ORIGINAL PAPER

Nagoya J. Med. Sci. 67. 109 ~ 116, 2005

LONG-TERM RESULTS OF OSSEOINTEGRATED IMPLANT-RETAINED FACIAL PROSTHESES: A 5-YEAR RETROSPECTIVE STUDY

MASAKI J. HONDA¹, TAKASHI HATANAKA², YASUHIRO OKAZAKI¹ and MINORU UEDA¹

> ¹Department of Oral and Maxillofacial Surgery, Nagoya University Post Graduate School of Medicine, 65 Tsuruma-cho, Showa-ku, Nagoya 466-8550, Japan ²Oral Maxillofacial Surgery, Nakatsugawa Manicipal Central Hospital, 1522-1, Komanba, Nakatsugawa, Gifu 508-0011, Japan

SUMMARY

In this study a questionnaire survey was prepared and distributed to patients who had been fitted with a facial prosthesis at least 5 years earlier, with the aim of: 1) reviewing the implants statistically, and 2) examining psychological changes before and after the use of an implant-supported prosthesis. Twelve patients had been fitted with implant-supported prostheses that had a survival rate of 97.5% after 5 years. To examine psychological changes, the patients were given the Cornell Medical Index-Health Questionnaire (CMI) and a questionnaire we originally developed. Eight of the 12 responded to the questionnaire. The CMI results from those 8 patients confirmed that none of them had sustained any emotional impairment. Our results revealed that, although the patients wore their prosthesis both indoors and out, eyeglasses were still necessary. However, wearing the prosthesis lessened the psychological impact of the facial defect, while also easing anxiety with regard to interpersonal relations.

Key Words: Osseointegrated implants, Prosthesis, Cornell Medical Index Health Questionnaire, Psychological evaluation

INTRODUCTION

The face is the most noticeable part of the body, and many patients who suffer facial tissue defects as a result of malignant tumor resection or trauma may have, in addition to their functional impairments, an impaired social life stemming from esthetic problems. The esthetic repair of facial tissue defects, therefore, contributes greatly to improving such patients' quality of life (QOL), making the issue of reconstruction methods a critical one.

Prostheses using artificial materials are known to be effective in facial reconstruction that requires the restoration of fine morphology, as they can be molded into intricate shapes. They can also be used for a wide range of conditions because of the excellent color tone and texture that can be reproduced. However, facial prostheses have conventionally been anchored by the

Corresponding author: Masaki J. Honda, DDS, PhD

Address: Division of Stem Cell Engineering, The Institute of Medical Science, The University of Tokyo 4-6-1 Shirokanedai Minatoku, Tokyo 108-8639, Japan

Phone: 81-3-5449-5120 Fax: 81-3-5449-5121 E-mail: honda-m@ims.u-tokyo.ac.jp

application of adhesives or two-sided tape, and skin irritation from the adhesives or natural displacement caused by a lack of retentive strength have been problematic. Osseointegrated implants have recently come to be used as anchors for facial prostheses, and there are many reports on greatly increased retentive strength as well as on the utility of these implants.¹⁻⁴ However, there are currently few reported assessments or investigations from the user's viewpoint on the level of satisfaction and the effects on social life of patients for whom prostheses were used in reconstruction. Since 1990, implant-retained prostheses have been used at the Department of Oral and Maxillofacial Surgery of the Nagoya University School of Medicine not only orbital defects⁵⁻⁶ but for nasal and auricular defects as well. We reviewed the clinical observations of implants that had been placed as supports for prostheses more than 5 years earlier, and conducted a survey of patient attitudes using the Cornell Medical Index Questionnaire (CMI)⁷⁻¹⁰ and a questionnaire we originally developed for a psychological assessment of patients with respect to wearing their prostheses.

MATERIALS AND METHODS

The subjects included 8 males and 4 females who had undergone an operation for implant installation at the Department of Oral and Maxillofacial Surgery of the Nagoya University Hospital, and who had been wearing a facial prosthesis with an implant and magnetic abutment supports (implant-retained prosthesis) for more than 5 years. Their ages ranged from 22 to 72 years, with a mean age of 56.0 years. The defect was in the orbital region in 8 patients, the auricular region in 3, and the nasal region in 1. Nine patients had undergone reconstruction following a malignant tumor resection and 3 following trauma, the defect in the latter 3 was in the auricular region (Table 1). The observation period after the patients had received their implant-retained prosthesis ranged from 5 years 2 months to 12 years 11 months, with a mean of 8 years 9 months (Table 2).

The Brånemark System® from Nobel Biocare was used for the osseointegrated implants. Use of the fixtures employed in this study in the orbital, nasal, and auricular regions was approved

Table 1 Data on patients treated with implants								
Case	Age (year)	Sex	Disease	Region	Radiation (Gy)	Time of implant installation (years, months)		
1.	46	F	Trauma	auricula	(-)	1y 5m after trauma		
2.	64	М	S.C.C.**	orbit	(-)	3y 4m after t.r.*		
3.	66	М	S.C.C.	orbit	50.4	10y 6m after t.r.*		
4.	46	М	A.C.C.***	orbit	(-)	2y 11m after t.r.*		
5.	22	F	Trauma	auricula	(-)	1y 6m after trauma		
6.	57	М	A.C.****	orbit	60.0	simultaneously with t.r.		
7.	46	М	A.C.	orbit	40.0	simultaneously with t.r.		
8.	57	F	A.C.C.	orbit	(-)	simultaneously with t.r.		
9.	59	F	Trauma	auricula	(-)	9m after trauma		
10.	64	М	Basalioma	midfacial	(-)	7m after t.r.*		
11.	72	М	M.L.*****	orbit	(-)	1y 2m after t.r.		
12.	68	М	S.C.C.	orbit	40.0	simultaneously with t.r.		

 Table 1
 Data on patients treated with implants

*: tumor resection **: squamouscell carcinoma ***: adenocystic carcinoma ****: malignant lymphoma

5 YEAR STUDY OF MAXILLOFACIAL IMPLANTS

					F	~
Case	Follow-up	Length of implants	No. of implants	No. of lost implants	Time until 1st ope from tumor surgery	Time until 2nd ope from 1st ope
1	12y 11m	3 mm	3	0	10y 6m	8m
2	12y 2m	4 mm	3	0	3y 4m	11m
3	11y Om	4 mm	3	0	simultaneous	6m
4	11y 0m	4 mm	3	0	simultaneous	6m
5	9y 4m	3 mm	3	0	1y 2m	9m
6	9y 7m	4 mm	4	1	1y 3m	14m
7	7y 7m	4 mm	2	2 (sleep)	9m	7m
		7 mm	2	0		
8	7y 4m	7 mm	4	2 (sleep)	simultaneous 25m	
9	6y 10m	3 mm	3	0	simultaneous	8m
10	6y 9m	7 mm	4	0	2y 11m	9m
11	5y 4m	3 mm	3	0	1y 6m	6m
12	5y 2m	7 mm	2	0	1y 5m	7m

 Table 2
 Data on case treated with implants-retained prostheses

Table 3-A Questions Group I (survey of attitudes among prosthesis patients)

- What substitution did you use before you began using your current prosthesis? gauze: 4 adhesive prosthesis: 2 no prosthesis: 2
- Which feel more comfortable your current prosthesis or the one you used before? current prosthesis: 7 nothing: 1 gauze: 0 adhesive prosthesis: 2
- 3) Which is easier to put on and take off the prosthesis you are currently using or the one you used before?
 - current prosthesis: 7 no prosthesis: 1
- 4) Are you more comfortable facing others when wearing your current prosthesis or the one you used before?

current prosthesis: 7 no prosthesis: 1

Table 3-B Questions Group II (Survey of attitudes among prosthesis patients)

1)	Have you psychologically accepted the fact that you have lost a part of your face?			YES:	6	NO: 2	
2)	From your viewpoint, have the people close to you (family, friends, etc.) accepted that fact?			YES:	5	NO: 3	
3)	Do you wear your prosthesis when going out in public?	YES:	5	SOME	ETI	MES: 2	NO: 1
4)	Do you wear glasses, a hat, sunglasses or other items in addition to your prosthesis when going out?			YES:	7	NO: 1	
5)	Compared with the time before your facial appear- ance changed, did you go out more or less often in the period from the time your appearance changed until you began wearing your present prosthesis?		M	ORE:	5	LESS: 3	i
6)	Have you gone out more or less often since you began wearing your present prosthesis?		M	ORE:	4	LESS: 4	
7)	Do you wear your prosthesis at home?			YES:	6	NO: 2	

Fable	4	QuestionGroup	III.
--------------	---	---------------	------

Taking your status before you lost part of your face as 100, how do you rate your current level of satisfaction? Please respond for each of the following items: shape, color tone, feeling when wearing the prosthesis, functionality, handling method, psychological aspects.

Case	Shape (%)	Color (%)	Feeling (%)	Handling (%)	Psychology (%)	Average (%)
1	80	80	80	80	80	80
2	80	70	80	80	80	78
3	90	90	95	95	90	92
5	90	90	100	100	100	96
6	80	80	80	60	60	72
10	50	50	50	50	0	40
11	80	70	70	80	70	74
12	70	60	70	80	80	72
Average	77.5	73.8	80.8	78.1	70.0	75.5

by the Nagoya University Ethics Committee, and consent was obtained from all patients after it had been explained to them that this was a new procedure not formally yet approved by the Japanese Ministry of Health, Labor and Welfare.

All the fixtures used in this study had a diameter of 3.75 mm. Table 2 shows the fixture length, location and number of implants, observation period from time of facial tissue defect until primary surgery, and healing period from primary surgery until secondary surgery.

Two questionnaire surveys were conducted to investigate the psychological impacts of their facial tissue defects, and to determine their attitudes toward wearing the prosthesis. Responses were received from 8 of the 12 patients. Four patients rejected participation in the psychological investigation due to the inconvenience involved. The other 8 patients included 5 with orbital prostheses, 2 with auricular prostheses, and 1 with a nasal prosthesis.

The CMI was used to screen patients for emotional impairment.⁷⁻¹⁰⁾ Following an interview, an originally developed questionnaire (survey of attitudes toward prosthesis; Table 3.4) was completed by each patient in a separate room without a physician present. This was a self-completed questionnaire consisting of 12 questions in 3 groups. Group I consisted of 4 questions designed to compare the implant-retained prosthesis with one the subject had worn previously, so that we might investigate the utility of the implant-retained prosthesis (Table 3-A). Group II consisted of 7 questions related to appearing in public, which we used to investigated whether their appearance had been satisfactorily restored with use of the implant-retained prosthesis, resulting in their patient's social life (Table 3-B). Group III featured a single question in which individual items were scored, allowing us to assess the level of satisfaction with the implant-retained prosthesis. The maximum score was 100, and the minimum 0 (Table 4).

RESULTS

A total of 40 osseointegrated implants were placed in the facial region of the 12 patients. The lengths were 3 mm for 6 implants, 4 mm for 6, 7 mm for 6, and 10 mm for 6. The individual implants varied from subject to subject, depending on the bone width and depth at each site. The implants were placed according to the manufacturer's guidelines in a 2-stage process. One

implant failed leaving an implant-survival rate of 97.5%. The implants included 17 in the superior border of the orbit, 9 in the inferior border of the orbit, 9 in the temporal bone posterior to the external acoustic meatus, 2 in the maxilla at the base of the nose, 1 in the medial border of the orbit, and 1 in the lateral border of the orbit. The implant that failed was the one placed in the medial border of the orbit. In the superstructure of the prostheses, the respective abutments were connected to metal frames including samarium cobalt magnetic attachments, and each prosthesis was retained by magnetic force. The mean number of attachments used in each case was 2.5, and their magnetic force was 660 gw per attachment.

One complication that occurred in all cases during use of the implant-retained prostheses was a change in the color tone, which had to be corrected once a year. Another complication observed was the loss of eyebrows, which had to be reimplanted. However, there were no cases in which the prosthesis had to be remade.

Results of the questionnaires were as follows.

CMI responses were assessed according to the judgment criteria of Fukamachi.¹¹) Six subjects were judged to belong in Group I, and 2 in Group II. These results indicate that none of the subjects were suffering emotional impairment due to their facial-tissue defect. In response to a question in Group I asking what device subjects had used before the present implant-retained prosthesis, 4 of the 8 subjects answered that they concealed the defect with gauze, and 2 used a paste adhesive-type prosthesis.¹⁴ Two patients with auricular defects used nothing. In a comparison between gauze or paste adhesive-type prostheses and the implant supported prostheses, 1 auricular patient failed to notice any difference. All other subjects responded that the implant-retained prosthesis was superior on all questioned items, including those on the comfort of the prosthesis when worn, ease of attachment and removal, and comfort level during face-to-face contact with others. The above-mentioned auricular-defect patient refused to use any prosthesis even after these items had been shown to him.

Among patients in Group II on the survey of prosthesis patients' attitudes, when asked "Do you wear the prosthesis when you go out", 5 responded that they always did, 2 that they sometimes did, and 1 that he did not. In response to the question of whether patients with orbital or nasal prostheses wore eyeglasses when they went out, all 6 responded that they did. Two patients with an auricular defect responded that they concealed their prosthesis with their hair. To the question on how often they went out, 3 responded that they went out just as often during the period from the time they sustained the facial defect until the time they first wore an implant-retained prosthesis as they had before they sustained the facial defect. The other 5 answered that there had been a decrease in the number of times they went out. Four of these 5, however, responded that the frequency with which they went out increased again after they began wearing the prosthesis. The reason they gave was that, before receiving the prosthesis, they themselves could not psychologically accept their facial defect. After being fitted with the prosthesis, they came to accept the reality of their facial defect as well of the underlying disease itself. They also answered that they thought the prosthesis had changed the way their families regarded them. Three patients complained of the prosthesis coming loose due to an unforeseen impact.

One subject reported that even after receiving the prosthesis he did not go out as often as before because he could not psychologically accept his facial defect. He mentioned that he also felt his family seemed unable to accept it. The responses of this patient with regard to level of satisfaction with all aspects of the prosthesis was the lowest of all the respondents, with a mean satisfaction rate of 40% (Table 4).

The 3 subjects who reported no change in how often they went out after sustaining their facial defect responded that they had psychologically accepted the reality of their facial appearance,

as did their families. In response to the question on whether they wore their prostheses inside the home, 6 said that they did and 2 that they did not.

Results of the attitude survey of the prosthesis patients are shown in Table 4.

DISCUSSION

Use of implants in the facial region

The mean follow-up observation period of the facial osseointegrated implants described herein was 8 years 9 months, and the implant survival rate was 97.5%. Those findings were not inferior to past data on osseointegrated implants applied to the facial region.¹⁻⁴⁾ The reason that the one implant failed is thought to be that it did not achieve sufficient integration in the early stages.

The most appropriate placement of fixtures in patients who have ophthalmic content defects is considered to be the bone of the superior border of the orbit.^{12,13} In addition, depending on the individual patient, it is also possible to place fixtures in the maxilla or zygomatic bone in the region of the inferior border of the orbit, as well as in the zygomatic bone of the lateral orbit. Moreover, depending on the shape of the frontal sinus, it may also be possible to place a fixture 7 mm in length in the superior border area. Fixture locations for patients with auricular or nasal defects are determined on the basis of 3-dimensional CT, plain CT, and facial PA radiograph images. However, it is necessary to consider the design of the prosthesis when deciding on implant locations. Since it is necessary to keep the abutment within the edges of the prosthesis, the thickness to be restored by the prosthesis as well as the direction and length of the abutment pose important problems to be considered. Therefore, the fixture implant position cannot be determined by the bone thickness alone. In the present cases, at locations determined in this way, the bone was assessed by the torque present at the time the fixture was inserted. The bone in all implant locations was Class II or above,¹⁵⁻¹⁷⁾ and good integration of the fixture in the early stages was one factor in the high success rate. However, since the patients were so few in number, this factor will need further investigation in the future.

Manipulability of prosthesis

In all 12 cases presented herein the abutment and metal frame, including a samarium cobalt magnetic abutment, were fastened with screws. In the orbital and auricular prostheses the metal frame and main body of the prosthesis were attached using a minimum of 2 such attachments, so that the retentive force was 1.32 kgw or above. For the nasal prosthesis 4 of those same attachments were used for a retentive force of 2.64 kgw. Using these levels of retentive force, no detachment of the prosthesis was experienced in normal daily life. Conventionally, prostheses were supported by two-sided tape, but this proved unsatisfactory because it supplied insufficient retentive force and caused skin irritation or other conditions. Many advantages were gained by fixation of the prosthesis using magnetic abutments with implants as supports. The first advantage was a lower frequency of detachments as a result of enhanced retentive strength. We also learned from the present survey that prostheses retained with adhesives would often become detached without the user being aware of it. The second advantage was that the prosthesis could be attached with high precision in the area of the facial defect, this, however, required that the magnets be precisely aligned. Thus, the prosthesis was always attached in the same position, i.e., precise by in the center of the face. The third advantage was that there was no longer any skin irritation from adhesive agents, making it possible to wear the prosthesis for long periods. The final advantage was that the edges of the prosthesis could be made thinner for improved aesthetics due to the elimination of the adhesive tabs in places where they had to be previously

that from sneezing, indicating that some patients required an even stronger retentive force.

applied. This also made the prosthesis lighter, so that it was less likely to slip out of position. However, 3 patients complained of the prosthesis coming off due to a sudden exertion, such as

Changes in patient attitudes after being fitted with a implant-retained prosthesis

Seven of the 8 subjects responded that they wore their prosthesis when appearing in public. The one patient who did not do so had an auricular defect, and said that his hair rendered the prosthesis unnoticeable and that attaching it was bothersome. Two patients who reported going out less often after sustaining their facial defect said they ventured out more often after receiving the implant-retained prosthesis. These results indicate that wearing the prosthesis improved their former esthetic appearance lost due to the facial defect, and decreased their anxiety with regard to interpersonal relationships that resulted from the esthetic damage. In addition, patients were able to accept their facial defect thanks to the implant-retained prosthesis, and noted favorable changes their attitude toward the people around them, including family and friends. Thus, treatment with the implant-supported prosthesis is thought to have eased their psychological impairment. It was clear to us that, as the patients' appearance was restored by wearing the prosthesis, they came to feel that their families could better accept their facial defect. The above responses suggest that the implant-retained prostheses not only restored their aesthetic appearance but also changed its psychological impact.

Responses to questions about the level of satisfaction for each item in Group III of the attitude survey showed a high mean satisfaction rate of 72.0% to 96.0% among patients who had accepted their facial defect, but a low mean satisfaction rate of 40% among those who had failed to do so; the psychological aspect of some was as low as 0%. The level of satisfaction with implant-retained prostheses was considered related to the level of psychological acceptance of the facial defect. When deciding whether to adopt implant-retained prosthesis treatment in the future, it will be necessary, depending on each case, to examine the psychological aspects of individual patients and to persuade them to work with a psychiatrist. In addition, it will be necessary to establish a long-term prognostic management program, while increasing the number of cases. Since some patients will show no psychological state and level of satisfaction with the prosthesis, there is an urgent need to establish a method of preoperative assessment in the selection of cases for whom treatment with an implant-retained prosthesis would be appropriate. This is an issue we intend to address in the future.

CONCLUSIONS

We used osseointegrated implants as supports for facial prostheses. The mean follow-up observation was 8 years 9 months, and the implant success rate was 97.5%. The level of satisfaction with implant-retained prostheses was high among patients who had accepted their facial defect, and in some cases its use eliminated the anxiety felt in social settings. However, we found a low level of satisfaction with the prosthesis in patients who were unable to come to terms with their facial defect. As a result, questions arise as to whether the use of implant-retained prostheses is appropriate in such cases.

ACKNOWLEDGMENTS

The authors wish to thank Drs Atsushi Niimi (Nagoya University) and Yasuhiro Nosaka (Nagoya University) for their assistance in surgical and clinical procedures.

REFERENCES

- Roumanas, E.D., Freymiller, E.G., Chang, T.L., Aghaloo, T. and Beumer, J. 3rd.: Implant-retained prostheses for facial defects: an up to 14-year follow-up report on the survival rates of implants at UCLA. *Int. J. Prosthodont.*, 15, 325–332 (2002).
- Schoen, P.J., Raghoebar, G.M., van Oor,t R.P., Reintsema, H., van der Laan, B.F., Burlage, F.R., Roodenburg, J. and Vissink, A.: Treatment outcome of bone-anchored craniofacial prostheses after tumor surgery. *Cancer*, 92, 3045–3050 (2001).
- Kovacs, A.F.: A follow-up study of orbital prostheses supported by dental implants. J Oral Maxillofac Surg., 58, 19–23 (2003).
- Tolman, D.E., Tjellstrom, A. and Woods, J.E.: Reconstructing the human face by using the tissue-integrated prosthesis. *Mayo Clin Proc.*, 73, 1171–1175 (1998).
- 5) Ueda, M., Hibino, Y. and Niimi, A.: Usefulness of dental implants in maxillofacial reconstruction. J. Long Term Eff. Med. Implants., 9, 349–366 (1999).
- Honda, M., Niimi, A. and Ueda, M.: New orbital prosthesis with a blinking eyelid: report of a case. J. Oral Maxillofac Surg., 57, 730-733 (1999).
- Brodman, K., Erdman, A.J., Jr., Lorge, I. and Wolff, H.G.: The Cornell Medical Index: an adjunct to medical interview. J.A.M.A., 140, 530–534 (1949).
- Brodman, K., Erdman, A.J., Jr., Lorge, I. and Wolff, H.G.: The Cornell Medical Index-Health Questionnaire (II): as a diagnostic instrument, *J.A.M.A.*, 145, 152–157 (1951).
- 9) Brodman, K., Erdman, A.J., Jr., Lorge, I., Gershenson, C. and Wolff, H.G.: The Cornell Medical Index-Health Questionnaire (III): the evaluation of emotional disturbances, *J. Clin. Psychol.*, 8, 119–124 (1952).
- Brodman, K., Erdman, A.J., Jr., Lorge, I., Gershenson, C. and Wolff, H.G.: The Cornell Medical Index-Health Questionnaire (IV): the recognition of emotional disturbances in a general hospital, *J. Clin. Psychol.*, 8, 289–293 (1952).
- 11) Fukamachi K.: Cornell Medical Index. Sankyo-bo. pp. 15-65.
- Nerad, J.A., Carter, K.D., LaVelle, W.E., Fyler, A. and Branemark, P.I.: The osseointegration technique for the rehabilitation of the exenterated orbit. *Arch Ophthalmol.*, 109,1032–1038 (1991).
- Jackson, I.T., Tolman, D.E., Desjardins, R.P. and Branemark, P.I.: A new method for fixation of external prostheses. *Plast. Reconstr. Surg.*, 77, 668–672 (1986).
- 14) Jebreil, K.: Acceptability of orbital prostheses. J. Prosthet. Dent., 43: 82-85 (1980).
- 15) Jensen, O.: Site classification for the osseointegrated implant. J. Prosthet. Dent., 61, 228-234 (1989).
- 16) Shahlaie, M., Gantes, B., Schulz, E., Riggs, M. and Crigger, M.: Bone density assessments of dental implant sites: 1. Quantitative computed tomography. *Int. J. Oral. Maxillofac. Implants.*, 18, 224–231 (2003).
- 17) Truhlar, R.S., Orenstein, I.H., Morris, H.F. and Ochi, S.: Distribution of bone quality in patients receiving endosseous dental implants. *J. Oral Maxillofac Surg.*, 55 (12 Suppl 5), 38–45 (1997).