Fate of Implant-Retained Craniofacial Prostheses: Life Span and Aftercare

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Purpose: *To assess the need for surgical and prosthetic aftercare of craniofacial prostheses supported by endosseous implants.* ***Materials and Methods:*** *A retrospective clinical study assessing the surgical and prosthetic aftercare from implant placement to last visit of follow-up was performed in consecutively treated patients with implant-retained craniofacial prostheses in a department of oral and maxillofacial surgery between 1988 and 2003.* ***Results:*** *Ninety-five patients were rehabilitated with implant-retained craniofacial prostheses. Mean follow-up was 88 months (median, 79 months). Two hundred seventy implants were placed; 153 implants in the mastoid region, 99 in the orbital region, and 18 in the nasal region. The craniofacial defects were due to genetic disorders (24 patients), trauma (12 patients), and ablative tumor surgery (59 patients). In the latter group, 104 implants (33 patients) were placed in irradiated bone. Thirty implants were lost; 8 implants in nonirradiated bone (95.2% overall implant survival rate; mastoid, 95.7%; orbit, 94.1%; nose, 87.5%) and 22 implants in irradiated bone (78.8% overall implant survival rate; mastoid, 86.2%; orbit, 73.8%; nose, 90.0%). Irrespective of the craniofacial defect, on average every 1.5 to 2 years a new facial prosthesis was made, mostly for reasons because of discoloration (31.2%), problems with attachment of the acrylic resin clip carrier to the silicone (25.3%), rupture of the silicone (13.3%), or bad fit (10.9%). Severe skin reactions around implants or beneath prostheses were only observed in the orbital region.* ***Conclusion:*** *Implant-retained craniofacial prostheses are a reliable treatment option for the restoration of craniofacial defects. The need for surgical aftercare was minor, and prosthetic aftercare predominantly consisted of making new prostheses.* Int J Oral Maxillofac Implants 2008;23:89–98

Key words: *aftercare, craniofacial prostheses, extraoral implants, implant survival, radiotherapy*

Craniofacial defects can occur because of trauma, congenital disorders, and ablative oncologic surgery. For emotional and cosmetic reasons, these defects can be very distressing to patients.[1] Currently, craniofacial deformities are reconstructed with surgical techniques,[2] prosthetic techniques,[3] or a combination of the two. Because surgical reconstruction is difficult to perform and can have disappointing esthetic results, craniofacial defects are usually prosthetically reconstructed with the use of silicone and acrylic resin materials. Craniofacial prostheses made from these materials can match a natural cosmetic situation.

Mechanical retention of craniofacial prostheses has been achieved by surgical intervention, such as the use of a rotation flap to create a skin tunnel in which an extension of the prosthesis is elaborated.[4] Other more common fixation methods have included fixation of the prosthesis on glasses and gluing the prosthesis to the skin with silicone-based adhesives.[3] None of these fixation methods are optimal because they often limit the patient's activities. These limitations have been shown to influence the prosthetic outcome unfavorably.[5] In addition, it is difficult to

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Table 1 Overview of Implant Survival Rates for Craniofacial Implants Located in the Mastoid, Orbital and Nasal Areas*

	Year of publication	No. of implants		Survival rates (%)		Dose (Gy) delivered to implant region
		Non-XRT	XRT	Non-XRT	XRT	
Mastoid						
Parel and Tjellström (USA)[30]	1991	162	4	98.1	100	40–60
Parel and Tjellström (Sweden)[30]	1991	354	6	98.3	100	40–60
Jacobsson et al[12]	1992	234	0	91.4	–	–
Wolfaardt et al[31]	1993	87	0	98.9	–	40–70
Lundgren et al[32]	1993	33	3	100	100	48–66
Roumanas et al[18]	1994	37	3	91.9	100	45–68
Granström et al[25]	1994	40	36	95.0	81.2	–
Watson et al[22]	1995	60	0	95.0	–	–
Tolman and Taylor[13]	1996	306	12	99.0	100	26–70
Visser et al (this study)	2008	124	29	95.7	86.2	40–70
Orbit						
Parel and Tjellström (USA)[30]	1991	54	37	96.3	56.8	40–60
Parel and Tjellström (Sweden)[30]	1991	61	44	91.8	45.5	40–60
Jacobsson et al[12]	1992	38	43	92.1	62.8	–
Wolfaardt et al[31]	1993	29	28	96.6	96.4	40–70
Granström et al[25]	1994	28	78	68.0	52.6	–
Tolman and Taylor[13]	1996	55	43	100	79.0	26–70
Schoen et al[15]	2001	14	35	100	88.9	40–70
Toljanic et al[10]	2005	61	92	83.6	66.3	–
Visser et al (this study)	2008	34	65	94.1	73.8	40–70
Nose						
Granström et al[25]	1994	20	11	80.0	46.0	–
Tolman and Taylor[13]	1996	31	5	81.0	100	26–70
Flood and Russell[20]	1998	13	17	100	94.1	–
Parel and Tjellström (USA)[30]	1991	44	10	79.5	80.0	40–60
Visser et al (this study)	2008	8	10	90.0	87.5	40–70

*Only studies reporting on at least 30 implants were included. To ease comparison of the literature results with results of the current study, survival rates observed in this study were added.
XRT = radiotherapy.

correctly position a prosthesis with skin adhesives, which can dissolve, leading to loss of retention, and can cause skin irritation and allergic reactions.

In 1977 the concept of retention of auricular prostheses on endosseous implants (flange fixtures) placed in temporal bone was introduced.[6,7] Retention was achieved with clip retention on a bar construction. The extraoral use of implants was based on the success of Brånemark and coworkers with osseointegrated dental implants. The advantages of affixing an auricular prosthesis on implants included the easier maintenance of such prostheses (no adhesives),[3–8] easier mounting of the prosthesis in the right position (only 1 position is possible), and improved retention compared to adhesive-retained craniofacial prostheses.[9,10]

Implant-retained prostheses have evolved to a widely used form of therapy for the rehabilitation of patients with craniofacial defects,[10] both in nonirradiated[11,12] and irradiated areas.[11,13–15] It has been shown that implant success rates are dependent on the implant location and radiation status. Implant success rates have ranged from 81% to 100% for the mastoid area, 45% to 100% for the orbit, and 46% to 100% for the nasal floor (Table 1). Overall success rates for implants are higher in the mastoid than in the orbital and nasal areas and higher in nonirradiated areas than in irradiated areas.

When compared to patients wearing adhesive prostheses, patients with implant-retained facial prostheses were more satisfied with their prostheses overall.[15–16] In addition, high satisfaction scores for implant-retained craniofacial prostheses have been reported regarding shape (100% satisfaction), color (85%), and ease of positioning (98%).[17] Most studies with a follow-up of at least 5 years have focused on implant survival rates[10,18–20] and peri-implant skin reactions.[21] To the best of the authors' knowledge, there is only 1 case series assessing the need for surgical and prosthetic aftercare of implant-retained craniofacial prostheses.[22] Therefore, the aim of this study was to assess the need for surgical and prosthetic aftercare of auricular, orbital, or nasal craniofacial prostheses supported by endosseous extraoral implants.

Table 2 Group Characteristics

	No. of patients at start of study	Mean age in years (range)	Gender ratio (male/female)	Subcategory (no. of patients)			Total no. of implants	No. of patients receiving XRT before implant placement	No. of patients receiving XRT after implant placement	Lost to follow-up
				CD	ONC	Trauma				
Mastoid implants and ear prosthesis	60	47 (8–85)	40/20	23	28	9	153	2	9	10
Orbital implants and ear prosthesis	26	60 (23–81)	20/6	1	22	3	99	2	15	9
Nasal implants and prosthesis	9	70 (53–84)	5/4	0	9	0	18	2	3	3
Total	95	53 (8–85)	65/30	24	59	12	270	6	27	22

CD = congenital disorder; ONC = oncology; XRT = radiotherapy.

MATERIALS AND METHODS

Patients

A retrospective clinical study assessing surgical and prosthetic aftercare from implant placement to the last follow-up visit was conducted. The sample consisted of consecutively treated patients with implant-retained craniofacial prostheses in a department of oral and maxillofacial surgery between 1988 and 2003.

Study Design

Patient records were assessed for implant survival and the need for prosthetic and surgical aftercare from implant placement to the last follow-up visit. According to the standard treatment protocol, recalls were performed 1 week, 6 weeks, 3 months, 6 months, and 12 months after placement and subsequently annually unless complications occurred earlier. Patients were divided into 3 groups (ear, orbit, and nose), each of which was subdivided into 3 categories (congenital, trauma, and oncology; Table 2). In addition, it was noted whether the patients had received radiotherapy in the implant area. *Aftercare* was defined as all care provided by the team during the evaluation period (from the day the implants were inserted until December 2005 or until the patient was lost to follow-up). To be included in the study, the patient had to have worn an implant-retained craniofacial prosthesis for at least 6 months.

Surgical aftercare included loss of implants and the occurrence of surgical complications, including subcutaneous tissue reduction and skin tissue transplantations. Need for ointment application was considered surgical aftercare. Prosthetic aftercare was scored as need of clip repairs, fabrication of new prostheses, repair of bar construction, fabrication of new bars, consultation for activation of clips, hygiene instructions, and tightening of loose abutments. In addition, skin reactions around the abutments connected to the implants were rated according to the skin reaction scale of Tolman and Taylor.[7] Skin reactions were scored as *(0)* no irritation, *(1)* slight redness, *(2)* tissue redness and moist but no granulation tissue present, *(3)* tissue redness and moist with granulation tissue present, or *(4)* active infection present requiring removal of abutment. Skin reactions beneath the prostheses (eg, redness of the skin due to allergic reactions or fungal infections) were scored as either present or absent. The highest score per patient was counted. No weight factors were used to rate the various variables scored.

Surgical Treatment

All patients received an implant-retained craniofacial prosthesis (Brånemark; Nobel Biocare, Göteborg, Sweden). Treatment planning and surgery were carried out by experienced oral and maxillofacial surgeons and maxillofacial prosthodontists participating in a multidisciplinary team specialized in the treatment and rehabilitation of patients with craniofacial defects. In the mastoid region and superior orbital rim, extraoral implants 3 or 4 mm in length were placed. Seven- and 10-mm-long implants (actually intraoral implants) were placed in the floor of the nose or the inferior orbital rim. In the mastoid region, 2 or 3 implants were placed along the arc posterior to the external auditory meatus. For the nasal defects, in all cases, 2 implants were placed in the inferior piriform area. In the orbital region, 2 or 3 implants were placed in the superior orbital rim. An additional implant or two was often placed in the inferior orbital rim or the zygoma. A template was used to ensure optimal implant placement.

In all cases the implants were placed with a 2-stage procedure.[1,7,11] Implant placement was done

under general anesthesia and uncovering under local anesthesia. In the case of malignancies, it was considered preferable to place implants during ablative surgery and prior to radiotherapy. In some cases the implants were placed to support an already-existing conventional craniofacial prosthesis in patients who already had been subjected to ablative surgery and radiotherapy. A broad-spectrum antibiotic was provided in these cases from 1 day before until 2 weeks after placement of the implants.

During the first stage, the implants were inserted in the bone adjacent to the defect area and covered by skin. To ensure adequate osseointegration, the healing time was at least 3 months for implants inserted into the temporal bone and 6 months for implants inserted into the orbital or nasal bone. In cases where postoperative radiotherapy was performed (starting 6 weeks after ablative surgery), the osseointegration period was increased by 3 months. Second-stage surgery consisted of exposing the implants, thinning the subcutaneous tissue, and placing abutment cylinders of appropriate heights (3 or 4 mm) and healing caps on the implants. After placing healing caps on the abutments, gauze soaked in ointment (Terra Cortril; Pfizer, New York, NY) was wrapped around the abutments to promote skin healing during the healing period. The gauze dressings were changed weekly for approximately 2 to 3 weeks. The suprastructures and craniofacial prostheses were subsequently made beginning 3 weeks after abutment connection.

Prosthodontic Treatment

Approximately 6 weeks after implant surgery, a temporary, adhesive-retained craniofacial prosthesis was made for use during the osseointegration period of the implants. Fabrication of the implant-retained prosthesis began 3 weeks after abutment connection.[23]

Craniofacial prostheses were made of silicone elastomers (up to 2000 MDX-44210 silicone; Dow Corning Europe, Brussels, Belgium, and from 2000 VST50 silicone; Technovent, Leeds, UK). These silicone elastomers were bonded using an A-330 Gold Platinum primer (Technovent) on an acrylic resin baseplate with either clips or magnets inside. The type of attachment used was dependent on the location of the prosthesis. For most orbital prostheses, magnets (Magnacap; Innovadent Technics, Leeds, UK, or Steco magnets; Steco-System-Technik, Hamburg, Germany) were used, because magnets need less space in the prosthesis compared to bar-clip attachments. For some orbital prostheses and all ear and nose prostheses, an acrylic resin baseplate with clips was used. When using an acrylic resin plate with clips, retention was usually achieved with a bar-clip retention system—a Friatec bar and clips for ear and orbital prostheses (Prec-Horix standard; Alphadent, Antwerpen, Begium) or Haderclips for nasal prostheses (Friadent, Mannheim, Germany).

The silicone elastomer was intrinsically pigmented with silicone paste (Technovent) to achieve a good match to the skin and finished by extrinsic coloration (KT199; Factor II, Lakeside, AZ) if needed. Following extrinsic coloration, the prosthesis was sealed with transparent silicone (Medical adhesive A, Technovent).

Patients were instructed to clean the suprastructures and surrounding skin daily with either a very soft toothbrush (Vitis- supersoft dental brush, Laclede, Rancho Dominiquez, CA) and Superfloss (Procter & Gamble/Oral B, Frankfurt am Main, Germany) or a small shoestring in combination with water and a gentle soap.

Statistical Analysis

The data were analyzed using *t* tests and χ^2 tests (SPSS for Windows, version 10.0; SPSS, Chicago, IL). For all tests a significance level of .05 was chosen.

RESULTS

Patients

Between January 1988 and December 2005, 95 patients (65 males, 30 females; 52 ± 9 years, range, 8 to 85 years) were rehabilitated with an implant-retained craniofacial prosthesis at the Department of Oral and Maxillofacial Surgery of the University Medical Center Groningen, The Netherlands (Table 2). Mean follow-up was 88 ± 8 months (median, 79 months; range, 8 to 213 months). Twenty-four patients were treated because of genetic disorders, 12 patients because of defects resulting from trauma, and 59 patients had defects resulting from ablative tumor surgery (Table 2). Thirty-three of the 59 oncology patients had received radiotherapy at the implant region (mean, 60 ± 9 Gy; range, 30 to 70 Gy) either before (n = 6) or after (n = 27) placement of the implants (Table 2). In the majority of the cases, the implants were placed during ablative surgery.

Table 3 shows the mean follow-up periods for the various implant locations in months. Nineteen patients died during follow-up, mainly because of oncologic problems (recurrence of the tumor, metastases). Other reasons for loss to follow-up were moving to another part of the country (n = 1), severe psychological problems (n = 1), and travel distance (n = 1; Table 2). No patients died because of complications related to implant therapy.

Table 3 Mean Follow-up in Months

Location	All patients (range)	Implants placed in areas that received XRT* (range)	Implants placed in Non-XRT areas (range)
Mastoid	95 (20–213)	64 (24–129)	102 (20–213)
Orbit	80 (8–204)	71 (15–156)	94 (8–204)
Nose	51 (9–76)	48 (9–76)	55 (41–60)

*XRT before or after implant placement.

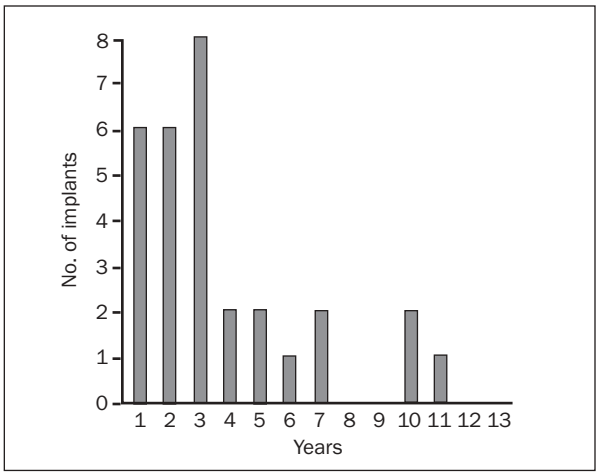

Fig 1 Number of implants lost as a function of time (years) after placement.

Table 4 Total No. of Implants, No. of Lost Implants, and Overall Survival Rates

Defect	Congenital disorders (lost/placed)	Trauma (lost/placed)	Oncology (lost/placed)	Overall (lost/placed)	No. of implants lost/total in XRT areas (success rate)	No. of implants lost/total in non-XRT areas (success rate)	XRT before implant placement (lost/placed)	XRT after implant placement (lost/placed)	Overall success rate (%)
Ear	2/58	2/31	5/64	9/153	4/29 (86.2%)	5/124 (96.0%)	0/7	4/22	94.1
Orbit	1/5	0/10	18/84	19/99	17/65 (73.8%)	2/34 (94.1%)	5/7	12/58	80.8
Nose	0/0	0/0	2/18	2/18	1/10 (90%)	1/8 (87.5%)	0/4	1/6	88.9
Total (270)	3/63	2/41	25/166	30/270	22/104	8/166	5/18	17/86	88.8
Overall success rate (%)	95.2	95.1	84.9	88.8	78.8	95.2	72.2	80.2	

Implants

In total, 270 implants were placed. Of these 270 implants, 104 implants (86 before XRT and 18 after XRT) were located in irradiated areas. Thirty implants were lost in 20 patients[22]; 22 implants in irradiated bone and 8 implants in nonirradiated bone (Table 4). If loss of implants occurred, in about one third of the cases (7 of 20 patients), more than 1 implant was lost. Loss of implants predominantly occurred in the 16 patients treated with ablative tumor surgery; 13 had received radiotherapy. Nineteen implants were lost in 11 patients with orbital prostheses, 9 implants were lost in 7 patients with ear prostheses, and 2 implants were lost in 2 patients with nasal prostheses. Of the 30 lost implants, 2 implants were mobile during second-stage surgery and were removed. The other 28 implants were lost during the follow-up (Fig 1). The overall implant survival rate was 88.8%—78.8% (22/104) for irradiated patients and 95.2% (8/166) for the nonirradiated patients (Table 4). Except for the nose, the survival rates were lower in irradiated than in nonirradiated areas ($P < .05$). Six lost implants were successfully replaced (n = 4 patients); 1 implant in the nose, 3 in the mastoid area, and 2 in the orbital area. The other 24 implants were not replaced because a sufficient number of implants were left to support the prosthesis (11 patients) or because of deterioration of the patient's health (5 patients).

Surgical Aftercare

Application of ointment to treat the infected skin around the implants (other than the standard gauze dressings applied after abutment connection) and subcutaneous tissue reduction were the surgical aftercare most frequently required. Most surgical aftercare was needed in patients with ear and orbit prostheses. Sixty-six percent of the auricular prosthesis patients and 61% of the orbital patients needed additional applications of ointment; no nasal implant patients needed additional ointment application ($P < .05$). Moreover, in the ear and orbital group, the irradi-

Table 5 Overview of the Need for Prosthetic and Surgical Aftercare Related to the Radiation Status

	Mastoid				Orbit				Nose			
	Non-XRT		XRT		Non-XRT		XRT		Non-XRT		XRT	
	n	%	n	%	n	%	n	%	n	%	n	%
Prosthetic aftercare												
Hygiene instructions	23	46	5	45	5	55	7	41	2	50	2	40
New bar fabrication	4	8	0	0	0	0	0	0	0	0	0	0
Activation of clips	13	26	0	0	1	11	1	6	1	25	0	0
Repair of clips	10	20	2	180	0	7	0	0	3	75	2	40
Surgical aftercare												
Application ointment	35	71	5	45	7	77	9	53	0	0	0	0
Thinning of skin	20	41	1	9	4	44	4	23	2	50	0	0
Skin transplant	0	0	0	0	0	0	0	0	0	0	0	0

XRT: radiotherapy.

Table 6 Overview of the Skin Reactions Observed

	Ear				Orbit				Nose			
	Non-XRT		XRT		Non-XRT		XRT		Non-XRT		XRT	
Skin reaction	n	%	n	%	n	%	n	%	n	%	n	%
0	14	28	7	64	2	22	6	35	2	50	3	60
1	12	24	1	9	1	11	5	29	1	25	1	20
2	14	28	2	18	5	56	2	12	1	25	1	20
3	9	20	1	9	1	11	3	18	0	0	0	0
4	0	0	0	0	0	0	1	6	0	0	0	0

The highest score per patient was taken.

ated patients needed significantly less surgical aftercare (ointment applications, thinning of the skin, $P < .05$) than the nonirradiated patients (Table 5).

No skin transplantations had to be performed. In addition, clinically relevant skin reactions were not observed beneath the surface of the prosthesis, although occasionally such reactions were observed around abutments. Scores of 0, 1, and 2 were most frequently recorded (0 in 36% of the patients, 1 for 22%, and 2 for 26%). Skin reaction type 3 was seen occasionally (15%), and skin reaction type 4 rarely (1%; Table 6). In general, skin reactions were milder in radiated than in nonirradiated patients ($P < .05$). Type 1 and 2 reactions were treated successfully by cleaning the abutments and skin with 1.5% H_2O_2 and instructing the patients to improve their oral hygiene. In cases of type 3 and 4 reactions, additional application of ointment was needed. Furthermore, in 2 patients in whom the skin was very sensitive due to radiation, problems with skin adhesives occurred during the intermediate stage of the prosthodontic rehabilitation (wearing of a temporary adhesive-retained prosthesis during the osseointegration phase of the implants). These problems were resolved successfully by using a milder (water-based) skin adhesive (Cosmesil skin adhesive; Factor II).

Surgical complications needing larger interventions developed in 3 patients. In a trauma patient (loss of an ear due to a car accident) who received an implant-retained ear prosthesis, the free-skin flap in the implant area showed disturbed wound healing and persistent skin problems. Seven years after implantation, both implants were lost. New implants were placed successfully, but the skin problems persisted. In a second patient, the nasal septum had to be reshaped after ablative surgery and implant placement to form a more ideal base for a nasal prosthesis. In a third patient, a 9-year-old boy with an ear prosthesis who did not allow his parents to clean the skin in the implant region, severe skin problems occurred related to a bad hygiene regimen. Temporary application of an antibiotic ointment and counseling between the patient and his parents resulted in a better hygiene regime and a healthy appearance of the skin.

Prosthetic Aftercare

Irrespective of the site of the craniofacial defect, on average, a new silicone facial prosthesis had to be made every 1.5 to 2 years (Table 7). Reasons for remaking a craniofacial prosthesis predominantly consisted of discoloration of the prosthesis (31.2%),

Table 7 Mean Life Span of Implant-Retained Craniofacial Prostheses per Location in Months

	Time between implantation and first prosthesis		Time between first and second prosthesis		Time between second and third prosthesis		Time between third and fourth prosthesis	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Nose	8.3	2.8	13.4	11.5	13.3	10.6	NA	
Mastoid	7.4	4.1	22.2	14.5	19.5	12.1	18.2	13.6
Orbit	10.3	5.8	28.6	17.6	19.9	12.3	20.1	9.8

*Not applicable; few fourth nasal prostheses made to date.

Table 8 Reasons for Fabricating New Prostheses (%)

	Mastoid	Orbit	Nose	All 3 groups
Discoloration	31.5	26.6	40.0	31.2
Attachment problems of acrylic carrier to silicone	30.0	15.0	11.0	25.3
Rupture of silicone	15.4	9.2	6.6	13.3
Fitting	9.2	16.6	11.0	10.9
Broken carrier	5.5	0.0	6.6	4.4
Lost implant	1.3	6.6	13.3	3.1
Lost prosthesis	1.3	0.0	6.6	1.4
New suprastructure	1.8	0.0	0.0	1.4
Other	4.0	26.0	4.9	9.0

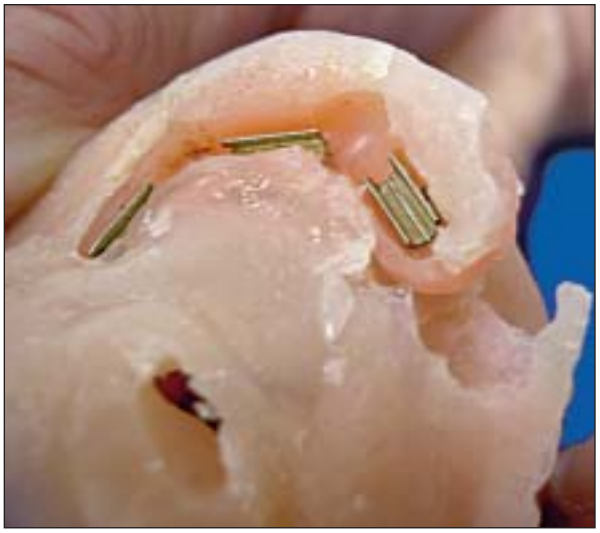

Fig 2 Loosening of clip carrier from the silicone.

attachment problems with the acrylic resin clip carrier to the silicone (25.3%; Fig 2), rupture of the silicone (13.3%), and bad fit (10.9%). In these cases it was not possible to repair the prosthesis, and a new prosthesis had to be made. Other reasons for fabricating new prostheses were loss of prosthesis, loss of implants, broken clip carriers, and bad fit after thinning of the skin. Moreover, causes limited to orbital prostheses included unhappiness with the appearance of the prosthesis (5%); contamination of the prosthesis material due to ingrowth of micro-organisms (fungi), probably originating from the skin flora (5%); and loss of a prosthetic eyeball (3%). Fabricating second and subsequent prostheses was less time-consuming than fabricating the first prosthesis. When form and fit were satisfying, the original mold was re-used. In those cases a new clip carrier was made (if needed), and the mold was filled with silicone of the right color. On average, this took 2 appointments.

Ear prostheses ruptured significantly more often than orbit and nasal prostheses (Table 8; $P < .05$). Moreover, patients with implant-retained ear prostheses scored relatively high on activating clips. Patients with nose prostheses scored relatively high on replacement of (Hader) clips (55% of the patients), while repair of clips was needed significantly less in patients wearing ear (20%) or orbital (10%) prostheses ($P < .05$). Furthermore, fabrication of a new bar construction was needed 4 times in cases of ear prostheses because of implant loss.

Many patients were in need of repeated hygiene instructions (46% of patients with ear prostheses, 44% of those with nose prostheses, 46% of those with orbital prostheses). Among patients in need of extra hygiene instructions, significantly more sessions per patient were needed in the orbital group than in the ear prosthesis group (2.9 times per patient versus 1.3 times per patient; $P < .05$).

DISCUSSION

Implant-retained craniofacial prostheses have been shown to be a reliable treatment option for prosthetic rehabilitation of facial deformities, with a high success rate and only a minor need for surgical aftercare, even in radiated areas. Moreover, compared to adhesive prostheses, patients rehabilitated with implant-retained craniofacial prostheses have reported higher satisfaction scores.[15,20] However, whether these high satisfaction scores reflect an improved quality of life is unclear.

Surgical Aftercare

Implant survival is a major topic related to the need for surgical aftercare. Implant survival is dependent on the location of the implant. As often reported in the literature, and as shown in the present study, implant survival is the highest in the mastoid area, followed by the nasal and orbit areas (Table 1). A factor underlying this difference in survival rates may be differences in bone quality between the various areas. It has been assumed that, eg, orbital bone is thinner and more dense than mastoid bone.[13] Tolman and Taylor[13] posited that this difference in volume and density could result in irradiation having a more destructive effect on the vascularity of the orbit, compromising the potential for osseointegration. Finally, implants designed for extraoral use are machined and lack the special surface treatments common nowadays for implants designed for intraoral use. Modifying the surface characteristics of extraoral implants might improve implant survival. All these topics, however, need further study.

Although it is commonly accepted in the literature that loss of intraorally placed implants is greatest during the first year after placement,[24] loss of implants in craniofacial area predominantly was observed over a longer time period[12,25] (Fig 1). A possible explanation for this variation between early and late implant loss might be related to differences in loading of intra- and extraoral implants. In the oral cavity, implants are subjected to multidirectional forces (eg, during chewing and speech), while extraoral implants are mainly subjected to unidirectional forces (positioning and removal of the prosthesis). In other words, while survival of intraoral implants is commonly thought to depend on osseointegration, mechanical retention might be a significant additional factor for survival of extraoral implants in cases of insufficient osseointegration. In the latter cases, mechanical retention of the implant still is thought to be sufficient to support a craniofacial prosthesis, while such retention is considered insufficient for maintenance of an intraoral implant because of the much higher loading forces to which the latter is subjected.

Skin reactions appeared to be milder in irradiated patients than in nonirradiated patients. This difference in skin reactions might be related to radiation-induced changes in the peri-implant skin. First, irradiated skin is thinner (more atrophic) than healthy skin. A thinner layer of peri-implant soft tissues is associated with fewer peri-implant problems; similar results have been observed for intraoral implants.[1] Second, irradiated skin is drier than healthy skin; thus, the skin-prosthesis interface is less moist and thought to be less prone to development of infections.[26]

Prosthetic Aftercare

Prosthetic aftercare predominantly consisted of making new prostheses. The average life span of a craniofacial prosthesis in this study ranged between 1.5 and 2 years, with some patients using their prosthesis for more than 5 years. This average life span was similar to that reported in the case series of Watson et al.[22] In the latter study, the maximum life span was 36 months. To the best of the authors' knowledge, there are no studies reporting on the life spans of adhesive-retained prostheses. However, with normal use and proper care, it has been assumed that a craniofacial prosthesis should last 24 to 36 months.[27] Moreover, as reported in Table 7, the life span of subsequent craniofacial prostheses seemed to grow shorter as a function of the number of prostheses made. This might, at least in part, be related to an overrepresentation of patients who frequently needed new prostheses. The relatively short life span of craniofacial prostheses could be considered a disadvantage, but making replacement prostheses is not as time-consuming as making a first prosthesis, because the original mold can be re-used. A mold can be re-used more than 10 times if it is treated with care.

Following tumor ablation, a reconstruction is performed with adhesive craniofacial prostheses for the convenience of the patient during the osseointegration period. Although this approach increases costs and the need for aftercare, it also enables patients to recover from self-esteem difficulties at an earlier stage. Patients can live their normal social life earlier and become informed about the possibility of esthetic restoration. In the Netherlands the healthcare insurance companies have committed to allowing clinicians to follow this protocol.

A striking phenomenon was the rather rapid discoloration of silicone prostheses being a major reason for making new prostheses. This phenomenon has also been reported in other studies.[20,22] In the latter studies, bleaching by the sun, sea, and nicotine were considered possible causes for this discoloration. Other contributing factors might be the use of intrinsic colors and/or bacterial flora. This hypothesis should be tested by studying whether discoloration can be prevented or delayed by using selected pigments or dyes (eg, replacing red colors by brown colors). Also more knowledge concerning the (in)growth of bacterial and fungal flora on or into the silicones of the craniofacial prostheses is needed. The otorhinolaryngology literature shows that the failure of silicone-based voice prostheses was strongly related to deterioration of the silicone material by micro-organisms present in the biofilm. For example, it has been reported that *Candida* species

were amongst the predominant strains isolated from the biofilms on silicone tracheoesophageal voice prostheses.[28] Electron microscopic examination of failing voice prostheses showed colonization and disruption of the silicone material by penetrating yeast hyphae.[29]

Furthermore, in agreement with the studies of Reisberg[27] and Watson et al,[22] the present study also revealed many problems concerning loss of bond between the acrylic resin baseplate, the clips, and the silicone. In many cases the bonding between silicone and the acrylic resin baseplate could not withstand the forces needed to remove the prosthesis from the bar suprastructure. This insufficient bonding strength is thought to be related to the lack of bonding between silicones and acrylic resins. After 2004, the bonding procedure was changed to conform with the latest recommendations of the manufacturer. After preparing the acrylic resin as described earlier, a thin layer of A-2000 silicone elastomer (Technovent, Factor II) is now applied as an intermediate between the acrylic resin baseplate and the body of VST 50 HD silicone (Technovent, Factor II). The manufacturer claims that this results in better bonding between the acrylic resin and the silicone. However, no follow-up studies on the validity of this claim are available yet.

For the retention of orbit prostheses, magnets were usually used instead of clips. Magnets are practical not only where space for the retention device is limited but also where there is high muscle activity adjacent to the prosthesis.[8] The use of magnets minimizes the stress delivered to the implants. Conversely, for reconstruction of nasal defects, no magnets were used, as suprastructures in the nasal region are exposed to a moist environment which is believed to promote corrosion of magnets.[18] The type of suprastructure applied, might be the basis for the lower scores of orbital patients with regard to clip repair and fabrication or repair of bars. For nose prostheses, the Hader clip retention system was used, and the aftercare related to repair of clips was much higher in this group of patients. Hader clips tended to break or lose attachment very quickly. This high clip repair rate could be interpreted as negative, but Hader clips are easy to replace at low cost (chairside procedure, no need for a technician).

Adequate hygiene is mandatory to prevent periimplant problems, including inflammation of the skin.[8,21] The higher need of hygiene instructions in orbital patients when compared to the other groups may be related to the visual handicap of this patient group.[8]

CONCLUSION

Implant-retention can be considered safe and reliable for craniofacial prosthetic restoration. Survival rates of craniofacial implants were high in nonirradiated areas (95%) and satisfactory in irradiated areas (80%). Skin reactions around implants and beneath prostheses were mostly mild. The average life span of silicone craniofacial prostheses is relatively short (on average 1.5 to 2 years), so lifetime aftercare must be provided. The main reasons for the replacement of craniofacial prostheses were discoloration, problems with attachment of the acrylic resin clip carrier to the silicone, rupture of the silicone, and bad fit.

ACKNOWLEDGMENTS

The authors are very grateful for the valuable contributions of Mr G. van Dijk, Mr A. K. Wietsma, Dr H. Reintsema, and Dr C. Stellingsma to this study.

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