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(54) Title: IMPLANT ABUTMENT

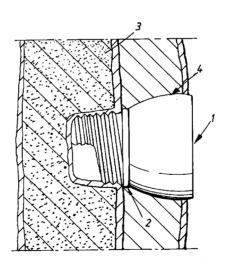


Fig. 1

(57) Abstract: The present invention relates to a percutaneous implant abutment for bone anchored implant devices adapted to be anchored in the craniofacial region of a person, such as bone anchored hearing aids. The abutment comprises a skin penetration body having a skin contacting surface. The skin contacting surface has been modified in such a way that the shear modulus of the skin contacting part of the percutaneous Iy implant abutment is reduced to less than 35 GPa. Preferably the surface of the skin contacting part of the percutaneous Iy implant abutment is coated with a bio- compatible polymer or a ceramic material with a thickness of $0.001-50 \mu m$. As an alternative, or in combination, an enlargement treatment can be provided to the surface re¬ sulting in a 10 % surface increase and a roughness value Sa of $0.5-10 \mu m$. By such surface modifications specific adverse skin reactions are reduced.



Implant abutment

The present invention relates to a percutaneous implant abutment for bone anchored implant devices adapted to be anchored in the craniofacial region of a person, such as bone anchored hearing aids. Implant devices of this type normally comprise a screw-shaped bone anchoring element (fixture) for permanent anchorage in the bone tissue and an abutment sleeve for skin penetration. The complete structure can either be in one piece or the skin penetrating abutment could be connected to the fixture prior, during or after the implantation procedure by means of a screw connection or the like.

The invention can for instance be used in connection with hearing aid devices of the bone conduction type, e g bone anchored hearing implants such as Baha®, marketed by Cochlear Bone Anchored Solutions AB in Göteborg, Sweden. The Baha® implant comprises an external unit which transforms sound to mechanical vibrations which are conducted via the abutment and the fixture into the bone of the skull. The vibrations are transmitted mechanically via the skull bone directly to the inner ear of a person with impaired hearing and allows for the hearing organ to register the sound. A hearing aid device of the BAHA® type is connected to an anchoring element in the form of an implanted titanium screw installed in the bone behind the external ear and the sound is transmitted via the skull bone to the cochlea (inner ear), i e the hearing aid works irrespective of a disease in the middle ear or not. The bone anchoring principle means that the skin is penetrated which makes the vibratory transmission very efficient.

This type of hearing aid device has been a revolution for the rehabilitation of patients with certain types of impaired hearing, but also as anti-stuttering means. It is very convenient for the patient and almost invisible with normal hair styles. It can easily be connected to the im-

planted titanium fixture by means of a bayonet coupling or a snap in coupling. One example of this type of hearing aid device is described in US Patent 4,498,461 and in SE 9702164-6 it is described a one-piece implant of this type, in which the fixture is integrated with a first coupling device. In WO 2005/037153 it is described how this type of hearing aid device can be used as an anti-stuttering device.

A well known problem with percutaneous implants is the infections and inflammation at the skin-implant interface. The infections are a result of bacterial colonization occurring at the area around the interface. There is generally a lack of integration of the skin to the implant which results in a gap between the two. This gap is unfortunately an ideal environment for the bacteria and if this zone is not properly managed, it is likely that an infection will occur. By creating an integration of the skin to the implant the adverse skin reactions associated with bone anchored percutaneous implants are expected to be reduced.

Creating integration between the skin and the implant requires that the implant is suitable for this purpose and that the soft tissue does not dissociate itself from the skin penetrating implant abutment by encapsulating the abutment in fibrous tissue.

In the field of dental implants it is previously known to use different types of abutments which penetrate the oral mucosa. However, it should be understood that there is a physiological difference between breaching the skin barrier compared to the oral mucosa. In the oral cavity the skin is not involved and there is another type of force situation. In contrast to dental implants the present invention relates to extraoral implants.

One object of the present invention is to provide an im-

plant abutment of the skin penetrating type in which specific adverse skin reactions are reduced.

It is recognized that bone anchored percutaneously implants are subjected to mostly shear forces, while percutaneously implants which are not bone anchored are subjected to several other types of forces, such as pull and torsion. Such different types of forces are also mostly involved in dental applications. Mostly shear forces are especially the case for implants with inherent movements such as bone anchored hearing implants due to the generation of vibratory movements.

It is also recognized that the effect that the shear forces has on the skin leads to tissue damage not only from a mechanical point of view but, more importantly, an indirect biological reaction which leads to foreign body reaction or dissociation from the material (encapsulation of the implant by fibrous tissue, etc). Some rections are acute and some are noticed after several weeks.

A further object of the invention is therefore to provide an implant abutment in which the shear forces between the implant abutment and the skin have been reduced. This would have a great impact on the wound healing and integration around bone anchored percutaneously implants.

According to the invention the shear modulus of the skin contacting part of the percutaneously implant abutment is reduced. Preferably the shear modulus should be less than 35 GPa.

Specifically, the shear modulus is reduced by a modification of the surface of the skin contacting part of the percutaneously implant abutment.

According to a preferred embodiment the surface of the skin contacting part of the percutaneously implant abut-

ment is coated with a biocompatible polymer with a thickness of $0.001-50~\mu m$.

According to a another preferred embodiment the surface of the skin contacting part of the percutaneously implant abutment is coated with a ceramic material with a thickness of $0.001-50~\mu m$.

According to even another preferred embodiment a surface enlargement treatment has been provided to the surface of the skin contacting part of the percutaneously implant abutment. Preferably a 10 % surface increase, compared to a conventional machined surface, is created resulting in a roughness value Sa of 0.5-10 μ m.

It should be understood that there are percutaneously implants as such that are made of polymers (catheters etc) but they are not bone anchored and they are not exposed to the typical shear forces that are the case for implants with inherent movements such as bone anchored hearing implants due to the generation of vibratory movements.

In the following the invention will be described more in detail with reference to the accompanying drawings, in which

figure 1 illustrates an implant according to the invention anchored in the bone in the craniofacial region of a person,

figure 2 illustrates an implant according to the invention for bone anchorage,

figure 3 is a LM picture of the interface between the skin and the contacting part of the implant abutment, and

figure 4 is a SEM picture of the surface structure of the skin contacting part of the implant abutment.

Figure 1 illustrates a percutaneous implant 1 anchored in the bone in the craniofacial region of a person. The implant is specifically intended to be used for a bone anchored hearing aid or the like. The implant comprises a screw-shaped bone anchoring element (fixture) 2 for permanent anchorage in the bone tissue 3 and an abutment device 4 for skin 5 penetration. The complete structure can either be in one piece or the skin penetrating abutment 4 could be connected to the fixture prior, during or after the implantation procedure by means of a screw connection or the like. The screw-shaped anchoring element, the socalled fixture 2 is made of titanium which has a known ability to integrate with the surrounding bone tissue, socalled osseointegration. The fixture has a threaded part 2a which is intended to be installed into the skull bone and a flange 2b which functions as a stop when the fixture is installed into the skull bone. The apical part of the fixture has a known tapping ability with in this case three self-tapping edges 2c. A fixture of this type is described in the above-mentioned SE 0002627-8 and will therefore not be described in any detail here.

The skin penetrating part, the abutment 4 of the implant, comprises a substantially conical abutment sleeve. Conical abutment sleeves are previously known per se as separate components or as an integral part with the fixture, a one-piece implant. The abutment sleeve is provided with a first coupling part in order to cooperate with a second coupling part (not shown) by means of snap-in action or the like.

According to the invention the shear modulus of the skin contacting part of the percutaneously implant abutment 4 has been reduced. Preferably the shear modulus should be less than 35 GPa.

Specifically, the shear modulus is reduced by a modifica-

tion of the surface of the skin contacting part of the percutaneously implant abutment, illustrated by the structured abutment surface in figure 2. According to a preferred embodiment the surface of the skin contacting part of the percutaneously implant abutment is coated with a biocompatible polymer or a ceramic material with a thickness of $0.001\text{--}50~\mu\text{m}$. The coating is applied in such a way that non-interconnected pores or crevices are created. Generally the coating should be applied in such a way that a structured surface such as a porous surface or a surface with indentations or a fibrous surface is obtained. A typical porous surface is illustrated by the SEM picture in figure 4.

The polymer coating is comparatively soft and decreases the shear stresses on the skin. Preferably a layer of a porous polymer is used for the coating with a thickness of about 30 nm. Such design is allowing the skin to heal into the polymer matrix.

Also a polymer containing a pharmaceutical drug that increases the production of extra-cellular matrix proteins in the soft tissue, such as collagen or keratin, might be used. The increased stability of the tissue increases the resistance to shear stress.

Also other types of materials might be used for increasing the skin tissue integration. Specifically, chemical substances such as pharmaceutical drugs and antioxidants, or biochemical substances such as proteins, biopolymers, growth factors, DNA, RNA or biominerals might be used. These substances are then associated to the implant with a purpose of increasing the amount of, or number of connections to extra cellular matrix proteins. Antibiotic, steroid or anti-inflammatory substances might also be used.

As an alternative to said coatings or substances, or in combination, a surface enlargement treatment can be provi-

ded to the surface of the skin contacting part of the percutaneously implant in order to increase the surface roughness. Such treatment can be achieved by using techniques that includes grit-blasting, polishing, micro-machining, laser treatment, turning, anodic oxidation, oxidation, chemical etching, sintering or plasma deposition of a titanium surface. Preferably such treatment should result in a 10 % surface increase, compared to a conventional machined surface and a roughness value Sa of 0.5-10 μ m, measured by means of White Light Interferometry.

Figure 3 is a LM picture of the interface between the skin 5 and the contacting part of the implant abutment 4 of a polyurethane coated titanium material. The figure illustrates the situation after a healing period of 8 days and indicates a substantial integration of the abutment into the skin 5.

Figure 4 is a SEM picture of the surface structure of the skin contacting part of the implant abutment having an anodically oxidized surface.

It should be understood that only that part of the abutment surface which is in contact with the skin need to be modified. Other parts of the abutment such as the lower and upper end surfaces, i.e. the surfaces connected to the fixture and the coupling device respectively, might have a conventional, machined and/or polished surface.

Preferably the implant design includes a flange or a skirt perpendicular to the abutment orientation in order to mechanically increase the surface area and stability and thereby also reduce the shear stress on the implant-skin interface. Also the implant design might include one or more retention grooves or waists. Otherwise, however, the abutment should be designed without any sharp edges or corners in order to simplify the surface modification procedure.

The invention is not limited to the examples illustrated so far but can be varied within the scope of the following claims and for different extraoral applications. Specifically it should be understood that any combinations of the said surface modifications could be used, e.g. using composites, structured ceramic coatings, polymer/pharmaceutical drug coatings, anodized flange etc.

CLAIMS

1. Percutaneous implant abutment for bone anchored implant devices adapted to be anchored in the craniofacial region of a person, such as bone anchored hearing aids, comprising a skin penetration body having a skin contacting surface c h a r a c t e r i z e d i n that the skin contacting surface has been modified in such a way that the shear modulus of the skin contacting part of the percutaneously implant abutment is reduced to less than 35 GPa and/or a 10 % surface increase, compared to a conventional machined surface, has been achieved.

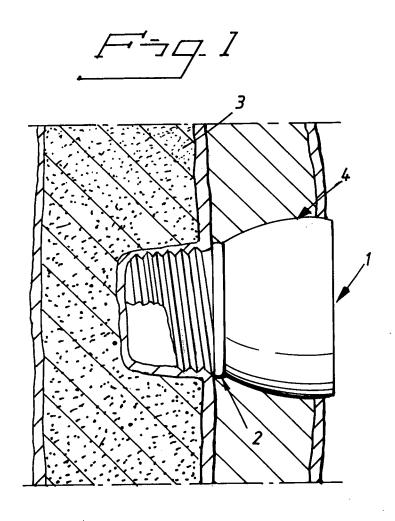
- 2. Abutment according to claim 1 c h a r a c t e r i z e d in that the shear modulus is reduced by modifying the surface of the skin contacting part of the percutaneously implant abutment by means of a coating.
- 3. Abutment according to claim 2 c h a r a c t e r i z e d in that the surface of the skin contacting part of the percutaneously implant abutment is coated with a biocompatible polymer with a thickness of $0.001-50~\mu m$.
- 4. Abutment according to claim 2 c h a r a c t e r i z e d in that the surface of the skin contacting part of the percutaneously implant abutment is coated with a ceramic material with a thickness of $0.001-50~\mu m$.
- 5. Abutment according to claim 2 c h a r a c t e r i z e d in that an enlargement treatment has been provided to the surface of the skin contacting part of the percutaneously implant abutment resulting in a roughness value Sa of 0.5- μ m.
- 6. Abutment according to claim 5 c h a r a c t e r i z e d in that the enlargement treatment is achieved by using techniques that includes grit-blasting, polishing, micromachining, laser treatment, turning, anodic oxidation, ox-

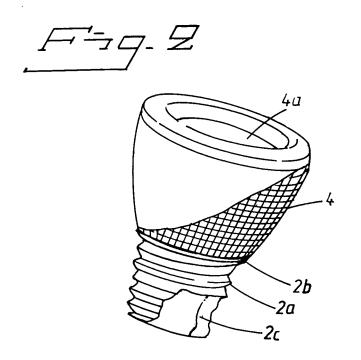
idation, chemical etching, sintering or plasma deposition.

- 7. Abutment according to claim 3 or 4 c h a r a c t e r i z e d in that the coating is applied in such a way that a structured surface, such as a porous surface or a surface with indentations or a fibrous surface is obtained.
- 8. Abutment according to claim 3 or 4 c h a r a c t e r i z e d in that the coating is applied in such a way that non-interconnected pores or crevices are created.
- 9. Abutment according to claim 3 c h a r a c t e r i z e d in that the polymer coating is comparatively soft and porous and has a thickness of about 30 nm.
- 10. Abutment according to claim 3 c h a r a c t e r i z e d in that the polymer coating is containing a pharmaceutical drug that increases the production of extra-cellular matrix proteins in the soft tissue, such as collagen or keratin.
- 11. Abutment according to claim 3 or 4 c h a r a c t e r i z e d in that the coating comprises chemical substances such as pharmaceutical drugs and antioxidants, or biochemical substances such as proteins, biopolymers, growth factors, DNA, RNA or biominerals in order to increase the amount of, or number of connections to extra cellular matrix proteins.
- 12. Abutment according to claim 3 or 4 c h a r a c t e r i z e d in that the coating comprises antibiotic, steroid or anti-inflammatory substances.
- 13. Abutment according to claim 2 c h a r a c t e r i z e d in that only that part of the abutment surface which is in contact with the skin is modified while other parts of the abutment such as the lower and upper end surfaces, i.e. the surfaces connected to the fixture and the coupling de-

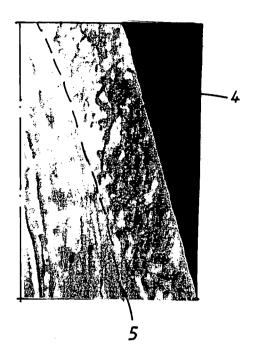
vice respectively, have a conventional, machined and/or polished surface.

- 14. Abutment according to claim 2 c h a r a c t e r i z e d in that the outer design includes a flange or a skirt perpendicular to the abutment orientation in order to mechanically increase the surface area and stability and thereby also reduce the shear stress on the implant-skin interface.
- 15. Abutment according to claim 2 c h a r a c t e r i z e d in that the outer design includes one or more retention grooves or waists.
- 16. Abutment according to claim 2 c h a r a c t e r i z e d in that it has a sleeve-shaped body having a rounded outer surface without any sharp edges or corners in order to simplify the surface modification procedure.

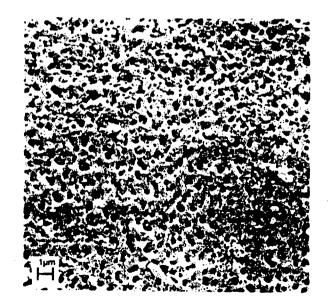








7-79-4



International application No.

PCT/SE2008/000337

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61F, A61L, H04R

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE, DK, FI, NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
X	US 4645504 A (BYERS), 24 February 1987 (24.02.1987), column 2, line 25 - line 66; column 3, line 60 - column 4, line 24, figure 2, abstract	1	
A	,	2-16	
			
X	CA 1068052 A, MACGREGOR D C, 1979-12-18; (abstract) Retrieved from: WPI database, WEEK 198002, AN 1980-01734C	1	
A		2-16	
A	US 4052754 A (HOMSY), 11 October 1977 (11.10.1977), abstract, figures	1-16	
			

Į	Χ	Further documents are listed in the continuation of Box C.	X	See patent family anno	ex
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- Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

1 6 -07- 2008

"&" document member of the same patent family

Date of the actual completion of the international search Date of mailing of the international search report

Name and mailing address of the ISA/

Swedish Patent Office Box 5055, S-102 42 STOCKHOLM

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15 July 2008

Authorized officer

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Form PCT/ISA/210 (second sheet) (July 2008)

International application No.
PCT/SE2008/000337

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C (Continu	ation). DOCUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Α .	US 20060093175 A1 (WESTERKULL), 4 May 2006 (04.05.2006), abstract, figures	1-16
A	EP 0367354 A1 (STICHTING BIOMATERIALSSCIENCE CENTER), 9 May 1990 (09.05.1990), abstract, figures	1-16
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A	WO 2004091432 A2 (MEDICAL RESEARCH PRODUCTS-B, INC.), 28 October 2004 (28.10.2004), abstract, figures	1-16
A	US 20040204686 A1 (PORTER ET AL), 14 October 2004 (14.10.2004), abstract, figures	1-16
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International application No. PCT/SE2008/000337

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Claims Nos.: 1 in part because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Present claim 1 relates to a product defined by reference to the following parameter:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
This international Scalening Additionly found indiciple inventions in this international application, as follows.
1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest
the payment of a protest fee. The additional search fees were accompanied by the applicant's protest but the applicable
protest fee was not paid within the time limit specified in the invitation. No protest accompanied the payment of additional search fees.
130 protest accompanied the payment of additional scalen rees.

International application No. PCT/SE2008/000337

Box II.2

P1: surface increase.

The use of this parameter in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT. It is impossible to compare the parameter the applicant has chosen to employ with what is set out in the prior art. The lack of clarity is such as to render a meaningful complete search impossible. Consequently, the search has been restricted to the following:

The surface of the skin contacting part has a shear modulus below 35 GPa and/or a rough structure, thus allowing integration between the percutaneous abutment and the skin.

Thence it follows that a reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability only is established for those parts mentioned above.

International application No. PCT/SE2008/000337

International patent classification (IPC)

A61F 11/04 (2006.01) **H04R 25/00** (2006.01) **A61L** 27/56 (2006.01)

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Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number 08-782 28 85).

Cited literature, if any, will be enclosed in paper form.

Information on patent family members

26/01/2008

International application No.

PCT/SE2008/000337

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