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Evaluation of the success rate, prosthesis-related quality of life, and satisfaction in patients undergoing rehabilitation with an implant-supported auricular prosthesis

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Abstract. The aim of this study was to evaluate the success rate, prosthesis-related quality of life (QoL), and satisfaction of patients undergoing rehabilitation with endosseous implants in the auricular region. This was a retrospective mixed cohort study involving 22 consecutive eligible patients (11 female, 11 male) with ear defects, treated during 1999–2019. The variables analysed were sex, age at the time of implant placement, date of last prosthesis delivery, level of education, aetiology of the deformity, and radiation history. The questionnaire results were analysed using IBM SPSS Statistics software. The correlation between QoL and satisfaction was evaluated using the Pearson correlation coefficient. Implant success was calculated clinically using the number of integrated implants, mobility, and presence of a purulent discharge. For the 22 patients, the mean duration since prosthesis placement was 10.2 ± 5.2 years. Among 47 implants inserted, one failed because of osseointegration failure. Hence, the overall success rate of the auricular implants was 97.9%. The mean ± standard deviation total QoL score and satisfaction score were 52.5 ± 7.10 (maximum possible score 80) and 42.1 ± 6.29 (maximum possible score 55), respectively. The results demonstrate the importance of prosthetic rehabilitation for improved patient QoL and satisfaction.

Keywords: Prostheses and implants; Maxillofacial prosthesis implantation; Rehabilitation; Quality of life; Satisfaction; Questionnaire.

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Facial appearance has great importance in human social interactions[1]. Cancer, congenital malformations, or trauma may cause extensive craniofacial defects that the individual cannot conceal due to exposure of the site. Therefore, such deficiencies impose severe functional and psychological stress on the affected individual[2]. Microtia is a congenital ear anomaly that varies widely in extent, from a mild structural anomaly to complete lack of the external ear (anotia)[3]. Facial deformity can reduce self-esteem and increase anxiety, and may lead to behavioural problems and withdrawal from society[4–6].

In the past, the use of a costochondral graft was the most common method for ear reconstruction. This requires several surgical procedures, performed by a highly skilled surgeon. Among the most important complications associated with this approach are donor site morbidity, visible scars and cartilage loss over time[7], pneumothorax, infection, cartilage framework exposure[8], and chest wall depression[9]. Prosthetic replacement of missing parts of the body can be an acceptable therapeutic alternative. The traditional methods for the retention of facial prostheses include adhesives, glasses, and soft and hard tissue undercuts[10]. In 1982, Brånemark and Albrektsson[11] introduced subcutaneous craniofacial implants for bone conduction hearing aids.

The aim of this study was to determine the success rate of extraoral implants used in external ear rehabilitation and to assess the satisfaction of patients who received this treatment and its impact on their quality of life (QoL).

Materials and methods

This retrospective mixed cohort study was conducted in the Oral and Maxillofacial Surgery Department, School of Dentistry, Tehran University of Medical Sciences. The study population was derived from all patients treated with an extraoral implant-supported auricular prosthesis for an ear deformity between 1999 and 2019.

Inclusion criteria were patient age ≥18 years, sufficient mental ability for implant care and sufficient literacy for completion of the questionnaires, and the patient had to have had the ear implant for at least 6 months. Exclusion criteria were the presence of any significant or recurrent disease, complex defects requiring multiple prostheses (ear, nose, eye), and non-completion of the treatment (implant insertion but no prosthesis).

Surgical methods

The patients included in this study underwent the following surgical processes: after determining the diagnosis and treatment plan, a computed tomography (CT) scan was taken to estimate the thickness of the temporal bone. The implants were inserted in two stages, with the second stage performed under local anaesthesia at an average interval of 4 months. Two or three extraoral short implants (3–5 mm) were inserted in the temporal bone in the ear site. These were pure titanium, self-tapping ITI implants with an SLA surface (sandblasted, large grit, acid-etched) (Institut Straumann AG, Basel, Switzerland).

The implants were located 20 mm away from the centre of the external auditory canal, at the 1 and 4 o'clock positions on the left side, and the 8 and 11 o'clock positions on the right side. The distance between implants was at least 15 mm, depending on the patient's condition[12]. Any remnants of the auricle were removed[13]. Furthermore, thinning of the subcutaneous tissue was performed to reduce skin mobility and eliminate hair follicles. To determine the correct location of the ear, an acrylic oral device was applied as a surgical template. In patients with a unilateral deformity, the location was determined according to the position of the opposite ear. In a patient with bilateral anotia due to a burn injury, the locations were based on anatomical facial landmarks (Fig. 1).

Since the main aim of this study was the evaluation of the success rate, QoL, and satisfaction of the patients who received auricular prostheses, complete details of the prosthesis and laboratory manufacturing steps are not addressed here.

Outcomes evaluation

The outcomes of this study were the auricular implant success rate, prosthesis-related QoL, and patient satisfaction. Auricular implant success was defined as implants in clinical function without any mobility or pain, and no signs of infection or pus discharge. To evaluate prosthesis-related QoL, a questionnaire was designed based on a review of the previous literature relevant to the current study and both the World Health Organization (WHO) Quality of Life-BREF (WHOQOL-BREF) and Glasgow Benefit Inventory (GBI) questionnaires. The items considered when designing the questionnaire were comfort, colour, fit, frequency of use, comfortable to keep clean, ease of installation and removal, aesthetics, reliability of retention, and value of the treatment (in terms of the psychological effect on the patient's life and the financial and time costs) .

The designed QoL part of the questionnaire consisted of 16 questions (questions 1–16 in Supplementary material Table S1). Each question was scored on a 5-point rating scale (1, very low; 2, low; 3, moderate; 4, high; 5, very high). The total possible score range was 16 to 80, with higher scores indicating higher QoL.

The patient satisfaction part of the questionnaire included 11 items (questions 17–27 in Supplementary material Table S1). Each item was scored on the same 5-point rating scale as used for the QoL questions, with the total possible score range being 11–55, and higher scores showing higher satisfaction.

The face validity (qualitative and quantitative) and content validity (qualitative and quantitative) of the questionnaires were considered, and the reliability of the questionnaire was assessed using the test–retest method.

To determine the qualitative content validity, the questionnaire was provided to five specialists in the field of oral and maxillofacial surgery at the School of Dentistry, Tehran University of Medical Sciences to assess the items included. The experts were asked to provide their written feedback and recommendations to modify each item in terms of grammar, use of appropriate words, placement of the items in the correct part, and scaling. Two methods were used to evaluate the quantitative content validity: the content validity ratio (CVR) and the content validity index (CVI).

To assess the relevancy and clarity of the items, the experts were asked to provide their opinions. Relevancy was assessed on a 4-point Likert scale as follows: 1 = not relevant, 2 = somewhat relevant, 3 = relevant but needs some revisions, 4 = relevant. Similarly, a 4-point Likert scale was used for clarity. The CVI was calculated as the number

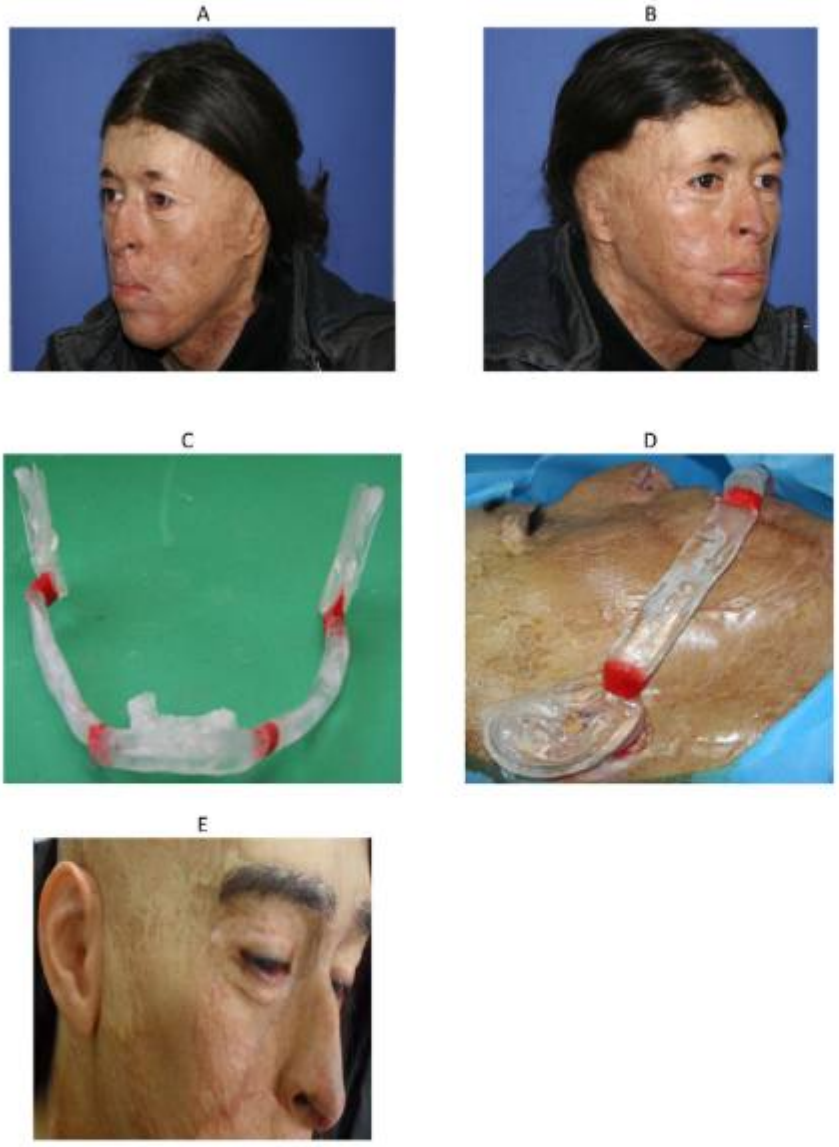

Fig. 1. The burn patient. (A, B) Preoperative lateral views. (C) Oral acrylic device to determine the correct positions of the prostheses. (D) Placement of the template. (E) Postoperative lateral view.

of specialists giving ratings of 3 or 4 for each item divided by the total number of specialists. If the CVI value of the item was above 0.78, the item was relevant, between 0.70 and 0.79, the item needed revisions, and if the value was below 0.70, the item was eliminated. To compute the CVR, a 3-point Likert scale was applied for how essential the item is: 1 = not essential, 2 = useful but not essential, 3 = essential. A Lawshe table was used to identify the critical value for CVR. Items with a computed CVR value above the critical value were considered to remain in the questionnaire.

To assess the qualitative face validity, the five specialists were interviewed about the level of difficulty, appropriateness, and ambiguity of the items. In the quantitative approach, respondents were asked to rate each item in the questionnaire as 'Not at all important', 'Slightly important', 'Fairly important', 'Important', or 'Very important'. Finally, the average rating given to each item was computed and multiplied by the percentage of respondents who considered that item 'important' or 'very important'. A score was calculated for each item. Items with a total score of less than 1.5 were removed from the set of items. Also, the questionnaire was given to three patients who were subsequently excluded from the study to evaluate the face validity of the questionnaire.

In addition, the demographic and clinical characteristics of the patients, including age at the time of implant placement, sex, level of education, date of last prosthesis delivery, aetiology of the deformity, and history of radiation to the treated field were recorded.

Statistical methods

The statistical analyses were performed using IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA). *P*-values less than 0.05 were considered statistically significant. All tests were two-sided. Quantitative variables were described using the mean ± standard deviation (SD). Qualitative data were summarized using the number and percentage. The Shapiro–Wilk test was applied to examine the normality assumption. The association between two quantitative variables was evaluated using the Pearson correlation test. A two-sample independent *t*-test was applied to compare mean values of continuous variables between two categories. The effects of predictors on patient QoL were assessed using multiple linear regression analysis with forward selection algorithm.

Results

Twenty-seven patients were eligible to be included in the current study. Three patients were randomly selected to assess the questionnaire validity and were subsequently excluded from the survey. One patient refused to participate in the study and another received the implants but was not motivated to complete the prosthetic therapy. Finally, 22 patients were recruited into the study. One burn patient received bilateral implants, two on each side (Fig. 1). Among the 21 patients with a unilateral deformity, 20 received two implants and one patient received three implants (Fig. 2).

The demographic and clinical characteristics of the study patients who underwent auricular rehabilitation are summarized in Table 1. The mean duration since prosthesis placement was 10.2 ± 5.2 years. Out of 47 auricular implants, one (2.1%) failed due to osseointegration failure. Thus, the success rate of the auricular implants was 97.9%.

The frequency distribution of the patients' responses to each item of the QoL and satisfaction questionnaires is

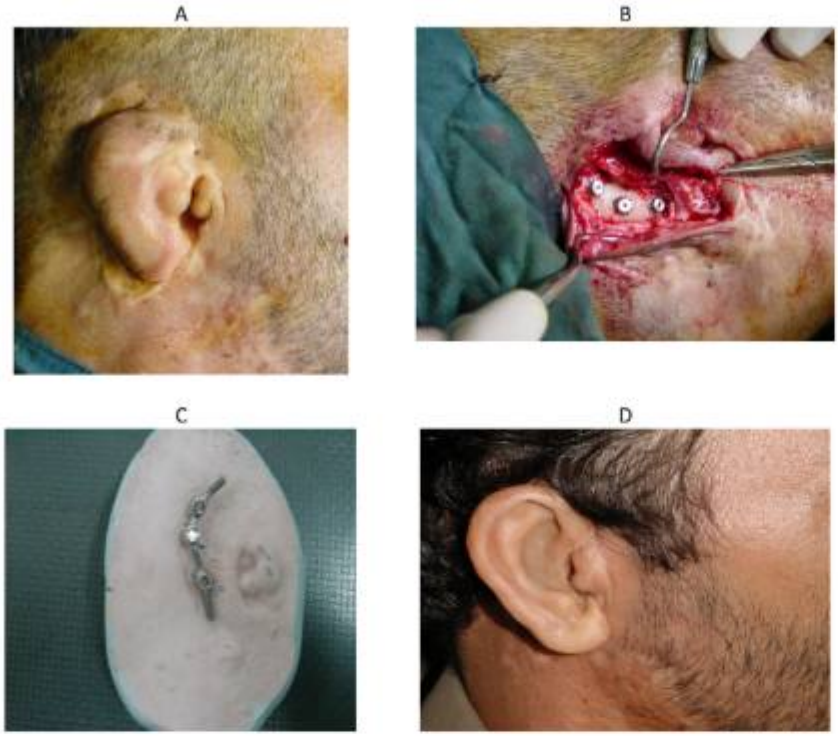

Fig. 2. (A) Presurgical photograph of a patient with a reconstructed right ear after multiple plastic surgery interventions; (B) implant insertion; (C) bar construction; and (D) the epithesis in situ.

Table 1. Summary of the demographic and clinical characteristics of the patients who underwent auricular rehabilitation.

Characteristics	Mean ± SD, or *n* (%)
Age, years	32.5 ± 6.7
Sex	
Male	11 (50%)
Female	11 (50%)
Level of education	
Illiterate	0 (0%)
No high school certificate	3 (14%)
High school diploma/certificate	8 (36%)
Bachelor degree	9 (41%)
Master degree or PhD	2 (9%)
Aetiology of the deformity	
Congenital	10 (45%)
Disease	5 (23%)
Trauma	5 (23%)
Burn	1 (5%)
Bite	1 (5%)
Duration of the prosthesis use, years	10.2 ± 5.2
Positive history of radiation to the treated field	1 (5%)

SD, standard deviation.

presented in Supplementary material Table S1. The mean ± SD total QoL score was 52.5 ± 7.10 (range 37–66; maximum possible score 80). The mean ± SD patient satisfaction score was 42.1 ± 6.29 (range 30–53; maximum possible score 55). There was a significant positive correlation between QoL and satisfaction scores (Pearson correlation test: $r = 0.61$, $P = 0.003$).

According to the Pearson correlation test, there was no significant association between the total QoL score and either age ($r = -0.08$, $P = 0.72$) or the duration of prosthesis use ($r = -0.28$, $P = 0.21$). Also, there was no significant difference in total QoL score between the male and female patients (*t*-test, 55.09 ± 6.70 and 49.91 ± 6.79, respectively; $P = 0.09$), between patients with an academic education (bachelor degree or higher) and those with a diploma/high school certificate (*t*-test, 54.73 ± 6.23 and 50.27 ± 7.48, respectively; $P = 0.14$), or between patients with congenital malformations and those with acquired malformations (*t*-test, 52.90 ± 6.23 and 52.17 ± 8.01, respectively; $P = 0.82$). The results of the multiple linear regression model that included sex and education status (with two categories, diploma/high school certificate vs academic education) as independent variables and the total QoL score as the dependent variable are summarized in Table 2.

No significant association was found between the patient satisfaction score and either age ($r = -0.17$, $P = 0.44$) or the duration of prosthesis use ($r = -0.10$, $P = 0.66$). Furthermore, no significant difference in patient satisfaction score was observed between the male and female patients (*t*-test, 41.82 ± 6.78 and 42.45 ± 6.07, respectively; $P = 0.82$), between patients with an academic education (bachelor degree or higher) and patients with a diploma/high school certificate (*t*-test, 42.36 ± 6.36 and 41.91 ± 6.52, respectively; $P = 0.87$), or between patients with congenital malformations and those with acquired malformations (*t*-test, 41.80 ± 6.42 and 42.42 ± 6.44, respectively; $P = 0.82$).

Discussion

The purpose of this research was to investigate the success rate of extraoral implants used in external ear rehabilitation, and to assess the satisfaction of patients who have received this treatment and its impact on their QoL. In addition, it was hypothesized that there would be correlations between implant success, satisfaction scores, and QoL scores. Therefore, specific aims of the study were to correlate important clinical variables with the success rate of auricular implants and their impact on QoL and satisfaction.

The overall success rate of the auricular implants over the 20-year study period was 97.9%. Several studies have reported that the success rate of extraoral implants is within the range of 40–100%[14–16]. Factors associated with success include the implant location, aetiology of the deformity, patient care of the prosthesis, patient acceptance, the quality and quantity of bone, and occurrence of any peri-implant soft

Table 2. Summary of the multiple linear regression analysis to determine the parameters predictive of quality of life.

Characteristics	Unstandardized coefficient	Standardized coefficient		*t*-statistic	*P*-value
		B	SE		
Sex Female vs male	0.41	5.63	2.74	2.06	0.05
Education Diploma vs academic	0.36	4.97	2.74	1.82	0.08

SE, standard error. Adjusted $R^2 = 0.19$.

tissue reaction. Studies have reported that the mastoid bone provides the best quality and volume of bone in the facial skeleton for achieving osseointegration[17,18].

Regarding the aetiology of the deformity, the current study found that congenital ear malformation was the most common (45%). Among the acquired injuries, the majority were caused by disease or trauma; there was only one patient with bite injury as the aetiology. Kolodzynski et al.[19], in their investigation of 105 patients with an acquired ear deformity, stated that the most frequent cause of the defect was bite injuries (23%). Moreover, a clinical audit study by Henry et al.[20] reported that the majority of facial injuries caused by human bites involved the ear. Although other studies have suggested that the incidence of microtia is two-fold higher in males than females[21,22], no difference in the prevalence of microtia was observed between the sexes in the present study; of the 10 patients with microtia, five were female and five were male. This may be due to the small sample size in this study. Unilateral microtia is more common than bilateral microtia and occurs in 79–93% of cases[23–25]; this was confirmed in the present study (all patients with microtia had the condition unilaterally).

Only one patient had received radiotherapy, and this did not affect the treatment success. However, taking into consideration the small population of this study, a relationship between radiation and treatment success cannot be reliably established. The success rate of implant-retained prostheses in the auricular and orbital region in patients who had undergone irradiation was reported to be 87.8% by Schoen et al.[26] In a systematic review of 70 publications, including 2355 patients and 8184 craniofacial implants, radiotherapy was found to be a significant factor in implant failure[27].

According to the statements of the current study patients, a significant reduction in many of the symptoms occurred following prosthetic replacement. The prosthesis improved their QoL, and only two patients continued to feel depressed and anxious about their prosthesis. Daily maintenance and keeping the prosthesis clean using a soft toothbrush and diluted 3% hydrogen peroxide are essential parts of the daily tasks. For 86.4% of the patients, regular cleaning was straightforward and did not require much time.

In research by Mevio et al.[28], all patients were pleased with their prosthesis during the 3-year follow-up. Furthermore, their statistical analysis showed a significant increase in the patients' QoL, and they resumed social communication and physical activity. The majority of the current study patients were satisfied with the appearance, convenience, and ease of use of their prostheses. They used their prostheses on average four times daily for an average of 8 h and 28 min, which is consistent with the results of other studies[14–16]. The prosthesis location is another factor affecting QoL; it has been observed that people who use auricular prostheses have a higher QoL than those with orbital and nasal prostheses[29], and also the greatest rate of satisfaction[30].

The QoL of patients with adhesive prostheses is lower than that of patients with implant-based ones[31]. Furthermore, the retention and stability of implant-supported prostheses are higher and they are often lighter, thereby improving psychosocial outcomes because of improved self-confidence[32].

In this study, three outcomes were examined. Although many clinical studies have already been conducted on the biological response to implant-retained auricular prostheses, less attention has been paid to the impact of the prosthesis on the patient's lifestyle and social integration. Accordingly, an attempt was made to address this issue in a comprehensive way. Regarding the limitations of this study, the inclusion of a control group of patients whose ears were reconstructed with a costochondral graft would have improved the analysis and interpretation of the results, as would a larger sample size.

In conclusion, the results of this study demonstrate the success of implant-supported auricular prostheses. The benefits of bone-anchored auricular prostheses for the patient are comfort, greater satisfaction, ease of positioning, improved retention, and improved quality of life. Some limitations of this study that could be addressed are the small sample size and lack of a control group, due to the low frequency of patients with congenital and acquired auricle loss referred to Tehran University of Medical Sciences. To allow statistically significant conclusions to be drawn, further studies with larger sample sizes are recommended.

Ethical approval

The Research Ethics Committee of Tehran University of Medical Sciences approved the study (approval no. IR.TUMS.DENTISTRY.REC.1398.021).

Patient consent

Obtained.

Funding

None.

Competing interests

None.

Declaration of Competing Interest

All of the authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ijom.2025.02.006.

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