *Abhutamapi Pashyati*- Visualisation of non-existing things like dots, threads or hair
- Glare
- *Dwidha- Bahuda Darshana* – Diplopia
- Immature cataract confirmed by ophthalmoscopy and slit lamp biomicroscopy.

Inclusion criteria

- Patients within the age group of 40-70years.
- Visual acuity 6/9 or less.
- Patients with senile immature cataract.
- Patients with Lakshanas of ***Dwitiya Patalagata Timira***.
- Patients with two or more symptoms mentioned in the diagnostic criteria.

Exclusion criteria

- Senile mature cataract and hypermature cataract.
- Visual acuity less than 6/60.
- Congenital, Developmental, Traumatic, Complicated, and Metabolic cataract and cataract involving other systemic diseases that may interfere with the course of study.
- Any other ocular pathology that can cause diminution of vision (glaucoma, diabetic retinopathy, macular degeneration, retinitis pigmentosa)
- Patients under steroid treatment or any kind of immunosuppressive therapy, or under any cataract-inducing medications.
- Patients associated with any inflammatory and infectious ocular conditions.
- Patients below the age of 40years and above the age of 70years.
- ***Anjana Anarha***

Investigations

- Visual acuity

- Slit lamp examination
- Direct Ophthalmoscopic examination
- Auto refractometer

Intervention

Table No. 01.

Karma	***Anjana***
Drug	***Nayanasukha Varthi***
Time of application	Once a day in the morning
Site	***Kanninika* to *Apanaga Sandhi***
Dose	1 ***Harenu*** (50mg)
Duration	60 days

- **Trial drug:** ***Nayanasukha Varthi Anjana***
- **Observation period:** Visual acuity, Slitlamp examination and Ophthalmoscopic examination were done on the 0^{th}, 30^{th}, 60^{th} and 90^{th} day.
- **Follow up:** 30^{th} day, 60^{th} day and 90^{th} day
- **Total duration:** 90days

- **Assessment criteria**

Patients were assessed with subjective and objective parameters formulated for *Dwitiya Patalagata Timira* (Senile immature cataract)

Subjective parameters

- Glare
- Diplopia – Uniocular
- Blurred vision
- Floaters/ Black spots
- Visual acuity – Snellen's chart for distant vision; Jaeger's chart for near vision and pinhole test.

Objective parameters

- Slit lamp examination
- Direct ophthalmoscopic examination
- Autorefractometer

Parameters for Grading Index

The International Panel of the International Ocular Inflammation Society (IOSI) proposed a grading system to assess the severity of ocular symptoms. This system utilises a Visual Analogue Scale (VAS) with scores ranging from 0 to 10. Based on the intensity of symptoms, the grading is categorized as follows: Grade 0 – absence of signs, Grade 1 – mild signs, Grade 2 – moderate signs, and Grade 3 – severe signs.

Table 02: Showing VAS Score of grading.

Grade	Scoring on a numeric VAS Scale
No signs (0)	0
Mild (1)	1-3
Moderate (2)	4-7
Severe (3)	8-10

GRADING OF SUBJECTIVE PARAMETERS

Table 03: Showing grading of subjective parameter

Glare	0 – No Glare 1 – Glare at night from dim light 2 – Glare in daytime from dim light 3 - Glare
Uniocular diplopia	0-No Diplopia 1- Gaze-evoked diplopia 2-Discontinuous diplopia in primary and reading position 3-continuous diplopia in primary and reading position.
Floaters	0-No floaters 1-Small and single floater& Small and multiple 2- Large and single floater & Large and multiple floater 3- Very large floaters
Blurred vision	0-Absent 1-Occasional 2-Intermittent adjustment with eye squeezing 3-Frequent tolerable with refractive aids

Objective parameters assessed with the help of Snellen's vision chart for distant and near, ophthalmoscopic examination and Slit lamp examination.

Table 04: Showing grading for DV / BCVA DV.

Grading of Distant Vision (DV) / BCVA DV/ Pinhole using Snellen's chart	0- 6/6 1- 6/9,6/12 2- 2- 6/18,6/24 3- 3- 6/36,6/60

Table: 05: Showing grading for NV / BCVA NV.

Grading of Near Vision (NV)/ BCVA NV Using Roman test type	0- N6 1-N8, N10 2-N12, N14, N18 3-N24, N36

Table 06: Showing grading for AR reading.

AUTOREFRACTOMETER READING	0- 0 1- -0.25 to -1 2- -1.25 to -2 3- -2.25 to -3 4- -3.25 to -4 5- -4.25 to -5 6- -5.25 to -6

Grading for lenticular opacification

Lenticular opacity observed and photographed through the slit lamp was graded using the standard scale of Lens Opacity Classification System III (LOCS III).

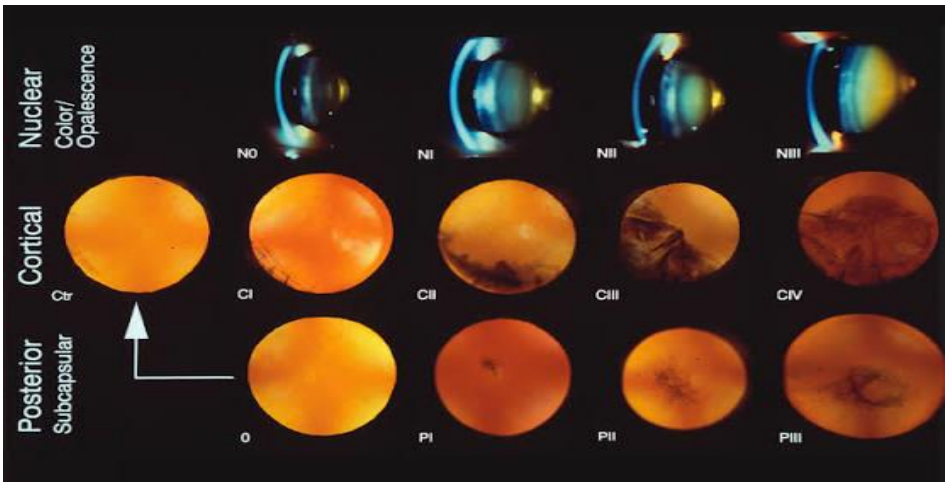


Figure 01: LOCS III grading.

Gradation Index for Overall Assessment

The overall therapeutic response was evaluated by comparing the observations recorded before and after treatment. The outcomes were categorized as complete remission, marked improvement, moderate improvement, mild improvement, or unchanged based on the predefined assessment criteria.

The percentage of improvement was calculated for each parameter and graded according to the following criteria:

- ✓ Complete remission: 100% relief in symptoms and no recurrence during follow up study was considered as complete remission.
- ✓ Marked improvement: 75 – 100% improvement in signs and symptoms.
- ✓ Moderate improvement: 50 - 75% improvement in signs and symptoms.
- ✓ Mild improvement: 25 - 50% improvement in signs and symptoms.
- ✓ Unchanged: Less than 25% reduction in symptoms or recurrence of the symptoms to a similar extent of severity is noted as recurrence.

RESULTS

To identify the significance of changes in each parameter before and after treatment within the group, statistical analysis was performed using repeated-measures ANOVA and the Wilcoxon signed-rank test. Post-hoc analysis was performed using Tukey's test.

Effect of treatment on blurred vision

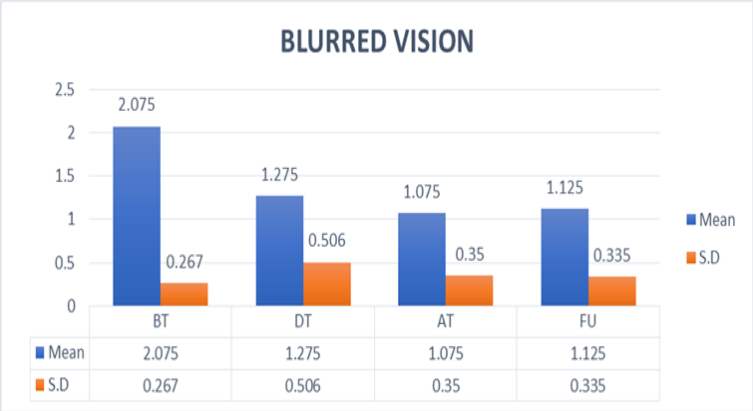
Table No.07 – Effect of treatment on blurred vision within the group.

Column	Mean	Std Dev	Median
BT	**2.075**	**0.267**	**2.000**
DT	**1.275**	**0.506**	**1.000**
AT	**1.075**	**0.350**	**1.000**
FU	**1.125**	**0.335**	**1.000**

Table No. 08: Effect of treatment on blurred vision between assessments.

Comparison	Q value	P value	Significance
BT vs DT	**7.655**	**<0.05**	**Yes**
BT vs AT	**9.492**	**<0.05**	**Yes**
BT vs FU	**9.063**	**<0.05**	**Yes**

DT vs AT	**1.837**	**>0.05**	**No**
DT vs FU	**1.408**	**>0.05**	**No**
AT vs FU	**0.429**	**>0.05**	**No**



Graph No. 01: showing the treatment effect on blurred vision.

The mean score showed a progressive reduction from 2.075 ± 0.267 before treatment to 1.275 ± 0.506 during treatment, 1.075 ± 0.350 after treatment and 1.125 ± 0.335 at follow-up, indicating statistically significant improvement ($p<0.05$).

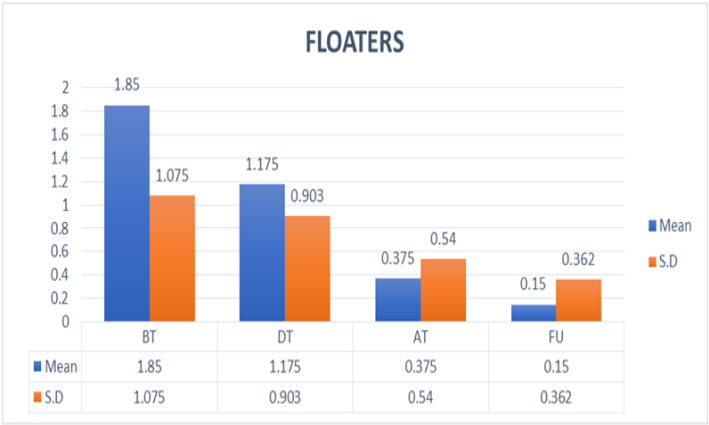
Effect of treatment on floaters

Table No. 09: Effect of treatment on floaters within the group.

Column	Mean	Std Dev	Median
BT	**1.850**	**1.075**	**2.000**
DT	**1.175**	**0.903**	**1.000**
AT	**0.375**	**0.540**	**0.000**
FU	**0.150**	**0.362**	**0.000**

Table No. 10: Effect of treatment on floaters between assessments.

Comparison	Q value	P value	Significance
BT vs DT	**3.980**	**<0.05**	**Yes**
BT vs AT	**9.063**	**<0.05**	**Yes**
BT vs FU	**10.227**	**<0.05**	**Yes**
DT vs AT	**5.083**	**<0.05**	**Yes**
DT vs FU	**6.246**	**<0.05**	**Yes**
AT vs FU	**1.164**	**>0.05**	**No**



Graph No. 02: showing the treatment effect on floaters.

The mean score of floaters reduced progressively from 1.850 ± 1.075 before treatment to 0.150 ± 0.362 at follow-up, indicating marked clinical improvement after treatment.

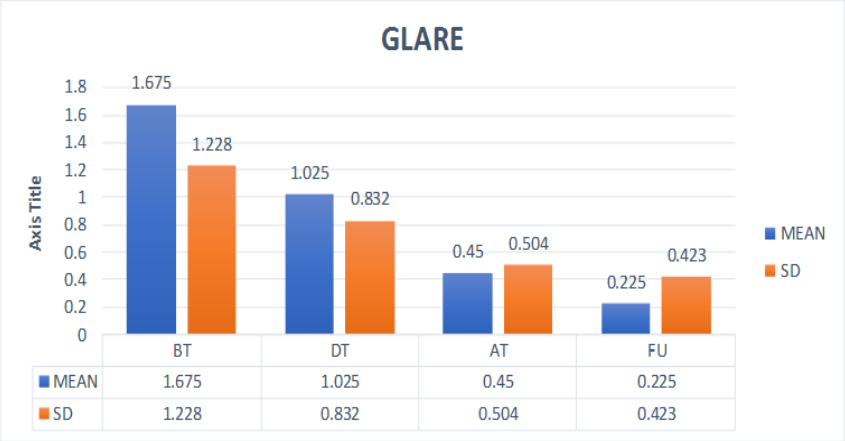
Effect of treatment on glare

Table No. 11: Effect of treatment on Glare within group.

Column	Mean	Std Dev	Median
BT	1.675	1.228	2.000
DT	1.025	0.832	1.000
AT	0.450	0.504	0.000
FU	0.225	0.423	0.000

Table No. 12: Effect of treatment on Glare between assessments.

Comparison	Q value	P value	Significance
BT vs DT	3.613	<0.05	No
BT vs AT	7.532	<0.05	Yes
BT vs FU	8.941	<0.05	Yes
DT vs AT	3.919	<0.05	Yes
DT vs FU	5.328	>0.05	Yes
AT vs FU	1.408	>0.05	No



Graph No. 03: showing the treatment effect on glare.

The mean score of glare reduced progressively from 1.675 ± 1.228 before treatment to 0.225 ± 0.423 at follow-up, indicating marked clinical improvement after treatment.

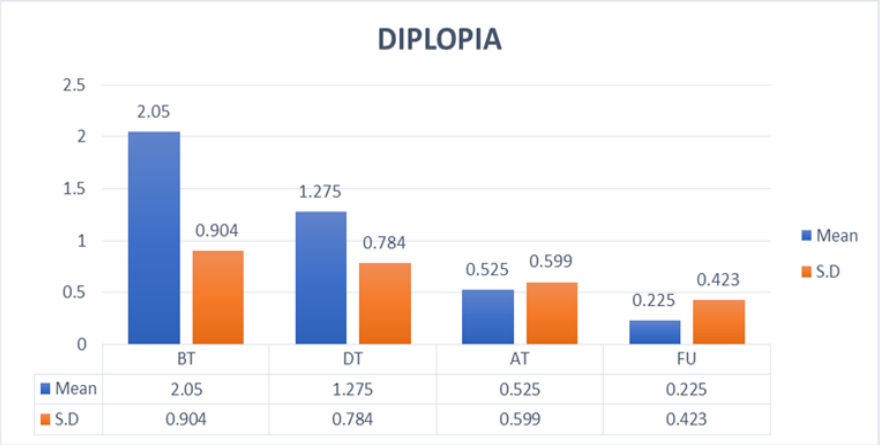
Effect of treatment on uniocular diplopia

Table No. 13: Effect of treatment on uniocular diplopia within group.

Column	Mean	Std Dev	Median
BT	2.050	0.904	2.000
DT	1.275	0.784	1.000
AT	0.525	0.599	0.000
FU	0.225	0.423	0.000

Table No. 14: Effect of treatment on diplopia between assessments.

Comparison	Q value	P value	Significance
BT vs DT	4.409	<0.05	Yes
BT vs AT	9.492	<0.05	Yes
BT vs FU	11.084	<0.05	Yes
DT vs AT	5.083	<0.05	Yes
DT vs FU	6.675	<0.05	Yes
AT vs FU	1.592	>0.05	No



Graph No. 04: showing the treatment effect on uniocular diplopia.

The mean score of diplopia reduced progressively from 2.05± 0.904 before treatment to 0.225 ± 0.423 at follow-up, indicating marked clinical improvement after treatment.

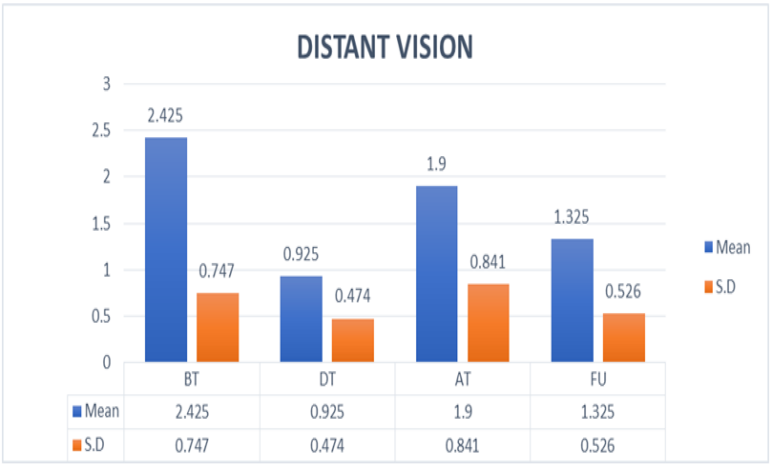
Effect of treatment on distant vision

Table No. 15: Effect of treatment on Distant vision within group.

Column	Mean	Std Dev	Median
BT	**2.425**	**0.747**	**2.000**
DT	**0.925**	**0.474**	**1.000**
AT	**1.900**	**0.841**	**1.000**
FU	**1.325**	**0.526**	**1.000**

Table No. 16: Effect of treatment on Distant vision between assessments.

Comparison	Q value	P value	Significance
BT vs DT	**10.717**	**<0.05**	**Yes**
BT vs AT	**3.735**	**<0.05**	**Yes**
BT vs FU	**8.083**	**<0.05**	**Yes**
DT vs AT	**6.981**	**<0.05**	**Yes**
DT vs FU	**2.633**	**>0.05**	**No**
AT vs FU	**4.348**	**<0.05**	**Yes**



Graph No. 05: showing the treatment effect on distant vision.

In this study, the mean score reduced progressively from **2.425 ± 0.747** before treatment to **0.925 ± 0.474** during treatment**, 1.9 ± 0.841** after treatment, and **1.325 ± 0.526** at follow-up, indicating significant clinical improvement with **p<0.05.**

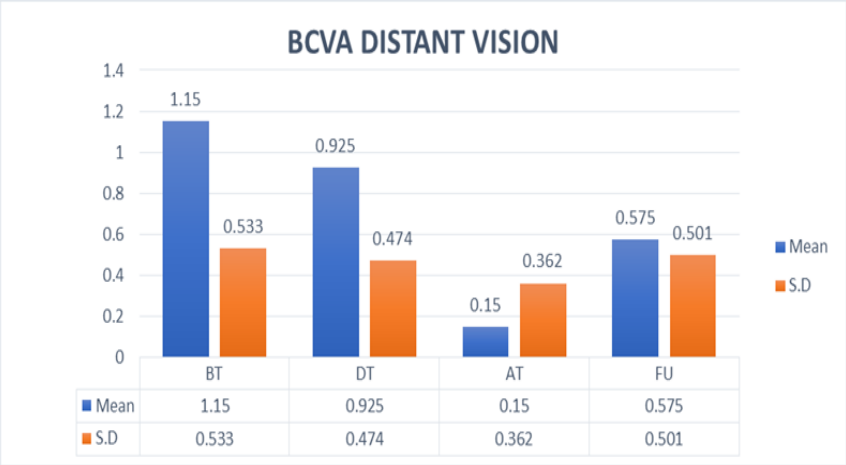
EFFECT OF TREATMENT ON BCVA DISTANT VISION

Table No. 17: Effect of treatment on BCVA Distant vision within group.

Column	Mean	Std Dev	Median
BT	1.150	0.533	1.000
DT	0.925	0.474	1.000
AT	0.150	0.362	0.000
FU	0.575	0.501	1.000

Table No.18 – Effect of treatment on BCVA Distant vision within the group assessment.

Comparison	Q value	P value	Significance
BT vs DT	1.837	>0.05	No
BT vs AT	8.573	<0.05	Yes
BT vs FU	5.021	<0.05	Yes
DT vs AT	6.736	<0.05	Yes
DT vs FU	3.184	>0.05	No
AT vs FU	3.552	>0.05	No



Graph No. 06: showing the treatment effect on BCVA distant vision.

In this study, the mean score reduced progressively from **1.15 ± 0.533** before treatment to **0.925 ± 0.474** during treatment**, 1.15 ± 0.362** after treatment, and **0.575 ± 0.501** at follow-up, indicating significant clinical improvement with **p<0.05.**

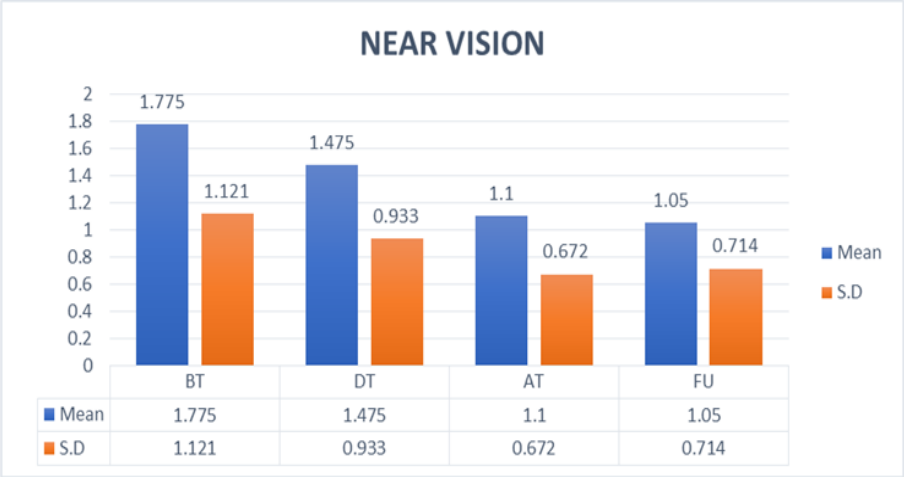
Effect of treatment on near vision

Table No. 19: Effect of treatment on Near vision within the group.

Column	Mean	Std Dev	Median
BT	1.775	1.121	2.000
DT	1.475	0.933	1.000
AT	1.100	0.672	1.000
FU	1.050	0.714	1.000

Table No. 20: Effect of treatment on Near vision between assessments.

Comparison	Q value	P value	Significance
BT vs DT	2.205	>0.05	No
BT vs AT	5.266	<0.05	Yes
BT vs FU	5.756	<0.05	Yes
DT vs AT	3.062	>0.05	No
DT vs FU	3.552	>0.05	No
AT vs FU	0.490	>0.05	No



Graph No. 07: showing the treatment effect on Near vision.

In this study, the mean score reduced progressively from **1.775 ± 1.121** before treatment to **1.475 ± 0.933** during treatment**, 1.1 ± 0.672** after treatment, and **1.05 ± 0.714** at follow-up, indicating significant clinical improvement with **p<0.05.**

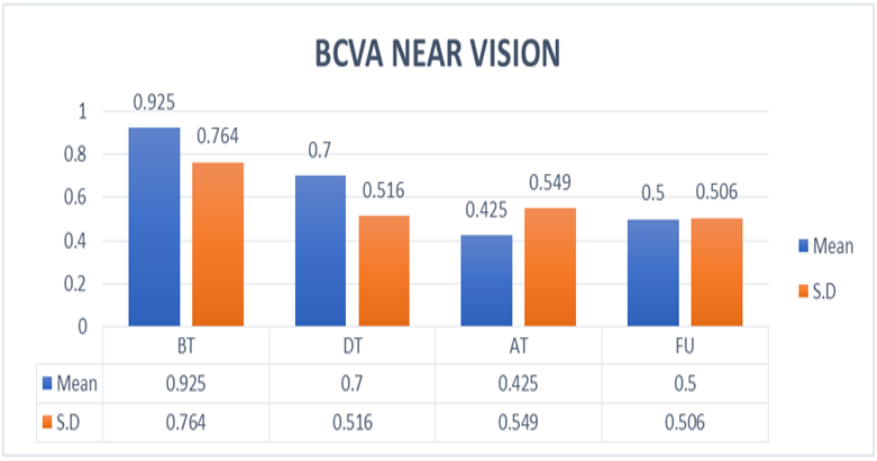
Effect of treatment on BCVA near vision

Table No.21 – Effect of treatment on BCVA Near vision within groups.

Column	Mean	Std Dev	Median
BT	0.925	0.764	1.000
DT	0.700	0.516	1.000
AT	0.425	0.549	0.000
FU	0.500	0.506	0.500

Table No. 22: Effect of treatment on BCVA Near vision between assessments.

Comparison	Q value	P value	Significance
BT vs DT	1.592	>0.05	No
BT vs AT	3.919	<0.05	Yes
BT vs FU	3.307	>0.05	No
DT vs AT	2.327	>0.05	No
DT vs FU	1.715	>0.05	No
AT vs FU	0.612	>0.05	No



Graph No. 08: showing the treatment effect on BCVA Near vision.

In this study, the mean score reduced progressively from **0.925 ± 0.764** before treatment to **0.7 ± 0.516** during treatment**, 0.425 ± 0.549** after treatment, and **0.5 ± 0.506** at follow-up, indicating significant clinical improvement before and after treatment with **p<0.05.**

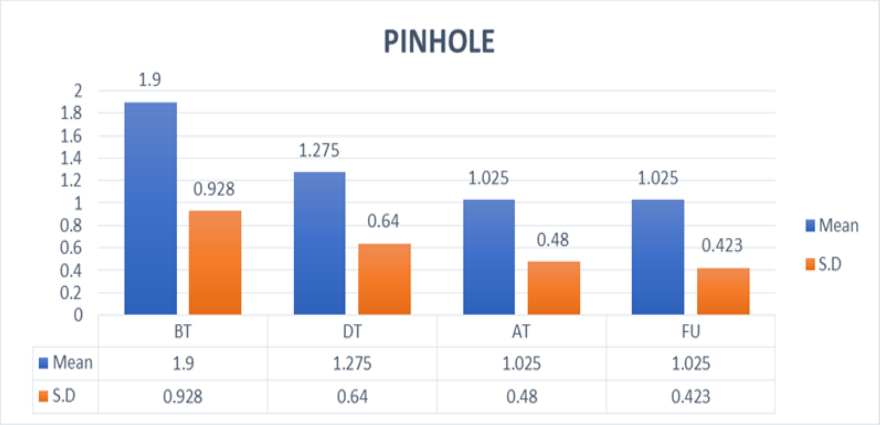
Effect of treatment on pinhole improvement

Table No. 23: Effect of treatment on Pinhole improvement within group.

Column	Mean	Std Dev	Median
BT	1.900	0.928	2.000
DT	1.275	0.640	1.000
AT	1.025	0.480	1.000
FU	1.025	0.423	1.000

Table No. 24: Effect of treatment on the pinhole improvement between assessments.

Comparison	Q value	P value	Significance
BT vs DT	4.715	<0.05	Yes
BT vs AT	6.491	<0.05	Yes
BT vs FU	6.430	<0.05	Yes
DT vs AT	1.776	>0.05	No
DT vs FU	1.715	>0.05	No
AT vs FU	0.0612	>0.05	No



Graph no 09: showing the treatment effect on pinhole.

The mean score of pinhole reduced progressively from 1.9± 0.928 before treatment to 1.025 ± 0.423 at follow-up, indicating marked clinical improvement after treatment.

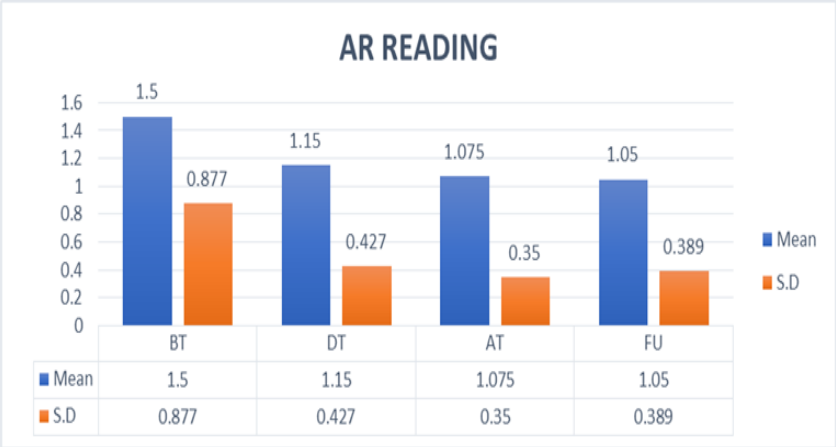
Effect of treatment on autorefractometer reading

Table No. 25: Effect of treatment on Autorefractometer reading within group.

Column	Mean	Std Dev	Median
BT	1.500	0.877	1.000
DT	1.150	0.427	1.000
AT	1.075	0.350	1.000
FU	1.050	0.389	1.000

Table No. 26: Effect of treatment on AR Reading between assessments.

Comparison	W value	P value	Significance
BT vs DT	-45.000	P = 0.004	Yes
BT vs AT	-45.000	P = 0.004	Yes
BT vs FU	-55.000	P = 0.002	Yes
DT vs AT	-6.000	P = 0.250	No
DT vs FU	-10.000	P = 0.125	No
AT vs FU	-1.000	P = 1.000	No



Graph No. 10: showing the treatment effect on AR reading

The mean score of AR Reading reduced progressively from 1.5± 0.877 before treatment to 1.05 ± 0.389 at follow-up, indicating marked clinical improvement after treatment.

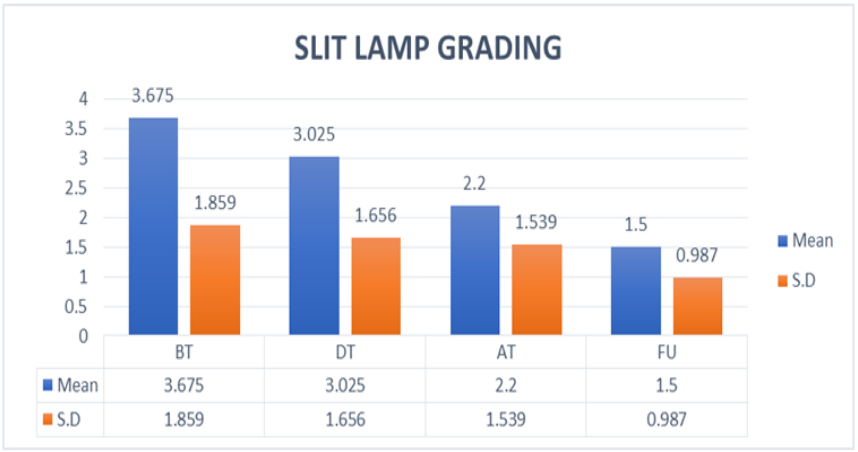
EFFECT OF TREATMENT ON SLITLAMP GRADING

Table No. 27: Effect of treatment on Slitlamp grading within group.

Column	Mean	Std Dev	Median
BT	3.675	1.859	5.000
DT	3.025	1.656	4.000
AT	2.200	1.539	3.000
FU	1.500	0.987	2.000

Table No. 28: Effect of treatment on Slitlamp within the group assessment.

Comparison	W value	P value	Significance
BT vs DT	-351.000	<0.001	Yes
BT vs AT	-780.000	<0.001	Yes
BT vs FU	-780.000	<0.001	Yes
DT vs AT	-561.000	<0.001	Yes
DT vs FU	-652.000	<0.001	Yes
AT vs FU	-325.000	<0.001	Yes



Graph No. 11: showing the treatment effect on Slitlamp grading.

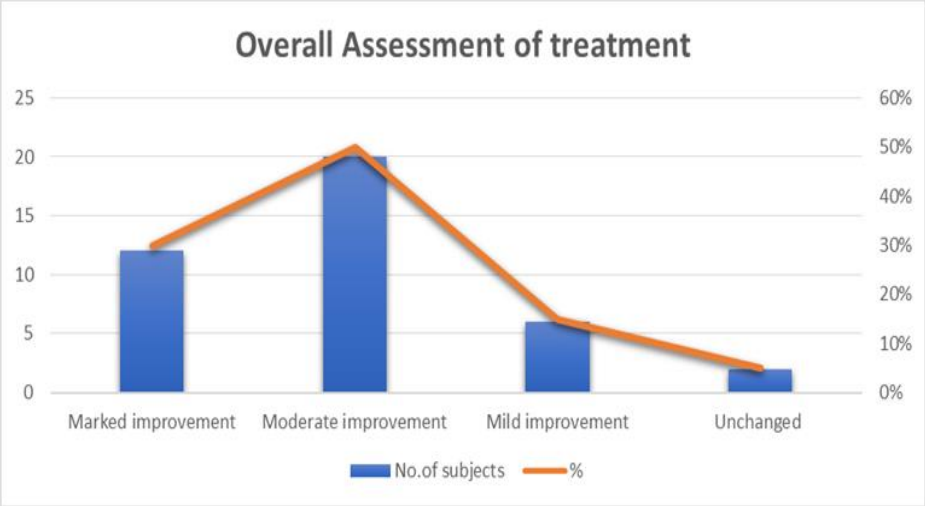
In this study, the mean score reduced progressively from **3.675 ± 1.859**before treatment to **3.025 ± 1.656** during treatment**, 2.2 ± 1.539** after treatment, and **1.5 ± 0.987** at follow-up, indicating significant clinical improvement before and after treatment with **p<0.05.**

This indicates a major improvement was seen before, during and after treatment, and was maintained throughout the follow-up.

OVERALL ASSESSMENT OF *NAYANASUKHA VARTHI ANJANA* ON *DWITIYA PATALAGATA TIMIRA* (SENILE IMMATURE CATARACT)

Table No. 29: Overall assessment.

Overall assessment	No. of subjects	%
Marked improvement	12	30%
Moderate improvement	20	50%
Mild improvement	6	15%
Unchanged	2	5%



Graph No. 12: showing overall assessment of treatment.

In the present study, 20 (50%) subjects showed moderate improvement, 12 (30%) showed marked improvement, 6 (15%) subjects showed mild improvement and 2(5%) subjects showed unchanged.

DISCUSSION

Visual acuity

- **Blurred vision:** Reduction in lens opacity improves transmission of light through the lens. ***Chakshushya*** and ***Rasayana*** properties improve the functional efficiency of ocular tissues. ***Lekhana*** action may reduce ***Kapha***-induced turbidity in the lens.
- **Distant vision and BCVA distant vision:** ***Lekhana*** of anterior cortical or posterior subcapsular opacities (which most affect distance vision) directly clears the optical axis. ***Deepana-Pachana*** action corrects the ***Ama-Kapha*** accumulation obstructing the ***Drishti Patala*** (lens), restoring axial transparency. ***Chakshushya Karma*** replenishes the functional capacity of ***Alochaka Pitta***, improving photoreceptor signal quality.
- **Near vision and BCVA near vision:** ***Chakshushya Dravyas*** nourish the neuromuscular apparatus of accommodation. ***Vata-Shamaka*** action improves ciliary body tone and elasticity of the crystalline lens, restoring accommodative amplitude. Enhanced ocular nourishment supports functional visual activity.
- **Pinhole:** Persistence of good pinhole visual acuity throughout treatment confirms no retinal or optic nerve toxicity from the ***Anjana***.
- **Autorefractometer reading:** ***Deepana-Pachana*** corrects the ***Ama*** responsible for aberrant protein deposition, altering the refractive index of the lens nucleus. Reduction in myopic shift (decrease in minus sphere) on autorefraction indicates regression of nuclear sclerosis — ***Lekhana*** acting on the dense nuclear core.

Glare: ***Pitta-Shamaka*** action (***Tikta, Madhura Rasa Dravyas***) reduces vitiated ***Alochaka Pitta***, normalising light-processing capacity, photosensitivity and excessive visual discomfort. Reduction of anterior cortical lens opacities decreases forward light scatter (the primary optical basis of glare). Improved transparency of ocular media enhances contrast sensitivity.

Floaters: ***Vata*** pacifying action may help reduce the perception of vitreous disturbances. Improved ocular nourishment and microcirculation may stabilise degenerative ocular changes. Cleansing and soothing effects on ocular tissues may reduce subjective visual disturbances.

Diplopia (Uniocular): ***Lekhana Karma*** helps to dissolve the focal lens opacities, creating irregular refractive zones. ***Vata-Shamaka*** action corrects irregular ciliary muscle tone contributing to unstable accommodation. ***Chakshushya*** properties stabilise the neuromuscular coordination of the ciliary body and zonular apparatus. Reduction of lenticular refractive index variation (caused by early nuclear sclerosis) improves single-image formation.

Lenticular opacity

- **Cortical cataract:** ***Lekhana*** and ***Kapha-Shamaka Karma*** help reduce the progression of the quantum of cortical lens opacity.
- **Nuclear cataract:** ***Tikshna-Ushna*** properties act on protein aggregation and help in the reduction of nuclear opalescence and nuclear cataract.
- **PSC:** ***Pitta*** – ***Shamaka*** and antioxidant effects may prevent protein denaturation within the lens, protecting the posterior capsule epithelial cells from oxidative damage in PSC.

CONCLUSION

The present clinical study was undertaken to assess the therapeutic efficacy of ***Nayanasukha Varthi Anjana*** as a safe, economical, and non-surgical management option for senile immature cataract. Analysis of the study findings revealed significant improvement in both subjective and objective parameters following treatment. The results suggest that ***Nayanasukha Varthi Anjana*** has a beneficial role in the management of ***Dwitiya Patalagata Timira*** and may help in delaying the progression of cataract, thereby postponing the need for surgical intervention in suitable cases and satisfying both the objectives of the study.

Therefore, it may be concluded that ***Nayanasukha Varthi Anjana*** is a safe, effective, and cost-effective therapeutic modality for the management of ***Dwitiya Patalagata Timira*** (Senile Immature Cataract).

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