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Al_2O_3-Ceramic as material for dental implants: experimental and clinical study for the development of screw- and extension-implants

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ABSTRACT – A screw implant and a blade-vent implant were developed for the alloplastic substitution of teeth. Forty implants were observed for 18 months in five beagles; these implants were under maximal functional mastication. No implant was lost. The screw implant showed a tight attachment of bone over the whole implant surface. With the blade-vent implant we observed a partial interposition of connective tissue. This difference seems to depend on the different insertion techniques. Photoelastic studies showed a good stress distribution through enlarged and rounded off attachment surfaces. The described insertion techniques allowed a primary tight attachment of the implant surface and bone support, which led to an immediate stability of position. In the screw implant the physiologic mobility of teeth was imitated by means of a resilient element. Data from 30 cases were gained in a clinical 3-year follow-up. One case failed. For conclusive judgement, a longer period of time and more clinical cases are necessary, but existing data are encouraging.

As soon as the excellent bio-compatibility of ceramics and the improved quality of aluminumoxide ceramics were known, it was the logical consequence that this material should be used as an intraosseous implantable tooth substitute. Continuing development in this area is desirable, as implantation of alloplastic materials – up till now usually metal alloys – is still a great problem. A completely enclosed implant of aluminumoxide ceramics, such as an endoprosthesis of the hip[16] or an orbital floor reconstruction[11], can already be considered with few problems.

The problems of dental implantation have, however, by no means been solved and will encompass more work and thought. This, on one hand, is based on the fact that the implant perforates the tissue of the jaw open to the oral cavity, which makes the tissue of the sulcus around the implant particularly susceptible to infection; on the other hand, the problems are based on the seemingly contrary demands that the alien

object should heal completely and firmly into the body tissue, but that an elastic quasi-periodontal mechanism or ligament should form to absorb the masticatory stress, which is not only strong but also without defined direction. The last two points are the reason for many-sided problems which can be roughly divided into the following topics: material, implant shape, implantation technique and masticatory stresses.

Materials and methods

The implants used were made of high density multicristalline aluminium oxide (99.7 % Al_2O_3 + 0.25 % MgO). The ceramic has a compressive strength of 4900 MN/m² and a flexural strength of 490 MN/m² (Feldmühle, Plochingen, FRG).

The biocompatibility of the implants was tested on 12 beagle dogs. In the last series of tests we were able to observe five dogs with 40 implants. The implants had crown reconstructions which were duplicates of the extracted teeth and were under maximum functional masticatory force during a period of 18 months.

The development of the implant shapes was tested with photoelastic studies[18,19].

Clinical follow-up tests of 30 implants for 3 years consisted, besides other parameters, of measuring gingival sulcus depths with flexible periodontometers. To get a reproducible judgement of the degree of the peripheral mucosa infection, gingival crevicular fluid (GCF) was withdrawn intracrevicularly from the sulcus, according to the method of LÖE & HOLM-PEDERSEN[15] and measured with a periometer (Periotron, Harco, Winnipeg, Canada)[6].

Results

The main indications for an implant are the replacement of a single tooth, and the terminal edentulous and the toothless mandible. These different indications encompass different stress distributions and anatomic situations and therefore two completely different implant shapes. We developed a screw-shaped implant and an extension implant, building on established principles of the modern osteosynthesis process. The implants are shown in Figure 1.

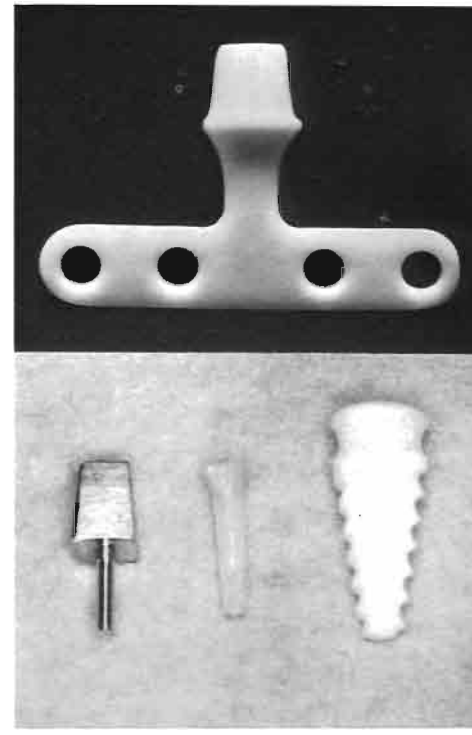

Fig. 1. Two different implant shapes have been developed as representative for the main indications. Above, the extension implant and, below, the screw implant with resilient body (by courtesy of Osteo).

In the histologic serial sections we found the reactionless impaction of the implant in the bone formerly observed by other examiners. A particular feature of the screw implant was a close connection to the bone without the development of a connective tissue layer. In some of the animals with extension implants, island-like connective tissue areas could be seen along the implant surface.

Photoelastic studies showed a force concentration on the lower edge of the extension implant; this concentration is, however, less in rounded-off ceramic plates than it is

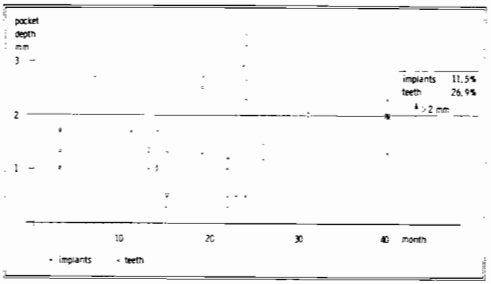

Fig. 2. The time-diagram shows the mean gingival sulcus depths of the implants and control teeth of the same individuals (Implants: $n = 26$, $\bar{x} = 1.27$, $\tilde{x} = 1.3$, $s = 0.79$; control teeth: $n = 26$, $\bar{x} = 1.74$, $\tilde{x} = 1.9$, $s = 18.46$).

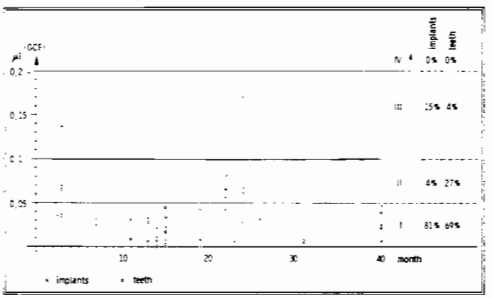

Fig. 3. The time-diagram shows the mean gingival crevicular fluid (GCF) of the implants and control teeth of the same individuals (Implants: $n = 26$, $\bar{x} = 0.037$, $\tilde{x} = 0.024$, $s = 0.043$; control teeth: $n = 26$, $\bar{x} = 0.037$, $\tilde{x} = 0.033$, $s = 0.029$.)

in wedge-shaped implants. The rounded-off lower edge contributes to an acceptable picture in the frontal plane, which in other cases of extension implants was less favourable and resulted clinically in a continuing sinking of the implant. The screw-shaped implant has a taper of 13°, which imitates the form of a natural root to a certain extent. We chose a screw thread for anchorage in the bone to get a larger contact area and a good stress distribution in the axial direction, and derived from these two points better primary stability of the implant. The modified screw thread with rounded edges was turned upside down, so that the flatter area of the thread was able to give better support to axial stress. The photoelastic experiments showed that this thread form turned out best in quality comparisons of axial, horizontal and slanting stress.

The mean period of clinical observation was 18.4 months, the longest period being 3.25 years. One of the implants was lost after 3 months. All patients presented a normal medical history. An implant was indicated when oral hygiene was good and the dimension of the alveolar bone was adequate, so that the implant was embedded deeply enough, yet no risk was taken that it would collide with either the maxillary cavity or the mandible canal. Thirteen implants were made in the left lower jaw, twelve in the right lower jaw and two in the right upper jaw. In each case it was a second-class situation; that is, anterior teeth were present which could be attached to the implant by a bridge.

The gingival sulcus depths were compared with the depths in neighbouring teeth (neighbouring tooth and same tooth on the opposite side of the same jaw) of the same individual. Results are shown in Figure 2. The mean pocket depth was better, with 1.3 mm at the implants, compared to 1.7 mm at the natural teeth. If a pocket depth of 2 mm represents a limit to the pathologic, 12 % of the implants and 27 % of the natural teeth were pathologic. These results of the GCF-scores were also compared with results from natural teeth of the same individual. These are shown in Figure 3. The mean GCF was the same with 0.037 µl at the implants and the teeth. To use the classification of LANGE & TOPOLL[14], there was no unit in the worst class IV, while 81 % of the implants and 69 % of the natural teeth were in class I. A mathematically significant correlation on the 0.001 % level was found between the scores of the im-

plants and teeth with one test method, but not between the two methods.

Discussion

The choice of material in the case of half-open intraosseous implants is particularly important for reactionless acceptance of the material by the body tissue. In the past few years many materials have been tested for their bio-compatibility. The implant materials can be divided into the following groups:

(1) Metal alloys;
(2) Bio-inert ceramics; and
(3) Bio(re)active masses.

JACOBS, KIRSCH & LEHNERT[11] showed in their studies that even passivated metal alloys showed a definite tendency to infectious reactions. Bioreactive and active materials cannot yet be used in the aesthetic forms required for dental implants as they cannot withstand the masticatory force and can therefore only be used as a layer on alloplastic nonresorbable carriers. For these reasons, we have chosen to use aluminum-oxide ceramics for our implants as their properties have been certified in experimental follow-ups[9,13,17], as well as in clinical observation and evaluation[3,4,20].

One advantage of Al_2O_3-ceramics is its chemical and corrosion resistance. It is also inert towards toxic and infectious reactions. It has enough stability under fast change of temperature, high masticatory stress and oral liquids to be clinically satisfactory. The electroneutrality of the material makes it non-susceptible to the development of calculus.

During the whole examination period with the dogs, not one implant was lost. The finding that a partial connective tissue layer between implant and bone occurred only at the extension implant might be connected to the fact that it is impossible with known methods to obtain a really close contact over the complete surface area of the implant and not just a point or linear contact during insertion[22].

The development of the extension implant arose from the special anatomic situation and the particular force distribution in the lateral area of toothless jaws. There are particular indications especially when the alveolar bone atrophy is of long duration and has resulted in a wedge-shaped thin process; in this case advantage can be taken of the stretched shape of the extension implant. The surface area of the implant is enlarged by perforations in the material, through which the bone grows after insertion. The strip of bone that develops over the implant and the bone growing into the perforations in the implant contribute to protection against pulling forces.

Usually a terminal edentulous mandible needs treatment with a removable prosthesis. Figure 4 shows a solution with a removable bridge. Precision attachments were used to allow exact investigation and construction of a removable prosthesis in the event of implant failure. Limiting anatomic structures of the implant shape are in the anterior direction the next natural tooth, in the caudal and posterior direction the

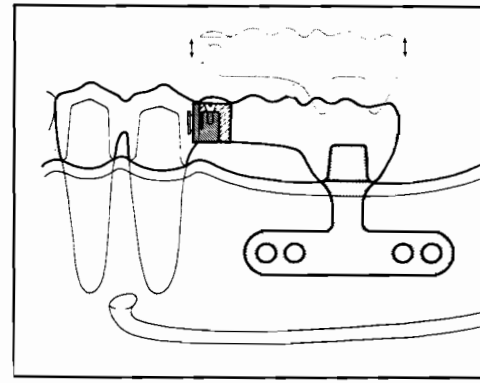

Fig. 4. The fixed bridgework on an extension implant is removable by a screwed precision attachment.

mandibular canal, in the cranial direction the shape of the alveolar bone, and in the buccolingual direction the width of the mandibular bone, especially below the mylohyoid crista.

The histological picture after preparing the implant bed always showed a fragmented fracture with opening of the bone marrow. By damaging the bone tissue during the preparation of the implant bed, HAM & HARRIS[7] found that principally the same process is induced as can be seen during the healing period of a bone fracture. The studies done by FRIEDENBERG & FRENCH[5] show a direct connection between the development of callus (the connective tissue scar) and the mechanically undisturbed implant. For this reason the primary requirements of the implant technique are optimal closeness of the implant surface and the neighbouring bone structure, complete and immediate stability of the implant and a careful working method.

During implantation of the extension implant, special care must be taken to make the bone groove straight and the walls exactly parallel, so that the primary stability that is required is guaranteed. This can be done with standardized wheel milling cutters as well as with cylindrical drills for depth compensation. After the implant has been embedded, the mucosal wound is closed with a poncho flap[8]. This special flap makes it possible to close the wound without a suture over the area of the bone groove. The wound is then in an area that is easy to keep clean and is easily observed post-operatively even after the provisional prosthesis has been incorporated. Primary stability is supported by immediate incorporation of a prefabricated acrylic bridge.

This is not necessary in the case of a screw implant, as the exact correspondence of thread cutter and implant gives an optimal position and leads to acceptable primary stability. When the screw of the implant is turned into the bone a slight amount of pressure develops, and this ensures exact contact for bone and implant without deposits of necrotic tissue or blood clots. In this case the healing period and incorporation of the implant are awaited and the superconstruction can then be made.

One main factor in the incorporation of implants is directly related to the masticatory stress. In natural teeth the maximal forces are subdued by the periodontal ligament. In the case of the screw-shaped implant for substitution of one tooth, we tried to develop the idea of KANTH[12] of an intramobile suspension. During the construction of a buffer system, we started with the idea that because of the large implant surface area the axial forces can be ignored to a great extent and only the very unfavourable horizontal stress must be delayed and softened. As the inside plastic construction is subjected to material fatigue, a superstructure was chosen that can be removed from its anchorage in the implant post. While in temporary bridges and crowns care must only be taken to extinguish any mesio- or laterotrusive contacts, in the case of the final reconstruction an exact central occlusion must be obtained and excursions must be registered.

First clinical results have been obtained for extension implants. The results of the examination of the measurement of the periodontal pockets and GCF measurements are surprisingly good and exceed results of other similar experiments with comparable metal implants[1,2,21]. Direct comparison, however, is not possible as the period of experimentation was too short and the number of investigated implants was too small.

The aim of this contribution was to outline the various steps in the development of an implantation system, and each step is subject to a special study. In our opinion,

it will be possible to discuss the results of the studies only after a clinical control period of about 5 years or longer. For this reason a great many data are noted at every reexamination of our patients. The long-term results must be awaited even if the present prognosis seems encouraging.

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