A MANUAL OF THE SYSTEM

Clinical Guidelines for Dental Implant Treatment

Kari Luotio
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Edited by Kari Luotio
Osfix - from philosophy to system

The main task of dental implantology is occlusal rehabilitation. We should call the end product a prosthesis, whether it is removable or not. As described, a prosthesis is a substitute for an organ or its function. At best, a patient should be able to forget that they using a prosthesis and its existence should in itself be satisfying to them. If we can fulfil these criteria, we have given the patient a gift, a gift which is one of the most important they will ever receive.

The field of dental implantology increased rapidly until the beginning of the last decade. This is explained not only by the increasing level of dentists’ knowledge and skills, but also by the various national social security systems in Central Europe and some Scandinavian countries. Today, these systems are less effective as a result of economic depression. This has forced the development of reasonable, simplified and rational dental implant systems such as the Osfix system.

It is possible to describe dental implantology as controlled risk-taking, based on skilled surgery in the jawbone, modern titanium fabrication and precision dental laboratory manufacturing. This involves three obligatory conditions for the implantologist: 1. A knowledge of anatomy; 2. the ability to handle tissues such as the mucous membrane, muscles, nerves, veins, bones, extra oral tissues, and even sinuses; and 3. the ability to assemble prefabricated titanium parts and hand-made dental laboratory products. If any of these claims are not fulfilled, the risk-taking is no longer controlled.

Anatomical hand books were written a long time ago, therefore the idea of this book is not to teach surgical anatomy. However, *repetitio est mater studiorum*. It is not a waste of time to consider applied implantological anatomy, because a small misalignment of an implant may result in tremendous technical problems between the bone surface and occlusion becoming apparent. It is impossible to overstate the importance of the advice of experienced implantologists and the enormous knowledge which is available in other implantological books.

It may be that surgeons are born, i.e. surgical capability is mainly inherent, not the result of academic education. If the implantologist has “good hands” the bone tissue also “feels good”. Some details in the Osfix system may be at odds with general implantological faith and might contradict accepted “facts”. However, when the results are of a top-level European standard, it is a time to reconsider. The philosophy of Osfix is 10 years old, today Osfix is a system for which more and more references are available - scientific and clinical.

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Professor Kotilainen has expressed his view that today, some implantological truths might be collapsing as a result of technical advances. One of these dogmas is the use of gold alloys in prosthetic frameworks, another is the need for titanium angulated abutments and the third is the as-machined titanium surface of the implant. The reality of competition between implant companies has broken down the last; almost every company uses rough surfaced, i.e. sandblasted, acid-etched or plasma-sprayed implants today. The second dogma is now falling down because more and more companies are offering prosthetic components which are an integrated part of the cast work and are in direct contact with the implants. Moreover, the need for angulated parts may be avoided with skilful working. The last dogma still stands. However, if the implantologist does not wish to face that conflict, it is always possible to use precious metal, i.e. gold prefabricated cast-on components, in the Osfix system as well.

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The author would like to thank the above mentioned for their assistance in the project to develop a new implant system. In addition, the author extends his gratitude to everyone else who has participated in the process: performing their graduation work for the company, colleagues giving professional advice and financial support to the project.
ABBREVIATIONS:

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<tr>
<td>Ag</td>
<td>Silver</td>
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<td>Au</td>
<td>Gold</td>
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<tr>
<td>B-Hb</td>
<td>Blood haemoglobin</td>
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<tr>
<td>B-leuc</td>
<td>Blood leucocytes</td>
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<tr>
<td>B-sed</td>
<td>Blood sedimentation rate</td>
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<tr>
<td>Cl</td>
<td>Chloride</td>
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<tr>
<td>Cr</td>
<td>Chromium</td>
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<tr>
<td>Co</td>
<td>Cobalt</td>
</tr>
<tr>
<td>DLC</td>
<td>Diamond Like Coating</td>
</tr>
<tr>
<td>fB-glu</td>
<td>Blood glucose during fast</td>
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<tr>
<td>HCl</td>
<td>Saltic acid</td>
</tr>
<tr>
<td>Nm</td>
<td>Newton meter</td>
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<tr>
<td>RAD</td>
<td>Unit of radiation. More details e.g: <a href="http://bartleby.com/64/C004/037.html">http://bartleby.com/64/C004/037.html</a></td>
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<tr>
<td>Ti</td>
<td>Titanium</td>
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<tr>
<td>TiN</td>
<td>Titanium nitrate</td>
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ESSENTIAL TERMS

- Support legs i.e. integral abutments
- Totally fixed (acrylic) denture
- CoCr / Au framework with integral abutments (custom made)
- Prosthetic screws (prefabricated)
- Implants (prefabricated)
- Support legs i.e. integral abutments
- Implants
- Acrylic teeth (prefabricated)

"gingival acrylic" i.e. red prosthodontic acrylic connecting teeth and framework (custom made).
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CLINICAL

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1. INTRODUCTION

1.1 The Osfix Dental Implant System - A brief review of literature and presentation of the products

1.1.1 Surgery

A factor important to the success of the implant is the unstressed recovery allowed by two-phase surgery. The result of the primary recovery after implantation is full osteointegration, in which the implant is joined, without any connective tissue layer, directly to the bone. It should also be mentioned in this context that the implant is then completely surrounded with compact bone which will remain around the implant when it is subject to strain at a later stage. This phenomenon has been studied by Kraut et al. (1991) by the use of tension tests. They discovered that the mechanical immobility of the implant improved continuously, starting 2 weeks after surgery and continuing until 24 weeks. This finding clearly supports a half-year recovery period before subjecting the implant to strain. Their research also indicated that the extraction forces are considerably greater from the mandible than from the maxilla. As a contrast, no correlation with the primary stability during the procedure could be found.

The Osfix system allows the use of an internally cooled drilling system during primary surgery. The relevance of internal cooling has been researched by Haider et al. (1993) in a histological study based on the contact percentage of new bone grown onto the surface of the implant. In this work, external cooling showed better results in the initial phase of the drilling when the bit forces were concentrated on the surface bone, but the advantages of internal cooling are apparent when the drill moves deeper into compact bone. This phenomenon has also been thermographically studied, even though such tests do not necessarily hold any implications for the clinical importance of these phenomena. The test results showed the most significant differences when no cooling was used (Watanabe et al. 1992).

References at the end of Part I
1.1.2 The prosthetic structure

The importance of prosthetic constructions for the success of implants, mentioned above, has been studied by Hertel and Kalk (1993) using a group of 81 patients: the effect of the distance between implants was compared with radiologically observed loss of bone. The most significant loss was found amongst overdenture patients with a supporting bar fixed on two implants in a toothless mandible. The conclusion was reached that the optimal placing of implants is ca. 25 mm distance apart. Implant losses caused by a poor structure of the prosthesis were rare, and whenever an implant was lost, a prevalent factor was the patient’s ability and will to care for his oral hygiene. There are also some infection factors, such as Kellett and Smith’s (1991) finding that the loss of an implant may follow a specific infection with a ecosystem and bacterial flora which is often seen in connection with periodontal illnesses.

1.1.3 Cobalt chrome as frame material

It is general practice that an implant frame is made of gold alloy but, mainly for reasons of economy, cobalt chrome alloy is a promising material for the same purpose. Cobalt chrome alloy is a material commonly used for other dental prostheses and its properties are well-known by both dentists and dental technicians. One of the disadvantages of cobalt chrome alloy is its hardness, which makes the material difficult to handle in a dental laboratory. Eventual allergenic reactions to cobalt chrome should also be taken into consideration, although they are extremely rare. All structures should be designed to enable the removal of the cobalt chrome alloy components from implant and dental structures. According to some studies, cobalt chrome alloy components may dissolve in oral conditions (Stenberg 1982, Moberg 1985). Galvanous corrosion has been claimed to cause loss of bone around the implant (Adell et al. 1981, Lemons 1988, Geis-Gerstorfer et al. 1989). The clinical follow-up of implant prostheses does not, however, support this claim (Hulterström and Nilsson 1994, Luotio 1997), but indicates that the loss of bone is at a similar level as that for gold-based structures (Albrektsson et al. 1986, Cox and Zarb 1987).

1.1.4 Expected success rate

The success rates of implants have, over the years, become quite clearly defined. Scientific follow-up studies on implants with a roughened surface structure hold a reasonably good promise for the success of the treatment. Fugatsotto et al. (1993) followed 2,023 implants placed into a total of 974 patients. All prosthetic structures were represented from single tooth implants to full dentures completely fitted to the bone, and full prostheses supported with a bar. The cumulative success rate at the end of
the 5 year follow-up study was 93 % for
the maxilla and 96 % for the mandible. A
study by Babbush and Shimura (1993)
followed 1,059 implants placed in a
total of 322 patients; the final success
rate in a 5 year follow-up was 96 %. A
division of success rates between
jaws gave a rate of 92 % for the
maxilla and 99 % for the mandible. Thus the primary success rate of the
implantation process was good: of
more than 1,000 implants, only 9
were lost at secondary surgery due to
inadequate integration. The remaining
28 implants were lost during the 5 year
follow-up period. This study confirmed
the implantologically accepted fact
that the longer and wider the implant,
the better the result.

1.1.5 Special techniques in surgery

Special techniques in implantology are
described, to some extent, in the
literature. The common factor in
these techniques seems to be the
use of various films to direct
ossification, and the potential of
hydroxyl apatite. Implants have also
been used in immediate implantations
and expansions of the crista, in which
missing bone areas are filled with
porous hydroxyl apatite and covered
with films that enhance ossification
(Novaes and Novaes 1992, Ettinger et
al. 1993), as well as maxillary sinus
transfer operations. In this process,
a hole is carefully made in the bony
wall of the sinus, without breaking the
mucosa. The mucosa on the base of
the sinus is lifted with a bent periosteal
elevator from the future implantation
site, which enables direct visibility
when drilling the holes through the
base of the sinus. The bony drilling
waste is collected and finally, together
with venal blood and corallic hydroxyl
apatite, it is placed around the implants
and the sinus lift cavity (Luotio,
Petrelius 1994). All these methods
remain highly experimental and very
little scientific material is available
thereon. Thus a general application
is not yet justified and, for the time
being, Osfix implants should not be
used in experimental surgery.

Similar conditions apply to the use of
some new cleansing methods such as
the air-abrasive equipment developed
to cleanse transmucosal extensions
and infected implant surfaces. Even
though studies have shown that such
equipment does not, as such, impair
the surface of the implant or make it
more attractive to bacteria (Barnes et
al. 1991), at present the use of these
systems involves rather high risks and
possibilities for complications (Van de
Velde et al. 1991).
1.1.6 Presentation of the product

The Osfix implant is a cylindrical implant with an apical screw portion for improved primary stability. The implant has an internal hexagonal structure for tightening during surgery. The implant is made of grade 2 pure titanium and the implant surface is mechanically coarsened. The upper section of the implant is polished. The length of the implants are 11.0 and 13.5 mm and the outer diameter 3.75 mm. The Osfix implant is primarily designed for use in bar retained over-dentures in the lower jaw in totally edentulous patients, but many other indications are valid, as described later.

Osfix implants are products made by Osfix International Ltd Oy. They are friction fastened, mechanically roughened implants in which primary stability has been increased with a threaded tip. The Osfix implant is a bridge implant that enables the construction of dolder-type bar structures to support the prosthesis. The main differences between the Osfix implant and other existing implants is the simplicity of the structure, the low component count and the low price of the product.

The base of the Osfix implant is formed by the actual implant cylinder, which is fitted to the jawbone. This is covered during the first operation with a primary screw. In a subsequent operation, the screw is removed from the implant cylinder and replaced by an impression post, which is fitted into place with occlusal screws included in the set. The impression posts are then delivered to a dental laboratory where they are cast into part of the superstructure.

a minimum of three OSFIX implants are needed for each frame structure
1.2 The Structure of Osfix and Biosfix implants

1.2.1 Osfix

The basic element of the Osfix implant is a titanium implant cylinder equipped with an apical screw, which is fixed in the alveolar bone. The cover screw is screwed onto the cylinder in the first operation. In a subsequent impression procedure, the cover screw is removed and a bridge construction is made and fitted in place with the prosthetic screws supplied by Osfix. The prosthetic structure of Osfix differs from other systems in that the Osfix implant is the first dental implant system which has been designed to use cobalt chrome frameworks.

A minimum of three Osfix implants are needed for each frame structure. It is important to understand that a bridge may not be built on one or two implants, as rotational movement of the bridge is an absolute contraindication in this system. For single crowns and short bridges, the Biosfix implant should be used, as it is a single tooth implant supplied with a rotation check or hexagon.

The prosthetic screw not only secures but also aligns the components.

Only three parts: Implant, screw and prothesis
1.2.2 BiOsfix

BiOsfix is a titanium implant for single teeth and short bridges (two implants). This system is compatible with the Osfix surgical system, although it offers a prosthetic solution of its own. The basic principles of the implant are very similar to those of Osfix, it is a sandblasted implant with a mechanically polished collar to provide good contact with the connective tissue, and a built-in rotation check, the hexagon, or an internal “bolt head”. A major development in prosthetics is the fact that the implant structure can be completely dismounted. If the surface structure has to be renewed, e.g. for a front tooth implant made during the growing period, it is possible to dismantle the whole implant and replace the crown with a larger one. Similarly, it is possible to repair severe cases of loosening screws in single tooth implants without loss of the prosthetic structure.
BiOsfix is based on cast-on components i.e.
metal ceramic crowns. Machined titanium
components are available to order.

Important

Prosthetic variations of BiOsfix:
- Cementation on custom made abutment
- Screw retained crown
Only three parts: Implant, crown and screw
1.3 The Prosthetic superstructure

1.3.1 Totally osteointegrated prostheses

In the Osfix system, these are constructed on a maximum of five or six implants in the bone, fitted with a metal framed, acrylated full denture: a chrome cobalt frame full denture with acrylic teeth is fitted on the implants. In some cases, the chrome cobalt frame also forms the lingual or palatal surface of the bridgework, but often it forms only the base that connects the implants. On or around this chrome cobalt structure, red acrylic replaces the resorbed alveolar ridge and gums, fitted with ordinary plastic prostheses. A hole for each implant passes through the whole structure. The prosthesis is held in place with six screws. When the prosthesis is finally taken into use, the screw openings are covered with composite filling material.

This method enables full stability and complete occlusion forces for the prosthesis, although problems such as air leaks may occur, especially in the maxilla between the palate and the prosthesis, or aesthetic problems due to transmucosal metal extensions in cases of incomplete lip-closure. Visual or phonetic compromises that complicate cleaning are often needed in the maxilla.

Due to anatomic limitations, the implants often need to be focused anteriorically. A fully osteointegrated prosthesis with a metal frame structure can take a cantilever in the maxilla up to 10 mm, and in the mandible up to 20 mm. With this kind of prosthesis, the occlusion forces fully correspond to those of natural teeth, whereas the occlusion forces of an ordinary prosthesis are only 1/4 - 1/5 those of natural teeth. Totally osteointegrated prostheses may also be partial prostheses fitted on three, four or even five implants in an edentulous rear or middle area. The structure of these either corresponds to the previous prosthesis, or is made of composite and metal frame. Ceramics are being tested in the Osfix system but are not yet in clinical use.
1.3.2 Prostheses supported with osteointegration

These are not permanently fixed to the implants, but may be removed by the patient. A typical prosthesis would be an overdenture built on three or four implants in the mandible, fastened to the Osfix bar in a manner that allows most of the occlusal stress to be transferred to the mucous membrane due to a seesaw movement.

1.4 Patient satisfaction

The biggest advantage is felt by patients whose lower prosthesis is supported with implants, which increases the stability of the prosthesis and reduces feelings of pain. Similar changes also occur in the maxilla, but in the case of the mandible, the changes could be described as dramatic. For the patient, important functional advantages are increased ease of speech and its clarity, as well as a more positive facial expression, and what is seemingly very important to the patients, the ability to laugh safely (see PART V).
1.5 Main Solutions

Removable Osfix denture

Fixed Osfix denture

Partial Osfix denture and BiOsfix crown
1.6 Components

OSFIX Components

OSFIX implants:
- Ø 3.75 mm
- Lengths: 11 mm and 13.5 mm

OSFIX Cover screws:
- Lengths: 0.5 mm and 1.5 mm

OSFIX Healing posts:
- Lengths: 3 mm, 4.5 mm, 6 mm and 7.5 mm

OSFIX Impression posts:
- wide, narrow, long

OSFIX Laboratory components:
- OSFIX Prosthetic screw,
- OSFIX Implant analogue
- OSFIX TM Extension burn-out
- OSFIX TM Extension cast-on

OSFIX adaptation drills
- Ø 2.8 mm
- Ø 2.6 mm

scale 3:2
BiOsfix Components

BiOsfix implants:
- Ø 4.2 mm and 5.0 mm
- Lengths: 11 mm, 13.5 mm and 16 mm

BiOsfix implant analogues:
- Ø 4.2 mm and 5.0 mm

BiOsfix Prosthetic kit Hexagon
- Ø 4.2 mm and 5.0 mm

BiOsfix healing posts:
- Ø 4.2 mm and 5.0 mm
- Lengths: 3.4 mm and 4.5 mm

BiOsfix Prosthetic screw

BiOsfix Copyposts:
- Ø 4.2 mm and 5.0 mm

PART I: Clinical

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3. PLANNING THE TREATMENT

4. THE PROCEDURES

5. EXAMPLES

6. FAILURES

PART II: Laboratory

PART III: Hygiene

PART IV: Sedation

PART V: Studies
OSFIX and BiOsfix Drills

- PILOT-DRILL
- STEP-DRILL L2
- STEP-DRILL L6
- STEP-DRILL S2
- STEP-DRILL S6
- Twist drill 3.7 mm
- Twist drill 3.3 mm
- Counter-sink 4.2 mm
- Counter-sink 5.0 mm

Scale 3:2
OSFIX and BiOsfix Instruments

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PART II: Laboratory

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2. OSTEOINTEGRATION AND TITANIUM IMPLANTS

2.1 Osteointegration

Osteointegration is defined as the direct contact of the implant with the bone, without any soft-tissue layer between. Titanium has been proven to be the best material for implants, as its osteointegration with stands a force of over 100 kg. Even with this force, the implant is not loosened, but is broken off the bone.

Early research and actual development work in osteointegrated implantology was made at the turn of the 60s and 70s, with commercial production beginning in the 70s. During the 1980s, many scientific symposia were held on implantology, and the first temporary approvals for titanium implants were granted by the ADA. Implants began to be placed in patients in meaningful quantities at the beginning of the 90s, at which time the development of the Osfix implant also began. The Osfix implant acquired sales permission for the whole European Union in 1998, when the quality assurance system in production and clinical studies were finalised.
Key factors in osteointegration

1. Grade 2 titanium of over 99 % purity.

2. An oxide layer forms on the titanium surface to which the glyco-protein layer will attach and later calcify.

3. The shape of the implant distributes the occlusion stress evenly to the bone. A triple surface increase has been created in the Osfix implant: the apical screw, the micro screw of the stem and the sand blasting on the surface of the implant multiply its surface area.

4. The use of the correct (internal) cooling during preparation. The temperature in the preparation area must not exceed 40 degrees Celsius, and the rotation speed of the drill must be below 2,000 rpm.

5. Two-phase surgery that allows osteointegration without disturbance; the implant structures will be subjected to strain only after the proper osteointegration period of 3-6 months.

6. High asepsis in procedures.

7. The formation of a proper epithelial integration in the second phase.

Osteointegration of sandblasted implants in the jaw bone of a dog (beagle).
Criteria for successful osteointegration

1. The implant is fully immobile in the secondary operation
2. The x-rays show no radiolucence around the implant
3. No marginal loss of bone can be observed
4. No permanent damage can be found in the nerves; neither pain nor infection
5. Success rate at a 10 year follow-up should be over 90% (Osfix 100% in 4 years)

Histological sample shows proper osteointegration in the animal test.
2.2 Rejection of foreign materials

The antigen-antibody reaction will reveal any alien proteins found in the living system. Corroding metal ions will form complexes with the system’s own proteins that are recognised as antigens. Therefore, titanium implants must be kept clear of any saliva or foreign metal contamination. The package efficiently protects the Osfix implant until the very moment it is placed in the bone, whilst the cylindrical primary insertion gives protection against contamination during the procedure.

2.3 Bone tissue

Bone is structurally divided into compact and spongy bone, or dense and cancellous bone; chemically into organic and inorganic bone, each of which amount to about 40% of the bone. The organic part consists of collagen, glycosaminoglycans and osteonectin. The inorganic part is almost entirely made up of hydroxylapatite.

The inside of the bone tissue is cancellous bone formed by thin bony lamellae. This trabecular architecture makes the structure of the bone lighter whilst maintaining its strength. This part of the bone contains the vascular system while the dense bone carries no blood vessels. On the surface of the dense bone is the biologically active cell layer of the bone, made up of osteoblasts and osteoclasts. Their task is to form new bone in the event of injuries. The outermost layer is the periosteum which is attached to the bone by ligaments.

The function of the bone is to act both as a supportive structure and as a store for calcium. The exchange of calcium between blood and bone tissue is many tenfold compared to the normal calcium intake from food. Most of the calcium stored in the skeletal structure is firmly bound in the bone and balanced hormonally by parathormone and calcitonin.
2.4 Healing of bone after a trauma

**Primary healing:** The bone heals after a trauma when the fracture is clean and full fixation is obtained. Blood coagulates in the area with extensive phagocytic activity during the first few days. Thereafter, a procallus is formed and great numbers of fibroblasts can be observed microscopically. When the connective tissue has become dense it is referred to as callus. This is where the first osteoblasts appear. Following this, maturation occurs or the osteogenic fibres in the callus begin to calcify. Compact bone is formed initially, and later it is organised into compact and spongy bone. Thus, the normal primary healing of the bone has taken place.

**Secondary healing:** Secondary healing is found in bone in cases of large, impure and comminuted fractures. No stability is reached and the situation is often complicated by infection. Granulation tissue and extensive infection forms in the area. This is followed by delayed healing and a vicious circle in which the infected granulation tissue does not contribute to the creation of stability. Finally, fibrous cartilage is formed in the area, thus reaching the final stage of this healing process, when a pseudarthrosis or false joint is formed in the bone.

**Healing in the implantation procedure:** Depending on the initial situation, any of the previous healing processes may appear after the implantation procedure. If secondary healing takes place, the implant is finally surrounded with pseudoperiodontal ligament corresponding to pseudarthrosis. The final stage is called fibrointegration. This type of healing can never produce long-lasting implantation, but if the implant is strained, fast resorption of bone occurs, followed by infectious reactions, leading to the loss of the implant.

The result of primary healing after implantation is full osteointegration, in which the implant is joined directly to the bone without any connective tissue layer. It may be noted that the implant is fully surrounded by compact bone which remains around the implant after the well-timed introduction of loading.
2.5 Epithelial attachment

In a natural tooth, the junctional epithelium is long and reaches right through the gingival enamel, up to the enamel dentine. The epithelium ends its migration when it reaches the fibrous attachment structure of the tooth. The junctional epithelium shows continuous migration of cells from the germinal layer up along the tooth surface, the epithelium cells finally scale off from the gingival papilla. The purpose of this migration is to stop infection factors from reaching into the dentoalveolar junction.

A normal junctional epithelium is formed against the mucosal piece of the implant. In successful implantation, when oral hygiene is good, a healthy connective tissue layer is, almost without exception, found under the epithelium, and thereunder begins unresorbed bone that is directly connected to the implant.

2.6 Implants

2.6.1 Subdivision

Implants can be divided into endodontal, subdermal, subperiosteal and endosteal implants, of which only the last mentioned will now be examined.

Endosteal dental implants are further divided into screw, plate and cylinder types. The materials used have been cobalt chrome, carbon, ceramics and titanium. The first screw types were developed as early as the 1940s and the chrome cobalt screw at the beginning of the 60s. Acrylic was also tried as a fixture material in those days, and carbon-glass in the 70s. In its day, the popular Linkov’s plate was a success, but reached only a 50 % success rate in long-term follow-up. The first implant material with a 90 % success rate was the ceramic developed in the 80s; aluminium oxide. The 90 % limit can, significantly, be surpassed only with titanium implants.

2.6.2 The osteointegrating titanium implants used

There are several titanium implant systems available in Europe, from various manufacturers. Almost all implant types based on titanium reach well over 90 % success rate in a 10 year follow-up. Cavity or thread preparations are extremely demanding procedures and this possibly accounts for a lower success rate than with more simply prepared models, such as Osfix. It must be remembered, though, that the implant adheres to the bone with its surface. Therefore the prognosis for short and narrow implants is much poorer than that for long and wide. Regardless of the make of implant, failures occur mainly with implants shorter than 10 mm.
3. PLANNING THE TREATMENT

3.1 Indications

**INDICATIONS FOR OSFIX IMPLANTATION**
1. An edentulous patient
2. A partly edentulous patient with a gap of at least three teeth

**INDICATIONS FOR BIOSFIX IMPLANTATION**
1. Lack of one tooth
2. Lack of two adjacent teeth
3. Other Indicators:

In addition to the above mentioned indications, there are a few more grounds for implant treatment. These alone or combined with other reasons, actual indications, may be the decisive factors for the implant treatment. The patient may have such a weak bone structure that the use of ordinary partial prostheses is extremely difficult. Poor muscle co-ordination and a hypersensitive mucosa are other common reasons for the failure of ordinary loose prostheses. A hypersensitive swallowing reflex usually prevents the patient from using an ordinary plate prosthesis in the maxilla. For some patients, even a partial lack of teeth may be so distressing that ordinary loose prostheses are, again, out of the question. It is also best these days to replace the loss of one tooth with an implant, as bridge constructions seem to be approaching professional malpractice.

**BiOsfix permits every kind of implantological indications if custom made angulated abutments and cemented bridges are used.**

3.2 Contraindications

1. Radiotherapy of over 5,000 rad i.e. radiation treatment with primary scale on the jaw area (see hyperbaric oxygen therapy)

2. Psychoses and dysmorphophobia or fear of changes in the appearance

3. Leukaemia, haemophilia, thrombocytopenia and diseases in ASA groups 3-4

4. Periodontitis and infections, for which a minimum of one year’s recovery after extraction is needed before implantation

5. Immediate extraction. A minimum of 3 months’ recovery period before implantation.

6. Tumours, which first have to be removed and the bone left to heal until normal.
As a relative contraindication, it is often mentioned that addiction to drugs, alcohol or cigarettes can prevent the patient from following the restrictions during the first few days. Smoking is considered a risk factor in the prognosis as it is.

A radiation dose below 4,000 rad or the amount of secondary radiation should always be discussed with the physician in charge of the radiotherapy. The same applies to high blood pressure and diabetes. Neither of these systemic diseases is an actual contraindication, if they are kept under control with medication. Consultation is nevertheless needed whenever the patient has a fairly serious systemic disease (ASA 3-4).

**BIOSFIX:**

*For single tooth replacement*

**OSFIX:**

*At least three implants in each framework*

Hyperbaric oxygen therapy

Radiation creates a contraindication for implantation as the preconditions for osteointegration and inflammatory response are weakened due to decreased secretion of saliva and cellular changes in the tissue. A real solution for an irradiated area is the use of hyperbaric oxygen treatment in implantation. The therapy is begun before the implantation as a series of 20 treatments, and is continued after the implantation with a series of 10 treatments. Each treatment consists of a 1.5 hours therapy with 2.4 atmospheric pressure oxygen. Increasing the number of treatments has no proven benefit.

The advantage of the treatment is the increase in oxygen content in the tissue of hypoxic bone, and the following restoration of the vascular system in the radiated tissue. Thus the injury reparation mechanisms are normalised in the tissue. For the success of the implantation, the advantages of hyperbaric oxygen treatment are obvious, as the implants would otherwise mostly be lost. After hyperbaric treatment, the success rate is increased to that of ordinary implantations. The treatment can be performed only in certain central hospitals.
3.3 Diagnosis and examinations needed

Implantological diagnosis is based on medical and dental history, and a clinical examination of the patient. These are compiled into a written description or summary of the case, supplemented by a treatment plan. The size, number and placement of fixtures is described, as well as the structure planned for the prosthesis.

The medical history consists of a careful record and the results of laboratory tests, if they have been considered necessary. The most common laboratory tests are haemoglobin, sedimentation rate, leukocyte count and, possibly, differential count, thrombocytes, coagulation factors or TT, blood-glucose level during fast and possibly calcium, if metabolic disturbances with calcium are suspected. The routine tests would include sedimentation rate, leucocytes and haemoglobin, and always blood-glucose level during fasting (B-sed, B-leuc, B-Hb, fB-glu).

The assessment of the patient for operation is primarily made by classifying the patient into one of the following groups (a modified ASA classification):

1. Healthy patient
2. Patient has a general disease which is kept under control with medication
3. Patient has a general disease (note also if patient has reached an advanced age) which causes problems in daily life despite medication
4. Patient has a general disease with a risk of serious attack or death as a result of strain.
The first group always qualifies for operation. For groups 2 and 3 it is recommended that some form of sedation be used during the procedures, and for groups 3 and 4 there also has to be a vascular connection, the ability to monitor vital functions (preoperative EKG and preoperative pulse oximeter) and a professional emergency specialist, such as an anaesthetist, present during the procedures. The treatment of group 4 patients should be avoided with implantological implications, or if treatment is chosen, it should take place in a unit corresponding to hospital conditions.

Dental history includes earlier procedures: fillings, periodontics, extractions, surgery or possible occlusal therapy.

Clinical examination concentrates on obtaining a full oral status. Plaster model analysis of the relation of jaws, anterior and lateral photograph of the patient’s face as well as intraoral photograph might also be useful.
The most important examinations are nevertheless radiological examinations or orthopantomogram, which is always needed. A lateral skull radiograph will show the relation of jaws and is valuable when the prosthesis structure is being planned. When implanting in the anterior of an edentulous mandible or the anterior of a partly edentulous maxilla, the above mentioned radiographs are quite sufficient. On the other hand, transversal tomograms are invaluable in the implantation of the posterior of the mandible, as well as a fully edentulous maxilla. When placing single implants in the premolar section of the maxilla, it is important to define the shape of the sinus and this is best done with tomography.
3.4 Placing the implants

3.4.1 Maxilla

Typical for the maxilla is a small total amount of bone and high ratio of spongious bone. The placing of the implants is further restricted by maxillary sinuses, the nasal cavity and incisive canal as well as the millary joint i.e. palatal suture. The best site for a long vertical implant is the canine tooth area between the nasal cavity and maxillary sinus. Besides these two implants, there is usually room for four other implants, one pair vertically under the nasal cavity and another behind the long implants roughly in the area of premolars. At the edge of premolars, the sinus already limits the length of implants, while the molar section can rarely be considered without a sinus lift operation which has not been studied with the Osfix implant.

The optimal placing of Osfix implants in the maxilla is as follows:

15-14 (inclined),
13, 11, 21, 23,
24-25 (inclined)
3.4.2 Mandible

The best area for implants in the mandible is the anterior area between the mental foramina, if this area contains ca. 10 mm of bone, it is sufficient for implantation. When placing the implants in the mandible, it should be remembered that the mandibular canal makes an anterior loop just before reaching the surface, and therefore the implant cannot be placed directly adjacent to the mental foramen. The molar area of the mandible may be used for implantation if there is ca. 11 mm of bone above the mandibular canal.

The sharp crestal area of the mandible makes the planning of implant treatment more complicated, as it has to be excised when installing the implant. It also has to be noted that the orthopantomograph is greatly enlarged (horizontally 50-70 %, vertically 10-30 %). The best result can be obtained when there is room between the mental foramina for:

- Six 11 mm long Osfix implants,
- Five or six 13.5 mm long Osfix implants, or
- Four or five 16 mm long implants (BiOsfix).

The basic solution in the mandible for Osfix implantation is, almost without exception, five 13.5 mm long implants, of which the outermost pair is placed at the foramen mentale with the apical head inclined towards the median line; the middle implants in the median line of the mandible and one pair between the two others (thus forming a fan shape):

- 44 (inclined),
- 43-42, 41-31, 32-33,
- 34 (inclined)
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In cases of bar constructions, 3 or 4 implants are used. Three implants are valid in resorbed bone cases and four in non-resorbed cases. However the distal implants should be inclined to allow sufficient space for the riders of the denture.
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3.4.3 The mutual placing of implants

The placing of the implants should allow enough bone to be left between the implants. A rule of thumb would be to leave a minimum of one implant’s width of bone: when 3.75 mm implants are used, ca. 4 mm bone should be left between the implants. It should also be noted that Osfix implants are always placed in a fan shape, avoiding parallel implantation. The fan may be divergent or convergent, but the space needed by impression posts should be borne in mind.
3.4.4 The superstructure

The superstructure i.e. prosthesis must be considered during the implantation phase. This means making sure the implants are not parallel, to ensure the maximum security for the superstructure.

The problems caused laterally by the occlusal relationship of the jaws should also be taken into account. A good method of predicting the restrictions in jaw relations is to draw the placement of the implants and the prosthetic structure on a lateral x-ray, and to think of the torsional forces of occlusion on the structure i.e. lever arms. A rule for cantilevers in the superstructure is, at a maximum, the last implant’s length. It must be remembered, however, that the bone structure of the maxilla is weaker than that of the mandible. Therefore cantilevers in the maxilla must be smaller than the length of the last implant while in the mandible it may be a little longer. In practice, the cantilevers may not exceed 20 mm in the maxilla or 10 mm in the mandible.

It is extremely important that the future position of the prosthetic screws are considered, especially in implantations on the anterior maxilla: the axis of the drill should always remain on the oral side of the facet line of prosthetic tooth or teeth.
3.4.5 Partial prostheses or short bridges

The fixation of a partial prosthesis to the bone is, almost without exception, based on three Osfix implants in an edentulous area. There is always room for these when the width of the edentulous area exceeds 20-25 mm. If the opening is narrower than 20 mm, two BiOsfix implants are used. In practice, four or more implants should be used in wide toothless areas where implants are faced with torsion forces, such as in the frontal area. In the molar area, implants also face rotational forces that tend to open occlusal screws, especially where a joint between the bridge and the implants does not fully prevent sideways movement.

3.4.6 Grading of bone for design construction

The outer compact layer of bone may be thin or thick, whilst spongy bone may be loose or dense. This grading alone offers four variations. The resorption in the bone may be slight, medium or strong. When this factor is taken into account, we face 12 different variations, each posing an individual implantation problem. Therefore, the quality of the bone should always be graded before implantation. The best bone for implantation is slightly resorbed, with a dense spongy bone. A poor one is a strongly resorbed bone with a thin compact layer and a loose spongy bone. Totally fixed prostheses cannot be fabricated in a strongly resorbed mandible, but overdentures supported by two, or preferably four, implants should be used. In such cases, the fastening of the overdenture to the implant uses the mesiostructure i.e. the Osfix bar. Dalbo-type fasteners should not be used, as they would place considerably greater occlusional and torsional forces on the implants compared to bar structures. It is extremely rare to find a patient with insufficient bone in the mandible for an overdenture solution. In the maxilla, an implant supported overdenture is not a good solution, as the thickness of the structures often severely disrupts speaking.
The lever arm of the construction should be kept in mind. Resorption of the bone always results in a higher lever arm, which increases the angulating or bending component of occlusal forces.
4. THE PROCEDURES

Appointments required for a prosthesis fixed to the jawbone

• Examinations  
• Planning  
• Placing the implants  
• Relining for the prosthesis (e.g. with a temporary soft material when needed)  
• Secondary operation after 3-6 months  
• Placing of the healing posts.  
• Impression  
• Fitting of the framework  
• Placing of the prosthesis and postoperative radiograph  
• Control call and training in oral hygiene  
• Annual recall, service and radiological follow-up of the prosthesis

4.1 Surgery - primary operations

4.1.1 Aseptic and other preparations

**Personnel:** Before the start of the implantation operation, all instruments must be sterilised. The elimination of the patient’s own flora must be ensured. The easiest way to do this is to make the patient wash his own face with a Hibiscrub® (chlorhexidin) skin wash, and rinse his mouth with a Corsodyl® (also chlorhexidin) solution. **After this, and before any other preparations, the patient’s blood pressure is measured. Blood pressure should also be measured after the procedure, and results recorded** (also note the points mentioned on the patient’s eligibility for operation). Before draping, the nurse will carefully cleanse the skin with alcohol. The drapes should be large enough to ensure that no contamination is transferred accidentally from the surfaces of the operating theatre to the sterile area. The outfit of the surgeon and the primary assistant includes bonnet, masks, sterile gloves and surgical gown. The implantation procedure practically always requires another nurse or an non-sterile or circulating assistant to open the implant cases and pass the sterile contents to the surgeon.

**Room:** When considering the suitability of an ordinary consulting room for implant surgery, the following points should be considered:

1. The microbiological purity of the air conditioning and ventilation system
2. How well the floor can be cleaned
3. Sufficient light that can be correctly directed under sterile conditions
4. Whether the suction system gets blocked when accumulated blood begins to coagulate in the tubes
5. The drill and engine should be powerful enough, and the handpiece able to be sterilised
If the normal dental surgery is used for implant surgery, some reorganisation facilities (see text) and separate prosthetic corner are recommended.
6. The room should have enough space for possible reorganisation

7. Mobile equipment units facilitate organisation

8. It must be possible to monitor the vital functions of a fully covered patient with automatic equipment e.g. with a pulse oximeter

**Instruments:** The cleaning programme for the correct surgical instruments includes three steps:

1. Soaking in a phenolic detergent solution that dissolves the proteins contaminating the instruments (e.g. in a dish-washing machine)

2. Rinsing with alcohol to dissolve the final remaining fats (e.g. slightly denatured alcohol is sprayed on the instrument basket)

3. Autoclave sterilisation

After cleaning, all instruments are sterilised either in the autoclave or in the hot air cabinet. It must be remembered, however, that the hot air cabinet usually blunts the edges of the cutting instruments. Therefore the autoclave is always used for these. Small instruments such as extra drills should be wrapped in double sterilisation packages to ensure easier handling in case they are needed during the procedure. Bowls should be placed in the autoclave on edge to prevent cold air remaining at the bottom of the bowl.

On the day of the operation, the operating room must be carefully cleaned and washed with a disinfectant. Sufficient drape material should always be secured. It can be obtained ready sterilised or as non-sterile “sheets” that can be sterilised in the autoclave.

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**OUTFIT AND STERILE ACCESSORIES**

**Surgeon + primary assistant**
- clean clothes
- surgical handwash with Hibiscrub®
- mask and bonnet
- sterile gown and gloves

**Patient**
- facial wash with Hibiscrub® + mouth rinse Corsodyl®
- cleansing with alcohol from nose to chin
- face drape and skin tape

**Non-sterile assistant**
- clean clothes
- mask and bonnet

**Surgical equipment**
- scalp, periosteal elevator, hooks, scissors, needle holder, clamps
- rinsing syringes, needle, solution and bowl
- a strong engine capable of 30,000 rpm
- sterile water pump
• fast (1:1 or 1:2) straight handpiece with fastening for external cooling water
• a speed reduced hand piece (e.g. Micro-Mega® 20 IMK, 1,500 rpm with a contra-angle head with internal cooling)
• suction tube with a plastic edge
• gauze folds, suture material

Before the operation, patient preparation including cannulation for sedation and connecting the monitors (e.g. pulse oximeter) is recommended. All the instruments and draping material must be sterilised before the operation. Sufficient instrumentation consists of a basic surgical instrument set, an Osfix set and equipment for additional irrigation, incision and suturing. Good aseptic protocol is followed during first stage surgery.
4.1.2 Medication

Local anaesthesia: Xylocain Adrenalin® (lidocain with epinephrine) provides an adequate haemostasis. Thus local anaesthesia is also infiltrated to reach haemostasis. Mandibular block injection can be avoided with implantation on the mandibular canal to prevent unnecessary nerve injuries. To reach sufficient anaesthesia in these cases, the use of both Xylocain Adrenalin® and Citanest Octapressin® (prilocaine with felypressin) are recommended, and they should also be injected under the periosteum!

Sedation: Dormicum® (midazolam) 15 mg one hour before procedure (7.5 mg for elderly people) per os or slow titration (2-10 mg) intravenously directly prior to procedure, when needed (see PART IV).

Antibiotics: Kefexin® 500 mg (cefalosporin) per os, 1x3, 10 days postoperatively.

Analgesic: Felden® 20 mg (piroxicam) per os, 2x1 2 days, 1x1 5 days and an addition of Indalgin® (indometacin and ethylc morphine) per os 1x3, when needed.

4.1.3 The operation

The procedure starts with an incision along the crista. The periosteum is then elevated and the mental nerve located, if the mandible is being treated. The location of the implants is defined. All soft tissue residue is carefully removed from the bone surface and the edge of the bone, particularly the sharp crista, is smoothed with a high speed drill (30,000-60,000 rpm), which is also used for the primary drilling. The drilling holes are then expanded to their final width using the slow speed handpiece (max. 2,000 rpm), internal cooling and the Osfix drill kit.
When all implant sites have been finished, the implants are placed and tapped into place.
The insertion screws are removed and the apical screw will now benefit from the use of a hex wrench to screw the implants even deeper into their holes i.e. implants are turned with a ratchet to their final depth. The implants are placed to allow the upper edge to remain slightly below the edge of the bone and the 1.5 mm thick primary cover screw to remain ca. 0.5-1 mm above the edge of the bone. Medical ointment (Terra-Cortril-P®, Pfizer, Brussels, Belgium, eye/ear ointment) is applied to the threaded hole at the marginal end of the implant, and the cover screw is screwed into place. The area is carefully rinsed and the wound is closed with continuing sutures. If sutures are resorbable (catgut) they are not removed during the healing period.
Two types of cover screws are available i.e. flat (1.0 mm) and normal (1.5 mm)
4.1.4 Postoperative treatment of the patient

After the procedure, the patient should be given time to rest at the surgery before leaving, and he should leave with an escort whenever sedation has been used. The patient is given a prescription for antibiotics and analgesics. The prosthesis is thinned sufficiently so as not to strain the possibly protruding implants. The prosthesis is fitted in place and a good fit is secured. Later, a soft relining material (Viscogel® or Ufigel®) is spread on the prosthesis’ base and placed in the patient’s mouth. A suitable timing for the second, i.e. impression, operation is 3-6 months from the initial operation.

The exposure of the cover screw during the healing period is quite common and causes very few real problems. Instructions for cleaning are essential; other actions are mostly harmful.

4.2 Secondary operations

4.2.1 Impression phase

The procedure begins with infiltrating local anaesthesia to the mucosa over the implants. A small incision along the crista is made at each implant head. The cover screws of the exposed implants are removed with a screwdriver or a round-headed spatula. Impression posts are screwed into the threaded hole of the implant, and an impression is taken using routine closed tray methods. In the case of a bar retained denture, it is recommended to remove acrylic lingually from the prefabricated new prosthesis at the location of the impression posts so that the prosthesis does not touch the posts when fitted. The base of the prosthesis is filled with impression silicone and the prosthesis is pressed on for the patient to bite the new prosthesis together to ensure correct occlusion.
Once the impression material has hardened, the tray/prosthesis is removed. The quality of the impression is tested by placing an impression post in each hole and testing for movement by hand. The impression is sent to the dental laboratory where the impression is equipped with laboratory pieces and cast in plaster. The cover screws are returned to the implants or replaced by a healing set, and the wound is closed normally.

If at this phase it is found that the implant is not secure, or that bone has been lost up to one third of the length of the implant, the implant must be removed in this procedure.
4.2.2 Mounting the prosthetics

Once the retention bar or other prosthetic has been completed, the implants are located with the help of the bar/frame: minimal openings are made, the cover screws are removed and the bar is pressed firmly in place so that the implant heads are clearly seen to rub against the metal bar. (If the healing set has been used during the healing period, the procedure is somewhat simpler.) It is important that the frame fits well against the implants, since due to the non-parallel implantation of the Osfix implant system, the frame must not be forced into place by tightening the prosthetic screws. The spaces between the prosthetic screws and the bar retention are sealed with an antibiotic steroid ointment (Terra-Cortril-P©, Pfizer, Brussels, Belgium). If some of the screws do not fit at the first appointment, do not try to force them in place because of the risk of thread damage. Leave the patient to “eat” the structure in place without the untightened screw. This will take 1-5 days. Thereafter, tighten all of the screws and the last one should now fit without any problems.

The prosthetic screws are tightened after one week because the structure and design of the Osfix system makes it almost impossible to secure the proper adjustment the first time. After tightening and regreasing the screws with Terra-Cortril-P©, they are covered with light-cured composite. The occlusion and fit of the denture are checked and minor adjustments made to assure stability and optimal function.
The framework is fabricated using burn-out or cast-on components.

After the insertion of the superstructure, the patient is placed in a regular recall system. Instructions regarding home-care are carefully supervised. During the follow-up, radiographs are taken and evaluated annually. The oral structures are examined clinically and the functional efficiency of the superstructure is checked.

4.2.3 Service of fixed prosthesis

It is essential in domestic care to carefully clean the implants and the frame structure of the prosthesis, often and regularly (see PART III). Possible tools are brushes, dental floss and a ca. 50 cm long slip of gauze which is best used as if polishing shoes. There is no need to avoid the use of the "bottle brush", as the metal stem inside the brushes cannot damage the chrome cobalt structure. Neither can ordinary curettes or ultrasonic equipment damage the Osfix structures. It is also possible to remove abundant calculus by unfastening the bridge structure and cleaning it in an ultrasonic bath.
5. EXAMPLES

5.1 Biosfix

BiOsfix implants are designed for single tooth replacement. First stage surgery is performed by making a buccal incision in the lower jaw (in the upper jaw a palatal incision is recommended) and the flap elevated to the lingual side.
A pilot drill is used to enlarge the hole to approx. 3.5 mm. The final drill is then placed and intruded until the counter-sunk portion is partly inside the bone. The implant is removed from its container using haemostats (mosquitoes) and placed into the socket with the same instrument. The implant is pushed inside with a finger or it may be carefully tapped in using a mallet and tapping pin.
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After removing the insertion screw, a ratchet is used to tighten the apical threads. Finally, the cover screw is attached and the wound closed with e.g. catgut sutures.
After second stage surgery and impression taking, the crown, which has integrated rotation control (prosthetic cast-on component) and a prosthetic screw, is delivered from the dental laboratory. The healing post is removed and ...
the crown is placed into the implant. The prosthetic screw is tightened with a torque-limiting hand-piece or with a ratchet. The ratchet must always used for the final tightening to 30-40 Nm.
5.2 Standard fixing bar

The first and second stage surgical procedures for Osfix implants are described in chap. 4.1.3. Only impression taking and prosthetic procedures are described in following:

After primary surgery, a healing period of three months is required before the commencement of second stage surgery. During this time, new dentures for both the upper and lower jaw are fabricated: Impressions are superimposed with a face-bow and the dentures are arranged following the rule that the canines are located in a line which is parallel with the line between the condyles of the jawbone.

Impression posts are screwed into the implant, it is also necessary to remove acrylic lingually from the prefabricated new prosthesis at the location of the impression posts. This is to prevent the prosthesis from touching the posts when fitted.
The base of the prosthesis is filled with impression silicone and the prosthesis is pressed on for the patient to bite the new prostheses together to ensure correct occlusion.

Once the impression material has hardened, the prosthesis is removed. The quality of the impression is tested by placing an impression post in each hole and testing for movement by hand. If the posts are not stable in the impression, the lingual surface is cut to enable the free discharge of additional impression material - from the holes left by the impression posts - when the prosthesis is refitted.

The impression is sent to the dental laboratory where the impression is equipped with laboratory pieces and cast in plaster. The cover screws are returned to the implants or replaced by a healing post (see next page), and the wound is closed normally.
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Once the retention bar or other prosthetic has been completed, the implants are located with the help of the bar/frame: minimal openings are made, the cover screws are removed and the bar is pressed firmly in place so that the implant heads are clearly seen to rub against the metal bar. It is important that the frame fits well against the implants, since due to the non-parallel implantation of the Osfix implant system, the frame must not be forced into place by tightening the prosthetic screws.

If the healing set has been used during the healing period, the procedure is somewhat simpler: The titanium healing posts are removed and the support legs of the bar intruded into the mucous membrane openings. Then prosthetic screws are placed into the holes and tightened, first with a screwdriver and then with ratchet and screwdriver.
After regreasing and retightening, one or two weeks later the openings above the screw slots are closed with normal light-curing filling composite.

5.3 Totally fixed prosthesis

The first and second stage surgical procedures for Osfix implants are described in chap. 4.1.3. Only impression taking and prosthetic procedures are described in following:

The healing posts are loosened using e.g. a screwdriver in a low-speed hand-piece. The posts are removed with tweezers or haemostats and the implants are filled with Terra-Cortril® ointment.
Impression posts are screwed into place. Impression taking by both the normal closed tray method and regular silicon techniques are performed.

After checking the fit of the framework with an x-ray and determining the correct occlusion with wax occlusal rims (fixed on the framework), the prosthesis is returned to the dental laboratory. In the case of the upper jaw, it is finally fixed, screws secured and closed as described in the previous example i.e. bar case.
The procedure for a lower jaw prosthesis is quite similar to that for the upper jaw, but the use of a low-speed hand-piece is almost unavoidable because of the oral angulation of the implants and the reduced space in the mouth. However, the hand-piece must not be used for the final tightening of the screw unless the equipment is fitted with a torque control system, but instead the ratchet and screwdriver must be used.
In a case where both implants and natural teeth are present in the same jaw, a non-fixed combination is recommended if it is not possible to leave the teeth intact. Crown pillars are prepared and impression posts are placed and impressions taken using the closed tray method.

5.4 Combination
In the laboratory, a model is cast and cast-on prefabricated components fixed onto the implant analogues. Then the normal wax-up procedure for metal ceramics is performed and cast using precious metal alloy.
The three piece bridge on the model...

...cleaned for fitting...

...and newly fitted.
5.5 Aesthetic problems

How to solve aesthetic problems if the implants are placed protruding buccally?

-Cut the prosthetic screws and support-legs (integral abutments) to the gingival level. If composite for normal fillings are placed on the openings, the aesthetics of the gingival margin is limited. However, this procedure is acceptable on palatal openings when lip support is adequate.
To achieve a better result, laboratory composite (Sinfony ®, Espe, Germany) is used. Initially, the gingival margin is built up with pink composite.

This is light-cured before adding normal filling material to fill the empty spaces in the gingival margin of the acrylic teeth. Now the aesthetic result is almost perfect.
6. FAILURES

6.1 Loss of Implants

The cause of loss of implants can be divided into two stages: primary and secondary losses. Primary loss of the implant occurs during the secondary operation or impression taking, or after short term loading (within the first year). This is almost always as a result of surgical failure: Implants used in cases of dehiscence of the bone, bone overheated during preparation, healing has not been trouble-free as a result of denture irritation, short implants are overloaded, etc. All of these are iatrogenic, i.e. doctor dependent, reasons. Secondary loss is mainly caused by poor hygiene control, very few other reasons exist.

6.2 Mistakes in structural design

The commonest mistakes in design are incorrect positioning of the maxillary and mandibular anterior implants. The first prevents the proper aesthetics of the fixed prosthesis, and do not leave space enough for the riders in bar constructions. This type of mistake happens most often with teams in which the surgeons are not taking part in the prosthodontic treatment at all. It is only a means of avoiding responsibility to say: “I placed the implant where the bone was”.

6.3 Mistakes in fabrication

During the impression, casting the model or framework, mistakes are also possible: The most frequent failure during impression taking is that the impression post moves, i.e. it is not stable in impression silicone. This causes an angulation failure between the implant and the framework extension. The commonest mistake in dental laboratories is that the posts have not been fixed properly, with glue, into the impression. Thus, whilst casting the model, one or more posts is detached by the vibration. This is visible in the framework as a vertical error. The final type of laboratory failure is a horizontal error which is caused by a poorly controlled casting procedure. Thus the casting procedure must be calibrated in every laboratory as described in the laboratory manual, part II.

6.4 Patient related factors

If the contraindications for implant treatment are excluded, the only patient related factor is the lack of proper cleaning of the implant work. This is avoided if the guidelines in part III are followed.
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1. INTRODUCTION

1.1 Osfix manual

This manual is an illustration of the laboratory procedures of the Osfix implant system intended for dental technicians.

The manual describes, step by step, the construction of a bar retained overdenture, a bridge and a fixed full arch bridge for which burn-out components are used. If cast-on components are used, the technical protocol follows general implant prosthetic principles, and the advices of this part are only trendsetting.

1.2 Osfix implant system

The Osfix implant is a cylindrical implant with an apical screw portion for simple and fast mounting and improved primary stability. The implant is made of grade 2 pure titanium and the implant surface is mechanically roughened. The length of the implant is 13.5 mm or 11 mm and the diameter is 3.75 mm. The Osfix implant is primarily designed for bar-retained mandibular overdentures for totally edentulous patients. It can also be used for fixed constructions with 5-6 implants or for bridges with at least 3 implants.

1.3 Osfix dental treatment

This two-stage implant system is the result of several years of development and research work in university dental clinics.

In the first surgical stage, the titanium implants are placed directly into the bone. The implants osteointegrate for 3-6 months. During this period, the patient wears their old dentures or a temporary construction is fabricated. It is not necessary for the patient to remain edentulous during the treatment.

In the second stage, the dentist takes an impression, on basis of which the dental laboratory fabricates the prosthetic restoration. Once the construction is complete, it is mounted in place and the occlusion is checked. Following this, there is a control visit one or two weeks after the insertion of the restoration. All operations are made under local anaesthesia including premedication when necessary. Post-operative pain can effectively be eliminated by the use of medication prescribed by the dentist.
1.4 The main differences between Osfix implants and other implant systems

1) The prosthetic construction is in direct contact with the implants.
2) There is no need for parallel implantation technique.
3) Cobalt chrome frameworks.

In principle, it is possible to use gold or titanium for the fabrication of the framework, but they have not been clinically tested in combination with the Osfix implant system. Deviations from the recommended prosthetic structures and special surgical measures are the responsibility of the dentist performing the treatment.

1.5 Laboratory components and instruments

The technical components of Osfix multiple implant system are:

- laboratory analogue
- impression post
- prosthetic screw
- burn-out cylinder
- two diamond adaptation drills (2.6 mm and 2.8 mm).
2. CALIBRATION OF CASTING PROCESS IN DENTAL LABORATORIES

In long-span constructions and precise cobalt chrome casting, it is very important to determine the right casting process and to standardise on it. Every laboratory should calibrate for investment material, oven and casting processes.

The following elements affect the final result of casting:

1) investment material
2) oven and temperature
3) casting process
4) cooling

The oven temperature and casting process are easy to standardise, but investment material should be standardised separately. One method of doing so is:

- to wax-up an arch that is supported by three implants
- to sprue normally
- to mix investment powder with different amounts of expansion liquid
  (initially ± 10% then ± 5%).

The arch that best fits the model allows the correct amount of expansion liquid to be determined.

Follow the manufacturer’s instructions for use when pre-heating cylinder and mixing investment material.
3. PREPARATION OF MASTER MODEL

- Screw laboratory analogues to impression posts.
- Add a drop of glue to the body of impression post.
- Place impression posts in the impression.
- Cast the impression in stone.
- Remove impression posts.
- Cut the impression into sections to check the fit of the posts.
- Fix the model in the articulator.

4. BAR RETAINED OVERDENTURE

4.1 Preparation of the denture for impression taking

- When preparing the lower denture, reduce the lingual area of the denture to allow space for impression posts and impression material.
- Reinforce the prosthesis with cold curing acrylic resin.
- Send the denture to the dentist.
- Returned denture with impression.
- Cast the impression in stone.
- Place burn-out cylinders on occlusal screws and retain in place.
4.2 Waxing-up the bar

• Join the acrylic bar pattern to the burn-out cylinders with wax.
• Cut the burn-out cylinders to the required height.

Recommendation: The position of the round bar should be parallel to the occlusal level and condylar axis.

The supra-gingival height of the bar is 1.5-2.0 mm.

4.3 Spruing

• Sprue with wax wires diameter 3.5 mm.
• Place the workpiece in the casting cylinder with burn-outs facing upwards so that the screw cylinders are also filled with investment material.
• Mix investment material (see calibration).
• Preheat casting cylinder and cast according to the instructions for use with investment material.
• Remove investment material.
• Sandblast (50µ) from the underside to prevent rounding of the edges.
4.4 Finishing

- Remove investment material from the screw cylinders by using adaptation drills (adaptation drill 2.6 mm on underside and 2.8 mm on top).

**Important**

*Do not push the 2.8 mm drill right through the cylinders as this will destroy the shoulders required by the prosthetic screws.*

- Fit the bar to the model.
- Model the bar to its final shape.
- Polish.
- Cut the prosthetic screws to the required height. (1-2 mm above the surface of the cylinder).
- Notch the screws for screwdriver.
4.5 Acrylic work

• Attach the bar to the model and position the riders.
• Block-out with wax all but the retaining parts of the riders and retention wire.
• Isolate the model.

4.6 Keypoints

• The bar should be parallel to the condylar axis.
• Check the fit of the denture.
• Rebase the denture with cold curing acrylic resin and strengthen with fibre if necessary.
• Finish the denture.
• The prosthetic screws must be at the right height.
5. BRIDGE

5.1 Waxing-up the framework

• Wax-up the framework to the burn-out cylinders.
• Model the framework according to the general principles of bridge fabrication.

5.2 Spruing

• Sprue, invest and cast following normal practice in bridge work (see calibration).
• Remove investment material residues from the screw cylinders by sandblasting and using adaptation drills (2.6 mm on underside and 2.8 mm on top).
• Fit the framework to the model.
• Model the framework to its final shape and polish it.

5.3 Finishing the framework

• Sandblast the framework to obtain retention for acrylic resin.
• Cut prosthetic screws to the required height (1-2 mm above the surface of the cylinder).
• Notch the screws for screwdriver.

5.4 Building-up the acrylic teeth

• When modelling teeth consider the best possible occlusion without loosing the anatomic shape of the teeth.

5.5 Keypoints

• The screw cylinders are filled with investment material.
• Equal distribution of bite force to all implants.
6. FIXED FULL ARCH BRIDGE

6.1 Setting-up teeth

• Try to set-up teeth so that there is space for the occlusal screws in the lingual area of the denture.
• Leave enough space for the bar.
• Take an index of the set-up.
• Boil-out the wax.

6.2 Waxing-up the framework

• Attach teeth to the index.
• Wax-up the framework by using the index.
• Make the framework of wire and fix it to burn-out cylinders.

Retainers can be placed on the framework at the wax-up stage, but it is not necessary if the completed framework is to be sandblasted and the teeth and the metal are not contaminated during acrylic work.
6.3 Spruing

- wax-up the framework to a circular form.

6.4 Fitting the framework and finishing

- Remove investment material residues from the screw cylinders by sandblasting and using adaptation drills (2.6 mm on underside and 2.8 mm on top).
- Fit the framework to the model.
- Sandblast the framework in order to obtain retention for acrylic resin.
- Cut the occlusal screws to the required height (1-2 mm above the surface of the cylinder).
- Notch the screws for screwdriver.

6.5 Acrylic work

- Set-up teeth using the index.
- Wax-up the work to its final shape.
- Take a new index.
- Boil-out the wax.
- Sandblast the surfaces of framework and teeth which come into contact with acrylic resin.
- Wet the surfaces with acrylic monomer.
- Pour cold-curing resin with reference to the index.
6.6 Keypoints

6.6.1 Occlusal balance

Occlusion area: the distance of the furthest contact point from the most labial implant is the same as the distance of the last contact point from the last implant, though max. 10 mm. Defining the occlusal centreline = the point where the construction carries the maximal load of horizontal force.

\[ A = B \]

\[ C = D \] (max 10 mm in upper jaw max 20 mm in lower jaw)

6.6.2 Gingival margin

Some space between the acrylic base and the gingiva is needed for cleaning by the patient. In the upper jaw, dental floss, and in the lower jaw, an interdental brush will be used.
7. DISINFECTION OF THE COMPLETED WORK

The dental laboratories and the dentists should agree on the disinfection practices. The seating of implants is always a surgical procedure. When the prosthesis is carefully cleaned, infection and complications are effectively prevented. This has a direct effect on the patient’s health and his adaptation to wearing the new prosthesis.
PART III
CLINICAL

Implant prostheses
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1. INTRODUCTION

Traditional dentures are often considered cumbersome and unpleasant; some people never get used to them. Users do not feel comfortable as they always have to think about how to keep the denture in place. Everyday functions such as eating, laughing and speaking may cause a feeling of insecurity. The poor stability of dentures may also cause aching pressure wounds i.e. sore spots on the mucosa. Implant treatments offer a solution for many of the problems involved in dentures, so the popularity of implant treatment will continue to increase. Special attention should be paid to the promotion of oral health and the prevention of oral diseases in this growing group of patients, as in many cases an implanted mouth will require the adoption of new cleaning methods. Therefore, patient guidance will become essential to enable the patients to organise their daily oral hygiene satisfactorily. Insufficient oral hygiene may, at worst, cause the loss of an implant. We also need to provide more information for dental hygienists, since they need to know how to clean an implanted mouth for the elderly or infirm who cannot do so themselves.

This guide to oral hygiene contains information on the health and care of an implanted mouth, and will help to explain the importance of oral hygiene to successful implant treatment. The guide deals with the cleaning of fixed prostheses as well as prostheses fitted with a bar. The guide will describe the oral cleaning methods, gingivitis, the effect of oral health on general health, and the importance of regular follow-up and maintenance treatment. The guide may be used when introducing the concept of implant treatment to potential patients, or those who have already had it. It can also be used in health-care training and in nursing to provide more information for nursing personnel, and in planning health education programmes.

1.10.2000

Jaana Turunen
2. ORAL HEALTH OF AN IMPLANT PROSTHESIS PATIENT

Good oral hygiene is essential for the success of an implant treatment. Insufficient oral care may, at worst, cause the loss of an implant. When cleaning the mouth, it is essential to remove the plaque, as it causes a similar infectious reaction around an implant as it would around a natural tooth. A healthy mouth feels fresh and pleasant. There is no pain, bacterial, viral or fungal infections. As well as making the mouth feel clean and healthy, oral health also contributes to general health. Oral infections open a route for bacteria to enter the body, causing illnesses that are localised in other parts of the body. It may also cause an existing general illness to become worse.

2.1 Plaque

Plaque is a light, paste-like coating made up of the bacteria naturally occurring in the mouth. The consumption of sugar-containing products causes an increase in the amount of plaque. The accumulation of plaque at the marginal gingiva around the metal parts protruding from the mucosa will cause gingivitis. This is why plaque must be removed every day.

2.2 Tartar

Tartar is formed by bacterial plaque which, due to the minerals present in saliva, has calcified into a coarse substance. Tartar sticks to the surface of both metal parts and prostheses and cannot be brushed away. The uneven and coarse tartar offers a good home for bacteria and plaque. Together, they maintain gingivitis.

2.3 Gingivitis

Gingivitis may arise in 2-10 days when bacterial plaque is concentrated on the margin of the gingiva. Its creation is affected by the system’s ability to resist bacterial intrusion in the gingival tissue. With insufficient cleaning, the plaque remains on the margin of the gingiva, working and irritating around the metal parts. When the plaque thickens and ages, it causes infection of the gingiva. The gingivitis may get worse if the plaque is not removed and the infection not treated. As the infection grows deeper into the tissue, the composition of the bacteria around the implant and in the periodontal pocket changes, and starts to destroy the tissues that hold the implant. As the bone around the implant begins to disappear, it will allow movement and eventually the loosening of the implant.
Symptoms of gingivitis:

• gingiva bleed easily when brushing or eating hard food
• gingiva are sore and swollen
• the colour of the gingiva changes from salmon pink to dark red
• bad taste and/or smell in the mouth.

2.4 Treating gingivitis

Gingivitis is best treated with careful brushing. Special attention must be paid to the cleaning of metal parts protruding from the mucosa at the margin of the gingiva. Even if the gingiva are bleeding, brushing should not be stopped, but the bleeding area should be brushed even more carefully. If a week of careful and regular brushing brings no improvement, the dentist should be consulted. Gingivitis breaks out and heals around the implant just as it does around a natural tooth.

2.5 Dry mouth

Dryness of the mouth is usually caused by a decreased secretion of saliva. The secretion of saliva may be reduced by e.g. medicines used, many general diseases, deficiency conditions, weakened general condition, or stress. Saliva helps keep the mucosa healthy. It forms a thin film on the surface of the oral cavity, thus preventing ulcers, bacterial, viral and fungal infections. Therefore it is important to keep the oral mucosa moist. Dryness of the mouth is relieved by rinsing the mouth with water and drinking. Saliva secretion is increased by foods that require chewing and xylitol products. There are special products available for the treatment of a dry mouth.
3. ORAL HYGIENE OF AN IMPLANT PROSTHESIS PATIENT

The oral hygiene programme includes:

1. Cleaning the metal parts/bar and the space between the prosthesis and the gingiva

2. Cleaning the prostheses

3. Cleaning the mucosa and surveying their condition

4. Regular follow-up and maintenance visits to the dentist

Oral cleaning must be done carefully and frequently, twice a day would be ideal. Special attention must be paid to cleaning the surfaces close to the tongue as they are more difficult to clean. There is an ample range of cleaning instruments on the market, so everyone should be able to find something suitable. A rule of thumb is to have one brush for open surfaces and another for enclosed spaces. The success of the cleaning operation may be checked with colour tablets and a mirror.

3.1 Suitable cleaning instruments

- toothbrush/electric toothbrush/special toothbrush

- plastic-coated interdental brush

- special dental floss, floss threaders if required

- solo brush and other special brushes

- prosthesis brush for cleaning the prostheses
PART III

1. INTRODUCTION

2. ORAL HEALTH OF AN IMPLANT PROSTHESIS PATIENT

3. ORAL HYGIENE OF AN IMPLANT PROSTHESIS PATIENT

3.1 Suitable cleaning instruments

3.2 Cleaning the implant-fixed bar

3.3 Cleaning a fixed implant prosthesis

3.4 Cleaning a removable prosthesis

3.5 Cleaning oral mucosa and surveying their condition

3.6 Intensive oral cleaning

3.7 Follow-up and maintenance calls

PART IV

PART V
3.2 Cleaning the implant-fixed bar

A small, soft brush is most suitable for the cleaning of the bar (picture 1). It is vital that the brushing motion consists of small back and forth movements at the margin of the gingiva where the gingiva and the metal parts meet.

An interdental brush or special dental floss may be used for cleaning the spaces in the bar. In addition to brushing, toothpaste or prosthesis paste may be used in cleaning. Polishing toothpastes should not be used.
3.3 Cleaning a fixed implant prosthesis

A small soft toothbrush is used for cleaning.

It is vital that the brushing motion consists of small back and forth movements at the margin of the gingiva where the gingiva and the metal parts meet. The space between the prosthesis and the gingiva should also be cleaned. For this, an interdental brush or ...
special dental floss may be used.

A floss threader may be used to pull the special dental floss under a fixed prosthesis. In addition to brushing, prosthesis paste may be used for cleaning a fixed prosthesis. Ordinary toothpaste would scratch the acrylic surface of the prosthesis.
3.4 Cleaning a removable prosthesis

Cleaning the prosthesis is as important as cleaning natural teeth, as tartar, plaque and an invisible film of bacteria build up on the surface of the prosthesis in the same way as they do on natural teeth. Clean prostheses feel and look better in the mouth, and the whole mouth feels fresher. Insufficiently cleaned prostheses may cause various bacterial, viral and fungal infections in the oral cavity. A dental prosthesis must be cleaned carefully at least twice a day and rinsed after every meal.

There are special brushes for cleaning loose prostheses, with a wide head for cleaning large areas and a narrow head to enter small holes. A soft brush is used to clean the mucosa. Prosthesis paste, washing-up liquid or mild soap may be used for cleaning. Prostheses must not be cleaned with ordinary toothpaste as it would scratch their acrylic surface.

Effervescent tablets may also be used for removing discolouration.

The prostheses are washed with lukewarm water, as very hot water may damage them. Special attention should be paid to the surfaces that are in contact with the mucosa. The mucosa are cleaned with a soft toothbrush before the prosthesis is replaced. Clean prostheses are replaced into a clean mouth.

When the prostheses are not in the mouth, they have to be kept moist e.g. in a glass of water or wrapped in damp paper in a watertight box. If allowed to dry out, the prosthesis may twist and become unusable.

If the prosthesis rubs or feels uncomfortable, the dentist should be contacted. Likewise, if the prosthesis suffers damage, if a prosthetic part or a screw has loosened or if the contact pieces, i.e. the bar’s riders, have been damaged, the dentist should, once again, be consulted.
3.5 Cleaning oral mucosa and surveying their condition

It is beneficial to rinse the mouth several times a day. In addition to cleaning, the brushing of the tongue, the gingiva and the palate improves circulation and keeps the tissue healthy. The prosthesis will hold better in a clean mouth. Cleaning offers the perfect opportunity to inspect the condition of the mucosa. If you feel or notice something unusual in the mouth, e.g. changes in the mucosa, coating, flushed areas, pain, swelling, bad smell or taste etc. you should contact your dentist.

3.6 Intensive oral cleaning

If oral cleaning is found to be insufficient, it may be temporarily intensified with chlorhexidine (Corsodyl®) rinsing. This may not be used for long-term cleaning, as the efficient antibacterial chlorhexidine may have adverse an effect on the balance of the oral bacteria if used continuously, which could permit fungal infections to flourish. The effect of mouthwashes other than chlorhexidine is insignificant. If they are preferred, a product containing no fluoride should be chosen. The use of chlorhexidine or ordinary mouthwashes does not replace brushing, but rather supplements it. Chloride hexine may cause a brown discolouration on the prosthesis and the surface of the tongue. The discolouration may be decreased by applying the product locally using an interdental brush or cotton stick. If necessary, the discolouration may be removed from the prosthesis by the dental technician. The discolouration of the tongue will be removed by itself.

3.7 Follow-up and maintenance calls

The most common reasons for losing an implant are insufficient oral hygiene at home, and the neglecting of regular maintenance inspections. Implant patients should attend regular maintenance consultations. Maintenance calls are, preferably, made annually: the structures will be dismounted if necessary, and the components serviced. Simultaneously, the success of oral hygiene may be controlled and the methods revised when necessary. The condition of the implants is also followed with X-rays. A regular and careful follow-up will lengthen the life of an implant prosthesis.
PART IV
SEDATION

Better surgery by sedating
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OSFiX implant treatment involves major operations. Thus the patients frequently require sedation. To reach an adequate and accurate effect, these drugs have to be administered to the vein. This is known as intravenous sedation (sedative medication introduced through the vein). It is not general anaesthesia. However, even intravenous sedation involves risks which must be recognised, and due precautions for treating possible complications must be made.

Why should we use intravenous sedation, facing its intrinsic risks, rather than oral sedation?

This is a question which fellow dentists frequently ask the author of this study. To answer it we need to look at some principles: orally, a useful dosage of diazepam is 10 mg for young and adults, 5 mg for children. Smaller doses will not produce a useful sedation. The dosages per os for midazolam are 7.5 to 15 mg.

Given orally, in the majority of patients these doses create good sedation, sufficient for a normal procedure. The problem is that a minority of patients will not experience any sedative effect with these doses. In the case of a nervous patient, their experience of the treatment will be most unpleasant. Another minority of patients will become oversedated with these doses, to the point that they are practically in a very deep anaesthesia during the whole procedure, which severely impairs the dentist’s work. Recovery from the procedure can then take several hours, which will paralyse the operations of the dental surgery for those hours.

Although the basic doses for intravenous sedation are 10 mg of diazepam and 5 mg of midazolam (note the difference in the efficiency ratio of midazolam), the individual amount for the patient is titrated to the exact point through intravenous dosage. Hence oversedation or undersedation will be extremely rare. There will be no problems with the procedures and the patient’s recovery is swift.

For the patient, intravenous sedation is a necessary alternative in dental care. It should nevertheless not involve risks which outweigh the advantages. The dentist and the dental surgery assistant must ensure that they have sufficient training for and a good command of this procedure. These skills must also be regularly rehearsed and developed. This is the only way to avoid emergencies and complaints.

The purpose of these instructions is to provide a theoretical basis for the understanding of intravenous sedation, but the practical application of the procedure necessitates manual training and a demonstrated command of the subject.
2. THE PATIENT FOR SEDATION

2.1 Examining the patient

A careful examination of the patient’s medical history is a precondition of safe intravenous sedation. An example of an easily completed medical history form is enclosed. This form should be further complemented by an interview, as this gives the best contact with the patient. It is important to define the patient’s weight and height so that the correct dosages can be chosen. The interview also provides the opportunity to draft a psychological profile of the patient. The dentist should aim at establishing the level of anxiety and the level of self-control in the patient. If the patient is extremely nervous and he/she reacts to the slightest stimulus during the examination, the administration of intravenous sedation should be seriously reconsidered. In addition to consent from the patient, intravenous sedation requires also the surgeon’s command of this method of treatment and its complications. Intravenous sedation is not suitable for a patient who:

- has an acute lung disorder
- has a serious functional disorder of the liver
- has an operational disorder of the kidneys
- is taking steroid medication
- is using psychiatric medication, including benzodiazepines
- has a serious muscular weakness, Myastenia gravis
- has a serious neurological illness
- suffers from an alcohol problem or a drug addiction
- is of advanced age or underage
- exhibits a sensitivity to benzodiazepine (extremely rare)
- is pregnant, extreme care should also be taken with breast-feeding mothers

In the event of any doubt that this treatment might be suitable for the patient, it is advised to consult his/her practising general physician. Despite the consultation it must be remembered, though, that the responsibility for the sedation lies with the dentist.

2.2 Clinical anatomy

When undertaking intravenous sedation it is important to know the anatomy of the vascular system of the hand. Suitable sites for injection for dental sedation are the cubical fossa and the dorsum of the hand. The advantages of the cubical fossa are the large veins that are easy to puncture, and the fact that the injection is less painful than when puncturing the dorsum of the hand. Eventual haematomas caused by the injection are less visible in the cubical fossa than the dorsum of the hand, and they are easily covered with clothes. The dorsum of the hand may,
at times, be the only possibility when the patient’s clothing prevents the use of the cubical fossa or when no visible vein is found in the cubical fossa.

Use of the cubical fossa does present the risk of accidentally allowing the cannula to penetrate an artery, or of causing arterial bleeding into the tissues. There may also be problems in the liquid flow of the cannula when the patient bends their arm.

The disadvantages of the dorsum of the hand are, above all, smaller veins, more sensitive site of injection and the visibility of the bruises.

The complications of cannulation are:

- bleeding from the injection area to surrounding tissues (haematoma)
- thrombus and infection of the vein (thromboflebitis)
- tenderness of the site of injection
- the possibility of the cannula penetrating an artery and
- the possibility of injecting the drugs into arterial circulation

The complications of an intra-arterial injection are very severe; in the worst case they may lead to the loss of the entire limb or a serious circulation disorder therein. Therefore, patients sedated intravenously must always be connected to a saline drip.

When a free-flowing liquid infusion tube is connected to the cannula which is placed in an artery, a fast and powerful blood intrusion to the infusion tube and upwards all the way to the infusion bottle or bag can be observed. At this point there can be no doubt about the cannula being misplaced. When the cannula alone is placed in the vein it is not possible to be absolutely certain that it is securely in the vein and not in an artery.
3. BENZODIAZEPINES

3.1 Operating mechanism

It is important to know the operating mechanisms of the applied drugs. In the clinical pharmacology of benzodiazepines the main issue is pharmacodynamics, or how the drug works in the body. Although it is easy to measure the drug plasma levels for most drugs, estimating the drug’s concentration at the receptor sites is extremely difficult. Many drugs are attached to receptors and their plasma levels do not necessarily correlate with their effect. This often causes problems in defining the correct dosage. This is also the case for benzodiazepines. Nevertheless it is apparent that there is no clear correlation between benzodiazepine plasma levels and their clinical effect. Hence it follows that the calculation of pharmacokinetic parameters from plasma levels is not clinically relevant. This applies e.g. to the half-life of benzodiazepines. The very effect of benzodiazepines is based on their connecting to receptors in the brain. Therefore their clinical effect has only a very vague correlation with their plasma levels.

3.2 Half-life

Half-life means the time taken for the plasma concentration to decrease by 50%. It is important to note that this is not the time the drug takes to disappear from the body, nor is it the time when the drug’s effect can be seen in the body. The terms ‘long half-life’, ‘short half-life may sometimes be confused with ‘long-acting’ and ‘short-acting’, therefore the meaning of each should be kept clearly in mind. For instance the half-life of diazepam is several dozens of hours (24-48), whereas its active sedation time is only a few dozen minutes.

The following steps shall be observed when dosing intravenous drugs:

1) The uptake or absorption phase, which is the time taken to inject the drug, in the case of drugs dosed straight into the vein. The absorption phase of oral drugs is long and it depends on the uptake of the drug.

2) The distribution phase, during which the drug is distributed into tissue components according to its properties, e.g. the liquid system or fatty tissues.

3) The elimination phase which begins when a balance between plasma and the other tissues of the body has been reached. Subsequently, the drug is eliminated through liver metabolism or kidney secretion according to the drug’s half-life. The patient’s clinical recovery will be enhanced once the drug is eliminated from his body.
3.3 Pharmacodynamics

All diazepines have the following four characteristics:

1) Hypnotic or sleep inducing
2) Anxiolytic (sedative, eliminating anxiety, calming)
3) Muscle relaxant effect
4) Prevention and reduction of convulsions.

The action of benzodiazepines is based on the stasis of benzodiazepine receptors. These receptors are found in the central nervous system. The receptors are very specific to the agonists and antagonists of benzodiazepine. They are not receptive to other sedative agents such as barbiturates.

3.4 Pharmacokinetic anomalies

In overdose cases where the patient has taken massive amounts of diazepam (as much as 400 times the usual dose), plasma levels are extremely high for several days. The patient will, however, recover clinically to the extent that he is fully alert and able to leave the hospital considerably sooner than the elimination time of the drug.

It is important to understand that the clinical maximum effect of a drug does not have a correlation with its plasma level. This is quite apparent when a drug is administered intravenously: while the drug’s plasma level is still increasing, the patient is much more sedated and tired than when the plasma level is already decreasing (compare with getting drunk and sobering up).

The lack of correlation between drowsiness and drug plasma levels is also evident when the patient is prescribed diazepam for continued use. The patients tend to be tired during the first few days, even though the plasma level is still rising over the following days. The steady state level, in which the elimination and further administration are in balance, is reached much later. The effect of a given dose depends more on the speed of increase of the plasma level than the plasma level itself.
4. THE COMMERCIAL DRUGS

4.1 Selecting a suitable drug

The ideal sedating agent should possess the following properties:

1) Sufficient sedative and anxiolytic properties
2) Amnesia or blocking memory for the duration of the procedure
3) Easy administration
4) No irritating effects on veins or tissues
5) Short and speedy recovery
6) No effect on cardiovascular or respiratory systems
7) Low toxicity
8) No side-effects
9) Compatibility with other drugs.

Both diazepam in an emulsified form and midazolam closely approach the above requirements. Therefore, they are widely used in connection with dental procedures as well as e.g. with gastroenterological procedures. The commonest drugs used in dental procedures are diazepam, midazolam and flumazenil.

4.2 Diazepam

Diazepam is available in 2 ml ampoules, each containing 10 mg diazepam.

Diazepam is available both in a water-alcohol solution, a combination which does irritate veins, and in an oil-water emulsion which does not have an irritating effect and which is the only acceptable solution for intravenous sedation. In many countries the trade name of the latter is Stesolid Novum 5mg/ml injection liquid and it is packed in 2 ml ampoules, meaning that one ampoule contains 10 mg diazepam. In Stesolid Novum, the diazepam is dissolved in an oil base. The organic solvents used in conventional parenteral diazepam products have been found to cause unpleasant symptoms and pain in 78% and thrombophlebitis in 30% of cases when injected into the vein, thus they may be considered unsuitable for intravenous sedation. The corresponding frequencies for the Stesolid Novum injections are 5.3 and 1.1%. Stesolid Novum is ready for injection and it may also be administered to small peripheral veins. Diazepam should never be injected into the muscle because of very insecure absorption.

The official indication of the drug is premedication before the procedure. Dosage for premedication is 0.1-0.2 mg diazepam/kg intravenously. A rule of thumb for the maximum dosage of diazepam in dental procedures is that doses over 20 mg may be used only for exceptionally lengthy procedures. The initial dose of diazepam should never exceed 20 mg. It should also be borne in mind that the clinical effect for elderly and weak patients is usually reached with smaller doses. This means in practice that elderly patients should be administered only
ca. 2.5 mg diazepam at a time and allowed a few minutes for the effects to become apparent after each dose. Other facts to remember are the contraindications and the fact that diazepam impairs the tolerance for alcohol, sedatives and sleeping tablets.

The effect of diazepam on the central nervous system is localised in the subcortical areas and the reflexes. Its half-life in the plasma is 24-48 hours. This long half-life causes a risk of the drug accumulating in the body if the doses are repeated before an earlier dose has been eliminated. If a patient uses diazepam daily for his medication, a dose given in the vein may lead to respiratory depression. Recording the drugs used in the patient’s medical history is therefore imperative.

The main metabolite of diazepam is desmethyldiazepam, which has a half-life of 100 hours. Yet diazepam may interact with any drug that has a depressant effect on the central nervous system. It can potentiate the effect of other hypnotics and sedatives on the brain. It may also increase the effects of alcohol. The use of diazepam is also problematic if the patient is taking anti-depressant medication. The slow elimination of diazepam and its metabolites may cause an exceptionally strong reaction if other sedatives are taken before complete elimination, this carries a risk of danger. On the other hand, these problems occur quite rarely, even though diazepam is a very common drug.

Following oral administration, diazepam is absorbed rapidly. A single dose of 10-15 mg gives a plasma concentration of 0.2-0.3 micrograms/ml within 2 hours. The elimination of the drug is initially rapid but it slows down into a total half-life of 1-2 days.

Following intravenous administration (10-15 mg), the plasma concentration of 1 microgram/ml is reached within 4 minutes and a strong sedative effect is immediate. The concentration then falls to 0.25 micrograms/ml per hour and the clinical effect is reduced at the same rate. The main effect of the intravenous dose falls within the first hour, thereafter the effect resembles that of an oral dose. To reach the same concentrations orally as are created intravenously for the first hour, extremely high doses of the drug would be needed.
4.3 Midazolam

Midazolam is available in 5 ml ampoules containing 5 mg midazolam or a content of 1 mg/ml, and in 3 ml ampoules containing 15 mg midazolam or a content of 5 mg/ml. The latter have been intended solely for use as a general anaesthetic and are not suitable for dental applications. The former, weaker solution should be used for dental procedures as it enables the safe titration of the dose.

Midazolam is sold under the trade name Dormicum. Midazolam can form water-soluble salts with acids which provide a well-tolerated water-soluble injection liquid. The drug has a short duration and is well suited for premedication. Midazolam typically shows a rapid onset and short duration due to a fast metabolism. Due to its low toxicity, the therapeutic scale of midazolam is wide. A short-term anterograde amnesia is experienced after intravenous dosage, and patients show a clear tendency towards dozing off once the desired sedation level has been reached. The elimination half-life is 1.5-3 hours.

The elimination half-life of the principal metabolite, alfahydroxy midazolam, is shorter than that of midazolam. With elderly people, the half-life of midazolam may become as much as three times longer. Therefore an intravenous dosage should be titrated against the patient’s response.

Midazolam interacts with the following drugs: analgesics, sleeping drugs, anxiolytes, antidepressants, neuroleptics, simeditine and anaesthesia. The initial dose is 2.5 mg 5-10 minutes before the operation. Additional doses of 1 mg may be given if necessary. Doses greater than 5 mg are generally not required to create the desired response. The easiest means of dosage is to titrate 1 mg of the drug through a cannula every second minute and then follow up for the response.

The effect of midazolam is so strong and individual that there is a risk of serious side effects. A respiratory depression may turn into the discontinuation of respiration which, undetected, leads to cardiac arrest. This is a great risk with elderly or weak patients, and resuscitation equipment should always be on hand.

Midazolam interacts with the following drugs: analgesics, sleeping drugs, anxiolytes, antidepressants, neuroleptics, simeditine and...
erythromycin. All these drugs contribute to a longer active period or a stronger response. It must especially be noted that midazolam should be administered with special caution to elderly people and weak patients, and to patients suffering from an obstructive pulmonary disease, chronic kidney deficiency or cardiac insufficiency.

### 4.4 Administration equipment

Disposable syringe: for premedication with midazolam, the most practical size is 5 ml, and for diazepam, 2 ml.

Needle: needles are needed for the transfer of the drug from the ampoules to the syringe. Ideal needles are as wide and long as possible, e.g. ones with a Luer connector.

Cannula: in intravenous sedation, the patient should also have a venal cannula. The ideal would be one with three entrances, which facilitates a possible change of infusion bag. The cannula needle may be very thin as only salt solution needs to be transferred through the cannula, a thin needle will also make the cannulation procedure much more pleasant. A suitable width of cannula is 20 G (gauge) which corresponds to a diameter of 1 mm, and a sufficient length for the needle is 30 mm. This size of cannula will allow the transfer of 50 ml liquid per minute which is quite sufficient in this case. With a thin cannula, the injection is painless and succeeds well. Venal irritation is also much smaller than when using a larger cannula.

Infusion liquid: A physiological sodium chloride liquid (0.9%), available at the pharmacy, is used in intravenous sedation. It comes in both glass and
plastic containers. A volume of half a litre is quite sufficient for sedation purposes. The rate of the infusion should be fast at the beginning of sedation, and when the sedation level is sufficient, the rate of the infusion may be set to one drop per 2-3 seconds (=1 ml/min).

Surgical tape: The cannula is attached so as to permit no movement. A strong adhesive tape, preferably in a γ-form bandage, should be employed.

4.5 First aid equipment

Additional oxygen is the most frequent supplement required in intravenous sedation. An oxygen cylinder is an absolute necessity and no procedures should be started if there is not enough oxygen for several hours’ administration. Nasal cannula are ideal for administering oxygen during the procedure as an oxygen mask cannot be used.

Precautions against respiratory arrest shall be made with a emergency resuscitator, “Ambu”, that is connected to the oxygen. During the procedure the sedationist must have both the possibility and the ability to perform an endotracheal intubation for the patient if needed. This makes intravenous sedation a suitable next step after becoming experienced with nitrous oxide. The above mentioned resuscitation methods must be learnt before a permit to use nitrous oxide will be granted.

Pharmacies have a wide range of various surgical tape materials packed in rolls, so finding a suitable one for attaching the cannula should cause no problems.

Venous stasis: A venous stasis is attached above the cannulation site to raise the veins. It should direct the pressure to prevent the return of the blood through the veins but to allow the blood pressure to fill the limb.

The resuscitation drugs listed in the general dental studies should be available at the surgery. These are 1) epinephrine, 2) diazepam, 3) atropine, 4) cortisone, and various liquids to solve the above, as well as the syringes and needles to administer them. In addition to these, intravenous sedation procedures require certain drugs primarily intended to cure respiratory depression and to support the cardiovascular system. These drugs are:

- nalorphin (Nalorfin®), which cures the respiratory depression caused by opiates;
- flumazenil (Lanexat®) to impede the benzodiazepine receptors and thus cure the respiratory depression caused by benzodiazepines. Flumazenil is a benzodiazepine antagonist and it is available in 5 ml ampoules. They contain 0.5 mg of the drug or 0.1 mg/ml. It is important to always have the antagonist within reach in case any problems should arise during the procedures.
• doxazepam; (Dopram®), which stimulates the respiratory centre in the brain;
• salbutamol (Ventoline®) opens the pulmonary tubes e.g. in connection with status asthmaticus;
• etilephrine (Effortil®) which is used to increase the volume per minute of the heart and to increase blood pressure.

All the above mentioned drugs are in injection form and require the correct training in addition to learning their properties from the available literature. It is of the utmost importance that all necessary emergency/resuscitation drugs are within reach of the dental surgeon performing the operation, and that the expiry dates of ampoules are duly followed. Moreover, the ampoules should not be opened until immediately before use as an opened ampoule will not keep.
The safety and well-being of the patient are the responsibility of the operating dental surgeon. All sedated patients must be monitored. The cost of monitoring equipment is no excuse for not monitoring the patient. Monitoring results should be carefully recorded. The most important monitors of all are the eyes and ears of the person carrying out the procedure, which means that the patient must be observed closely during the whole procedure. This is the way to avoid unnecessary problems. If the data gained through electronic monitoring is in contradiction with clinical observations, human intelligence and observation skills are needed to solve the situation. Even though monitoring is essential, it will never replace the human senses, only enhance them.

5.1 Blood pressure monitors

There is a variety of pulse and blood pressure monitors on the market, the simplest of which measure the blood pressure automatically at the press of a button, the more complicated ones measuring the blood pressure independently at pre-set intervals. All monitors should permit the recording of the results with a printer. There should be no drastic changes in blood pressure during intravenous sedation, so continuous monitoring is not necessary. The basic requirement is the ability to measure and record the pressure before and after the procedure, as well as during the procedure according to the patient’s symptoms.
5.2 Pulse oximetry

The functions of the body depend on a continuous intake of oxygen. This vital supply has been secured by many means, the most important of which is the ability of haemoglobin to bind oxygen. The amount of oxygen bound in haemoglobin depends on the prevailing oxygen pressure, but an essential fact is that the dependence is not linear but creates a co-ordination curve forming a gentle S. The amount of oxyhaemoglobin, oxygenated haemoglobin, in the total amount of haemoglobin, is called oxygen saturation, measured as a percentage. The flat end of the oxygen dissociation curve of haemoglobin ensures good oxygen saturation across a wide variation of oxygen pressure. On the other hand, the steep fall of the curve enables the quick delivery of oxygen to the areas with oxygen pressure characteristic of certain tissues.

Oximetry measures oxygen saturation, or the percentage of oxyhaemoglobin. It can also be measured in a laboratory test from an arterial blood sample, but nowadays oximetry normally refers to a non-invasive monitoring system in which the monitoring occurs continually through the skin. The oximeter is usually connected to a finger, but other monitoring sites such as the earlobe are also suitable.

Pulse oximetry was developed for clinical use in the mid-1970s in Japan. During the 1980s, this monitoring system became extremely popular and, during the last few years, it has, in many countries, even been considered compulsory in the control of general anaesthesia. Since 1986, pulse oximetry has become so popular worldwide that it is considered by many to be the most important monitoring system in anaesthesia.

Pulse wave oximetry also utilises the information contained in the pulse wave. Even though it used only to function in the monitoring of the timing of the saturation, the pulse wave printed on the screen is becoming a regular feature of the equipment. The size of the pulse wave is subject to great variation according to various factors and thus it reflects the changes in blood flow at the monitoring site.

5.2.1 Monitoring during sedation

The most feared of possible emergencies in connection with sedation is a sudden lack of oxygen. Therefore pulse oximetry is a safety factor which enables the quick detection of a sudden lack of oxygen and the counteraction of its consequences. Attention must be paid to a continual decrease of saturation before it reaches the stage of an actual lack of oxygen. Pulse oximetry is particularly applicable at the onset of sedation as it is during this phase that most changes in saturation occur. Even extensive local anaesthesia creates more decreases in saturation than is
commonly believed. Saturation may decrease in cases where anaesthesia has to be complemented with intravenous analgesics or sedatives. The situation is usually relieved with the application of oxygen.

5.2.2 Emergency situations

There would be plenty of use for pulse oximetry when estimating the danger of sudden emergencies and the corresponding efficiency of corrective measures. Lack of oxygen is connected with many acute illnesses and damage and therefore constitutes a concrete risk factor. A pulse oximeter also immediately displays the effectiveness or ineffectiveness of the corrective measures. If the patient is transferred to a hospital, the monitoring should be continued as unexpected changes in the patient’s condition may arise in emergencies.

5.2.3 Sources for default

There are certain sources of default within pulse oximetry and pulse wave oximetry, although as such they are quite reliable methods.

The absorption of red light is not specific to oxyhaemoglobin, as the same phenomenon is created by the bonding of carbon monoxide to haemoglobin. This is visible, e.g., in a patient who is a heavy smoker.

In pulse oximetry, the saturation and pulse rate values require a pulsating circulation, but the values remain reliable even during poor peripheral circulation.

Pulse oximetry measures oxygen saturation which decreases only slightly, although there may be a considerable decrease in the venal oxygen pressure. Therefore, the shape of the dissociation curve should always be considered when interpreting the oxygen saturation values.
6. INTRAVENOUS SEDATION IN PRACTICE

Before beginning intravenous sedation, the dentist should make sure that all necessary resuscitation equipment and drugs are close at hand, that there is sufficient oxygen in the oxygen cylinder and that the drugs have not passed their expiry dates.

6.1 Cannulating the vein in the crook of the arm

Before the patient arrives, the following equipment should be prepared:

- a 5 ml syringe
- a large needle (G 21) for the suction of the drug
- intravenous cannula
- alcohol swab
- drugs
- venous stasis
- infusion fluid package
- infusion tube

The patient's weight should be determined beforehand or, if it has not been, it should be verified at this point. The drug is nevertheless dosed primarily according to individual reactions and only secondarily in accordance with the patient's weight.

The patient is placed into an almost supine position, his blood pressure is taken and the probe for the pulse oximeter is attached, then the initial values for blood pressure and oxygen saturation are recorded.

The cannulation can also be carried out completely without pain with an emulsion ointment or plaster (Emla ®) to numb the skin for the cannulation procedure. The plaster is more practical for cannulation purposes as it is individually packed and can be attached by the patient or his parent in an agreed place. The anaesthetic effect begins after 1 hour and thus to be useful the product should be supplied in advance, for the patient to apply at home. More detailed information on the product can be found in the national Pharmaca.

A venous stasis is placed on the patient's arm to provide good visibility of the veins. When fitting the venous stasis, it should be remembered that the pressure should not be so great that arterial circulation in the arm is obstructed. Following this, the cannula is attached and fixed to the skin with adhesive tape.

The salt solution is placed in the infusion stand and the chamber of the intravenous line is filled with the liquid. The whole length of the tube is checked carefully for air bubbles. The infusion tube is attached to the cannula and for a while the infusion valve is set to allow maximum flow. This is to ensure that the flow is free and the surrounding tissue is not swelling as a sign of paravenous infusion. At this point it will be evident if the injection has punctured an artery, as blood will rush up the injection tube.
6.2 Administering the drug and observing the effects

When the infusion is working normally, the administration of midazolam begins. With a disposable syringe, midazolam (1 mg/1 ml) is given in 1 mg doses. The doses are repeated every 2 minutes. A conversation is held with the patient throughout the administration, on any subject, to observe the impairment of the motor co-ordination of speech. Other motor disorders can be observed e.g. by asking the patient to touch his nose before every new dose of drugs. The point at which the patient closes his eyes is also noted, and pulse oximeter values are observed. An appropriate level of sedation is reached when one of the following observations is made:

- the patient’s speech becomes slurred
- the patient closes his eyes or seems to be somnolent
- the value in the pulse oximeter decreases by 2-3% of the initial value as a result of decreased respiration rate.

Sedation is commenced, and especially for anxious patients, local anaesthetics containing epinephrine should be avoided as a possible tachycardia reaction caused by epinephrine may disturb a good sedation. Calmness should always be maintained when handling the patient as he is awake and by no means anaesthetised.

After the sedation phase, it is possible to give additional doses of midazolam if the patient’s bearing indicates the need for further medication. However, the pulse oximeter should be observed before every additional dose, and no further doses should be given if the pulse oximeter value is equal to or lower than 95%.

If sedation is to be followed by a surgical procedure, it is worth reminding the patient that he may sleep while the team is preparing the operating room ready for surgery. The patient will usually fall asleep a few minutes after the conversation with him has stopped.

Before surgical procedures it is always good to give the patient a small dose of fentanyl (50 microgram/ml) immediately before the surgery, e.g. 25 micrograms of fentanyl is usually sufficient. The advantage of this is that the patient reacts less to small sensations of pain which may arise despite sedation. As fentanyl is also a powerful respiratory depressant, the value displayed by the pulse oximeter must be checked before administering the drug. In conventional treatment (e.g. extraction, root treatments etc.) the treatment should be initiated immediately after the sedation becomes effective. An additional 1 mg of midazolam (see the pulse oximeter) is recommended, where after the saliva aspirator is placed on site. A recommended suction fan is the short loop-form aspirator. These aspirators work like a string, thus helping the patient to keep his mouth open.
6.3 Recovery from sedation

6.3.1 Oxygen saturation

Oxygen saturation is monitored closely, both during the procedure and during the recovery from sedation. If oxygen saturation falls below 90%, it is important to immediately check the patient’s respiration movements and openness of airways. It is also diagnostic to know if the decrease is sudden or slow. In some cases, the reason may be local to the point of measurement: it should be checked that the probe does not apply so much pressure to the monitoring site that it obstructs circulation. In such an event, the probe should be moved to another finger, but only after the exclusion of genuine oxygen desaturation. Should you suspect a malfunction of the probe, use your own finger to test the function of the probe.

If the value remains unchanged, airways are open and the patient is breathing, additional oxygen should immediately be given to the patient. A nasal cannula and a regular 3-10 l oxygen cylinder (e.g. AGA) are suitable, providing that there is enough oxygen for several hours’ use. The administration of additional oxygen will repair, almost without exception, the onset of hypoxia. If the respiratory depression is caused by benzodiazepines and the low oxygen saturation is not increased by oxygen administration, the patient should be intravenously administered some flumazenil (Lanexat 0.1 mg/ml à 5 ml). This drug can be dosed in 0.1 mg i.e. 1 ml portions which are repeated every minute until the oxygenation has returned to normal. The dosage may rise to a maximum of 1 mg (10 ml).

If respiration depression is caused by benzodiazepines, return to normal oxygenation is very fast and will occur during the very first doses.

As flumazenil is a benzodiazepine antagonist, it blocks the same receptors as those to which benzodiazepines are attached. Therefore flumazenil may be given in a sufficiently small amount to prevent an eventual respiration depression, but not to lose the sedation. The procedure may then continue normally.
6.3.2 Flumazenil

In addition to treating complications, flumazenil may be used to end the sedation of a patient after a short procedure. The patient may be given 0.05 mg per 5 minutes of flumazenil, until he can walk without assistance. As the half-life of flumazenil is shorter than that of benzodiazepine, re-sedation may occur within 2-3 hours, the patient and his escort should be notified of this possibility.

The initial dose of 0.2 mg flumazenil is administered through the cannula while it is still in place in the cubical fossa. It must be noted here that the cannula should remain in place during the whole procedure and must not be removed until the patient is fully recovered. A few seconds after being given flumazenil, the patient is likely to open his eyes. When the patient is fully awake he is given permission to sit up and, after a few further minutes, he is also given written instructions for recovery which are also referred to orally. The instructions should essentially forbid driving and the consumption of alcohol. At this stage, there is no point in explaining excessively complicated things to the patient. The instructions will order the patient to rest for the following day.

The advantages of the benzodiazepine antagonist are:

1) an efficient emergency drug for oversedated patients
2) full co-operation of the patient
3) a safer recovery period

The possibility of using flumazenil as an antagonist in overdose cases makes it an extremely important drug for securing the sedation process. It must be kept within reach whenever a patient is sedated. Some patients are very sensitive to benzodiazepines, and in such cases an antagonist may even prove to be a life-saving drug. Elderly patients are much more sensitive than the young to the effect of benzodiazepines. In cases where general anaesthesia is contraindicated due to the patient’s respiratory illness, intravenous sedation is the only method to enable certain procedures, and flumazenil ensures that the sedation is safe. A general rule to observe in the case of elderly patients is not to send them home immediately after treatment with intravenous sedation, but rather to arrange for overnight monitoring for them in the ward.

When the patient is sedated, his level of consciousness has decreased and this may encumber complicated procedures, e.g. the preparation of a dental crown. A suggestion is to perform the unpleasant procedures immediately at the beginning of sedation. Once the stage is reached when the patient need no longer be sedated but co-operative, he is given flumazenil until he can contribute to the procedure (e.g. the fitting of occlusion and dentures).

Patients who have undergone treatment under intravenous sedation and have been given flumazenil to
eliminate the sedation can sit and stand normally. It must, however, be remembered that they remain sedated and cannot fully look after themselves. It is crucial to remember that the effective time of flumazenil is shorter than that of midazolam and, in theory, the sedation with eventual respiratory depressions may return, even though the long duration of dental procedures makes it highly unlikely. The presence of an escort is, even in these cases, absolutely necessary. The escort gives the patient a feeling of security and someone to talk to about the experience.

After the procedure, the patient may be sent home 3 hours after the last dose of midazolam. He should be provided with an adult escort. Both the patient and his escort should be reminded of the written instructions which the patient received on his previous visit; the main points being that the patient’s ability to observe traffic is impaired in the 12 hours to follow, and that he should not consume alcohol during this time, as it would increase the effect of the drugs and vice versa. Some people may show unpredictable individual reactions. The patient should be made aware of the dentist’s office and home telephone numbers in case any help is needed after the treatment.
Intravenous injections may produce a reaction at the injection site, later turning into a thrombophlebitis. This is an inflammatory reaction found at the injection site: redness of skin, swelling and pain. The vein may be blocked due to the infection (thrombus), but although painful, this is not a dangerous condition. Haematomas can also found at the injection site. They are generally a result of damage occurring in the vein, and the consequent bleeding into the surrounding tissues. To avoid paravenous injections, please ensure that the needle really is in the vein. The most reliable way to control this is to connect the infusion bottle to the cannula. If the cannulation has failed, do not try the same vein again but use another vein which should be as large as possible. With appropriate technique, an extravasous injection will be observed almost as soon as it has occurred. The cannula is then removed and a compression bandage is tied on the site, eventually lifting the hand slightly to avoid swelling. If a thrombophlebitis is developing, it will heal itself in a few days, or one to two weeks.

There are descriptions in medical literature of the broken tip of a metallic needle or the plastic parts of a cannula ending up in the bloodstream. The breaking of a venal cannula and the introduction of a loose part into circulation is, without exception, poor medical practice caused by the cannulation technique, and as such will lead to prosecutions and claims.

7.2 Hypoxia

A serious hypoxia is a very rare complication of diazepam or midazolam, and it occurs most frequently as a consequence of an obstruction in the respiratory passages. When the sedation is too strong, the airways are not held open naturally. The patient will perform breathing movements but no air is passing. During a partial obstruction, the patient sounds as if he is snoring. Drugs may interact to emphasise the respiratory depression effect of diazepam. Oversedation and overdose will also cause respiratory depression. It is important to titrate the sedation dose to the exact point. As mentioned above, pulse oximetry of the patient is of the utmost importance.
7.3 Fainting

An extremely nervous patient may produce a vasovagal collapse, either before or during the administration of the drug. In this case the procedure should immediately be discontinued and normal instructions against fainting should be followed. First, the limbs are raised. No dental procedure should be carried out during this appointment. The patient is given a new appointment and it should be considered whether part of the diazepam or midazolam should be given beforehand per os for instance 1-2 hours before the appointment.

7.4 Psychogenic complications

Patients who are under psychiatric medication or treatment are not suited to intravenous sedation. There are some descriptions of paradoxical excitement which is mainly found in children, but in individual cases there have been aggressive reactions even with adults. The only way to deal with the situation seems to be to discontinue the procedure. A more common reaction is a decrease in the patient’s conscious inhibition, so that the patient becomes very talkative and says things he would not normally mention. When initiating sedation, it is good to lead the conversation towards harmless topics, as the amnesia caused by the drug may further distort the recollection on the contents of the conversation. Some cases have been recorded in which patients undergoing intravenous sedation have had sexually coloured illusions, the worst of which have even led to prosecution of the sedating physician. This is why it is very important that all monitoring is set up before the sedation. This particularly applies to EKG monitoring; the patient should not, whilst under sedation, undergo procedures which he would not expect a dentist to perform. For security reasons, it is also vital that another member of staff is present during the whole of the treatment process: at the initiation of sedation, during the procedure and during the recovery period. A good precaution for the dentist’s legal protection is to make a video recording of the procedure and to file the tapes.

7.5 Other complications

There is a small group of patients who, after being given a few milligrams of diazepam or midazolam, will fall into deep sleep, as the dose does not depend on the patient’s weight. A large patient may reach deep sedation while a small patient who weighs very little may take a much larger dose. The latter group may look the dentist in the eye after a 10 mg dose and say, “It doesn’t make any difference at all”. What must be remembered, however, is that the patient may be sedated despite his claims to the contrary. This case would call for psychomotor tests such as asking the patient to touch his
nose. It is likely that he cannot perform this trick. Requesting a signature on a piece of paper would easily reveal the depth of the sedation. Increasing the dose for an extremely resistant patient may lead to a quick and deep drop into oversedation. Therefore, a key rule is not to give the patient more than 10 mg midazolam or 20 mg diazepam intravenously.

The intravenous administration of midazolam has few cardiovascular effects. The problems i.e. intra-arterial injections are easily avoided when the following is kept in mind:

• Only use a vein that is clearly visible, and only after placing the cannula should the infusion tube be connected.

• Always ask how the patient feels both at the beginning of the infusion and when giving the first drugs. Ask whether he can feel any local pain and if not, all is well.

An intra-arterial infection may cause an ischemy and necrose of the distal part of the whole arm. In case of acute respiratory or oral infection causing the obstruction of airways, intravenous sedation is contraindicated. Acute dental patients are ill-suited to intravenous sedation. Thus acute processes must first be brought under control through draining or antibiotics, only then can the procedure be undertaken under local anaesthesia and intravenous sedation.

7.6 Legal aspects

Sedation creates operational disorders in the patient’s memory which may cause misunderstandings, leading at their worst to prosecution of the dentist. Therefore, certain principles should be adopted:

• the most important principle is to explain all procedures diligently to the patient, and to give him written instructions.

• careful recording of the patient’s medical history

• the patient must come with a reliable escort

• the procedure must be suitable for intravenous sedation

• the staff must be trained

• emergency equipment and drugs must be close at hand and effective

• if teeth need to be extracted during the procedure, the patient must be informed of this in advance, before the procedure

• no payments shall be made at the sedation appointment

• the patient shall be told what preparations the procedure will require and what he has to observe after the procedure.
When these instructions are followed, everything is likely to go well. If problems do arise with a patient, they can usually be solved in a quiet and informative discussion with the patient. If not, it might be useful for the dentist to contact a more experienced colleague. The patient should also be offered a meeting with this more experienced colleague. If legal procedures must be taken, the primary task is to contact the lawyer of the dentist or the dentists’ union.

7.7 Conclusions

Intravenous sedation is, both for the dentist and his patient, a pleasant, efficient and safe means of treating anxiety problems. The basis for this security is, however, the appropriate skills of the staff. Therefore, in the conditions prevailing in the northern European dental education tradition, instructions could be given where the dentist should first be qualified in using nitrous oxide, thus already having a command and practice of patient handling, intravenous injections and endotracheal intubations. Thereafter the dentist could attend an intravenous sedation course and commence an apprenticeship with a colleague who is experienced in sedation. Individual sedation should be commenced only when the dentist has thorough knowledge of this anesthesiological method. The skill should also be continuously maintained. Endotracheal intubation exercises should not be practised only once, but this life-saving procedure in a severe complication should be practised annually at a central hospital. Neither should intravenous sedation remain a measure to be taken only when the treatment cannot be carried out in any other way. The skills to carry out the sedation would then be too weak and the result could be an extremely difficult patient that would test the skills of even an experienced sedationist. The best way to maintain sedation skills is to use the method constantly.
Instructions for an extensive dental procedure:

- Please have an X-ray and the laboratory tests taken within a week of the control appointment. Please bring the X-ray pictures and laboratory results to the next appointment.

- The procedure will be made under local anaesthesia and using a sedative premedication. Therefore, no pain or fear is experienced during the treatment.

- Please dress lightly: a short-sleeved shirt and loose-fitting trousers. Do not use make-up or other chemicals on the face. Nail varnish should be removed. Wrist watch, rings, necklaces and other jewellery should be left at home if you are to undergo a surgical procedure.

- **EATING AND DRINKING IS FORBIDDEN 4 HOURS PRIOR TO THE APPOINTMENT.** Therefore please take the medication you may have been prescribed exactly 4 hours before the appointment.

- You should be accompanied by an adult escort who will ensure your safe journey home and who will be available to you until the following morning.

- During the 24 hours after the procedure **YOU MUST NOT:**
  - leave home alone
  - drink alcohol
  - drive a vehicle
  - go to work

- Please also make sure that you have informed the operating dentist of all your possible illnesses and medications.

- A feverish cold or cough as well as other feverish illnesses, until they have been cured, will prevent any treatments. Neither can the treatment be carried out in the case of an open labial herpes.

- If you have to cancel your appointment, please do so 2 weeks before the agreed time.

- Immediately before coming to the appointment, please use the toilet.
PART V
STUDIES

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2001


ANIMAL STUDY:
THE EFFECT
OF SANDBLASTING ON
OSTEOINTEGRATION

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1.1 ABSTRACT

In this study, a total of 40 aluminium oxide sandblasted, custom made and cast pure grade-2 titanium implants were inserted into the mandibular bones of 10 beagle dogs. Characterisation of the implant surface was performed by standard SEM-methods. X-ray measurements and histomorphometrics were used to analyse the osteointegration properties. The surface of the titanium after sandblasting shows extensive roughening and the surface consists of 70-80 % titanium and 20-30 % aluminium, both as oxides. The success rate of immediate implantation was limited, but all of the implants, none of which were more than 1mm above the bone margin, met the success criteria. Examination by conventional microscopy proves that the majority (65 %) of the implant surface is in contact with bone.
The purpose of this study was to characterise the surface of pure titanium which has been abraded or roughened with aluminium oxide sandblasting and to chart the progress of the osteointegration of sandblasted titanium implants in beagle dogs. A further aim was to determine the depth at which dental implants should be inserted in the mandible bone to achieve optimal osteointegration.

### 1.2 AIM OF STUDY

This study aimed to characterise the surface of pure titanium which has been abraded or roughened with aluminium oxide sandblasting and to chart the progress of the osteointegration of sandblasted titanium implants in beagle dogs. A further aim was to determine the depth at which dental implants should be inserted in the mandible bone to achieve optimal osteointegration.

### 1.3 MATERIALS AND METHODS

In this study, a total of 40 implants were inserted into the mandibular bone of 10 beagle dogs. The implants were custom made and cast using pure grade-2 titanium and sulphur-based investment material (Rematitan®). Before implantation, the fixtures were sandblasted using aluminium oxide and then sterilised in an autoclave. All the implants were of the dimensions 3.0 x 8.0 mm.

The animals used in this study were adult beagle dogs. Ten animals, males and females, of mean age 11.1 months (range 10-12 months) and of mean weight 11.5 kg (range 9.5-14.5 kg) formed the study group. The extractions were performed under intravenous anaesthesia with pentobarbital sodium (Mebunat®, Orion, Finland), 20mg/kg. The implants were inserted in the mandible after bilateral extraction of the last posterior teeth, two implants per quadrant into the alveolar sockets of both roots. The surgical procedure was done under the aseptic conditions in which extractions are normally performed. Neither high-level surgical aseptics nor flap elevations were used.

Post-operatively, procain penicillin with dihydrostreptomycin, 1ml/10kg (Compiotic®, Pfizer, Switzerland), was administered subcutaneously daily for one week. A soft diet was maintained for the first 7 days, followed by a normal diet until the predetermined healing period of 3 months had passed. The implants were not loaded during the 3-month healing period. During this period the animals were housed in a facility designed for long-term animal care.

After 3 to 4 months healing period the animals were put down using a lethal barbiturate injection, the lower jaw was sectioned with forceps in order to isolate the pieces of bone with implants and penultimate molar. Each block was placed in 10 % formaline solution.

The samples were examined radiologically immediately after isolating the sections of implanted bone. The x-ray film used in this study was technical fine grain film (Kodak Industrex). The images were photographically transformed into positive pictures, which were analysed by measurement. The dimensions of integration and bone pocket formation...
were measured from the pictures. Fifteen specimens were selected for light microscopic analysis, selecting these for measurement by excluding possible failures.

The specimens were dehydrated in alcohol and embedded in hard methyl methacrylate resin. The specimens were then mechanically sawn along the long axis of the implant to a thickness of 5 mm and machine ground to approximately 10 micrometres. Thereafter, the specimens were stained in 1% toluidine blue for histological analysis. Histological investigation was accomplished with a light microscope for histomorphometric analysis. The percentage of bone in direct contact with the implant surface was calculated from the sides of the higher grades.

1.4 RESULTS

1.4.1 Analysis of titanium material

The implants were analysed by light microscopy and scanning electron microscopy. The surface of titanium after sand blasting shows extensive roughening.

The implants used in this experimental study contain some particles of aluminium oxide intruded into the titanium material. However these particles were rare. The x-ray emission shows that the surface contains 70-80% titanium and 20-30% aluminium, both oxides.
1.4.2 Primary success rate

The success rate of immediate implantation was 67%, only 19 implants from the original 27 were considered successful (the depth of bone pocket was less than 1mm) and 8 implants were unsuccessful (the depth of bone pocket was greater than 1mm). The majority of the unsuccessful implants (7) represented cases in which at least 2mm of the implant was above the bone margin. On the other hand, all of the implants which were 1mm or less above the bone margin met the success criterion.
1.4.3 Microscopic evaluation of osteointegration

In histological evaluation a close contact between compact bone and the surface of the titanium implant can easily be detected. The light microscope evaluation shows that the majority (65 \%) of the implant surface is in contact with bone. A minority of the surface is covered with epithelium or connective tissue.

<table>
<thead>
<tr>
<th>Implant no.</th>
<th>Contact with solid bone (% of area)</th>
<th>Fibrotic tissue (% of area)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant 1</td>
<td>60.6 %</td>
<td>39.4 %</td>
</tr>
<tr>
<td>Implant 2</td>
<td>52.9 %</td>
<td>47.1 %</td>
</tr>
<tr>
<td>Implant 3</td>
<td>67.0 %</td>
<td>33.0 %</td>
</tr>
<tr>
<td>Implant 4</td>
<td>68.2 %</td>
<td>31.8 %</td>
</tr>
<tr>
<td>Implant 5</td>
<td>84.6 %</td>
<td>15.4 %</td>
</tr>
<tr>
<td>Implant 6</td>
<td>93.5 %</td>
<td>6.5 %</td>
</tr>
<tr>
<td>Implant 7</td>
<td>77.5 %</td>
<td>22.5 %</td>
</tr>
<tr>
<td>Implant 8</td>
<td>77.8 %</td>
<td>22.2 %</td>
</tr>
<tr>
<td>Implant 9</td>
<td>57.9 %</td>
<td>42.1 %</td>
</tr>
<tr>
<td>Implant 10</td>
<td>45.2 %</td>
<td>54.8 %</td>
</tr>
<tr>
<td>Implant 11</td>
<td>15.2 %</td>
<td>84.8 %</td>
</tr>
<tr>
<td>Implant 12</td>
<td>78.4 %</td>
<td>21.6 %</td>
</tr>
<tr>
<td>Implant 13</td>
<td>16.9 %</td>
<td>83.1 %</td>
</tr>
<tr>
<td>Implant 14</td>
<td>100 %</td>
<td>0 %</td>
</tr>
<tr>
<td>Implant 15</td>
<td>74.1 %</td>
<td>25.9 %</td>
</tr>
<tr>
<td>Mean</td>
<td>64.7 %</td>
<td>35.3 %</td>
</tr>
</tbody>
</table>
1.5 DISCUSSION

The success rate of this immediate implantation technique was only 67%. This result demonstrates the benefit of submerged implantation technique. Fugazzotto (1993) and his co-workers studied a large group of submerged implants in humans. Their absolute success rate were 96.4% and 98.4% in maxilla and mandible respectively. Cumulative success rates were, at the end of study, 92.9% and 95.8%. These implants were followed in function for 6 to 60+ months. Babbush and Shimura (1993) also studied a total survival rate of rough surface implants. The five-year survival rate of a total of 1,059 implants was 95%. More recently, De Leonards et al. (1999) finalised the results of a five year study, in which they achieved a 98% success rate with 100 rough surface implants in submerged implantation. However, Watzek et al. (1995) also found very promising results in immediate implantation. After a mean follow up period of 27.1 months, 97.7% of the implants were found to be functioning successfully. The results of their study indicate that immediate implantation can be considered to be a very promising implant treatment method, if specific parameters and surgical details including proper flap elevation and sufficient bone quality and quantity are taken into account.

The surface of an implant roughened by aluminium-oxide sandblasting does not prevent osteointegration, even though small quantities of aluminium oxide can be detected on the surface of implant following the sandblasting treatment. Feighan et al. (1995) concluded that the length of the bone-implant interface for the implants that had been sandblasted with aluminium oxide was significantly greater than for plain polished implants. Sandblasting affected the area of bone formation on the implant and the shear strength at the bone-implant interface. Wennerberg (et al. 1995) and Piattelli et al. (1998) also concluded strong osteointegration of aluminium-oxide sandblasted titanium implants.

The primary success rate of immediate implants was low in this study, but the area of solid bone in direct contact with the implant surface was equal to other studies: Titanium implant systems were apposed by more bone than ceramic systems. Between 41% and 50% of the surface of integrated ceramic implants were apposed by bone, whereas between 50% and 65% of the surfaces of titanium implants were apposed by bone according to the studies of Steflik et al. (1996). Similarly, Sennerby et al. (1991) have found that in humans, a large proportion of the implant surface (56-85%) appeared to be in direct contact with the mineralised bone. Trisi et al. (1999) also investigated osteointegration of rough surface titanium implants in human low-density jawbone. Bone-implant contact was between 59-77% whereas the results for implants with a smooth surface was only 4-7%. This study showed that a rough implant surface may enhance the rate of osteointegration, but it is not able to
significantly change the bone density. A problem arises when attempting to compare these results because the direction of cutting the specimens is not standardised i.e. sagittal cutting shows mainly spongious bone and frontal cutting compact bone.

1.5.1 Conclusions

The pure titanium which was abraded by aluminium oxide sandblasting shows a rough surface containing minor aluminium remnants. This surface demonstrates normal osteointegration properties in beagle dogs but only in cases with optimal insertion depth. Our results are in harmony with clinical experiences in the cases with insufficient bone quality in which - similarly - the optimal position of implant and marginal bone were not reached. The clinical success in implantation depends mainly on the optimal position of the implant and the quality of the bone.

1.5.2 Acknowledgements

The authors want to thank the Professors R-P. Happonen and A. Yliurpo of the School of Dentistry at the University of Turku for their help in producing the histological preparates.
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The OSFIX Dental Implant System - A Three-year Follow-up Study

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2.1 Abstract

Osfix implants are pure grade 2 titanium implants, the surfaces of which have been mechanically roughened by sand blasting with aluminium oxide. The integration property of the surface processing has been previously studied with animal tests and histology. The aim of the Osfix clinical study was to verify the success rate of the Osfix system. A total of 59 patients were operated on and the number of implants inserted was 210. After a 3 month healing period, impressions for the bar structures were taken and the mesiostructure bars fabricated. These bars were then connected to an over-denture.

The follow-up results are available for 57 patients (203 implants). At the time of the secondary operation, all of the implants were stable. At the 3 year follow-up inspection, no implants were lost. The success rate was 100 % for the implants followed for 3 years. Patients were radiographically evaluated annually and the mean marginal bone loss was 0.59mm (SD 0.42) after 1 year, 0.47mm (SD 0.42) after 2 years and 0.58mm (SD 0.50) after 3 years. After the first year’s initial marginal bone loss, no increase in bony pocket depth was detected. No clear relationship between age, gender or number of implants inserted was noted.
2.1.1 Aim of the Clinical Study

The purpose of this clinical study was to verify the success rate of the Osfix system and to observe the events causing possible de-integration.

2.2 Patients and Methods

2.2.1 Implants

The Osfix implant is a cylindrical implant with an apical thread for increased primary stability. The implant has an internal hexagon for tightening during surgery. The implant is made of grade 2 pure titanium and the implant surface is mechanically coarsened by sand blasting with aluminium oxide. The length of the study implant was 13.5mm and the outer diameter 3.75mm.

2.2.2 Patients

Operations were performed on 59 patients, 45 of them at the University of Kuopio and 14 at the University of Tampere. The number of inserted implants was 210. Two patients were withdrawn from the study (because of lack of follow-up information). The study sample consisted of 57 patients and 203 implants. The age of the patients varied between 41 and 75 years. Of the patients analysed, 34 were women and 23 men. Twenty-five of them received 3 implants and a further 32 each received 4 implants.

<table>
<thead>
<tr>
<th>Gender</th>
<th>M</th>
<th>F</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>23</td>
<td>34</td>
<td>40%</td>
</tr>
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<table>
<thead>
<tr>
<th>Age (y.)</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>55.4</td>
<td>8.4</td>
<td>41-75</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of implants per patient</th>
<th>3</th>
<th>4</th>
<th>44%</th>
<th>56%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25</td>
<td>32</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.2.3 Surgery

The implant site was exposed by a large mucoperiosteal flap. A horizontal incision was made on the crest of the ridge, extending distally to the mental foramen. A vertical releasing incision in the median line was sometimes required to achieve better visibility of the field of surgery. The mucoperiosteal flap was then raised and the position of the mental foramens identified and accessory local anaesthetics injected into them. Palpation of the undercuts with the aid of a periodontal probe or elevator was performed in order to avoid critical areas in the lingual area during surgery. The alveolar crest was smoothed with a large round drill and the implant sites marked with a small round drill. The implant bed was prepared with a standard drilling set cooled by external irrigation with cold saline to a diameter of 3.7mm and depth of 15mm. The Osfix system allows free angulation, but requires 5-15 degrees angulation between holes.

The implants that would come into contact with the bone were removed from sterile ampoules and inserted directly into the implant site to avoid contamination with foreign material. Four implants were used in the cases of no or moderate resorption and three implants in the cases of severe resorption of the jaw bone (figures on next page). The implants were initially tapped into the holes with a mallet and thereafter screwed and tightened with a ratchet. The upper edge of the implant was placed 0.5-1.0mm below the upper bone margin. Before wound closure, a primary cover screw was screwed onto the implant. The cover screw, which is 1.5mm in height, remains 0.5-1.0mm above the level of the bone. An antibiotic steroid ointment (Terra-Cortril-P, Pfizer, Brussels, Belgium) was applied to the cover screw. Finally, the wound was sutured with interrupted and continuing sutures.

2.2.4 Prosthetic procedures

After primary surgery, a healing period of 3 months is required before second stage surgery. During this period, new dentures for both the upper and lower jaws were fabricated. Impressions were taken with a facebow and the dentures constructed according to the principle that the canines should be parallel with a line between the condyles of the jawbone. Impressions for the bar retention structure were taken at this secondary operation. The positions of the cover screws were identified with a probe and exposed with a scalpel. The cover screws were unscrewed and the impression posts inserted. The impression was taken with a newly fabricated lower jaw denture, which had been relieved to make space for the impression material. The impression material was a vinyl polyxane (Express, 3 M Dental
Products, St. Paul, MN, USA). Finally, the impression posts were unscrewed and the wound re-closed with catgut sutures. The cover screws were then reinserted until the next appointment. The impression posts were placed in the impression, which was sent to the Osfix laboratory for production of the mesiostructure.

In the dental laboratory, the Osfix Bar was produced using prefabricated burn-out components and cast using cobalt chrome alloy (Wironit extra hard, Bego, Bremen, Germany).

At the final appointment, the cover screws were removed and the Osfix Bar screwed onto the implants with prosthetic screws. The space between the prosthetic screws and the bar retention were sealed with an antibiotic steroid ointment (Terra-Cortril-P, Pfizer, Brussels, Belgium). The prosthetic screws were retightened after one week, because the structure and design of the Osfix system is so accurate that friction between the components may prevent complete tightening at the initial fitting. Once the screws had been retightened, they were covered with light-cured composite. The occlusion and fit of the denture were checked and minor adjustments made to assure stability and optimal function.
2.2.5 Follow up

After the insertion of the superstructure, the patient was placed on a regular maintenance schedule. Instructions regarding home-care were carefully supervised. During the follow-up study, radiographs were taken and evaluated once a year. The annual clinical evaluation is carried out for 5 years following the operation, the parameter measured being the depth of bony defects surrounding the implants.

Of the operated patients, 53 were analysed at the beginning of the study. After that, 40 patients were followed for 2 years and 18 patients for three years or more. This high level of drop-out is a result of x-ray phobia: Some patients refused to allow annual radiographs to be taken which explains the decline in numbers of the study group over the years.

Bone defects were measured from orthopantomograms with a mm scale on both the mesial and distal side of each implant. Dividing the results by 1.3 eliminated the effect of orthopantomic enlargement. The changes in bone defects compared to the baseline situation were analysed per patient. The method of evaluation of bone loss/regrowth surrounding Osfix implants is presented in figure below.
2.2.6 Statistics

The bone defects were measured on the mesial and distal side of each implant. This implied that at each follow-up visit there were 6-8 measurements to be taken for each patient. This information was summarised by calculating two annual summary statistics for each patient: the mean bone defect and the maximum bone defect. The changes in bone defects from the baseline were calculated. A Wilcoxon Signed Rank test was used to compare the results between different time points. The analysis of variance (ANOVA) was used to study the effects of gender, age and number of implants 2 years after implantation. SPSS (Version 10.0) was used for the statistical analyses. P-values less than 0.05 were considered statistically significant.

2.3 Results

2.3.1 Success rate

Of the 203 implants inserted, 143 were analysed during the 2-year and 62 during the 3-year follow-up periods. After 3 years, no implants had been lost. The 3-year success rate of Osfix implants was 100%. The mean marginal bone loss per patient was 0.58 mm (SD=0.5) after 3 years evaluation.

<table>
<thead>
<tr>
<th>Mean bone defect (mm) per patient.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>0 year</td>
</tr>
<tr>
<td>No. of patients</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
</tr>
<tr>
<td>Median</td>
</tr>
<tr>
<td>SD</td>
</tr>
<tr>
<td>Min</td>
</tr>
<tr>
<td>Max</td>
</tr>
</tbody>
</table>

* Wilcoxon Signed Rank Test

\[
\begin{align*}
\text{p-value} & = 0.06^* \\
& \quad \quad 0.43^*
\end{align*}
\]
The Maximum bone defect (mm) per patient.

<table>
<thead>
<tr>
<th></th>
<th>0 year</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>57</td>
<td>45</td>
<td>40</td>
<td>18</td>
</tr>
<tr>
<td>Mean</td>
<td>0</td>
<td>1.66</td>
<td>1.56</td>
<td>1.88</td>
</tr>
<tr>
<td>Median</td>
<td>0</td>
<td>1.54</td>
<td>1.54</td>
<td>1.54</td>
</tr>
<tr>
<td>SD</td>
<td>0.63</td>
<td>0.88</td>
<td>1.03</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>0.77</td>
<td>0.00</td>
<td>0.77</td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td>3.85</td>
<td>4.62</td>
<td>4.62</td>
<td></td>
</tr>
</tbody>
</table>

* Wilcoxon Signed Rank Test

The Maximum bone defects are shown in table above and bone defect distribution after 2 years follow-up is presented in figure below.

Distribution of bone defects after 2 years (40 patients/143 implants).
When comparing the different groups of patients, a low statistical significant difference in bone loss between men and women was noted (p=0.06) (upper table). However, the results are not as hypothesised. The relationship between age and bone loss was contradictory. In the younger age group the mean bone defects were deeper and the finding was statistical significant (p=0.035), but the maximum bone defects were not related to age (p=0.56) (lower table below). The amount of inserted implants was not related to growth of bone defects (p=0.58) (table in next page). Only 2 years’ results are presented in these tables and because the low number of patients in the 3rd year did not permit statistical analysis.

### Bone defects (mm) of men and women after two years.

<table>
<thead>
<tr>
<th></th>
<th>Gender</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Males vs. females p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Bone defect</td>
<td>Male</td>
<td>16</td>
<td>1.83</td>
<td>1.01</td>
<td>p=0.12</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>24</td>
<td>1.38</td>
<td>0.75</td>
<td></td>
</tr>
<tr>
<td>Mean bone defect</td>
<td>Male</td>
<td>16</td>
<td>0.63</td>
<td>0.33</td>
<td>p=0.06</td>
</tr>
</tbody>
</table>

### Bone defects (mm) of different age groups after 2 years.

<table>
<thead>
<tr>
<th></th>
<th>Age group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Differences between the age groups. p-value (ANOVA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. bone defects</td>
<td>40-49</td>
<td>13</td>
<td>1.60</td>
<td>0.38</td>
<td>p=0.56</td>
</tr>
<tr>
<td></td>
<td>50-59</td>
<td>18</td>
<td>1.67</td>
<td>1.19</td>
<td></td>
</tr>
<tr>
<td></td>
<td>60+</td>
<td>9</td>
<td>1.28</td>
<td>0.67</td>
<td></td>
</tr>
<tr>
<td>Mean bone defects</td>
<td>40-49</td>
<td>13</td>
<td>0.70</td>
<td>0.36</td>
<td>p=0.035</td>
</tr>
<tr>
<td></td>
<td>50-59</td>
<td>18</td>
<td>0.31</td>
<td>0.39</td>
<td></td>
</tr>
<tr>
<td></td>
<td>60+</td>
<td>9</td>
<td>0.47</td>
<td>0.46</td>
<td></td>
</tr>
</tbody>
</table>
2.4 DISCUSSION

The success rates of implants have, over the years, become quite clearly defined. Scientific follow-up studies on implants with a roughened surface structure hold good promise for the success of the treatment. Fugazzotto et al. (1993) followed 2,023 implants placed into a total of 974 patients. All types of prosthetic structure were well represented, from single tooth implants to full dentures completely fitted to the bone and full prostheses supported with a bar. The cumulative success rate at the end of the 5-year follow-up study was 93 % for the maxilla and 96% for the mandible. A study by Babbush and Shimura (1993) followed 1,059 implants placed in a total of 322 patients; the final success rate in a 5-year follow-up was 96 %. A division of success rates between the jaws gave a rate of 92 % for the maxilla and 99 % for the mandible. Thus the primary success of the implantation was good: of over 1,000 implants, only 9 were lost at secondary surgery due to inadequate integration. The remaining 28 implants were lost during the 5-year follow-up period. Correspondingly, in the Osfix study group 203 implants were placed without any loss before secondary operation, neither was there any loss in the group of analysed patients at the 3-year follow-up inspection. Part of the reason for these excellent results is that the Osfix System does not have very short or very narrow implants. Previous studies have confirmed the accepted fact that the longer and wider the implant, the better the result.

Good oral hygiene is crucial to the success of implant treatment. Implant losses caused by poor structure of the prostheses were rare and whenever an implant was lost, the prevalent factor was the patient’s inability and lack of will to care for his oral hygiene (Hertel and Kalk 1993). Kellet and Smith (1991) reported that the loss of an implant might follow a specific infection with an ecosystem and bacterial flora often encountered in connection with periodontal illnesses. One of the Osfix patients had a
similar suppurative infection around the implants during second stage surgery but, after careful curettage, medication and good home care, the infection disappeared, allowing the placement of the final prostheses.

The marginal bone loss surrounding the implant has been used as a parameter in various studies. In a 15-year follow-up study of mandibular fixed prostheses supported by implants, the marginal bone loss around the implants was, on average, 0.5mm during the first year and, after that, about 0.05mm annually. Long-term results of the implant treatment were successful and the study shows that smoking and oral hygiene were the main causes of bone loss around implants. (Lindquist et al. 1997)

<table>
<thead>
<tr>
<th>Number of inserted implants</th>
<th>follow-up period (years)</th>
<th>treatment</th>
<th>success rate</th>
<th>average bone loss</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>273</td>
<td>15</td>
<td>Fixed prostheses</td>
<td>98.9%</td>
<td>1.2</td>
<td>Lindquist et al. 1997</td>
</tr>
<tr>
<td>84</td>
<td>5</td>
<td>Single implants</td>
<td>97.6%</td>
<td>1.2</td>
<td>Malevez et al. 1996</td>
</tr>
<tr>
<td>107</td>
<td>5</td>
<td>Single implants</td>
<td>97.2%</td>
<td>&lt;1</td>
<td>Henry et al. 1996</td>
</tr>
<tr>
<td>155</td>
<td>5</td>
<td>Fixed/over-dentures</td>
<td>98.7%</td>
<td>0.5</td>
<td>Makkonen et al. 1997</td>
</tr>
<tr>
<td>80</td>
<td>3</td>
<td>Single implants</td>
<td>98.8%</td>
<td>0.48</td>
<td>Wannfors and Smedberg 1999</td>
</tr>
<tr>
<td>133</td>
<td>2</td>
<td>Fixed partial dentures</td>
<td>97.7%</td>
<td>0.24</td>
<td>Karlsson et al. 1998</td>
</tr>
<tr>
<td>203</td>
<td>3</td>
<td>Over-dentures</td>
<td>100%</td>
<td>0.58</td>
<td>Present study</td>
</tr>
</tbody>
</table>
Karlsson et al. (1998) has studied maxillary and mandibular fixed partial dentures supported by implants for 2 years. He has evaluated the difference between two different implant surfaces: machined and TiO-blasted. The amount of installed implants was 133. When the results of both implants and jaws were combined, the marginal bone loss was 0.24mm (SD=0.69) after 2 years follow-up. No statistically significant difference was found between studied implant types. Wannfors, with his co-workers (1999), has studied single implant restorations. Eighty implants were inserted and only 1 implant was lost during the 3-year follow-up period. The average marginal bone loss was 0.48mm during the evaluation period.

In the Osfix clinical study the mean marginal bone loss was 0.58mm (SD=0.5) after a 3-year evaluation period. This result is in agreement with the other above-mentioned studies (Table on previous page). There was no clear significant difference in marginal bone loss related to gender, and men’s more frequent use of tobacco may explain this minimal difference. Nor could the difference between age groups be clearly related to the growth of bone defects after 2 years follow-up. However, no differences were found related to the number of inserted implants.

This study confirms earlier studies, which describe implant treatment as a safe method with few surgical complications and minimal marginal bone loss. The complications caused by poor structure of the prostheses were rare, but good oral hygiene is considered to be a very important factor in the success of implant treatment.

2.5 CONCLUSIONS

The complication level was very low when inserting Osfix implants. The mean bone loss per patient was 0.58mm during the 3-year observation period. No implants were lost; hence the success rate of the Osfix implant is 100 % after 3 years follow-up in 1999.

2.6 ACKNOWLEDGEMENT

We wish to extend our gratitude to Mrs. Tuija Poussa for her assistance with the statistical analysis.
REFERENCES


FOLLOW-UP STUDY:
THE EFFECTS OF OSFIX IMPLANTATION ON THE QUALITY OF LIFE, AND PERCEPTIONS ON HOME CARE

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2 Pohjois-Savo Polytechnic, Kuopio, Finland

3.1 ABSTRACT

The purpose of the study was to determine the effects of implantation on the quality of life and to obtain information on the oral home care of patients. The subject group were patients who had received implants and a Dolder-type bar construction for a mandibular prosthesis, and who had a traditional removable prosthesis on the maxilla. The questionnaire was mailed to 58 people. Forty-nine questionnaires were returned, representing a reply rate of 84%.

Implantation did have an effect on the patients’ quality of life. The patients considered their present mandibular and maxillary prostheses significantly better than those they had used previously. They were particularly satisfied with the prostheses on the mandible. Those patients who replied considered the present prosthesis on the mandible better than those they had used previously (p<0.0001). The prosthesis on the maxilla was also regarded as considerably better than those they had used previously (p<0.0001). The main benefit resulting from implantation was the ease of laughing and mastication.

The oral home care of implant patients had worked out well. The patients felt confident with the various cleaning methods used in their oral care, and they considered themselves able to clean both the bar and the prostheses well. The most common cleaning aids were the toothbrush and interdental brush, which were used on average twice a day.
Traditional dentures are often considered cumbersome and unpleasant; some people never get used to them. Implant treatments offer solutions for many problems caused by the use of prostheses (Salonen 1996; Hujanen 1996). Users do not feel comfortable as they need to think about how to keep the prosthesis in place. Everyday functions such as eating, laughing and speaking may cause a feeling of insecurity (Seddon and Smith). The poor stability of the prosthesis may also cause sore pressure cuts on the mucosa (Laine and Lindqvist 1996). Implant treatments offer a solution for many of the problems caused by the use of prostheses (DuCoin 1996; Myers Kracher and Schmeling Smith 1998). Long-term implant treatment requires, in addition to successful ossification and a well planned and executed prosthesis structure, satisfactory oral hygiene (Talonpoika and Uusitalo 1997). Oral home care is an important part of implant treatment. To maintain a healthy tissue, careful removal of plaque around the implant is essential. Plaque causes gingivitis and bleeding in the same way as it does in the tissue around a natural tooth. To maintain oral health, the care of an implant patient includes cleaning at home and regular appointments at a dental clinic (Torres 1995). To secure the success of home care, it is important that the patient is confident with the oral cleansing methods (Babbush 1991; Spindler 1999). Because efficient oral cleansing has a direct effect on the success of the implant treatment, the role of the medical staff in patient guidance is enhanced (Seddon and Smith). When choosing the cleansing aids, the main emphasis should be simplicity in use and the minimum number of implements, as an excessive number of articles may be considered cumbersome (Myers Kracher and Schmeling Smith 1998).

### 3.2.1 Aim of study

The purpose of the study was to determine the effects of implantation on the quality of life, and to obtain information on the oral home care of patients.
Anonymous questionnaires were sent to 58 patients who had received implants and a Dolder-type bar construction for a mandibular prosthesis, and who had a traditional prosthesis on the maxilla. Forty-nine questionnaires were returned, representing a reply rate of 84%. No reply was disqualified. Of the answers received, 32 were from women and 17 from men. The age of the subjects ranged between 40-82 years.

The questionnaire consisted of 25 questions, of which 3 were open questions, 3 opinion-based questions to be measured with a linear meter (VAS: Visual Analogy Scale), and the remaining part structured questions (Statements with Likert scale, “yes-no” questions and multi-choice questions). There was also a question on the subject’s sex and year of birth.

This report concentrates on analysing the questions concerning the quality of life and oral hygiene at home, two of the questions metering VAS-change, and three being multi-choice questions.

The patients’ experiences of prostheses and their ability to care for the them was measured with VAS technique (length of line 10 cm). The results are given as medians and ranges. A Wilcoxon signed ranks test was used to compare the variables, and Spearman rank correlations were calculated to study the associations between these variables.

The box plot figures were drawn to describe the distributions of variables. The box represents the interquartile range and the whiskers indicate the highest and lowest values, excluding outliers. A line across the box indicates the median. SPSS (Version 9.0) statistical program was used for statistical analyses.
3.4 RESULTS

The patients’ experiences of present prostheses were good. They found great relief for many functions involving the use of the mouth. The main change brought about by implantation was felt to be easier laughing and mastication. Speaking and social interaction were also considered more comfortable.

<table>
<thead>
<tr>
<th>Effects of Implantation on</th>
<th>positive</th>
<th>no effect</th>
<th>negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speech</td>
<td>37</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Mastication</td>
<td>48</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Appearance</td>
<td>31</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>Interaction</td>
<td>43</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Laughing</td>
<td>48</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

All subjects considered their present mandibular prosthesis better than their previous one (p<0.0001). The prosthesis on the maxilla was also considered substantially better than the previous one (p<0.0001). Fifty-four percent (26/48) of the patients estimated the present prosthesis on the maxilla better than the one they had used previously. For 42%, the status in the maxilla remained the same (20/48). Only 4% (2 patients) felt their previous prosthesis had been better. The VAS changes have been presented in figure below.

Patients’ experiences on previous and present mandibular and maxillary protheses (VAS 0=very poor, 10=very good) and their desire for implant fixture of the maxillary prosthesis (VAS0=desire, 10=great desire).

Statistical significances:
A => C: p < 0.0001* B => D: p<0.0001*

* Wilcoxon signed ranks test
Only one patient did not feel the need to have an implant fixture for the maxillary prosthesis. Desire for maxillary implants did not increase with satisfaction with the present mandibular prosthesis, \( r=0.03, p=0.86 \), but rather with the lack of satisfaction with the present prosthesis \( r=-0.42, p=0.003 \).

The oral home care of the patients had been carried out well. The bar that was fitted on the implants was cleaned sufficiently frequently. Toothbrushes and interdental brushes were the most commonly used tools for this. The patients felt most confident with the toothbrush and prosthesis brush. The use of the interdental brush was satisfactory, whereas the ability to use other cleaning aids varied considerably.

The patients considered themselves able to clean both the bar and the prosthesis well. They felt, however, that they could clean the prosthesis better than the bar \( p=0.002 \).

<table>
<thead>
<tr>
<th>Cleansing times</th>
<th>&gt; 2x</th>
<th>2x</th>
<th>1x</th>
<th>1+</th>
</tr>
</thead>
<tbody>
<tr>
<td>number of replies</td>
<td>27</td>
<td>18</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

The oral home care of the patients had been carried out well. The bar that was fitted on the implants was cleaned sufficiently frequently. Toothbrushes and interdental brushes were the most commonly used tools for this. The patients felt most confident with the toothbrush and prosthesis brush. The use of the interdental brush was satisfactory, whereas the ability to use other cleaning aids varied considerably.

The patients considered themselves able to clean both the bar and the prosthesis well. They felt, however, that they could clean the prosthesis better than the bar \( p=0.002 \).

### Cleansing tools used.

<table>
<thead>
<tr>
<th>tool</th>
<th>number of replies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prosthetic brush</td>
<td>23</td>
</tr>
<tr>
<td>Toothbrush</td>
<td>34</td>
</tr>
<tr>
<td>Solo brush</td>
<td>10</td>
</tr>
<tr>
<td>Inter-dental brush</td>
<td>10</td>
</tr>
<tr>
<td>Gauze</td>
<td>33</td>
</tr>
<tr>
<td>Dental floss</td>
<td>22</td>
</tr>
<tr>
<td>Bar cleansing</td>
<td>0</td>
</tr>
<tr>
<td>Cleansing of prostheses</td>
<td>0</td>
</tr>
</tbody>
</table>
3.5 DISCUSSION

Implantation had a positive effect on the patients’ quality of life. They felt their present prostheses were much better than their previous ones. Particular improvement was felt with the mandibular prosthesis. Some need was also felt to fix the maxillary prosthesis on implants. The main changes felt after the implantation were easier laughing and mastication. The patients’ experiences on the improvement of oral functions as a result of implant treatment were similar to those stated in previous studies (Ducoin 1996, Cibirka et al. (1997), Myers Kracher and Schmeling Smith 1998). In addition to the changes mentioned above, the patients felt their appearance had improved, their speech had become easier and their interaction with other people had become more pleasant. In addition to functional benefits, the requirements of the patients for factors increasing social interaction are considered important (Myers Kracher and Schmeling Smith 1998).

3.5.1 CONCLUSIONS

1. Implantation did have an effect on the improvement of the patients’ quality of life, and they felt their present mandibular and maxillary prostheses were significantly better than those they had used previously.

2. The patients felt confident about oral home care.

It is essential that the implant prosthesis patient is meticulous about their oral home care, both in quality and frequency. Daily oral hygiene includes the cleansing and examination of the bar structure, prostheses and mucosa. Special attention must be paid to the cleansing of the bar structure. As the mandibular prostheses may be unfastened, visibility of the implant-fixed bar is improved and its cleansing is facilitated (Lawrence 1991). Oral home care was carried out well among the subjects. They cleaned the bar sufficiently frequently and with the right methods, which is essential for the success of the implant treatment. In addition to this, it is important that they considered oral hygiene to be important and were interested in their personal oral hygiene. On the whole, the patients felt confident with the new cleansing methods.
REFERENCES


The Behaviour of OSFIX Implant Components in Overload Situations

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2 The Helsinki Polytechnic, Finland

4.1 ABSTRACT

The purpose of the study was to determine the effects of overloading on BioSfix single tooth implants and the prosthetic screws joining the crown and the implant. The implants and the screws were submitted to fatigue and fracture resistance tests with appropriately designed equipment. The screw material was both grade 2 and grade 4 titanium and the implants were made of grade 2 titanium. Observations were made on the differences between the different grades on the basis of the tests.

In an overload situation, the screws acted as fuses, breaking at the safety groove and protecting the implant from damage. Even in the fatigue test, the screws resisted hundreds of thousands of 200 N cycles. The number of cycles needed to break the screws was 150,000 → 850,000, by which time 6 out of 11 screws tested had broken (range 150,000 - 300,000).

These fracture resistance tests demonstrated that the fracture resistance of grade 4 titanium was greater; the fracture resistance of grade 2 alloy was between 239.48-261.94 N and that of grade 4 alloy 289.39-302.53 N. The distortion of grade 4 titanium before fracture was, however, less than that of grade 2 titanium. This makes grade 2 titanium safer in the event of concussion. Under the forces exerted by chewing, the screw is adequately strong. Normally, the bending moments on the implant during chewing remain below 200 N.

In emergency situations the implants bent, whereas the fatigue test did not inflict any changes.

On the basis of the tests it can be stated that in an overload situation the implant and the prosthetic screw will yield at the planned point, and that the grade 2 titanium used as implant and screw material is sufficiently strong and flexible, even in emergency situations.
One of the possible complications of implant treatment is the occurrence of an implant fracture. Biomechanical overload and metal fatigue are the most common causes of fractured implants. (Piattelli et al. 1998) Clinical studies indicate that loosening or fracture of implant prostheses occurs in 5 to 45% of cases during the first year. The nature of the loosening of prosthetic components is complicated, since it involves cycling fatigue, oral fluids and varied chewing patterns and loads. (Sakaguchi & Borgersen 1995). Implant fractures can cause significant problems. Some researchers suggest that these problems could be related to prosthetic and functional stresses associated with progressive bone loss. (Zarb & Schmitt 1990 and Rangert & Forsmalm 1993). The fact remains that chewing and maximum bite forces differ widely between individuals.

Richter (1998) investigated the in vivo horizontal bending moments on implants.

An implant in the molar position that is connected to a mesial tooth by a prosthesis is loaded by vertical and horizontal forces during any oral function. Vertical loads are transmitted directly to the bone around the implant. The most important result of his study was that chewing loads in the transverse direction caused the highest bending moments in the implant and the surrounding bone. These were 4 to 5 times greater than the bending moments in a mesiodistal direction. Horizontal forces are transmitted via a lever arm, creating bending moments.

In his study, a specially designed load cell was placed directly in the implant permitting the measurements of bending moments. The transverse loads during chewing resulted in the highest bending moments of 170 Nmm max. and the highest stress in the bone was 6.2 MPa at the crest on the buccal side. The mesial bending is not critical (52 Nmm mean max. moment).

Richter (1995) also studied in vivo vertical forces on implants during oral functions. Implants in the molar position that were fixed to a premolar with a prosthesis withstood maximum vertical forces of 60 to 120 N during chewing. Single molars and premolars carried maximum vertical forces of 120 to 150 N. The high stress areas are located at the implant’s neck (Siegele 1989). Implant fractures may be a result of implant design and manufacturing, non-passive fit of the framework or biomechanical overload (Balshi et al. 1996).
4.3 AIMS OF THE STUDY

The aim of the study was to determine the effects of overloading on BioSfix single tooth implants and the prosthetic screws (joining the crown and the implant). In exact terms the following was defined:

**Transformations in the implant caused by overloading**

a) under stress (fatigue test)

b) in an emergency situation (fracture resistance test)

**For the prosthetic screw:**

a) the number of chewing cycles required for a fracture

b) the force required for a fracture

c) the fracture point
4.4 MATERIALS AND METHODS

Materials used:

| Cobalt chrome alloy (REMANIUM 2000): |
|------------------|---|---|
| Cobalt (Co)      | 0.61 |
| Chrome (Cr)      | 0.25 |
| Molybdenum (Mo)  | 0.07 |
| Tungsten (W)     | 0.05 |
| Silicon (Si)     | 0.015 |
| Other: Mn, Ce, N |
| Heat coefficient: 14 * 10⁻¹ |
| Melting point: 1415 °C |

| Titanium |
|------------------|---|---|
| Quality: grade 2 | grade 4 |
| Analysis % Fe    | 0.30 | 0.50 |
|                  | 0.25 | 0.40 |
| O                 | 0.03 | 0.05 |
| N                 | 0.10 | 0.10 |
| C                 | 0.015 | 0.015 |
| H                 | 1688 °C |
| Heat coefficient: 8.4 * 10⁻¹ |

Mechanical work:

Grade 2: Oy Galvano Ab Jyrso Espoo
Grade 4: Ki -Technology Oy Oulu
Cold curing acrylic: (PalaXpress®)

Tested items:

Implants

The tests were made on dental implants developed by Osfix International Ltd to be placed in the bone. The dental implant, made of titanium (grade 2), is a cylindrical structure with apical thread and internal rotation check (internal hexagon). The surface of the implant has been mechanically coarsened and the implant is intended mainly for replacing single teeth. Bridge structures for two implants can also be fabricated. The product classification is 2B (MDD Annex 9 implanted items). The main and critical forces against the structure are received by the level or buffer surface of the implant.
Prosthetic screws

The purpose of the screw is to fasten the prosthetic structure to the implant and to stabilise the structure, which consists of various components, in this case of cobalt chrome alloy, to make it as rigid as possible. To control fractures, a safety groove has been made on the screws immediately above the threads.

The crown

For test purposes, a superstructure in the shape of a tooth was made of cobalt chrome by lost wax casting. The waxing was done on a burn-out developed by Osfix Ltd. The same superstructure was used in all tests.

Fatigue test

Equipment

The implants were tested on fatigue equipment in which the mandible denture was made from cobalt chrome. The maxilla was made of acrylic base with one implant. The cobalt chrome structure was fitted on the implant with grade 2 titanium prosthetic screws.

The fatigue test equipment was the Pro-Test (J. H. Engineering Ky), which has been developed for such tests. The equipment enables the regulation of concussion frequency and the pressure between the jaws of the implement. The concussion frequency was regulated based by concussions/second, and changes in pressure were made through atmospheric pressure and a valve. The equipment could also be programmed with the desired number of concussions, which was then completed unless the power was switched off.
Testing

The jaws were set for light chewing and they were burdened as follows: five implants with rounded edges were strained 1,000,000 times/structure. Repetitions were made twice a second by pressing the parts together occlusally at 200 N. The fatigue was continued until a prosthetic screw broke. The test was then paused and, after changing the screw, the test was continued in the same way until the 1,000,000 limit.

When the one million concussion limit was reached, the acrylic was removed from around the implant. For the next implant, retentions were made in the hole thus created. A new implant was fitted in place of the previous one with a silicon index, and new acrylic was poured around the implant. The acrylic was hardened as above.

Analysis

The fracture surfaces appearing in the prosthetic screws were observed with a scanning electron microscope (SEM), Philips XL-20, with an EDS analysator (manufacturer EDAX).

Fracture resistance test

Equipment

The test equipment was Zwick Z250 stress device/meter. A suitable implant holder as well as a presser piece was manufactured for the fracture resistance test. The superstructure of the implant was always the same cobalt chrome structure that was also used in the fatigue test.

Testing

The test was made on the same implants as in the fatigue test, as they remained unbroken. To fasten the cobalt chrome structure, two different types of prosthetic screws were used: grade 2 and grade 4.

The implant holder was tightened to enable the presser piece to strike the structure from above, 10mm from the widest part beginning at the implant socket. The presser piece struck directly on the titanium prosthetic screw that emerged from a hole in the cobalt chrome structure. The test had to be made with the palatinal side of the cobalt chrome structure uppermost, as the facial surface was too round.
Analysis

The results of the test were recorded on the equipment’s computer, from which the desired information could be obtained as figures or graphs. For the test, the equipment was adjusted to gather information on fracture resistance or the greatest force that finally broke the screw. The device also gave the lower yielding limit, or the point at which permanent change in the metal was detected.

4.5 RESULTS

Implants

In the fatigue test no changes were observed in the implants, so the implant itself survived the one million concussions limit.

Prosthetic screws

The electron microscope pictures, taken after the fatigue test, show that the titanium prosthetic screws have slowly given in to fracture. The fracture surfaces on the yielded area have long crystal structures, appearing to be stretched and parallel. Before breaking they have undergone final

![Image of electron microscope picture](image.png)

- **INITIAL POINT OF FRACTURE**
- **FINAL POINT OF FRACTURE**
- **DIRECTION OF ADVANCE OF FRACTURE**
- **AREA FRACTURED BY FATIGUE**

---
fracture which is rough and small structured. The number of cycles (upper table below) needed to break the prosthetic screws was 150,000 -> 850,000, at which point 6 out of 11 tested prosthetic screws had broken (range 150,000 - 300,000, mean 263,333).

The fracture resistance curves were similar in structure for both grade 2 and grade 4 titanium prosthetic screws (figures next page). The fracture resistance for grade 2 alloy was between 239.48-261.94 N and for grade 4 alloy 289.39-302.53 N respectively (lower table below). The results show that grade 4 alloy is ca. 20 % stronger. It was also observed in the graphic curves that grade 4 could better resist bending. Grade 2 alloy screws bent 3.40-3.93 mm before breaking. The bend in grade 4 alloy was 2.44-2.69 mm.

Breaking point: All broken prosthetic screws broke along the safety groove both in the fatigue test and in the fracture resistance test.

<table>
<thead>
<tr>
<th>Results of the fatigue test.</th>
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<tbody>
<tr>
<td>broken screws</td>
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<tr>
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<table>
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<th>Results of the fracture resistance test.</th>
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<tr>
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<td>mean</td>
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</tbody>
</table>
The fracture resistance curves

a) grade 2 titanium

b) grade 4 titanium
4.6 DISCUSSION

The purpose of the study was to determine the effects of overloading on BiOsfix single tooth implants and the prosthetic screws joining the crown and the implant. On the basis of the tests, the durability of BiOsfix implant material during chewing was evaluated, as well as the safety of the implant in a possible concussion situation.

In an overload situation, the screws acted as "fuses", in that they gave way and thus protected the implant from damage. Even in the fatigue test, during which the screws were subjected to a force of 200 N, the screw endured hundreds of thousands of cycles. In an overload situation the screw broke at the correct point or along the safety groove, which facilitates the repair of the implant structure. A comparison of the fracture resistance graphs between grade 2 and grade 4 titanium qualities shows that grade 2 titanium has lower fracture resistance, but bends more before breaking than grade 4. This makes it safer in a concussion situation (violence, accident), as it would be less likely that the superstructure of the implant would be entirely removed when the screw bends.

When we observe the durability of the screw when subjected to chewing loads, we can state the screw is sufficiently strong. In the test the screws and implants were burdened with 200 N for hundreds of thousands of cycles. The bending moments on the implant during chewing usually remain at a maximum of 170 N (Richter 1998). It has to be noted, however, that chewing forces differ widely between individuals. Mericske-Stern et al. (1995) made a comparison between maximum chewing forces of implant patients. The chewing forces on an implant-supported, fixed prosthesis varied between 200-300 N. The force is, however, shared by several implants.

In an emergency situation, the implant showed distortion between the superstructure and the implant. This damage could, nevertheless, in most cases be repaired with burn-out components. On the other hand, the fatigue test created no changes in the implant.

4.7 CONCLUSIONS

On the basis of the tests it can be stated that the prosthetic screw will yield at the planned point in an overload situation, and that the grade 2 titanium used in both implants and prosthetic screws is sufficiently strong and elastic in an emergency situation.
REFERENCES


COATING:

THIN FILMS ON THE SURFACE OF COBALT CHROME

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2 University of Kuopio, Institute of Oral Surgery
3 Tampere University of Technology, Institute of Materials Science,

5.1 ABSTRACT

Three different coatings for cast CoCr-alloy dental implant frameworks were studied. Coatings were approx. 1 mm thick TiN+Ti - and Ti+TiN -double layers and Ti+DLC gradient structure film manufactured with PVD deposition methods. The corrosion resistance of these films was studied with immersion tests, electrochemical polarisation tests and by measuring the amount of dissolved metal ions. The corrosive medium was a physiological saline solution. The structures of the films were studied with a scanning electron microscope (SEM). All the films studied provided good corrosion protection and the amount of dissolved Co-ions was reduced by up to 90% compared to the base material. This reduction may have important clinical significance in cases of allergy to the components of CoCr-alloy and in cases where there is a need to enhance biocompatibility.
5.2 INTRODUCTION

Dental implant frameworks (i.e. mesio- and super-structures) are conventionally made of gold alloys. However, mainly for economic reasons, cobalt chrome alloy is an interesting material for the same purpose. Cobalt chrome alloy is commonly used in prosthodontics and it is a well-known material by both dentists and dental technicians. One of the disadvantages of cobalt chrome alloy is its hardness, which makes the material difficult to handle in a dental laboratory. Possible allergic reactions to cobalt chrome should also be considered, even though they are extremely rare (Moberg 1958, Stenberg 1982, Kotilainen 1991). Nevertheless, all structures must be designed to enable the removal of cobalt chrome alloy components from implant and dental structures. According to the previously mentioned studies, all cobalt chrome alloy components may also dissolve in oral conditions. Galvanic corrosion has been claimed to cause loss of bone around the implant (Adell et al. 1981, Gels-Gerstorfer et al. 1989). The clinical follow-up made on implant prostheses does not, however, support this claim (Hulterström et al. 1994, Luotio 1997) but the loss of bone is at the same level as with gold-based structures (Alberktsson et al. 1986, Knotek et al. 1992). To produce a coating on cast CoCr-alloy seems to be a more practical and economical method to achieve more corrosion resistant implant frameworks than producing e.g. a titanium prosthesis. The casting of titanium requires considerably more complex technology including a protective gas atmosphere.

5.1.2 The aims of this study were:

1) to describe the surface of CoCr-alloy after it was coated with common biocompatible materials.
2) to investigate if it is possible to decrease the solubility of cobalt chrome components with thin film technology.
3) to determine an adequate method for coating dental implant frameworks.
5.3 MATERIALS AND METHODS

5.2.1 Film deposition

Three different thin films were studied. Ti-DLC (Diamond-Like Carbon) film with a gradient structure from pure Ti to pure DLC was made by DIARC-Technology Oy, Helsinki, Finland, with a pulsed carbon plasma arc PVD method. Two double layer films, TiN-Ti and Ti-TiN, were made by Surfcoat Oy, Mikkeli, Finland, by unbalanced magnetron sputtering. The studied thin films and deposition methods are given in table below. In both techniques, deposition was made in a vacuum at room temperature. The base material was cast CoCrMo alloy (Wironit extra hard, Bego, Germany), with a nominal composition of Co 63; Cr 30; Mo 5; Si 1.1; Mn 0.5; C 0.4. The test plates were custom made and hand polished using methods standard in dental laboratories. The size of the test plates was \( A = 4 \text{ cm}^2 \) and thickness 0.5 mm. The films are denoted below according to the top layer of the films as marked in table below.

<table>
<thead>
<tr>
<th>Film</th>
<th>Fyther</th>
<th>Structure</th>
<th>Deposition technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ti/DLC</td>
<td>DLC</td>
<td>Gradient from Ti to DLC</td>
<td>Pulsating carbon plasma arc</td>
</tr>
<tr>
<td>Ti/TiN</td>
<td>TiN</td>
<td>double layer:</td>
<td>Unbalanced magnetron sputtering</td>
</tr>
<tr>
<td>TiN/Ti</td>
<td>Ti</td>
<td>double layer: Ti and outer layer TiN</td>
<td>Unbalanced magnetron sputtering</td>
</tr>
</tbody>
</table>

5.3.2 Characterisation

The microstructural studies of the films were carried out with a Philips XL30 scanning electron microscope (SEM). The coating thickness was determined from the SEM micrographs.

5.3.3 Corrosion tests

The corrosion tests were all made using 0.9 % physiological saline solution (Medipolar®) as a corrosion medium. The pH-value was set to 4.7 with HCl. The duration of the immersion test was 2 months and the weight loss was measured to an accuracy of 0.1 mg. The electrochemical polarisation measurements were carried out with EG & G® Parc computer controlled potentiostat/galvanostat, model 273A. The reference electrode was Ag/AgCl and the counter electrode platinum. A potentiodynamic measuring technique was used and the potential was changed at a speed of 0.5 mV/min. Dissolution tests were performed by polarising the samples electrochemically near corrosion potential. The immersion time before the first measurement was 24 hours, after which the electrolyte was changed for a new one. After that, the immersion time was 48 hours; so the total testing time was 72 hours. The amount of ions dissolved were determined from the solution by ICP analysis.
5.3 RESULTS AND DISCUSSION

5.3.1 Thickness and structure of the films

DLC-film:

The film composition changes gradually from pure titanium to diamond-like carbon structure. When the film thickness during deposition reaches the value of 400-500 nm, the morphology of the film changes, this can be seen in the SEM-micrograph. The total thickness of the film is app. 1 mm. Some porosity can be seen on the surface of the film as well as some macro particles. These are formed in the upper half of the film, when the amount of the DLC is more than 50 % and they are macro-droplets from the process. The pores are mainly situated near the agglomerates and so they are also present only within the upper half of the film. The average pore size is approx. 200 nm.
**TiN-film:**

In the sputtered Ti/TiN film, the inner layer of Ti works as an adhesion-enhancer for the subsequently deposited layer of TiN-film. The thickness of the Ti layer is approx. 150 nm. The thickness of the outer TiN layer was 1 mm. The cross-section of the film is very smooth and dense, but some porosity can be seen on the surface. The pores are mainly located on the scratches left from the grinding of the base material.

![TiN-film image](image)

**Ti-film:**

The thickness of the inner TiN layer is app. 1 µm. The outer layer of Ti is 200-300 nm thick. The hard TiN beneath gives support and load-carrying properties to the thin Ti top layer and makes the film more resistant to wear and mechanical damage. The TiN is formed into a slightly columnar structure, but the Ti-layer seems to be very dense. Adhesion between TiN and Ti layers is good. Some porosity is seen on the surface, but less than on the surface of Ti/TiN-film.

![Ti-film image](image)
5.3.2 Corrosion tests

5.3.2.1 Immersion tests

After two months immersion in the 0.9 % physiological saline solution, only very small weight changes were measured. For comparison, uncoated plate was also tested. The back of the test plates was covered with Araldite® glue during the test. After immersion, the plates were dried at 80°C for 30 minutes. No actual weight loss was detected, only a very slight weight increase due to the products of corrosion. The results are given in table below.

Following the test, the samples were studied with the SEM to discover whether corrosion products or other damage were present. No differences were detected in the coated materials when compared to the as-deposited films. Instead, two different phase areas could be seen in the pure base material, CoCr-alloy after the test. This is evidently due to the etching effect of the saline solution. Corrosion phenomena were observable on the uncoated plate after 1,440 hours in physiological saline solution at room temperature but not on the coated plates. Similar results were obtained by Knotek et al. (1992) for CoCr material after only 100 hours of immersion test at 60°C in the same liquid.

<table>
<thead>
<tr>
<th>Material</th>
<th>weight change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>base material CoCr-alloy</td>
<td>0.2</td>
</tr>
<tr>
<td>TiN -film</td>
<td>0.1</td>
</tr>
<tr>
<td>Ti-film</td>
<td>0.0</td>
</tr>
<tr>
<td>DLC-film</td>
<td>0.1</td>
</tr>
</tbody>
</table>

5.3.2.2 Electrochemical polarisation tests

In the electrochemical potentiodynamic polarisation tests the potential was scanned from -600 mV to 1200 mV. The corrosion current density was quite similar in all tested materials, being from 0.01 mA/cm² (Ti-film) to 0.02 mA/cm² (TiN - and DLC-films and base material). All tested films had some open porosity, which affected both the corrosion current density and the corrosion potential. The corrosion potential was -380 mV vs. Ag/AgCl for CoCr-plate and around -200 mV for the coated plates. No clear passivation effect was detected in this saline solution. The Ti-film passivated around the potential of 200 mV vs. Ag/AgCl, but the passive area was quite narrow, only from 200 to 400 mV vs. Ag/AgCl. Based on these results, the chloride content in physiological saline solution is high enough clearly to disturb the formation of the protective passive layer on CoCr-alloy.
5.4.2.3 Measurements of dissolved ions

In order to have more information on the protective behaviour of the coatings, the dissolved metal ions in the corrosive media were measured. Diluted into the liquid, the cobalt was found to dissolve at much higher rate (nearly 3 times faster) than the chromium from the base material. No other ions from the cast alloy were detected. Some traces of dissolved Ti ions were detected from the TiN film, indicating some extent of dissolution in the film. From the studied materials, the Ti-film seemed to be the densest and the most corrosion resistant, since the smallest amounts of Co and Cr were detected in the solution. When Ti-film was used, the amount of dissolved Co was reduced to 9 % of that detected for uncoated CoCr-alloy. With DLC-film the amount of Co was reduced to 30 % and with TiN-film to 60 % of the uncoated alloy. The results are shown in table below. These results reveal that the sputtered Ti-film gives a higher protection than the TiN-film prepared by the same coating process.

<table>
<thead>
<tr>
<th>Metal Ions, ppm after 24 hours</th>
<th>CoCr</th>
<th>Ti-film</th>
<th>DLC-film</th>
<th>TiN-film</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cr: 5.14 Co: 8.7</td>
<td>Cr: 0.24 Co: 1.31</td>
<td>Cr: 0.74 Co: 2.2</td>
<td>Cr: 1.61 Co: 4.41</td>
<td></td>
</tr>
<tr>
<td>Metal Ions, ppm after 72 hours</td>
<td>Cr: 5.37 Co: 14.68</td>
<td>Cr: 1.12 Co: 2.5</td>
<td>Cr: 2.65 Co: 4.49</td>
<td>Cr: 4.6 Co: 8.49</td>
</tr>
</tbody>
</table>

5.4.3 Medical point of view

All the examined materials have been accepted as highly biocompatible in medical literature. Titanium has been used as implant material for over 30 years and TiN coating is in common use and produced for dental applications by one Danish company (Gradjean 1995) at least. From a clinical point of view, the surface hardness of the exposed metallic framework is important because calculus removal is a procedure which is highly abrasive and potentially damaging. Thus the DLC is the most interesting material. Moreover, it is in common use in heart valve prostheses (Elizondo et al. 1996, Monties et al. 1997) and under consideration for hip prosthesis (Nordsletten et al. 1996). The biocompatibility of DLC is well documented Kornu et al. (1996) using both cell culture and animal tests.

In dental use, if not implanted, the only theoretical channel for systemic effects is the digestive canal. The question is academic, not practical, because large amounts of diamond are swallowed for decades after every dental operation as a result of the wearing of diamond drills. Moreover, diamond is carbon which has been used as a medicine for centuries.

When coatings are used in dental prostheses, we have to accept that these frameworks are not serial products, but custom made. Thus the structures always contain areas which are not perfectly polished and the behaviour of the coating material in such surfaces needs further study.
5.4.4 Conclusions

All the studied films were slightly porous due to the coating processes. Surface scratches were found to be the preferred sites for pore formation. The structure of the sputtered Ti-layer seemed to be the densest of these studied films whereas TiN tended to form a slightly columnar structure. The DLC film contained some small agglomerates within the upper half of the film.

All the coatings were able to reduce the amount of dissolved ions from the base material. The reduction of dissolved Co-ions was from 40 to 90 %. The lowest reduction was observed in TiN coating which is in common use for decreasing the corrosion of surgical drills. This study showed that the use of TiN may no longer be the best material for the purpose, because we now have better alternatives.

The other facts affecting the choice between these films are hardness, coverage of the coating if complex shape frameworks are coated, availability of the coating and cost. Both Ti and DLC are promising coatings to prevent CoCr ion release and the hardness of the surface of DLC makes it most interesting. The problem of DLC is that the gradient process with titanium is not in common use and the commonly used process with tungsten does not produce stable coatings for biocompatible use.

5.4.5 Acknowledgements

We would like to thank Professor Jouni Tummavuori from the University of Jyväskylä, Finland, for valuable help in the chemical analyses. In addition we are very grateful for the dedicated handwork of Ms. Satu Luukkainen, dental technician, in producing and polishing the plates.
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