PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/70 | A1

(11) International Publication Number: WO 96/16608

(43) International Publication Date: 6 June 1996 (06.06.96)

(21) International Application Number: PCT/IB95/01069

(22) International Filing Date: 28 November 1995 (28.11.95)

(30) Priority Data:
08/346,902 30 November 1994 (30.11.94) US

(81) Designated States: AU, CA, CN, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

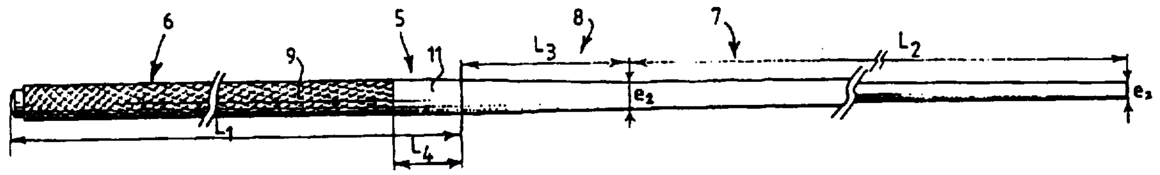
Published
With international search report.

(71) Applicant: SOFAMOR, S.N.C. [FR/FR]; 158, rue de l'Eglise, Boîte postale 4, F-62180 Rang-du-Fliers (FR).

(72) Inventors: GAYET, Louis, Etienne; 3, rue du Grand-Foc, F-86280 Saint-Benoit (FR). RIDEAU, Yves; 23, route de Furigny, Cisse, F-86170 Neuville-du-Poitou (FR).

(74) Agents: MARTIN, Jean-Paul et al.; Cabinet Lavoix, 2, place d'Estienne-d'Orves, F-75441 Paris Cédex 09 (FR).

(54) Title: VERTEBRAL INSTRUMENTATION ROD



(57) Abstract

This rod comprises a first cylindrical part, being a lumbosacral part (6), which is rigid in all directions, a second part, being a dorsal part (7), which is rigid in a frontal plane, in order to prevent scoliosis, and flexible in a sagittal plane, and a dorsolumbar transition zone (8) connecting the lumbar and dorsal parts and profiled in a progressive manner so that its thickness in the sagittal plane diminishes progressively and its width in the frontal plane increases progressively: this profile is such that the second moment of area of the transition zone remains substantially constant over its entire length. The profile, thus defined, of the transition zone has the aim of avoiding, to a great extent, the risks of breaking due to the fatigue in this zone, resulting from the various movements of the patient in a chair, in particular the flexion/extension movements in a sagittal plane, promoted by the rectangular profile of the dorsal part of the rod.

VERTEBRAL INSTRUMENTATION ROD

The present invention relates to a vertebral instrumentation rod for the early fixation of an unstable spine, in its growth phase, in patients suffering from muscular dystrophy or myopathy.

It is known that children suffering from muscular dystrophy are most often affected by a very severe form, Duchenne's muscular dystrophy (DMD). Due to the fact that the muscles of the trunk are attacked, these children almost all develop scoliosis.

The main characteristic of DMD lies, moreover, in the constant presence of a progressive respiratory insufficiency, the principal factor in a poor life prognosis. The current therapeutic advances in this field permit survival for a great many years. This explains the extreme importance of providing improved comfort in the seated position; the preservation of the serious deformations of the spine, sagittal (kyphosis) or frontal (scoliosis), is thus imperative.

As a result of this progressive respiratory insufficiency, as well as cardiac problems at a relatively advanced stage of DMD, the anaesthetic risks become much greater starting from an average age of about 13 - 14 years, a period in which the worsening of the scoliosis becomes very marked. It is for this reason that it has been proposed, since 1982, to treat this spinal deformation when the first signs appear indicating with certainty the future presence of scoliosis. Thus, all children with DMD can, without exception, benefit from surgical treatment of the spine: the more severe the DMD, the earlier the intervention will be.

The aim is therefore to fix a spine in its growth phase, seeking a preventive effect rather than a corrective effect, with the need to take into consideration a physiological position of the pelvis, the condition for maintaining a satisfactory equilibrium of the trunk in a permanent manner. The period of operability is situated, on average, between 10 and 13 years of age.

Moreover, this instrumentation must therefore be designed in such a way as to fulfil a double function: maintain spinal stability in the frontal plane and ensure a certain anteroposterior mobility, or mobility in the sagittal plane. This degree of spinal mobility promotes a balancing of the trunk, which improves the functional possibilities of the upper limb. Indeed, obtaining too rigid a spine constitutes an additional functional handicap, when the function of the upper limbs is greatly impaired.

The instrumentation developed by LUQUE is thus known, which extends over the lumbar and dorsal spine and consists of two L-shaped rods, connected at each level to the posterior arches of the vertebrae by metal wires placed around the laminae. The stresses are at their maximum on the steel wires at the ends of the rod effecting the convexity, and on the steel wires at the middle of the rod effecting the concavity. This instrumentation makes it possible in theory to restore a good curvature in the sagittal plane (lumbar lordosis and dorsal kyphosis), but the experience gained reveals a great many long-term problems with this instrumentation.

Complications have been noted for example, such as migration or breaking of the rod in a relatively large number of cases, after periods of six months to three years.

The instrumentation developed by COTREL-DUBOUSSET is also known, the lumbar part of which is firmly fixed, while the thoracic or dorsal part follows the segmental vertebral fixation of Luque, without arthrodesis, in order to permit the growth of this part of the spine. A relatively large number of material defects have been observed with this instrumentation, in particular fatigue breaks in rods stressed by considerable mobility of the truck of the patient. Moreover, with these known types of instrumentation, the growth of the spine provokes a crankshaft effect in the thoracic part, which means that it is not possible to control all the pathological curvatures at this level.

The principal causes of breaking found in conventional rods are the following: fatigue failure if there is no posterior arthrodesis and if the equipment is too rigid or if the stresses are not well distributed; diameter and resistance of the rod too low; insufficient restoration, or no restoration, of lumbar lordoses and dorsal kyphoses in the sagittal plane.

This latter point is very important, since poor restoration of the lumbar lordosis compromises the entire equilibrium of the superjacent spine. A substantial residual kyphotic curvature in fact subjects the rods to considerable stresses and clearly promotes the subsequent breaking. The breaks suffered by the rod are more frequent at the level of the dorsolumbar hinge. In the flexion/extension movement, the lumbar spine has a greater amplitude than does the dorsal spine, which is controlled more by the costal grill.

The principle of the invention presented here is therefore to use two rods which are designed in such a way as to prevent foreseeable scoliosis from developing and to permit a certain mobility of the subject in the sagittal plane. The intervention is by definition carried out at an early stage, before the surge in spinal growth, in order to avoid as far as possible the operating risks which are always present at a more advanced stage of DMD. The mechanical objective is to propose rods which afford resistance over the course of time, in particular at the level of the dorsolumbar hinge which is under threat.

According to the invention, the vertebral rod comprises a first part, being a lumbosacral part, which is rigid in all directions, a second part, being a dorsal part, which is rigid in a frontal plane, in order to prevent scoliosis, and more flexible in a sagittal plane. These two parts, of different profiles, are connected via a dorsolumbar transition zone which is profiled in a progressive manner so that its second moment of area remains as constant as possible in the said zone.

Thus, between the two-different shapes of the rod, an optimized mode of transition is afforded which offers resistance in order to avoid the risks of fatigue failure.

According to one embodiment of the invention, the lumbosacral part is cylindrical and has a roughened surface, the dorsal part is of rectangular cross-section, the greater length of which extends in the frontal plane, the transition zone having a cross-section which becomes progressively rectangular and diminishes starting from the end of the cylindrical part, and the profile of which is such that its second moment of area remains substantially constant over the entire length of this transition zone.

According to a complementary characteristic of the invention, the thickness of the dorsal part, that is to say its width in the sagittal plane, diminishes progressively from the transition zone up to its free end, whereas its length in the frontal plane increases progressively, in order to ensure easy positioning, then decreases progressively up to its free end, near the cervical vertebrae.

Other particular features and advantages of the invention will emerge from the description which follows and in which reference is made to the attached drawings which illustrate one embodiment thereof by way of non-limiting example.

Figure 1 is a rear elevation view of a spine fitted with instrumentation defined as a function of known surgical treatment of the spine in DMD, for early fixation in its growth phase.

Figure 2 is a side elevation view of the spine and of the instrumentation in Figure 1.

Figure 3 is a broken longitudinal elevation view of an embodiment of the vertebral rod according to the invention, assumed to extend in a frontal plane.

Figure 4 is a plan view of the rod in Figure 3.

Figure 5 is a partial elevation view, on an enlarged scale, of the transition zone of the rod in Figures 3 and 4.

Figures 6 to 10 are cross-sections of the transition zone along the cutting lines 6.6, 7.7, 8.8, 9.9, 10.10 in Figure 5.

Figure 11 is a diagrammatic elevation view, in a frontal plane, of a vertebral rod consisting of a cylindrical part and of a rectangular part, the latter here being represented with a constant width in the frontal plane, for reasons of simplification, and the three axes defining the frontal, sagittal and horizontal planes being represented.

Figure 12 is a section along 12.12 in Figure 11.

Before proceeding to the description of the vertebral rod illustrated in the drawings, it will be appropriate to set out in greater detail the specifications which it must satisfy:

1. Two requirements, namely mechanical and functional, must be distinguished:

1.1 Lower region (lumbar and sacral): maximum rigidity and strength (correction of initial scoliosis and lumbar kyphosis). Posterior arthrodesis performed in the majority of cases.

1.2 Upper region (dorsal): maximum flexibility and strength (control of the reverse curvature or of a second dorsal curvature inverse to the lumbar curvature). There is no arthrodesis here, and instead a flexibility increasing from distal to proximal is sought.

2. Surgical treatment is possible only during a limited period of time, and in a great many cases follow-up surgery is impossible. The equipment must therefore be reliable and withstand fatigue in children operated on at an age markedly below the average for spinal treatment.

3. The rods with a partially smooth surface must not break, which entails determining their diameter with precision and taking into consideration the possibility of work-hardening and a reduction in the depth of the asperities. If, despite everything, a subsequent break occurs, the assembly must make it possible to control any migration of the equipment, which means taking ito consideration an increase in the number of the transverse traction devices (DTT). From a mechanical point of view, the rods must be rigid in the frontal plane (limitation

of the lateral inclination) and horizontal plane (limitation of torsion), more flexible and resistant in the sagittal plane (from C7 to D9), in the upper part of the assembly where the stresses must be distributed uniformly; as regards the threatened zone (dorsolumbar hinge), from D9 to L1, the resistance must be increased.

Figures 1 and 2 illustrate known instrumentation of the COTREL-DUBOUSSET type, consisting of two rigid rods 1 and 2 which extend from the sacrum S to the upper dorsal vertebra D1. These rods are rigid, and each consists of a lumbar part 1a, 2a secured by means of pedicular screws 3 to achieve arthrodesis, and of a dorsal part 1b, 2b which has a diameter greater than that of the lumbar part 1a, 2a.

The dorsal parts 1b, 2b pass freely through rings 4 fixed to the vertebrae in a manner known per se in such a way that they do not impede the growth of the dorsal spine.

An embodiment of the rod according to the invention will now be described with reference to Figures 3 to 10.

The rod 5 comprises a first part, being a lumbosacral part 6, which is rigid in all directions and extends over a length L1, a second part, being a dorsal part 7, extending on a length L2, which is rigid in a frontal plane (ox,oz) (Figure 11) and flexible in a sagittal plane (ox, oy), and, finally, a dorsolumbar transition zone 8, extending over a length L3 and connecting the two parts 6, 7. This transition zone 8 is profiled in a progressive manner so that its moment of inertia, that is to say its second moment of area, remains as constant as possible in the said zone.

In the embodiment illustrated in the drawings, the lumbosacral part 6 is cylindrical and has, over the greater part of its length, a roughened surface 9, namely a knurling in the example shown. This roughened surface 9 extends from the sacral end of the part 6 and stops before the start of the transition zone 8 in such a way as to leave, between the latter and the end of the roughened surface 9, a smooth part 11 of length L4.

The transition zone 8 has a cross-section which becomes progressively rectangular and decreases from the end of the cylindrical part 11, as illustrated in Figures 5 to 10. Thus, at the limit between the zones 11 and 8, the cross-section 12 is circular, after which flattened surfaces 13 appear on the diametrally opposite sides, the width of these flattened surfaces 13 increasing (flattened surfaces 14, 15 in Figures 8 and 9). At the end of the transition zone 8, the cylindrical sides 10 situated between the flattened surfaces 15 are transformed in turn into flattened surfaces 16 in order to form, with the complementary flattened surfaces 17, a rectangular cross-section. It should be noted that as soon as the flattened surfaces 13 appear, the ridges connecting these to the cylindrical sides are progressively rounded (18, 19, 20).

At the same time, from the start to the end of the transition zone 8, the thickness e of the rod, which extends in a sagittal plane once positioned on the spine, diminishes progressively from an initial value e1 to a reduced final value e2. The profile, thus formed, of the transition zone 8 is such that its moment of inertia, hence its second moment of area, remains substantially constant over the entire length L3.

Finally, the thickness e2 of the dorsal part 7 diminishes progressively from the transition zone 8 to its free end, where it has a value e3. The width l in the frontal plane of this dorsal part 7 correspondingly increases progressively from a value l2 (Figure 4) up to a maximum value l3, then decreases progressively to a value l4 at its free end.

It will be understood that the progressive diminution in the thickness e in the sagittal plane (ox, oy) confers upon the dorsal part 7 a certain flexibility in this sagittal plane, allowing the patient flexion/extension movements. In contrast, the increase in the width l of the dorsal part 7 in the frontal plane (ox, oz) confers upon it a rigidity in this plane, which makes it possible to prevent the development of scoliosis.

A more detailed description will now be given of an embodiment of a rod 5, and in particular of its transition zone 8 which must be formed in such a way as to eliminate, almost completely, any risk of breaking at this level. This rod can be made of a suitable bio-compatible metal or biocompatible metal alloy, for example of work-hardened austenitic stainless steel 316L, which has the following characteristics:

- YOUNG's modulus : E = 200,000 MPa
- POISSON's ratio : V = 0.21
- limit of elasticity : $R_{0,2}$ = 900 MPa
- breaking stress : Rm = 1050 MPa
- endurance limit : Rv = 350 MPa
- at 5,000,000 cycles.

Figures 11 and 12 illustrate the reference (Ox,y,z) associated with a rod of length L = 500 mm, represented in a simplified manner as consisting of a cylindrical part which has a length of 200 mm, and of a rectangular part which has a length of 300 mm.

Study of the rigidity R of the rod:

If a force F is exerted at the end of the rod, the rigidity R of the rod is equal to:

R = F / f, f being the maximum deflection of the rod.

Moreover, $f = \alpha / EI$ where E is the YOUNG modulus of the rod in question, I its second moment of area, and α the angle between the initial and deflected positions of the rod.

The rigidity thus depends on I (second moment of area of the section, on which it is possible to act in order to fulfil the specifications).

The rigidity in the cylindrical section, which corresponds to a proximal part of the rod, having a diameter of, for example, d = 5 mm, will thus be directly proportional to the second moment of area I

$$I = \pi d4 / 64 = 30.68 \text{ mm}^4$$

The rigidity in the rectangular section, which corresponds to the distal part of the rod, will also be directly proportional to the second moment of area; during flexion/extension movements in the sagittal plane, the second moment of area I is equal to:

$$I z = b h^3 / 12$$

During flexion/extension movements in the frontal plane, that is to say in fact during the movements of lateral inclination of the rod, the second moment of area will be equal to:

$$I y = h b^3 / 12$$

Study of the resistance of the rod:

The maximum stress is σ max, equal to M / I / v, from which it follows that I / v = M / σ max.

The resistance of the rod thus depends on I / v, that is to say the modulus of resistance on flexion.

The resistance in the proximal cylindrical section will thus be proportional to the modulus of resistance on flexion: $I / v = \pi d^3 / 32 = 12.27\ mm^3$

The resistance in the distal rectangular section will also be proportional to the modulus of resistance on flexion, i.e.:

- in the sagittal plane $I z / v = b h^2 / 6$
- in the frontal plane $I y / v = hb^2 / 6$

In view of the specifications set down, and on the basis of the observations made with regard to breaks in rods already implanted, it is possible to establish an order of priority in the design of the rods, taking into account their resistance and their rigidity.

1. High resistance of the rods, in the sagittal plane:

that is to say high modulus of resistance on flexion

$$Mf = I z / v = b h^2 / 6$$

2. Low rigidity of the rods, in the sagittal plane:

that is to say relative flexibility of the rods in the flexion movements, that is to say low second moment of area

$$I f = Jz = b h^3 / 12$$

3. High resistance of the rods, in the frontal plane:

that is to say high modulus of resistance on flexion

$Ms = I z / v = h b2 / 6$

4. High rigidity of the rods, in the frontal plane:

that is to say high second moment of area

$I s = I y = h b^3 / 12$

Thus, to have great rigidity in the frontal plane, a high ratio hb^3 will be necessary.

To have a rigidity which decreases in the sagittal plane, from proximal to distal, it will be necessary to have a ratio bh^3 decreasing from proximal to distal.

To have a high resistance in the two planes, it will be necessary to have high hb^2 and bh^2 ratios. Each solution will therefore only be a compromise.

By giving different values to Mf, If, Ms and Is, it is possible to determine the different values for h and b.

The material cannot in fact be changed for the time being; there will therefore still be a YOUNG modulus equal to 200,000 N/mm^2. It is therefore only by acting on the shape of the rod, and more particularly on the distal rectangular shape, that is to say by acting on the values of h and b, that it is possible to satisfy these four priorities, classed from 1 to 4, established on the basis of the specifications.

Calculation of b and h, giving priority to the rigidity:

$$I_f = \frac{b h^3}{12}$$

$$I_s = \frac{h b^3}{12} \quad \longleftrightarrow \quad \frac{I_f}{I_s} = \frac{h^2}{b^2} \quad \longleftrightarrow \quad \boxed{h = b\sqrt{\frac{I_f}{I_s}}}$$

$$I_f = \frac{b h^3}{12}$$

$$I_s^3 = \frac{h^3 b^9}{(12)^3} \quad \longleftrightarrow \quad \frac{I_f}{I_s^3} = \frac{b h^3}{12} \times \frac{(12)^3}{h^3 b^9}$$

$$\longleftrightarrow \quad \frac{I_f}{I_s^3} = \frac{144}{b^8}$$

$$\longleftrightarrow \quad \boxed{b = \sqrt[8]{144 \times \frac{I_s^3}{I_f}}}$$

Calculation of b and h, giving priority to the resistance:

$$\frac{bh^2}{6} \Big/ \frac{hb^2}{6} \longleftrightarrow \frac{M_1}{M_s} = \frac{h}{b}$$

$$\boxed{h = b\,\frac{M_1}{M_s}}$$

$$\frac{bh^2}{6} \Big/ \frac{h^2b^4}{36} \longleftrightarrow \frac{M_1}{M_s^2} = \frac{bh^2}{6} \times \frac{36}{h^2b^4}$$

$$\longleftrightarrow \frac{M_1}{M_s^2} = \frac{6}{b^3}$$

$$\longleftrightarrow \boxed{b = \sqrt[3]{6 \times \frac{M_s^2}{M_1}}}$$

From the tests which have been carried out, it has been found that the number of breaks in rods according to the invention is considerably less compared to the number of breaks occurring with the rods of the prior art.

The surgical method for positioning this instrumentation is as follows:

- Restoration of good lumbar lordosis and good dorsal kyphosis. The lumbar lordosis must be secured by arthrodesis in order to have a result which is stable over time, and a uniform development of the superjacent thoracic spine. The deformations in the frontal plane are, by contrast, minimal at the age when the operation is performed;

- no dorsal arthrodesis, on the one hand, so as to diminish the consequences on vitality and prevent inhibition of growth, and, on the other hand, the equipment must be sufficiently flexible in the anteroposterior plane in order to permit balancing of the trunk.

By way of non-limiting example, it is difficult for the diameter of the cylindrical part to exceed 5.3 mm, since an increase in this diameter would make it necessary to replace the pedicular screws. In the case of children a limitation is imposed by the size of the pedicles on the one hand, and by the space taken up by the screw heads on the other hand.

Furthermore, the studies carried out have shown that the rigidity of the assembly is more important in the frontal plane than in the sagittal plane. It is the passage from a cylindrical section to a rectangular section, decreasing in the transition zone 8, and subsidiarily an increase in the number of DTT (Transverse Traction Device) which allows this advantage to be won.

It should be recalled that the rod proposed by the invention is adapted for surgery at an early stage. It is therefore necessary to operate on pliant and reducible scoliosis. It is in fact difficult for the rods of rectangular cross-section to be curved in the frontal plane and they could not be placed on spines affected by stiff and irreducible scoliosis. The concept of the rectangular cross-section of the dorsal part 7 of the rod 5 is thus inseparable from that of early surgery, that is to say, as has already been indicated, in children of approximately 11 to 13 years of age.

It is also advantageous for the knurled zone 9 to be interrupted a little before the start of the transition zone 8 so as not to accumulate the changes in shape at the same site and, in so doing, create a cause for decrease in the fatigue strength.

The invention is not limited to the embodiment described and can comprise various alternatives within the scope of the claims which follow.

CLAIMS

1. Vertebral instrumentation rod (5) for the early fixation of an unstable spine, in its growth phase, in patients suffering from muscular dystrophy, characterized in that this rod comprises a first part, being a lumbosacral part (6), which is rigid in all directions, a second part, being a dorsal part (7), which is rigid in a frontal plane (Ox, oz), in order to prevent scoliosis, and flexible in a sagittal plane (Ox, Oy), and these two parts, of different profiles, are connected via a dorsolumbar transition zone (8) which is profiled in a progressive manner so that its second moment of area remains as constant as possible in the said zone.

2. Rod according to Claim 1, characterized in that the lumbosacral part (6) is cylindrical and has a roughened surface (9), the dorsal part (7) is of rectangular cross-section, the greater length (13) of which extends in the frontal plane (Ox, Oz), the transition zone (8) having a cross-section which becomes progressively rectangular and decreases starting from the end of the cylindrical part with its thickness (e) in the frontal plane (xz) which diminishes progressively, whereas its width (l) in the sagittal plane (xy) increases progressively, the profile of this transition zone thus being such that its second moment of area remains substantially constant over the entire length of this transition zone.

3. Rod according to Claim 2, characterized in that the thickness (e2) of its dorsal part (7) diminishes progressively from the transition zone (8) to its free end, whereas the width (l) of this dorsal part, in the frontal plane (Ox, Oz), increases progressively in order to ensure easy positioning, then decreases progressively as far as its free end.

4. Rod according to Claim 2, characterized in that the roughened surface (9) of the cylindrical part (6) is interrupted before the start of the transition zone (8), from which it is separated by a zone (11) having a smooth surface.

5. Rod according to Claim 2, characterized in that, d being the diameter (in mm) of the cylindrical part (6) and I the second moment of area of its section, the rigidity R of the said cylindrical part is directly proportional to the second moment of area

$$I = \pi d^4 / 64 \text{ (in mm}^4\text{)}$$

and b being the length in the frontal plane (Ox, Oz) of a section of the rectangular part of the rod, that is to say the thickness of the latter, and h its width in the sagittal plane (Ox, Oy), the rigidity of this rectangular part is directly proportional to the second moment of area (I) which, during flexion/extension movements in the sagittal plane, is

$$I z = b h^3 / 12,$$

in that the resistance of the cylindrical section is proportional to the modulus of resistance on flexion:

$$I / v = \pi d^3 / 32 \text{ (mm}^3\text{)}$$

and similarly the resistance in the rectangular section

- in the sagittal plane $I z / v = b h2 / 6$
- in the frontal plane $I y / v = h b2 / 6$,

in such a way that a high resistance of the rod in the sagittal plane corresponds to a high modulus of resistance on flexion

$$Mf = Iz / v = b h^2 / 6,$$

in that a low rigidity of the rod in the sagittal plane corresponds to a relative flexibility on flexion, hence to a low second moment of area:

$$I f = I z = b h^3 / 12$$

a high resistance of the rod in the frontal plane corresponds to a high modulus of resistance on flexion

$$Ms = I z / v = b h^2 / 6$$

and a high rigidity in the frontal plane corresponds to a high second moment of area

$$I s = I y = h b^3 / 12$$

6. Rod according to Claim 5, in which, by giving priority to the rigidity, b and h are defined by the following relation:

$$h = b\sqrt{\frac{I_f}{I_s}}$$

7. Rod according to Claim 5, in which, by giving priority to the resistance, h and b are defined by the relations below:

h = b Mf / ms

$$h = b\frac{M_f}{M_s}$$

$$b = \sqrt[3]{6 \times \frac{M_s^2}{M_f}}$$

8. Instrumentation for the fixation of the spine, in its growth phase, in patients suffering from muscular dystrophy, characterized in that it comprises two vertebral rods (5) equipped with means for attachment to the spine, and each rod comprises a first part, being a lumbosacral part (6), which is rigid in all directions, a second part,.being a dorsal part (7), which is rigid in a frontal plane (Ox, oz), in order to prevent scoliosis, and flexible in a sagittal plane (Ox, Oy), and these two parts, of different profiles, are connected via a dorso-lumbar transition zone (8) which is profiled in a progressive manner so that its second moment of area remains as constant as possible in the said zone.

FIG.1

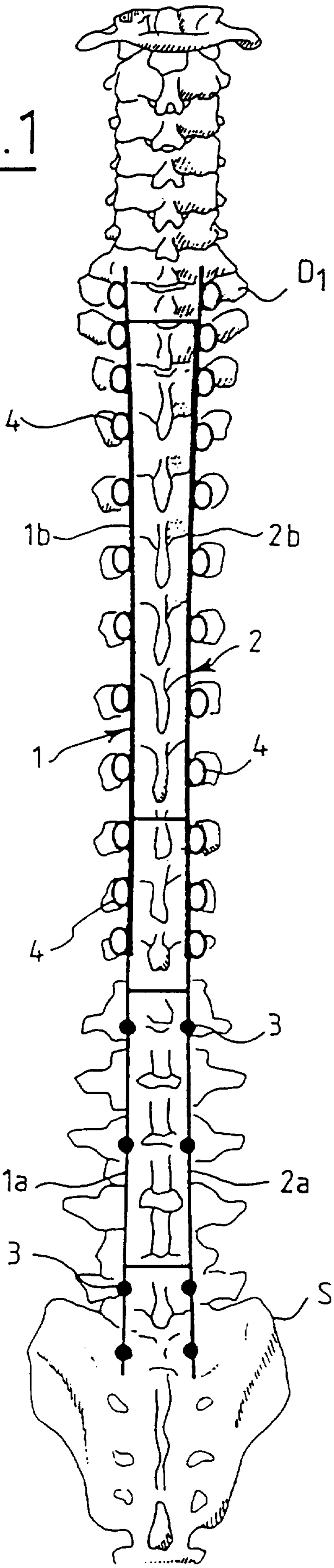
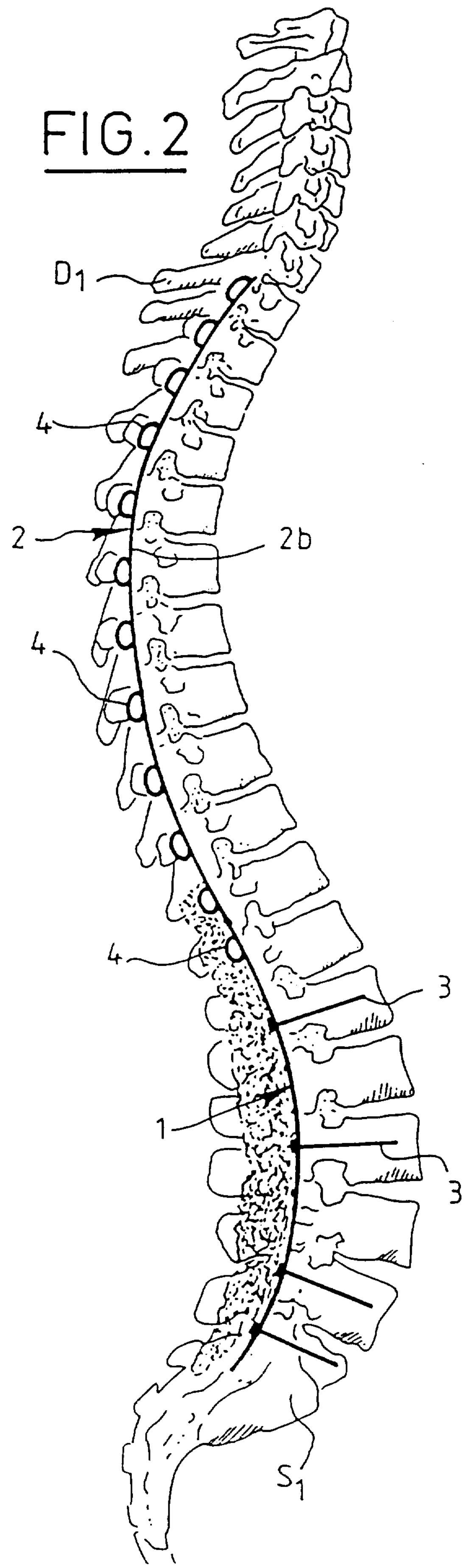


FIG.2



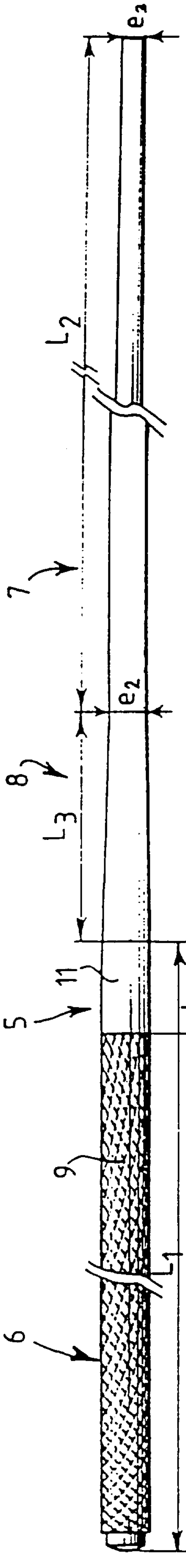


FIG. 3

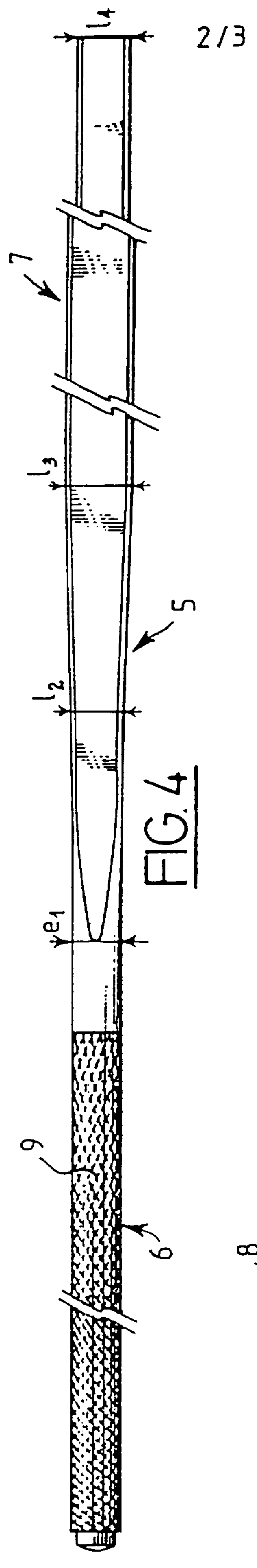


FIG. 4

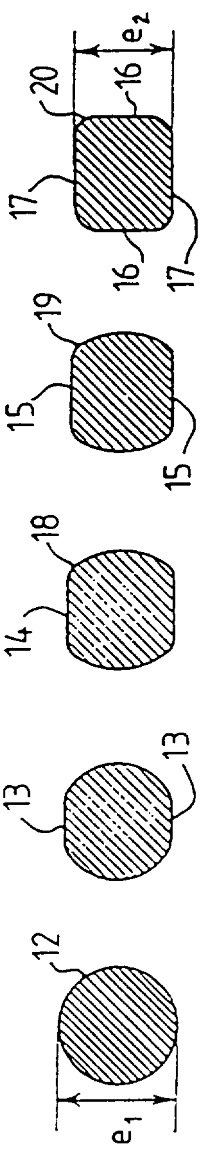


FIG. 6 FIG. 7 FIG. 8 FIG. 9 FIG. 10

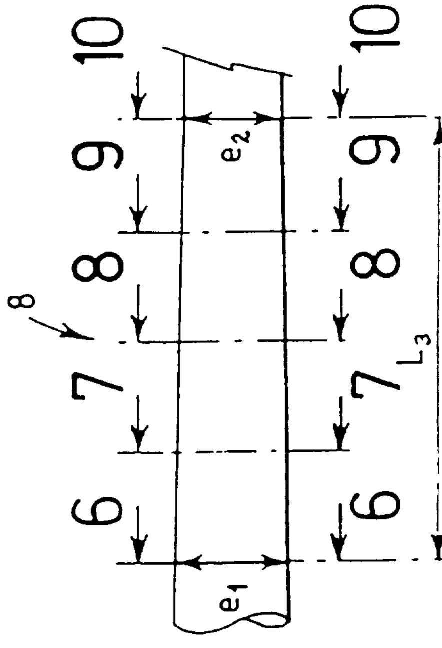


FIG. 5

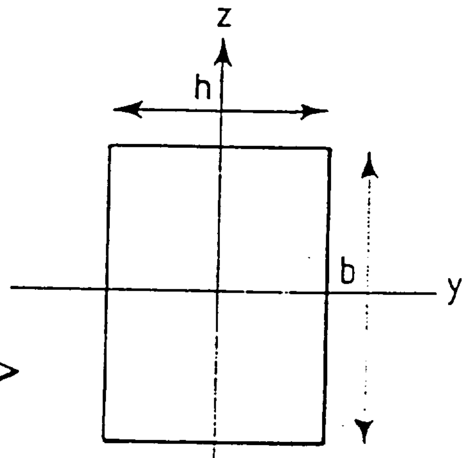


FIG. 12

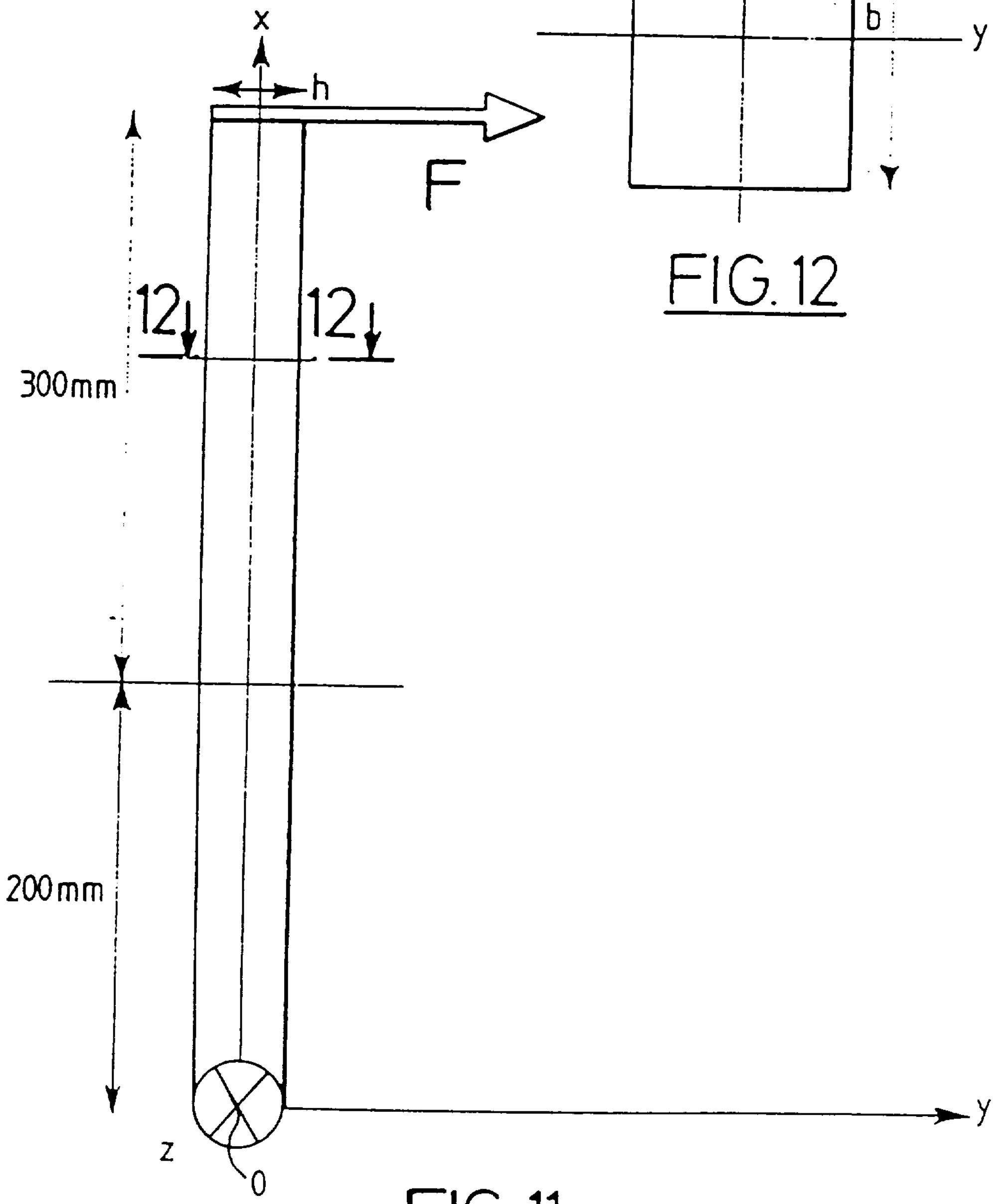


FIG. 11

INTERNATIONAL SEARCH REPORT

Inter. al Application No
PCT/IB 95/01069

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/70

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 6 A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 301 489 (ACROMED CORPORATION) 1 February 1989	1,8
Y	see column 7, line 36-48; figures	2-7

Y	FR,A,2 687 561 (JEANSON) 27 August 1993 see abstract; claim 6; figures	2-7

A	US,A,5 217 461 (ACROMED CORPORATION) 8 June 1993	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in 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 document 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

1

Date of the actual completion of the international search	Date of mailing of the international search report
20 February 1996	01.03.96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Steenbakker, J

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. ıal Application No
PCT/IB 95/01069

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-301489	01-02-89	US-A-	4887595	19-12-89
		CA-A-	1319059	15-06-93
		DE-A-	3874042	01-10-92
		JP-A-	1121046	12-05-89
FR-A-2687561	27-08-93	JP-A-	6007371	18-01-94
		US-A-	5360429	01-11-94
US-A-5217461	08-06-93	NONE		