Clinical Trial of Modified Ankylos Implants for Extraoral Use in Cranio- and Maxillofacial Surgery

Karl Andreas Schlegel, MD, DDS[1]/Stefan Schultze-Mosgau, PhD, MD, DDS[2]/Stefan Eitner, DDS[3]/
Joerg Wiltfang, PhD, MD, DDS[4]/Stephan Rupprecht, MD, DDS[1]

Purpose: *Epithetic solutions in the maxillofacial region are indicated if plastic surgery reconstruction is not a valid option for an extensive defect. The purpose of this study was to examine whether the extraoral implants used provided sufficient retention to be used as anchoring aids.* ***Materials and Methods:*** *Between November 1999 and September 2002, 33 identical modified Ankylos implants for extraoral anchorage were placed in 10 patients for the fixation of various epitheses in the midfacial (eye, nose) and ear regions in the course of a clinical trial.* ***Results:*** *Over a follow-up period of 2 to 34 months, all implants remained osseointegrated (as confirmed radiographically), and the implants and epithetic restorations were clinically stable.* ***Discussion:*** *The results demonstrated that the lasting retention of maxillofacial epitheses provided by implants assures patients that their epitheses are securely fixed.* ***Conclusion:*** *The demonstrated extraoral implant system not only achieved sufficient osseointegration but also showed good clinical handling and easy fixation possibilities for epithetic anchorage.* INT J ORAL MAXILLOFAC IMPLANTS 2004;19:716–720

Key words: *extraoral implants, maxillofacial epitheses, osseointegration*

In cases of congenital, traumatic, or surgical defects of the ear, orbit, nose, or midfacial region, reconstruction using either autogenous tissue or a maxillofacial epithesis is indicated.[1–4] Plastic surgical reconstruction may be the preferred option for the esthetic and functional rehabilitation of patients with such defects.[5] However, a maxillofacial epithesis is indicated if the scope of the operation, the size of the defect, the general health, or the age of the patient contraindicate reconstructive surgery. A prosthetic restoration can also be indicated to achieve temporary or permanent visual accessibility to the defect area so that an early diagnosis of any recurrence in the follow-up treatment of a tumor is possible.[6] Furthermore, the anatomic reconstruction of a difficult shape (especially the ear, nose, or eye) is often solved more easily and with more esthetically satisfying results by an epithesis rather than by autogenous tissue transfer.[7]

An intraoral maxillofacial prosthesis normalizes phonation and ingestion by restoring the separation of the oral and nasal cavities. While intraoral maxillofacial prostheses are often retained using clasps or telescopic crowns in the conserved jaw segment, extraoral maxillofacial epitheses rely on adhesives and the use of undercut areas in the defect for retention. However, these methods do not always provide adequate retention for the maxillofacial epithesis. In addition to the psychologic trauma caused by their disfigurement, patients with defects live in fear of the maxillofacial epithesis coming loose or falling off in public. Both patients and

[1]Senior Staff Member, Department of Maxillofacial Surgery, University of Erlangen-Nuremberg, Erlangen, Germany.
[2]Associate Professor, Department of Maxillofacial Surgery, University of Erlangen-Nuremberg, Erlangen, Germany.
[3]Senior Staff Member, Department of Prosthetic Dentistry, University of Erlangen-Nuremberg, Erlangen, Germany.
[3]Professor and Head, Department of Maxillofacial Surgery, University of Schleswig-Holstein, Kiel, Germany.

Correspondence to: Dr Schlegel, Klinik und Poliklinik für Mund-Kiefer-Gesichtschirurgie, Friedrich-Alexander-Universität Erlangen-Nürnberg, Glückstr. 11, 91054 Erlangen, Germany. Fax: +49 9131 853 4219. E-mail: schlegel@mkg.imed.uni-erlangen.de

physicians want stable retention of the maxillofacial prosthesis. One newer solution is the placement of implants in the margins of the defect, which can provide stable retention for all types of maxillofacial epitheses (Fig 1).

Several factors should be considered before the decision to anchor an epithesis with implants is made. The defect must be of sufficient size for implant placement to be useful. Implant support tends to work best with large, relatively heavy prostheses and is contraindicated for small, relatively light ones. Previous or planned therapeutic irradiation can have a negative effect on implant survival. Implants osseointegrate best when placed in healthy, immovable tissue, with no muscular movement at the margins.

Tumor lesions and previous treatment with irradiation of the potential implant area have historically been regarded as contraindications to implant placement because of the side effects of irradiation and complications that might result.[8] The main complications are reduced healing capacity of the hard and soft tissue[1] and skin and mucosal infections, resulting in increased probability of implant loss and bone exposure, which may lead to osteoradionecrosis.[9]

Clinical trials have demonstrated that, even with irradiated patients, a success rate of 86% after 44 months can be achieved using extraoral implants.[1] The failure rate increased if trials were extended over a longer period.[10–12] This can be explained by the delayed irradiation damage, which causes progressive endarteritis to the hard and soft tissue.[9] Adjuvant chemotherapy can also be a decisive factor. Chemotherapy prior to implant placement does not appear to have any negative effects if it is completed at least 6 weeks prior to implantation, whereas considerably higher losses occurred with patients who had undergone postplacement chemotherapy.[13]

Another factor to consider is implant length, which may depend on the amount of bone available and the type of prosthesis framework. Clinical tests have confirmed that 3-mm-long implants should not be used if at all possible, as they have an increased risk of failure.[10,12] Abutment length does not seem to have any significant effect on the result. Frameworks incorporating a bar extension have had a significantly negative effect on implant survival.[10]

Osseointegrated craniofacial implants were first used clinically in 1976.[14,15] Development of these implants was based on previous experience with intraoral endosteal implants and experimental tests on implants that penetrated the skin. A number of extraoral implant systems have become established since then,[16] of which the Ankylos extraoral implant (Friadent, Mannheim, Germany) is the most recent. This dental implant has been on the market since 1987 and has a special thread with irregular flank geometry and depth. The curvature of the thread flanks, which begins at the cervical area and increases towards the apex, transfers loads toward the apex in the relatively elastic spongiosa region, while reducing loading in areas near the cortex.[17] Ankylos maxillofacial implants are supplied in lengths of 4, 5, or 6 mm, with a cervical diameter of 3.5 mm (Fig 2).

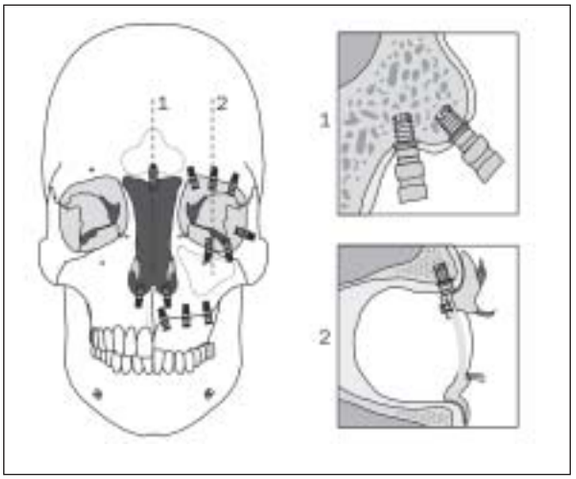

Fig 1 Diagram illustrating the positioning of extraoral implants. Two implants are normally placed in the nasal bone region *(1)*. With orbital restorations *(2)* it is necessary to ensure that the implants do not interfere with the planned maxillofacial prosthesis.

Fig 2 The Ankylos implants used were 3.5 mm wide and *(left to right)* 4, 5, or 6 mm long.

The purpose of this study was to examine whether the tested extraoral implants could provide sufficient retention to be used as anchoring aids.

MATERIALS AND METHODS

Between November 1999 and September 2002, a total of 33 Ankylos implants were placed and

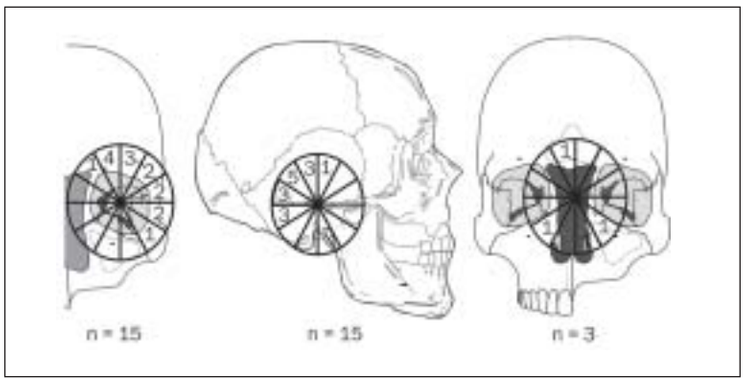

Fig 3 Diagrams showing the number of implants placed and their specific positions within the 3 regions. N = the number of implants placed in each region.

Table 1 Patient Characteristics

Patient	Age (y)	Gender	Medical history	Implant/ prosthesis site
HF	8	M	Ear dysplasia	Ear
MM	63	F	Basal cell carcinoma	Orbit
BF	47	F	Basal cell carcinoma	Orbit
OC	67	M	Squamous cell carcinoma	Orbit
HM	56	M	Basal cell carcinoma	Orbit
WB	14	M	Ear dysplasia	Ear
KM	41	M	Meningioma	Orbit
HL	71	F	Squamous cell carcinoma	Nose
WC	12	M	Ear dysplasia	Ear
HK	61	F	Squamous cell carcinoma	Orbit

restored with prostheses in 10 patients (Table 1). The study was approved by the Ethics Committee of the Friedrich Alexander University of Erlangen-Nuremberg, Germany. Fifteen of the implants were 4 mm long, 9 were 5 mm long, and 9 were 6 mm long (Fig 2). The 6-mm implants were generally placed in the periorbital region, and the 4- and 5-mm implants were used to retain ear epitheses in the periauricular region. The etiology of the defects, the topographic distribution, and number of implants used for each patient are listed in Table 1 and Fig 3. None of the patients included had undergone radiotherapy in the implantation area.

Thin-section computerized tomographic diagnosis with corresponding coronal reconstruction and the use of stereolithographic models helped to record the preoperative bone strength fairly precisely[18] so that intracranial perforation during preparation of the implant site could be avoided. After determining the optimum position of the implants in relation to the prosthesis, the bony site was revealed by repositioning the soft tissue. If the soft tissue layer was thicker than 4 mm, the flap was reduced to 3 mm by removing hair follicles and subepithelial gland tissue before it was repositioned. After the periosteal skin flaps were mobilized, the implants were placed using a standard set of instruments and surgical templates, which were fabricated using diagnostic casts.

When the bony site was being prepared for the implant, the cortical bone was marked using a bur in the region of the implant site. The predetermined depth was then prepared using a twist drill. The implant cavity was prepared with a system-specific reamer instrument to create the negative form of the implant before implant placement. Then the soft tissues, which had been remodeled as described, were repositioned and a multilayered closure of the wound was completed. In most cases, a pressure bandage was applied for the first 3 days to prevent postoperative hematoma. The sutures were removed after 10 days. Postoperative radiographic examination followed to assess implant positions.

A second surgery to expose the implants was carried out approximately 3 to 4 months after placement. The soft tissue was reduced further at this stage if necessary. After removing the inner so-called "grub" screws, healing spacers, which were available in 3 lengths (4, 5, and 6 mm), were immediately screwed into place. The area of skin penetration around the implant was wrapped with strips of gauze saturated with Aureomycin (Wyeth, Madison, NJ). These remained in place for the first 5 days postoperatively and were used for localized compression of the soft tissue. After renewed suture closure, the sutures were left for 10 days. An impression was then made.

Clinical and radiographic follow-up was done every 6 months after prosthetic reconstruction. In the first year after implant placement, clinical examinations were conducted every month.

RESULTS

There were no implant complications or failures, either during placement of the implants or during the operation to expose them (re-entry). In no case was the inner cortical margin of the neurocranium perforated. There were no problems related to clinical handling with the system, which is compatible with the Ankylos dental implant system. The effectiveness of the implants supporting maxillofacial prostheses depended on the location and size of the defect.

Magnets were used on all implants used to retain auricular epitheses (3 implants per prosthesis). Magnets were used on 15 implants to support orbital restorations (2 to 4 implants per prosthesis). In the case of 1 patient, 3 implants were used to support a bar-retained nasal restoration. In each case the connector of the superstructure to the prosthesis projected at least 2 mm to a maximum of 5 mm above the skin. There was only one case of skin irritation that resulted in tissue proliferation. The 5-mm space between the implants allowed patients to clean them daily at home using cotton swabs, hydrogen peroxide, and Bepanthen ointment (Roche, Basel, Switzerland).

During follow-up examinations, the peri-implant skin reaction of patients was registered. Five grades of peri-implant skin reaction were differentiated: no clinical sign of inflammation (grade 0); a slight inflammation of the peri-implant tissue (grade 1); slight inflammation and weeping (grade 2), which could be treated with a topical local antibiotic with 1% triamcinolone cream and 0.5% bacitracin; an infection such that local surgical revision of the peri-implant skin was necessary (grade 3); and peri-implant infection requiring the removal of the implant (grade 4). On examination, a skin reaction in the abutment emergence area of 2 implants was observed in 1 patient with 3 implants. In this case, 1 implant had a grade 2 peri-implant infection and 1 a grade 3 peri-implant infection. For the grade 2 case, topical treatment using a local antibiotic (Aureomycin with 1% triamcinolone cream and 0.5% bacitracin) on a gauze wrapped around the implant post for 5 days resulted in a complete remission of the inflammation. For the second post, an additional reduction of the peri-implant skin thickness showed similar results after 10 days.

DISCUSSION

Extraoral implants should retain maxillofacial prostheses securely enough for patients to become confident in social situations. They should not have the fear associated with an adhesive-retained prosthesis becoming loose. Naturally they would like to have this confidence permanently, which gives rise to the question of whether extraoral implants used for maxillofacial prostheses can function on a long-term basis following successful osseointegration.[1,13,18] Survival times should be comparable with those achieved by intraoral implants. Opinions found in the literature differ greatly regarding survival times and rates, and the reported data should be taken into consideration when considering rehabilitation following a tumor surgery resulting in a defect or radiation treatment.[1,14,19]

In comparative experiments of different extraoral implant systems in a animal model, Wiltfang and associates[20] found approximately 5% greater bone-implant contact with press-fit implants. Consequently, it is recommended that implants be placed as described herein, without using the preplacement thread-tapping procedure normally used intraorally. This increases initial stability.

As far as the site is concerned, the ligament bony site does not have central blood vessels and depends, at least in part, on nutrition from the periosteal soft tissue (periosteum), which can be affected by ensuing radiotherapy. Holgers and colleagues also established this during immunohistochemical tests on irradiated skin biopsies.[21] They found an accumulation of inflammation and immunologically competent cells in the soft tissue of the implant emergence areas. They surmised that a cellular defense barrier existed to keep the inflammation at the emergence site. Other authors have described an intact keratinized epidermis surrounding the implant abutments.[22]

No problems with retention occurred during the observation period of this study. Additionally, the use of single standing magnet attachments clinically seemed to reduce the number of inflammatory skin reactions. Inflammation occurred in only 1 patient on 2 of the 3 implants he received, and this vanished after topical treatment combined with a reduction in the thickness of the skin flap surrounding the emerging magnet posts.

CONCLUSION

The extraoral implant system under consideration was able to stabilize epitheses effectively. These implants were used to support orbital, nasal, and auricular prostheses over a period ranging from 2 to 34 months.

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