PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5:

A61F 2/44

(11) International Publication Number: WO 91/06261

(43) International Publication Date: 16 May 1991 (16.05.91)

(21) International Application Number: PCT/US90/05318

(22) International Filing Date: 18 September 1990 (18.09.90)

(30) Priority data: 432,088 6 November 1989 (06.11.89) US

(71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 1240 South Loop Road, Alameda, CA 94501 (US).

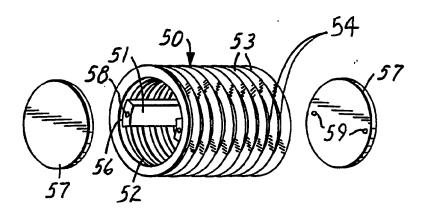
(72) Inventors: RAY, Charles, D.; 19550 Cedarhurst, Wayzata, MN 55391 (US). DICKHUDT, Eugene, A.; 801 Conntinental, New Brighton, MN 55112 (US).

(74) Agent: MEYER, Sheldon, R.; Fliesler, Dubb, Meyer & Lovejoy, Four Embarcadero Center, Suite 400, San Francisco, CA 94111-4156 (US). (81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent)*, DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent).

Published

With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: SURGICAL METHOD AND APPARATUS FOR FUSING ADJACENT BONE STRUCTURES



(57) Abstract

A fusion cage (10) having an external thread (12) can be surgically inserted into a threaded bore extending laterally between the adjacent bony structures such as two vertebrae (94, 95) with the thread (12) penetrating into cancellous bone of each of the vertebrae (94, 95). The fusion cage (10) is easily screwed into place by hand without damage to the bony structures (94, 95). Cage (10) is then packed with a bone-growth-inducing substance such as cancellous bone. When a pair of such cages (10) are implanted between adjacent vertebrae (94, 95), patients have been able to sit without pain by the second or third day, much earlier than has been possible in prior spinal fusions except those involving steel plates and screws. Eventually, the ingrowth of bone through perforations (13) in the valley (14) of the thread (12) of the fusion cage (10) forms a permanent interconnection between



DESIGNATIONS OF "DE"

Until further notice, any designation of "DE" in any international application whose international filing date is prior to October 3, 1990, shall have effect in the territory of the Federal Republic of Germany with the exception of the territory of the former German Democratic Republic.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES .	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML.	Mali
BB	Barbados	FR	France	MR	Mauritania
BE	Belgium	GA	Gabon	MW	Malawi
BF	Burkina Faso	GB	United Kingdom	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JР	Japan	SD	Sudan
CF	Central African Republic	KP	Democratic People's Republic	SE	Sweden
CG	Congo		of Korea	SN	Senegal
CH	Switzerland	KR	Republic of Korea	ŞU	Soviet Union
CI	Côte d'Ivoire	LI	Liechtenstein	TD	Chad
CM	Cameroon	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		



SURGICAL METHOD AND APPARATUS FOR FUSING ADJACENT BONE STRUCTURES

5

CROSS-REFERENCE TO RELATED APPLICATION

This is a division and continuation-in-part of our copending application S.N. 07/259,031, filed October 17, 1988.

BACKGROUND OF THE INVENTION

Field of the Invention

The invention concerns method and apparatus for fusing two adjacent bony structures such as a bone joint, especially adjacent vertebrae of the spine.

Description of Related Art

20 Subsequent to injury, diseases or other degenerative disorder, the disc, a ligamentous cushion between vertebrae, may undergo a painful deterioration. The disc shrinks and flattens out, and the distance between the vertebral bodies begins to 25 collapse. Subsequently, there may be a progressive degeneration leading to mechanical instability, where painful translocations occur between adjacent vertebrae. The movement-induced pain may be so disabling that in many such cases, the vertebral 30 motion must be eliminated. Thus, rigid fusions may be the only present means to stop the translocations and relieve the pain.

It is generally held that successful fusions demand a contiguous growth of bone to create a solid mass that will unite the movable elements into one unit. Otherwise, the fusion cannot achieve the tasks



35

5

10

15

20

25

30

of pain reduction, maintenance of intervertebral height, and immobility of the vertebrae. When fusion bone is first placed, it is soft and moveable, having no cohesive strength. Therefore a variety of appliances have been developed that attempt to hold the vertebrae quite still under conditions of normal spinal activity and daily stress. Bone graft material is placed between the vertebrae, the outer or cortical surfaces of which have been removed or deeply scarified so as to promote the ingrowth of the graft into these recipient sites. Thus positioned, the bone graft slowly unites the vertebrae. Such an appliance is not meant to permanently secure immobility of the segments. Bone ingrowth is required for this.

Dependency upon such an appliance as the sole stabilizer is ultimately unsuccessful due to the development of a mechanical gap or transition between the bone and the appliance, leading to structural failure of the bone and adjacent connective tissue. Such failure is seen in fractures, erosion and absorption of bone with potential further collapse. The pain may also become progressively disabling.

Approximately 150,000 lumbar spinal fusions were performed in the USA during 1987, as reported by the American Hospital Association. There are may methods for intervertebral fusion. The most successful have achieved a success rate of about 90% in random cases. However, several of these techniques, especially those requiring complex appliances, are difficult to master and are hazardous to nerve and vessel structures normally lying close to the involved bones.



WO 91/06261 PCT/US90/05318

- 3 -

From a biomechanical point of view, the most important location of a spinal fusion is at the mechanical center of rotation between the vertebrae. This point is centered within the disc space. Therefore, an interbody fusion is the most rigid and thus the most sought after method among surgeons. Current methods of interbody fusions are, however, the most hazardous of all spinal fusion methods.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions. Typically, a plug, dowel or segment of bone is driven tightly into a cavity carved inside the interbody, intradiscal space. Since there must be a bone-to-bone bridge created during the fusion process, connective tissue and discal tissue must be removed. Deep cuts within the bone must penetrate into the softer, cancellous region to promote bone growth across the space.

Intervertebral fusions using circular bone grafts have been reported in the orthopedic and neurosurgical literature for some years. B.R. Wiltberger in a paper published in Clinical Orthopedics, Vol 35, pp 69-79, 1964, reviewed various methods of intervertebral body fusion using posterior bone dowels driven firmly into a suitably smaller hole between the adjacent vertebrae. Upon doing so the dowel can split or crack or collapse. The stretched bone might also split and it can be compressed by the dowel to the point that it will not grow normally due to collapse of formerly open pores or vascular channels. If this occurs, there may be a late absorption of surrounding bone and the dowel might



5

10

15

20

25

30

DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

