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# EPA Consensus Project Paper: Do Implant Retained Prostheses Improve the Quality of Life of Patients with Extraoral Maxillofacial Defects - A Systematic Review


## Keywords

*Patient Satisfaction*
*Quality of Life,*
*Implant Prostheses*
*Extraoral Maxillofacial Defects*



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## ABSTRACT

*Background: There is limited evidence available regarding patient satisfaction and quality of life assessment in patients with extraoral maxillofacial prostheses. Objectives: This systematic review aims to understand the impact of extraoral implant retained prosthesis in improving the quality of life in patients with extraoral maxillofacial defects/abnormalities. Methods: A comprehensive search was performed of nine electronic databases up to August 2022, which yielded three articles that satisfied the inclusion criteria. The study characteristics and findings were extracted, and the included studies were assessed for quality. Results: Three cohort studies were selected. Despite the lack of uniformity in the quality of life instruments, there was a general trend in improvement in the quality of life for patients with implant retained extraoral prostheses. The studies were also deemed to be of high quality on assessment. Conclusion: Given the limitations of this systematic review, there exists limited evidence indicating that implant prostheses may enhance the quality of life for individuals with extraoral maxillofacial defects or abnormalities.*


## INTRODUCTION

Extraoral maxillofacial defects, whether congenital or acquired due to trauma, tumors, or infection, exert a profound influence on patients. These conditions not only impact their physical well-being but also have far-reaching effects on their psychological and social aspects, significantly compromising their overall quality of life.[1]

To address these complex challenges, two primary approaches emerge. Firstly, surgical reconstruction, while effective, often necessitates multiple procedures. However, it may not always be a feasible or preferred option for the patient and can sometimes result in less than satisfactory cosmetic outcomes. Alternatively, prosthetic rehabilitation utilizing extraoral maxillofacial prostheses presents an alternative strategy. These prostheses can serve to enhance both function and aesthetics, providing patients with a vital tool for improving their quality of life. Secure retention of these prostheses can be achieved through various methods, including utilizing

undercuts, adhesives, employing mechanical retentive aids such as spectacles, or connecting them to intraoral prostheses.[2] Nevertheless, some limitations have been linked to the utilization of these retention techniques. The use of adhesives frequently leads to the build-up of oils and debris on the prosthesis surface, requiring frequent cleaning. Furthermore, the routine removal of adhesive from the skin may result in skin irritation and tissue inflammation, ultimately affecting the prosthesis's marginal adaptation and overall aesthetic appearance.[2]

The introduction of osseointegrated implants in the maxillofacial region has significantly addressed these limitations associated with medical-grade adhesives. This approach has proven to be a reliable treatment option with a high long-term success rate for extraoral maxillofacial/facial prostheses.[3] Implants offer enhanced retention and stability, pose minimal surgical risks and complications, and contribute to an overall improvement in the quality of the prosthesis.[4]

Patients' perception of treatment outcomes and their satisfaction are critical factors in evaluating the quality of care delivered. Those who require extraoral maxillofacial prostheses often face a myriad of functional and psychosocial challenges. The true success of prosthetic rehabilitation is realized when the patient no longer experiences self-consciousness about the prosthesis, and it substantially improves their psychological and social well-being, as well as their overall functionality.[5] Unfortunately, in this context, psychological evaluation and assessment of treatment outcomes are occasionally overlooked.

The existing body of literature underscores the predictability and efficacy of implant-retained extraoral maxillofacial prostheses.[6] However, there is a notable scarcity of research pertaining to patient satisfaction and the enhancement of quality of life associated with these prostheses. Quality of life refers to an individual's sense of well-being, where they find satisfaction in those aspects of life that hold significance and meaning, enabling them to lead a comfortable existence with minimal limitations on personal aspirations.[7]

The primary objective of this systematic review is to investigate the impact of extraoral implant-retained prostheses on the quality of life of individuals with extraoral maxillofacial defects/abnormalities. The null hypothesis posits that there is no significant difference in the improvement of quality of life, regardless of whether patients with extraoral maxillofacial defects/abnormalities receive implant or non-implant prostheses.

# MATERIALS AND METHOD

This systematic review was conducted using the guidelines for Preferred Reporting Items for Systematic Reviews and Meta–analysis (PRISMA) statement.[8] The PICO format was applied to define the research question in this review. The PICO are as follows:

P - the population was patients with extraoral maxillofacial defects or abnormalities.

I - the Intervention: implant-retained extraoral maxillofacial prostheses.

C - compared with conventional extraoral maxillofacial prostheses retained using adhesives, undercuts, etc.

O - the outcome was quality of life.

The inclusion and exclusion criteria are as follows:

| Inclusion criteria | Exclusion criteria |
|---|---|
| 1. Patients with extraoral maxillofacial abnormalities/defect | 1. Patients with intraoral maxillofacial abnormalities/defects |
| 2. English- language and English translation available | 2. Animal or lab studies |
| 3. Full-text article available | 3. Non-English language |
| 4. Systematic reviews and meta-analyses, single or multiple group prospective randomized controlled (RCTs), non-randomized controlled trials, cohort studies, case series and case reports | 4. Full-text article unavailable |
| | 5. Cross-sectional studies, narrative reviews, and review protocols |

## SEARCH METHODOLOGY

A comprehensive electronic search was performed by one of the authors (SN) with the databases and search engines provided by PubMed, EMBASE, Ebscohost, Cochrane Central Register of Controlled Trials, Web of science, Scopus, SciELO, LILACS and Google Scholar up to August 2022 with a lower limit from 1970. Reference searching of data yielded 11 results. A search strategy consisting of combinations of text words was implemented. The keywords used were: ("ear" OR "auricular" OR "nose" OR "orbital" OR "facial" OR "nasal" OR "ocular" OR "eye" OR "prosth*" OR "defect*" OR "crani*" OR "epithes*" OR "anaplast*") AND ("maxillofacial" OR "maxillofacial prosthetic") AND ("implant supported" OR "implant retained"). This search strategy was modified to conform to the different databases. Hand-searching of the reference list of the included papers was carried out.

The identified studies were entered into Covidence, and duplicate studies were removed. Two authors (AM and ASM) independently examined the gathered articles by title and abstract (kappa score – 0.59). Any disagreement was adjudicated by a third reviewer (SN). Full text of articles identified from the title and abstract screenings were reviewed thereafter by two authors (AM and ASM) (Kappa score – 0.65), and disagreements were resolved by a third reviewer (SN).

Study characteristics of the shortlisted articles were extracted, and this included participant characteristics such as number of patients, age, type of defect, type of prosthesis and comparator, number and type of information and type of study. Information regarding the quality of life outcomes was extracted



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to include the instrument used and whether it is a validated, when the quality of life measurement occurred in the study, the particular prostheses provided on which the QOL is being measured and if any statistical analysis was carried out.

## QUALITY ASSESSMENT

All the included studies were assessed using the Newcastle-Ottawa scale (NOS) for non-randomised trials (9) by two reviewers (SSK and SN). Any disagreement was resolved with a discussion with a third reviewer (CSJ). The NOS assigns up to a maximum of nine points for the least risk of bias in three domains.

# RESULTS

## STUDY SELECTION

Electronic searches from all sources retrieved 1944 citations (*Figure 1*). 231 citations were excluded as duplicates and 1674 articles were excluded after title and abstract screening (kappa score: 0.59). Among 39 studies selected, 36 were excluded for the following reasons: wrong outcomes (n =10), Non-English language (n = 7), Full text unavailable (n =4), Wrong study design (n = 14), Wrong patient population (n =1))(kappa score: 0.65). Three studies were included in the final review.[2,5,7,10]

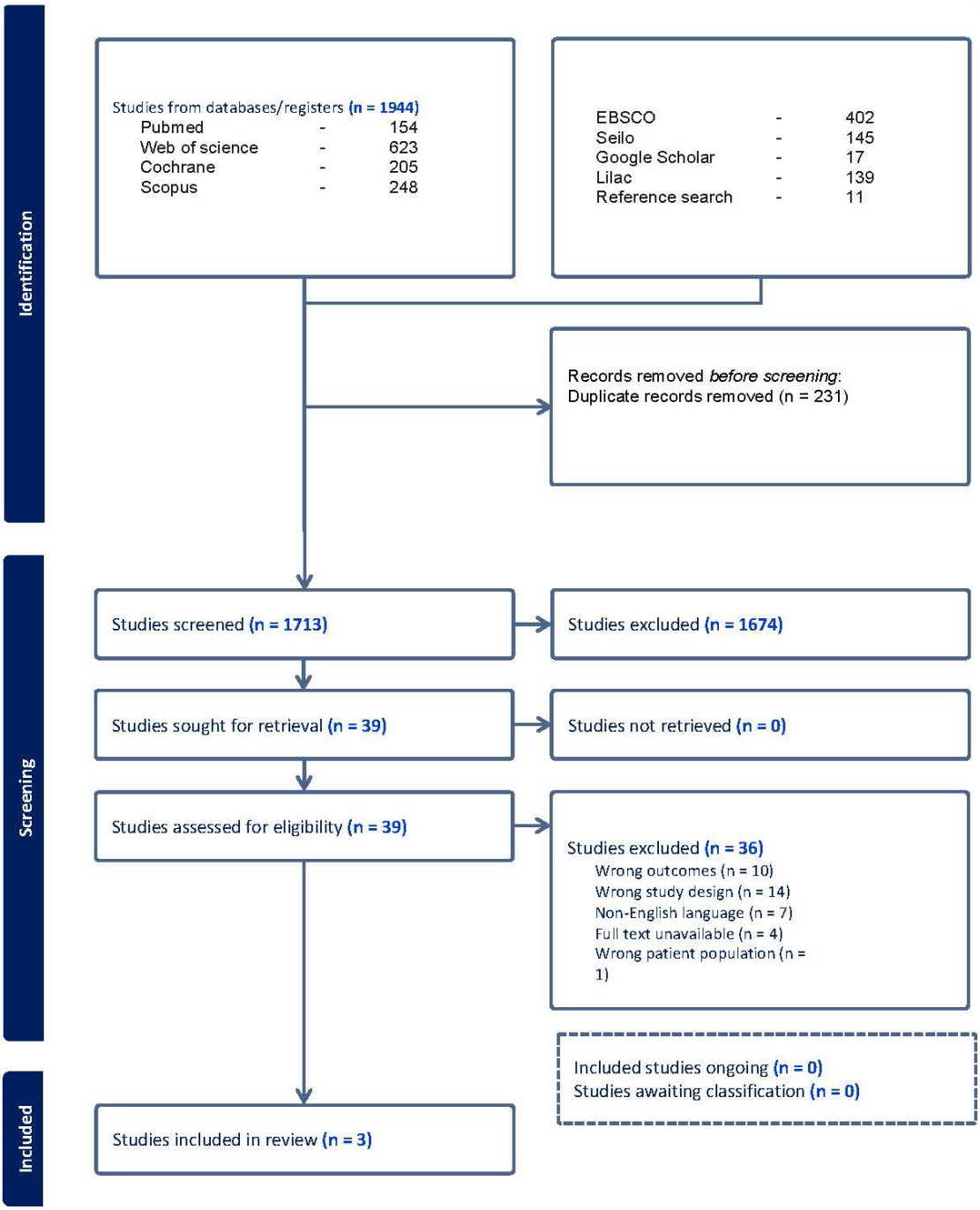


**Figure 1:** PRISMA flow diagram of search strategy and outcomes. (PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-analysis).

## STUDY CHARACTERISTICS

The three studies[2,7,10] included in the review were all cohort studies.[11] In these studies, the population's age range spanned from 14 to 88 years old, and the sample size ranged from 5 to 28, respectively. The studies by Nemli 2013[7] included patients with orbital, auricular, and nasal defects; Arcuri *et al*.[2] chose subjects with facial anatomical defects; and Smolarz-Wojonowska *et al*.[10] evaluated individuals with auricular or nasal defect, partial facial defects, or who received prosthetic rehabilitation for maxillectomy. The number and type of implants were mentioned for two studies[2,10] whereas there was no mention of the number or type of implants used in Nemli *et al* 2013.[7] *(Table 1.)*

## SUMMARY OF FINDINGS

Due to a lack of uniformity in the quality of life instruments, a narrative synthesis was performed. In the three included studies,[2,7,1] two of them utilised known questionnaires[2,7] and the third[10] utilised a questionnaire which the authors created. Of the two known questionnaires, only one study Nemli 2013,[7] reported use of a validated questionnaire. All studies had pre- and post- treatment evaluation although only two studies[2, 7] have mentioned when it was carried out. The impact of implant-supported prostheses was assessed before and after the implant placement in the three studies with adhesive-retained prostheses/glasses prosthesis/bandages as control. The effect of treatment on a patient's quality of life at repeated/long term intervals was not recorded in any of the studies. Nemli *et al*.[7] carried out statistical analysis of their results while the other two did not report on statistical analysis.[2,10] Generally all of the studies recorded an improvement in the quality of life results when extraoral implant-retained prostheses were used, compared to conventional adhesive retained or bandage. *(Table 2)*

## METHODOLOGICAL QUALITY ASSESSMENT

The Newcastle-Ottawa scale (NOS) was used to assess the quality of the three studies.[9] The NOS was developed to assess the quality of nonrandomised studies with its design, content and ease of use. Of the three studies, two scored 8 out of 9 and the third scored 7 out of 9. From a quality standpoint 7-9 points shows high quality. *(Table 3)*

# DISCUSSION

Maxillofacial prostheses have been used to restore both form and function that have been compromised due to craniofacial abnormalities or defects. Research innovations is ongoing in the pursuit of novel techniques and developing superior materials for improving outcomes in patients with craniofacial abnormalities or defects. Assessing the quality of life is now regarded as an essential facet of such studies as this type of rehabilitation is intricately linked to an individual's or a group's health, well-being and contentment.

**Table 1.** Study characteristics.

| Author | No. of patients | Age | Type of Defect | Comparator | Type of prosthesis | Number and type of Implants | Type of study |
|---|---|---|---|---|---|---|---|
| **Arcuri 1997[2]** | 5 | 36 to 88 | Maxillary facial – 3, Nasal - 2 | Facial prostheses | implant retained prostheses | 19 implants in 5 patients (Nobel Biocare, Chicago, Ill.) | Cohort study |
| **Nemli 2013[7]** | **82** 54 - A retrospective group (participants treated and under care) | 15 to 77 (mean - 43.8) | Retrospective: 20 auricular, 26 orbital, 8 nasal | | | Not mentioned | Cohort study |
| | 28 - A prospective group (participants willing to be treated) | 14 to 75 (mean -44.9) | Prospective: 12 auricular, 10 orbital, 6 nasal | Conventional retained prostheses and covered with bandage | Implant-retained prostheses | | |
| **Smolarz-Wojnowska 2014[10]** | 30 (26 extraoral) | 19 to 83 (mean – 67.2) | Ear – 10<br>Nasal – 3<br>Orbital - 7<br>Partial facial defects - 6 | Adhesive retained or glasses prosthesis | Implant-retained extraoral maxillofacial prostheses | 94 in 30 patients (69 Straumann EO System (Basel, Switzerland), 15 Branemark (Zurich, Switzerland) 10 Zygoma/Branemark | Cohort study |



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**Table 2.** Summary of findings.

| Study | Quality of life instrument | Validation of the instrument | When was quality of life measured? | Prostheses provided to patients on which QOL was measured. | Quality of life results | Statistical Analysis of results |
|---|---|---|---|---|---|---|
| **Arcuri 1997[2]** | Nobel Biocare | NR | Measured on same patients before beginning implant therapy and 6 months after delivery of implant retained prostheses. | CP – facial prosthesis or covering<br>IP - Nasal, nasal-facial/ maxillary obturator. | Improvement in the quality of life for the patients with implant retained prostheses. | None |
| **Nemli 2013[7]** | Sloan et al | Yes | Measured on same patients at baseline with CP and 6 months after insertion of IP. | CP – 3 conventional retained prostheses, 21 covered with bandage.<br>IP – Auricular, orbital, Nasal prostheses. | All patients had better functional outcomes when they were provided IP compared to CP in most parameters evaluated for the prospective group. | P<.001 in all parameters between pretreatment and posttreatment in the prospective group |
| **Smolarz-Wojnowska 2014[10]** | Author created | NR | NR | CP – Adhesive (nose, orbit and partial face prostheses) or glasses prosthesis (ear prostheses).<br>IP – Orbital prostheses, auricular prostheses, nasal prostheses, facial prostheses. | Patient satisfaction from implant retained prostheses usage was good | None |

NR – Not reported; CP – Conventional prostheses; IP – implant prostheses

**Table 3.** Risk of bias assessment for the included non-randomised trials - Newcastle-Ottawa Scale.[9]

| | Selection (One star for each item) | | | | Comparability (2 stars available) | Outcome (one star for each item) | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Study** | **Representativeness of the exposed cohort** | **Selection of the non exposed cohort** | **Ascertainment of exposure** | **Demonstration that outcome of interest was not present at start of study** | **Comparability of cohorts on the basis of the design or analysis** | **Assessment of outcome** | **Was follow-up long enough for outcomes to occur?** | **Adequacy of follow up cohorts** | **Total Score** |
| **Nemli 2013[7]** | * | * | * | * | * | * | * | * | 8 out of 9 |
| **Smolarz-Wojnowska 2014[10]** | * | * | * | * | * | * | | * | 7 out of 9 |
| **Arcuri 1997[2]** | * | * | * | * | * | * | * | * | 8 out of 9 |

(7-9 – high quality; 4-6 – high risk of bias; 0-3 – very high risk of bias)

We conducted a thorough literature search to address a clearly defined research question, following established guidelines for conducting a systematic review.[8] The reviewers demonstrated a notable degree of consensus, as indicated by interrater reliability scores ranging from 0.59 to 0.65. As a result, we can have confidence in the strength and reliability of the findings.

This systematic review has highlighted a significant dearth of evidence concerning the influence of implant-supported prostheses on the quality of life in patients with extra-oral maxillofacial defects. No well-structured systematic reviews or randomized controlled trials were found during our search. It is possible that potential eligible studies may have been excluded due to language restrictions, predominantly non-English studies, or difficulties in translation into English, which could introduce a selection bias. It is important to note that the included studies generally featured reasonable sample sizes among participants except for one.[2] Although statistical analysis was only carried out on one study,[7] it did reveal statistically significant results in its analysis. Therefore, the findings of this systematic review could be interpreted with some degree of certainty.

One of the challenging aspects of this review was navigating the multitude of questionnaires employed across three studies. The term "quality of life" encompasses a broad concept that comprises numerous distinct attributes (referring to the constituent elements or factors constituting a comprehensive entity). These attributes can be gauged through a range of subdimensions, each associated with a specific number of indicators. This concept encompasses both objective components and an individual's subjective interpretation thereof. The latter is notably influenced by the preferences and priorities of the population. Given the challenge of comparing quality of life across diverse populations and regions, a comprehensive set of indicators is indispensable for this task.

The studies employed a mix of self-developed and known questionnaires to evaluate quality of life. Only one study, Nemli *et al* 2013,[7] undertook questionnaire validation; the absence of any mention of such validation in the other studies suggests its omission. Our inference is that no study encompassed all the domains intended for evaluating an individual's quality of life post maxillofacial prosthetic rehabilitation.

The existing questionnaires did not account for the patients' expectations and the timing of the quality of life assessment. For example, in cases of terminal illness, individuals might not anticipate a substantial improvement in their quality of life due to already diminished expectations. Furthermore, it is also likely that the impact of treatment on a patient's quality of life would vary over time.

Patient-reported outcome measures (PROMs) play a vital role as assessment tools, directly gathering data from patients to assess various facets of their health status that profoundly influence their overall quality of life. These facets encompass a range of elements, including symptoms, functional capacity, and the physical, mental, and social dimensions of health. PROMs not only provide a snapshot of a patient's health status at a specific moment in time but can also be employed longitudinally to track changes, whether they represent improvements or deteriorations in quality of life. This versatility renders PROMs a crucial instrument in both research and clinical trials, facilitating rigorous assessments of intervention effectiveness. Additionally, PROMs ensure that the outcomes measured are truly meaningful to patients, clinicians, and policymakers, thus guiding informed decision-making processes.

Presently, there exists a lack of consensus on the most effective outcome metrics for adoption in research related to extraoral and facial prostheses. It is imperative to undertake the development and validation of a comprehensive questionnaire that encompasses all pertinent aspects of this field. To maximize its effectiveness, it is advisable to involve all stakeholders in the assessment and reporting process. One promising strategy is the utilization of a standardized set of questions designed to pinpoint the critical areas that necessitate evaluation and reporting within extraoral and facial prosthesis research. This approach holds the potential to promote consistency in research practices on a global scale, thereby facilitating more robust analysis and comprehension of the subject matter.

It was evident from the studies that implant-supported prostheses improved quality of life; with the quality assessment carried out revealing that the studies were of high quality. Therefore, the null hypothesis can be rejected.

## CONCLUSION

Within the constraints of this systematic review, it is reasonable to assert that the studies included in this review demonstrated a notable improvement in the quality of life for patients who received implant prostheses as part of the restoration or rehabilitation of their extraoral abnormalities or defects. Furthermore, these studies were evaluated as being of high quality.

Nevertheless, it is acknowledged that the quality of life measurement tools employed in these studies exhibited significant variability. This underscores the need for further research in this area to establish standardized outcome metrics that can be consistently applied across studies.

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