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CLINICAL RESEARCH

Bar-clip versus magnet-retained auricular prostheses: A prospective clinical study with a 3-year follow-up

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With the absence or loss of an ear due to a congenital disorder, trauma, or malignant disease, an auricular prosthesis can be provided. In some patients, surgical ear reconstruction is an option, but this may be difficult, especially in burn victims or after oncological resections followed by radiotherapy. Even when 3D technology is used to fabricate a mold, the esthetic results are often disappointing.¹⁻³ Therefore, in most situations, silicone auricular prostheses are provided.

Auricular prostheses can be retained with skin adhesive or with extraoral implants. Although implant retention is generally preferred, the choice between adhesive and implants depends on technical and patient-related factors.^{4,5} Skin adhesives have disadvantages. Placing the prosthesis in the correct position can be difficult, the adhesives can dissolve leading to loss of retention, the skin, especially after radiation therapy, can

become irritated, and skin reactions can result from intolerance to components of the adhesive or the solvent.⁵

ABSTRACT

Statement of problem. Implant-retained auricular prostheses, on a bar-clip or with a magnetic retention system, are considered successful treatment for missing ears. However, which of these 2 retention systems is preferred by patients is unknown.

Purpose. The purpose of this clinical study was to assess which retention system is mostly preferred by patients wearing implant-retained auricular prostheses: bar-clip retention or magnetic retention.

Material and methods. All consecutive patients visiting the clinic between March 2014 and November 2014 for a routine follow-up of their implant-retained auricular prostheses on a bar-clip retention system were asked to enroll in this descriptive study comparing patient preference for the retention system: bar-clip versus magnets. Participants were asked to complete a questionnaire to obtain patient satisfaction scores regarding their auricular prosthesis before and 3 months after changing to a magnetic-retained auricular prosthesis. After 3 months, participants were asked to state their preference for either their previous bar-clip system or the new magnetic system. If they did not prefer the magnetic system, participants were able to return to their previous bar-clip system. The study follow-ups were performed at 6, 12, 24, and 36 months. Again, patient satisfaction was scored with the aid of the same questionnaire, and prosthetic care and aftercare were also assessed.

Results. Of 20 eligible patients, 17 participants (12 men, 5 women) enrolled in the study. The mean score for patient satisfaction for the bar-clip system at the start of the study was high (8 ± 1.62). After 3 months, 2 participants wanted to return to their previous bar-clip system, followed by 1 more at the 6-month evaluation and 2 more at the 1-year evaluation. After 3 years, 9 of 16 participants (57%) preferred the magnetic-retained auricular prosthesis. During the 3 years of follow-up, aftercare was considered minor for both the bar-clip and the magnetic system. No participants developed peri-implantitis. All participants indicated that cleaning and placing the magnetic-retained auricular prosthesis was easier than the bar-clip system.

Conclusions. The majority of the participants (59%) in this study, especially the elderly participants, preferred the magnetic retention system. When compared with the bar-clip system, no additional aftercare was needed. (*J Prosthet Dent* 2020;124:240-7)

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Clinical Implications

Until recently, magnetic retention systems for auricular prostheses have been considered inadequate because of poor retention. However, the new magnets for retaining auricular prostheses have provided a valid alternative to the bar-clip retention system. As magnetic and bar-clip systems have inherent advantages and disadvantages, clinicians can now choose the retention system that is best for the patient, taking frailty and technical properties, such as the available space for housing the retention system, into account.

Auricular prostheses retained on extraoral implants placed in the temporal bone were introduced in the 1970s.^{6,7} Advantages of implant retention relative to adhesives include easier maintenance of the prosthesis (no adhesives have to be applied or removed),^{5,6,8} easier placement of the prosthesis in the correct position (only 1 position is possible), and improved and more reliable retention.^{5,9,10} Moreover, with the development of digital technology, the planning and placement of extraoral implants has become safer, easier, and more predictable.¹¹ Today, implant-retained auricular prostheses are the treatment of choice for many clinicians.

Various systems have been used to attach the prosthesis to the implants, the most common being bar-clip retention and magnetic retention. For auricular prostheses, the bar-clip system is the most used retention system.¹² The most important benefit of the bar-clip system over the magnetic system might be its strong retention: patients can be confident that the retention of the prosthesis will not fail. The main drawback of the bar-clip system is the difficulty of maintaining good hygiene underneath the bar, which is important as inadequate hygiene can result in local irritation of the peri-implant tissue. Other potential disadvantages of the bar-clip system include difficulties in positioning the prosthesis, fracture of a retention clip, loss of retention force of the clip, fracture of the acrylic resin clip base, and detachment of the acrylic resin clip base from the silicone prosthesis.^{13,14}

Using magnets for retaining auricular prostheses could have several advantages over the bar-clip system such as easier cleaning and easier placement of the prosthesis. An additional technical advantage might be the option of placing the contra-magnets directly in the silicone material. With the bar-clip system, an acrylic resin base with clips is embedded in the silicone material. As a result, fabricating an implant-retained auricular prosthesis with magnets can be easier as it requires fewer technical steps. In the last few years, new types of

magnets have become available that are promoted as having better retention. However, magnets also have disadvantages, including less resistance to lateral movement, and detachment of the magnets in the silicone prosthesis may occur.

With respect to retention strength, skin connection, and the placement and maintenance of the prosthesis, the authors are unaware of studies on patient perspectives or preferences, and long-term results (3 years and above) are lacking. Therefore, the purpose of this clinical study was to assess which retention system is mostly preferred by patients wearing an implant-retained auricular prosthesis: the bar-clip system or the magnetic system. The null hypothesis was that the 2 systems would have similar patient preferences.

MATERIAL AND METHODS

The institutional review board provided a waiver (M14.150992) for this observational study of test subjects as defined in the Medical Research Involving Human Subjects Act. Written informed consent was obtained from all participants, and the study was performed in accordance with the Declaration of Helsinki.

Between March 2014 and November 2014, all consecutive patients who visited the clinic for oral and maxillofacial surgery and maxillofacial prosthodontics at the University Medical Center Groningen, the Netherlands for a routine follow-up inspection of their implant-retained auricular prosthesis on a bar-clip retention system were asked to participate in this study. Additional inclusion criteria were that the participants had worn their prosthesis for at least 3 years and had never had another type of retention system. Participants were asked whether they were willing to exchange their bar-clip retained auricular prosthesis (Fig. 1) for a magnetic-retained (2 magnets) auricular prosthesis (Fig. 2). All participants who enrolled in the study were satisfied with their implant-retained auricular prosthesis on a bar suprastructure; none enrolled because they were dissatisfied with their existing prosthesis. The participants were informed about the study and consented to participate because they were interested in a different system and because they wanted to help science. No other incentive, financial or otherwise, was involved.

All participants were provided with a magnetic-retained auricular prosthesis (2 magnets). After placing the magnetic-retained auricular prosthesis, participants were instructed on how to perform their daily peri-implant hygiene with the aid of a soft toothbrush. In addition, tools such as interdental brushes or a small shoestring were advised. A small shoestring was recommended as small shoestrings are firm and easy to handle and their surface is slightly rough and therefore able to remove skin debris around the abutments/

Figure 1. A, Intaglio of auricular prosthesis with bar-clip system. B, Bar suprastructure to retain auricular prosthesis with bar-clip system.

Figure 2. A, Backside of the silicone ear prosthesis with the clip retention in situ. B, Magnets to retain auricular prosthesis with magnetic retention system.

magnets. Furthermore, they can be washed and reused. As all participants had worn an implant-retained auricular prosthesis for at least 3 years, the participants were familiar with this information. During the recall visits in the clinic, the prosthesis, peri-implant health, and peri-implant self-care were evaluated.

Before the new auricular prosthesis with magnet retention was fabricated, patient satisfaction concerning their implant-retained auricular prosthesis on a bar-clip system was assessed with a questionnaire. This time point was referred to as T_0 . The questionnaire consisted

of 12 questions, including patient satisfaction with their auricular prosthesis in general, ease of placement or removal, satisfaction with fit, experience of maintaining peri-implant hygiene, retention of the auricular prosthesis, and their satisfaction with regard to esthetics (Table 1). The participants were requested to answer all questions using a 10-point scale according to a visual analog scale (VAS), in which 10 stands for excellent and 1 for very poor.

After 3 months (T_1), the participants were recalled, asked to complete the same questionnaire, and asked

Table 1. Questionnaire given to participants at T₀, T₁, T₂, T₃, T₄, and T₅

No.	Questions	Options for Answer
1	How satisfied are you with your current implant-retained auricular prosthesis?	Scale 1 to 10 (1=very poor, 10=excellent)
2	How satisfied are you with the fit of the implant-retained auricular prosthesis?	Scale 1 to 10 (1=very poor, 10=excellent)
3	How satisfied are you with the color of the implant-retained auricular prosthesis?	Scale 1 to 10 (1=very poor, 10=excellent)
4	How satisfied are you with the shape of your implant-retained auricular prosthesis?	Scale 1 to 10 (1=very poor, 10=excellent)
5	How satisfied are you with the retention of your implant-retained auricular prosthesis?	Scale 1 to 10 (1=very poor, 10=excellent)
6	How satisfied are you with the ease of placing the implant-retained auricular prosthesis in the correct position?	Scale 1 to 10 (1=very poor, 10=excellent)
7	How satisfied are you with the ease of removing the implant-retained auricular prosthesis?	Scale 1 to 10 (1=very poor, 10=excellent)
8	How satisfied are you with the ease of cleaning the skin around the implants?	Scale 1 to 10 (1=very poor, 10=excellent)
9	How satisfied are you with the ease of cleaning the prosthesis itself?	Scale 1 to 10 (1=very poor, 10=excellent)
10	How satisfied are you with the health of the skin around the implant?	Scale 1 to 10 (1=very poor, 10=excellent)
11	How satisfied are you with the life span of the implant-retained auricular prosthesis?	Scale 1 to 10 (1=very poor, 10=excellent)
12	Do you have any other remarks?	Open question
13	From T ₁ through T ₅ , question 12 was added) Which prosthesis do you prefer the most? A. The bar-retained prosthesis B. The magnetic retention prosthesis	A or B (A=bar-retained, B=magnetic-retained)

which retention system they preferred. If they were not satisfied with the fixation of the prosthesis on magnets, the participants returned to their previous bar-clip retention system. The original auricular prostheses and bars were retained to simplify replacement of the bar-clip system in that situation. Standard follow-up care was performed every 6 months. Evaluation for this study was performed at 6 months (T₂), 12 months (T₃), 24 months (T₄), and 36 months (T₅). During all follow-up visits, the participants were asked to complete the same questionnaire used at baseline (T₀). In addition, all prosthetic care and aftercare given between T₁ and T₅ was assessed. Prosthetic aftercare specifically related to the magnets was scored together with the need for repair of the magnets inside the auricular prostheses, fabrication of new prostheses, hygiene instructions, and tightening or loosening of magnets.

The condition of the peri-implant tissues was examined by clinicians (W.D.N., A.V.) before and after placing the magnets and new prosthesis. The condition was scored according to the Holgers classification¹⁵ on a 0 to 4 scale: 0, healthy with no irritation; 1, slight redness; 2, red and slightly moist tissue; 3, redness and moist tissue; 4, infection removal abutment required.

Participants considered for inclusion in this study had been provided at least 3 years previously with 3- to 4-mm-long extraoral implants with an external flange and

Figure 3. Acrylic resin base with magnets to be embedded in silicone auricular prosthesis.

4.0-mm diameter (Entific Medical Systems Co Ltd) to retain their auricular prosthesis on a bar-clip system (Fig. 1). The prosthetic treatment consisted of replacing the bar-clip retention system with a magnetic retention system. This procedure was performed by the same experienced maxillofacial prosthodontist (W.D.N.).

At the first appointment, the bar was removed from the implants. A duplicate prosthesis was made in wax by using the original mold as described by Visser et al.¹³ The wax prosthesis was fitted to the auricular region and modified if needed. Next, impression posts were placed on the implants, and after perforating the wax ear at the desired location for the magnets in the auricular prosthesis, an impression was made with the wax ear in the correct position. A new auricular prosthesis in wax was made as a trial wax model to fit on the planned magnetic abutments. At the trial session, the existing bar was unscrewed from the implants, and the new magnets were placed on the implants so that the trial wax model with magnetic retention could be fitted. If the fit of the prosthesis was satisfactory, a new mold for fabricating an auricular prosthesis with magnets was made. After fitting the wax model with magnets, the magnets were removed, and the bar was replaced until the new prosthesis was ready. Color matching of the new silicone prosthesis was achieved with the aid of a digital skin color measurement system (E-skin system; Spectromatch Co Ltd). Inside the silicone prosthesis, maxi lip (ML3-S) and auricular magnets (MLL2-OR-S) were incorporated (Technovent Co Ltd). Auricular magnacap magnets from the S-range (BMC2-OR-S) (Technovent Ltd.) were placed. According to the manufacturer, the maxi lip magnet provides extra stability against external displacement forces. To ensure that the magnets would not release from the silicone prostheses, they were embedded in an acrylic resin carrier (Fig. 3) and connected to the silicone material by using a silicone reline

Table 2. Overview of all included participants and main results of evaluation at T₁, T₂, T₃, T₄, and T₅

Sex, Men/ Women	Age at the Start of Study in years	Cause of Defect	Number of Implants	Experience With Bar- Clips in years	Overall Satisfaction With Bar-Clips at T0	Overall Satisfaction With Magnets T1	Overall Satisfaction With Magnets T2	Satisfaction Retention With Bar-Clips at T0	Satisfaction Retention With Magnets at T5
M	23	Con	2	5	9	7	6	6	4
M	25	Con	2x2	14	8	8	8	9	8
M	25	Con	2	16	8	9	10	9	8
M	30	Con	2	14	5	7	6	7	4
W	39	Con	2	17	3	1	n.a	5	n.a
M	43	Con	2	12	8	n.a	n.a	9	n.a
M	44	Con	2	15	8	8	8	8	8
M	47	Trau	2	15	8	9	8	6	3
M	48	Con	2	14	8	8	10	7	8
M	49	Onc	2	3	7	6	7	6	4
M	49	Con	3	20	8	8	8	6	6
W	57	Con	3	18	9	10	10	9	9
W	58	Con	2	13	7	9	9	8	7
M	59	Onc	3	19	7	9	8	8	8
W	59	Trau	2	19	7	9	5	7	8
W	78	Onc	2	13	10	7	10	10	8
M	80	Onc	2	13	9	9	8	8	8

BC, bar-clip; Con, congenital; M, man; Ma, magnets; n.a, not applicable; Onc, oncology; Trau, trauma; W, woman.

Table 3. Overview of participants who returned back from magnetic retention system to bar-clip retention system at T₁, T₂, T₃, T₄, and T₅

T ₀ start of study	17 part start with magnets
T ₁ 3 months	2 part returned back 15 part left with magnets
T ₂ 6 months	1 part returned back 14 part left with magnets
T ₃ 1 year	2 part returned back 12 part left with magnets
T ₄ 2 years	2 part returned back 10 part left with magnets
T ₅ 3 years	0 part returned back 10 part left with magnets

Part, participants.

material (Mucopren; Kettenbach GmbH & Co). Before the application of the silicone material into the mold, the reline material was placed on the clean and dry acrylic resin carrier. The mold was then closed and processed as usual. According to the instructions of the manufacturer, O-rings were placed in the prosthesis after completion of the fabrication process. After the auricular prosthesis had been fabricated, the bar suprastructure was removed, and the magnets with the new auricular prosthesis were placed. For each participant, all molds and bar suprastructures were retained so that if participants wanted to change their suprastructure or needed a repair, all materials were available.

RESULTS

In total, 17 (12 men and 5 woman) of 20 eligible patients with implant-retained auricular prostheses agreed to participate in the study. Reasons for not participating were lack of interest due to long travel distance (n=2) and

severe mobility problems (n=1). At the 3-year time point, 1 participant was lost to follow-up (died due to cancer unrelated to the implant-retained auricular prosthesis). Median age of the participants at the start of the study was 44 years (interquartile range 16.7; range 23 to 79 years). The median time of wearing an implant-retained auricular prosthesis at the start of the study was 14 years (interquartile range 4, 5; range 3 to 20 years) (Table 2). Absence of 1 ear (16 participants) or 2 ears (1 participant) was due to oncologic reasons (n=4), trauma (n=2), or congenital problems (n=11). None of the oncological participants had been treated with radiotherapy. As shown in Table 2, none of the participants had motor or visual disabilities, and most of the bars were anchored on 2 implants (n=16).

As shown in Table 2, the overall patient satisfaction with the implant-retained auricular prosthesis on a bar-clip system at baseline was relatively high on average: 8.0 on a 10-point scale. Three months after replacing the bar-clip system with the magnetic retention system, the average satisfaction score increased slightly from 7.6 for the bar-clip retention system to 7.8 in favor of the magnetic retention system. Although almost all participants were very satisfied, 1 participant indicated at the T₁ evaluation that he was very dissatisfied with the magnets, giving the magnets a score of 1. He stated that he could not get used to the magnets and felt insecure with his new magnetic-retained auricular prosthesis. He therefore decided to return to his bar-clip system at T₁. Another reason given by one of the participants for returning (Table 3) was a slight increase in subjective skin

Table 2. (Continued) Overview of all included participants and main results of evaluation at T₁, T₂, T₃, T₄, and T₅

Satisfaction With Daily Maintenance Bar-Clip	Satisfaction With Daily Maintenance Magnets at T1	Skin Condition Bar-Clips at T0	Skin Condition Magnets at T1	Skin Condition Magnets at T2	Patient's Preference at T1	Patient's Preference at T2	Patient's Preference at T3	Patient's Preference at T4
9	8	1	1	1	Ma	Ma	BC	BC
5	9	1	2	0	Ma	Ma	Ma	Ma
8	9	1	0	0	Ma	Ma	Ma	Ma
5	3	3	2	1	Ma	BC	BC	BC
1	1	1	1	n.a	BC	BC	BC	BC
7	n.a	1	0	n.a	BC	BC	BC	BC
6	9	1	0	0	Ma	Ma	Ma	BC
5	9	1	0	0	Ma	Ma	Ma	BC
7	9	1	0	0	Ma	Ma	Ma	Ma
7	8	0	1	1	Ma	Ma	BC	BC
6	7	1	1	2	Ma	Ma	Ma	Ma
8	9	0	0	0	Ma	Ma	Ma	Ma
8	9	0	0	0	Ma	Ma	Ma	Ma
6	7	1	1	1	Ma	Ma	Ma	Ma
7	10	2	0	2	Ma	Ma	Ma	Ma
4	5	0	0	0	Ma	Ma	Ma	Ma
9	7	0	0	0	Ma	Ma	Ma	Ma

irritation around the magnetic abutments (Table 2). During the 3-year follow-up, 7 of the 17 participants returned to the bar-clip system (43%) (Table 3). After 2 years, however, no additional participants returned. Participants who returned to the bar-clip system were generally younger than those who stayed with the magnets (Table 2).

During the 3-year follow-up, only mild peri-implant skin problems were seen, and the skin could be cleaned easily. The Holger score¹⁵ for the most severe skin reaction was 2 (Table 2). Skin tissue and peri-implant health was good (Holger score 0 to 2) at the start of the study and did not change during the evaluation period. All participants were able to clean the skin effectively. Furthermore, prosthetic maintenance during the follow-up was minor and consisted of standard evaluations every 6 months. In 8 participants, renewal of the rubber O-rings inside the Magnacap of the prosthesis was needed, which was a straightforward chairside procedure. None of the prostheses had to be replaced because of technical problems with the magnetic retention system. The only reason for replacing the prosthesis was discoloration of the silicone material, which is normal for such prostheses, given the average life span of 1.5 to 2 years.¹³

DISCUSSION

The purpose of this study was to assess which retention system was preferred by most patients wearing an implant-retained auricular prosthesis: the bar-clip

retention system or retention with the aid of magnets. The null hypothesis of this study was that the both systems would have similar patient preferences. The null hypothesis was rejected as most participants (59%) favored magnets.

In 2008, de Sousa and Mattos¹⁶ also compared the bar-clip system with the magnetic system. Owing to the lack of retention of the magnets, the bar-clip system in their study was evaluated as the retention system of first choice. More recently, Sigua-Rodriguez et al¹⁷ compared 3 retention systems for auricular prostheses: the bar-clip system with a retention strength of (29.60 N), the ball/O-ring system (9.41 N), and the magnetic system (8.61 N).¹⁷ Based on the retention strength, they concurred with de Sousa and Mattos¹⁶ that the bar-clip retention was the best treatment option. However, earlier magnets did not have the high-quality retention forces of the magnets used for the present study. In addition, measuring technical retention forces in the laboratory, as was done by researchers such as Rodriguez et al,¹⁷ might give the impression that the bar-clip system is preferable. However, the best retention system for the patient should be considered as a mix of technical and mechanical properties, and the individual circumstances of the patient such as age, manual ability, and level of activity daily life (ADL) should be taken into account.¹² No recent clinical studies were found that compared bar-clip retention systems with the recently introduced magnets that were used in this study. Furthermore, the authors are unaware of any other study that assessed long-term

(≥ 1 year) patient satisfaction. Previously, the magnetic system was not popular for retaining an auricular prosthesis as the retention strength was usually limited or even poor. However, in the past few years, new magnets with an additional O-ring lock attachment have become available with substantially more stability and retention, possibly leading to patient satisfaction scores equal those for the bar-clip systems, as found in the present study. Especially, the older participants in this study preferred the magnetic retention system (Table 2). These elderly individuals indicated that the retention was adequate and that maintenance and placement of the magnetic prostheses was much easier than the bar-clip system. Their magnetic-retained auricular prosthesis was easier to remove, making this system ideal for patients suffering from sarcopenia. In addition, magnets are easier to clean, which can help patients with visual or manual handicaps. The participants who returned to the bar-clip retention were all relatively young (Table 2) and had a more active lifestyle.

These new magnets with an O-ring lock attachment have disadvantages. First, the higher retention strength of the new magnets can cause rupture of the silicone prosthesis when the magnets are bonded directly into the silicone material instead of being placed in an acrylic resin base. Therefore, in this study, the magnets were not directly bonded into the silicone prosthesis but into an acrylic resin base before being embedded in the prosthesis. Second, the position, number, and angulation of the extraoral implants greatly influenced the retentive strength and stability of the prosthesis. Because the magnets have a large diameter, fabricating an implant-retained auricular prosthesis on 3 magnets is difficult when 3 implants are situated close to each other, which often happens in the small region beneath an auricular prosthesis. When the angulation of the implants is excessive or the implants are placed too deep, the O-ring lock inside the Magnacap in the auricular prosthesis will not snap onto the magnetic abutment, resulting in significantly lower retention forces. Therefore, the magnetic abutment must be placed at least 2 mm above the skin, and placing more than 2 implants is not advisable when using a magnetic retention system to retain the auricular prosthesis. Third, clinicians should take the jaw movements of the patient into account when planning the location of the implants, as large jaw movements can dislocate a magnetic-retained auricular prosthesis.

A strength of this study was that the 17 participants of different ages all had substantial experience (at least 3 years) in wearing an implant-retained auricular prosthesis with a bar-clip system and were, therefore, able to compare both systems well. A second strength was that all participants were followed up for 3 years and were all treated by the same experienced maxillofacial team with

the same materials. A limitation was that 17 participants is a relatively small group. However, this study was the first of its kind, and when compared with other studies in the field of maxillofacial auricular prosthesis, 17 participants is a relatively large group. Most other studies on maxillofacial auricular prostheses have been published as case reports or with an even smaller group size.¹⁷ Designing a study with a larger group requires a multicenter approach, which also has challenges and limitations.

CONCLUSIONS

Based on the findings of this clinical study, the following conclusions were drawn:

1. Most of the participants (59%), especially the elderly participants, preferred the magnetic retention system.
2. When compared with the bar-clip system, no additional aftercare was needed for the magnetic retention system.
3. Advantages of the magnets included the ease of placing and removing the prosthesis and cleaning the peri-implant skin.
4. The lower retention forces of the magnets compared with those of the bar-clip system was a disadvantage, especially for the younger participants in this study.
5. The choice for a bar-clip or magnetic-retained auricular prosthesis is therefore an individual choice; both systems are good treatment options with inherent strengths and limitations.

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