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(54) **METHOD AND APPARATUS FOR
PROVIDING NUTRITION TO
INTERVERTEBRAL DISC TISSUE**

09/688,716, filed on Oct. 16, 2000, which is a continuation-in-part of application No. 09/638,726, filed on Aug. 14, 2000, now Pat. No. 6,340,369.

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(57) **ABSTRACT**

An intervertebral disc is treated by providing supplemental nutrition to increase viability and longevity. In the preferred embodiment, the invention uses one or more porous stents that function to irrigate the disc space. The stents provide channels for diffusion of fluids and nutrients from the vertebral endplates. The stents may extend across the vertebral endplates to facilitate the transfer of nutrients and oxygen from the vertebral bodies.

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/639,309, filed on Aug. 14, 2000, now Pat. No. 6,419,702, and which is a continuation-in-part of application No.

METHOD AND APPARATUS FOR PROVIDING NUTRITION TO INTERVERTEBRAL DISC TISSUE

REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 09/639,309, filed Aug. 14, 2000, which claims priority of U.S. Provisional Patent Application Serial No. 60/148,913, filed Aug. 13, 1999; and is a continuation-in-part of U.S. patent application Ser. No. 09/688,716, filed Oct. 16, 2000, which is a continuation-in-part of U.S. patent application Ser. No. 09/638,726, filed Aug. 14, 2000, now U.S. Pat. No. 6,340,369. The entire content of each application is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This invention relates generally to the treatment of intervertebral discs, and more particularly, to apparatus and methods for providing supplemental nutrition to intervertebral discs.

BACKGROUND OF THE INVENTION

[0003] Intervertebral discs provide mobility and a cushion between the vertebrae. At the center of each disc is the nucleus pulposus which, in the adult human, is composed of cells and an insoluble extracellular matrix which is produced by the nucleus itself. The extracellular matrix is composed of collagen, proteoglycans, water, and noncollagenous proteins. The nucleus pulposus is surrounded by the annulus fibrosis, which is composed of cells (fibrocyte-like and chondrocyte-like), collagen fibers, and non-fibrillar extracellular matrix. The components of the annulus are arranged in 15-25 lamellae around the nucleus pulposus.

[0004] The cells of the nucleus pulposus have chondrocyte-like features. In an adult human, the cells of the nucleus pulposus obtain nutrients and eliminate waste by diffusion through blood vessels in the endplates of the vertebrae adjacent to the disc. Blood vessels do not course into the nucleus pulposus. The relative vascular isolation of the nucleus pulposus imparts isolation of nucleus pulposus cells from the body's immune system.

[0005] To date, the treatment of degenerative disc disease has relied for the most part on eliminating the defective disc or disc function. This may be accomplished by fusing the vertebra on either side of the disc. In terms of replacement, most prior-art techniques use synthetic materials to replace the entire disc or a portion thereof. My pending U.S. patent application Ser. No. 09/415,382 discloses disc replacement methods and apparatus using synthetic materials.

[0006] Unfortunately, disc replacement using synthetic materials does not restore normal disc shape, physiology, or mechanical properties. Synthetic disc replacements tend to wear out, resulting in premature failure. The problems associated with the wear of prosthetic hip and knees are well known to those skilled in orthopedic surgery. The future of treating degenerative disc disease therefore lies in treatments which preserve disc function. If disc function could be restored with biologic replacement or augmentation, the risk of premature wearout would be minimized, if not eliminated.

[0007] However, some researchers believe the vertebral endplates of vertebrae involved in degenerative disc disease

do not allow sufficient diffusion of nutrition to the disc cells. Diseased endplates could thus lead to death of the intradiscal cells. Accordingly, any technique capable of providing or augmenting the delivery of such nutrition would be welcomed by patients and the medical community.

SUMMARY OF THE INVENTION

[0008] This invention is directed to a method of treating an intervertebral disc by providing supplemental nutrition to increase viability and longevity. In the preferred embodiment, the invention uses one or more porous stents that function to irrigate the disc space. The stents provide channels for diffusion of fluids and nutrients from the vertebral endplates. The stents may extend across the vertebral endplates to facilitate the transfer of nutrients and oxygen from the vertebral bodies.

DETAILED DESCRIPTION OF THE INVENTION

[0009] The invention resides in a methods and apparatus for providing nutrients to an intervertebral disc situated between the endplates of upper and lower vertebra. According to the method, a passageway is formed into the disc space. The process further includes the steps of placing a cannulated element in the passageway, and providing one or more substances beneficial to the intervertebral disc through the cannulated element. In the preferred embodiment, the cannulated elements take the form of porous stents which extend through the vertebral endplates.

[0010] The endplate stents according to the invention may be used to feed the disc cells within the disc naturally, and/or cells transplanted into the disc. In one application, transplanted disc tissue is placed around the disc stents at the time the disc tissue is added to the disc. Alternatively, the cells are grown in culture around the stents. In this way, the stents may support the growth of larger colonies of cells in cell culture. Given that colonies of cells grown in culture can reach a critical size where the cells in the center of the group can become deprived of nutrition, the stents would provide a channel for nutrients to the cells in the center of the colony.

[0011] In the embodiments involving the transplantation of biologic material in the form of nucleus pulposus cells or other tissues, live cells or tissues are harvested from a human or animal donor and introduced into the disc being treated. The harvested biologic materials are preferably kept viable until placed into the disc being treated. The harvested biologic materials may be introduced into the disc using any suitable transfer technique, including the formation of a passageway through the annulus fibrosis and the use of a needle and syringe or small cannula. Alternatively the step of transplanting may include percutaneously or laparoscopically injecting the cells or tissues into the disc being treated.

[0012] The invention may further include the use of an optional reservoir filled with therapeutic materials to aid the disc cells. For example, a refillable reservoir may be filled with cell-culture nutrients and placed in an accessible location under the skin of the flank. Other applicable therapeutic substances include, growth factors, differentiation factors, hydrogels, polymers, antibiotics, anti-inflammatory medications, or immunosuppressive medications.

[0013] If a transplanted nucleus pulposus is utilized, it is preferably harvested from a live human, though recently

deceased human or animal donors may alternatively be used. Depending upon the extent of the harvest, the recipient may function at least in part as a donor, or the tissues from others, including fetal or embryo sources, may be used, preferably having a familial relationship to minimize or avoid the need for immunosuppressive substances. Guidelines for tissue procurement including surgical technique of removal, number of hours between death of the donor and tissue procurement, and testing of the donor for infectious disease, are well described in the literature.

[0014] Similarly, the guidelines for storage of living tissues are well known to those skilled in the art. The text "Organ Preservation for Transplantation" by Karow and Pego, 1981, describes such methods. Briefly, the tissue storage method must maintain cell viability and preserve sterility. Examples of present storage methods include: refrigeration, refrigeration with tissue culture medium such as: hemolyzed serum, autologous serum, Medium 199 with 5% dextran (McCarey-Kaufman medium), Medium 199 with chondroitin sulfate, Medium 199 supplemented with inorganic salts, short chain fatty acids, and/or ketone bodies, and cryopreservation techniques, among others. Details are provided in U.S. Pat. Nos. 4,695,536 and 4,873,186, the entire contents of which are incorporated herein by reference.

[0015] To minimize exposure to the recipient's immune system, the harvested nucleus pulposus is preferably inserted through a small hole in the annulus fibrosis using a blunt-tipped needle or cannula forced through the laminae. Upon withdraw of the needle, after injecting the transplanted nucleus pulposus, the separated fibers of the lamella return to their normal position, thereby sealing the annulus.

[0016] The annulus fibrosis is thicker in the anterior and lateral portion of the disc. Thus, the needle would preferably be inserted into the anterior or lateral portion of the disc. Those skilled in the art will realize the needle could be directed into the lateral portion of the disc percutaneously with fluoroscopic guidance and into the anterior portion of the disc laparoscopically.

[0017] The host nucleus pulposus may be morselized to allow insertion into the disc through a small cannula or needle. The increased surface area of the nucleus pulposus after morsellization may also aid diffusion of nutrients and wastes products to and from transplanted disc cells. Alternatively large sections of the transplanted nucleus pulposus could be added to the disc if the annular defect was sealed after transplantation.

[0018] The transplanted nucleus is preferably added to the patient's nucleus pulposus. Alternatively, the patient's nucleus could be removed with standard techniques (enzy-

matically (chymopapain) or with the aid of a laser, suction device, shaver, or other surgical instrument). If the nucleus is removed the hole in the annulus should be small and sealed to prevent the ingrowth of vascular tissue. Vascular ingrowth could lead to a graft versus host reaction.

[0019] Additional therapeutic substances could be added to the transplanted nucleus. For example, resorbable culture medium, tissue growth or differentiation factors (recombinant generated morphogenetic proteins, PDGF, TGF- β , EGF/TGF- α , IGF-I, β FGF), hydrogels, absorbable or non-resorbable synthetic or natural polymers (collagen, fibrin, polyglycolic acid, polylactic acid, polytetrafluoroethylene, etc.), antibiotics, antiinflammatory medication, immunosuppressive medications, etc. could be beneficial.

I claim:

1. A method of providing nutrients to an intervertebral disc situated between the endplates of upper and lower vertebra, comprising the steps of:

forming a passageway into the disc space;

placing a cannulated element in the passageway; and

providing one or more substances beneficial to the intervertebral disc through the cannulated element.

2. The method of claim 1, wherein the passageway extends through one of the vertebral endplates.

3. The method of claim 1, wherein the beneficial substance contains a nutrient.

4. The method of claim 1, wherein the beneficial substance contains a therapeutic agent.

5. The method of claim 4, wherein the therapeutic agents include one or more of the following:

culture media, growth factors, differentiation factors, hydrogels, polymers, antibiotics, anti-inflammatory medications, or immunosuppressive medications.

6. The method of claim 1, further including the step of transplanting cells or tissues into the disc.

7. The method of claim 1, wherein the step of transplanting the cells or tissues includes the use a needle and syringe or small cannula through the annulus fibrosis.

8. The method of claim 1, wherein the step of transplanting the cells or tissues includes percutaneously or laparoscopically injecting the cells or tissues into the disc being treated.

9. The method of claim 1, further including the step of providing a reservoir containing the beneficial substance in communication with the cannulated element.

10. The method of claim 1, wherein the cannulated element is a stent.

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专利名称(译)	用于向椎间盘组织提供营养的方法和设备		
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[标]申请(专利权)人(译)	FERREE BRET 一个		
申请(专利权)人(译)	费里布雷特A.		
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摘要(译)

通过提供补充营养来治疗椎间盘以增加活力和寿命。在优选实施例中，本发明使用一个或多个多孔支架，其用于冲洗盘空间。支架为来自椎骨终板的流体和营养物的扩散提供通道。支架可以延伸穿过椎骨终板以促进来自椎体的营养物质和氧的转移。