

PROSTHETIC IMPLANTS

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2
3 This invention relates to an improved method of making
4 prosthetic implants, methods of treatment incorporating
5 the use of such implants, and to the prosthetic
6 implants themselves.

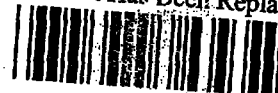
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8 The invention is of particular usefulness in relation
9 to maxillofacial surgery and will be particularly
10 described with reference to that field, but may also be
11 utilised in the treatment of disease or damage in other
12 parts of the body.

13
14 Maxillofacial surgery may be necessary to deal with
15 congenital defect, accidental damage, or malignant
16 tumours. Such surgery presents particular difficulties
17 since the aim is to achieve a result which is not only
18 functional in dealing with the particular problem
19 addressed, but also ensures that a patient is left with
20 a good level of ability to breath, eat and speak, while
21 at the same time achieving a satisfactory aesthetic
22 appearance.

23
24 Techniques are known in which diseased or damaged bone
25 is excised and replaced. The replacement may be by way
26 of grafting bone taken from other parts of the
27 patient's body. More recently replacement bone has
28 been achieved by attaching a titanium armature to sound
29 bone to act as a support for grafted bone cells derived
30 from bone in other parts of the patient's body. In
31 either case, it is then necessary to attempt to reform

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1 the adjacent soft tissue over the resulting implant.

2

3 Another known technique is the use of microvascular
4 free transfer osseofasciocutaneous flaps, in which a
5 flap of bone and skin, for example from the forearm and
6 optionally with attached muscle, is transferred to the
7 mouth, with the blood vessels of the flap being
8 connected to those of the head by microscopic surgery.

9 A functional result may be achieved, but is non-
10 anatomical.

11

12 Such techniques are extremely time consuming and
13 difficult. A typical maxillofacial repair may require
14 a surgical procedure lasting up to about 15 hours, and
15 the procedure will involve opening a second surgical
16 site (typically in the region of the iliac crest) to
17 obtain bone or bone cells for grafting.

18

19 An object of the present invention is to enable
20 reconstructive surgery of this nature to be carried out
21 much more rapidly, thus markedly reducing the stress on
22 the patient caused by the surgery, while reducing the
23 load on the surgical team and also markedly reducing
24 the costs of the surgery.

25

26 In accordance with one aspect of the present invention,
27 a method of making a prosthetic implant comprises the
28 steps of obtaining a set of data defining the body
29 parts of interest in three dimensions, using said set
30 of data to create a three dimensional model of at least
31 part of the body parts of interest, and using the three
32 dimensional model to develop and fit to size a
33 prosthetic implant which entirely replaces body parts
34 which are missing or are to be excised from the
35 patient.

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1 The invention also provides a prosthesis made by the
2 foregoing method.

3
4 From another aspect, the invention provides a method of
5 treating damaged, diseased or missing body parts which
6 comprises excising damaged and/or diseased body parts
7 and selected adjacent parts, and replacing excised
8 and/or missing parts entirely by a prosthetic implant
9 secured to the sound adjacent bone structures. In the
10 preferred form of the method, both bone and soft tissue
11 are replaced by a single prosthetic implant made of a
12 material onto the surface of which soft tissue is
13 capable of growing in a manner to prevent the incursion
14 of infection; such a material will typically be
15 titanium.

16
17 The foregoing method is preferably carried out by
18 obtaining a set of data defining the body parts of
19 interest in three dimensions, using said set of data to
20 create a three dimensional model of at least part of
21 the body parts of interest, and using the model to
22 develop and fit to size the prosthetic implant prior to
23 surgery.

24
25 In preferred forms of the invention the prosthesis
26 extends through a body surface such as skin or mucous
27 membrane, for example in the palate or nasal cavity.

28
29 The prosthetic implant may be provided with mechanical
30 attachment means for the releasable attachment of
31 further prosthetic devices such as dentures.

32
33 The set of data defining the body parts of interest is
34 preferably reduced by CAT scanning. The data resulting
35 from the CAT scanning may be manipulated by computer,
36 for example to derive from a CAT head scan a set of

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1 data defining three dimensionally only the bony
2 structures of the skull.

3

4 The three dimensional model may conveniently be
5 produced by stereolithography in a manner known per se
6 by laser irradiation of a photoreactive polymer.

7

8 A further aspect of the invention provides a connector
9 block comprising a body and a post extending from the
10 body, the post being shaped for selective attachment to
11 dental prostheses, and the body being formed with
12 passages for rivets for attachment to a surgical plate.

13

14 Preferably, the body is rectangular, and the connector
15 block is formed integrally from titanium.

16

17 Embodiments of the invention will now be described, by
18 way of example only, with reference to the drawings, in
19 which:

20 Fig 1 is a flow chart illustrating the method of
21 the present invention;

22 Figs 2a and 2b are schematic views in side and
23 front views respectively of a skull having an area of
24 damage in the lower jaw;

25 Figs 3a and 3b are similar view of the skull with
26 the damaged area excised;

27 Figs 4a and 4b are similar views of the same skull
28 with a prosthesis implanted;

29 Figs 5a and 5b are schematic cross-sections
30 illustrating a healthy jaw and a jaw with an implant;

31 Fig 6 is a schematic side view of an alternative
32 mounting arrangement; and

33 Fig 7a, 7b and 7c are respectively side, end
34 and plan views of a connector block embodying a further
35 aspect of the invention.

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1 Referring to Fig 1, the process of the present
2 invention is based upon the use of a CAT scan to derive
3 a set of data defining in three dimensions the body
4 part of interest, for example the skull. Accordingly,
5 a conventional CAT scan provides data to a data
6 processing step in which the data defining the bony
7 structures are retained and the soft structure data
8 discarded.

9
10 The processed data is then used to produce a replica of
11 the patient's skull by stereolithography. There are
12 techniques well known per se for the production of
13 three dimensional models from digital data by
14 stereolithography by laser irradiation of a bath of
15 photoreactive polymer. In this way, a model of the
16 patient's skull in its existing form is obtained.

17
18 The data from the CAT scan can also be processed to
19 provide a further set of data defining in three
20 dimensions a desired replacement part. This further
21 data is then used to produce a replacement part by CNC
22 machining from solid titanium.

23
24 At this stage, the surgical team have a true scale
25 model of the existing skull plus a machined replacement
26 for part of the skull. These can be used in the
27 workshop (that is, in non-surgical, non-sterile
28 conditions) to refine the surgical operation to be
29 performed. In particular, the surgeon can plan the
30 best positions to cut to obtain sound bone on which to
31 mount the implant. The cutting and mounting can be
32 performed experimentally on the model skull, and the
33 shape of the machined implant can be refined in this
34 process.

35
36 Optionally, as indicated in Fig. 1, during the workshop

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1 stage cutting jigs may be produced which are located
2 with respect to well-defined points on the skull and
3 provide a guide to enable the surgeon to cut the bone
4 accurately in the planned planes.

5
6 Once the surgical plan and prosthetic implant have been
7 refined in the workshop, the prosthesis is implanted
8 surgically in the conventional manner. Typically, the
9 prosthesis will be secured to sound bone by means of
10 bone screws or expansion-type fixings.

11
12 An important feature of the present invention is that
13 the prosthesis is of a material, typically titanium,
14 which is compatible with passing through the surface of
15 soft tissue without permitting the ingress of infection
16 along the exposed surface of the implant. This allows
17 the prosthesis to be a complete replacement for excised
18 parts.

19
20 For example, in the case where part of the upper or
21 lower jaw or the palate must be removed, the parts
22 removed are replaced only by the implant, without
23 attempting to separate and then reposition the soft
24 tissue of the gum or palate. This is not only much
25 less time consuming in surgery, but also makes the
26 surgical site functional much more quickly post-
27 operatively.

28
29 Figs. 2 to 4 illustrate such a procedure schematically
30 with reference to a damaged lower mandible.

31
32 As seen in Fig. 2 a lower jaw 10 has an area of damage
33 12 involving both the jaw and the teeth. Fig. 3
34 illustrates the damaged area cut back to sound bone at
35 14 and 16. In Fig 4, a solid implant 18 of titanium
36 has been attached to the sound bone areas 14, 16 by

1 bone screws 20. The implant 18 is provided with posts
2 22 to which a denture may be directly mounted. It will
3 be understood that the implant 18 extends into the
4 interior of the patient's mouth, within which it will
5 be visible, and the margin of the healthy, non-excised
6 gum will grow onto the surface of the implant.

7
8 The stages of Figs. 2 to 4 will be carried through
9 first in the workshop on the model skull, and only
10 thereafter on the patient surgically.

11
12 For simplicity of description, Fig 4 shows the implant
13 18 being attached by simple bone screws 20. In view of
14 the loads typically placed on the mandible, it is
15 preferable to obtain a more secure mechanical
16 engagement. One such arrangement is illustrated in Fig
17 5. The implant 18 is secured (for example, rivetted or
18 welded) to a plate 24 which in turn is attached to the
19 sound bone areas 14, 16, to lie along the underside of
20 the mandible. The example shown makes use of a "Thorp"
21 plate which has regularly spaced apertures 26. The
22 plate 24 is attached to the bone by fasteners which
23 comprise a titanium cylinder 28 passed through one of
24 the apertures 26 into a bore drilled in the bone, and a
25 screw 30 engaging internally in the cylinder 28 to
26 produce a wedging effect. This arrangement is less
27 prone to loosen than bone screws, and copes well with
28 bone regrowth.

29
30 Figure 5 illustrates in more detail the relationship of
31 the implant, bone and soft tissue.

32
33 Figure 5a shows schematically a healthy jaw including
34 mandible 60, tooth 62 and soft tissue 64.

35
36 In Figure 5b, it will be seen that the implant 18

1 entirely replaces excised bone and soft tissue, without
2 any need to recreate bone or soft tissue. The
3 remaining soft tissue 64 locates on the surface of the
4 implant 18. Figure 5b also illustrates a denture 66
5 releasably secured to the implant 18 by engagement with
6 a post 68 upstanding from the body of the implant 18.
7 Posts of this nature are known per se for securing
8 dentures in oral reconstruction.

9
10 The implant 18, in the example of Fig 6, is secured to
11 the plate by titanium rivets 32.

12
13 In a modification (not shown), the implant may be made
14 in a modular fashion, with the total volume to be
15 replaced being provided by a number of interfitting
16 parts which may, for example, be secured to a common
17 mounting plate such as the plate 24 of Fig 6. This
18 arrangement may simplify the surgical procedure in
19 certain cases.

20
21 Fig 7 shows a connector block 50 which may be used with
22 the embodiments described above, or for other
23 applications.

24
25 The block 50, which is machined from solid titanium,
26 has a rectangular body 52 with an upstanding post 54.
27 The top of the post 54 is formed into a part-sphere 56
28 for attachment of dentures, bridgework, etc.

29
30 The body 52 is formed with parallel, circular passages
31 58 which enable the connector block 50 to be connected
32 to an apertured device such as a "Thorp" plate by
33 rivets, as in Fig 6.

34
35 The part-sphere 56 is suitable for certain known types
36 of connection. It may be replaced by alternative

1 formations at the top of the post, for example for
2 cooperation with screw-type connections.

3

4 Modifications may be made to the foregoing embodiments
5 within the scope of the invention.

6

7 For example, the invention may be applied to disorders
8 of growth such as the situation where one cheekbone
9 fails to grow and is sunken with regard to the other
10 cheekbone. In this case, an implant can be produced by
11 the techniques described but based on data from the
12 normal cheekbone, and secured to the defective bone as
13 an onlay.

14

15 In another example, a tumour of leg tissue may be
16 excised and the requisite volume filled by an implant
17 secured to a leg bone.

18

19 In both of these cases, the tissues overlying the site
20 would be separated to allow insertion of the implant,
21 and then reclosed. The implant thus does not penetrate
22 the body surface post-operatively, and biocompatible
23 materials other than titanium may be used.

24

1

2 **CLAIMS**

3

4 1. A method of making a prosthetic implant comprising
5 the steps of:

6 obtaining a set of data defining the body parts
7 of interest in three dimensions,

8 using said set of data to create a three
9 dimensional model of at least part of the body
10 parts of interest, and

11 using the three dimensional model to develop
12 and fit to size a prosthetic implant which
13 entirely replaces body parts which are missing or
14 are to be excised from the patient.

15

16 2. A method of treating damaged, diseased or missing
17 body parts which comprises excising damaged and/or
18 diseased body parts and selected adjacent parts,
19 and replacing excised and/or missing parts
20 entirely by a prosthetic implant secured to the
21 sound adjacent bone structures.

22

23 3. The method of claim 2, in which both bone and soft
24 tissue are replaced by a single prosthetic implant
25 made of a material onto the surface of which soft
26 tissue is capable of growing in a manner to
27 prevent the incursion of infection.

28

29 4. The method of claim 3, in which said material is
30 titanium.

31

32 5. The method of any of claims 2 to 4, carried out by
33 obtaining a set of data defining the body parts of
34 interest in three dimensions, using said set of
35 data to create a three dimensional model of at
36 least part of the body parts of interest, and

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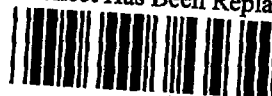


- 1 using the model to develop and fit to size the
2 prosthetic implant prior to surgery.
3
- 4 6. The method of claim 1 or any of claims 2 to 5, in
5 which the prosthetic implant extends through a
6 body surface such as skin or mucous membrane.
7
- 8 7. The method of claim 6, in which said body surface
9 is the palate or nasal cavity.
10
- 11 8. A prosthetic implant made by the method of any of
12 claims 2, 5, 6 and 7.
13
- 14 9. The prosthetic implant of claim 8, provided with
15 mechanical attachment means for the releasable
16 attachment of a further prosthetic device.
17
- 18 10. The prosthetic implant of claim 9, in which said
19 further prosthetic device is a denture.
20
- 21 11. The method of claim 1 or claim 6, in which the set
22 of data defining the body parts of interest is
23 produced by CAT scanning.
24
- 25 12. The method of claim 11, in which the data
26 resulting from the CAT scanning is manipulated by
27 computer.
28
- 29 13. The method of claim 12, in which the data is
30 manipulated to derive from a CAT head scan a set
31 of data defining three dimensionally only the bony
32 structures of the skull.
33
- 34 14. The method of claim 13, in which a three
35 dimensional model may conveniently is produced
36 from aid data by stereolithography.

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- 1 15. A connector block for use in maxillofacial
2 surgery, the connector block comprising a body and
3 a post extending from the body, the post being
4 shaped for selective attachment to dental
5 prostheses, and the body being formed with
6 passages for rivets for attachment to a surgical
7 plate.
8
9 16. The connector block of claim 15, in which the body
10 is rectangular, and the connector block is formed
11 integrally from titanium.
12

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