Cross-Sectional Study

ORAL HEALTH-RELATED QUALITY OF LIFE FOLLOWING PROSTHETIC REHABILITATION IN POST-MUCORMYCOSIS CASES: A CROSS-SECTIONAL STUDY PROTOCOL

Rucha Chiddarwar[1], Anjali Borle[1], Seema Sathe[1], Surekha Godbole[1]*

[1]*Department of Prosthodontics, Sharad Pawar Dental College and Hospital, Datta Meghe Institute of Higher Education and Research, Wardha, India.*
ruchachiddarwar1702@gmail.com

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ABSTRACT

Following the devastating second wave of COVID-19 in 2021, there was a sharp rise in mucormycosis cases, leaving many individuals with significant facial disfigurement, oral dysfunction, and emotional trauma. For survivors, regaining both function and confidence has become a major challenge. Prosthetic rehabilitation offers a vital pathway to restoring oral health-related quality of life (OHRQoL) by addressing both physical impairments and psychosocial distress. In addition to determining the clinical and demographic parameters that affect the post-rehabilitation results of mucormycosis survivors, this study attempts to evaluate the effects of prosthetic treatment on their quality of life. 20 patients receiving care at Sharad Pawar Dental College and Hospital in Wardha will participate in a cross-sectional study that will use clinical and demographic information in addition to validated OHRQoL questionnaires. Statistical comparisons will examine quality of life before and after rehabilitation, while exploring variables like age, gender, and surgical extent. Ethical approval has been obtained, and all participants will provide informed consent. Results, anticipated within a year, are expected to offer meaningful insights into how tailored prosthetic care can improve the overall well-being of these patients and guide future clinical practices.

Key words: Mucormycosis, Prosthetic rehabilitation, Oral health-related quality of life, Study protocol.

Introduction

The first wave of COVID-19 in 2020 led to the cessation of global activities, but the second wave in 2021 unleashed a devastating pandemic, with the pandemic alarming number of cases of Mucormycosis, an invasive fungal infection that was previously uncommon. This uncommon but potentially lethal fungal infection was the cause of around 41000 recorded cases and 4000 fatalities between May to July 2021. As a result of most of these cases, which occurred during SARS-CoV-2 outbreaks in India, the Government of India declared an epidemic of mucormycosis in May 2021. In response to the problem, otorhinolaryngologists prioritised emergency care using a multidisciplinary approach for patients with mucormycosis. Usually, there were two steps in the therapy protocol: medical management with intravenous Amphotericin and functional endoscopic sinus surgery with repeated surgical debridements [1].

Uncontrolled diabetic mellitus with ketoacidosis, haematological malignancies, solid organ and stem cell transplants, iron chelation therapy with deferoxamine, and corticosteroid medication use are the primary risk factors for mucormycosis. Mucormycosis had a major adverse effect on a patient's life in a number of areas, including their environment, social interactions, sleep patterns, physical as well as mental status, and capacity to work [2]. The World Health Organization has defined health as "a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity." Within this framework, Oral Health Related Quality of Life (OHRQoL) plays a crucial role in the overall health and is acknowledged by the WHO as a significant aspect of the Global Oral Health Program. OHRQoL has gained prominence in the last two decades as a relatively new but rapidly expanding field. Numerous authors have delved into the evolution of OHRQoL, documenting the factors that have contributed to its increasing recognition. Slade *et al*. have highlighted that the transition in health perception, moving beyond the absence of disease and infirmity to encompass complete physical, mental, and social well-being, is central to understanding HRQoL and subsequently OHRQoL [3].

A correlation between a higher number of lost teeth or fewer functioning teeth with a lower self-perceived oral health condition was found. Maintaining natural teeth can greatly enhance the patient's mental health, even if they only have them in one jaw. Oral function can be affected by modifications of orofacial muscles, saliva flow, opening of the jaw, etc. Because of the changing structure of the mouth and face, this can present issues for prosthodontic treatment, making it challenging to deliver the patient a solid and pleasant prosthesis. Restoring function is the aim of oral rehabilitation, which will improve patient outcomes [4]. There is evidence indicating that facial disfigurements resulting from trauma or illness can be equally distressing. Studies have indicated that receiving primary cancer therapy frequently results in a marked reduction in social connections with companions in private as well as public environments, with some patients reporting social isolation.

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People with facial deformities may be more susceptible to psychological suffering, like depression, low self-esteem, and unhappiness with their appearance, because of the social stigma associated with these diseases. McGrouther concludes that social stigma can result from even slight facial defects [5].

This area offers valuable insights into the psychological and social impact of prosthetic rehabilitation because people who have had prosthetic restoration of a lost facial feature provide researchers and doctors a rich array of experiences. While there are differences within this patient group, the majority will go through phases of grieving, getting ready for getting a face prosthesis (including expectations for the procedure), adjusting to other people's reactions after receiving the prosthesis, and maintaining their new facial prosthesis over time. However, little is understood about how giving facial prosthetics affects people's social and psychological well-being [6]. Patients with head and neck cancer may face major functional, cosmetic, and other challenges as a result of therapies like radiation therapy and chemotherapy. After cancer treatment, oral rehabilitation becomes essential for helping patients regain some semblance of normalcy in their quality of life. There are numerous surveys available to assess these individuals' overall therapy results. LORQ was created to assess the oral health-related quality of life with regard to oral rehabilitation in head and neck cancer cases, which is one prominent example. Later on, the LORQ developed into LORQ version 3 (LORQv3), which included more in-depth questions about oral function and patient dental and prosthetic problems [7, 8].

Although the number of mucormycosis survivors is increasing, there is limited understanding of how prosthetic rehabilitation impacts their daily lives, particularly from the patient's perspective. Existing research rarely explores how individuals feel and function after treatment or how factors like age, gender, and socioeconomic background may influence their recovery. This study aims to bridge that gap by evaluating patient-reported outcomes following prosthetic rehabilitation. It will document the sociodemographic profiles of post-mucormycosis patients, assess the impact of prosthetic treatment on their oral health-related quality of life (OHRQoL), and explore the role of sociodemographic factors in shaping these outcomes [9-13].

Materials and Methods

This study has received approval by the Institutional Ethics Committee of Datta Meghe Institute of Higher Education and Research (DMIHER(DU)/IEC/2024/57) dated May 11, 2024. It is a cross-sectional study with a sample size of 20, which would be conducted in the Dept of Prosthodontics and Crown and Bridge at Sharad Pawar Dental College and Hospital, Sawangi, Wardha. All patients included in this study had previously been treated for mucormycosis and subsequently received prosthetic rehabilitation at this hospital. The study will record the following information: name, age, gender, address, education, COVID-19 status, time of mucormycosis diagnosis, and time of prosthesis installation. An interview-based questionnaire will be administered and will be translated into the local language by clinicians to patients as a basis for discussion and assessment. The questionnaire emphasizes the functional and psychological effects of the treatment on patients. Considering the inclusion and exclusion criteria **(Table 1)**, participants would be selected, and closed-ended questions would be asked to patients **(Tables 2 and 3)**. Conversations between the patient and clinician will be recorded to assess their feedback on the prosthetic rehabilitation, with informed consent obtained beforehand.

Table 1. Criteria for Selection of Patients (Detailed Inclusion and Exclusion Parameters for Participant Recruitment)

Inclusion Criteria	Exclusion Criteria
Those patients who have been previously treated for mucormycosis and subsequently received prosthetic rehabilitation	Patients who are unable to give informed consent
Age category -18 years and above.	Patients who are diagnosed with cancer or any life-threatening disease.
Patients who are willing to give informed consent to answer the interview-based questionnaire.	

Table 2. Questionnaire for Functional Aspect – Evaluation of Masticatory Efficiency, Oral Comfort, Prosthesis Adaptation, and Impact on Daily Activities

1	**Did you face any difficulties with chewing or swallowing?**
2	Did you experience dryness in your mouth or excessive drooling?
3	Did you encounter any speech problems?
4	Did your ability to chew affect your food choices?
5	Did your dentures cause gum soreness or ulcers?
6	Were you concerned that your dentures or implant-retained teeth might fall out?
7	Have you struggled with pronouncing words because of your dentures?
8	Have you noticed a decrease in your sense of taste due to issues with your dentures?
9	Have you experienced pain or discomfort in your oral cavity?
10	Have your dentures made it challenging to eat certain foods?
11	Have your dentures made it difficult to carry out your usual tasks?

Table 3. Questionnaire for Emotional aspect - Assessment of Psychological Well-Being, Self-Perception, and Denture-Related Emotional Distress

1	**Were you dissatisfied with your facial appearance?**
2	Did your chewing ability impact your public interactions in any way?
3	Did you feel embarrassed to talk due to your dentures or implant-retained teeth?
4	Did you decline any invitations due to embarrassment about your dentures or implant-retained teeth?
5	Were you unhappy with your upper or lower dentures or implant-retained teeth?
6	Have you felt self-conscious about using your dentures?
7	Have you experienced stress or tension due to denture problems?
8	Have you struggled to relax because of your dentures?
9	Have you felt embarrassed with your dentures?
10	Have you been more irritable with others because of issues with your dentures?
11	Have you felt that life is not enjoyable due to dentures?

Sample size

The sample size is determined using the following formula

$n = z^2 P(1-P)/ d^2$, to determine the required number of patients to estimate the prevalence of Mucormycosis. For a 95% confidence level, the Z-statistic (z) was set at 1.96, and the Level of significance was 5%. The calculation used an expected Prevalence (P) of 0.025 and a desired Margin of Error (d or E) of 0.07 (7%). Substituting these values into the formula resulted in

$n = 1.96^2 \times 0.025(1-0.025) /0.07^2 \approx 19.11$, leading to a required minimum sample size of 20 patients for the study [14-17].

Statistical analysis

All the results will be calculated using R software, version 4.3. Descriptive statistics will be used to summarize socio-demographic characteristics. For categorical variables, percentages and frequencies will be provided, while means with standard deviations or medians with interquartile ranges will be presented for continuous variables [18, 19].

To compare pre- and post-rehabilitation quality of life scores within individuals, either paired t-tests or Wilcoxon signed-rank tests will be employed. Subgroup analyses will be conducted to examine changes in quality of life across different socio-demographic factors, using analysis of variance (ANOVA) or appropriate non-parametric tests for categorical variables [20-25].

Additionally, multivariable regression analysis will be performed to identify predictors of changes in quality of life. This analysis will adjust for potential confounders such as age, gender, and socio-economic status. Statistical significance will be determined at the 5% level ($P < 0.05$).

Results and Discussion

After the study, we will assess whether patients will be satisfied with their prosthetic treatment. This research will aid clinicians in evaluating potential complications and future consequences of prostheses, enabling them to proactively implement preventive measures. This study protocol is ongoing, and we anticipate collecting and analyzing results within one year; however, no outcomes have been presented yet [26-33].

The prevalence of mucormycosis, once a rare condition, rose sharply during the second wave of COVID-19. Many affected individuals required extensive surgical interventions, such as endoscopic sinus surgery with multiple debridements, orbital decompression, and, in severe cases, craniectomy. As a result, individuals experienced severe health issues as well as severe financial hardships because of extended hospital stays and expensive prescription drugs. The psychosocial impact on both patients and their families was equally profound.

To better understand these multidimensional outcomes, the development of a targeted questionnaire to assess the perceived effects of such interventions is essential. This tool would need to be both specific and sensitive to the unique experiences of these individuals [7].

In 2004, Pace-Balzan *et al*. conducted a preliminary investigation of the Liverpool Oral Rehabilitation Questionnaire (LORQ), which included 25 questions focused on denture satisfaction and oral function, measured on a four-point Likert scale. The test-retest reliability showed strong agreement, suggesting the instrument's consistency. The pilot study demonstrated good reliability and used qualitative data collection and analysis methods to capture participants' perspectives. These approaches are especially valuable when exploring the broad psychosocial and functional effects of facial disfigurement and prosthetic rehabilitation [8].

Qualitative methods are especially valuable when studying small, specific populations, such as individuals who have lost part of their face. Although generalizations from these studies are limited due to small sample sizes, the goal is not statistical representativeness but a deeper understanding of patient experiences and perceptions of prosthetic rehabilitation [34, 35].

Insights from such research are critical for identifying key areas for future exploration in patients using facial prostheses [36-41]. The loss of facial structures affects social interactions at three levels: acquaintances, family, and

intimate partners. Intimate relationships tend to be the most affected, while familiar circles may require less adaptation. Interactions with acquaintances often involve discomfort, commonly expressed through staring—contrary to earlier observations that emphasized avoidance. This discrepancy may stem from observers' uncertainty about facial prostheses, prompting prolonged visual scrutiny to comprehend the situation [42, 43].

Patients are generally expected to adapt well to most aspects of dental rehabilitation, including psychological and functional components.

Although this study addresses an important and often overlooked aspect of healthcare by focusing on how prosthetic rehabilitation impacts the quality of life in mucormycosis patients, providing valuable insights into patient-centered outcomes, it may also face several limitations, including a small and potentially non-representative sample size, selection bias. Cultural, socioeconomic factors, and the limited scope of the questionnaires, may also influence the results, potentially overlooking other significant aspects of quality of life.

Conclusion

The COVID-19 pandemic has caused a rapid increase in mucormycosis cases, requiring multidisciplinary teams to address the infection's complex manifestations in the nasal cavity, maxillary sinuses, palate, and orbit. This surge has imposed substantial psychological, physical, and financial burdens on patients. Effective management now demands equal attention to postoperative care and quality of life monitoring to control morbidity. The study indicates that factors such as age, comorbidities, and severity of illness impact long-term outcomes, underscoring the need for ongoing psychological support. Despite a small sample size, the findings support the hypothesis that comprehensive, multidisciplinary care and future research into interventions like facial prostheses are essential for addressing the broader psychosocial aspects of recovery.

Trial registration
The study is registered with the Clinical Trial Registry-India under the CTRI Registration number CTRI/2024/07/070675.

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