



University of Kentucky
UKnowledge

Biomedical Engineering Faculty Patents

Biomedical Engineering

12-30-1997

Implant Having Reduced Generation of Wear Particulates

David A. Pienkowski
University of Kentucky, pienkow@uky.edu

Follow this and additional works at: https://uknowledge.uky.edu/cbme_patents



Part of the [Biomedical Engineering and Bioengineering Commons](#)

[Right click to open a feedback form in a new tab to let us know how this document benefits you.](#)

Recommended Citation

Pienkowski, David A., "Implant Having Reduced Generation of Wear Particulates" (1997). *Biomedical Engineering Faculty Patents*. 6.
https://uknowledge.uky.edu/cbme_patents/6

This Patent is brought to you for free and open access by the Biomedical Engineering at UKnowledge. It has been accepted for inclusion in Biomedical Engineering Faculty Patents by an authorized administrator of UKnowledge. For more information, please contact UKnowledge@lsv.uky.edu.



US005702456A

United States Patent [19]
Pienkowski

[11] **Patent Number:** **5,702,456**
[45] **Date of Patent:** **Dec. 30, 1997**

- [54] **IMPLANT HAVING REDUCED GENERATION OF WEAR PARTICULATES**
- [75] **Inventor:** David A. Pienkowski, Lexington, Ky.
- [73] **Assignee:** The University of Kentucky Research Foundation, Lexington, Ky.
- [21] **Appl. No.:** 623,605
- [22] **Filed:** Mar. 28, 1996

McKellop, et al.; "Friction and Wear Properties of Polymer. . . on a Multichannel Screening Device"; J of Biomedical Materials Research; 15, 619-653; (1981).

Murall Jasty; "Clinical Reviews: Particulate Debris and Failure of Total Hip Replacements"; Journal of Applied Biomaterials; 4, 273-276; (1993).

Dowson, et al.; "Wear Particles: From the Cradle to the Grave"; The Institute of Tribology, Leeds University; Tribology Series, 21; Symposium Sep. 1991.

Related U.S. Application Data

- [62] Division of Ser. No. 276,972, Jul. 19, 1994, Pat. No. 5,515,590.
- [51] **Int. Cl.⁶** **A61F 2/30**
- [52] **U.S. Cl.** **623/18; 623/66**
- [58] **Field of Search** **623/16, 18, 19, 623/20, 22, 23, 66**

Primary Examiner—David Isabella
Attorney, Agent, or Firm—King & Schickli

[57] **ABSTRACT**

A method is provided for reducing the amount of wear particulates generated by a total joint orthopaedic implant. The implant consists of two matched articulating components. The method includes the steps of placing the total joint orthopaedic implant in a fluid bath and articulating the implant in the fluid bath for at least 1,000 cycles. The articulation may be performed in three stages. In the first, the implant is articulated under a load of substantially 0.1-500 Newtons with sliding speeds of substantially 0.01-0.5 meters per second. During a second stage the articulation takes place under a load of substantially 200-2,500 Newtons with sliding speeds of substantially 0.01-0.5 meters per second. In the third stage the articulation takes place under a load of substantially 2,500-10,000 Newtons at sliding speeds of 0.5-2.0 meters per second.

[56] **References Cited**

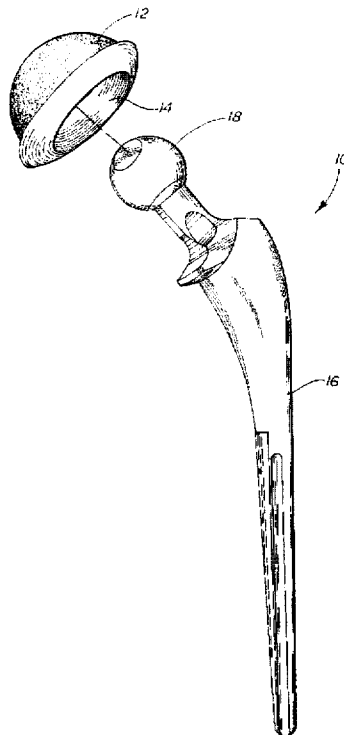
U.S. PATENT DOCUMENTS

5,308,412	5/1994	Shetty et al.	623/18
5,310,408	5/1994	Schryver et al.	623/18
5,370,696	12/1994	Jamison et al.	623/18
5,415,704	5/1995	Davidson	623/18
5,545,227	8/1996	Davidson et al.	623/18

OTHER PUBLICATIONS

- "The Osteolysis Challenge"; Orthopaedic Insight; vol. 1, No. 3; Feb. 1994.
- "Arcom Processed Polyethylene, Uniform Compression Molded: Test Results"; Biomet, Inc. (1993).

10 Claims, 1 Drawing Sheet



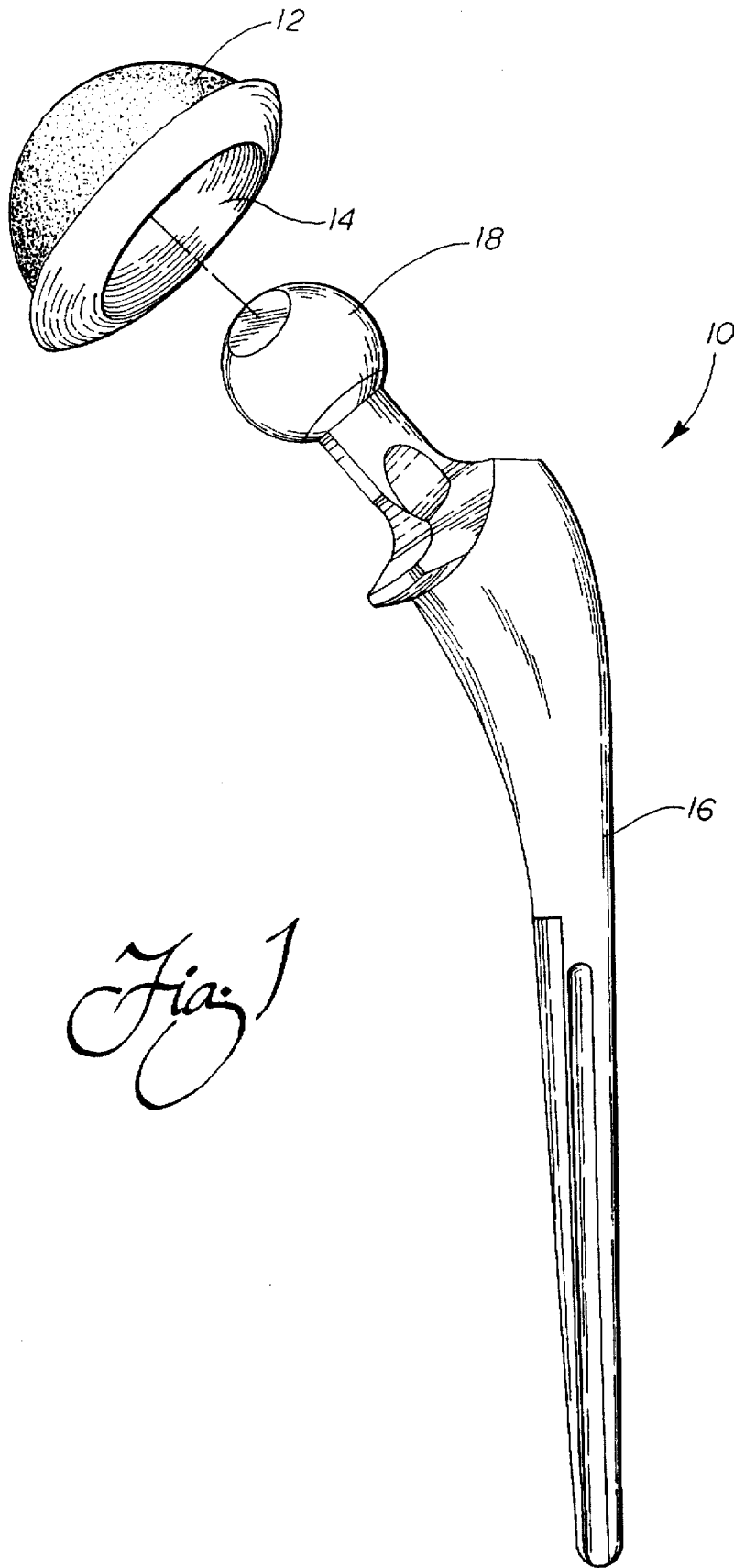


Fig. 1

IMPLANT HAVING REDUCED GENERATION OF WEAR PARTICULATES

This is a division of application Ser. No. 08/276,972, filed Jul. 19, 1994, now U.S. Pat. No. 5,515,590.

TECHNICAL FIELD

The present invention relates generally to the field of orthopaedic implants and, more particularly, to a method for reducing the amount of wear particulates generated by a total joint orthopaedic implant following implantation in a patient.

BACKGROUND OF THE INVENTION

Each year over 500,000 human joints require replacement as a result of debilitating disease or damage from an accident. Hip and knee joints represent a majority of these. To meet this need, a large number of total joint orthopaedic implants have been designed and are presently being marketed by various manufacturers. Examples of these are shown, for example, in U.S. Pat. Nos. 5,021,063 to Tager; 5,030,238 to Nieder et al.; 5,108,452 to Fallin; and 5,180,394 to Davidson.

Total joint orthopaedic implants generally comprise two articulating components. The first of these components includes a concave polymer surface. The second of these components includes a convex counterface, typically formed of either metal or ceramic that is adapted to slide or roll over the soft polymer surface.

Ultrahigh molecular weight polyethylene remains the dominant polymer for utilization in the construction of concave bearing surfaces in total joint orthopaedic implants at the present time. To prevent undue wear to this bearing surface, the hard metal or ceramic counterface of the other component of the total joint orthopaedic implant should have an exceptionally smooth surface as roughness is directly related to the wear rate. The average surface roughness of, for example, a hip joint is about 0.025 μm . It should be appreciated, however, even such a smooth hard, metal or ceramic surface generates wear particulates from the softer polymer surface. These wear particulates, unfortunately have been shown to be associated with adverse tissue reactions over time.

Specifically, the wear particulates stimulate cellular activity in the form of an immune system response. More specifically, inflammation and foreign body reactions result including macrophage and foreign body giant cell activity. This process leads to the production of bone resorbing cytokines (e.g. IL-1, IL6, P6E-2, etc.) which lead to destruction of the bone tissue holding the implant securely in place. These conditions likely contribute to the loosening of prosthetic components eventually resulting in pain and failure of the total joint orthopaedic implant.

The shape, size and volume of the wear particulates produced may determine the type and extent of the adverse tissue and cellular reactions that are stimulated. It is hypothesized that very small wear particulates are transported away from the implant site and eliminated by the lymphatic system. More specifically, these very small particulates are phagocytized and transported through the lymphatic system by macrophages. The volume or rate of the particulates that the macrophages can phagocytize and transport, however, may be less than the volume or rate of particle generation. Accordingly, the lymphatic system may become overloaded as a result of increased wear rates with the resulting particulate generation leading to an accumulation of wear

particulates in the tissues around the total joint orthopaedic implant. This may produce a chronic inflammatory response that eventually leads to bone resorption.

Although larger wear particulates generally remain in the tissue surrounding the implant, they also can produce a chronic foreign body response which may eventually give rise to bone resorption. Accordingly, it should be appreciated that wear particulates have been repeatedly associated with aseptically loosened implants, a condition that eventually requires total joint orthopaedic implant replacement surgery. A need is therefore identified for a procedure to reduce the number, or modulate the shape and size of wear particulates generated in a human from a total joint orthopaedic implant. By successfully addressing this need, it is possible to increase the service life of the total joint orthopaedic implant and thereby reduce the need for difficult, painful and costly revision surgery. Recognizing the problem resulting from wear particulate generation, a number of solutions have been proposed. As set out in the article entitled "Clinical Reviews: Particulate Debris And Failure of Total Hip Replacements" by Murali Jasty in the *Journal of Applied Biomaterials*, Volume 4, pp 273-276 (1993), these approaches include: the use of polyethylene components with more than 8 mm wall thickness and the use of head sizes smaller than 32 mm; the use of nontitanium alloys; the use of circumferential porous coatings on the femoral components; the use of prosthetic designs and surgical techniques to obtain intimate bone porous coating apposition and rigid initial fixation at surgery, the minimizing of the modularity of the components and the surface hardening of the metal surface with techniques such as nitrating or ion implantation.

While each of these approaches is successful to some degree, none is directed to removing laps, folds and other surface irregularities (which form wear debris and would otherwise be produced in the body after implantation) prior to the implanting of the total joint orthopaedic implant into a patient. Further, while some clinical studies of the generation of wear particulates in a total joint implant have been completed and still others are ongoing, there has been absolutely no suggestion in the art that any method could be utilized to pre-wear the implants prior to implantation so as to significantly reduce the amount, or change the shape or size of wear particulates generated following implantation and thereby increase the service life of the total joint orthopaedic implant.

SUMMARY OF THE INVENTION

Accordingly, it is a primary object of the invention to provide a method for reducing the amount, or changing the shape and size, of wear particulates generated by a total joint orthopaedic implant following implantation so as to thereby effectively reduce the resulting stimulation of the immune system of the patient. In this way, potent bone resorbing cytokines are not stimulated by these wear particulates, the implant remains firmly attached to the bone, and a longer implant service life is provided.

Yet another object of the invention is to provide a relatively simple, inexpensive and easily completed method for the pre-breaking-in or pre-wearing of a total joint orthopaedic implant consisting of two matched articulating components. Specifically, the components are articulated in a cyclical manner to remove laps, folds, and other surface irregularities prior to implantation. These laps, folds and irregularities would otherwise lead to the production of wear debris, the stimulation of cytokine release, and ultimately, contribute to the loosening and failure of the implant.

Yet another object of the present invention is to provide an improved method for substantially reducing the amount or volume of wear particulates generated by a total joint orthopaedic implant following implantation wherein the implant is pre-worn to remove laps, folds, and other surface irregularities and provide good component-component fit and bearing surface polish. Further, the implant bearing surfaces are hardened and a boundary lubricant layer is also generated so as to significantly reduce the friction, wear particle generation and wear particle burden imposed by the implant on surrounding tissue following implantation. Advantageously, this effectively increases the overall service life of the implant, not only serving to reduce the inflammation and pain associated with total joint implants in the past, but also in many cases substantially postponing or altogether eliminating the need for subsequent revision/replacement surgery.

Still another object is to provide a total joint orthopaedic implant that is pre-broken-in or pre-worn in order to remove laps, folds, and other surface irregularities prior to implantation thereby reducing wear particulate generation after implantation and consequently increasing the service life of the implant.

Additional objects, advantages and other novel features of the invention will be set forth in part in the description that follows and in part will become apparent to those skilled in the art upon examination of the following or may be learned with the practice of the invention. The objects and advantages of the invention may be realized and obtained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

To achieve the foregoing and other objects, and in accordance with the purposes of the present invention as described herein, an improved method is provided for reducing the amount or volume of wear particulates generated by a total joint orthopaedic implant after it is implanted in the body of a patient. More specifically, the method includes the step of placing the total joint orthopaedic implant, consisting of two matched articulating components, in a fluid bath so that the implant is completely submerged in the fluid. Preferably, the fluid has a viscosity between 1-2000 times that of water. More preferably, the fluid may be selected from a group of fluids having components consisting of water, fetal calf serum, bovine serum, natural or synthetic synovial fluid and any mixtures thereof. The method also includes a step of articulating the total joint orthopaedic implant in the fluid bath, preferably all at a constant temperature, for at least 1,000 and more preferably 10,000 cycles whereby the total joint orthopaedic implant is pre-worn outside the body of the patient. This is done to remove laps, folds, and other irregularities that would otherwise be removed and particles generated in the body following implantation where such particles would inflame tissues and stimulate cellular activity and specifically, the immune system of the patient.

Advantageously, by removing a substantial portion of the wear particulates, which have been shown to be generated in greater volume during the earliest cycles of articulation of the total joint implant, and further by providing good surface-to-surface fit and polish, the wear particulate burden imposed by the implant on the surrounding tissue is reduced following implantation. As a result, the immune system response in the patient is reduced or possibly eliminated, along with the associated inflammation, bone resorption and pain. Thus, patient comfort is increased. Additionally, as loosening of the implant from the destruction of the supporting bone is stimulated by wear particle mediated cyto-

ine release from the immune system reactions of the patient, the loosening process is slowed thereby increasing the overall service life of the implant. In many applications, the resulting service life of the total joint implant will be extended for a sufficient period of time to allow the patient receiving the implant to avoid the need for revision surgery.

In accordance with yet another aspect of the present method, there is the step of establishing a boundary lubricant layer on the total joint orthopaedic implant and particularly, the relative sliding polymer and metal or ceramic weight bearing surfaces. This is done by including boundary lubricant layer forming solutes in the fluid bath. The solutes may, for example, be selected from a group of materials consisting of polytetrafluoroethylene, hyaluronic acid, lubricin, other natural or synthetic solvents or solutes and any mixtures thereof.

In accordance with a still further aspect of the present invention, the fluid from the fluid bath may be drained and replaced concurrently while the articulating and establishing steps are ongoing. Accordingly, as boundary lubrication layer forming solutes are absorbed and incorporated into the surface of the joint implant, and particularly in the sliding load bearing surface areas, those solutes are replaced. Accordingly, a greater concentration of solutes is available throughout the entire processing period so as to increase the level of absorption into the implant. As a result of lubricant absorption, friction between the wear bearing surfaces is reduced following implantation and the production of troublesome wear particulates is thereby further minimized.

Alternatively, in certain applications and when utilizing the present method to process certain implant materials with certain boundary lubrication layer forming solutes, it may also be desirable to filter the fluid in the fluid bath. In this way, particulates that are generated during the early cycles of articulation are removed from the fluid. As a result of removal by filtration, such particulates are not continually passed through and squeezed between the relative sliding load bearing surfaces of the matched articulating components of the implant where such particulates would otherwise function as a third-body abrasive and further increase particulate generation and destruction of the implant bearing surface. Filtering is in fact a particularly important step of the method during the final stage of articulation wherein the smooth polishing and hardening of the matching load bearing surfaces is an essential aspect of the present invention.

In accordance with yet another aspect of the present invention, the articulating and establishing steps of the method are completed in accordance with specific processing parameters. Preferably, the cycling of the orthopaedic joint implant is completed at between 0.01-100 Hz. Further, there is the loading of the total joint orthopaedic implant so as to carry a time-varying load of between 0.1-10,000 Newtons during articulation. This time variation of load may follow a square, triangular, or sinusoidal loading regime, or a more clinically relevant load profile such as the Paul curve. Most preferably, the loading occurs at the lower end of this range during the initial stages of articulation. This allows wearing in and stripping away of pronounced laps and folds during the initial stages of processing without gouging, scoring, pitting, abrading or otherwise damaging the bearing surfaces. Further, this initial processing may be done dry or in the presence of only a very low viscosity lubricant such as water.

As the cycling continues, the loading is increased to a level approximately equivalent to the loading expected to be placed upon the implant following implantation in the

patient. This allows fine wearing in and some localized surface hardening of the mating load bearing surfaces. Preferably, during this second stage of processing, the method includes a further step of varying the load carried by the total joint orthopaedic implant during articulation to simulate the load expected to be placed upon the implant by a patient during actual use following implantation.

This method also includes a provision for loading the implant using a load and frequency profile that closely matches that load and frequency profile which will be applied by the actual patient into which this specific articulating pair, now being "broken-in" will be surgically implanted. In this way, the implant is pre-worn in a manner that is effectively "customized" to its eventual operative environment so that particulate generation following implantation is absolutely minimized. Typically, this second stage of processing is performed with the implant submerged in a fluid bath having particular solvents, solutes, and physical properties.

In the final stage of processing, loading and sliding speeds are greatly increased to cold work and harden the load bearing surfaces. Simultaneously, lubricant present in the fluid bath is forced into and absorbed by these bearing surfaces so as to form a boundary lubricant layer. As a result of the present process, in many cases it is anticipated that particulate generation following implantation will be of a nature in both size, shape and volume so that the macrophages of the patient should be able to successfully phagocytize and transport the resulting particulates through the lymphatic system without activating the cascade of cytokines which destroy bone. In this way, a physiological equilibrium is achieved and the service life of the implant is significantly extended. As a result inflammation and pain are also substantially eliminated. Accordingly, this invention represents a significant advance in the art.

In accordance with still another important aspect of the present invention, a pre-broken-in or pre-worn total joint orthopaedic implant is provided in accordance with the present method.

Still other objects of the present invention will become apparent to those skilled in this art from the following description wherein there is shown and described a preferred embodiment of this invention, simply by way of illustration of one of the modes best suited to carry out the invention. As it will be realized, the invention is capable of other different embodiments and its several details are capable of modification in various, obvious aspects all without departing from the invention. Accordingly, the drawings and descriptions will be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawing incorporated in and forming a part of the specification, illustrates several aspects of the present invention and together with the description serves to explain the principles of the invention. In the drawing:

FIG. 1 is a perspective view showing a total joint orthopaedic implant processed in accordance with the present method.

Reference will now be made in detail to the present preferred embodiment of the invention, an example of which is illustrated in the accompanying drawing.

DETAILED DESCRIPTION OF THE INVENTION

The method for reducing the amount of wear particulates generated by a total joint orthopaedic implant system of two

matched articulating components broadly comprises the steps of placing the total joint orthopaedic implant 10, including the acetabular cup or socket 12 with the concave polymer surface 14 and the femoral stem or prosthesis 16 with the head 18 having a convex counterface formed from metal or ceramic, in a fluid bath. Next is the articulating the implant in the fluid bath for at least 1,000 and more preferably at least 10,000 cycles. In accordance with this method, the total joint orthopaedic implant is pre-worn outside the body of the patient to remove laps, folds and other particulates and provide good surface-to-surface fit and polish so as to reduce the wear particulate burden imposed by the implant on surrounding tissue following implantation. This advantageously serves to increase the overall service life of the implant in a manner that is described in greater detail below.

More specifically, the method of the present invention is based upon the Archard equation:

$$T=kLV/H$$

wherein

T=rate of wear particle generation

k=a constant for a specific test system

L=load (or force)

V=sliding velocity of the two surfaces

H=material hardness.

In this equation, the value of the constant k depends on a number of factors including temperature, area of the wear interface, the fluid environment of the two matched articulating components, the surface finish, the number of wear cycles and other factors.

Still more specifically, the method of the present invention is particularly adapted to achieve a high precision fit and finish between the two articulating components so that the components are essentially matched to one another for smooth, low friction, low wear operation in vivo. Thus, the final fitting of the components is achieved external to the body in a specific controlled environment. Advantageously, this has a number of benefits over prior art procedures wherein modular, previously unmatched components are selected by the surgeon and are implanted in the patient. There final wearing in and precision fitting of the two surfaces are achieved but, unfortunately, the wear debris produced during initial removal of laps and folds is all delivered to the tissues at the expense of adverse biological side effects and reduced total joint implant service lifetime.

Specifically, wear particulates and debris are produced in the patient during the wearing in period in a manner that results in inflammation and problematic immune system response. This problem is substantially delayed or avoided by use of the present method of pre-wearing or breaking in outside of the body.

The present method also functions to establish a boundary lubrication layer on the cooperating load bearing surfaces of the matched articulating components. Advantageously, the boundary lubrication layer functions after implantation to provide smooth low friction operation of the implant while also minimizing wear for the overall benefit of the patient. Advantageously, by providing both a precision matched fit and a boundary lubrication layer, the present method effectively functions to smooth operation of the implant and also significantly reduce the generation of wear particulates and maximizes implant service life longevity.

Further, while some wear particulates are still likely to be produced over time, those produced are generally of smaller size so that they may be phagocytized by macrophages and

transported away through the lymphatic system. Further, the volume or number of particulates produced are likely to be reduced sufficiently so that the lymphatic system is not overloaded. Thus, as a result of the present invention, an equilibrium state is achieved wherein no serious problematic immune system response leading to bone resorption and loosening of the implant is generated in the patient. As a result, the life of the implant is significantly increased and the risk of the patient having to undergo revision or replacement surgery is significantly reduced or eliminated. Of course, the inflammation and pain associated with and leading up to implant failure are also typically avoided.

In accordance with the more detailed aspects of the present invention the fluid in the fluid bath in which the implant is submerged during articulation has a viscosity of between 1–2000 times that of water. The solvent of the fluid bath may be water, and various solutes may be added, but in the later stages of the wearing in process the fluid is preferably selected from a group of fluids consisting of water, fetal calf serum, bovine serum, natural synovial fluid, synthetic synovial fluid and any mixtures thereof. Of course, the fluid bath may also include a relatively low concentration of preservatives or antimicrobial agents to prevent the growth of bacteria, fungi, or other microorganisms present in the fluid during implant processing.

To establish the boundary lubrication layer on the total joint orthopaedic implant, it is necessary to include a boundary lubrication layer forming solute in the fluid bath. Such a solute may, for example, be selected from a group consisting of polytetrafluoroethylene, hyaluronic acid, lubricin and any mixtures thereof. It should be appreciated, however, that these boundary lubricant layer solutes are only presented for purposes of example and that other such solutes may be utilized.

Generally, it is also preferred to drain the fluid from and replace the fluid in the fluid bath during the articulating and establishing steps. This advantageously, has the effect of replacing the boundary lubricant layer forming solutes as they are adsorbed and incorporated into the surfaces of the matched articulating components. Advantageously, by maintaining a higher concentration of boundary lubricant layer forming solutes in the fluid bath throughout the present method, it is possible to establish a more effective boundary lubrication layer particularly on the cooperating load bearing surfaces of the matched components.

Further, it is often desirable to filter the fluid in the fluid bath during the articulating of the matched components of the implant. In this way, particulates produced during articulation are removed from the fluid bath. Accordingly, these particulates are no longer present in the fluid to be drawn in between and through the relatively sliding load bearing surfaces of the implant where they could act as an abrasive and prevent the formation of the desired smooth, polished finish of those cooperating surfaces in the later stages of the present method.

Preferably, the method of the present invention is completed in multiple stages. In the first stage, the components of the implant are articulated under loads of between, for example, 0.1 to 500 Newtons at sliding surface velocities ranging from 0.01–0.5 meters per second. Some of these loads and sliding speeds are less than those to which the implant is expected to be subjected to following implantation in the patient. However, they are sufficient to remove the most pronounced laps and folds from the cooperating load bearing surfaces of the matched components. During this initial stage, it may also be desired to utilize water alone or only a very low viscosity lubricant in order to facilitate wear

particle formation and removal of the lap and fold wear debris. Preferably, this first stage is performed for at least 100 cycles and, more preferably for a total of between 500–5000 cycles.

During a second stage of the method, higher load forces are applied. More specifically, load forces equaling or slightly exceeding those experienced during normal body movement are preferably utilized. Further, the load may be varied during articulating (e.g. in accordance with a square, triangular, sinusoidal or a Paul type curve) so as to simulate the load expected to be placed upon the implant by a patient during actual use following implantation. This is done for the purpose of causing local cold working and localized wear hardening on the wear surfaces. In this way, the hardness or wear resistance of the material surface is increased. This is desired to reduce the subsequent rate of wear of the implant following implantation. More specifically, during this second stage of articulation the implant is subjected to a load of between approximately 200–2500 Newtons and sliding surface velocities of between 0.01 and 0.5 meters per second. Again, this second stage of processing may be accomplished dry or in the presence of only a low viscosity lubricant such as water. This increases the speed of wear and hence, reduces processing times. This second stage of processing is also performed for at least 100 cycles and, more preferably for a total of 500–5000 cycles. During a third stage of the wearing in process, loads are greatly increased in excess of that expected to be experienced during standard and normal gait of a patient at velocities equal to or greater than that experienced during normal gait. More specifically, during this third stage the implant may be articulated under loads between, for example, 2,500–10,000 Newtons at sliding surface velocities of between 0.5 and 2.0 meters per second. Third stage processing is preferably performed for at least 100 cycles and, more preferably for a total of 500–10,000 cycles.

The third stage of the method is completed in a fluid bath incorporating a boundary lubrication layer forming solute. The purpose of the third stage is to utilize relatively high loads and rapid sliding velocities to physically or chemically create a boundary lubricant layer on the load bearing surfaces of the matched components. More specifically, the elevated pressures and increased sliding velocities impart energy into the system that facilitates reaction of the lubricating solutes and solvents with the wear surfaces. The ultimate objective of this stage of the process is to insure the formation of a layer of boundary lubrication that will last throughout the lifetime of the implant. The high pressures and the sliding velocities also function to further harden and increase the wear resistance of the bearing surfaces of the implant.

As a result of the incorporation of the boundary layer lubricant, smooth low friction sliding action of the implant following implantation is insured. Further, as a result of the increased hardening of the wear surfaces at loads and sliding velocity speeds greatly exceeding those to which the implant will be subjected following implantation, particulate generation following implantation is significantly reduced so as to achieve the benefits previously described.

In accordance with still yet another aspect of the present invention, all the processing parameters relating to load, sliding velocities, lubricants and cycling frequencies may be customized to meet the needs of different patients into which the implants will eventually be implanted. Indeed, specific processing procedures will be developed for customizing the implants to be received in patients of differing weights, heights, sexes, levels of activity, skeletal dimensions etc.

In summary, numerous benefits result from employing the concepts of the present invention. Advantageously, the present method of wearing in or breaking in an implant represents a significant advance in the art. More specifically, the volume of wear particulates generated by a total joint orthopaedic implant consisting of two matched articulating components is substantially reduced by the present method. Accordingly, the tissue burden is relieved and the inflammation and pain that might otherwise develop over time are typically avoided. In fact, in many cases an implant processed in accordance with the present method will be received, and will wear, in an almost equilibrium state with the immune system of the patient. Accordingly, the life of the implant is significantly increased and in most cases complicated, costly and painful revision or replacement surgery may be avoided.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiment was chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with breadth to which they are fairly, legally and equitably entitled.

I claim:

1. A total joint orthopaedic implant, comprising: a pair of matched pre-worned articulating components; said components being matched by:
 - placing said total joint orthopaedic implant in a fluid bath; and
 - articulating said total joint orthopaedic implant in the fluid bath for a predetermined number of cycles whereby the total joint orthopaedic implant is pre-worn outside the body of a patient to remove laps, folds and other particulates and provide good surface-to-surface fit and polish so as to reduce the wear particulate burden imposed by said total joint orthopaedic implant on surrounding tissue following implantation and thereby increase overall service life of the total joint orthopaedic implant.
2. A total joint orthopaedic implant, comprising: a pair of matched pre-worned articulating components; said components being matched by:
 - placing said total joint orthopaedic implant in a fluid bath, fluid in said fluid bath having a viscosity between 1-2000 times that of water and being selected from a group consisting of water, fetal calf serum, bovine serum, natural synovial fluid, synthetic synovial fluid and any mixtures thereof;
 - articulating said total joint orthopaedic implant in the fluid bath for a predetermined number of cycles; and
 - establishing a boundary lubrication layer on said total joint orthopaedic implant by including boundary lubricant layer forming solutes in said fluid bath, said solutes being selected from a group consisting of polytetrafluoroethylene, hyaluronic acid, lubricin and any mixtures thereof;
 - whereby the total joint orthopaedic implant is pre-worn outside the body of a patient to remove laps, folds and other particulates and provide good surface-to-

surface fit and polish so as to reduce the wear particulate burden imposed by said total joint orthopaedic implant on surrounding tissue following implantation and thereby increase overall service life of the total joint orthopaedic implant.

3. A total joint orthopaedic implant, comprising: a pair of matched pre-worned articulating components; said components being matched by:
 - placing said total joint orthopaedic implant in a fluid bath, fluid in said fluid bath having a viscosity between 1-2000 times that of water and being selected from a group consisting of water, fetal calf serum, bovine serum, natural synovial fluid, synthetic synovial fluid and any mixtures thereof;
 - articulating said total joint orthopaedic implant in the fluid bath for a predetermined number of cycles; and
 - establishing a boundary lubrication layer on said total joint orthopaedic implant by including boundary lubricant layer forming solutes in said fluid bath, said solutes being selected from a group consisting of polytetrafluoroethylene, hyaluronic acid, lubricin and any mixtures thereof;
 - filtering the fluid in the fluid bath so as to remove particulates being generated; and
 - loading said total orthopaedic joint implant with a force between 0.1-10,000 Newtons;
 - whereby the total joint orthopaedic implant is pre-worn outside the body of a patient to remove laps, folds and other particulates and provide good surface-to-surface fit and polish so as to reduce the wear particulate burden imposed by said total joint orthopaedic implant on surrounding tissue following implantation and thereby increase overall service life of the total joint orthopaedic implant.
4. A total joint orthopaedic implant, comprising: a pair of matched pre-worned articulating components; said components being matched by:
 - placing said total joint orthopaedic implant in a fluid bath fluid, said fluid bath having a viscosity between 1-2000 times that of water and being selected from a group consisting of water, fetal calf serum, bovine serum, natural synovial fluid, synthetic synovial fluid and any mixtures thereof;
 - articulating said total joint orthopaedic implant in the fluid bath for a predetermined number of cycles including cycling the total joint orthopaedic implant at 0.01-100 Hz; and
 - establishing a boundary lubrication layer on said total joint orthopaedic implant by including boundary lubricant layer forming solutes in said fluid bath, said solutes being selected from a group consisting of polytetrafluoroethylene, hyaluronic acid, lubricin and any mixtures thereof;
 - filtering the fluid in the fluid in the fluid bath so as to remove particulates being generated; and
 - loading said total orthopaedic joint implant with a force between 0.1-10,000 Newtons;
 - whereby the total joint orthopaedic implant is pre-worn outside the body of a patient to remove laps, folds and other particulates and provide good surface-to-surface fit and polish so as to reduce the wear particulate burden imposed by said total joint orthopaedic implant on surrounding tissue following implantation and thereby increase overall service life of the total joint orthopaedic implant.
5. A total joint orthopaedic implant, comprising: a pair of matched pre-worned articulating components;

said components being matched by:

placing said total joint orthopaedic implant in a fluid bath; and

articulating said total joint orthopaedic implant in the fluid bath at sliding speeds of between 0.01–2.0 meters per second for a predetermined number of cycles whereby the total orthopaedic joint implant is pre-worn outside the body of a patient to remove laps, folds and other particulates and provide good surface-to-surface fit and polish so as to reduce the wear particulate burden imposed by said total joint orthopaedic implant on surrounding tissue following implantation and thereby increase overall service life of the total joint orthopaedic implant.

6. A total joint orthopaedic implant, comprising:

a pair of matched pre-worned articulating components;

said components being matched by:

articulating the total joint orthopaedic implant during a first stage of processing under a load of substantially 0.1–500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second;

articulating the total joint orthopaedic implant during a second stage of processing under a load of substantially 200–2,500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second; and

articulating the total joint orthopaedic implant during a third stage of processing under a load of substantially 2,500–10,000 Newtons at sliding speeds of 0.5–2.0 meters per second.

7. A total joint orthopaedic implant, comprising:

a pair of matched pre-worned articulating components;

said components being matched by:

articulating the total joint orthopaedic implant during a first stage of processing under a load of substantially 0.1–500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second;

articulating the total joint orthopaedic implant during a second stage of processing under a load of substantially 200–2,500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second;

articulating the total joint orthopaedic implant during a third stage of processing under a load of substantially 2,500–10,000 Newtons at sliding speeds of 0.5–2.0 meters per second; and

establishing a boundary lubrication layer on said total joint orthopaedic implant by including boundary lubricant layer forming solutes in said fluid bath, said solutes selected from a group consisting of polytetrafluoroethylene, hyaluronic acid, lubricin, and any mixtures thereof.

8. A total joint orthopaedic implant, comprising:

a pair of matched pre-worned articulating components;

said components being matched by:

articulating the total joint orthopaedic implant during a first stage of processing under a load of substantially 0.1–500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second;

articulating the total joint orthopaedic implant during a second stage of processing under a load of substan-

tially 200–2,500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second;

articulating the total joint orthopaedic implant during a third stage of processing under a load of substantially 2,500–10,000 Newtons at sliding speeds of 0.5–2.0 meters per second;

establishing a boundary lubrication layer on said total joint orthopaedic implant by including boundary lubricant layer forming solutes in said fluid bath, said solutes selected from a group consisting of polytetrafluoroethylene, hyaluronic acid, lubricin, and any mixtures thereof; and

draining fluid from and replacing fluid in the fluid bath during the articulating and establishing steps.

9. A total joint orthopaedic implant, comprising:

a pair of matched pre-worned articulating components;

said components being matched by:

articulating the total joint orthopaedic implant during a first stage of processing under a load of substantially 0.1–500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second;

articulating the total joint orthopaedic implant during a second stage of processing under a load of substantially 200–2,500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second;

articulating the total joint orthopaedic implant during a third stage of processing under a load of substantially 2,500–10,000 Newtons at sliding speeds of 0.5–2.0 meters per second;

establishing a boundary lubrication layer on said total joint orthopaedic implant by including boundary lubricant layer forming solutes in said fluid bath, said solutes selected from a group consisting of polytetrafluoroethylene, hyaluronic acid, lubricin, and any mixtures thereof;

filtering fluid in the fluid bath so as to remove particulates generated during the articulating and establishing steps; and

draining fluid from and replacing fluid in the fluid bath during the articulating and establishing steps.

10. A total joint orthopaedic implant, comprising:

a pair of matched pre-worned articulating components;

said components being matched by:

articulating the total joint orthopaedic implant during a first stage of processing under a load of substantially 0.1–500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second;

articulating the total joint orthopaedic implant during a second stage of processing under a load of substantially 200–2,500 Newtons at sliding speeds of substantially 0.01–0.5 meters per second;

articulating the total joint orthopaedic implant during a third stage of processing under a load of substantially 2,500–10,000 Newtons at sliding speeds of 0.5–2.0 meters per second; and

varying the load during articulating to simulate the load placed upon the total joint orthopaedic implant by a patient during actual use following implantation.

* * * * *