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Study to Understand The Correlation Between Hba1c Values and Severity of Diabetic Retinopathy

Anupama Raju Taklikar¹, Nair Athira T², Srinath Raju Taklikar³

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ABSTRACT

Purpose: The purpose of this study is to understand the correlation between HbA1C values and severity of disease in diabetic patients with diabetic retinopathy and diabetic patients without diabetic retinopathy.

Methods: 47 patients with diabetes were examined at a tertiary center. All of these patients underwent tests like visual acuity, slit lamp examination, dilated fundus examination, blood tests including random blood sugars and HbA1C levels. Duration of the disease and medications taken were also noted for all the patients.

Results: In this study, a total of 47 patients were evaluated with a mean age of 57.72 ± 12.42 years. 18 out of 27 patients (66.6%) with HbA1c values more than 10% showed signs of diabetic retinopathy with a mean HbA1c value of $12.5 \pm 1.8\%$. 4 out of 13 patients (30.7%) with HbA1c values between 6.9% to 10% showed signs of diabetic retinopathy with a mean HbA1c value of $8.7 \pm 1.3\%$. None of 7 patients with HbA1c values less than 6.9% showed signs of diabetic retinopathy.

Conclusion: Higher levels of HbA1C levels and longer duration of disease are found to be associated with diabetic retinopathy disease.

KEYWORDS

- Diabetes Mellitus • Diabetic Retinopathy • HbA1c

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INTRODUCTION

Diabetes mellitus is a long-term metabolic disorder marked by elevated blood sugar levels, resulting from insufficient insulin production, insulin resistance, or both. As per the International Diabetes Federation, 77 million adults in India, aged 18 and above, are affected by type 2 diabetes.¹

Diabetic retinopathy (DR) is a microvascular condition caused by the prolonged impact of diabetes mellitus. It can result in damage to the retina that threatens vision and may ultimately lead to blindness.² Nonproliferative diabetic retinopathy is characterized by microvascular changes that are usually asymptomatic. It advances quietly through mild, moderate and severe stages without causing vision loss. The cumulative rate of progression from mild nonproliferative retinopathy to vision-threatening complications is approximately 14–16%.³

Glycated hemoglobin (HbA1c) indicates long-term blood glucose levels and is used as a marker to assess the average blood glucose concentration over the past 1–2 months. The Hemoglobin A1C (HbA1C) test is a crucial tool in diabetes management because it provides an accurate measure of long-term blood sugar control.⁴ By assessing the percentage of glycated hemoglobin, it reflects average blood glucose levels over the past two to three months. Its strong link to the risk of diabetes-related complications, such as nerve damage, kidney issues, eye problems, and heart disease, makes it a valuable indicator.

Maintaining HbA1C levels within the target range can significantly reduce these risks. Regular monitoring helps healthcare providers and patients evaluate treatment effectiveness and make necessary adjustments for better outcomes.

One of the main challenges in linking the severity of hyperglycemia to long-term complications of diabetes is the absence of a reliable and objective method for assessing diabetic control. The use of glycated proteins, serum proteins, and primary hemoglobin has introduced a new approach to evaluating glycemia.⁶

HbA1c has long been recognized as a marker for assessing the long-term control of diabetes

mellitus. Several studies have explored the correlation between HbA1c levels and various stages of diabetic retinopathy (DR).⁶

OBJECTIVES

To study the correlation between HbA1c level values and the severity of disease in diabetic patients with diabetic retinopathy and diabetic patients without diabetic retinopathy.

METHODOLOGY

A descriptive observational study was conducted on 47 elderly patients with type 2 diabetes mellitus. The study was conducted from November 2023 to April 2024 at the Outpatient Department of Ophthalmology, Navodaya Medical College Hospital and Research Centre, Raichur. All the male and female patients above 40 years of age and diagnosed with type 2 diabetes mellitus were included in the study. Patients with Type 1 diabetes mellitus, gestational diabetes, patients who were below the age group of 40 years and patients with dense lens opacities were excluded from this study. The study was conducted after Institutional Ethical Committee approval. Informed consent was obtained from all patients, in regional language in the prescribed format and explained about the study purpose and procedures prior to their enrollment in study. 47 patients were enrolled in the study.

Proper history was recorded from each and every patient. Factors like duration of the disease and the medications used by the patients including oral hypoglycemic agents and insulin injections were recorded during history taking. The patients also underwent detailed ophthalmic examination like best corrected visual acuity, slit lamp biomicroscopy and dilated fundus examination. Fundus fluorescence angiography (FFA) and Optical Coherence Tomography (OCT) was done in indicated patients. All patients underwent biochemical tests like HbA1c levels and Random blood sugar levels.

RESULTS

A total of 47 patients were enrolled in the study (Chart 1).

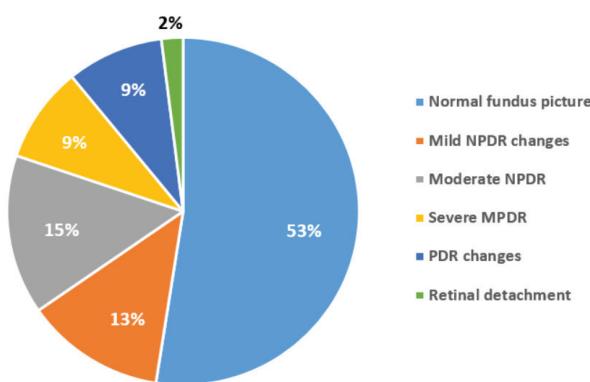


Chart 1: Distribution of patients in the clinical examination

Table 1: Gender Distribution

Male Patients	Female Patients
26 (55.3%)	21 (44.6%)

Table 2: Age Distribution

Age distribution	Patients
41 - 50 yrs	10
51 - 60 yrs	17
61 - 70 yrs	13
71 - 80 yrs	7

The mean age of the patients was 57.72 ± 12.42 years (Table 2) and 44.6% of the patients were females (Table 1).

Table 3: Hypoglycemic agents used

Types of Hypoglycemic Agent Used	No. of Patients
Insulin along with oral hypoglycemics	9 patients (19.2%)
Oral hypoglycaemic agents	38 patients (80.8%)

9 patients were found to be using insulin along with the oral hypoglycemic agents and 38 patients were using only oral hypoglycemic agents (Table 3). Out of 7 patients who were diagnosed with diabetes less than 1 year ago only 2 patients (28.5%) showed signs of diabetic retinopathy with a mean HbA1c value of $10.05 \pm 2.07\%$ in affected patients. 28 patients had a history of diabetes for a duration between 1 year to 10 years, only 11 patients (39.2%) showed signs of diabetic retinopathy with a mean HbA1c value of $10.07 \pm 2.42\%$.⁷ patients had a history of diabetes for more than 10 years, out of which 6 patients (85.7%) showed signs of diabetic retinopathy with a mean HbA1c value of $10.07 \pm 2.88\%$. (Table 4)

Table 4: Correlation between duration of disease and diabetic retinopathy changes

Duration of disease	No. of patients	Diabetic retinopathy fundus	Mean HbA1c value of affected participants
Less than 1 year	7 patients	2 patients (28.5%)	$10.05 \pm 2.07\%$
1 year to 10 years	28 patients	11 patients (39.2%)	$10.07 \pm 2.42\%$
More than 10 years	7 patients	6 patients (85.7%)	$10.07 \pm 2.88\%$

18 patients out of 27 patients (66.6%) with HbA1c values more than 10% showed signs of diabetic retinopathy with a mean HbA1c value of $12.5 \pm 1.8\%$. 4 patients out of 13 patients (30.7%) with HbA1c values between 6.9% to 10% showed signs

of diabetic retinopathy with a mean HbA1c value of $8.7 \pm 1.3\%$. None of 7 patients with HbA1c values less than 6.9% showed signs of diabetic retinopathy. (Table 5)

Table 5: Correlation between HbA1c and diabetic retinopathy changes

HbA1c value range	Total no. of patients	Patients with diabetic retinopathy	Mean HbA1c value of affected participants
Less than 6.9 %	7 patients	None	None
6.9 % to	13 patients	4 patients (30.7%)	$8.7 \pm 1.3\%$
More than 10 %	27 patients	18 patients (66.6%)	$12.5 \pm 1.8\%$

DISCUSSION

A strong correlation was found between the level of HbA1c values and the severity of diabetic retinopathy levels in our study. HbA1c was found to be playing a major role in determining the severity of diabetic retinopathy in the diabetic patients. Controlled HbA1c helped in controlling the progression of the disease. People who were regular on medications were found to be having controlled levels of HbA1c levels.

Bukke SN et al found a statistically significant correlation between HbA1c levels and the severity of diabetic retinopathy, with more severe grades of diabetic retinopathy manifesting in patients with higher levels of HbA1c.⁶

Sharma PK et al in his study stated that HbA1c levels were significantly higher in the NPDR and PDR groups compared to the No DR group. The mean HbA1c value was highest in the PDR group at 9.04 ± 1.89 , followed by the NPDR group at 8.40 ± 1.07 , and lowest in the No DR group at 6.75 ± 0.51 .⁸

Cho et al in his study stated that the occurrence of retinopathy was minimal until the HbA1c levels reached the range of 48–51 mmol/mol (6.5–6.8%). Based on receiver operating characteristic curve analysis, in his study, the optimal HbA1c threshold for detecting any diabetic retinopathy was 49 mmol/mol (6.6%), while moderate to severe retinopathy was best identified at 52 mmol/mol (6.9%).⁹

The HbA1c threshold of 48 mmol/mol (6.5%) recommended by the American Diabetes Association demonstrated similar accuracy in detecting both any retinopathy and moderate to severe cases.⁹

In our study we found that the HbA1c value of 8.7 % of greater significance as larger no. of study population showed diabetic retinopathy changes above this value.

CONCLUSION

A strong correlation was found between diabetic retinopathy and HbA1c. Patients with longer duration of diabetes mellitus, who were regular on medication were found to be having controlled HbA1c levels. Patients with uncontrolled diabetes were found to be having higher HbA1c levels. Long standing diabetes in

patients , in general, showed higher incidences of diabetic retinopathy.

Support: Nil

Conflict of interest: Nil

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Osteo-Odonto-Keratoprosthesis (OOKP) Outcomes in India: A Systematic Review

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ABSTRACT

Purpose: To evaluate the outcomes of osteo-odonto-keratoprosthesis (OOKP) procedures performed in India and assess anatomical retention, visual improvement, and postoperative complications.

Methods: A systematic literature search of PubMed, Scopus, IndMed, and Google Scholar was performed up to March 2025. Studies reporting clinical outcomes of OOKP in Indian patients were included. The PRISMA guidelines were followed. Primary outcomes were anatomical retention and improvement in best-corrected visual acuity (BCVA).

Results: Six studies met the inclusion criteria, encompassing 217 patients. The most common indications were Stevens-Johnson Syndrome (42%), chemical burns (27%), and mucous membrane pemphigoid (14%). Anatomical retention rates ranged from 70% to 95%. Visual improvement to $\geq 20/200$ was noted in 68%–85% of cases. Major complications included glaucoma (15–33%), laminar resorption (10–25%), and mucosal necrosis (up to 20%).

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Conclusion: OOKP offers a viable solution for end-stage corneal blindness in Indian patients, yielding favorable visual and anatomical outcomes. High complication rates and limited accessibility necessitate further innovation and policy-level interventions.

KEYWORDS

- Osteo-odonto-keratoprosthesis • Corneal blindness • India • Visual outcomes
- keratoprosthesis • Ocular prosthesis

INTRODUCTION

Corneal blindness remains a major contributor to visual impairment across the globe, with a particularly high prevalence in developing countries such as India. In the Indian context, the burden of corneal blindness is profound due to a combination of factors: a large and aging population, high rates of ocular trauma and infections, and limited access to high-quality eye care services. It is estimated that more than one million people in India suffer from bilateral corneal blindness. A significant proportion of these individuals are not suitable candidates for conventional penetrating keratoplasty (PK) due to underlying conditions that severely compromise the ocular surface. These include chronic cicatrizing disorders such as Stevens-Johnson Syndrome (SJS), ocular cicatricial pemphigoid (OCP), and extensive chemical or thermal burns. These diseases often result in a hostile ocular surface characterized by dryness, vascularization, and keratinization, rendering traditional corneal grafting procedures ineffective or unsustainable¹.

In these refractory and advanced cases, keratoprosthesis (KPro) represents a viable alternative. Among the various types of kerat prostheses developed over time, the osteo-odonto-keratoprosthesis (OOKP), famously known as "tooth for an eye surgery," remains the most durable and effective solution, particularly in cases with severely damaged ocular surfaces. OOKP is a highly specialized and technically demanding procedure that involves the use of the patient's own tooth and surrounding alveolar bone as a biological skirt to support an optical polymethyl methacrylate (PMMA) cylinder. This bio-integrated approach enables excellent anatomical retention and long-term visual rehabilitation, even in eyes deemed untreatable

by other methods. The technique was originally pioneered by Professor Benedetto Strampelli in the early 1960s and was later refined and popularized by Professor Giancarlo Falcinelli, leading to the development of the Modified Osteo-Odonto-Keratoprosthesis (MOOKP) technique.²

In India, adoption of the OOKP technique has gradually increased, especially in select tertiary care centers with access to multidisciplinary teams including ophthalmologists, oral and maxillofacial surgeons, and anesthesiologists. The growing awareness of this technique as a last-resort option for restoring vision in end-stage ocular surface disorders has led to a modest but steadily increasing body of clinical research from Indian centers. These studies have provided insights into patient selection, surgical modifications, long-term follow-up, and complication management in the Indian patient population.³

Despite its potential, OOKP continues to face several challenges in India. These include high complication rates, limited institutional expertise, lack of standardized training, financial constraints, and restricted accessibility. Moreover, the Indian patient demographic presents unique challenges such as delayed presentation, poor systemic health, and lower socioeconomic status all of which impact long-term outcomes.⁴

This systematic review aims to consolidate and critically analyze the existing Indian literature on OOKP. By focusing on anatomical retention rates, visual rehabilitation outcomes, and postoperative complication profiles, we hope to provide a comprehensive overview of the current state of OOKP in India. The findings are expected to inform clinicians, policymakers, and researchers in shaping future strategies for optimizing the use and

delivery of this complex yet vision-restoring intervention in the Indian healthcare system.⁵

MATERIAL METHOD

Search Strategy

A systematic review was conducted by the PRISMA guidelines. Literature was searched

across PubMed, Scopus, IndMed, and Google Scholar using the following terms:

(Osteo-odonto-keratoprosthesis or OOKP) and (India) and (visual outcomes or anatomical retention or complications).

The last search was conducted in March 2025.

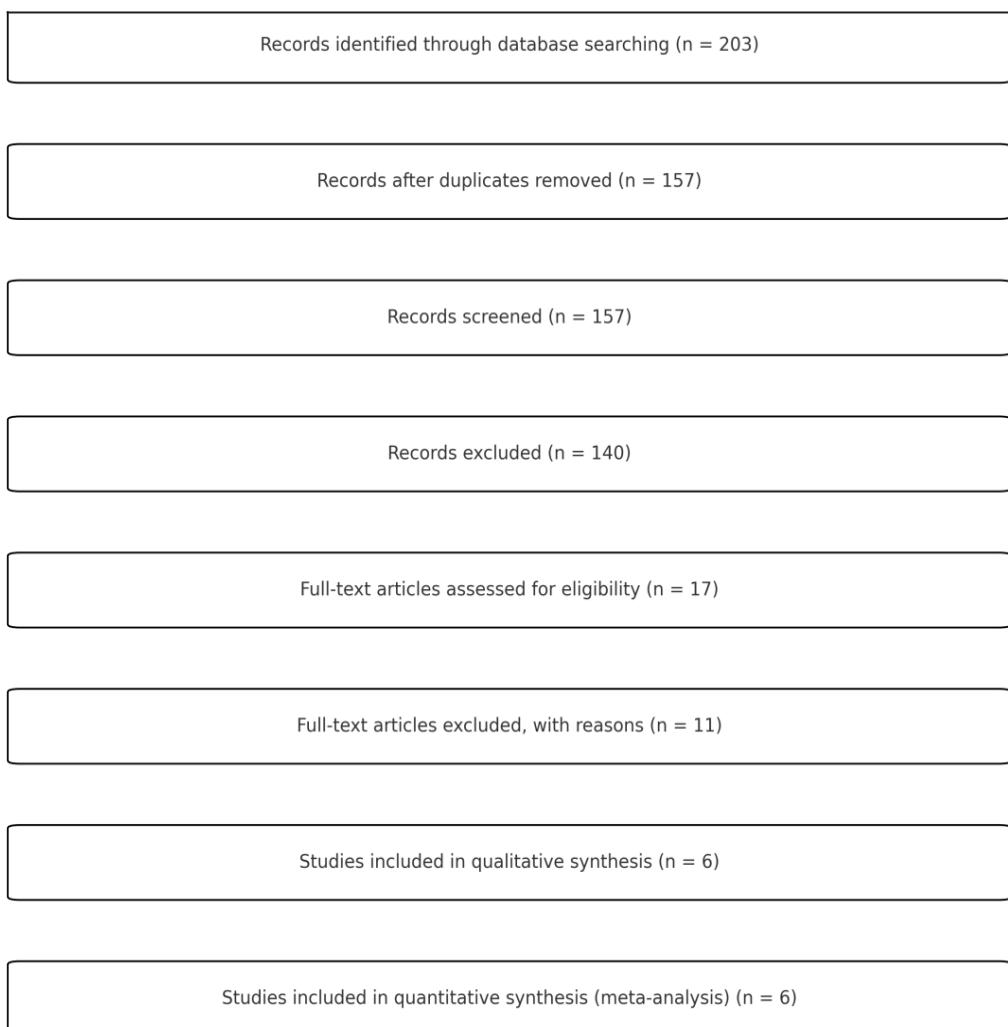


Figure 1: PRISMA Flow Diagram

Flowchart depicting the systematic literature search and study selection process by PRISMA guidelines. Six studies were included in the final review.

Inclusion and Exclusion Criteria

Inclusion:

- Studies from India

- ≥ 5 OOKP patients
- Reporting anatomical retention, visual acuity, and complications

Exclusion:

- Non-human studies
- Reviews or case reports
- Studies lacking outcome data

2. **Full-text Screening:** After the initial screening, the full-text of potentially relevant articles was assessed. This stage focused on ensuring the studies met the inclusion criteria: conducted in India, included at least 5 OOKP patients, and provided data on anatomical retention, visual acuity, and complications.
3. **Discrepancy Resolution:** Any discrepancies in the screening process were resolved by a third reviewer. The use of multiple reviewers ensured that no relevant studies were missed, and the selection process remained objective.
4. **Data Extraction:** A pre-designed data extraction form was used to capture relevant study information, including patient demographics, surgical outcomes, complication rates, and follow-up durations. The data extraction process was piloted on a subset of studies before full-scale extraction to ensure consistency and

- accuracy.
5. **Software Tools:** The screening and data extraction process were managed using Rayyan, a web-based tool that facilitates systematic review processes, including screening and data extraction. It provided a collaborative platform for the reviewers and helped track the inclusion and exclusion of studies.

Quality Assessment

Two reviewers independently extracted data and assessed study quality using the Newcastle-Ottawa Scale (NOS). Discrepancies were resolved by a third reviewer.

RESULTS

Study Characteristics

Six studies involving 217 patients were included. Most were retrospective observational studies conducted in tertiary care centers.

Table 1: Quality assessment of included studies using the newcastle-ottawa scale (NOS)

Study	Selection	Comparability	Outcome	Total Score	
Honavar et al. (2000)	****	**	***	9	High-quality study with excellent patient selection, controlled for key confounders, and had clearly defined outcomes
Iyer et al. (2016)	***	**	***	8	Very good quality, though selection could have been slightly more rigorous. Strong in outcome and comparability.
Jain et al. (2020)	****	*	***	8	Excellent selection and outcome measures, but controlled for fewer confounders.
Bhalekar et al. (2017)	****	*	**	7	Moderate quality; decent methodology but weaker in comparability and outcome domain.
Sukhija et al. (2021)	****	**	**	8	Good overall quality with balanced scores, but minor limitations in selection and follow-up.
Narayanan et al. (2015)	*****	*	**	8	Strong in patient selection, but limited confounding control and slightly weaker outcome assessment.

Quality Assessment of Included Studies

The methodological quality of the six included studies was evaluated using the Newcastle-Ottawa Scale (NOS), which assesses non-randomized studies based on three domains: **selection of participants, comparability of study groups, and assessment of outcomes**. Each study was independently rated, with a maximum attainable score of 9 points.

All studies demonstrated moderate to high quality, with total NOS scores ranging from 7 to 9. The highest score was achieved by **Honavar et al. (2000)**, which received full marks in the selection and outcome domains, as well as two stars in comparability, yielding a total score of 9. This indicates rigorous participant selection, adequate adjustment for confounders, and robust outcome assessment.

Most other studies scored between 8 and

7, reflecting minor limitations in either the selection or comparability domains. For instance, Iyer et al. (2016) and Jain et al. (2020) scored 8, with strong selection and outcome criteria but slightly limited control over confounding factors. Bhalekar et al. (2017) scored 7, indicating relatively lower methodological rigor, particularly in the domains of outcome and comparability.

Overall, the assessment suggests that the included studies provide **reliable and valid data** for synthesizing outcomes related to OOKP in India. However, the variation in comparability scores highlights the need for **standardized protocols and multicentric prospective studies** to ensure more consistent adjustment for potential confounders in future research.

Risk of Bias in Individual Studies

After evaluating each study, we assigned risk of bias ratings based on the NOS scores:

- **Honavar et al. (2000):** This study received a high score of 9 (★★★★★★★★) with excellent patient selection, robust outcome assessment, and strong comparability measures. Therefore, it is considered to have a low risk of bias.
- **Iyer et al. (2016):** Scored 8 (★★★★★★★★) due to strong selection and outcome measures, although there were slight limitations in controlling confounding factors. This suggests a moderate risk of bias.
- **Jain et al. (2020):** Scored 8 (★★★★★★★★) with strong selection and outcome measures but limited control over confounders. Hence, there is a moderate risk of bias.
- **Bhalekar et al. (2017):** Scored 7 (★★★★★), indicating moderate quality. The study had weaknesses in

comparability and outcome assessment, suggesting a moderate to high risk of bias.

- **Sukhija et al. (2021):** Scored 8 (★★★★★★★), suggesting that the study had good overall quality, with minor limitations in selection and follow-up, resulting in a moderate risk of bias.
- **Narayanan et al. (2015):** Scored 8 (★★★★★★★), indicating strong patient selection but limited control over confounders, resulting in a moderate risk of bias.

Risk of Bias in the Overall Synthesis

The overall synthesis of evidence is based on studies of varying methodological quality. While most studies had moderate to high quality, the differences in their design (retrospective, observational) and methodology (particularly in controlling for confounders and outcome measures) introduce some degree of bias. This must be considered when interpreting the findings, especially when comparing studies with different quality ratings.

To address the potential impact of these biases on the review's conclusions, the synthesis included a narrative summary of findings rather than a meta-analysis. The heterogeneity of outcomes, study designs, and the differing quality of included studies prevent the use of quantitative methods such as pooling data for a meta-analysis. Therefore, findings from individual studies are presented with due consideration for their risk of bias and study limitations.

This risk of bias assessment highlights the need for future studies on OOKP to use prospective, multicenter designs with more stringent control of confounders to strengthen the evidence base and reduce the impact of bias on clinical decision-making.

Table 2: The various studies included in the analysis with their outcomes

Authors	Study year	Patients (n)	Major indications	Follow-up	Anatomic retention	VA >20/200
Honavar et al.	2000	32	SJS, chemical burns	3 years	82%	76%
Iyer et al.	2016	50	MMP	5 years	85%	88 %

Jain et al.	2020	45	Alkali burns	3 years	78%	72%
Bhalaker et al.	2017	23	MMP	2 years	91%	68%
Sukhija et al.	2021	34	SJS	4 years	70%	74%
Narayanan et al.	2015	33	Mixed	3 years	85%	80%

Complications

- Glaucoma: 15%–33%
- Laminar resorption: 10%–25%
- Buccal mucosa necrosis: 15%–20%
- Retroprosthetic membrane: 10%–15%

Figure 2. Anatomical Retention and Visual Improvement Rates

Clustered bar chart showing anatomical retention and improvement in best-corrected visual acuity (BCVA $\geq 20/200$) across six studies. The highest retention was reported by Bhalekar et al. (91%), while the highest visual recovery was observed in Iyer et al. (88%).

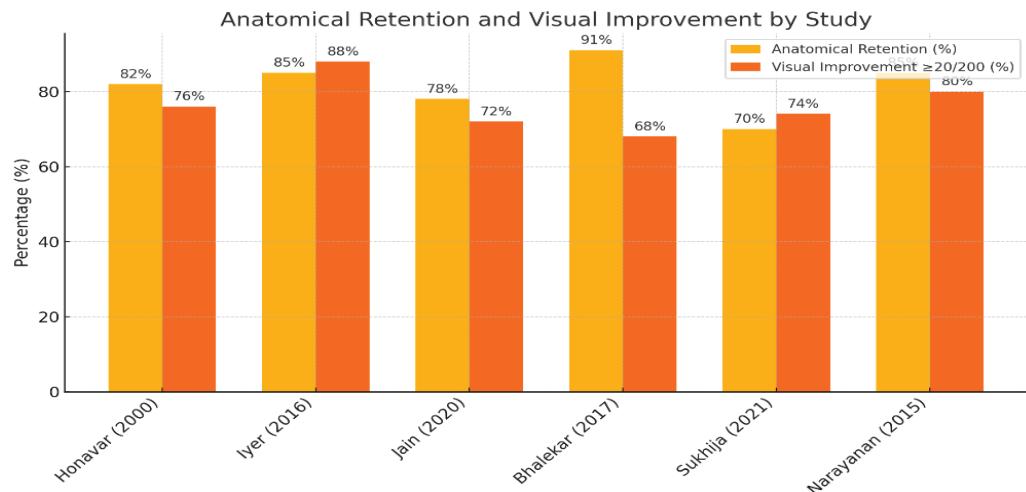


Figure 3. Post-operative Complications in OOKP Patients

Pie chart representing the average proportion of major complications reported across included studies. Glaucoma (24%) and

buccal mucosa necrosis (17.5%) were the most frequently observed complications.

Distribution of Postoperative Complications in OOKP Patients

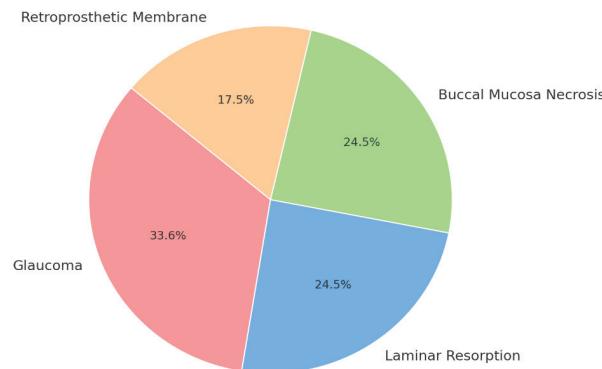
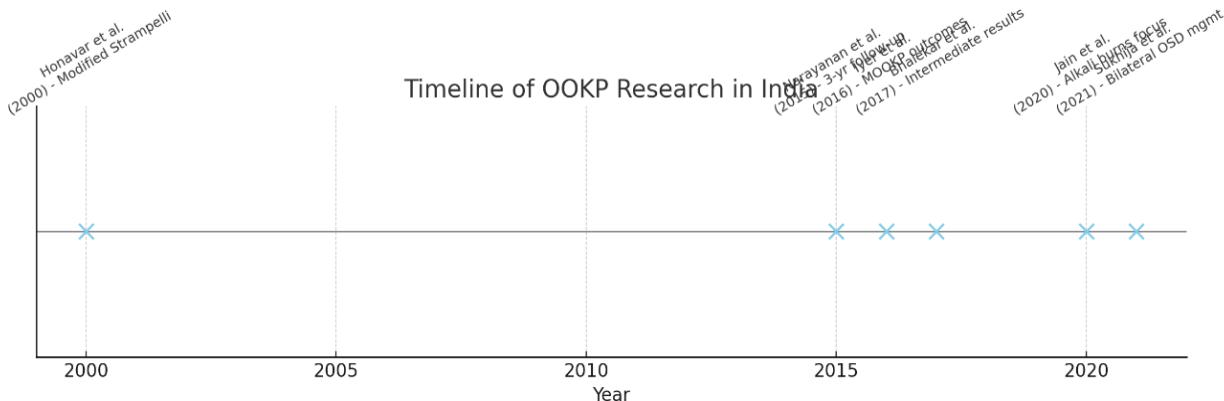


Figure 4: Timeline of OOKP Research in India

Timeline showing major publications on OOKP in India from 2000 to 2021, including milestones such as the introduction of Modified

OOKP (MOOKP) and expanded follow-up data.



DISCUSSION

The findings of this systematic review highlight the clinical efficacy and relevance of osteo-odonto-keratoprosthesis (OOKP) as a surgical intervention for patients with end-stage ocular surface disorders in India. Despite the intricate nature of the procedure and the necessity for specialized surgical skill, the anatomical retention and visual rehabilitation outcomes reported across Indian centers appear to be on par with international benchmarks. A significant proportion of patients achieved best-corrected visual acuity (BCVA) $\geq 20/200$, a level considered sufficient for ambulatory vision, thereby restoring a degree of independence and quality of life in individuals who were previously blind.³

A unique epidemiological observation in the Indian context is the predominance of Stevens-Johnson Syndrome (SJS), mucous membrane pemphigoid (MMP), and chemical injuries as leading indications for OOKP. This differs from Western literature, where autoimmune disorders and aniridia are more commonly cited⁶. These etiologies in India are often rooted in socioeconomic disparities, such as delayed access to primary care, underreporting of medication-related reactions, and a high incidence of industrial and agricultural chemical injuries due to poor occupational safety practices.⁴

Although the visual outcomes are encouraging, the review underscores significant

post-operative complication rates. Glaucoma remains the most frequent complication, with reported incidence ranging from 15% to 33%. If uncontrolled, it can severely compromise visual outcomes and may require long-term pharmacologic or surgical management.^{3,4} Laminar resorption, occurring in up to 25% of cases, and buccal mucosa necrosis (15–20%) are other noteworthy complications that demand close postoperative surveillance.⁴ Retroprosthetic membrane formation, seen in approximately 10–15% of patients, can also impair vision and may necessitate surgical intervention.

Survival rates of the OOKP lamina in the Indian context have been favorable, particularly in centers with established multidisciplinary teams and structured follow-up protocols. Studies from tertiary care centers report anatomical retention rates of 85–90% at 2–5 years and visual survival (i.e., maintaining functional vision) in 70–80% of cases over similar durations.^{2,5} However, survival rates beyond 5 years decline slightly due to complications such as laminar degradation, mucosal breakdown, or device extrusion.⁵ These findings underscore the need for lifelong monitoring and possible revision procedures to sustain long-term outcomes.

The surgical success of OOKP is highly dependent on technical precision, interdisciplinary coordination, and adherence to follow-up. Patient compliance is often

challenged by geographical and financial barriers, especially in rural areas, where access to tertiary ophthalmic services is limited.⁵ In response, innovations like the Modified OOKP (MOOKP) and alternative mucosal grafts are being explored to mitigate complications and enhance implant longevity.²

Nevertheless, the accessibility of OOKP in India is currently limited to a handful of high-volume academic institutions. The cost, infrastructure demands, and multidisciplinary expertise required for the procedure restrict its availability. It is, therefore imperative to develop national-level guidelines, training modules, and subsidized care pathways to expand access to eligible patients across the country. Public health policies should focus on establishing referral networks and increasing awareness of surgical options for severe ocular surface diseases.

In conclusion, OOKP represents a transformative, though resource-intensive, solution for select patients with bilateral corneal blindness. The Indian experience with OOKP demonstrates that with appropriate expertise and follow-up, the procedure can yield survival rates and visual rehabilitation outcomes comparable to global standards. To broaden its impact, systemic support through training, innovation, and policy integration is vital for ensuring equitable and sustained delivery of this sight-restoring intervention.^{1,3,6}

PUBLIC HEALTH SIGNIFICANCE

From the standpoint of a public health dentist in India, osteo-odontokeratoprosthesis (OOKP) represents a critical intervention for patients suffering from end-stage corneal blindness, particularly those with severe ocular surface disorders like Stevens-Johnson Syndrome (SJS), chemical burns, or mucous membrane pemphigoid (MMP). These conditions make traditional corneal transplant procedures unsuitable, and OOKP provides a viable solution for restoring vision and improving quality of life for many of these patients. However, from a public health perspective, several barriers limit the broader application of OOKP across India.

Corneal blindness remains a significant public health concern in India, with over

a million individuals affected by bilateral blindness. Socioeconomic disparities, limited healthcare infrastructure, and a shortage of trained specialists in rural and underserved regions compound the problem. OOKP, while highly effective in specialized centers, remains largely concentrated in tertiary care hospitals in urban areas. In many rural regions, patients continue to face significant barriers in accessing advanced eye care, including OOKP. Public health dentistry recognizes that corneal blindness in India often results from preventable causes such as burns, infections, and trauma, which disproportionately affect individuals from lower socioeconomic backgrounds due to lack of timely medical intervention, awareness, and access to adequate healthcare services.¹

Moreover, OOKP's success relies not only on a skilled surgical team but also on the ability to ensure long-term postoperative care, which can be challenging in resource-limited settings. Public health efforts must prioritize strengthening healthcare systems to improve access to skilled professionals, adequate surgical facilities, and structured follow-up care. This is especially important considering the high prevalence of complications such as glaucoma, laminar resorption, and buccal mucosa necrosis, which require ongoing monitoring.²

To improve the reach and effectiveness of OOKP in India, a multi-pronged approach is necessary. First, national-level public health policies should aim to promote the establishment of regional centers of excellence for OOKP, ensuring that more patients, especially from rural and underserved areas, can benefit from the procedure. Additionally, public health initiatives should focus on expanding training programs for ophthalmologists, maxillofacial surgeons, and dental professionals to increase the pool of skilled personnel who can perform this complex surgery³.

Furthermore, a robust public health strategy should also involve raising awareness about the availability of OOKP as a treatment option, addressing common misconceptions, and advocating for government support to make the treatment more accessible through

subsidized care or insurance coverage for economically disadvantaged patients. Collaboration between healthcare systems, dental professionals, and community health workers is crucial to reach the populations most in need and to ensure that those who undergo OOKP receive the necessary follow-up care to manage complications and optimize long-term outcomes.⁴

In conclusion, while OOKP is a transformative intervention for patients with end-stage corneal blindness in India, its widespread adoption and success will depend on improved accessibility, enhanced training for healthcare professionals, and public health policies that ensure equitable access to this life-changing procedure for all individuals, regardless of their socioeconomic background or geographic location.

CONCLUSION

In India, osteo-odonto-keratoprosthesis (OOKP) has emerged as a life-changing surgical option for individuals suffering from end-stage corneal blindness, especially those who are unsuitable for conventional corneal transplantation due to severe ocular surface pathology. The outcomes reported from Indian centers are encouraging, with many patients achieving significant anatomical retention and visual rehabilitation. However, the potential of OOKP to transform lives is currently limited by several systemic challenges. The procedure is available in only a handful of tertiary care centers due to its complexity, the need for a multidisciplinary surgical team, and the specialized infrastructure required. There is also a pressing need for more trained personnel including ocular surface specialists, maxillofacial surgeons, and anesthesiologists who are familiar with the nuances of this multi-stage surgery. Furthermore, postoperative success relies heavily on rigorous, long-term follow-up to manage complications such as glaucoma, laminar resorption, or mucosal graft failure. Unfortunately, structured follow-up systems are often lacking or inconsistent, particularly for patients from rural or underserved areas. To unlock the full potential of OOKP in India, it is essential

to establish broader accessibility through the development of regional centers of excellence, standardized surgical training programs, and national guidelines for patient selection and follow-up care. In parallel, government-supported financial assistance schemes and awareness campaigns can help ensure that eligible patients, regardless of socioeconomic background, can access this life-restoring intervention.

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Pseudoexfoliation Syndrome: A Comprehensive Overview

Dinesh K.

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ABSTRACT

Pseudoexfoliation syndrome (PXS) is a systemic, age-related fibrillopathy characterized by the progressive accumulation of abnormal extracellular material throughout the body, most notably in the ocular tissues. This deposition can lead to a variety of ocular complications, including glaucoma, cataract, and zonular weakness, significantly impacting vision. This paper aims to provide a comprehensive overview of PXS, encompassing its epidemiology, pathogenesis, clinical manifestations, diagnosis, management, and current research directions.

INTRODUCTION

Pseudoexfoliation syndrome, first described by John G. Lindberg in 1917, is a relatively common condition, particularly in individuals of Scandinavian and Mediterranean descent. Its defining feature is the presence of distinctive, grayish-white, dandruff-like deposits on the anterior lens capsule, iris, and other intraocular structures. While these deposits are often observed during routine eye examinations, their systemic nature and propensity to induce significant ocular morbidity make PXS a clinically important entity. Understanding its pathophysiology and management strategies is crucial for ophthalmologists and other healthcare professionals to effectively address the visual challenges faced by affected individuals.

EPIDEMIOLOGY

The prevalence of PXS varies widely across different populations, highlighting the role of genetic and environmental factors. Scandinavian countries, particularly Iceland, exhibit the highest prevalence rates, exceeding 20% in individuals over 60 years of age. Other regions with elevated rates include Mediterranean countries and certain populations in Africa and Australia. Prevalence increases with age, and a slight female predominance is generally observed. While the exact cause of these geographical variations remains unclear, they underscore the importance of considering ethnicity and geographic origin in risk assessment.

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ETIOLOGY AND PATHOGENESIS

The precise etiology of PXS remains incompletely understood, but it is considered a complex multifactorial disease. Genetic predisposition plays a significant role, with the LOXL1 gene on chromosome 15q24.1-2 being the most consistently implicated. Polymorphisms in this gene, particularly rs1048661, rs3825942, and rs2569190, have been strongly associated with PXS susceptibility across various populations. LOXL1 encodes lysyl oxidase-like 1, an enzyme involved in cross-linking of elastin and collagen fibers, suggesting a potential role in abnormal extracellular matrix deposition.

However, genetic factors alone do not fully explain the pathogenesis of PXS. Environmental factors, such as exposure to ultraviolet radiation, oxidative stress, and homocysteine, are also thought to contribute. The proposed mechanisms include the following:

- **Abnormal Extracellular Matrix Production:** Dysregulation of LOXL1 function may lead to the aberrant synthesis and assembly of extracellular matrix components, resulting in the formation of pseudoexfoliative material.
- **Immune-Mediated Mechanisms:** Inflammatory processes and immune responses may contribute to the production and deposition of pseudoexfoliative material.
- **Oxidative Stress:** Increased oxidative stress, linked to aging and exposure to environmental toxins, can damage cellular structures and promote the formation of abnormal protein aggregates.
- **Vascular Dysregulation:** Evidence suggests that PXS may be associated with vascular dysfunction, contributing to ischemia and cellular stress, further exacerbating the pathological process.

The current understanding posits that a combination of genetic vulnerability and environmental triggers leads to the accumulation of pseudoexfoliative material, ultimately resulting in cellular dysfunction and tissue damage.

CLINICAL MANIFESTATIONS

PXS is primarily an ocular disease, affecting various structures within the eye. Key clinical

findings include:

- **Pseudoexfoliative Material:** The hallmark of PXS is the presence of grayish-white deposits on the anterior lens capsule, typically arranged in a central disc, a clear zone, and a peripheral granular zone (target pattern). These deposits can also be found on the pupillary margin, iris, ciliary body, and corneal endothelium.
- **Pseudoexfoliation Glaucoma (PXG):** A significant proportion of individuals with PXS develop glaucoma, characterized by elevated intraocular pressure (IOP) and optic nerve damage. PXG is often more aggressive and difficult to control than primary open-angle glaucoma (POAG). The exfoliative material clogs the trabecular meshwork, impairing aqueous outflow and leading to IOP elevation.
- **Cataract:** PXS is associated with an increased risk of cataract development, often of the posterior subcapsular type. Additionally, PXS can lead to weakened zonules, the fibers that support the lens, making cataract surgery more challenging and increasing the risk of complications such as zonular dehiscence and lens subluxation.
- **Zonular Weakness:** Degradation of zonular fibers is a common finding in PXS, increasing the risk of lens subluxation and vitreous loss during cataract surgery. This weakness may be due to direct damage to the zonules by the pseudoexfoliative material or to impaired synthesis and maintenance of zonular proteins.
- **Corneal Endothelial Dysfunction:** Studies have indicated that PXS can affect the corneal endothelium, leading to decreased cell density and increased polymegathism and pleomorphism, potentially increasing the risk of corneal edema after intraocular surgery.
- **Iris Transillumination Defects:** Loss of pigment from the iris pigment epithelium can result in transillumination defects, visible as areas where the iris appears thinner when illuminated from the back.

Beyond the eye, PXS has been linked to systemic manifestations, including cardiovascular disease, hearing loss, and Alzheimer's disease, suggesting a broader

systemic impact of the fibrillopathy. However, further research is needed to fully elucidate these associations.

DIAGNOSIS

The diagnosis of PXS is primarily based on clinical examination. Key diagnostic tools include:

- **Slit-Lamp Biomicroscopy:** This is the gold standard for identifying pseudoexfoliative material on the anterior lens capsule, iris, and other intraocular structures. Careful examination under high magnification is essential for detecting subtle deposits.
- **Gonioscopy:** Examination of the angle between the iris and cornea to assess the trabecular meshwork and detect pseudoexfoliative material deposition in the angle structures.
- **Intraocular Pressure (IOP) Measurement:** Regular IOP monitoring is crucial for detecting elevated IOP and managing glaucoma.
- **Optic Disc Examination and Visual Field Testing:** These tests are used to assess optic nerve damage and visual field loss associated with glaucoma.
- **Dilated Fundus Examination:** To evaluate the retina and optic nerve head.
- **Optical Coherence Tomography (OCT):** Used to assess nerve fiber layer thickness and ganglion cell complex loss, which can be helpful in diagnosing and monitoring glaucoma.
- **Confocal Microscopy:** Enables detailed in-vivo imaging of corneal endothelial cells for assessment of cell density and morphology.

While genetic testing for LOXL1 polymorphisms is available, it is not routinely used for diagnosis, as these polymorphisms are associated with increased risk but are not diagnostic of PXS.

MANAGEMENT

The management of PXS focuses on preventing or mitigating the associated ocular complications, particularly glaucoma and cataract.

Glaucoma Management

- **Medical Therapy:** Topical medications, such as prostaglandin analogs, beta-blockers, alpha-adrenergic agonists, and carbonic anhydrase inhibitors, are used to lower IOP.
- **Laser Trabeculoplasty:** Selective laser trabeculoplasty (SLT) and argon laser trabeculoplasty (ALT) can improve aqueous outflow and lower IOP. However, the response to laser trabeculoplasty may be variable in PXG.
- **Glaucoma Filtration Surgery:** Trabeculectomy or glaucoma drainage devices are considered when medical and laser therapies fail to adequately control IOP. These surgeries may have a higher complication rate in PXG patients.
- **Minimally Invasive Glaucoma Surgery (MIGS):** Newer MIGS procedures often offer a safer alternative to traditional glaucoma surgeries, but their long-term effectiveness in PXG remains under investigation.

Cataract Management

- **Cataract Surgery:** Cataract surgery is indicated for patients with visually significant cataracts. Given the increased risk of zonular weakness, meticulous surgical technique is essential.
- **Preoperative Assessment:** Careful preoperative assessment of zonular integrity is crucial, including evaluating for phacodonesis (lens wobble) and performing thorough pupillary dilation.
- **Surgical Techniques:** Techniques such as capsular tension rings or segments, iris hooks, and gentle phacoemulsification techniques can help stabilize the lens and minimize complications.
- **Intraocular Lens (IOL) Implantation:** The choice of IOL depends on the individual patient's needs and the surgeon's expertise. Multifocal IOLs should be used with caution due to the potential for increased glare and halos in PXG patients.
- **Regular Monitoring:** Patients with PXS require regular comprehensive eye examinations to monitor for the development of glaucoma, cataract, and

other complications. This includes IOP measurement, visual field testing, optic disc evaluation, and slit-lamp examination.

CURRENT RESEARCH DIRECTIONS

Ongoing research efforts are focused on several key areas:

- **Elucidating the Pathogenesis of PXS:** Identifying the specific mechanisms underlying the production, deposition, and degradation of pseudoexfoliative material. This includes investigating the role of LOXL1 and other potential genetic and environmental factors.
- **Developing Diagnostic Biomarkers:** Identifying biomarkers that can detect PXS at an early stage, before significant ocular damage occurs.
- **Targeted Therapies:** Developing therapeutic strategies that can prevent or reverse the deposition of pseudoexfoliative material. This could involve targeting LOXL1, reducing oxidative stress, or modulating the immune response.
- **Improving Surgical Outcomes:** Developing new surgical techniques and technologies to minimize complications associated with cataract surgery in PXS patients, particularly those with zonular weakness.
- **Investigating Systemic Associations:** Further exploring the potential systemic manifestations of PXS and their implications for overall health.

CONCLUSION

Pseudoexfoliation syndrome is a significant cause of ocular morbidity worldwide, particularly due to its association with glaucoma and complicated cataract surgery. Early diagnosis and careful management are crucial for preventing or mitigating the associated visual complications. Ongoing research efforts are aimed at better understanding the pathogenesis of PXS, developing targeted therapies, and improving surgical outcomes. Further progress in these areas will ultimately lead to better care and preservation of vision for individuals affected by this prevalent condition.

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Prosthetic Rehabilitation of Ocular Defect: A Case Report

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ABSTRACT

The eye is a vital organ as well as an important component of facial expression. The loss of eye has a debilitating effect on the patient's quality of life. Maxillofacial prostheses are artificial replacements that repair and replace stomatognathic and related facial structures. Disfigurement induced by loss of eye causes severe physical and psychological anguish. Ocular prosthesis is the sole option for replacement of missing eye. For the manufacturing of the same, several materials and processes are employed. Among the various materials, resin has been proved to be the best. Using a stock eye or a customised ocular prosthesis can have advantages and disadvantages. We created a semi-customized ocular prosthesis with stock iris and customised sclera using our clinical report. This prosthesis combined the benefits of both stock and customized ocular prostheses, resulting in a functionally and cosmetically satisfying outcome.

KEYWORDS

• Prosthesis • Ocular • Eye • Maxillofacial • Case report • Silicone

INTRODUCTION

Eyes have language of their own, they tell more than words could ever say. The eye is the jewel of the body. "Eyes" are considered to be "mirror of the soul". They are a visual organ, the core of facial emotions, and the pinnacle of human aesthetic attractiveness. Anophthalmia

can be caused by cancer, trauma, sympathetic ophthalmic disease, painful blind eye, or congenital problems.¹ There are several surgical modes of therapy based on severity, such as exenteration, evisceration, or enucleation. Evisceration is a surgical procedure that involves removal of some of the intraocular

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contents of the globe while keeping the sclera, conjunctiva, extraocular muscles, and optic nerve of the eye intact. Enucleation is the surgical removal of the globe as well as a segment of the optic nerve from the orbit. The Exenteration procedure involves an en bloc removal of the whole orbit, which includes partial or total removal of the eyelids and is used mostly to remove malignant orbital. Ocular prosthesis is indicated in order to repair deformities created by evisceration or enucleation.²

A stock prosthesis and a custom made prosthesis are the two forms of ocular prosthesis. Typical stock ocular prosthesis comes in a variety of standard sizes, contours, shapes, and colours. They can be used as a temporary or urgent postoperative measures. Artificial eyes, moulded eyes, cosmetic contact shells, cosmetic contact lenses, and spectacle prostheses are all terminology for ocular prosthesis.¹

Various ways for fitting and fabricating the artificial eye have been published in the literature. Fitting a stock eye, altering a stock eye on a positive duplicate of the ocular defect, and fabricating the customized eye prosthesis are all part of the procedure. Sclera and iris are both custom-made in bespoke ocular prosthesis. The first two approaches are less time-consuming, but they frequently have drawbacks like as degraded aesthetics and inconsistent fit. Custom ocular prosthesis improves aesthetics and fit, but it is typically more time-consuming and complex.³

To achieve functionally and aesthetically acceptable results this clinical report describes a technique for making ocular prostheses using stock iris and custom-made sclera.

Based on the evaluation of the various previously described parameters, phthisis bulbi defects were divided into 4 major classes and 2 subclasses of class I and class II as follows:

Table 1: Classification⁴

Class	Condition	Treatment
I a	Corneal opacity with no enophthalmos and normal sclera without corneal sensitivity	Simple prosthetic and/or cosmetic lens
I b	Corneal opacity with no enophthalmos and normal sclera with corneal sensitivity	Simple prosthetic and/or cosmetic lens after reducing the corneal sensitivity
II a	Corneal opacity with mild enophthalmos and normal sclera without corneal sensitivity	Clear or transparent acrylic resin or silicone sclera shell
II b	Corneal opacity with mild enophthalmos and normal sclera with corneal sensitivity	Clear or transparent acrylic resin or silicone sclera shell after reducing the corneal sensitivity
III	Moderate enophthalmos with disfigured sclera	Ocular prosthesis or scleral shell
IV	Severe enophthalmos with disfigured sclera and loss of orbital fat	Ocular prosthesis or scleral shell after performing additional procedures such as dermal lid fillers or eyelid surgeries

CASE REPORT

A 62 year-old male patient reported to the Department of Prosthodontics and Crown & Bridge, with chief complaint of facial disfigurement due to shrunken eyelids of the right eye. Patient was using a conformer eye and wanted a customized one. History revealed an injury with instrument

while performing cataract surgery which lead to the decision of removal of the eye to prevent further complications; during childhood. On inspection, it was determined that the patient had an evisceration type eye defect and that the intraocular tissue bed was healthy, with appropriate depth under the upper and lower fornices for prosthesis retention (fig 1 a,b).

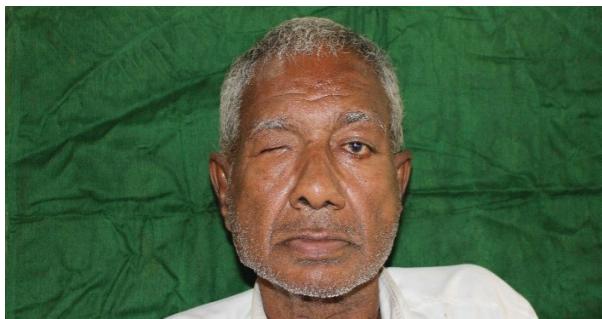


Fig. 1a: Pre-operative view



Fig. 1b: Pre-operative view

According to the classification system given by Himanshi *et al.*, the patient was categorized under Class IV.⁴ The patient would receive a customised acrylic resin ocular prosthesis. Prior to the procedure, the patient gave his written consent. A 2% lignocaine hydrochloride topical gel was administered to the ocular tissues of the right eye to minimise mucosal tissue irritation while making an impression. Irrigation was done using saline and then the socket was cleaned and dried with cotton pellets. Lubrication was done to the brows and eyelashes on the faulty side using petroleum jelly. The patient was made to sit in a semi-reclined position. Primary impression was made using 2ml disposable syringe loaded with monophase impression material (fig. 2). Cast was poured using dental stone onto which custom tray was fabricated for final impression (fig 3). Perforations were made on the tray to add retention to the final impression material. A 2ml disposable syringe was then attached to the custom tray fabricated (fig. 4). Syringe was loaded with light body impression material to make final impression (fig. 5). Final impression was poured using 2 pour technique; using dental stone and transparent glass for visibility of level of pour (fig 6). Patient was asked to perform eye movements like looking upwards,

downwards, right and left side while making impression.



Fig. 2: Primary Impression



Fig. 3: Primary Cast



Fig. 4: Custom Tray



Fig. 5: Secondary Impression



Fig. 6: Final Cast



Fig. 7: Iris Positioning

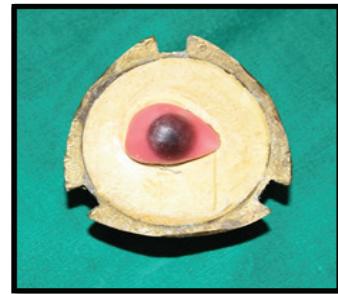


Fig. 12: Packing For Dewaxing



Fig. 8: Packing for Dewaxing



Fig. 13: Final Prosthesis



Fig. 9: After Dewaxing

After Placement of Fibers



Fig. 14: Final Prosthesis With Spectacle



Fig. 10: After Processing



Fig. 11: Placement of Fibers



Fig. 15: Final Prosthesis Without

Wax pattern was fabricated on the secondary cast and was checked in the patients socket for fullness and proper fit. Iris location was done in the same step. Photocopy of graph paper was made on projector paper. this paper was then spilted into two parts and placed on the spectacle using sticky wax. The upper, lower, medial and lateral points of the left iris was marked using marker and then this paper was shifted onto the inner side of the right glass of the spectacle and points were transferred from paper to glass followed by actual right side projector paper. Stock iris was then placed accordingly on the wax pattern (fig. 7).

This wax pattern was then invested into the flask using type 3 dental stone. Dewaxing was done. Packing was done using white heat cure (DPI) material of C and D shade and processed (fig 8-10).

After processing; approximately 0.5 to 1 mm of acrylic around the iris was trimmed using carbide bur. Using acrylic paint the colour of sclera was matched and wool fibers to simulate blood vessels were placed using polymoly (fig 11). Over this wax-up was done and again it was packed, dewaxed and cured again using clear acrylic (fig. 12). The prosthesis was the trimmed finished polished and was checked in patients socket and the delivered. The patient felt at ease and pleased with the prosthesis (fig. 13-15). The patient was shown the simple methods for placing and removing the prosthesis. The patient was given instructions for regular removal and cleaning of the prosthesis as well as the tissue bed. After one week and one month, there was a follow-up.

DISCUSSION

Prior to the introduction of methyl methacrylate ocular prostheses, most ocular prostheses were made of glass. Glass prostheses, while initially effective for aesthetic restoration, were limited by their inability to be customized in size, shape, or dimension, leading to functional and aesthetic challenges.^{5,22} Resin-based prostheses revolutionized ocular rehabilitation by offering improved durability, adaptability, and customization options. Despite these advantages, many clinicians consider prefabricated methyl methacrylate prostheses rigid and less modifiable compared to fully customized solutions.^{11,23}

Studies comparing prefabricated and custom ocular prostheses indicate that custom prostheses result in significantly better aesthetic outcomes due to their superior fit and the ability to replicate patient-specific anatomical features.²² Similarly, Patel *et al.* observed that resin-based custom prostheses offer greater strength and durability while improving patient comfort and reducing complications such as irritation and poor mobility.²³ These findings align with our approach, where a semi-customized prosthesis was used to balance the benefits of stock components with the tailored fit of a custom sclera.

When personalized to the patient using an appropriate impression process, resin prostheses offer improved pressure distribution and fit, leading to superior functional and aesthetic outcomes.^{4,12} Furthermore, the close fitting of the prosthesis to the tissue surface enhances its natural appearance and boosts mobility. Fernandes *et al.* emphasized that accurate impressions and meticulous adaptation of the prosthesis to the socket are key factors in ensuring patient satisfaction and functional success.²⁷

Matching iris colors has been a notable challenge with prefabricated eyes. Aydin *et al.* demonstrated the efficacy of digital imaging techniques for iris customization, achieving high levels of patient satisfaction.²⁴ In our case, the use of a pre-made iris button allowed us to achieve an aesthetic result while reducing fabrication time and costs compared to traditional hand-painting techniques. This hybrid approach has also been highlighted by Kumar *et al.*, who found that combining stock and custom components reduces manufacturing complexity without compromising aesthetic quality.²⁸

Our study's findings on the importance of volume restoration and prosthetic mobility align with earlier reports. Aggarwal *et al.* stated that ocular implants typically restore 65%–70% of the lost orbital volume, while the ocular prosthesis contributes the remaining 30%–35%, ensuring a balanced and functional outcome.^{7,17} In addition, Fernandes *et al.* showed that CAD/CAM technologies can improve the precision of iris positioning and scleral adaptation, thereby enhancing the mobility of custom prostheses.²⁷

Recent advancements in fabrication techniques, such as CAD/CAM technology and digital iris replication, have significantly reduced the time and cost associated with custom prostheses while improving their quality and aesthetics.^{26,27} Shankar *et al.* reported that integrating digital workflows for prosthesis fabrication minimizes manual errors and improves overall accuracy, which is consistent with the precise fit and satisfactory outcomes observed in our case.¹⁹

Finally, multidisciplinary approaches have gained attention in ocular rehabilitation. Henry *et al.* and Fernandes *et al.* highlighted that collaborative care involving ophthalmologists, maxillofacial prosthodontists, and psychological counselors addresses not only physical restoration but also the psychological well-being of patients with anophthalmia.^{21,30} This approach mirrors our efforts to ensure the patient's comfort and satisfaction through comprehensive treatment planning and follow-ups.

These findings underscore the evolving practices in ocular prosthesis fabrication and emphasize the need for tailored, patient centric approaches that combine advanced technologies, traditional techniques, and collaborative care.

CONCLUSION

Any prosthetic treatment should aim to restore the patient to society with a normal look and appropriate motility of the prosthetic eye. The deformity caused by eye loss can have serious psychological and social effects. However, with advances in ophthalmic surgery and ocular prosthesis, patients can be effectively recovered. The maxillofacial Prosthodontist should give prosthetic therapy to the best of his abilities while also considering psychological concerns and, if required, seeking the assistance of other specialists. Good result was achieved.

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The second page should carry the full title of the manuscript and an abstract (of no more than 150 words for case reports, brief reports and 250 words for original articles). The abstract should be structured and state the Context (Background), Aims, Settings and Design, Methods and Materials, Statistical analysis used, Results and Conclusions. Below the abstract should provide 3 to 10 keywords.

Introduction

State the background of the study and purpose of the study and summarize the rationale for the study or observation.

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Include summary of key findings (primary outcome measures, secondary outcome measures, results as they relate to a prior hypothesis); Strengths and limitations of the study (study question, study design, data collection, analysis and interpretation); Interpretation and implications in the context of the totality of evidence (is there a systematic review to refer to, if not, could one be reasonably done here and now?, What this study adds to the available evidence, effects on patient care and health policy, possible mechanisms)? Controversies raised by this study; and Future research directions (for this particular research collaboration, underlying mechanisms, clinical research). Do not repeat in detail data or other material given in the Introduction or the Results section.

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Standard journal article

[1] Flink H, Tegelberg Å, Thörn M, Lagerlöf F. Effect of oral iron supplementation on unstimulated salivary flow rate: A randomized, double-blind, placebo-controlled trial. *J Oral Pathol Med* 2006; 35: 540-7.

[2] Twetman S, Axelsson S, Dahlgren H, Holm AK, Källestål C, Lagerlöf F, *et al.*. Caries-preventive effect of fluoride toothpaste: A systematic review. *Acta Odontol Scand* 2003; 61: 347-55.

Article in supplement or special issue

[3] Fleischer W, Reimer K. Povidone iodine antisepsis. State of the art. *Dermatology* 1997; 195 Suppl 2: 3-9.

Corporate (collective) author

[4] American Academy of Periodontology. Sonic and ultrasonic scalers in periodontics. *J Periodontol* 2000; 71: 1792-801.

Unpublished article

[5] Garoushi S, Lassila LV, Tezvergil A, Vallittu PK. Static and fatigue compression test for particulate filler composite resin with fiber-reinforced composite substructure. *Dent Mater* 2006.

Personal Author(s)

[6] Hosmer D, Lemeshow S. *Applied logistic regression*, 2nd edn. New York: Wiley-Interscience; 2000.

Chapter in book

[7] Nauntofte B, Tenovuo J, Lagerlöf F. Secretion and composition of saliva. In: Fejerskov O,

Kidd EAM, editors. *Dental caries: The disease and its clinical management*. Oxford: Blackwell Munksgaard; 2003. p. 7-27.

No author given

[8] World Health Organization. *Oral health surveys - basic methods*, 4th edn. Geneva: World Health Organization; 1997.

Reference from electronic media

[9] National Statistics Online—Trends in suicide by method in England and Wales, 1979-2001. www.statistics.gov.uk/downloads/theme_health/HSQ20.pdf (accessed Jan 24, 2005): 7-18. Only verified references against the original documents should be cited. Authors are responsible for the accuracy and completeness of their references and for correct text citation. The number of reference should be kept limited to 20 in case of major communications and 10 for short communications.

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