Sept. 20, 1971 H. HAHN 3,605,123

BONE IMPLANT

Filed April 29, 1969

FIG. 1

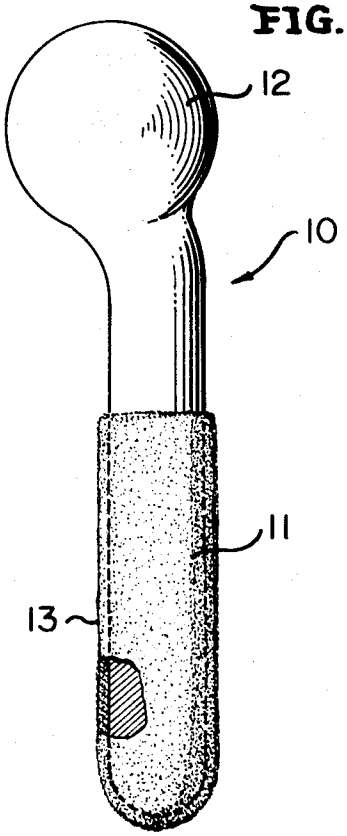


FIG. 2

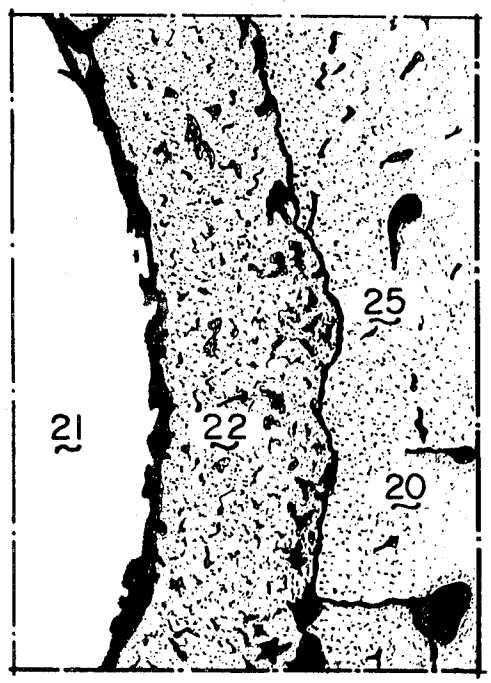
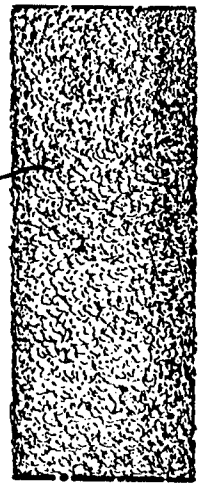


FIG. 3

FIG. 4



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3,605,123

BONE IMPLANT

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U.S. Cl. 3—1 31 Claims

ABSTRACT OF THE DISCLOSURE

A permanent implant for bone tissue which has a dense cast or wrought base portion of high strength metal, and a porous metal layer overlying and bonded to the base portion. The porous layer is thin in comparison with the thickness of the base portion and is preferably plasma flame coated on the base portion. The shape of the base portion depends upon the specific requirements of the bone tissue it is to replace or repair. The porous layer may cover only that part of the surface of the base portion which is to be in contact with the bone tissue after implantation, and permits the growth of bone tissue into the pores.

BACKGROUND OF THE INVENTION

The present invention relates generally to prosthetic parts, and is particularly concerned with improvements in prosthetic devices for use as high strength artificial bone implants adapted to promote a strong union with the bone matter into which such devices are implanted.

Devices in the form of plates, nails, pins, screws, and specially formed parts are commonly implanted into the skeletal structure of humans as artificial prosthetic means for permanent replacement of missing structural parts, or as permanent anchoring devices for maintaining a fixed relationship between the portions of a fractured bone. Clearly, in those situations where permanency is necessary or desirable, the implanted part should remain permanently adhered to the contacting bone surface. This requirement has been a source of some difficulty in the past, where prosthetic parts composed of high strength materials such as titanium, stainless steel, tantalum, or Vitallium (an alloy of cobalt, chromium, and molybdenum) have generally been found incapable of forming a strong union with the natural bone structure into which the implantation is made. Highly magnified photographs of sections taken through bone and implant where failure has occurred have revealed what appears to be an absence of coalescence between the artificial and natural parts, and in fact an actual separation between the implant surface and the bone matter adjacent thereto is often apparent.

Several techniques have been proposed in an effort to overcome this difficulty. For example, it has been suggested, in U.S. Pat. No. 2,537,070, that a bone reinforcing member in the form of a perforated stainless steel tube be used as a permanent artificial member to assure union between portions of a fractured bone. According to that disclosure, the tube is inserted into a hole drilled in the bone through the fracture line, and is then filled with pulverized bone matter. The bone matter is packed by tamping with a ram to force it through the apertures in the tube wall and against the bones to be mended. The purpose is said to be subsequent solidification of the bone matter and union with the bone.

Another technique, advanced in U.S. Pat. No. 3,228,393, involves providing a portion of the prosthesis with fenestrae. Bone grafts pass through the fenestrae, and cancellous bone is packed into remaining recesses and grooves in the fenestrae to eventually unite with the cortical bone of the grafts.

There is no evidence that either of these techniques has proven successful. Furthermore, they require lengthy and relatively difficult procedures in the midst of the implant operation, dealing with introduction and packing of foreign bone matter into the patient's bone structure. There is also the question of compatibility of the added bone matter with the existing bone.

Still another technique is described in U.S. Pat. No. 3,314,420, in which the implant is formed from a porous ceramic material filled with a synthetic organic plastic resin that adheres to the walls of the pores. The implant accepts growth of bone tissue against its surface to incorporate the artificial part into the skeletal structure of the patient. While this constitutes a generally easier and more efficient technique of implantation and skeletal repair, it suffers from the use of a structurally weak implant material.

SUMMARY OF THE INVENTION

The principal object of the present invention is to provide a prosthesis of high structural strength, with a capability of promoting substantially complete integration with the bone structure in which it is implanted.

I achieve that object by first providing a dense metal structure, preferably fabricated from wrought or cast metal, of appropriate shape for the part it is to replace or the function it is to serve, and capable of resisting the stresses to which it will be subjected during the normal activity of the person or animal into whose skeletal structure it is to be implanted. It is essential that the material of which this dense structure is composed have high strength; but, beyond that, it must also be easily formed in a desired shape, and it must be non-toxic to its host. Metals such as titanium, tantalum, stainless steel, and Vitallium have demonstrated these desirable properties over many years of use as prosthetic parts, but, as observed above, each has also demonstrated a failure to provide a strong bond with the bone structure into which it is implanted. As an important aspect of my invention, I provide on the surface of a dense structure composed of one of those metals, or of a metal of similar properties, and having the desired shape, a relatively thin highly porous layer that is effective in promoting the growth of bone tissue into the pores to produce a union between bone and artificial part. This poses a great number of problems, however, such as providing a strong bond between the base metal and the overlying porous layer, while assuring the provision of an extremely thin layer; ensuring compatibility of the base metal and the overlying material; elimination of any possibility of toxicity of the overlyng material to the system of the host into whom the artificial part is implanted; prevention of electrolytic effect between material of which the overlying layer is composed and the base metal; and maintenance of at least similar coefficients of thermal expansion between base metal and overlying layer to assure the continuance of a strong bond therebetween, to name a few of the problems.

Preferably, I coat the dense base metal with a thin porous film of the same metal to provide the desired chemical, electrochemical, and thermal compatibility and to overcome most of the problems noted above. The initial high strength bond between coating and base is preferably achieved by a flame spray process such as the plasma flame process. The result of this process is a densely adherent layer of the same metal as the base metal on the surface of the base metal, with no porosity or practically no porosity at the interface between coating and base metal and with gradually increasing porosity, including pore size and pore density, from the interface to the surface of the coating.

While I prefer to use the plasma flame process, I do not desire to limit my invention to such a process. For example, it is quite conceivable that a thin porous region can be provided at the surface of a dense wrought or cast metal prosthesis by a conventional chemical milling process, that is to say, without an actual application of a coating to the surface. At present, however, it appears questionable that suitable pore openings such as those obtained by plasma flame spray coating can be obtained by chemical milling.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view, partly in section, of a prosthetic part according to my invention;

FIG. 2 is a rendering of an actual photograph of a section, magnified 100 times, taken through the bone of an animal into which a prosthetic pin structurally similar to the member of FIG. 1 has been implanted several months earlier, and showing a portion of the pin, the coating thereon, and the bone;

FIG. 3 is a rendering of an actual photograph of a section like that of FIG. 2, but magnified 500 times, and showing only bone and pin coating; and

FIG. 4 is an exaggerated side view of the exterior of a pin with porous coating, similar to the pin used as the implant of FIGS. 2 and 3.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, a typical prosthesis **10** includes a long shaft or nail **11** and a ball **12** integral with the shaft. The prosthesis may be composed of a metal conventionally used for that purpose, such as titanium, stainless steel, tantalum, or Vitallium. Purely for the sake of example, reference will hereinafter be made to the use of titanium as the base metal. Ball **12** is to be smooth and to constitute with the pelvic socket a hip joint normally formed by a thigh bone and the pelvis. The lower portion of shaft or nail **11**, that is, the end opposite ball **12**, however, is to be anchored within the remaining portion of the thigh bone (femur) of the human or animal patient. To that end, the normally smooth surface of the dense titanium member **10** is coated, in the region **11** at which a strong bond is to be formed with the bone, with a thin porous layer **13** of titanium.

For the purpose of clarity, layer **13** is exaggerated in thickness relative to the thickness of the prosthetic part. In practice, the porous surface layer will be extremely thin in comparison to the thickness of the base metal on which it is coated. As an example, the coating thickness may be up to approximately 0.1 inch, but the optimum thickness (or thinness, depending on point of view), and the preferred thickness, is from about 0.015 to about 0.030 inch.

At the interface between layer **13** and the surface of the base metal (shaft **11**) the layer is almost completely dense, i.e., is for practical purposes free of pores or interstices. However, in approaching the exterior surface of layer **13**, the layer becomes progressively more porous, with some pores cut off from the surrounding environment by metal portions, others exposed at the exterior surface, and still others connected by interior passageways. In practice, the pores will range from about 30 microns (μ) to about 200μ wide at the opening, although the range of widths from about 40μ to about 70μ appears to be optimum.

In producing a prosthetic part such as **10**, the base metal is first formed, for example as a cast or wrought structure, in the shape desired for the specific application. As in the application exemplified by FIG. 1, it may be desired that the prosthetic part or implant have a smooth surface in one or more portions (as at **12**), and that it promote adherence with the bone tissue in one or more of its other portions. In accordance with the present invention, the surface areas to be coated with a porous

layer may be selected commensurate with these criteria, as by masking specified locales of the base metal surface that are to be free of any coating.

Preferably, the coating or layer **13** is applied to the base metal by a plasma spraying process, as is generally described in Nuclear Applications of Nonfisssionable Ceramics, Boltax and Handwerk et. (American Nuclear Society, 1966), in the section authored by myself and Joseph Pentacost, at pages 359 et seq., and elsewhere in Flame Spray Handbook, vol. III, "Plasma Flame Process" (Metco Ltd., 1965), for example. Briefly, in the plasma spray process, a mixture of nitrogen and hydrogen gases is fed under pressure of about 200 pounds or more toward the space between a central electrode and a surrounding outer electrode between which an arc is created by virtue of a voltage across the electrodes and a high current that flows upon breakdown of the central air gap. The combination of the electrode arc and the high pressure gas flow create a rapidly moving high energy flux at a temperature generally ranging from about 30,000° F. at its center to 20,000° F. at its periphery. It is into this high energy, high temperature flux that the material to be deposited (or more aptly, a material from which the material to be deposited is to be derived in a reaction with the heat of the flame) is fed. In the case of titanium as a base metal, titanium hydride powder carried by an inert carrier gas such as argon is delivered under pressure into the electrode area at which the flux is created, resulting in a plasma coating of substantially pure titanium metal on that portion of the titanium base metal of the prosthetic part which is unmasked and held in a region adjacent the high temperature flux. The coating thickness specified above and the size of the pore openings may be readily controlled by timing the delivery and amount of titanium hydride to the electrode region and the manner of exposure of the part to be coated to the plasma flux. Again, I do not restrict my invention to use of the plasma spray process, although that is preferred, and I again emphasize that a porous surface region may be provided on the base metal without use of any coating process, but instead by employing a chemical milling process. In the latter situation, undercut pores (i.e., pores having relatively small openings in the size range mentioned above, but having wider interiors) are obtained in the immediate vicinity of the surface of the base metal.

The improved surface adherence of bone to plasma coated titanium pins (although plasma coated stainless steel, tantalum, or Vitallium pins are similarly effective) was demonstrated in one experiment by implanting a total of six pins in the right and left femurs of a sheep. Of the three pins in each femur, one was a solid titanium pin used as a control specimen, and the others were "coarse" and "fine" plasma coated titanium pins, respectively, differing only in the general size of the pore openings at either end of the aforementioned 30μ to 200μ range, and each of the latter two pins having a coating thickness of approximately 0.035 inch. Each pin, including the control specimen, was provided with a head left exposed at the surface of the bone to permit subsequent attempts at rotation and/or removal with a torque wrench. The character and general appearance of the coating **13** on the plasma coated pins is quite vividly presented in FIG. 4, a rendering of an actual photograph of such a coated pin, magnified approximately six times. Some three months after the implantation of the six pins, the sheep was returned to the laboratory to permit tests of the extent of union of pins and bone tissue, and to attempt rotation of the pins in each femur. Prior to torque testing, sufficient bone material was removed from the underside of the head of each pin to ensure an absence of any interference between the bone and the underhead area of the pins. It was found that in both the right and the left femurs the solid titanium pin (control specimen) was easily rotated and removed from the bone, at a torque of

406,600 dynes per square centimeter on the control pin in the right femur, and of 1,617,800 dynes/cm.^{2} on the control pin in the left femur. On the other hand, each of the coated pins failed as a result of plastic deformation or shearing of the head during the torque tests. Failure occurred at the following torques, each value of which was therefore lower than the value of torque that would have been required to rotate the respective pin: for the coarse plasma coated pin 21,987,600 dynes/cm.^{2} in the right femur, and 16,611,100 dynes/cm.^{2} in the left femur; and for the fine plasma coated pin, 22,153,600 dynes/cm.^{2} in the right femur, and 22,402,500 dynes/cm.^{2} in the left femur.

The easy removal of the solid titanium control pins was followed by observation of the holes in the bones from which those pins had been removed, and each of these holes was found to be clean, i.e., to possess clean smooth walls, free of disruption. However, only one of the plasma coated pins could be removed, even under attempts at hammering out, and that was the "fine" plasma coated pin in the right femur. Removal of the latter pin resulted from shearing of the interface between the plasma coating and the base metal. Renderings of actual photographs of sections through bone and coated pin, magnified 100 and 500 times, are presented in FIGS. 2 and 3 respectively, and clearly demonstrate the manner in which the bone tissue has grown against and into the porous surface of the coating in each instance. In FIG. 2, the bone is designated by reference numeral **20**, the pin by reference numeral **21**, and the plasma coating by reference numeral **22**. If complete adherence were not present, a void or gap would have remained between bone tissue **20** and coating **22** in the region **25** of FIG. 2. Similar bonding or union is indicated in FIG. 3 with the bone designated **30** and the plasma coating designated **32**. Here again, it is readily observable that the bone tissue completely follows the rough contour of the coating surface. The dark areas at the interface between bone and coating in FIGS. 2 and 3, and between coating and base in FIG. 2, have been exaggerated slightly for the purpose of clarity. Actually, the photographs indicate a thorough bond between the materials at the respective interfaces.

A histological study of the coated pins in the bone revealed growth of bone tissue into the pores at the surface of the coating. Thus, the plasma coated prosthetic part was firmly anchored in place.

The present invention is applicable to prosthetic devices of all types and purposes, including dental applications such as the anchoring of one or more permanent artificial teeth in the jawbone. Whatever the application in which the prosthesis is used, it has been found that those parts produced according to the present invention possess impact strengths ranging up to 80 times that of prior art prosthetic parts. Reported failures caused by fatigue and impact in completely porous ceramic implants were completely absent in tests on dense metal implants having only a thin porous surface region.

I claim:

1. A prosthetic part for use on a bone implant, comprising a strong metal base, said metal base being substantially non-toxic to the biological system of the host into whose bone structure said prosthetic part is to be implanted, and a highly porous metallic region at a surface of said base, said porous region being extremely thin relative to the thickness of said base and extending over substantially that portion of the surface of said base which is to be in contact with the bone structure after implantation.

2. The prosthetic part according to claim **1** wherein the metal of which said base is composed is selected from the group consisting of titanium, stainless steel, tantalum, and Vitallium.

3. The prosthetic part according to claim **1** wherein said porous region is a layer bonded to the surface of said base, said layer being relatively dense at the interface with the base metal and of progressively greater porosity toward the exterior surface of said layer.

4. The prosthetic part according to claim **3** wherein said layer is composed of a material having a coefficient of thermal expansion substantially equivalent to that of said base metal.

5. The prosthetic part according to claim **4** wherein said layer is a plasma coating on the surface of said base.

6. The prosthetic part according to claim **5** wherein said layer has a thickness less than 0.1 inch.

7. The prosthetic part according to claim **6** wherein the pore openings at the exterior surface of said layer have widths in the range from about 30 microns to about 200 microns.

8. The prosthetic part according to claim **7** wherein said base metal is titanium and said porous layer is titanium.

9. The prosthetic part according to claim **3** wherein said porous layer is composed of at least substantially the same metal as said base metal.

10. A member adapted to promote adherence of bone tissue thereto, said member comprising a highly dense base portion of metal, and a region of high porosity metal coating on the surface of said base portion, said region being thin relative to the thickness of said base portion and arranged for promoting the growth of bone tissue to said member when said member is implanted with said region adjacent living bone tissue.

11. The invention according to claim **10** wherein said region is a layer of material overlying the surface of said base portion and bonded thereto.

12. The invention according to claim **11** wherein said layer extends over only a part of the surface of said base portion.

13. The invention according to claim **11** wherein the material of which said layer is composed is substantially the same metal as the metal of which said base portion is composed.

14. For use as a permanent bone implant, a structural member including a base composed of metal substantially free of interstices, said member possessing a shape commensurate with a bone repair function; and a porous metallic region, thin relative to the thickness of said base located on the surface of said base.

15. The invention according to claim **14** wherein said porous region covers only a part of the surface of said base conforming substantially to that portion of the member to be in contact with bone tissue.

16. The invention according to claim **14** wherein said porous region is a metal layer overlying and bonded to the surface of said base.

17. The invention according to claim **16** wherein both said base and said layer are composed of titanium.

18. An implant for bone tissue including a base portion of high strength metal and a porous metal layer overlying and bonded to said base portion.

19. The combination according to claim **18**, wherein said porous metal layer is plasma flame coated on said base portion.

20. The combination according to claim **19**, wherein said high strength metal and said porous metal layer are essentially the same metals.

21. The combination according to claim **18**, wherein said high strength metal and said porous metal layer are of essentially the same metal.

22. The combination according to claim **18**, wherein said high strenght metal is incapable of forming a strong union with said bone tissue absent said layer.

23. The combination according to claim **19**, wherein said high strength metal is incapable of forming a strong union with said bone tissue absent said layer.

24. The combination according to claim **19**, wherein said metal is selected from the group consisting of titanium, stainless steel, tantalum, and Vitallium.

25. A bone implant, including a base portion composed

of high strength metal and a porous layer overlying said base portion, said metal and layer being non-toxic to said bone, and being chemically, electrochemically and thermally compatible with each other, said porous layer being of gradually increasing porosity in proceeding from the interface of said base portion layer to the outer surface of said layer and of negligible porosity at said interface.

26. The combination according to claim **25**, wherein said porous layer is plasma flame coated metal.

27. The combination according to claim **25**, wherein said porous layer is metallic.

28. The combination according to claim **25**, wherein said porous layer has a thickness of between about .030" to .015".

29. A metallic bone implant having a porous metallic surface layer.

30. The combination according to claim **29**, wherein said implant and said surface layer are chemically, electrochemically, and thermally compatible and non-toxic to said bone.

31. The combination according to claim **30**, wherein said implant and said surface layer are of essentially the same metals.

References Cited

UNITED STATES PATENTS

448,745	3/1891	Wright	32—10
2,688,139	9/1954	Jardon	3—13
3,314,420	4/1967	Smith et al.	128—92

FOREIGN PATENTS

1,122,634	5/1956	France	128—92

LAWRENCE W. TRAPP, Primary Examiner

U.S. Cl. X.R.

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