A Contoured Anterior Spinal Fixation Plate

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There is a need for a specifically designed plate for anterior fixation of the vertebral bodies, contoured to fit closely around the lateral aspect of the spine and wide enough to allow multiple options for placement of at least three screws in each vertebra. The large-diameter cancellous screws should penetrate the opposite cortex. Existing bone plates are inadequate, because they are too narrow and do not allow positioning of more than two screws in each vertebra. The Biomedical Engineering Department of the National Research Council of Canada designed and tested the plate described in this article, with particular attention to providing smooth surfaces to prevent vascular complications. Three lengths of plates have been developed and are used in the area from T11 to L5, with a specific tapered plate for the L5 area to prevent contact with the overlying iliac vessels. This device should be used for stabilization following corpectomy for tumor, decompression of burst fractures, severe disc degeneration, pseudarthrosis, and the multiply operated back. Mechanical testing and clinical applications suggest that the design is functional and that insertion with standard anterior approaches is feasible.

Because existing orthopedic plates do not lend themselves easily to vertebral body fixation the National Research Council of Canada designed and developed a contoured anterior plate with standard cancellous screws.

Three different configurations have been used in the regions of the spine from T11 to L5, and others are being designed specifically for the thoracic region. They are used for stabilization after a corpectomy for tumor, decompression of burst fractures, severe disc degeneration, pseudarthrosis, and the multiply operated spine.

Previous attempts to develop anterior fixation plates have been disappointing. An anterior interbody fusion clamp was developed at the Cleveland Clinic by Humphries *et al.*,[3] with the objective of maintaining blood supply, attaining good bone contact, immobilizing adjacent bone structures, and preventing distraction. Although preliminary studies in dogs were promising, a clinical trial with 23 patients resulted in a 30% failure rate with respect to improvement of symptoms. An undesirable feature of this design was the presence of the implant on the anterior surface adjacent to major blood vessels.

The Dunn device[2] consisted of contoured

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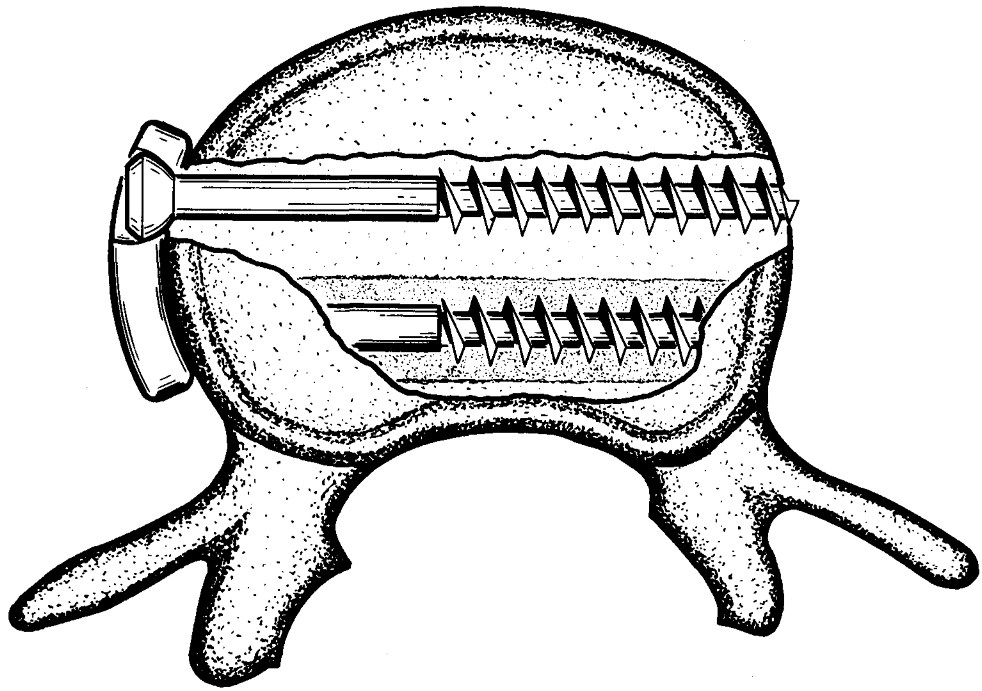


FIG. 1. Transverse sections of the plate, approximating the profile of the vertebral body. Supplemental cement may be used in the screw hole.

blocks fixed to the anterolateral surface of the vertebral bodies, linked by two threaded connecting rods.[1] This instrumentation led to serious vascular complications[13] and was therefore withdrawn from the market.

Ryan *et al.* developed a bolt–plate system[12] for use in the distal thoracic and proximal lumbar spine. This device was fastened by two bolts, one in each vertebral body, connected to a rectangular plate through a

TABLE 1. Mechanical Characteristics of Spinal Plate

3-point bending	
Rigidity	33 Nm/m^2
Strength*	23 Nm
Mean flexural rigidity	19 Nm^2
Eccentric loading of the unsupported plate**	
Bending yield strength	20 Nm (at 80 kg axial load)
Ultimate bending strength	30 Nm (at 123 kg axial load)

* Strength as defined by The American Society for Testing and Materials (ASTM) F382, 13:01, Philadelphia, ASTM, 1983.

** Simulates *in vivo* loading through a 24.5-mm offset of axial load.

slot and locked by a serrated washer. In principle, the single-bolt fixation in the vertebral body provides less resistance to rotation than could be attained using multiple fixation points.

DESIGN RATIONALE

To achieve strong mechanical fixation, the following design criteria were used: (1) control of motion for 6° of freedom for each of the motion units involved[7,9]; (2) restoration of axial loading continuity in each of the three structural columns[1,6]; (3) design of component parts to maintain stress levels below the material's endurance limit based on anticipated maximum loading[8,13]; and (4) construct strength to exceed that of the associated anatomic structures.[5,10]

Additional surgical considerations included ease of insertion and provision of smooth surfaces to minimize vascular risk.

The plate was designed with a low cross-sectional profile, approximating the curvature of the vertebral body in the lumbar and distal thoracic region in the coronal plane (Fig. 1). A rectangular longitudinal profile was used, based on the assumption that any two or three adjacent lumbar vertebral bodies could be linearly aligned (Fig. 2). The length of the plate varied from 6 to 9 cm. The width was 2.5 cm and thickness 0.5 cm. Stainless steel 316 L (low-carbon) prototypes were used for the pilot studies; 316 LVM (with vacuum melt) will be used in the commercial prototypes.

Fixation was achieved at each vertebral level, using two to three cancellous screws at sites selected from the plate's five-hole pattern overlying each body. These holes were machined at an angle converging outside the opposite side of the body to reduce the possibility of mutual screw interferences. The intent was to provide maximal choice of placement. The optimal screw placement patterns for any given operation are determined by factors such as construct biomechanics, bone quality, vertebral level, and local pathologic condition.

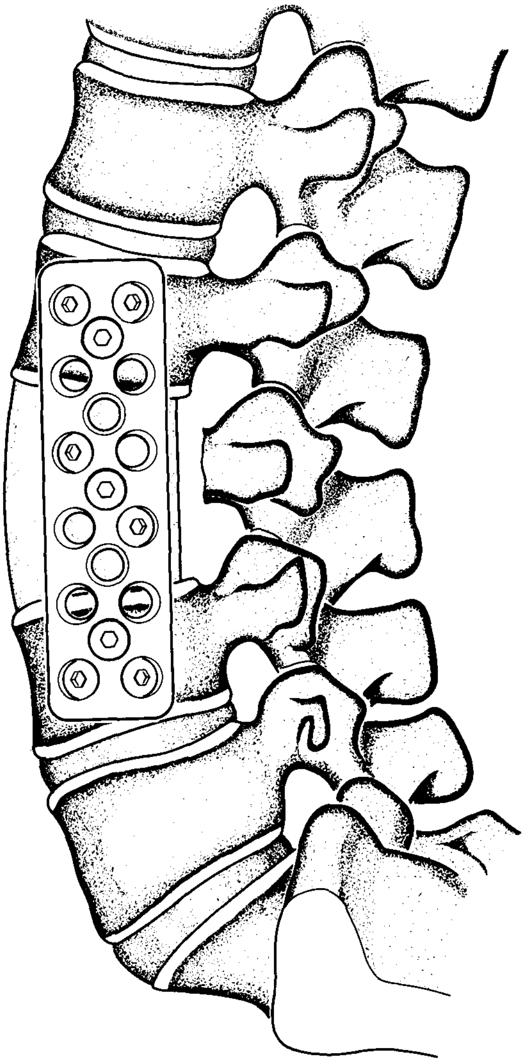


FIG. 2. Alignment of the vertebral plate following corpectomy for tumor with cement replacement.

EVALUATION

In the first phase of research, testing of the spinal plate was carried out to determine its

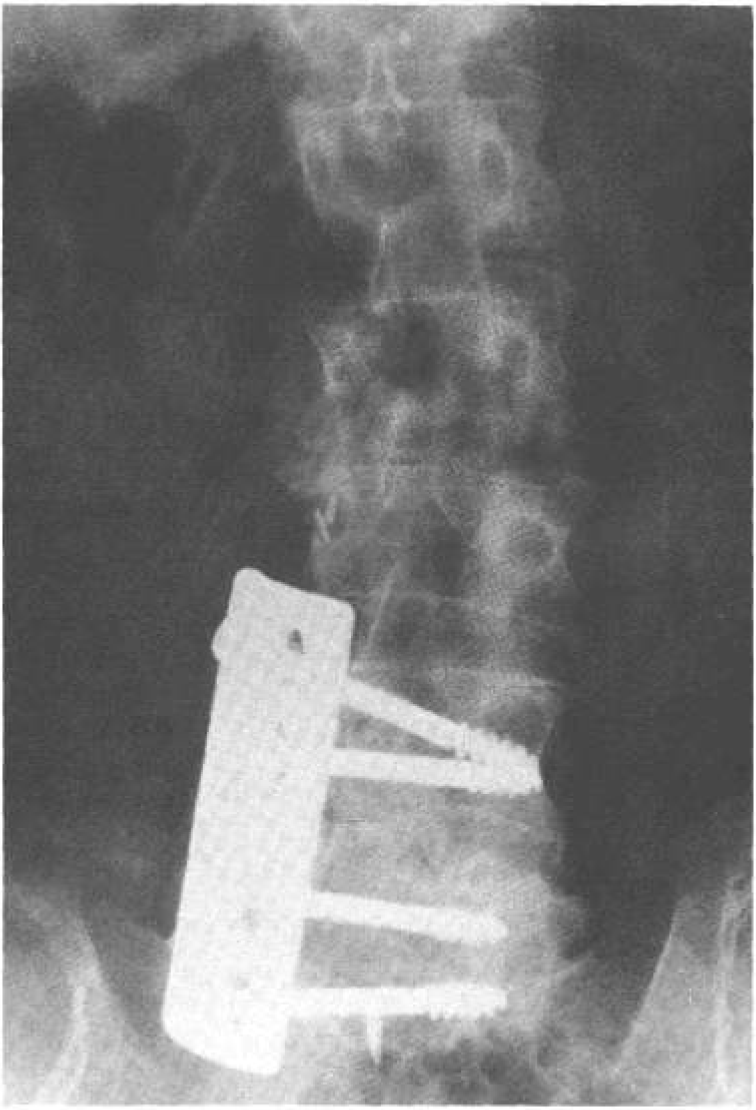


FIG. 3. Early prototype plate used in a 50-year-old obese patient with pseudarthrosis at L4-5.

mechanical characteristics. The measurements included bending stiffness, bending yield point, torsional stiffness, torsional yield, axial stiffness under eccentric loading, and yield strength under eccentric loading. The eccentric loading conditions represented a worst-case scenario in which the plate bridged a vertebral space with no intervening structure to transmit axial loading.

Good screw fixation is critical for achieving stabilization, and testing should extend beyond simple axial pull-out tests, as demonstrated by Zindrick *et al.*[14]

The preliminary results obtained for characterization of the plate as an independent component are shown in Table 1. These values may be compared with tests of the Roy–Camille *et al.* plate,[11] which underwent

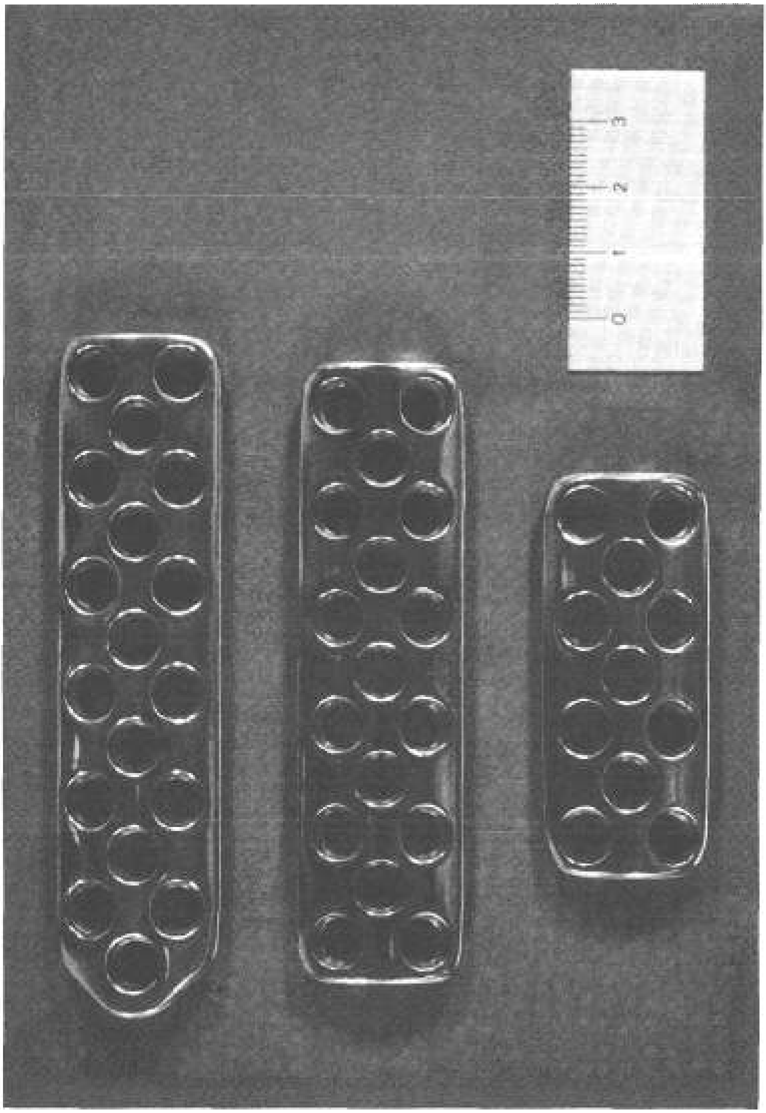


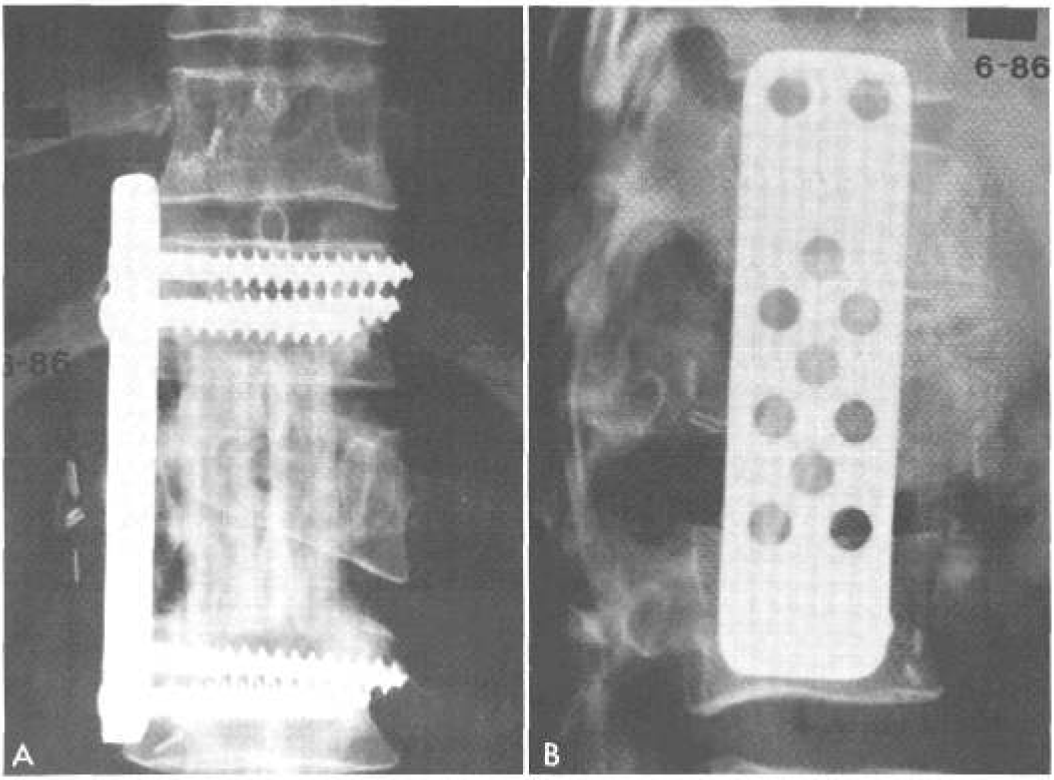
FIG. 4. Three designs of the plate, including tapered type for the lower lumbar region.

plastic deformation at 11.3 newton meters (Nm) and Schanz pins at 14.7 Nm, neither of which has been reported to fail in this mode of clinical use.[4]

SURGICAL TECHNIQUE AND CASE REPORT

Standard anterior exposures of the spine are performed at the lumbar and thoracolumbar levels. The segmental vessels are ligated and divided to include the vertebrae being stabilized. It is essential to elevate the periosteum anteriorly to include the opposite side of the vertebra so that a finger can be placed on the opposite cortex to ensure proper screw fixation (a drill guide is now under development to simplify this technique).

Following corpectomy for tumor or decompression for fracture, a bone graft (or cement for tumor) is placed in the defect. The plate is then



FIGS. 5A AND 5B. (A) AP and (B) lateral roentgenograms of the plate used for stabilization following anterior decompression and strut grafting for burst fracture.

centered as far posteriorly as possible, and a 4.5-mm unicortical temporary holding screw is inserted in each vertebral body. Two or, preferably, three 6.5-mm cancellous screws are then placed in each body. (Note: The smaller thoracic bodies may not safely accommodate more than two screws.) When the plate is used as part of a three-body construct with significant destruction of the bridged body, additional screws are placed in the cement strut; however, this technique is not recommended for bony struts.

CLINICAL MATERIAL

The first prototype plate was used to enhance an anterior fusion in an extremely obese, 50-year-old woman with a posterior pseudarthrosis at L4-5. At a two-year follow-up examination, she had minimal back symptoms and the roentgenogram showed a solid fusion (Fig. 3). The plate, however, was difficult to use because of its width and distal profile relative to the bifurcation of the great vessels.

Modifications to the design of the next prototype included a 4-mm reduction in width (to 2.5 cm), tapering of the distal end for lower lumbar applications, and an increase in available screw holes per vertebral body (from two to five). A variety of plate lengths were developed based on a center-hole pattern of five per vertebral body with single-hole spacing for each intervertebral disc (Fig. 4). Two bridging plates were developed, a 17-hole rectangular plate and an 18-hole distal taper plate, for use with corpectomy and fusion (Figs. 5A and 5B). In addition, for interbody fusion, an 11-hole rectangular fusion plate was produced (Fig. 4). These latter plates have been designed for use in the upper lumbar and thoracolumbar spine. Data on seven patients are listed in Table 2.

TABLE 2. Case Summaries

Patient	*Age (Years)*	*Sex*	*Diagnosis*	*Surgery*	*Plate*
1	82	M	Lung cancer; metastasis to L2	Anterior corpectomy; cement/NRC plate	18-hole
2	49	M	Degenerative disc L4-5	Interbody fusion L4-5; NRC plate	11-hole
3	49	M	Pseudarthrosis L4-5; degenerative disc L5-1	Interbody fusion L4-5 and L5-1; NRC plate L4-5	11-hole
4	21	M	L1 burst rotation fracture, intact neurologically	Anterior decompression; fibular strut grafts; NRC plate T12-L2	17-hole
5	33	M	L1 burst fracture; flaccid bowel and bladder	Anterior decompression; fibular strut grafts, NRC plate T12-L2	17-hole
6	36	M	Calcified, herniated disc T12-L1; impotence; right leg pain and spastic bladder	Anterior discectomy and interbody fusion; NRC plate	11-hole
7	55	M	Old fracture endplate; degenerative disc T12-L1; severe groin pain reproduced with discogram	T12-L1 anterior discectomy and interbody fusion; NRC plate T12-L1	11-hole

NRC = National Research Council.

DISCUSSION

The new plate described above obtains stability by a contoured fit to the vertebral body with multiple screw fixation sites. It is compatible with standard fracture fixation instruments and screws, although more precise lengths of screws are required. The early results are encouraging; longer clinical follow-up study is required, however, before the device can be recommended for other than controlled clinical trials.

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