



Longitudinal Study: Patient-Reported Outcomes in Zirconia vs. PFM for Full Mouth Rehabilitation, 2 Years Follow up

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ABSTRACT

Objective: This longitudinal study aims to explore patient-reported outcomes (PROs) and satisfaction levels among adults undergoing full mouth rehabilitation with zirconia and porcelain-fused-to-metal (PFM) restorations. **Methods:** A total of 100 adult participants requiring comprehensive dental rehabilitation will be recruited and randomly assigned to two groups: one receiving zirconia restorations and the other receiving PFM restorations. Data collection will occur at baseline, 6 months, 1 year, and 2 years following rehabilitation. To evaluate patient experiences, validated questionnaires will be employed, including the Oral Health Impact Profile (OHIP-14) to assess quality of life impacts, the Dental Satisfaction Questionnaire (DSQ) for overall satisfaction, and a Visual Analog Scale (VAS) for pain and comfort levels. Additionally, qualitative interviews will be conducted with a subset of participants to gain deeper insights into their experiences. **Results:** It is anticipated that patients receiving zirconia restorations will report significantly higher satisfaction levels and more favourable PROs compared to those with PFM restorations. Key determinants of satisfaction, including aesthetic appeal and comfort, are expected to emerge from qualitative analyses. **Conclusion:** This study aims to provide evidence-based insights that can guide clinical decisions regarding material selection in full mouth rehabilitation, underscoring the potential benefits of zirconia restorations in enhancing patient satisfaction

I. Introduction

Full mouth rehabilitation is a complex dental procedure designed to restore both function and aesthetics in patients facing extensive dental issues, such as severe wear, structural damage, or multiple missing teeth.⁴ This treatment typically involves a variety of restorative techniques to address these challenges comprehensively. Among the materials available for dental restorations, zirconia and porcelain-fused-to-metal (PFM) are two of the most commonly used options, each offering unique advantages and limitations.³

Zirconia, recognized for its high strength and excellent biocompatibility, has become increasingly popular in dental practices. Its superior mechanical properties allow for thinner restorations without sacrificing durability, which can be particularly advantageous in complex rehabilitative cases.⁵ In contrast, PFM restorations have been the standard choice for many years due to their strength and aesthetic capabilities. However, PFM may pose certain challenges, such as the visibility of metal margins and a higher risk of porcelain chipping over time.⁶

This longitudinal study aims to investigate patient-reported outcomes (PROs) and satisfaction levels among individuals receiving zirconia versus PFM restorations as part of their full mouth rehabilitation. By examining patients' experiences and perceptions over an extended follow-up period, the study seeks to provide valuable insights into how these materials impact overall satisfaction and treatment success. Understanding these outcomes can help guide clinicians in making informed decisions regarding material selection, ultimately enhancing patient care and treatment outcomes.

II. Objectives

- **Primary Objective:** To assess and compare patient-reported outcomes and satisfaction levels between zirconia and PFM restorations in full mouth rehabilitation over a 2-year period.
- **Secondary Objective:** To identify specific factors contributing to patient satisfaction, such as comfort, aesthetics, and functional performance of the restorations.

III. Methodology

A. Study Design

This research was conducted as a prospective longitudinal study over a period of two years. Such a design is particularly suited for examining changes in patient-reported outcomes (PROs) and satisfaction levels over time, allowing for the observation of trends and patterns in responses as patients adapt to their restorations. The study was take place in dental clinics that specialize in prosthodontics and rehabilitation, providing a controlled environment with access to necessary resources and expertise.⁷

B. Participants

The study will involve participants who meet specific inclusion and exclusion criteria to ensure the validity and reliability of the findings.

Inclusion Criteria:

- **Age:** Participants must be adults aged 18 years and older, as this demographic is likely to have fully developed oral structures and be able to provide informed consent.
- **Treatment Need:** Individuals must require full mouth rehabilitation, which may include multiple restorations such as crowns and bridges.
- **Informed Consent:** All patients must provide informed consent to participate in the study, ensuring that they understand the purpose, procedures, risks, and benefits associated with the research.

Exclusion Criteria:

- **Systemic Diseases:** Patients with systemic diseases, such as uncontrolled diabetes or autoimmune disorders, which may adversely affect oral health and healing, will be excluded from the study. This helps to eliminate confounding variables that could skew results.⁸
- **Prior Restorations:** Individuals with previous restorations that may influence the outcomes of new treatments will also be excluded. Prior dental work could affect the patient's perception of comfort and aesthetics.
- **Concurrent Treatments:** Patients undergoing other dental treatments simultaneously may introduce confounding factors. Therefore, individuals receiving concurrent therapies will be excluded to maintain the integrity of the results.

C. Sample Size

To ensure that the study is adequately powered to detect statistically significant differences between the two groups (zirconia and PFM restorations), a careful calculation of the required sample size is necessary. Based on preliminary studies that have explored patient satisfaction and clinical outcomes with these materials, sample size of 100 participants (50 in each group) is targeted. This sample size is calculated using the following considerations:

1. Effect Size: Previous research indicates that zirconia restorations may yield higher satisfaction rates compared to PFM restorations. An expected medium effect size will be used to determine the sample size needed to observe meaningful differences.⁹

2. Statistical Power: A power analysis will be conducted to ensure that the study has an 80% chance of detecting a true effect at a significance level of 0.05. This is standard in clinical research to minimize the risk of Type II errors.

3. Dropout Rate: Anticipating a dropout rate was minimum over the study duration due to various factors such as non-compliance or loss to follow-up, the initial target was adjusted to recruit 100 participants, thus ensuring that at least 98 complete the study.

By implementing these methodologies, the study aims to robustly assess the differences in patient-reported outcomes and satisfaction levels associated with zirconia and PFM restorations in full mouth rehabilitation.

D. Data Collection

1. Baseline Assessment:

Demographic Information: Initial data collection will include participants' age, gender, and relevant medical history. This information is crucial for understanding the population characteristics and potential confounding factors in the analysis. For instance, age can influence oral health outcomes, as older patients may have different restorative needs and responses to treatment.¹⁰

Where is 54 participant were male and 44 female where the male age ranging 33-62 years while female 38-64. Major cause of the tooth wear is bruxism in male and female apart from that second major cause is acidic exposure on teeth.^{11,12}

Participants Demographics - Table:1

S.N.	GENDER	AGE	MEDICAL HISTORY		
1.	Male 54%	33-62	Gastroesophageal Reflux Disease (GERD)	Acidic Foods and Beverages	Bruxism
			28 %	23%	49
2.	Female 44%	38-64	Gastroesophageal Reflux Disease (GERD)	Acidic Foods and Beverages	Bruxism
			26 %	17%	57

Clinical Assessments: A thorough clinical evaluation will establish each participant's oral health status before the restoration process begins. This will involve clinical examinations to assess periodontal health, tooth condition, and any existing restorations. A baseline Oral Health Impact Profile (OHIP-14) assessment will also be conducted to measure participants' initial quality of life related to oral health.¹³

Participants Clinical Assessments - Table:2

S.N.	ASSESSMENT	SCORE
1.	periodontal health	BPE score ranging 0-2
2.	tooth condition	33 % crown structure loss in 72 % participants 20-27 % crown structure loss in 19% participant 50 % or more crown structure loss in 9 % participants where patient vertical dimension decreased
3.	existing restorations	13% participants had a dental restoration history.

1. Restoration Details:

Detailed documentation of the types of restorations implemented was recorded, including the number of crowns, bridges, and the specific materials used (zirconia or PFM). This ensures that the study accurately reflects the diversity of restoration types and allows for a more granular analysis of outcomes related to specific restoration methods. This approach aligns with findings from recent studies that emphasize the importance of material choice on long-term success.¹⁴

- Where is 50 participant received Zirconium crowns and bridges and women more inclined to zirconium

due to aesthetic property of material. Small number of women received PFM crown due to cost. In other hand 50 participants received PFM crown where male more inclined it. Most of them focus on functional benefit rather than aesthetic.¹⁵

2. Follow-Up Assessments:

- Follow-up assessments will occur at four key time points: baseline, 6 months, 1 year, and 2 years post-rehabilitation. These intervals are chosen to allow sufficient time for the healing process and to evaluate the durability and functionality of the restorations. Regular follow-ups are essential to monitor any complications or failures, which can inform clinical practices and patient management.¹⁶

3. Patient-Reported Outcomes:

- The study will employ validated questionnaires to capture patient-reported outcomes (PROs):
- Oral Health Impact Profile (OHIP-14): This instrument assesses the impact of oral health on patients' quality of life, encompassing functional, social, and psychological aspects.¹³

- Dental Satisfaction Questionnaire (DSQ): This survey will gauge overall patient satisfaction with their dental care, focusing on materials used and perceived treatment effectiveness.¹⁷
- Visual Analog Scale (VAS): Patients will rate their pain and comfort levels associated with the restorations on a scale, allowing for a subjective measure of their experiences.¹⁸

4. Qualitative Interviews:

- To enrich the quantitative data, semi-structured interviews will be conducted with a subset of participants (approximately 20-30) to gain deeper insights into their experiences with the restorations. These interviews will explore themes such as aesthetics, comfort, functionality, and any issues encountered during the rehabilitation process. Qualitative data will provide a narrative context to the numerical findings, facilitating a comprehensive understanding of patient experiences and preferences.

Sample follow up outcome report - Table: 3

S.N.	Outcome Measure	Assessment Tool	Zirconia FMR (Expected Values for 50 participants)	PFM FMR (Expected Values for 50 participants)	Assessment Time Points
1.	Patient Satisfaction Levels	Dental Satisfaction Questionnaire (DSQ)	Average score: 8.5 (40 participants ≥ 8)	Average score: 7.0 (20 participants ≥ 8)	6 months, 1 year, 2 years
2.	Quality of Life Improvement	Oral Health Impact Profile (OHIP-14)	Average score: 15 (5 participants > 15)	Average score: 20 (15 participants > 20)	6 months, 1 year, 2 years
3.	Pain and Comfort Levels	Visual Analog Scale (VAS)	Average score: 2 (40 participants ≤ 2)	Average score: 5 (25 participants ≤ 5)	6 months, 1 year, 2 years
4.	Durability of Restorations	Clinical Assessment of Failures	90% survival rate (45/50 restorations)	80% survival rate (40/50 restorations)	1 year, 2 years
5.	Functional Performance	Patient-reported Functional Assessments	High functionality rating (≥ 75% reporting high)	Moderate functionality rating (≤ 50% reporting high)	6 months, 1 year, 2 years
6.	Aesthetic Appeal	Aesthetic Rating Scale	Average score: 8.0 (40 participants ≥ 8)	Average score: 6.5 (25 participants ≥ 6)	6 months, 1 year, 2 years
7.	Maintenance Ease	Patient-reported Maintenance Feedback	35 participants report easier maintenance	20 participants report more maintenance	6 months, 1 year, 2 years
8.	Qualitative Insights	Semi-structured Interviews	70% report positive experiences	Varied themes, 30% report dissatisfaction	6 months, 1 year, 2 years
9.	Overall Treatment Experience	Overall Treatment Experience Rating	Average rating: 8.0 (35 participants ≥ 8)	Average rating: 6.0 (20 participants ≥ 6)	6 months, 1 year, 2 years

Notes

- **Assessment Tools:** Specific questionnaires and scales used to measure each outcome.
- **Expected Values:** Based on a sample size of 100, with percentages indicating the number of participants meeting specific criteria.

Assessment Time Points: Specific intervals at which assessments were made to monitor changes and trends over time.

E. Data Analysis

- **Quantitative Data Analysis:** The quantitative data gathered from PRO scores will be analysed using appropriate statistical methods, such as repeated measures ANOVA, to compare differences in outcomes between the zirconia and PFM groups over time. This analysis will allow for the identification of statistically significant differences in patient satisfaction and functional outcomes, adjusting for potential confounding variables.¹⁹
- **Qualitative Data Analysis:** Thematic analysis will be employed for the qualitative interviews to identify recurring themes and insights related to patient experiences. This method involves coding the data and identifying patterns that reflect the participants' perspectives on their restorations. The qualitative findings will complement the quantitative results, providing a holistic view of the effectiveness of zirconia versus PFM restorations in full mouth rehabilitation.²⁰

IV. Expected Outcomes

The primary aim of this longitudinal study is to evaluate and compare patient-reported outcomes (PROs) and satisfaction levels between zirconia and porcelain-fused-to-metal (PFM) restorations over a two-year period. Based on preliminary literature and emerging trends in prosthodontics, several anticipated outcomes can be outlined.²¹

1. Higher Satisfaction Levels for Zirconia Restorations:

- It is expected that patients receiving zirconia restorations will report significantly higher satisfaction levels compared to those with PFM restorations. This hypothesis is supported by recent studies indicating that zirconia offers superior aesthetic qualities and comfort, which

are crucial determinants of patient satisfaction.²¹ Zirconia's translucency closely mimics natural tooth structure, enhancing visual appeal and overall satisfaction.⁷

2. More Favourable Patient-Reported Outcomes (PROs):

- The study anticipates that PRO scores, particularly those assessing quality of life related to oral health (measured by tools like the Oral Health Impact Profile), will reflect more positive outcomes for the zirconia group. This expectation is based on findings that suggest zirconia restorations contribute to better functional performance and reduced complications.
- Such positive outcomes can improve patients' daily lives by enhancing chewing ability and reducing discomfort.²²

3. Identification of Key Factors Influencing Satisfaction:

- The qualitative component of the study, including semi-structured interviews, aims to unveil specific factors that contribute to patient satisfaction. Themes related to aesthetics, comfort, and functional performance will be explored. Understanding these factors is crucial for practitioners to make informed material selections that align with patient preferences and expectations. Previous research has highlighted that factors such as material strength, aesthetic quality, and comfort play significant roles in patient satisfaction.²³

V. Ethical Considerations

1. Ethical Approval:

- Prior to commencing the study, ethical approval will be secured from the relevant Institutional Review Board (IRB). This process ensures that the study adheres to ethical guidelines and prioritizes participant welfare. Ethical oversight is essential to maintain the integrity of the research and protect participants' rights throughout the study.

2. Informed Consent:

- Informed consent will be obtained from all participants before their inclusion in the study. This consent process will clearly outline the

study's purpose, procedures, potential risks, and benefits. Participants will also be informed of their right to withdraw from the study at any time without facing any penalties or loss of benefits. Ensuring participants fully understand their involvement promotes ethical research practices and reinforces their autonomy.24

VI. Conclusion

This longitudinal study is designed to provide critical insights into the differences in patient-reported outcomes and satisfaction between zirconia and PFM restorations in full mouth rehabilitation. By focusing on PROs, the research aims to bridge the gap between clinical outcomes and patient experiences, which are often overlooked in traditional clinical assessments.

The findings from this study will contribute to the growing body of knowledge in the field of prosthodontics, enabling clinicians to make evidence-based decisions regarding material selection. Enhanced understanding of patient satisfaction will ultimately lead to improved patient care and outcomes, positioning zirconia as a potentially superior choice in full mouth rehabilitation. By identifying factors that influence satisfaction, this research could inform best practices and guidelines that prioritize patient-centred approaches in dental restoration.

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