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Review Article

Implant-retained craniofacial prostheses for facial defects

Abstract

Craniofacial prostheses, also known as epistheses, are artificial substitutes for facial defects. The breakthrough for rehabilitation of facial defects with implant-retained prostheses came with the development of the modern silicones and bone anchorage. Following the discovery of the osseointegration of titanium in the 1950s, dental implants have been made of titanium in the 1960s. In 1977, the first extraoral titanium implant was inserted in a patient. Later, various solitary extraoral implant systems were developed. Grouped implant systems have also been developed which may be placed more reliably in areas with low bone presentation, as in the nasal and orbital region, or the ideally pneumatised mastoid process. Today, even large facial prostheses may be securely retained. The classical atraumatic surgical technique has remained an unchanged prerequisite for successful implantation of any system. This review outlines the basic principles of osseointegration as well as the main features of extraoral implantology.

Keywords: osseointegration, titanium, implant, screw, plate system, episthesis, craniofacial prosthesis, extraoral implantology, surgical episthetics

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1 Craniofacial prosthetic rehabilitation

Defects or deformities in the head and facial area almost always lead to a severe emotional burden requiring rehabilitation [1]. Here the complex aesthetic units of ear, nose and orbital cavity are predominant. In principle, two paths can be followed, those of either plastic surgery or prosthetic rehabilitation. The procedures involved in plastic surgery are extremely suitable for the correction of less complex aesthetic units or partial defects of the ear, nose and orbital cavity. Particularly mobile areas such as the lips are difficult to be adequately treated with prostheses and should definitely be surgically reconstructed, even if the remaining defect is treated with a prosthesis. This may be accompanied by possible visible traces of flap raising in an adjacent aesthetic unit (donor site pathology).
Indications for bone-anchored prostheses are (modified according to [2], [3]):

- the necessity of optimal tumour aftercare, e.g. in the case of a high risk of recurrence,
- if local or general contraindications concerning procedures of reconstructive surgery exist (e.g. in the case of severely damaged skin following radiation),
- poor general condition,
- during individual stages in plastic reconstructive surgery (interim prosthesis),
- following failed reconstructive procedures,
- the rejection of reconstructive procedures on the part of the patient,
- high aesthetic demands,
- the desire for speedy rehabilitation,
- palliatively operated patients.

1.1 Materials for craniofacial prostheses

Figure 1: Orbital prosthesis made from silicon. Note the thin, transparent edges.

Following the large number of materials that have been tried out in the long history of anaplastology [4], as for example porcelain, natural rubber, gelatine and latex, two have established themselves: methacrylates and silicones. Methacrylates have the advantage of being more durable, they are, however, relatively hard. Silicones, on the other hand, are both soft and flexible and keep body temperature. Hair and skin features such as pigmentations can be easily introduced (Figure 1). The edges can be stretched so thinly as to become transparent. This enhances camouflage of the prosthesis as the intersection between the surrounding skin and the prosthesis is

fluid. With modern silicones it is possible to produce prostheses of outstanding cosmetic quality [5].

1.2 Methods of retention of craniofacial prostheses

The anchorage of prostheses can be achieved in four ways [6]:

- anatomical anchorage (to already existing anatomical structures such as undercut areas in the cavities of an orbital defect),
- mechanical anchorage (for example to spectacle frames),
- chemical anchorage (using adhesives [7])
- surgical anchorage (e.g. using surgically created retention elements [8])

Today, surgical anchorage is carried out using skin penetrating osseointegrated titanium implants (Figure 2) on the bone [1]. It has superseded surgical procedures such as various flaps [9], [10], [11], [12] for the creation of skin pockets for securing prostheses. Due to the secure retention, bone anchorage has contributed to a breakthrough in prosthetic rehabilitation [2], [13]. The first use of percutaneous titanium fixtures outside the oral cavity was by the Oto-Rhino-Laryngologist Anders Tjellström in 1977 for a bone-anchored hearing aid [14], and in 1979 for a bone-anchored prosthesis [15]. Nevertheless, still valid indications for conservative retention strategies may exist [16].

Figure 2: Implant systems for bone-anchored craniofacial prostheses. Left: Epitec system, back left: Brånemark system, back right: ITI system, front: universal plate of the Epiplating system, right: titanium bone screws with lengths of 4, 5.5 and 7 mm.

Bone anchorage has the following advantages [17]:

- enhanced and reliable retention
- retention is not affected by environmental factors (e.g. sweating)
- facilitated insertion of the prosthesis into the proper position by the patient himself
- the convenience of wearing is improved by not using adhesives and fewer skin occlusions
- the abovementioned thin, transparent edges of silicone prostheses can be maintained longer than with adhesive prostheses.

1.3 Coupling between implant and prosthesis

Typically, a metal bar is screwed onto the percutaneous posts onto which the prosthesis can then be clipped (Figure 3). This procedure has the advantage that the retention strength can be individually adjusted and altered by bending the clips. The bar construction, however, requires substantially parallel aligned percutaneous posts so that the least possible strain occurs. This parallelism of the posts is never achieved in the orbital area, and not always in the mastoid. For this reason, with very few exceptions, bar construction in the nasal and orbital areas can be regarded as obsolete [18], [19].
The advancement in magnetic connections thus represents huge progress. They facilitate the cleaning and insertion of the prosthesis by the patient. For this reason in the nasal and orbital areas magnets (Figure 10) are used almost exclusively today [20]. With auricular prostheses [21] they are used with non-parallel axes (here a bar construction can not be attached with low stress), with implants that are too close to one and other (distance of less than 15 mm) or in the case of individual hygiene problems. The magnet system Titanmagnetics® marketed by the company Steco consists of a samarium cobalt core (Sm_2Co_{17}) which is gastight and completely encased in titanium and is thus corrosion free [22]. Since the beginning of the nineties they have stood the test in a variety of configurations. The company Technovent markets another magnet system under the name Magna-Cap System. With the installation of long percutaneous posts or magnets with correspondingly long levers, the loading force imposed upon the implants should be gauged exactly in order to avoid a loosening of the implants as a result of too strong leverage [23]. This potential overload must also be considered with the alternative use of mushroom-shaped pushbutton systems [24].

2 Bone anchorage – osseointegration

The Swede Per-Ingvar Brånemark succeeded in the nineteen fifties in discovering that titanium possesses an exceedingly high bio-compatibility in bones (and also in other human tissue) [5]. He coined the term “osseointegration” [25]. This term was originally histologically on an optical microscopic level and defined as direct contact between implant and bone [26]. It was unclear, however, whether 100% bone contact was necessary for successful osseointegration [27]. In fact in the case of clinically successful implants a titanium-bone contact of on average only 70–80% was found [28]. On an electro-microscopic level there is a 20–500 nm wide amorphous gap between titanium and bone which is filled with collagens and calcified tissue [29]. A further weak point in the definition was that it offered no guidance on deciding whether an implant was clinically osseointegrated or not. Instead

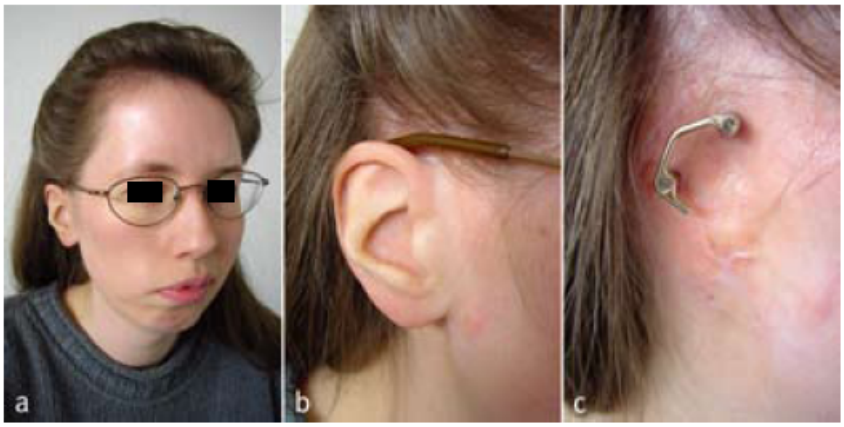

Figure 3: a) Female patient with bone-anchored auricular prosthesis (Epitheseninstitut Schneider) made from silicon for microtia and auditory canal atresia. b) Close-up. c) ar construction on 2 Brånemark implants.

Zarb and Albrektsson [30] provided the following compact definition: "Osseointegration is a process whereby clinically asymptomatic rigid fixation of alloplastic materials is achieved, and maintained, in bone during functional loading."

Within the context of physiological bone healing, two processes play an important part for osseointegration: osteoinduction and osteoconduction [31]. What is understood by osteoinduction is the ability to recruit undifferentiated mesenchymal cells and to stimulate their differentiation to preosteoblasts. The trauma in the course of a fracture, just as with the implantation, stimulates the accordant signalling cascade. This process is probably more significant for the formation of new bone tissue than the effect of the already present osteoblasts [32], [33]. What is understood by the term osteoconduction in this context is the ability for bone tissue to grow on a surface [31]. After the osteoinductive signals, sufficient blood supply and material factors play a role here. Copper and silver are, for example, not osteoinductive [34], however, stainless steel is [35]. It is important to understand that with osseointegration we are not dealing with a snapshot, but rather with a process. Through development and decomposition, constant remodelling takes place in living bone tissue. According to Frost's mechanostat theory, certain bending loading forces are necessary for bone formation and conservation [36], [37]. In vivo measurements revealed that functional loading with implant-retained auricular prostheses with clip retention lay within the physiological range [23].

Albrektsson et al. [26] named the following important factors for the long-term stability of the implant:

- biocompatibility of the material
- implant design
- implant surface
- condition of the recipient area
- surgical technique
- type and period of the functional loading

2.1 Implant materials

Since the work done by Brånemark, commercially pure titanium (c.p.Ti) is the most frequently utilised material in dental implantology. According to the manufacturer's data, this consists of 99.75% titanium and contains 0.05% iron, 0.1% oxygen, 0.03% nitrogen, 0.05% carbon and 0.012% hydrogen [38].

Titanium was discovered in England in 1791 by William Gregor. In 1795 the German chemist Heinrich Klaproth gave the new element the name titanium. It is one of the transition metals and has the atomic number 22. As an oxide with a content of 0.56%, titanium is the 9th most common element in the continental crust of the earth [39]. Usually, however, it is only present in low concentration. It was not until the introduction of the large-scale reduction of titanium tetrachloride with magnesium by Wilhelm Justin Kroll in 1946 that titanium was developed for commercial use.

The structure is polycrystalline with randomly ordered crystals [38]. Surface oxidation already takes place during the manufacturing process and cleaning. Of the different oxides that result from this, TiO_2, TiO, Ti_2O_5, titanium oxide is the most common. The titanium oxide layer is 5 nm thick and is the actual point of communication to the patient. What is special about titanium oxide is that it belongs to the most stable and corrosion-resistant materials. No other metal oxide has such a high dielectric constant which is almost comparable to that of water [38]. As well as titanium, other metals such as, for example, stainless steel, niobium, a number of titanium alloys, vitallium® (cobalt chrome molybdenum alloy) and ceramics also exhibit osseointegration.

The term c.p. titanium is now out of date. Today there is the international norm ISO 5832-2:1999 "Implants for surgery - Metallic materials – Part 2: Unalloyed titanium", which has been adopted unchanged as the German norm. According to this norm, after chemical composition 4 grades are identified. Internationally, however, the most importance is still given to the classification of the American Society for Testing and Materials (ASTM). The ASTM specification F-67 with grades 1–4 (Table 1) applies

Table 1: Chemical composition of non-alloyed titanium according to the American Society for Testing and Materials (ASTM) Specification F-67. The maximum marginal contents are given in % (m/m).

Element	Grade 1	Grade 2	Grade 3	Grade 4
Nitrogen	0.03	0.03	0.05	0.05
Carbon	0.08	0.08	0.08	0.08
Hydrogen	0.015	0.015	0.015	0.015
Iron	0.20	0.30	0.30	0.50
Oxygen	0.18	0.25	0.35	0.40
Titanium	residual	residual	residual	residual

for pure titanium for use as a surgical implant which, nevertheless, only differs slightly from the qualities of the ISO norm. The titanium mini-plates from well-known manufacturers are usually composed as a rule of grade 2–4 pure titanium (see Table 1).

In the case of osteosynthesis, screws or other mechanically bonded implants (e.g. parts of orthopaedic endoprostheses) the titanium alloy titanium-6aluminium-4vanadium (Ti_6Al_4V) is inserted as a rule. For use as a surgical implant, the ASTM specification F 136 applies according to which a thus termed implant may contain, alongside titanium, 0.25% iron, 0.13% oxygen, 0.05% nitrogen, 0.08% carbon and 0.012% hydrogen, 5.5–6.5% aluminium and 3.5–4.5% vanadium. This specification differs only slightly from the international norm ISO 5832-3:1996 "Implants for surgery - Metallic materials - Part 3: wrought titanium 6-aluminium 4-vanadium alloy". In animal experiments it was possible to demonstrate the osseointegration of titanium plates [40]. After 8 weeks a bone - screw contact of 77% in a pig mandible was achieved. Furthermore, a regeneration of bone under the titanium plate and bone growth on the plate occurred. Following the craniectomy of human skull previously provided with titanium mini-plates, it was possible to establish a bone – screw contact of 69.3% [41], that is to say in the magnitude/range which was also found with successful osseointegrated dental implants.

2.2 Surface quality

Most implants have a spiral macrostructure which ensures primary stability until osseointegration is accomplished. On the surface, however, differing levels of roughness (S_a) exist, depending on the implant [42]. Here 4 categories are classified (Table 2). As a rule the abutments and certain experimental polished implants are smooth. These have proved themselves unfavourable for osseointegration [42]. The original Brånemark implant was a turned screw with minimal roughness. These were regarded as the gold standard in dental implantology right up until the mid nineteen nineties [42]. They are still marketed for the extraoral area as the Vistafix™ system by the Cochlear company. Moderately rough implants exhibited a higher bone reaction than the minimally rough implants [43]. This does not mean, however, that higher clinical success is thus achieved [42]. In the case of dental implants over 2.0 µm S_a roughened by plasma spray, however, a higher peri-implantitis rate could be observed [44], [45], so that minimally or moderately rough implants provide the best results [42]. In dental implantology, implants with a moderately rough surface are currently being used most frequently [42], whereby here commercial factors possibly play a role. Current developments with bioactive surfaces are discussed further below.

Table 2: Classification of surface roughness according to S_a-values [42].

Surface Roughness	S_a
smooth	0.0–0.4 µm
minimally rough	0.5–1.0 µm
moderately rough	1.0–2.0 µm
rough	>2.0 µm

3 Extraoral implant systems

For many producers, extra-oral application plays a subordinate role to that of dental application. Currently the market for niche products for extraoral implants is changing, the result is that at the time of going to press it cannot be said with any certainty which systems will be available on the market in the future. The classic Brånemark system (Figure 2) as a solitary screw implant, as well the large number of analogous systems from the field of dentistry are collectively referred to here under the term "solitary implants". In order to distinguish these from classic titanium fixtures, the term "grouped implants" for grid and plate systems has been chosen, which are secured with several smaller bone screws. With these systems an implant can also bear several percutaneous abutments.

3.1 Extraoral systems with "solitary implants"

3.1.1 Brånemark system

The Brånemark system (Figure 3) was the first implant system to be used extraorally [14], [15]. The longest and most extensive experience has been gathered with this system [46]. Since the introduction of self-tapping implants, the necessity for tapping has ceased [47]. For the extraoral area, titanium screws of a length of 3 and 4 mm (and 5.5 mm) are available. The flange was originally designed to avoid an intracranial dislocation of the implant due to trauma. The flange is now available in closed

form. At present flangeless screws are also obtainable. Abutments can be held by a special clamp. It must be understood, however, that the clamp only reduces the torque by 10 Ncm so that care must be taken not to inadvertently overwind the implant. Currently the Brånemark system is being marketed by the Cochlear Company under the brand name Vistafix.

3.1.2 ITI systems

With ITI implants (International Team for Implantology) marketed by the Straumann company, a sand-blasted, large grit, acid-etched surface was introduced, the so-called SLA surface. The resulting roughness is two-staged: the greater roughness of ca. 20 µm is overlaid by a finer roughness of 2 µm intervals [48]. For the extraoral region self-tapping titanium screws with a diameter of 3.3 mm and a countersunk depth of 3.5 or 5 mm with a coned seat, as well as with a diameter of 2.5 or 4 mm with flange (Figure 2). The longer screws which were designed for the extraoral region are also available with the hydrophilic SLActive surface.

3.1.3 Other systems with solitary implants

Some systems which were designed for the extraoral region, as for example the IMZ system [49] marketed by Friatec (Friadent), or the epiplant system marketed by Mathys, are no longer on the market. Dentsply Friadent is currently marketing the Ankylos system. Yet another company, Southern Implants, is marketing extraoral screws of grade 4 titanium, as well as dental implants.

3.2 Extraoral systems with grouped implants

In 1956, Köle and Wirth [50] described subperiosteal frame implants made of Wisil®, a cobalt chrome alloy. These subperiosteal implants were adapted to the bone surface, without being anchored into the bone itself. The prosthesis attachment takes place on parts of the frame implant projecting through the skin. A patient with an auricular prosthesis and one with a nasal prosthesis were treated in this way. Both implants had healed with no adverse reactions after 8 years [51]. In contrast to this, the analogous use of subperiosteal implants in the jaw for fixing dental prostheses was less successful, which could be put down to the higher mechanical load [51].
Both systems described in the following are also used subperiosteally, but fixed with bone screws also used in osteosynthesis (Figure 2). In contrast to the solitary implants, the forces are distributed across the plate over several titanium bone screws. An already thinned out area can be used again following the loss of another (solitary) implant. In this way a secure fixing in anatomically difficult regions with limited bone area is possible.

3.2.1 Epitec system

The Epitec system, credited with being developed in 1991 by Mostafa Farmand [52] and the company Leibinger, represents a great advancement. The system consists of a mouldable quadratic titanium grid with 16 thread holes, the so-called 3D carrier plate, and self-tapping 2 mm titanium screws which are available in lengths of 4.5 and 6 mm. The 3D carrier plate has to be cut to the required shape. For reasons of stability, as many connecting bridges between the single screw holes as possible must be maintained. Single extensions are not stable. Plate retention results primarily from the use of these monocortical bone screws. Secondary to this, the 1 mm thick connecting bridges of the 3D carrier plate will be covered over by bone. A thinning of the skin is usually not recommended. Due to the easy pliancy, constructions extending into the defect are currently no longer recommended. In order to screw on the mountings, only a thread height of 1 mm with 2 screw leads is available.

3.2.2 Epiplating system

Figure 4: Examples for the attachment of implants of the Epiplating system in the auricular, nasal and orbital regions. The trimmed universal plate in the glabella is only expedient in the case of resected nasal bones.

The Epiplating system (Figure 4) was developed in 2000 by the Medicon company in collaboration with P. Federspil, Ph.A. Federspil and M. Schneider [53]. It is the adaptation of the 2.0 titanium mini-plate system produced by Medicon and used in traumatology to the requirements of anaplastology. Specially adapted implants are available for the auricular, orbital and nasal regions, as well as a universal plate. The titanium plates of the Epiplating system are 1 mm thick, but 2 mm in width and are thus stronger than the Epitec grid system. In the area of the tapped holes provided for the mountings, the thickness of the plate is 2 mm, appropriate for 4 thread turns, which counterbalances any tendency of loosening of the percutaneous base posts or magnets. To anchor the plates, titanium screws of 2 mm in breadth are used which are supplied as standard in the following lengths: 4, 5.5 and 7 mm. Thus the high stability known from plate osteosyn-

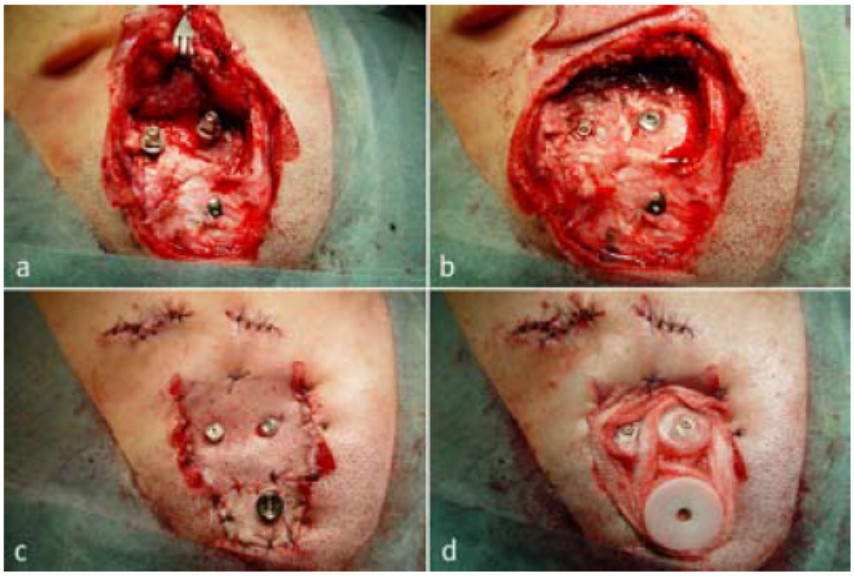

Figure 5: Patient with microtia grade III and canal atresia. a) An anterior based split thickness skin flap was raised. The hook holds the subcutaneous tissue still to be excised. A thin periosteal layer remains. On both Brånemark implants for auricular prosthesis the insertion posts have not yet been unscrewed. Further occipitally, a Brånemark implant for a bone-anchored hearing aid has been inserted. b) The subcutaneous tissue is resected. c) The split skin flap is folded back and sewn in. Abutments are screwed on. Any remnant of the auricle is removed. d) The split skin is packed under the healing cap.

thesis can be achieved. At the same time, the plates are more resistant against rotational forces which occur when screwing down and unscrewing the mountings. A counter instrument such as this as is usual in solitary implants does therefore not have to be used. Magnets can either be screwed directly into the plate or onto a base posts, as the height of the mounting requires. In addition, the Epiplating system can be combined with the hearing device abutment of the BAHA system [53], [54].

4 Implantation

4.1 Main features of the surgical technique

The basic principles of the surgical technique all date from the Brånemark technique. Basically we can differentiate between 2 stages: the first stage consists in essence of bone drilling and the insetting of the titanium implant. The second stage consists of the soft tissue reduction and achieving a hairfree surrounding skin areal, as well as the insertion of the percutaneous abutment through the skin. Both these steps can be carried out either in one operation (one-staged), or in two separate interventions (two-staged). In order to minimise the surgical trauma for the bone, the following points are of importance:

- The use of a new and sharp drill / cutting burr
- Low drill speed (1500–2000 Rpm)
- Extensive cooling through flushing with Ringer's solution

The surgical technique varies for solitary and grouped implant systems.

4.1.1 Surgical technique with solitary implant systems

In the past a thread had to be cut into the bone for implantation. Today, self-tapping titanium screws are available for all established systems. Special instruments are required. Palpating movements with the drill indicate whether there is still bone at the bottom of the hole. In order to avoid contamination, the titanium fixture should only be handled with titanium instruments. With torque control, the titanium fixture is screwed in mechanically with no more than 10–45 Ncm. The use of the 4 mm long fixtures is preferred. The skin thinning in the area around the titanium screw prevents pocket formation and skin movements around the implant which might lead to inflammation (Figure 5a-b). An attachment (called either percutaneous post or abutment) is screwed onto the titanium implant itself which then projects outwards through the skin (Figure 5c). A gauze strip packing presses the thinned skin to the periosteum (Figure 5d). With non-irradiated adults and a cortical bone thickness of 3mm, one-staged implantation is possible. The unloaded healing phase is 6 weeks. Otherwise two-staged procedure should be initiated at intervals of 3 months. With irradiated patients, an interval of 6 months should pass before the second stage.

4.1.2 Surgical technique with grouped implant systems

With grouped implant systems, instruments are predominantly used which are common in osteosynthesis. In addition, only a few special instruments are required. The implants are inserted subperiosteally (Figure 6). It is important to fit the implants as level as possible to the

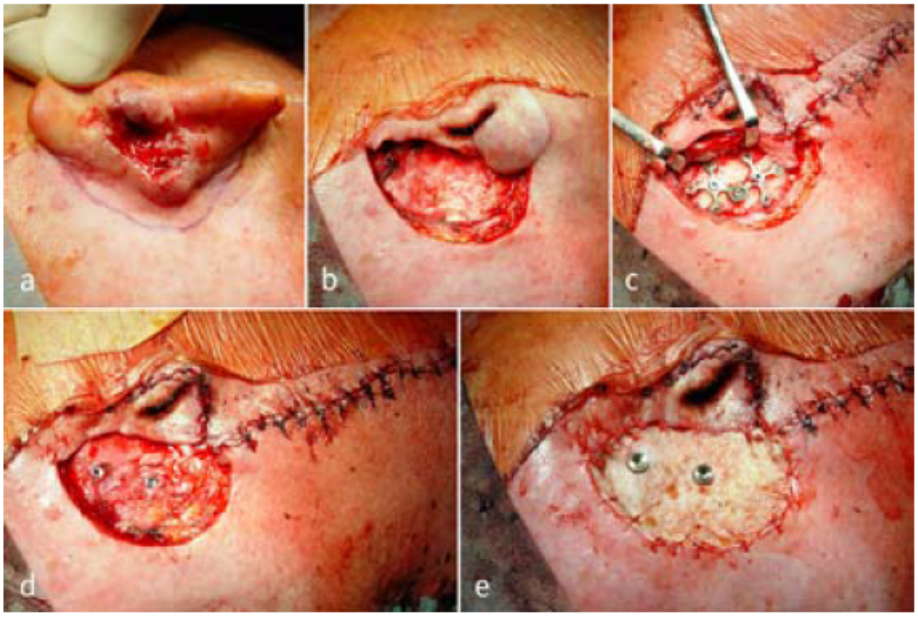

Figure 6: a) Squamous cell carcinoma of the back of the auricle. b) Intra-operative situation after tumour resection. The periosteum could be preserved. c) Subperiostal positioning of an Epiplating auricular plate. Parotidectomy and neck dissection have been performed. d) The periostal flap is folded back and perforated in the area of the tapped holes. e) A split thickness skin transplant is covering the periosteum.

Figure 7: a) Patient from Fig. 6. three years after surgery. b) With 3 year-old auricular prosthesis (Epitheseninstitut Schneider).

shape of the bone using bending pliers. This avoids tension on the plate. Before bending the grid or the plate, threads are secured by cover screws in order to avoid any distortion. Holes are drilled for the self-tapping titanium bone screws using a spiral drill (1.6 mm diameter). The atraumatic principles of implantology referred to above remain valid. At least 3 (4 would be better) screws should be inserted in order to achieve primary stability. Overwinding the screws must be avoided. The percutaneous passage with the abutment/magnet can be carried out directly in the area of a tapped hole in the plate (Figure 7). There is also the possibility, however, that skin penetration takes place at the back bone of the plate (e.g. nasal plate of the Epiplating system) outwards through the skin (Figure 9). The management of soft tissue is just as important as the implantation, but soft tissue reduction does not have to be carried out as radically as is the case with the Brånemark technique. On principle, an integration phase of 2 to 3 months is recommended. Under ideal circumstances, loading is also possible after 6 weeks.

4.2 Contraindications

Absolute contraindications with regard to an implantation are severe psychiatric disorders (e.g. dementia) and cachexia. A lack of hygiene, drug or alcohol addiction and minor psychiatric disorders are merely relative contraindications and should be assessed individually.

4.3 Planning implant position and regionally specific characteristics

The locations for percutaneous mountings should first and foremost correspond to the requirements of the anaplastologist. The bone is only of secondary importance. Whilst with solitary systems implantation area and that of the abutment are identical, this can be varied with grouped implant systems subject to the bone availability. Apart from standard situations, it is advisable to discuss the optimal region for the abutment with the anaplastologist before the procedure. This is also the case for the number of abutments or magnets required in individual cases. At the same time, a basis for trust is established between the anaplastologist and the patient which also helps to dissipate unreal expectations. One valuable gain is the presence of the anaplastologist in the operating theatre.

4.3.1 Ear

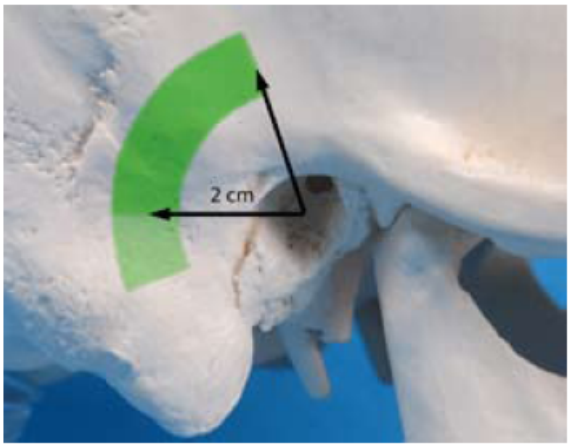

Figure 8: The ideal position for a structure for securing an auricular prosthesis on the right is marked in green. The distance to the centre of the auditory canal is 2 cm.

If the dial of a watch was to be projected onto the right ear, the classic regions for implantation would be eight o'clock or, even better, 9 o'clock, as well as between 10 and 11 o'clock at a distance of 2 cm from the external ear canal (Figure 8). This localisation corresponds roughly with the anthelix and thus allows a sufficiently high space for the abutment of the auricular prosthesis. Two abutments are sufficient for a bar construction. When using magnets, a third magnet can improve retention. This is then usually placed caudally from seven to eight o'clock. If 3 magnets are used, they should preferably not be in a straight line. Any remnants of the auricle still present should, as a rule, be removed. In an ideal pneumatisation the cortical bone in adults is partially only 1–2 mm thick. In this case grouped implant systems have particular advantages. As well as the classic auricular plate with 2 tapped holes with the Epiplating system, a new plate with 3 tapped holes is also available. The optimum distance of 1.5 cm between the magnets is, in the case of the Epiplating auricular plate, already taken into account. When using an Epitec grid, however, these points must be borne in mind during planning.

4.3.2 Nose

Due to the limited amount of bone available, the use of solitary implants in the nasal region is problematic. Provided that the nasal bone is completely removed, sufficient bone can be found around the glabella. Anchoring a nasal prosthesis to a solitary Brånemark implant in the glabella is possible. Otherwise solitary implants can be used solely at the nasal floor which, however, provides less a secure retention for the prosthesis. Good bone availability for the use of the Epiplating system can be found around the piriform aperture, and in particular at the frontal process of the maxilla (Figure 9, Figure 10). In addition, a universal plate of the Epiplating system can be implanted in the glabella (Figure 4).

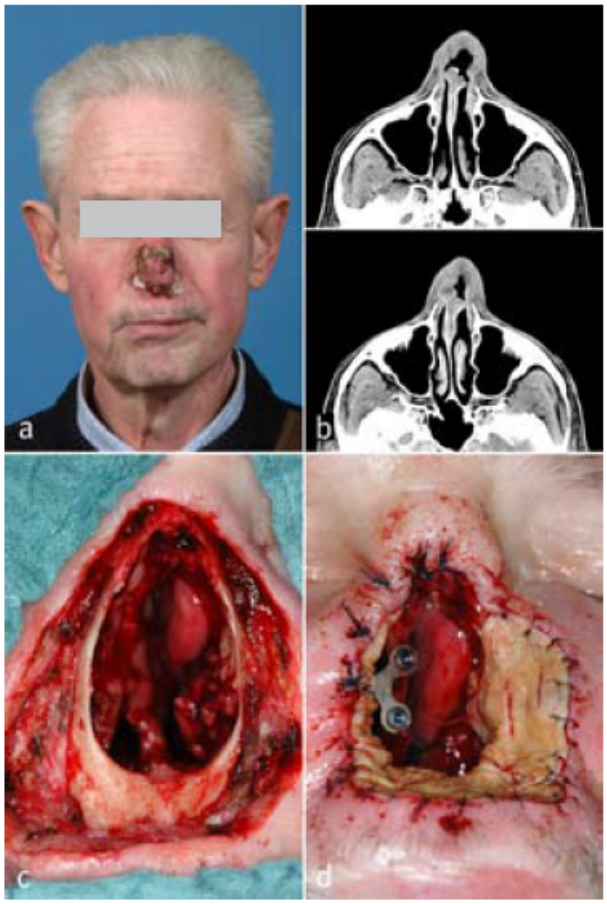

Figure 9: a) 67 year-old patient with a squamous cell carcinoma of the inner nose. Recurrence after primary radiotherapy 1 year earlier. b) The CT shows widespread infiltration. c) Intra-operative situation following tumour resection. d) An Epiplating nasal plate is inserted on the right. The tapped holes are secured with blue covering screws. Open wound areas are covered with split thickness skin transplants.

Figure 10: a) Patient from Fig. 9 two months after surgery. The implant is stable with no adverse skin reactions and is fitted with 2 magnet inserts (Steco). b) Patient with the bone-anchored nasal prosthesis (Epitheseninstitut Schneider).

4.3.3 Orbital cavity

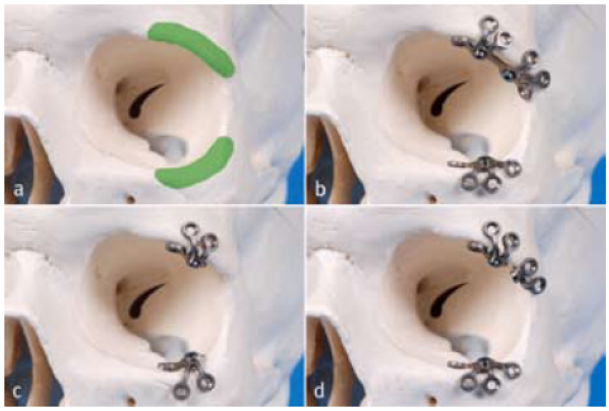

Figure 11: a) The ideal positions for implant placement for orbital prostheses are marked in green. b) Classic positioning of an orbital plate for 2 magnets (cranial) and 1 universal plate (caudal). The long eyelets of the orbital plate have been removed here. 4 arms were used form the universal plate. c) For smaller orbital defects, one magnet above and below is sufficient. Here an orbital plate was inserted in two halves. d) Other combinations are possible, here, for example, a halved orbital plate and a universal plate with 2 arms was inserted above. Below, a universal plate can be seen.

Classic implant regions are found in the laterocranial and laterocaudal orbital rim (Figure 11a). The mediocranial area is too close to the frontal sinus and the bone in the mediocaudal area is usually too thin. No magnets should be placed laterally as here there is not enough height for the prosthesis. In the standard situation, an orbital plate of the Epiplating system can be implanted laterocranially for 2 magnets, and a universal plate laterocaudally for one further magnet (Figure 11b, Figure 12, Figure 13). In the case of a small orbital cavity, 2 magnets distributed laterocranially and laterocaudally on one universal plate respectively are sufficient. Alternatively an orbital plate can also be divided and one half each distributed on the same positions (Figure 11c-d). In the case of a flat orbital cavity, the Epitec or Epiplating system can be placed through the orbital cavity like a ladder in the sagittal plane. Alternatively, the flat orbital cavity must be secondarily deepened in order to achieve the necessary height for the prosthesis of around 1cm. The free transplantation of a non-vascularised bone from the iliac crest with the insertion of 2 solitary implants [55] has also been reported. Alternatively, alongside the extraoral solitary implants, the longer dental implants may also be used. Thus Wächter et al. [56] report on the use of 8, 10 and 12 mm long ITI titanium screws in the orbital region.

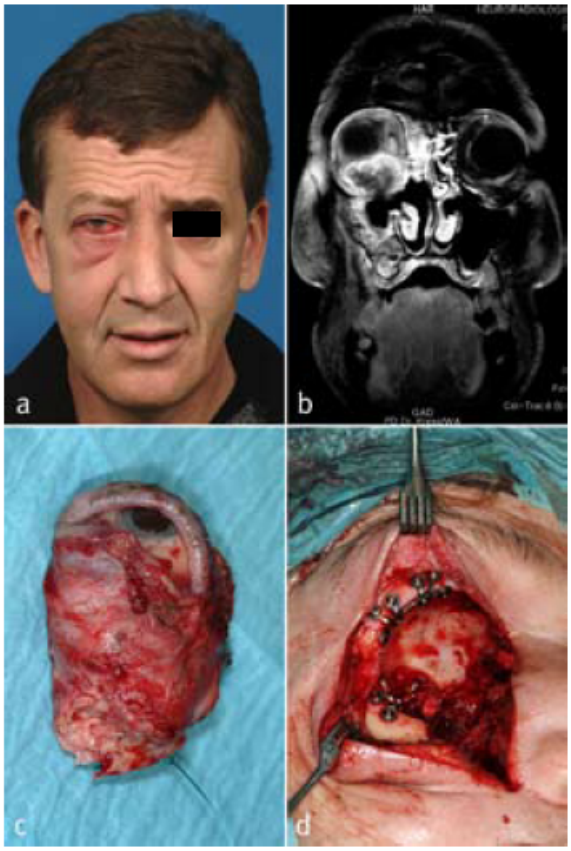

Figure 12: a) 48 year-old patient with a relapsed squamous cell carcinoma of the ethmoid. The primary tumour had been resected one year before via medifacial degloving R2. As the patient had initially refused an orbital exenteration, chemoradiation (66 Gy) was additionally carried out. b) Extensive infiltration of the orbital cavity can be seen in the MRI. c) The resected tumour specimen. d) An orbital plate and a universal plate are inserted.

4.3.4 Extensive facial defects and special applications

In the cases of defects that exceed one aesthetic unit, individual solutions using combinations of several of the above mentioned implant types have to be found. In the case of a missing frontal bone the possible solution lies in the use of the long plate of the Epiplating system which can be laid straight through the orbital cavity from the glabella to the malar bone (Figure 14). The zygomatic arch can also serve as an anchorage point for a universal plate. An accompanying measure is the split skin transplantation, (Figure 6, Figure 9, Figure 13) for a more

Figure 13: a) Patient from Fig. 12. The implants have been exposed and temporarily covered with healing caps until the magnets are screwed on. From this angle the cranial implant is not visible. The split thickness skin graft placed into the cavity has healed in. b) The patient is wearing the bone-anchored facial prosthesis (Epitheseninstitut Schneider).

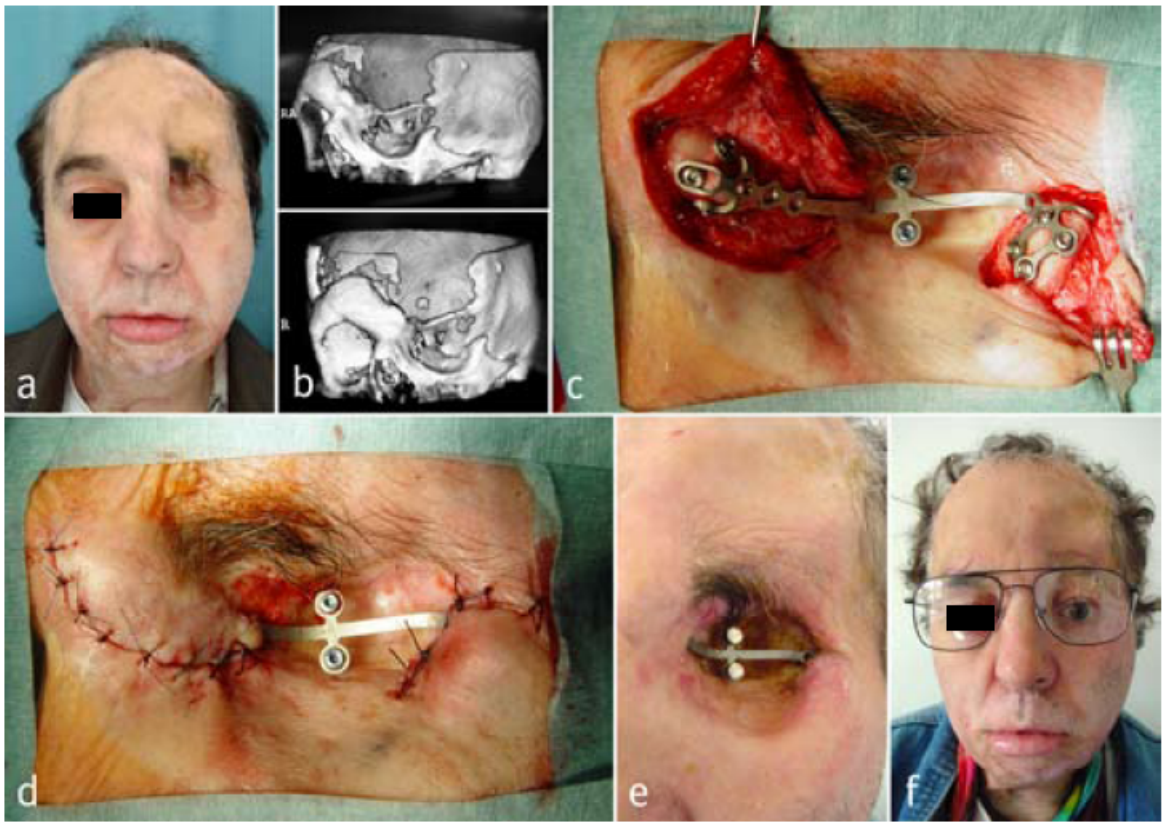

Figure 14: a) 49 year-old patient with a fronto-orbital facial defect 3 years after craniofacial resection. b) The bone defect is recognisable in the CT. The most important anchorage option in the region of the cranial orbital clip is missing. c) The long plate of the Epiplating system is fixed subperiostally in the region of the glabella and to the malar bone. The thread guides are secured by covering screws and lie in the centre of the orbital cavity. d) The wound is closed. e) The healing process is complete. Magnets (Steco) are screwed into the thread guides. f) The patient is provided with a bone-anchored orbital prosthesis (Epitheseninstitut Schneider). The patient wears glasses for improved camouflage and protection of the right eye.

Table 3: Cumulative survival rates for craniofacial implants in a variety of regions. Modified according to [88]. * indicates a multicentre study. The table does not claim to be complete.

	Number of Implants		Implant Survival Rate [%]	
	no RT	RT	no RT	RT
Mastoid				
Parel and Tjellström, 1991 (USA) [89] *	162	4	98·1	100
Parel and Tjellström, 1991 (Sweden) [89]	352	6	98·3	100
Wolfaardt et al., 1993 [90] *	87	0	98·9	-
Watson et al., 1995 [91]	60	0	95	-
Tolman and Taylor, 1996 [92] *	306	12	99	100
Visser et al., 2008 [88]	124	29	95·7	86·2
Orbital Cavity				
Parel und Tjellström, 1991 (USA) [89] *	54	37	96·3	56·8
Parel and Tjellström, 1991 (Sweden) [89]	61	44	91·8	45·5
Wolfaardt et al., 1993 [90] *	29	28	96·6	96·4
Tolman and Taylor, 1996 [92] *	55	43	100	79
Toljanic et al, 2005 [17] *	61	92	83·6	66·3
Visser et al., 2008 [88]	34	65	94·1	73·8
Nose				
Parel and Tjellström, 1991 (USA) [89] *	44	10	80	46
Tolman and Taylor, 1996 [92] *	31	5	81	100
Flood and Russel, 1998 [93]	13	17	100	94·1
Klein et al. 1999 [94]	29	12	89·7	50
Visser et al., 2008 [88]	8	10	90	87·5

speedy tissue repair. Facial prostheses can be coupled reciprocally with defect obturator prostheses so that they support each other [57].
Exposed nerves or exposed or reconstructed dura mater at the skull base usually require vascularised covering, ideally with a microvascular anastomosed free tissue transfer [58], [59], [60]. Here the required height for the prosthesis must be observed. If this is not the case, then the area must be thinned after healing.

4.4 Results of the implantation

By far the greatest experiences have been gathered by the classic Brånemark system. The best results are achieved in the mastoid: here the loss rate is only 8% [46]. On the other hand, a loss of 50% loss of Brånemark implants in the frontal bone, and 20% in the malar bone must be reckoned with [46]. These regions, however, are also more frequently irradiated. Schwipper at al. [61] report a loss rate of around 5.8% in the auricular region, 23.5% in the orbital region, 40% in the nasal region, and 17.4% with combination prostheses. With the author's patients the failure rate of Brånemark implants for auricular prostheses was 2.27% [62]. In an US American multicentre study an implant failure rate in the orbital region of 23% after 5 years and 42% after 10 years was found [17]. Table 3 summarise a selection of larger studies on Brånemark implants classified according to region and irradiation.
With the Epitec system, Farmand [63] reported the loss of 4 out of a total of 35 grids (12.5%), which admittedly came from the early period. Amongst the author's patients there was one loss out of 87 implants (1.15%) of the Epiplating system.
Here a nasal plate was involved which was placed on thin nasal bones. The Epiplating system has also been used successfully by other authors [54], [64], [65].

4.5 Complications

The most frequent problems come from the site of the skin penetration. In spite of extensive skin thinning, some patients occasionally experience adverse skin reactions. In comparison to oral implants, there are significant differences. The gingiva is made for mucosal penetration. Saliva and the cleaning properties of the tongue contribute significantly towards maintaining good condition in the implant area. Holgers et al. [66] have described a scoring system for the classification of these skin reactions: 0: no reaction, 1: reddish, 2: red and moist, 3: granulation tissue, 4: skin infection to such a degree that the abutment has to be removed. 92.5% of BAHA patients had a reaction-free periimplant skin (Holger score 0), 91.1% of those wearing an orbital prosthesis and 89.3% of those with an auricular prosthesis [67]. Important factors are thinning of the skin and personal hygiene. Otherwise complications are extremely rare. With their report of an intracerebral abscess following the changing of a percutaneous abutment in a BAHA patient, Deitmar et al. [68] described the first serious complication [69] of an extraoral osseointegrated implant worldwide.

4.6 Procedure with irradiated patients

Granström [70] found an overall failure rate of Brånemark implants (including dental implants)) of 23.3% with irradiated patients as compared to 10.8% with non-irradiated patients. Bones around the orbital cavity were significantly more affected with a failure rate of 40–50%. Unfavourable loading situations due to the prosthetic retention system also had an unfavourable influence. The influence of the radiation dosage expressed as "cumulative radiation effect" (CRE) according to Kirk et al. [71] became statistically significant from value of 30 relating to implant loss. However, only very few implants were used with such high CRE values. Traditionally in Sweden many patients received radiotherapy pre-operatively with the result that the vast majority of patients were already irradiated prior to implantation. Following a time period of 15 years between radiotherapy and implantation, a significantly higher loss was determined [70]. Hyperfractionation, on the other hand, had no influence on the survival of the implant [70]. With a hyperbaric oxygen therapy (HBO) a loss rate of only 8.5% as opposed to 40.2% without HBO was achieved [70]. Nevertheless, this procedure is not without controversy [72]. In a non-randomised US American multicentre study there was no significant difference in the survival rate of titanium implants in the orbital cavity region either with or without HBO [17]. The most favourable option is certainly to implant before radiation; no HBO therapy would then be necessary. Alternatively there should be a pause of I year following radiation before bone anchorage takes place. The author does not routinely use HBO. The procedure is carried out in two stages with a healing phase of 6 months.

4.7 Craniofacial prosthetic treatment of children

The treatment of children and adolescents with bone-anchored prostheses [21], [46], [73] is also possible. This question arises most frequently in cases of major auricular malformations. With children it is important to be as cautious as possible with the implantation as owing to scar formation the prospects for plastic surgery will at the very least deteriorate. In particular due to the progress made in surgical (re-) construction of the auricle [74], [75], it is important not to block this option for young patients. Even after previous surgery, the implantation of a porous polyethylene framework can be carried out if the superficial temporal vessels are preserved [76]. If the social and emotional state of the child requires no urgent action, any rehabilitation should only be carried out if young patients have a say in the matter or can decide for themselves. Proops [77] recommends provision with bone-anchored prostheses from the age of 10 years. An implantation should at best only be considered after puberty in adolescents [78]. A temporary solution is offered by an adhesive retained prosthesis. In the case of malformations in children it should not be forgotten that the young patients should indeed be cared for (and not the parents) and their wishes be respected [79].

5 Current developments

An orbital prosthesis was presented by Klein et al. [80] which can blink via myoelectric conduction from the opposite side. Up until now, however, such prostheses have been too heavy. A further field where exciting developments are awaited is that of robot-supported interventions [81], [82]. First steps have been taken in the area of implantology for bone-anchored prostheses [83].
Bioactive surfaces are on offer from a number of producers of dental implants [42] which in the advertising are referred to as "osteo-attractive". In this context, bioactivity is defined as a "characteristic of an implant material which allows it to cultivate a connection with living tissue" [84]. With such bioactive surfaces it is hoped that a speedier osseointegration will be achieved. Calcium phosphate bonded implants are available from several manufacturers [42]. A fluoridated implant (Osseospeed) is produced by Astra Tech. With TiUnite, Nobel Biocare offers an implant with an oxidised surface, where in one study no bioactivity could be demonstrated, however [85]. In the case of an oxidised magnesium implant, on the other hand, a speedier osseointegration could be observed [86]. One further field is that of the pharmaceutical coating of implants with, for example, the bone morphogenetic protein (BMP), or other bone growth factors. In animal experiments, a nano-porous TiO_2 coating also proved to be more favourable than standard implants [69]. Siegert and Stemmann [87] treated patients with a subcutaneously implanted double magnet, where the auricular prosthesis attached magnetically can be worn on intact skin. To what extent these approaches will be successful and better than previous procedures in the future still has to be shown by clinical studies.

6 Advantages and disadvantages of implant-retained prostheses

Implant-retained prostheses have both advantages and disadvantages (Table 4). In the majority of cases the advantages prevail. They are not the opposite of plastic reconstructive measures, but can rather frequently be used complementarily. They can also be used as a temporary measure before surgical reconstruction (interim provision). This would be expedient, for example, in the case of a defect after rhinectomy when complex reconstruction is to be carried out only after a period of 2 years so that the risk for tumour recurrence is minimal. Here, an implantation would not hinder later reconstruction. Implant-retained prostheses are indeed more than just an alternative.

Table 4: Advantages and disadvantages of implant-retained craniofacial prostheses

Advantages	Disadvantages
Well suited for complex anatomic regions (ear, orbital cavity, nose)	Not well suited for the replacement of mobile parts of the face
Optimal camouflage	Must be removed at night
No donor site defects	+/- colour matching with changing complexion
Cosmetic results excellent and predictable	Discoloration due to cigarette smoke
Simple and quick methods	Costs
Early recognition of tumour recurrence	New prosthesis every 2 years
Secure retention	Maintenance for percutaneous parts
Edges of the prosthesis become transparent and allow smooth transition from the facial skin to the prosthesis	“foreign bodies”

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Erratum

The figures 8 and 9 have been renumbered and the figures 12 and 14 have been switched. The references 1–20 have been modified. The text has been linguistically improved.

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