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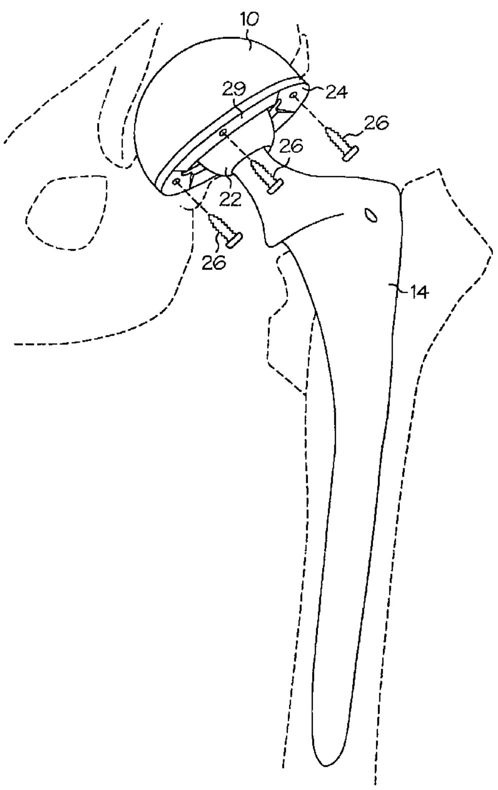
(54) Title: BIOLOGICALLY REABSORBABLE ACETABULAR CONSTRAINING COMPONENTS AND MATERIALS FOR USE WITH A HIP REPLACEMENT PROSTHESIS AND BIOREABSORBABLE MATERIALS TO AUGMENT HIP REPLACEMENT STABILITY AND FUNCTION



(57) Abstract: A prosthetic constraining device (24, 30, 32) for use with a hip replacement where a femoral stem (14) includes a ball (22) component at its proximalend received within an acetabular cup assembly (109 to form a ball joint type coupling, and where the constraining device (249 includes a ring having a central aperture, where the ring is adapted to be mounted to a rim of the acetabular cup assembly so that the femoral stem passes through the central aperture, where the diameter of the central aperture is less than the diameter of the ball component on the proximal end of the femoral stem, and where the ring (24) comprises a biological material, a biologically reabsorbable material and a combination of biologic, or biologically reabsorbable materials. Further embodiments of constraining devices for use with hip joints are disclosed; A mesh or webbing (30) used to hold the neck region of the femoral component (14), and a paste or glue (32) directed in proximity to the neck of a prosthesis and an acetabulum.

WO 03/086243 A2

PCT PATENT APPLICATION

Title: **BIOLOGICALLY REABSORBABLE ACETABULAR CONSTRAINING COMPONENTS AND MATERIALS FOR USE WITH A HIP REPLACEMENT PROSTHESIS AND BIOREABSORBABLE MATERIALS TO AUGMENT HIP REPLACEMENT STABILITY AND FUNCTION**

REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application Serial No. 60/371,058, entitled "BIOLOGICALLY ABSORBABLE ACETABULAR CONSTRAINING COMPONENTS AND MATERIALS FOR USE WITH A HIP REPLACEMENT PROSTHESIS AND BIOABSORBABLE MATERIALS TO AUGMENT HIP REPLACEMENT STABILITY AND FUNCTION", filed on April 9, 2002, and U.S. Non-Provisional Patent Application Serial No. 10/392,553, entitled "BIOLOGICALLY ABSORBABLE ACETABULAR CONSTRAINING COMPONENTS AND MATERIALS FOR USE WITH A HIP REPLACEMENT PROSTHESIS AND BIOABSORBABLE MATERIALS TO AUGMENT HIP REPLACEMENT STABILITY AND FUNCTION", filed on March 20, 2003, the disclosures of which are incorporated herein by reference.

BACKGROUND

Field of the Invention.

[0002] The present invention is directed toward constraining components for use with joints of the body. Examples of such joints include hip joints, shoulder joints, elbow joints, and ankle joints. More specifically, aspects of the present invention are directed toward biologic and biologically reabsorbable acetabular constraining components to at least temporarily augment the stability and function of the joint after repair or replacement surgery.

Background of the Invention.

[0003] Fig. 1 illustrates a prior art hip replacement prosthesis which includes an acetabular cup/shell **10** bonded to the pelvis **12** of a patient and a femoral component **14** or stem bonded to the patient's femur **16** where the acetabular cup/shell **10** and femoral component **14** are coupled together with a ball joint-type coupling **18**. Fig. 2 illustrates a side view of the acetabular shell **10** bonded to the patient's pelvis **12**. The acetabular shell includes a polyethylene, metal, or ceramic insert **20** seated therein.

[0004] A frequent complication with prior art hip replacement prosthetic components is dislocation of the ball **22** of the femoral component **14** from the acetabular shell **10**. Prior art attempts to overcome this problem utilize constraining mechanisms, such as locking rings. However, such constraining mechanisms may tend to limit hip range of motion permanently, may not allow for normal pari-articular scarring to occur to optimize long-term hip stability and range of motion, and may also increase stress transmission to the fixation interfaces of the acetabular shell **10** over time promoting mechanical breakdown of ingrowth or cement and/or locking mechanism failure between the acetabular shell **10** and polyethylene insert **20** resulting in backside acetabular wear.

SUMMARY

[0005] The present invention is directed to constraining devices that assist in inhibiting dislocation of a ball aspect of a prosthetic hip joint after surgery. Certain aspects of the present invention are directed to the use of a constraining mechanism for a prosthetic hip implant that is made of biologic and/or biologically reabsorbable material affixed between the acetabular cup and the femoral component of a hip prosthesis. Further aspects of the present invention are directed toward the use of biologic and/or biologically reabsorbable material to increase the rate of tissue formation (such as scar tissue formation) and subsequent time to host stability about the total hip replacement. Further aspects of the present invention are directed to the use of a biologic and/or biologically reabsorbable paste or glue material (either alone or in combination with any of the above aspects) to increase the rate of scar tissue formation and subsequent host stability about the hip joint after total hip replacement. Further aspects of the present invention are directed to the impregnation of helpful agents to any of the above biologic and biologically reabsorbable materials such as a clotting agent, a scarring agent, a preventative bone formation agent (anti-heterotopic ossification), a non-steroidal antiinflammatory drug (NSAID), and/or an antibiotic. Further aspects of the present invention are directed to the use of a biologic and/or biologically reabsorbable stabilizer that could span from the acetabulum and be fixed to the neck of the femoral component to act like a rubber band allowing motion of the femoral component while eventually scaring to provide permanent stability, used alone or in combination with any of the other aspects described above. Further aspects of the present invention are directed to the use of biologically reabsorbable screws or other fasteners to attach a constraining mechanism to the acetabular cup/shell (used either alone or in combination with any of the above aspects). Further aspects of the present invention are directed to the use of biologically reabsorbable mesh or webbing to retain the femoral component to the acetabulum or acetabular cup/shell component, used either alone or in combination with any of the above aspects.

[0006] Particular embodiments make use of constraining rings having geometries that are specifically adapted to provide the range of motion desired by patients after surgery, but with the additional benefit of doing so without substantially increasing the risks of impingement on the femoral component neck at the extremes of motion or dislocation and additional surgery to repair the dislocation. At least one of the exemplary embodiments utilizes a biologically reabsorbable material to temporarily inhibit such dislocation, allowing the physician to position and/or rotate the constraining device to reduce impingement and increase the available range of motion desirable in at least one axial direction. In such an embodiment, it is envisioned that the biologically reabsorbable material degrades in general proportion to the level of tissue developed by the patient's own body to supplement stability of the hip joint and inhibit dislocation. Thus, as the patient's need for an artificial constraining device decreases, so too does the artificial constraining device itself.

[0007] It is an aspect of the present invention to provide a prosthetic constraining device for use with a hip replacement prosthesis that includes an acetabular cup assembly adapted to be bonded to a patient's pelvis and a femoral stem adapted to be bonded to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, and where the constraining device includes a ring having a central aperture, where the ring is adapted to be mounted to a rim of the acetabular cup assembly so that the femoral stem passes through the central aperture, where the diameter of the central aperture is less than the diameter of the ball component on the proximal end of the femoral stem so that the ring assists in maintaining the ball joint type coupling between the acetabular cup assembly and the femoral stem, and where the ring comprises a biologic material, a biologically reabsorbable material or a combination of biologic, and biologically reabsorbable materials.

[0008] It is a second aspect of the present invention to provide a prosthetic hip prosthesis that includes: an acetabular cup assembly adapted to be bonded to a patient's pelvis; a femoral stem adapted to be bonded to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling; and, a constraining ring having a central aperture, mounted to a rim of the acetabular cup assembly so that the femoral stem passes through the central aperture, where the diameter of the central aperture is less than the diameter of the ball component on the proximal end of the femoral stem so that the ring assists in maintaining the ball joint type coupling between the acetabular cup assembly and the femoral stem, and where the constraining ring comprises a biologic material, a biologically reabsorbable material, or a combination of biologic and biologically reabsorbable materials.

[0009] It is a third aspect of the present invention to provide a prosthetic constraining device for implantation in proximity to a hip joint that includes an arcuate body defining a central aperture for allowing a femoral component to extend therethrough, where the arcuate body includes a distal surface having at least one depression extending radially thereacross to provide an increased range of angular motion of the femoral component, and including a proximal surface adapted to be mounted to an acetabular prosthesis, an acetabular bone, and/or an innominate bone to help prevent a femoral head of the femoral component from completely passing distally through the aperture.

[0010] It is a fourth aspect of the present invention to provide a constraining device for, at least temporarily, maintaining engagement of a prosthetic femoral stem component with a prosthetic acetabular component of a prosthetic hip assembly, where the constraining device comprises a biologic material, a biologically reabsorbable material, or a combination of biologic and biologically reabsorbable materials.

[0011] It is a fifth aspect of the present invention to provide an implantable constraining device for, at least temporarily, maintaining the integrity of a hip joint, where the constraining device comprises a biologic material, a biologically reabsorbable material, or a combination of biologic and biologically reabsorbable materials.

[0012] It is a sixth aspect of the present invention to provide a constraining device for implantation in proximity to a hip joint that includes a plate comprising at least one biologically reabsorbable material, having an aperture extending therethrough for allowing a femoral component to extend therethrough, where the plate includes a distal surface having at least one depression accommodating an increased range of angular motion of the femoral component, and includes a proximal surface adapted to be mounted to an acetabular prosthesis, an acetabular bone, and/or an innominate bone to assist in inhibiting a femoral head of the femoral component from completely passing distally through the aperture.

[0013] A seventh aspect of the present invention is directed to a method for providing at least temporary stability to a prosthetic hip joint which includes an acetabular cup assembly bonded to a patient's pelvis and a femoral stem bonded to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling. The method includes the step of mounting a constraining device to the prosthetic hip joint to provide stability to the prosthetic hip joint, where the constraining device comprises a biologic material, a biologically reabsorbable material, or a combination of biologic and biologically reabsorbable materials.

BRIEF DESCRIPTIONS OF THE DRAWINGS

[0014] Fig. 1 is a perspective view of a prior art femoral prosthesis fitted within a prior art acetabulum prosthesis.

[0015] Fig. 2 is a side representative view of a prior art acetabulum prosthesis implanted within the pelvis;

[0016] Fig. 3 is a cross-sectional, side elevational view taken along lines 3-3 of Fig. 4;

[0017] Fig. 4 is a top plan view of a first exemplary embodiment of the present invention;

[0018] Fig. 5 is a perspective view of the first exemplary embodiment of the present invention being mounted to the acetabular prosthetic cup;

[0019] Fig. 6 is a top plan view of one of many possible alternate configurations for the first exemplary embodiment of the present invention;

[0020] Fig. 7 is a perspective view of a second exemplary embodiment of the present invention mounted to the acetabular prosthetic cup and the femoral component; and

[0021] Fig. 8 is a sectional view of a third exemplary embodiment of the present invention positioned in proximity to the acetabular prosthetic cup and the femoral component.

[0022] Fig. 9 is a cross sectional view of an alternate exemplary embodiment of the present invention positioned in proximity to the acetabular prosthetic cup and the femoral component.

DESCRIPTION OF THE PRESENT INVENTION

[0023] The exemplary embodiments described herein relate to constraining devices, materials and techniques for use in hip replacement surgery. It will, of course, be apparent to those of ordinary skill in the art that the devices, materials and techniques disclosed herein may be useful for other types of implants and orthopedic surgeries.

[0024] As shown in Figs. 3-5, a first exemplary embodiment of the present invention is a constraining ring **24** adapted to be mounted on a distal end of the acetabular shell **10** (see Fig. 5) for maintaining the ball **22** of the femoral component **14** within the acetabular shell **10**. The constraining ring **24** is comprises a biologic and/or a biologically reabsorbable material that provides temporary stability to the hip joint for varying times until live tissue (such as scar tissue) forms and replaces the biologic and/or biologically reabsorbable material or stability is achieved through normal host compensatory mechanisms.

[0025] In an exemplary procedure, a physician would position the constraining ring **24** around the neck of the femoral component **14** and thereafter attach the ball **22** to the end of the neck of the femoral component **14**. This effectively maintains the position of the constraining ring **24** between the ball **22** and the base of the neck, as the cross section of the opening of the constraining ring **24** does not accommodate throughput of the ball **22** or the base of the neck of the femoral component **14**. After the physician has seated the ball **22** in the acetabular insert **20**, the constraining ring **24** is mounted onto the distal rim of the acetabular shell **10** with reabsorbable fasteners, such as, without limitation, clips, snaps, screws, sutures, and rivets **26**. It is likewise possible that the constraining ring **24** be mounted to the acetabular bone or the innominate bone, or to the acetabular insert **20**.

The constraining ring **24** acts to inhibit post-operative dislocation of the ball **22** from the acetabular shell **10**.

[0026] The reabsorbable constraining ring **24** of this exemplary embodiment includes angled cut out regions **28** (or cut-away regions) formed into the distal end of the constraining ring **24** and positioned radially on the anterior/superior and posterior/superior portions of the constraining ring **24** to improve range of motion for the femoral component **14**, while inhibiting dislocation. Typically, these cut out regions **28** would be positioned anteriorly to mitigate posterior dislocation when the hip is flexed and internally rotated. Conversely, these cut out regions **28** may be located posteriorly to mitigate anterior dislocation by inhibiting posterior impingement when the hip is externally rotated and extended. Further, the constraining ring **24** may also have an elevation(s) **29** that may be positioned to further augment stability. The interior surface of the constraining ring **24** may be contoured to better approximate the contour of the ball **22**, exhibiting generally greater cross section from proximal to distal end. In other words, the constraining ring **24** includes an inner surface that is substantially dome-shaped terminating at the aperture and having a diameter that narrows with the distance away from the proximal surface of the constraining ring **24**.

[0027] In this exemplary embodiment, the constraining ring **24** will be absorbed over a relatively short period (i.e., several weeks or months) and be replaced by tissue (such as scar tissue) that provides for long-term hip stability and, hopefully, normal range of motion.

[0028] Examples of biologic materials for use with the constraining ring **24** include, without limitation, extra cellular matrices (ECMs). Examples of ECMs include, without limitation, porcine small intestine submucosa (SIS), xenogeneic small intestine submucosa (xSIS), urinary bladder submucosa (UBS), laminated intestinal submucosa, glutaraldehyde-treated bovine pericardium (GLBP). The biologic materials may be layered, molded, formed, braided, perforated, multilaminated, grafted or otherwise manipulated to achieve the desired properties and dimensions associated with the constraining ring **24**.

[0029] Examples of biologically reabsorbable materials for use with the constraining ring **24** include, without limitation, MONOCRYL (poliglecaprone 25), PDS II (polydioxanone), surgical gut suture (SGS), gut, coated VICRYL (polyglactin 910, polyglactin 910 braided), human autograft tendon material, collagen fiber, POLYSORB, poly-L-lactic acid (PLLA), polylactic acid (PLA), polylactides (Pla), racemic form of polylactide (D,L-Pla), poly(L-lactide-co-D,L-lactide), 70/30 poly(L-lactide-co-D,L-lactide), polyglycolides (PGa), polyglycolic acid (PGA), polycaprolactone (PCL), polydioxanone (PDS), polyhydroxyacids, and resorbable plate material (see e.g. Orthopedics, October 2002, Vol. 25, No. 10/Supp.). The biologically reabsorbable materials may be layered, molded, formed, braided, perforated, multilaminated, grafted or otherwise manipulated to achieve the desired properties and dimensions associated with the constraining ring **24**. For example, the MONOCRYL (poliglecaprone 25), PDS II (polydioxanone), and resorbable plate materials may be block formed, while the surgical gut suture (SGS), gut, coated VICRYL (polyglactin 910), human autograft tendon material, collagen fiber, POLYSORB, poly-L-lactic acid (PLLA), polylactic acid (PLA), polyglycolic acid, and porcine small intestinal submucosa (SIS) material may be layered and formed. It is within the scope and spirit of the present invention that any of the above materials and techniques may be used individually, alternatively, or in conjunction to produce the constraining ring **24**.

[0030] Exemplary materials comprising the biologically reabsorbable screws **26** include, without limitation, poly-L-lactic acid (PLLA) and collagen. As will be apparent to those of ordinary skill in the art, there are many other biologic and/or biologically reabsorbable materials that can be used for the constraining ring **24** or screws **26**, all of which and others developed hereafter fall within the scope of the invention.

[0031] It is also within the scope of the present invention to "load" (disburse, coat, impregnate, etc.) the biologic and/or biologically reabsorbable material comprising the constraining ring **24** with agents that could hasten or assist in tissue development, prevent unwanted bone formation (including heterotopic ossification), and/or fight infection. Exemplary agents include, for example, without limitation, concentrated platelets (SYMPHONY from Depuy Orthapedic) and gentamicin.

[0032] Fig. 6 illustrates an alternate exemplary embodiment of the constraining ring **24**, having an alternate screw-hole **34** pattern, angled cut out region **28** pattern, and elevation **29** pattern.

[0033] In another alternate exemplary embodiment, as shown in Fig. 7, biologic and/or biologically reabsorbable mesh or webbing **30** could be used to hold the mid-neck region of the femoral component **14** to the acetabular shell **10** or to the acetabulum. Examples of biologic and biologically reabsorbable mesh or webbing materials for use in the present embodiment include, without limitation, extra cellular matrices (ECMs). Examples of ECMs include, without limitation, porcine small intestine submucosa (SIS), xenogeneic small intestine submucosa (xSIS), urinary bladder submucosa (UBS), laminated intestinal submucosa, glutaraldehyde-treated bovine pericardium (GLBP), VICRYL (polyglactin 910), collagen, and natural gut. (See e.g. Tissue Engineering, Feb. 2002, pp.63-71; Tissue Engineering, Jun. 2001, pp.321-34; J. Biomed. Material Resources, Nov. 2000, pp. 365-73; J Biomed Material Resources, Jul. 2001, pp. 101-8; Arthroscopy, Feb. 2001, pp. 151-9; Endothelium, 2001, pp. 11-24; Biomaterials, Oct. 2001, pp.2653-9; J. Surg. Res., Aug. 1997, pp. 179-86). By way of example, porcine small intestinal submucosa (SIS) may act as scaffolding for ingrowth of connecter tissue between the acetabular shell **10** and femoral component **14**. The mesh **30** may be attached between the femur and/or femoral component **14** (including the neck and ball **22**) and at least one of the constraining ring **24**, acetabular shell **10**, acetabular insert **20**, or surrounding bone. Attachment of the mesh **30** to any of the above components could be accomplished by way of suture, suture anchor, screw, rivet, or any other effective fastening mechanism or procedure. An exemplary mounting procedure might include a circumferential channel within the neck of the femoral component **14** being lined by a suture incorporated into the mesh **30**, with the suture drawn taught around the neck of the femoral component **14** mounting the mesh **30** thereto. Opposite the femoral component, the mesh **30** may be mounted to the acetabular insert **20** of the acetabular shell **10** with suture anchors. The mesh **30** may be used separately or in combination with the constraining ring **24** discussed above. Again, it will be apparent to those of ordinary skill in the art there are many other biologic and/or biologically reabsorbable materials that can comprise the mesh **30**, all of which currently developed and hereafter developed fall within the scope of the invention.

[0034] Another exemplary embodiment, as shown in Fig. 8, includes a biologically reabsorbable paste/glue **32** that rapidly converts into tissue (such as scar tissue). The paste/glue **32** is directed in proximity to the neck of the prosthesis and acetabulum and allows patients to decrease the time that they would need to abide by their post-operative hip precautions (such as no tying shoes, donning socks or toenail care). Typically, these precautions prevent the patient from doing any activities that require greater hip flexion than 90°. Examples of materials comprising the biologically reabsorbable paste **32** of the present invention include, for example, without limitation, porcine small intestinal submucosa (SIS) and VICRYL (polyglactin 910). The use of SIS, for example, in a paste form positioned in proximity to the neck region of the prosthesis nearing the end of the arthroplasty could stimulate more rapid tissue formation and substantially decrease the time period before patients could return to normal activities of daily living. It is also within the scope of the invention that agents such as antibiotics and/or clotting agents discussed above could also be added to the paste **32** to decrease the risk of infection in a similar fashion as physicians presently impregnate cement with antibiotics. The paste **32** enables efficient direct delivery of prophylactic antibiotics to the hip joint.

[0035] Referencing FIG. 9, a fourth exemplary embodiment of the present invention includes a constraining ring **24'** having a bladder **34** manipulatable to arrive at the cut out regions and the elevations **29'** for inhibiting dislocation of the ball **22** from the acetabular insert **20**. The constraining is attached to at least one of the acetabular shell, acetabular bone, or to the acetabular insert, through various forms of attachment discussed above, including rivets **26**. The bladder **34** may be configured to receive a reabsorbable fluid material injected therein that rapidly transitions to a solid state, thereby expanding at certain locations to provide one or more elevations **29'**, and providing little or no expansion to accommodate one or more cut out regions. The transition time between liquid and solid state may further enable a physician to custom mold the bladder **34** to inhibit luxation and minimize impingement. Likewise, the constraining ring **24'** may have a plurality of bladders **34** to create two or more elevations **29'**. It is within the scope of the invention that the bladder **34** be porous, biologic or biologically absorbable, or a combination of these. Further, it is within the scope of the invention that the bladder **34** and/or the contents include one or more agents to promote tissue formation, fight infection, and promote clotting.

[0036] With each of the above embodiments, it is within the scope of the invention to incorporate growth stimulating factors with the biologic or biologically reabsorbable materials. These could be incorporated into a bioreabsorbable paste or moldable scaffolding to provide a three dimensional framework for the creation of tissue engineered scar mass inhibiting dislocation of the femoral component **14**. Examples of such growth stimulating factors include, without limitation, growth factor beta (GFB-β), basic fibroblast growth factor (bFGF), fibroblast growth factor (FGF), epidermal growth factor (EFG), transforming growth factor-β1 (TGF-β1), vascular endothelial growth factor (VEGF), connective tissue growth factor (CTGF), platelet-derived growth factor (PDGF), direct-mediated gene transfer, fibroblast-mediated gene transfer, myoblast-mediated gene transfer,TGF-β gene family, adenovirus-mediated gene transfer, recombinant adenovirus-induced tendon adhesion formation, BMP-12, bone morphogenetic protein-2 gene transfer, growth and differentiation factor-5 (GDF-5) and, insulin like growth factor (IFG). (See e.g. Koski et al., "Tissue-Engineered Ligament---Cells, Matrix, and Growth Factors", July 2000 Tissue Engineering in Orthopedic

Surgery, Volume 31, No. 3), (see e.g., Boyer, "Using Growth Factors to Enhance Tendon and Ligament Repair", Orthopaedic Research Society Symposia, AAOS Annual Meeting New Orleans February 2003). Several of these growth factors have been proposed as possible mitogens in fibroblast growth.

[0037] It is also within the scope of the invention to incorporate connective tissue stem cells and progenitors with the biologic or biologically reabsorbable materials disclosed in the above embodiments. These connective tissue stem cells and progenitors may be incorporated into a bioreabsorbable paste **32** or moldable scaffolding to provide a three dimensional framework for the creation of engineered tissue for, in an exemplary application, inhibiting dislocation of the femoral component **14**. Examples of such connective tissue stem cells and progenitors include, without limitation, fibroblastic colony-forming cells, fibroplast colony-forming units (CFU-F), bone marrow stromal cells, mesenchymal stem cells (MSC), and vascular pericytes. (See e.g. Meschler et al. "Connective Tissue Progenitors: Practical Concepts for Clinical Applications", 2002 Clinical Orthopaedics and Related Research, No. 395, pp. 66-80).

[0038] It is also within the scope of the invention to incorporate hematopoietic stem cells and progenitors with the biologic or biologically reabsorbable materials disclosed in the above embodiments. These hematopoietic stem cells and progenitors may be incorporated into a reabsorbable paste or moldable scaffolding to provide any cell making up circulating blood and the immune system for, in an exemplary application, inhibiting infection after surgery.

[0039] It is also within the scope and spirit of the present invention to provide a constraining ring **24** as described herein comprising a biologically non-absorbable material, such as, without limitation, polymers, metals, ceramics, resins, and composites.

[0040] Constraining rings **24** comprising biologically non-absorbable materials may be mounted in a like manner as a reabsorbable constraining ring, but with non-absorbable fasteners, such as, without limitation, clips, snaps, screws, sutures, glues or rivets. These non-absorbable constraining rings **24** may have a planar distal surface that includes one or more depressions positioned axially thereabout for increasing the angular range of motion of the femoral component **14**. In such a configuration, the axial range of motion of the femoral component **14** may be maintained in all 360° without substantially changing the amount of surface area in contact between the neck of the femoral component **14** and the distal surface of the constraining ring **24**. Such constraining rings **24** may also include elevations **29** as discussed above.

[0041] It is additionally within the scope and spirit of the present invention to provide a constraining ring **24** comprising a biologic, biologically reabsorbable, and/or biologically non-absorbable material that allows a physician to manipulate the cut out regions **28** and the elevations **29** approximate the cut out regions **28** before and during surgery to better accommodate the patient's unique biomechanics as a result of the hip surgery. An exemplary embodiment may enable manipulation of the elevations **29** and cut out regions **28** by providing a keyway with segmented elevations **29** and cut out regions **28** moving therein. Likewise, an exemplary elevation **29** might be manipulatable by mounting a biologic, biologically reabsorbable, and/or biologically non-absorbable material in the form of a contoured augment onto the distal surface of the constraining ring **24**. It is likewise within the scope and spirit of the present invention to allow a physician to manipulate the dimensions and locations of biologic and/or biologically reabsorbable fasteners (such as a clip, snap, screw, suture, keyway, or rivet) utilized to secure the constraining ring **24**, elevations **29**, or mesh **30** to any of the above structural components.

[0042] It is further within the scope and spirit of the present invention to provide a constraining ring **24** having a non-circular aperture. Likewise it is within the scope and spirit of the present invention to provide a constraining ring **24** having a non-circular cross section.

[0043] Following from the above description and invention summaries, it should be apparent to those of ordinary skill in the art that, while the apparatuses and methods herein described constitute exemplary embodiments of the present invention, it is to be understood that the inventions contained herein are not limited to these precise embodiments and that changes may be made to them without departing from the scope of the inventions as defined by the claims. Additionally, it is to be understood that the invention is defined by the claims and it is not intended that any limitations or elements describing the exemplary embodiments set forth herein are to be incorporated into the meanings of the claims unless such limitations or elements are explicitly listed in the claims. Likewise, it is to be understood that it is not necessary to meet any or all of the identified advantages or objects of the invention disclosed herein in order to fall within the scope of any claims, since the invention is defined by the claims and since inherent and/or unforeseen advantages of the present invention may exist even though they may not have been explicitly discussed herein.

[0044] What is claimed is:

1. A prosthetic constraining device for use with a hip replacement prosthesis that includes an acetabular cup assembly adapted to be bonded to a patient's pelvis and a femoral stem adapted to be bonded to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, the constraining device comprising:

a ring having a central aperture, the ring being adapted to be mounted to a rim of the acetabular cup assembly so that the femoral stem passes through the central aperture, the diameter of the central aperture being less than the diameter of the ball component on the proximal end of the femoral stem so that the ring assists in maintaining the ball joint type coupling between the acetabular cup assembly and the femoral stem;

the ring comprises a ring material taken from the group consisting of a biologic material, a biologically reabsorbable material, and a combination of biologic and biologically reabsorbable materials.

2. The prosthetic constraining device of claim 1, further comprising a plurality of fasteners for mounting the ring to the rim of the acetabular cup assembly, wherein the fasteners comprise a fastener material taken from the group consisting of a biologic material, a biologically reabsorbable material, and a combination of biologic and biologically reabsorbable materials.

3. The prosthetic constraining device of claim 2, wherein the fastener material includes at least one, or an equivalent, of:

a poly-L-lactic acid material; and
collagen.

4. The prosthetic constraining device of claim 2, wherein the fasteners are taken from the group consisting of screws, snaps, sutures, clips, and rivets.

5. The prosthetic constraining device of claim 1, wherein the ring material includes at least one, or an equivalent, of:

extra cellular matrices (ECMs);
poliglecaprone 25;
polydioxanone;
surgical gut suture (SGS);
gut;
polyglactin 910;
human autograft tendon material;
collagen fiber;
poly-L-lactic acid (PLLA);
polylactic acid (PLA);
polylactides (Pla);
racemic form of polylactide (D,L-Pla);
poly(L-lactide-co-D,L-lactide);
polyglycolides (PGa);
polyglycolic acid (PGA);
polycaprolactone (PCL);
polydioxanone (PDS);
polyhydroxyacids; and
resorbable plate material

6. The prosthetic constraining device of claim 5, wherein the extra cellular matrices (ECMs) includes at least one of:

porcine small intestine submucosa (SIS);
xenogeneic small intestine submucosa (xSIS);
urinary bladder submucosa (UBS);
laminated intestinal submucosa; and
glutaraldehyde-treated bovine pericardium (GLBP).

7. The prosthetic constraining device of claim 1, wherein the ring includes a distal surface having at least a first depression extending radially thereacross to provide an increased range of angular motion of the femoral stem.

8. The prosthetic constraining device of claim 7, wherein the first depression is located in at least one of the anterior/superior and posterior/superior regions of the ring when the ring is mounted to the acetabular cup assembly.

9. The prosthetic constraining device of claim 8, wherein the distal surface of the ring has at least a second depression extending radially thereacross to provide increased range of angular motion of the femoral stem in at least two directions.

10. The prosthetic constraining device of claim 9, wherein the first depression is located in the anterior/superior region and the second depressions is located in posterior/superior region of the ring when the ring is mounted to the one acetabular cup assembly.

11. The prosthetic constraining device of claim 10, wherein the aperture includes an inner surface that is substantially dome-shaped, having a diameter that narrows with the distance from the proximal surface of the ring.

12. The prosthetic constraining device of claim 7, wherein the circumferential width of the first depression is at least slightly larger than a diameter of a neck of the femoral stem.

13. The prosthetic constraining device of claim 7, wherein the distal surface of the ring further includes an elevated section to reduce angular movement of the femoral stem in the radial direction of the elevated section.

14. The prosthetic constraining device of claim 13, wherein the elevated section is located in the posterior region of the ring when the constraining device is mounted to the acetabular cup assembly.

15. The prosthetic constraining device of claim 7, wherein the aperture includes an inner surface that is substantially dome-shaped, having a diameter that narrows with the distance from the proximal surface of the ring.

16. The prosthetic constraining device of claim 1, wherein the ring material is loaded with an agent to promote the formation of scar tissue.

17. The prosthetic constraining device of claim 1, wherein the ring material is loaded with an antibacterial agent.

18. The prosthetic constraining device of claim 1, wherein the ring material is loaded with an agent to limit the formation of bone tissue.

19. The prosthetic constraining device of claim 1, wherein the ring material is loaded with at least one of connective tissue stem cells and connective tissue stem cell progenitors.

20. The prosthetic constraining device of claim 19, wherein the connective tissue stem cells and connective tissue stem progenitors are taken from the group consisting of: fibroblastic colony-forming cells, fibroplast colony-forming units (CFU-F), bone marrow stromal cells, mesenchymal stem cells (MSC), and vascular pericytes. .

21. The prosthetic constraining device of claim 1, wherein the ring material is loaded with a growth stimulating factor.

22. The prosthetic constraining device of claim 21, wherein the growth stimulating factor is taken from the group consisting of: growth factor beta (GFB-β), basic fibroblast growth factor (bFGF), fibroblast growth factor (FGF), epidermal growth factor (EFG), transforming growth factor-β1 (TGF-β1), vascular endothelial growth factor (VEGF), connective tissue growth factor (CTGF), platelet-derived growth factor (PDGF), direct-mediated gene transfer, fibroblast-mediated gene transfer, myoblast-mediated gene transfer,TGF-β gene family, adenovirus-mediated gene transfer, recombinant adenovirus-induced tendon adhesion formation, BMP-12, bone morphogenetic protein-2 gene transfer, growth and differentiation factor-5 (GDF-5), and insulin like growth factor (IFG).

23. The prosthetic constraining device of claim 1, wherein the ring material is loaded with at least one of hematopoietic stem cells and hematopoietic stem cells progenitors.

24. The prosthetic constraining device of claim 1, further comprising a bladder operatively coupled to the ring.

25. The prosthetic constraining device of claim 24, wherein the bladder is porous and adapted to contain at least one of a clotting agent, an antibiotic agent, and a scar tissue promoter.

26. The prosthetic constraining device of claim 24, wherein the bladder is reabsorbable and contains at least one of a clotting agent, an antibiotic agent, and a scar tissue promoter.

27. A prosthetic hip prosthesis comprising:

an acetabular cup assembly adapted to be bonded to a patient's pelvis;

a femoral stem adapted to be bonded to the patient's femur, the femoral stem including a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling; and a constraining ring having a central aperture, mounted to a rim of the acetabular cup assembly so that the femoral stem passes through the central aperture, the diameter of the central aperture being less than the diameter of the ball component on the proximal end of the femoral stem so that the ring assists in maintaining the ball joint type coupling between the acetabular cup assembly and the femoral stem;

the constraining ring comprises a ring material taken from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically reabsorbable materials.

28. The prosthetic hip prosthesis of claim 27, further comprising a plurality of fasteners mounting the constraining ring to the rim of the acetabular cup assembly, wherein the fasteners comprise a fastener material taken from the group consisting of a biologic material, a biologically reabsorbable material, and a combination of biologic and biologically reabsorbable materials.

29. The prosthetic hip prosthesis of claim 27, wherein the constraining ring includes a distal surface having at least a first depression extending radially thereacross to provide an increased range of angular motion of the femoral stem.

30. The prosthetic hip prosthesis of claim 29, wherein the first depression is located in at least one of the anterior/superior and posterior/superior regions of the constraining ring.

31. The prosthetic hip prosthesis of claim 30, wherein the distal surface of the constraining ring has at least a second depression extending radially thereacross to provide increased range of angular motion of the femoral stem in at least two directions.

32. The prosthetic hip prosthesis of claim 31, wherein the first depression is located in the anterior/superior region and the second depressions is located in posterior/superior region of the constraining ring.

33. The prosthetic hip prosthesis of claim 32, wherein the aperture includes an inner surface that is substantially dome-shaped, having a diameter that narrows with the distance from the proximal surface of the constraining ring.

34. The prosthetic hip prosthesis of claim 27, wherein the distal surface of the constraining ring further includes an elevated section to reduce angular movement of the femoral stem in the radial direction of the elevated section.

35. The prosthetic hip prosthesis of claim 34, wherein the elevated section is located in the posterior region of the constraining ring.

36. The prosthetic hip prosthesis of claim 27, wherein the ring material is loaded with an agent to promote the formation of scar tissue.

37. The prosthetic hip prosthesis of claim 27, wherein the ring material is loaded with an antibacterial agent.

38. The prosthetic hip prosthesis of claim 27, wherein the ring material is loaded with an agent to limit the formation of bone tissue.

39. A prosthetic constraining device for implantation in proximity to a hip joint, comprising an arcuate body defining a central aperture for allowing a femoral component to extend therethrough, the arcuate body including a distal surface having at least one depression extending radially thereacross to provide an increased range of angular motion of the femoral component, and including a proximal surface adapted to be mounted to at least one of an acetabular prosthesis, an acetabular bone, and an innominate bone to prevent a femoral head of the femoral component from completely passing distally through the aperture.

40. The constraining device of claim 39, wherein the depression is located in at least one of an anterior/superior and posterior/superior region of the arcuate body when the constraining device is mounted to the one acetabular prosthesis, acetabular bone and innominate bone.

41. The constraining device of claim 40, wherein the distal surface has at least two of the depressions extending radially thereacross to provide increased range of angular motion of the femoral component in at least two directions.

42. The constraining device of claim 41, wherein the first depression is located in the anterior/superior region and the second depression is located in the posterior/superior region of the arcuate body when the constraining device is mounted to the one acetabular prosthesis, acetabular bone and innominate bone.

43. The constraining device of claim 41, wherein the arcuate body is substantially annular.

44. The constraining device of claim 43, wherein the aperture includes an inner surface that is substantially dome-shaped, having a diameter that narrows with the distance from the proximal surface of the arcuate body.

45. The constraining device of claim 44, wherein the depression includes a step change in height with respect to the distal surface of the arcuate body.

46. The constraining device of claim 39, wherein the proximal surface of the arcuate body is adapted to be mounted to an acetabular prosthesis component, and the composition of material comprising the arcuate body and the acetabular prosthesis component are substantially the same.

47. The constraining device of claim 39, wherein the circumferential width of the depression is at least slightly larger than a diameter of a neck of the femoral component.

48. The constraining device of claim 39, wherein the distal surface of the arcuate body further includes an elevated section to reduce angular movement of the femoral component in the radial direction of the elevated section.

49. The constraining device of claim 48, wherein the elevated section is located in the posterior region of the arcuate body when the constraining device is mounted to the one acetabular prosthesis, acetabular bone and innominate bone.

50. The constraining device of claim 39, wherein the arcuate body is substantially annular.

51. The constraining device of claim 39, wherein the aperture includes an inner surface that is substantially dome-shaped, having a diameter that narrows with the distance from the proximal surface of the arcuate body.

52. The constraining device of claim 39, wherein the proximal surface of the arcuate body is adapted to be mounted to an acetabular prosthesis component, and the composition of material comprising the arcuate body and the acetabular prosthesis component are substantially the same.

53. A constraining device for, at least temporarily, maintaining engagement of a prosthetic femoral stem component with a prosthetic acetabular component of a prosthetic hip assembly, the constraining device comprises a material taken from the group consisting of a biologic material, a biologically reabsorbable material, and a combination of biologic and biologically reabsorbable materials.

54. The constraining device of claim 53, wherein the material includes at least one, or an equivalent, of:

extra cellular matrices (ECMs);
poliglecaprone 25;
polydioxanone;
surgical gut suture (SGS);
gut;
polyglactin 910;
human autograft tendon material;
collagen fiber;
poly-L-lactic acid (PLLA);
polylactic acid (PLA);
polylactides (Pla);
racemic form of polylactide (D,L-Pla);
poly(L-lactide-co-D,L-lactide);
polyglycolides (PGa);
polyglycolic acid (PGA);
polycaprolactone (PCL);
polydioxanone (PDS);
polyhydroxyacids; and
resorbable plate material

55. The constraining device of claim 54, wherein the extra cellular matrices (ECMs) includes at least one of:

porcine small intestine submucosa (SIS);
xenogeneic small intestine submucosa (xSIS);
urinary bladder submucosa (UBS);
laminated intestinal submucosa; and
glutaraldehyde-treated bovine pericardium (GLBP).

56. The constraining device of claim 53, wherein the material is in the form of a constraining ring adapted to be mounted to a rim of an acetabular cup assembly the acetabular prosthesis component.

57. The constraining device of claim 53, wherein the material is in the form of a mesh adapted to be attached between the acetabular prosthesis component and the prosthetic femoral stem component.

58. The constraining device of claim 53, wherein the material is in the form of a webbing adapted to be attached between the acetabular prosthesis component and the prosthetic femoral stem component.

59. The constraining device of claim 53, wherein the material is in the form of a band attached between the acetabular prosthesis component and the prosthetic femoral stem component.

60. The constraining device of claim 53, wherein the material is adapted to be substantially absorbed by a patient's body after implantation and to be substantially replaced by scar tissue.

61. The constraining device of claim 60, wherein the material is adapted to be substantially absorbed and replaced by scar tissue within approximately 6 months after implantation.

62. The constraining device of claim 53, wherein the material is loaded with an antibacterial agent.

63. The constraining device of claim 53, wherein the material is loaded with a clotting agent.

64. An implantable constraining device for, at least temporarily, maintaining integrity of a hip joint, the constraining device comprises a material taken from the group consisting of a biologic material, a biologically reabsorbable material, and a combination of biologic and biologically reabsorbable materials.

65. The implantable constraining device of claim 64, wherein the material is in the form of a mesh adapted to be attached between the hip bone and the femur.

66. The constraining device of claim 64, wherein the material is in the form of a webbing adapted to be attached between the hip bone and the femur.

67. The constraining device of claim 64, wherein the material is in the form of a band attached between the hip bone and the femur.

68. The constraining device of claim 64, wherein the material is adapted to be substantially absorbed by a patient's body after implantation and to be substantially replaced by scar tissue.

69. The constraining device of claim 68, wherein the material is adapted to be substantially absorbed and replaced by scar tissue within approximately 6 months after implantation.

70. The constraining device of claim 64, wherein the material is loaded with an antibacterial agent.

71. The constraining device of claim 64, wherein the material is loaded with a clotting agent.

72. The constraining device of claim 64, wherein the material is loaded with an agent to promote the formation of scar tissue.

73. The constraining device of claim 64, wherein the material is loaded with an agent to limit the formation of bone tissue.

74. The prosthetic constraining device of claim 64, wherein the material is loaded with at least one of connective tissue stem cells and connective tissue stem cell progenitors.

75. The prosthetic constraining device of claim 74, wherein the connective tissue stem cells and connective tissue stem progenitors are taken from the group consisting of: fibroblastic colony-forming cells, fibroplast colony-forming units (CFU-F), bone marrow stromal cells, mesenchymal stem cells (MSC), and vascular pericytes..

76. The prosthetic constraining device of claim 64, wherein the material is loaded with a growth stimulating factor.

77. The prosthetic constraining device of claim 76, wherein the growth stimulating factor is taken from the group consisting of: growth factor beta (GFB-β), basic fibroblast growth factor (bFGF), fibroblast growth factor (FGF), epidermal growth factor (EFG), transforming growth factor-β1 (TGF-β1), vascular endothelial growth factor (VEGF), connective tissue growth factor (CTGF), platelet-derived growth factor (PDGF), direct-mediated gene transfer, fibroblast-mediated gene transfer, myoblast-mediated gene transfer,TGF-β gene family, adenovirus-mediated gene transfer, recombinant adenovirus-induced tendon adhesion formation, BMP-12, bone morphogenetic protein-2 gene transfer, growth and differentiation factor-5 (GDF-5), and insulin like growth factor (IFG).

78. The prosthetic constraining device of claim 64, wherein the material is loaded with at least one of hematopoietic stem cells and hematopoietic stem cells progenitors.

79. A constraining device for implantation in proximity to a hip joint, including a plate comprising at least one biologically reabsorbable material, having an aperture extending therethrough for allowing a femoral component to extend therethrough, the plate including a distal surface having at least one depression accommodating an increased range of angular motion of the femoral component, and a proximal surface adapted to be mounted to at least one of an acetabular prosthesis, an acetabular bone, and an innominate bone to inhibit a femoral head of the femoral component from completely passing distally through the aperture.

80. The constraining device of claim 79, further comprising a biologically reabsorbable mesh mounted in proximity to the femoral component at a first location and mounted in proximity to at least one of an acetabular prosthesis, an acetabular bone, and an innominate bone at a second location.

81. The constraining device of claim 79, wherein the biologically reabsorbable material is loaded with a clotting agent.

82. The constraining device of claim 79, wherein the biologically reabsorbable material is loaded with antibiotic agent.

83. The constraining device of claim 79, wherein the biologically reabsorbable material is loaded with an agent to promote the formation of scar tissue.

84. The constraining device of claim 79, wherein the biologically reabsorbable material is loaded with an agent to limit the formation of bone tissue.

85. The prosthetic constraining device of claim 79, wherein the biologically reabsorbable material is loaded with at least one of connective tissue stem cells and connective tissue stem cell progenitors.

86. The prosthetic constraining device of claim 85, wherein the connective tissue stem cells and connective tissue stem progenitors are taken from the group consisting of: fibroblastic colony-forming cells, fibroplast colony-forming units (CFU-F), bone marrow stromal cells, mesenchymal stem cells (MSC), and vascular pericytes. .

87. The prosthetic constraining device of claim 79, wherein the biologically reabsorbable material is loaded with a growth stimulating factor.

88. The prosthetic constraining device of claim 87, wherein the growth stimulating factor is taken from the group consisting of: growth factor beta (GFB-β), basic fibroblast growth factor (bFGF), fibroblast growth factor (FGF), epidermal growth factor (EFG), transforming growth factor-β1 (TGF-β1), vascular endothelial growth factor (VEGF), connective tissue growth factor (CTGF), platelet-derived growth factor (PDGF), direct-mediated gene transfer, fibroblast-mediated gene transfer, myoblast-mediated gene transfer,TGF-β gene family, adenovirus-mediated gene transfer, recombinant adenovirus-induced tendon adhesion formation, BMP-12, bone morphogenetic protein-2 gene transfer, growth and differentiation factor-5 (GDF-5), and insulin like growth factor (IFG).

89. The prosthetic constraining device of claim 79, wherein the biologically reabsorbable material is loaded with at least one of hematopoietic stem cells and hematopoietic stem cells progenitors.

90. A method for providing at least temporary stability to a prosthetic hip joint which includes an acetabular cup assembly bonded to a patient's pelvis and a femoral stem bonded to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, the method comprising the step of:

mounting a constraining device to the prosthetic hip joint to provide stability to the prosthetic hip joint, wherein the constraining device comprises a material taken from the group consisting of a biologic material, a biologically reabsorbable material, and a combination of biologic and biologically reabsorbable materials.

91. The method of claim 90, wherein the constraining device has a substantially annular body defining an aperture, and wherein the mounting step includes the step of mounting the constraining device about a rim of the acetabular cup assembly such that the femoral stem passes through the aperture.

92. The method of claim 91, wherein the mounting step includes the step of fastening the constraining device to the rim of the acetabular cup assembly with fasteners comprised of a material taken from the group consisting of a biologic material, a biologically reabsorbable material, and a combination of biologic and biologically reabsorbable materials.

93. The method of claim 92, wherein the fasteners are taken from the group consisting of screws, snaps, sutures, clips, and rivets.

94. The method of claim 90, wherein the material is loaded with at least one of: an agent to promote formation of scar tissue, a clotting agent, and an antibacterial agent.

95. The method of claim 90, wherein the material is adapted to be substantially absorbed by a patient's body after the mounting step and to be substantially replaced by scar tissue.

96. The method of claim 90, wherein the constraining device is in the form of a mesh and the mounting step includes the steps of:

attaching the mesh to at least one of the patient's femur and the femoral stem; and

attaching the mesh to at least one of the patient's pelvis and the acetabular cup assembly.

97. The method of claim 90 wherein the constraining device is in the form of a webbing and the mounting step includes the steps of:

attaching the webbing to at least one of the patient's femur and the femoral stem; and

attaching the webbing to at least one of the patient's pelvis and the acetabular cup assembly.

98. The method of claim 90, wherein the constraining device is in the form of a band and the mounting step includes the steps of:

attaching the band to at least one of the patient's femur and the femoral stem; and

attaching the band to at least one of the patient's pelvis and the acetabular cup assembly.

99. The method of claim 90, wherein the constraining device is in the form of a paste material and the mounting step includes the step of applying the paste material to at least a portion of the patient's prosthetic hip joint.

100. The method of claim 99, wherein the material is loaded with at least one of: an agent to promote formation of scar tissue, a clotting agent, and an antibacterial agent.

101. The method of claim 100, wherein the material is adapted to be substantially absorbed by a patient's body after the mounting step and to be substantially replaced by scar tissue.

102. The method of claim 90, wherein the constraining device includes a bladder comprising at least one of reabsorbable material and non-reabsorbable material.

103. The method of claim 102, wherein the constraining device includes a bladder includes at least one of a clotting agent, an antibiotic agent, and a scar tissue promoter.

104. The prosthetic constraining device of claim 90, wherein the material is loaded with at least one of connective tissue stem cells and connective tissue stem cell progenitors.

105. The prosthetic constraining device of claim 104, wherein the connective tissue stem cells and connective tissue stem progenitors are taken from the group consisting of: fibroblastic colony-forming cells, fibroplast colony-forming units (CFU-F), bone marrow stromal cells, mesenchymal stem cells (MSC), and vascular pericytes..

106. The prosthetic constraining device of claim 90, wherein the material is loaded with a growth stimulating factor.

107. The prosthetic constraining device of claim 106, wherein the growth stimulating factor is taken from the group consisting of: growth factor beta (GFB-β), basic fibroblast growth factor (bFGF), fibroblast growth factor (FGF), epidermal growth factor (EFG), transforming growth factor-β1 (TGF-β1), vascular endothelial growth factor (VEGF), connective tissue growth factor (CTGF), platelet-derived growth factor (PDGF), direct-mediated gene transfer, fibroblast-mediated gene transfer, myoblast-mediated gene transfer,TGF-β gene family, adenovirus-mediated gene transfer, recombinant adenovirus-induced tendon adhesion formation, BMP-12, bone morphogenetic protein-2 gene transfer, growth and differentiation factor-5 (GDF-5), and insulin like growth factor (IFG).

108. The prosthetic constraining device of claim 90, wherein the material is loaded with at least one of hematopoietic stem cells and hematopoietic stem cells progenitors.

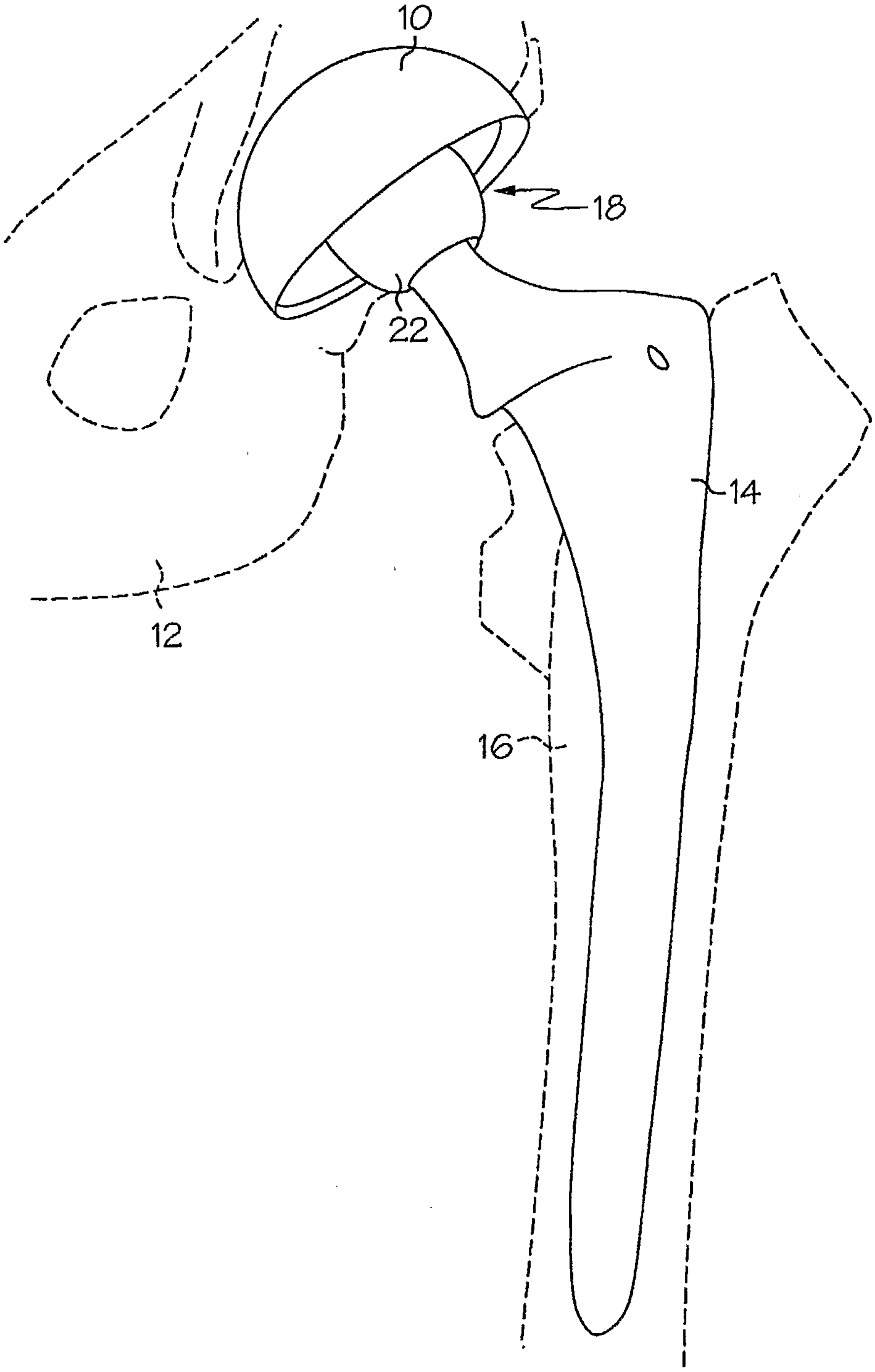


FIG. 1

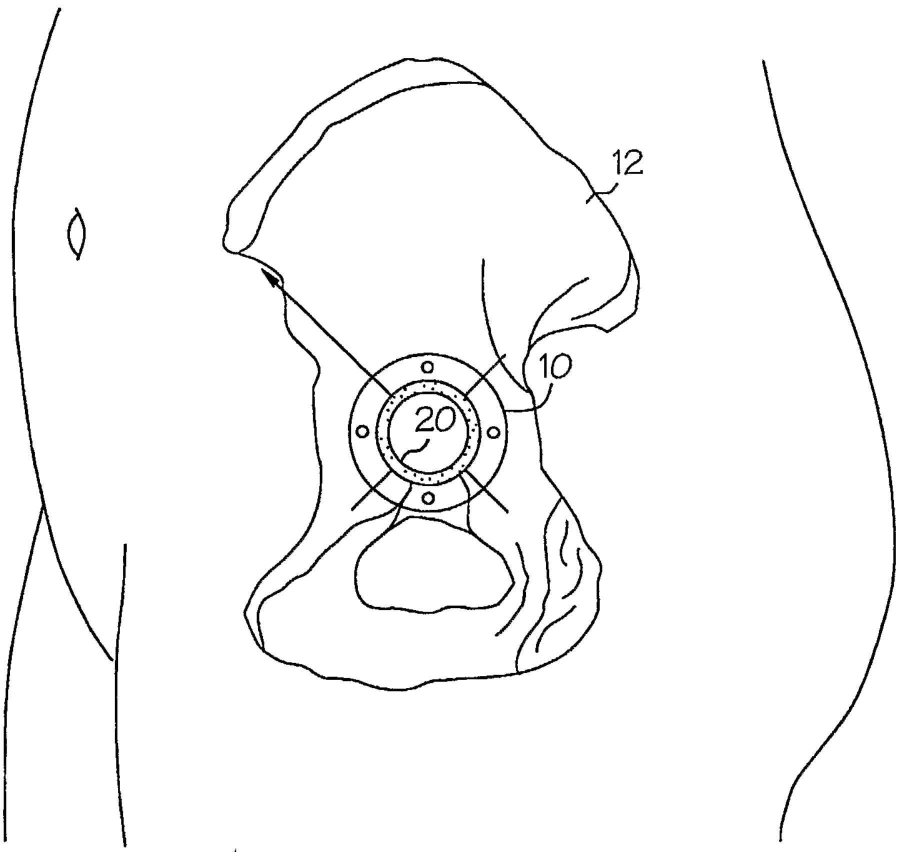


FIG. 2

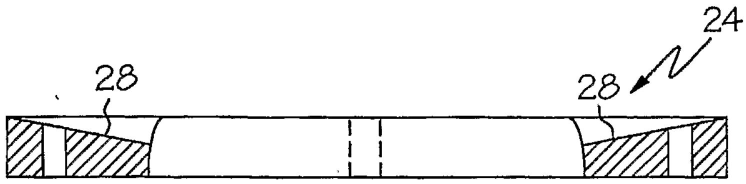


FIG. 3

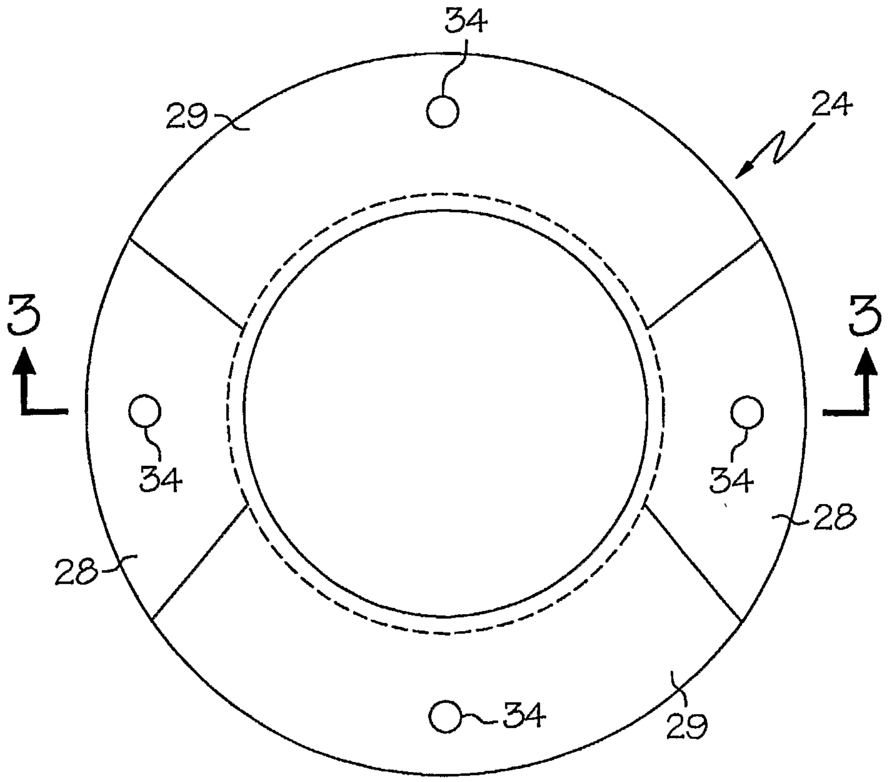


FIG. 4

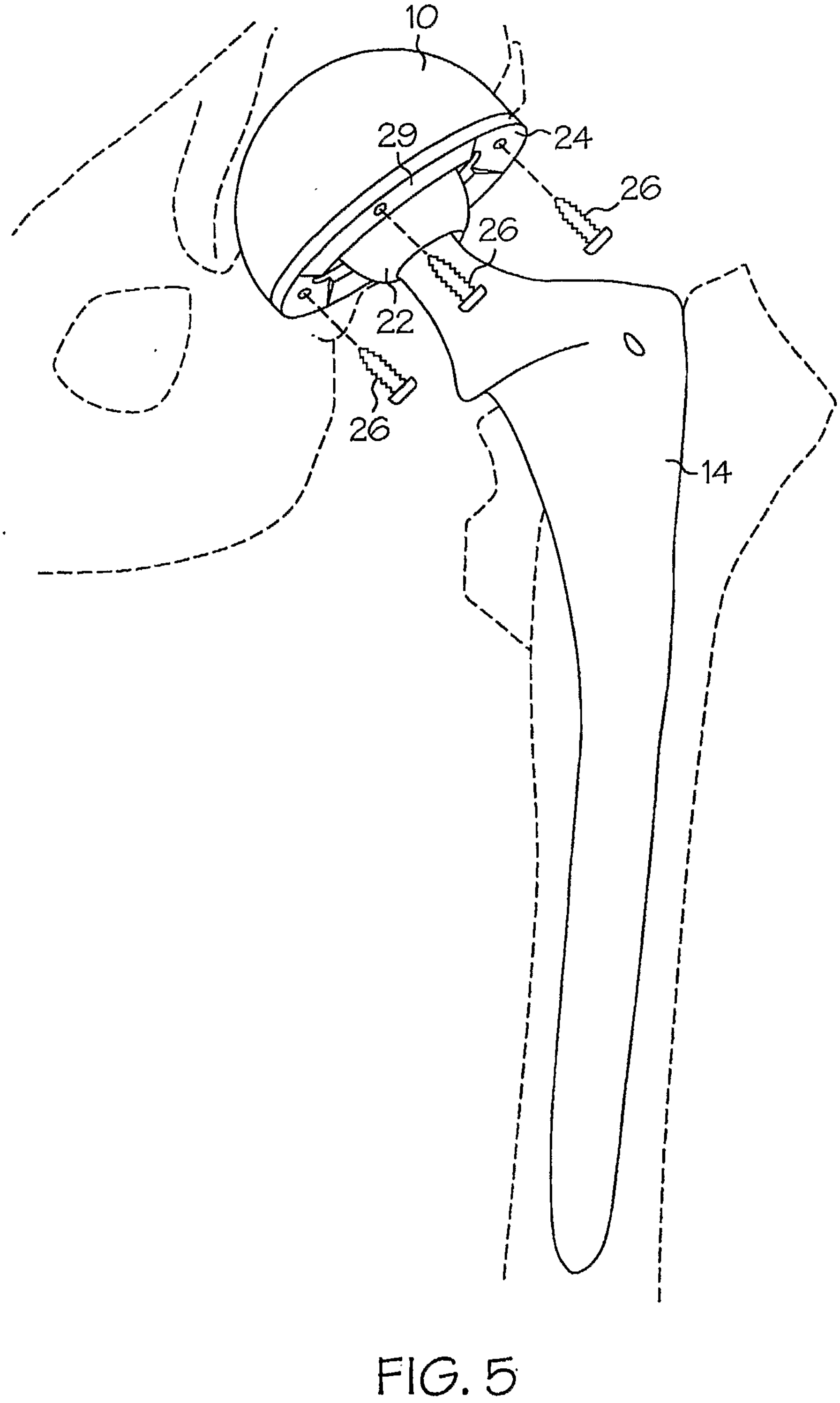


FIG. 5

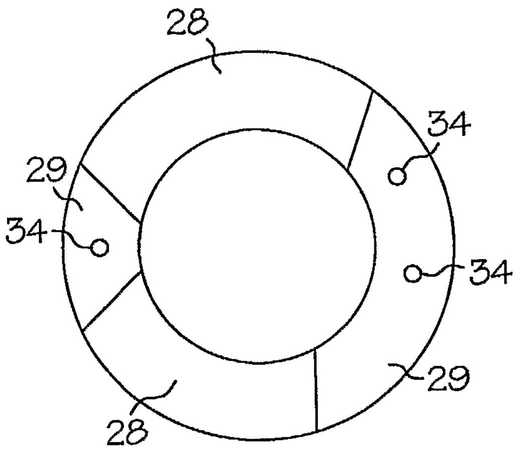


FIG. 6

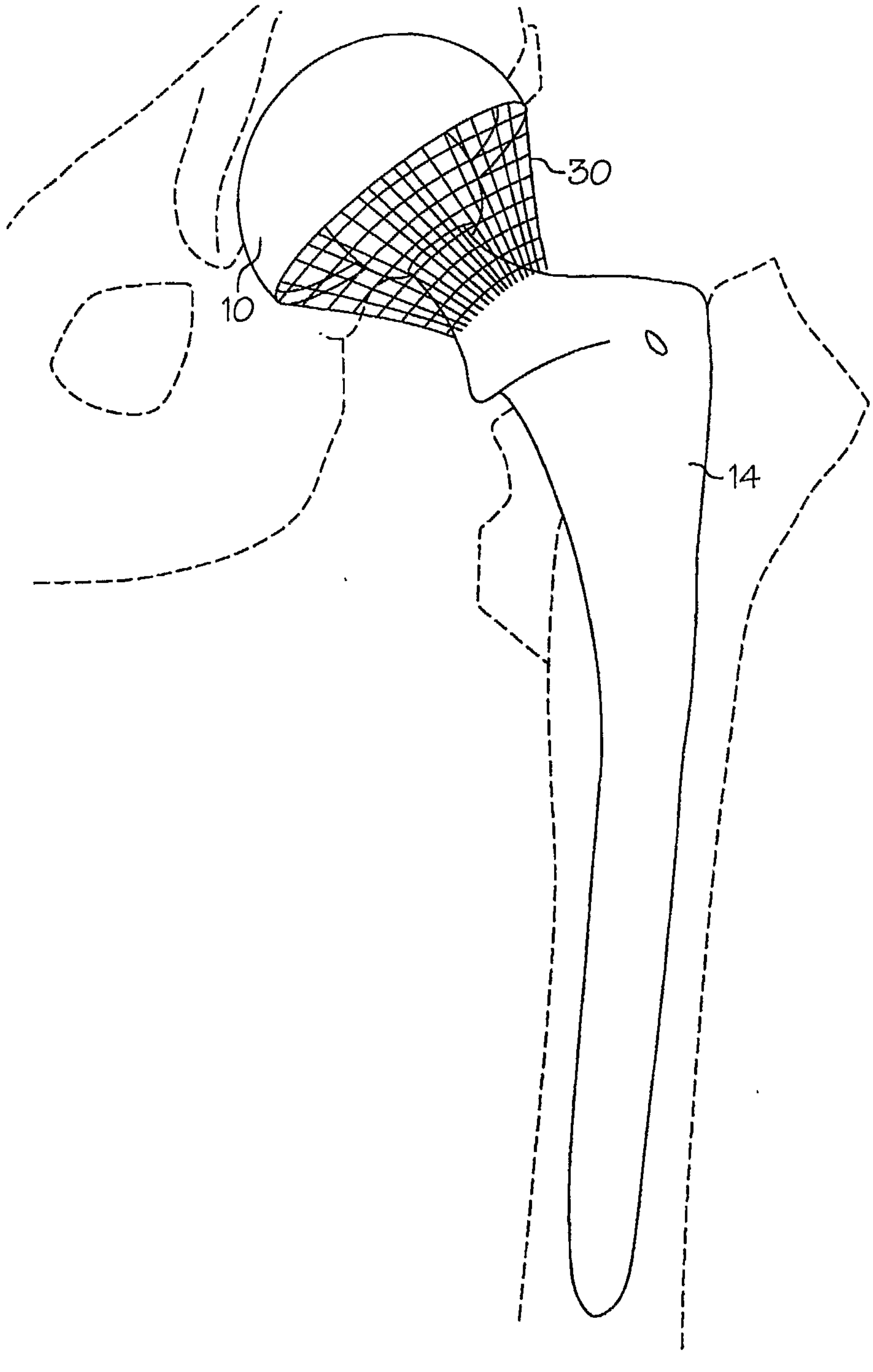


FIG. 7

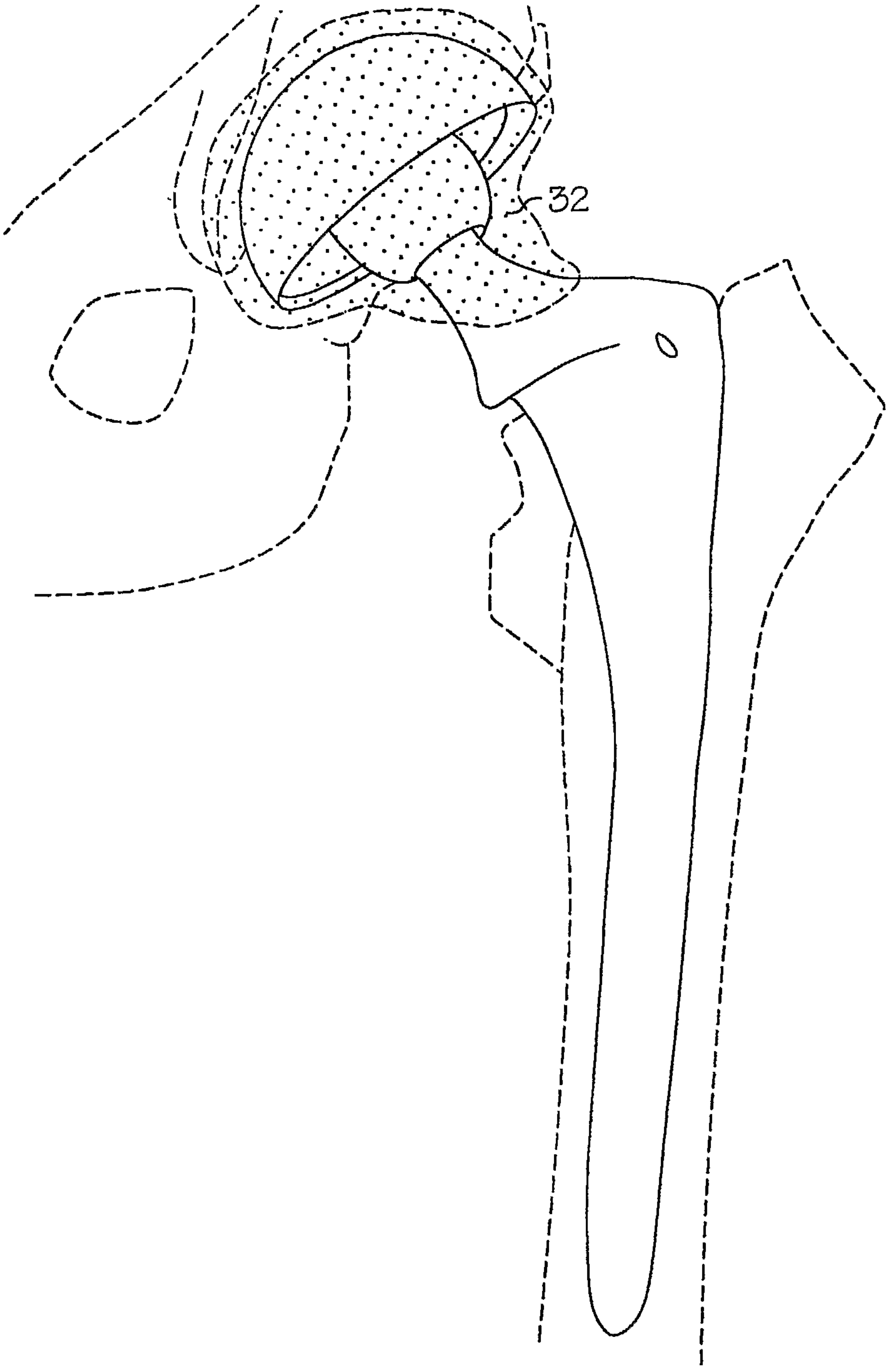


FIG. 8