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[Continued on next page]

(54) Title: DRILL BURR AND METHOD FOR PERFORMING HOLES IN SUBCHONDRAL BONE TO PROMOTE CARTILAGE REPAIR

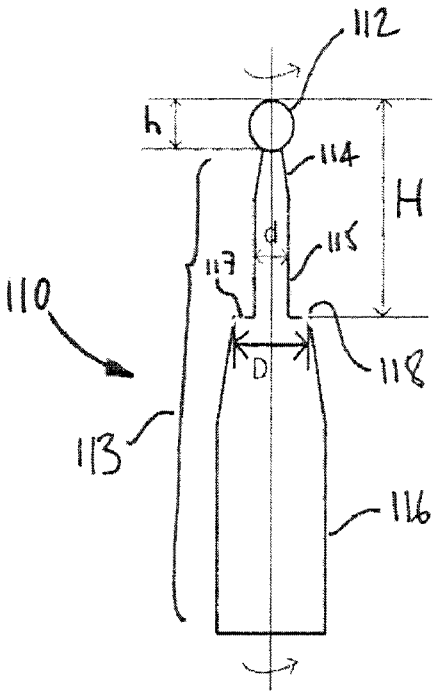

Fig. 1

(57) Abstract: A method for performing holes in subchondral bone to promote cartilage repair comprises selecting a drill burr having a drilling head and an axial stop, as a function of the distance between the tip of the drilling head and the axial stop and of a desired depth to reach a desired subchondral bone marrow compartment of a patient; drilling a hole through a base of a cartilage lesion with the drill burr to reach the desired subchondral bone marrow compartment of the patient; abutting the base of the cartilage lesion defining a periphery of the hole with the axial stop while drilling; and withdrawing the drill burr from the hole; whereby the hole has the desired depth and reaches the desired subchondral bone marrow compartment to promote cartilage repair.

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ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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DRILL BURR AND METHOD FOR PERFORMING HOLES FN SUBCHONDRAL BONE TO PROMOTE CARTILAGE REPAIR

CROSS-REFERENCE TO RELATED APPLICATION

This patent application claims priority on United States Provisional Patent Application No. 61/032,610, filed on February 29, 2008.

FIELD OF THE APPLICATION

The present application relates to cartilage repair and, more particularly, to a surgical tool and to a method for stimulating bone marrow to promote cartilage repair.

BACKGROUND OF THE ART

Adult articular cartilage is composed of three stratified layers with distinct morphological characteristics, namely the superficial zone, the transitional zone and the radial zone. The superficial zone includes the articulating surface and contains chondrocytes with a discoidal morphology, a tangential orientation of collagen fibrils. The transitional zone, below the superficial zone, contains chondrocytes with a rounder morphology and displays a more isotropic orientation of collagen. The bulk of adult articular cartilage lies in the deepest zone, or radial zone, named to depict the radiating pattern of vertically oriented collagen fibrils emanating from the calcified cartilage layer just below the articular cartilage. The polygonally shaped chondrocytes of the radial zone are organized in vertical columns.

Below the radial zone lies the layer of calcified cartilage interdigitating with the subchondral bone plate that contains small vascularised osteons protruding into the calcified zone. This cortical

subchondral bone plate then melds with marrow-rich cancellous bone. Although the above-described general morphological characteristics of adult articular cartilage are conserved across species and between different joint surfaces, the proportion of each zone and their detailed structures vary with age, species and site.

The bone-marrow stimulation family of known surgical techniques includes Pridie drilling, abrasion arthroplasty and microfracture. These methods share the common feature of intentionally injuring subchondral bone below the cartilage lesion in order to induce wound repair and tissue regrowth. Animal studies in multiple species have clearly demonstrated the intrinsic ability of injured subchondral bone to repair itself and to generate chondral repair tissue, albeit a tissue lacking hyaline articular structure and with limited reproducibility.

A randomized comparative clinical study found that microfracture was superior to autologous chondrocyte implantation (ACI) in terms of subjective clinical outcomes at two years post-treatment, and that biopsy histological appearances were similar in the two groups. A recent mixed retrospective/prospective study using MRI to compare five-year outcomes of ACI and microfracture found that, while microfracture led to slightly less lesion filling with uncharacterized tissue, it was associated with a much lower rate of reoperation compared to ACI (10% vs. 60%). Given this low level of morbidity of microfracture and an acceptable level of clinical success, microfracture remains a primary choice in many treatment algorithms for lesions of limited size (less than 2 cm^2).

Unfortunately, historical widespread and nonstandardized use of microfracture has resulted in uncontrolled and inconsistent surgical technique,

follow-up measures and physiotherapy programs, and consequently there remains a lack of understanding as to why microfracture appears successful for some patients and surgeons, and not for others. In addition, despite intrinsic differences between microfracture and the older and less favoured methods of Pridie drilling and abrasion arthroplasty, there have been no controlled animal studies, or clinical studies directly comparing these approaches to identify which features or consequences of these different methods influence their success. Bone-marrow stimulation procedures are widely practiced in North America, but with little scientific evidence to guide their proper implementation. There is a general lack of understanding of mechanisms and parameters that control success versus failure of bone-marrow stimulation methods for cartilage repair.

Animal studies of spontaneous repair of osteochondral lesions have determined that the manner in which the cartilage lesion is surgically prepared can greatly influence the repair response. Skeletally mature animals must be used in these studies, since bone-marrow-derived repair is clearly much more efficacious in young animals than in older ones. Detailed studies in an abraded equine model (46) and in drilled rabbit trochlea have identified the following sequence of events in the reparative process: hematoma formation in the subchondral space, proliferation and migration of inflammatory and stromal cells from the cancellous marrow into the fibrin clot, transformation of the fibrin clot into a vascularised provisional and cellular granulation tissue, bone remodelling, and frequently the induction of growth plate-like structures, or chondrogenic foci, within granulation tissue. These latter structures then grow in a manner similar to that seen in cartilage development where zones of proliferation, hypertrophy, calcification,

vascular invasion and endochondral bone formation can be identified.

The above processes achieve variable levels of success in cartilage repair, in part due to variations in several surgically determined factors that can critically influence the success of bone-marrow stimulation procedures including: 1) size of the lesion; 2) depth of the lesion and damage to viable subchondral bone; 3) presence of the calcified cartilage layer; 4) the number of channels accessing deep marrow; 5) post-operative articulation and load-bearing. Location of the lesion can also influence success. Calcified cartilage appears to be a very effective barrier to marrow-derived repair according to several studies and species. Although removal of all calcified cartilage from cartilage lesions may maximize spontaneous repair, evidence also suggests that excessive debridement which impinges too deep into subchondral bone can result in lack of repair, subchondral cysts and ultimately, poor clinical outcome, as in abrasion arthroplasty that was performed too aggressively.

SUMMARY OF THE APPLICATION

It is therefore an aim of the present application to provide a novel method and a novel tool for performing holes in subchondral bone to promote cartilage repair.

Therefore, in accordance with a first embodiment, there is provided a method for performing holes in subchondral bone to promote cartilage repair comprising: selecting a drill burr having a drilling head and an axial stop, as a function of the distance between the tip of the drilling head and the axial stop and of a desired depth to reach a desired subchondral bone marrow compartment of a patient; drilling a hole

through a base of a cartilage lesion with the drill burr to reach the desired subchondral bone marrow compartment of the patient; abutting the base of the cartilage lesion defining a periphery of the hole with the axial stop while drilling; and withdrawing the drill burr from the hole; whereby the hole has the desired depth and reaches the desired subchondral bone marrow compartment to promote cartilage repair.

Further in accordance with the first embodiment, selecting the drill burr comprises identifying the desired depth as a function of pre-operative imagery.

Still further in accordance with the first embodiment, selecting the drill burr comprises identifying the desired depth by performing test holes in the bone.

Still further in accordance with the first embodiment, selecting the drill burr comprises identifying the desired depth by performing a qualitative assessment of a region of the bone to be drilled.

Still further in accordance with the first embodiment, drilling the hole comprises drilling the hole having a depth of at most 10.0 mm.

Still further in accordance with the first embodiment, drilling the hole comprises drilling the hole with a depth ranging between 2.0 and 6.0 mm.

Still further in accordance with the first embodiment, drilling the hole comprises drilling the hole having a diameter ranging between 0.5 and 4.0 mm.

Still further in accordance with the first embodiment, drilling the hole comprises drilling the hole having a diameter ranging between 0.9 and 2.0 mm

In accordance with a second embodiment, there is provided a drill burr for performing holes in subchondral bone to promote cartilage repair comprising:

a drilling head; and a neck connected to the drilling head, a stop positioned at a specific axial distance from the drilling head on the neck, the specific axial distance corresponding to a desired depth between a base of debrided cartilage and a subchondral bone marrow compartment, and a connector portion adapted to connect the drill burr to a drill; whereby an abutment between the stop and the base of debrided cartilage during drilling enables a hole of the desired depth to be performed.

Further in accordance with the second embodiment, the drill burr comprises an irrigation space adjacent to the drilling head to irrigate a hole during drilling.

Still further in accordance with the second embodiment, the neck has a frusto-conical body between the drilling head and the stop, the frusto-conical body having a smaller diameter than the drilling head proximally to the drilling head to define the irrigation space between the drilling head and the neck.

Still further in accordance with the second embodiment, the drill burr comprises a cylindrical portion between a distal end of the frusto-conical body and the connector portion.

Still further in accordance with the second embodiment, the drilling head has a diameter ranging between 0.5 to 4.0 mm.

Still further in accordance with the second embodiment, the drilling head has a diameter ranging between 0.9 to 1.0 mm.

Still further in accordance with the second embodiment, the specific axial distance between the stop and a tip of the drilling head is at most 10.0 mm.

Still further in accordance with the second embodiment, the specific axial distance between the stop

and a tip of the drilling head ranges between 2.0 and 6.0 mm.

Still further in accordance with the second embodiment, the stop is a ring mounted to the neck of the drill burr.

Still further in accordance with the second embodiment, the stop is a shoulder defined between a distal end of the neck and the connector portion.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic side view of a drill burr in accordance with a first embodiment of the present application;

Fig. 2 is a schematic side view of a drill burr in accordance with a second embodiment of the present application; and

Fig. 3 is schematic view of a drilling head used with the drill burrs of Figs. 1 and 2.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Fig. 1, a drill burr in accordance with a first embodiment is generally shown at 110. The drill burr 110 is used to drill holes through cartilage zones and calcified cartilage so as to reach the subchondral bone, to promote bone marrow stimulation for cartilage repair.

The drill burr 110 has a drilling head 112. As an example, the drilling head 112 has a diameter "h" of approximately 0.9 mm, and is shown in greater detail in Fig. 3.

The drilling head 112 is connected to the drill by way of a neck 113. The neck 113 has, amongst other parts, a frustoconical portion 114, a cylindrical portion 115, and a connector portion 116. The frusto-conical portion 114 is connected to the drilling head

112. The frustoconical portion 114 provides an irrigation space during drilling to avoid overheating the periphery of the hole, so as to reduce the risk of cell necrosis. Other configurations are considered in the neck 113 to provide irrigation during drilling.

The cylindrical portion 115 connects the frustoconical portion 114 to the connector portion 116 and has a diameter "d" that does not exceed the diameter of the drilling head 112, and preferably ranges between 0.5 mm and 0.8 mm, as an example. The connector portion 116 interfaces the drill burr 110 to the drill.

The junction between the cylindrical portion 115 and the connector portion 116 features an abutment shoulder 117 that is used as an axial stop during the drilling operation. The abutment shoulder 117 has a diameter greater than the diameter of the drilling head 112. Accordingly, when a hole is drilled using the drill burr 110, the abutment shoulder 117 abuts against the periphery of the drilled hole, so as to control the depth of the drilled hole. Therefore, the diameter "D" of the abutment shoulder 117 is greater than 0.9 mm, as an example.

The drill depth is illustrated by "H" and is the distance between the tip of the drilling head 112 and the surface of the abutment shoulder 117. Therefore, the drill depth is defined as a function of the expected depth between the exposed and debrided cartilage lesion and the desired subchondral bone marrow compartment, as it is desired to reach the deep cellular subchondral bone marrow in drilling to promote bone marrow stimulation. In one embodiment, the drill depth "H" is of 6.0 mm, but could be any other suitable value.

In order to avoid damaging the surrounding cartilage during drilling, the abutment shoulder 117 preferably has a rounded edge 118.

Referring to Fig. 2, a drill burr in accordance with another embodiment is generally shown at 120. The drill burr 120 has a drilling head 122, similar to the drilling head 112 of the drill burr 110. Therefore, the drilling head 122 has a diameter "h" of approximately 0.9 mm, for instance, and is shown in greater detail in Fig. 3. Other types of drilling heads and diameters thereof are considered as well.

The drilling head 122 is connected to the drill by the neck 123. The neck 123 has, amongst other parts, a frustoconical portion 124, a cylindrical portion 125, and a connector portion 126. The frusto-conical portion 124 is connected to the drilling head 122. Again, the frustoconical portion 124 provides an irrigation space during drilling to avoid overheating the periphery of the hole, so as to reduce the risk of cell necrosis. Other configurations are considered in the neck 123 to provide irrigation during drilling.

The cylindrical portion 125 connects the frustoconical portion 124 to the connector portion 126 and has a diameter that does not exceed the diameter of the drilling head 122. The connector portion 126 interfaces the drill burr 120 to the drill.

The junction between the cylindrical portion 125 and the connector portion 126 features an abutment shoulder 127 that supports with the cylindrical portion 125 a stopper 128. The stopper 128 is a ring that is fitted over the cylindrical portion 125 and that abuts against the abutment shoulder 127. Accordingly, the abutment shoulder 127 sets the axial position of the stopper 128 on the neck 123. By way of example, the width "W" of the stopper 128 ranges between 1.0 and 1.5 mm.

The stopper 128 is used as a stop during the drilling operation. Therefore, the stopper 128 has a diameter greater than the diameter of the drilling head

122. When a hole is drilled using the drill burr 120, the stopper 128 abuts against the periphery of the drilled hole, so as to control the depth of the drilled hole. Therefore, the diameter "D" of the stopper 128 is greater than 0.9 mm, for example.

The drill depth is illustrated by "H" and is the distance between the tip of the drilling head 112 and the exposed surface of the stopper 128. Therefore, the drill depth is defined as a function of the expected depth between the exposed cartilage and the subchondral bone, as it is desired to reach the subchondral bone in drilling to promote bone-marrow stimulation. In one embodiment, the drill depth "H" is of 2.0 mm, but could be any other suitable value.

A drill hole is preferable to a pick hole, since the drill hole does not create a compact bone interface that slows down the repair process like the pick hole may do. More important is that a deeper drill hole at a controlled depth is more effective than a shallow drill hole. Current practice does not control depth of drill holes. Thus the present application describes a drill burr with a controlled depth using abutment surfaces that are either permanent or adjustable to obtain the desired depth. The tool will provide the orthopedic surgeon with the means necessary to obtain optimal cartilage repair.

Although the preferred range of diameters for the drilling heads 112 and 122 is between 0.9 and 1.0 mm, it is considered to drill holes having diameters between 0.5 to 4.0 mm, to appropriately promote cartilage repair. As for the desired depth of the holes, it is not more than 10.0 mm, but preferably between 2.0 and 6.0 mm.

Now that the drill burrs 110 and 120 have been detailed, a method for drilling holes in bones to promote bone marrow stimulation, for instance using the

drill burrs 110 or 120, is described. It is pointed out that before drilling, the cartilage lesion is first debrided with a curette or like tool using standard techniques to remove residual flaps of cartilage and the thin layer of calcified cartilage that separates noncalcified cartilage from bone.

Firstly, a drill burr, such as the drill burrs 110 or 120, is selected as a function of a desired depth of the hole to reach the cell-rich cancellous bone marrow portion of the subchondral bone of a patient. Various factors can be used to determine the desired depth, such as the type and quality of subchondral bone (dense, porous, sclerotic, etc.) and the location of the cartilage damage on the bone, as part of a qualitative assessment. Moreover, specific patient information may be taken into account in determining the desired depth, such as age and physical condition (e.g., diseases such as arthritis, etc.). In another example, the desired depth is determined by performing test holes to visually determine the suitable depth to reach the subchondral bone. Pre-poerative imaging may also be used to determine the depth of the holes. For instance, X-ray tomography may be performed pre-peratively.

Once the desired depth has been determined, and the selected drill burr has been installed on the drill, the hole is drilled through the base of the debrided cartilage lesion to reach the desired subchondral bone marrow compartment of the patient.

Because of the presence of the abutment surface 117 (Fig. 1) or of the stopper 128 (Fig. 2), the drill burr 110 or 120 (or other suitable drill burr) abuts the cartilage defining a periphery of the hole, at the desired depth. The drill burr may therefore be withdrawn from the hole, whereby the hole has the desired depth and reaches the desired subchondral bone compartment to promote cartilage repair.

It is observed that numerous holes may be performed in a damaged cartilage region, by repeating the necessary steps of the method once the drill burr has been selected and installed on the drill.

CLAIMS:

1. A method for performing holes in subchondral bone to promote cartilage repair comprising:

selecting a drill burr having a drilling head and an axial stop, as a function of the distance between the tip of the drilling head and the axial stop and of a desired depth to reach a desired subchondral bone marrow compartment of a patient;

drilling a hole through a base of a cartilage lesion with the drill burr to reach the desired subchondral bone marrow compartment of the patient;

abutting the base of the cartilage lesion defining a periphery of the hole with the axial stop while drilling; and

withdrawing the drill burr from the hole;

whereby the hole has the desired depth and reaches the desired subchondral bone marrow compartment to promote cartilage repair.

2. The method according to claim 1, wherein selecting the drill burr comprises identifying the desired depth as a function of pre-operative imagery.

3. The method according to claim 1, wherein selecting the drill burr comprises identifying the desired depth by performing test holes in the bone.

4. The method according to claim 1, wherein selecting the drill burr comprises identifying the desired depth by performing a qualitative assessment of a region of the bone to be drilled.

5. The method according to claim 1, wherein drilling the hole comprises drilling the hole having a depth of at most 10.0 mm.

6. The method according to claim 1, wherein drilling the hole comprises drilling the hole with a depth ranging between 2.0 and 6.0 mm.

7. The method according to claim 1, wherein drilling the hole comprises drilling the hole having a diameter ranging between 0.5 and 4.0 mm.

8. The method according to claim 1, wherein drilling the hole comprises drilling the hole having a diameter ranging between 0.9 and 2.0 mm.

9. A drill burr for performing holes in subchondral bone to promote cartilage repair comprising:

a drilling head; and

a neck connected to the drilling head, a stop positioned at a specific axial distance from the drilling head on the neck, the specific axial distance corresponding to a desired depth between a base of debrided cartilage and a subchondral bone marrow compartment, and a connector portion adapted to connect the drill burr to a drill;

whereby an abutment between the stop and the base of debrided cartilage during drilling enables a hole of the desired depth to be performed.

10. The drill burr according to claim 9, further comprising an irrigation space adjacent to the drilling head to irrigate a hole during drilling.

11. The drill burr according to claim 10, wherein the neck has a frusto-conical body between the drilling head and the stop, the frusto-conical body having a smaller diameter than the drilling head proximally to the drilling head to define the irrigation space between the drilling head and the neck.

12. The drill burr according to claim 11, further comprising a cylindrical portion between a distal end of the frusto-conical body and the connector portion.

13. The drill burr according to claim 9, wherein the drilling head has a diameter ranging between 0.5 to 4.0 mm.

14. The drill burr according to claim 9, wherein the drilling head has a diameter ranging between 0.9 to 1.0 mm.

15. The drill burr according to claim 9, wherein the specific axial distance between the stop and a tip of the drilling head is at most 10.0 mm.

16. The drill burr according to claim 9, wherein the specific axial distance between the stop and a tip of the drilling head ranges between 2.0 and 6.0 mm.

17. The drill burr according to claim 9, wherein the stop is a ring mounted to the neck of the drill burr.

18. The drill burr according to claim 9, wherein the stop is a shoulder defined between a distal end of the neck and the connector portion.

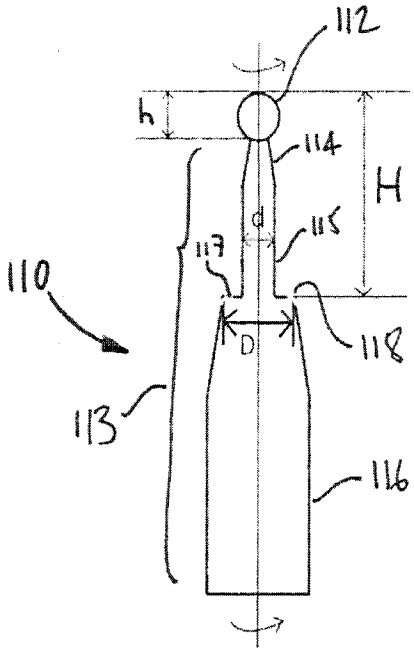

Fig. 1

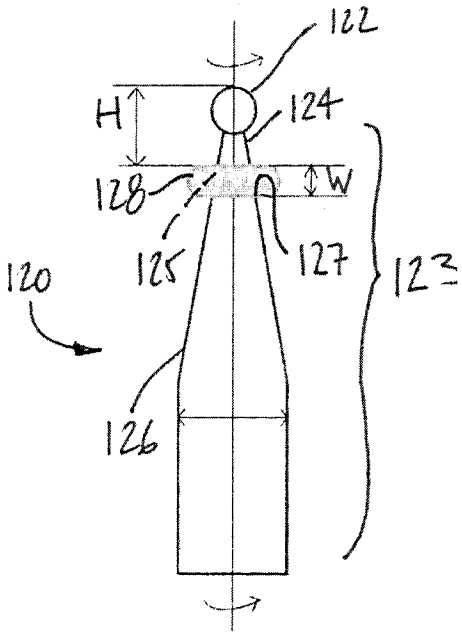

Fig. 2

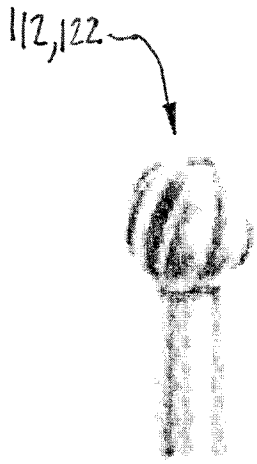

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2009/000226

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61B 17/16*** (2006.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC (2006.01): A61B, A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
CPD: (drill* or bur*) and depth* and (stop or shoulder or abutment) and *conical <AND> (a61c or a61b <IN> ipc)
WEST: 606/172 and (bone$ or tooth or teeth) and (drill$ or bur$); 433/$[CCLS] AND ((drill$3 or bur$2) and (deep or depth)...

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,514,258 B1 (IMPLANT INNOVATIONS, INC.) 4 February 2003 (04-02-2003)	9, 10, 13-18
Y	* Col. 2, lines 38-62; col. 3, lines 31-36; col. 7, lines 26-36; col. 8, lines 6-24 * * Figures 8a-8d, 16a *	11, 12
Y	CA 2 041 006 (NOBELPHARMA AB) 25 October 1991 (25-10-1991) * Figure 2 *	11, 12

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 May 2009 (29-05-2009)	5 June 2009 (05-06-2009)

Name and mailing address of the ISA/CA	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Luc Gollain 819- 994-8175

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2009/000226

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1. [x] Claim Nos. : 1-8
because they relate to subject matter not required to be searched by this Authority, namely :

Claims 1-8 are directed to a method for treatment of the human or animal body by surgery which the International Search Authority is not required to search.

2. [ ] Claim Nos. :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :

3. [ ] Claim Nos. :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows :

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2009/000226

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US 6514258B1	04-02-2003	AU 1709700A	22-05-2000
		WO 0025695A1	11-05-2000
CA 2041006A1	25-10-1991	AT 117522T	15-02-1995
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		EP 0454639B1	25-01-1995
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		GR 3015819T3	31-07-1995
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