

Use of Titanium Prosthesis to Bridge a Vertebral Gap in the Spine

-A Preliminary Experimental Study

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Abstract

Resection of a vertebral body for spine tumour or fracture results in a vertebral gap which has to be bridged by autogenous graft, allograft, bone cement or metal spacer. Recently, there have been several metal spacers in the market. We have designed a titanium vertebral spacer which is extensible by way of a threaded mechanism. Coating with hydroxyapatite enables bone ingrowth onto the surface of the titanium spacer. Biomechanical analysis, using the Instron biaxial electro-servo-hydraulic testing machine, showed that the segment bridging the spacer was rigid and stiffer than the adjacent vertebral body motion segment. Histological study showed that there was bone growth across the vertebral gap indicating fusion had taken place.

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Introduction

Bridging a vertebral gap in the spine is one of the commonest problems facing the spine surgeon after dealing with a tumour,¹ infection or a fracture.² The gold standard today is still the autogenous graft,³ though other solutions are the allograft,^{4,5} bone cement fashioned as a block,⁶ ceramics⁷ and the various designs of the commercially available metallic cages.^{8,9} The solutions, other than autografts, eliminate the donor site morbidity^{10,11} seen with the autograft.

We have developed a vertebral "prosthesis" (Fig. 1) which we feel could be a solution to this problem of a vertebral gap. The design of the prosthesis (Figs. 2a-c) is such that it is perforated at both ends, extensible by a screw-on mechanism to allow different lengths to be bridged and hollow for bone graft or graft substitutes to be inserted. The prosthesis is made of titanium and of the 10 developed, 5 had hydroxyapatite (HA) coating on the outer surface excluding the ends. The dimensions are 2.5 cm in length and 1.5 cm in diameter. The dimensions of the prosthesis were determined by measuring the discs space heights from plain X-rays of the lumbar spine of the adult pigs.

The goal of this study was to test the design in a pig model in which a vertebral gap was created.

Materials and Methods

Ten pigs, weighing 35 to 40 kg, were anaesthetised with intramuscular injection of ketamine at 10 mg/kg as premedication and induced with an intravenous injection of thiopentone at 10 mg/kg. The pigs were ventilated on a respirator. Anaesthesia was maintained with 1.5% halothane. The surgical approach to the lumbar spine was developed by the authors, using a direct

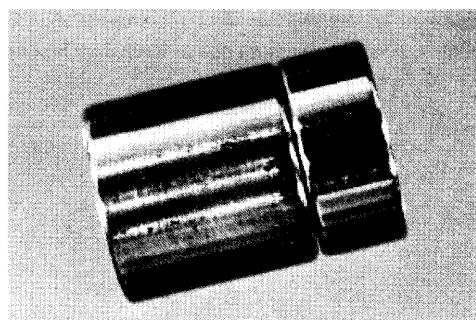


Fig. 1. Titanium prosthesis which is a cylinder with two parts screwed onto each other.

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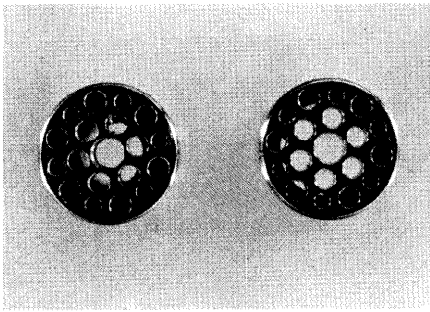


Fig. 2a. End-on view of the prosthesis which is perforated.

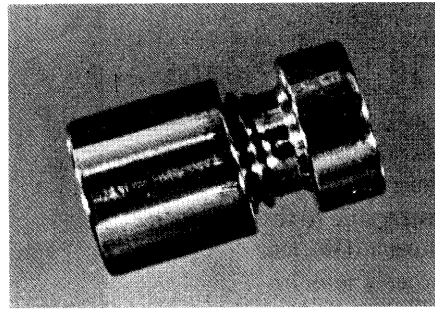


Fig. 2b. Prosthesis which is being unscrewed thereby extending the length

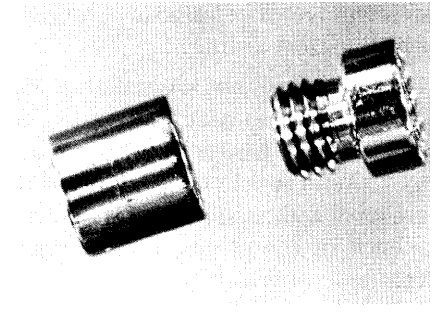


Fig. 2c. Prosthesis completely unscrewed.

lateral approach with the incision in line with the transverse processes of the vertebrae. The superficial muscles were divided in line with the incision. The tips of the transverse processes were reached and the ventral paraspinal muscles were carefully stripped off the transverse processes and the lumbar vertebral bodies. A large enough gap was created in the lumbar spine, by excising the L3/4 disc and the adjacent vertebral bodies, to accept the prosthesis.

Five HA-coated and five uncoated prostheses were inserted. All prostheses had autogenous bone graft inserted into its hollow space and the prosthesis was stabilised with two 1/3 tubular plates (Synthes® Mathys, Switzerland) and screws. Reversal of anaesthesia was by turning off the halothane. The pigs were X-rayed (Fig. 3) and returned to their cages while the anaesthesia was wearing out. Three pigs were noted to be paralysed distal to the level of the prosthesis insertion, resulting in them having paralysed hind legs after the procedure.

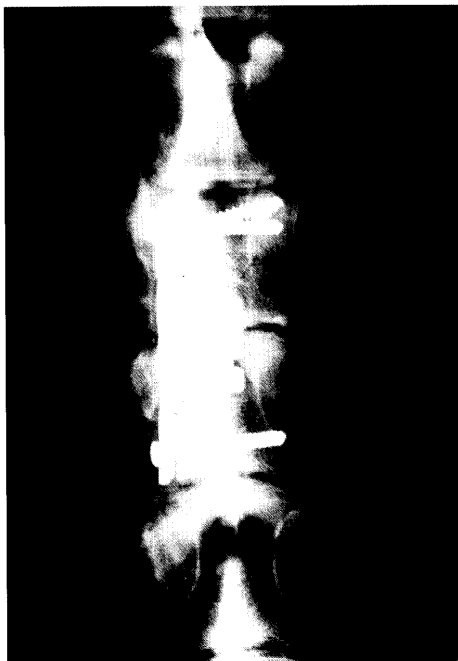


Fig. 3 Immediate postoperative X-ray of the prosthesis-plate of the prosthesis and the side fixation plates.

insertion

The other seven pigs were not adversely affected by the procedure. The pigs were allowed unrestricted activity in their pens. They were fed dry feed with water *ad lib*.

The pigs were sacrificed at 6 months and the lumbar spine was harvested as a whole. Pre-sacrifice X-rays were not taken as this would mean putting the animals under anaesthesia for this to be done. The fixation plates were removed and the lumbar spine specimens sectioned into 3 motion segments: upper-the L1 and L2 vertebrae and the L1/2 disc, middle -which was the test specimen and lower-the L5 and L6 vertebrae and the L5/6 disc.

Biomechanical testing was done on the test specimens with the upper and lower segments serving as controls. The test specimens and controls were fixed onto a custom-made jig with torsion attachment and testing was done using the Instron Test Station No. 8511 (Instron Corp, USA) (Fig. 4). The specimens were preloaded with 1 kg and tested at 5, 10 and 25 kg. The rate of torsion applied was 1 kg/N/m² at 1 minute intervals and the twist angles noted. Axial and bending force testing were attempted as these are the common forces to which the spine is subjected to. However due to the presence of the very stiff titanium prosthesis present in the prosthesis-vertebral complex, there was no movement produced in both the HA-coated and uncoated test specimens. The

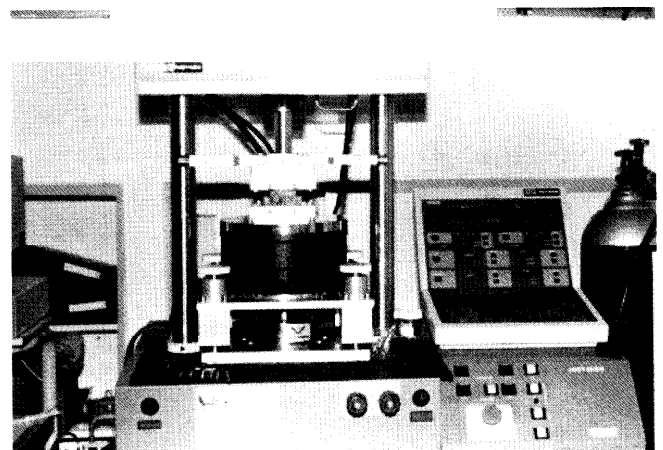


Fig. 4. Testing on the Instron Test Station

specimens were not tested to failure as these were needed for histological testing.

The test specimens were then sectioned with a Leica (Leica, Germany) diamond wafer saw to 1 mm thick specimens, for histological preparation and examination. Thinner specimens sectioning was not possible as there were technical difficulties in sectioning due to the presence of the strong titanium prosthesis. The test specimens, in which the uncoated prosthesis was implanted, could not be subjected to histological sectioning as the prosthesis bone interface was loose and the surrounding tissue was fibrous tissue.

Results

Gross inspection of the harvested lumbar spine specimens showed that the prosthesis-plate complex was completely covered over with bony or fibrous tissue (Fig. 5). The immediate postoperative X-rays showed the prosthesis-plate complex in the proper position. The biomechanical testing showed that the test specimens in which the HA-coated prostheses were implanted showed the curve to the left of their controls, indicating a significantly increased stiffness at 5, 10 and 25 kg loads when compared to their own controls (Fig. 6). This was statistically significant at $P < 0.05$ using the Mann-Whitney U test. This was, however, not so with the uncoated HA test specimens, which were either of the same stiffness or of lesser stiffness than their controls ($P > 0.05$) (Fig. 7). There was also no statistically significant difference between the control motion segments.

The HA-coated prostheses test specimens, on histo-



Fig 5 Harvested spine specimen showing the prosthesis-plate complex covered completely with bone or fibrous tissue (A).

logical examination (Fig. 8), all showed bone tissue enveloping the prosthesis. The new bone was completely apposing the prosthesis at the HA-coated site of the prosthesis. There was some fibrous tissue present only at the top end of the prosthesis which was the screw-on portion part of the prosthesis. The fibrous tissue covered the surface of the whole top end. Appos-

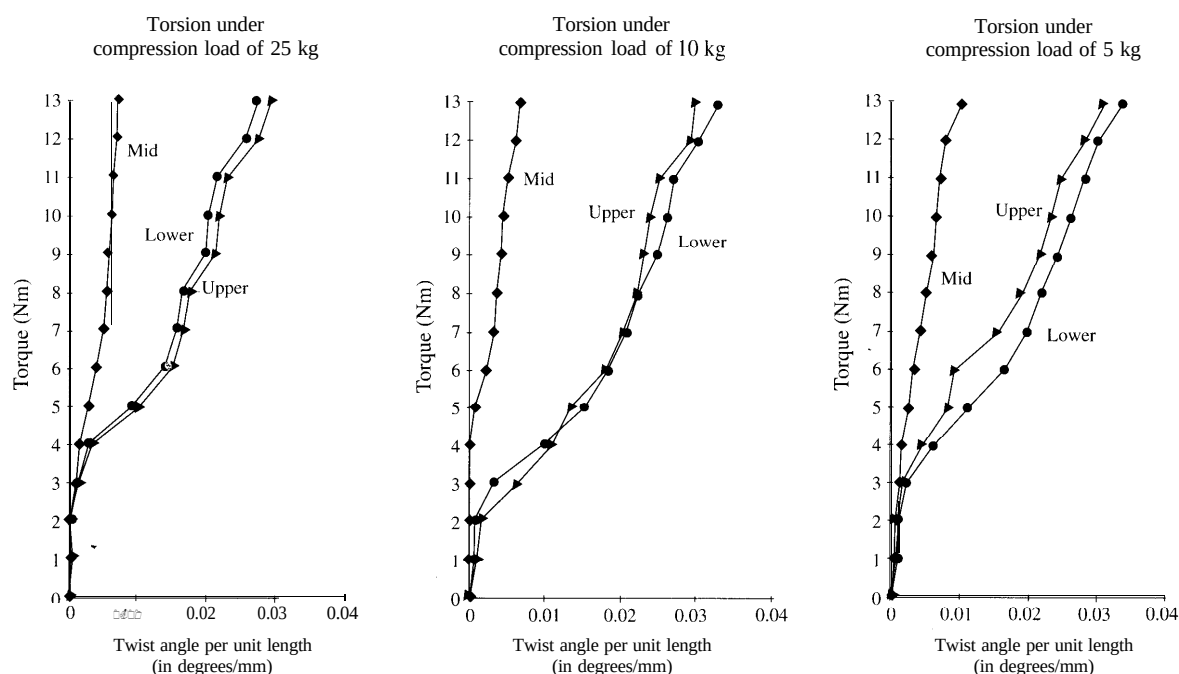


Fig. 6. Graph of hydroxyapatite-coated specimen tested at 25, 10 and 5 kg of loading. Test specimen (Mid) is stiffer than its controls (Upper & Lower).

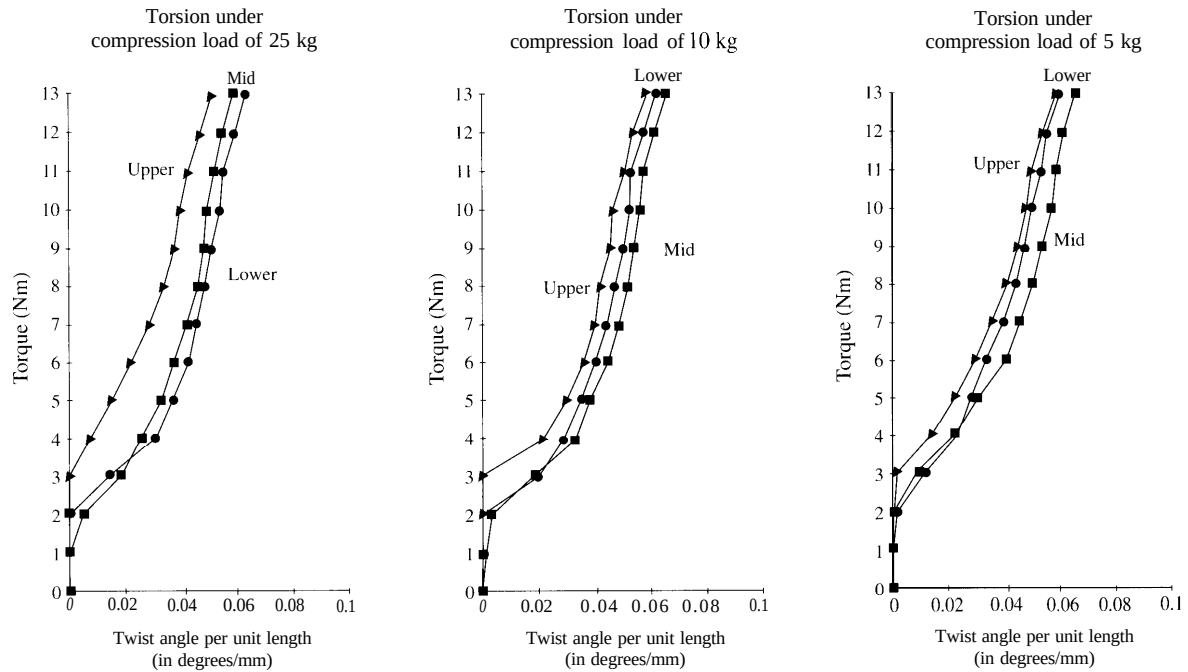


Fig. 7. Graph of uncoated specimen tested at 25, 10 and 5 kg of loading. Test specimen (Mid) is less stiff than its controls (Upper & Lower)



Fig 8. Histology of the hydroxyapatite-coated specimen showing fibrous tissue (A) at the top end; necrotic tissue in the chamber (B); attempt for bony ingrowth (C); living bone closely apposed to the prosthesis (D).

ing this fibrous tissue was bone. The bone graft inserted into the prosthesis was found to be necrotic in all the specimens. There did seem an attempt of bone ingrowth into the prosthesis.

Discussion

Using cages of various designs and compositions to bridge a gap in the spine has been for around for some time. All cages of different material composites have a space for the placement of bone-graft or its substitutes to be placed within the cage and this would ensure bone ingrowth into the cages. The exception is when methylmethacrylate is used as a solid block. The concept in this experimental design was to develop a prosthesis which would give initial immediate stability to a vertebral gap by the inherent strength of the prosthesis itself and its fixation, and through bone tissue ingrowth in the long term, through achieving a solid fusion. The design was also to give the prosthesis the capability of being extendable so as to fit gaps of some variability of within 7mm. We coated 5 of the prostheses with hydroxyapatite as this material is known to allow close bone apposition and ingrowth.¹² We had noted that Moss Miami (Depuy® Warsaw, IN) is a mesh-like device and that it is put in length-wise. The BAK/Proximity (Sulzer® Minneapolis, MN) and Ray (Surgical Dynamics® Norwalk, CT) threaded fusion cages are designed with perforations and are inserted breath-wise. They are strong enough to give immediate stability. None of these commercially available devices have hydroxyapatite coatings. To our knowledge, there are no cages which are rigid enough to give immediate stability through its inherent strength, extendable and which could be put in length-wise and thus bridge a potentially larger gap and coated with hydroxyapatite.

We were able to obtain initial stability in both the HA-coated and uncoated groups, as the 7 pigs that were not affected by the procedure, were able to stand up and move around normally immediately after the anaesthesia had worn out. The authors were not sure that the HA-uncoated specimens were able to give long term stability to the spine. This was the reason to produce the coated and uncoated prostheses and test them out under similar conditions. The long term stability, in terms of bony fusion, was obtained only in the HA-coated prosthesis group.

Biomechanical testing was done with the test specimen compared with its own upper and lower lumbar spine motion segments serving as controls. The authors are introducing a new concept and felt that this would be the ideal way to test the specimen rather than compare it with the motion segment of another animal as this may introduce too many variables which might have a bearing on the results. The curves labelled upper and lower in Figures 6 and 7 are the control motion segments which were harvested and had no surgical procedure done on them. The graphs show these curves match and coincide with each other, in torsion under various loads of compression, indicating that there is not much difference in the stiffness, statistically, of the upper and lower motion segments, which served as controls.

We were not able to obtain bony ingrowth into the prosthesis, as shown by histology that the bone inserted into the prosthesis was necrotic. This is due to design limitations with the perforations being too small and only confined to the ends of the prosthesis. Another observation was that in this group in which fusion was obtained, there was some fibrous tissue in direct apposition to the screw-on portion of the prosthesis with bony tissue noted at the other end. This is probably due to micromotion being present at the screw-on end. By improving on the design where direct fixation of the prosthesis to the vertebrae is done, we would be able to stabilise the prosthesis at both its ends thus providing a better environment for bone apposition to the prosthesis and eliminating the need for fixation plates. This would in turn allow for bony ingrowth into the prosthesis. Hydroxyapatite coating would also be added to the whole prosthesis, instead of limiting it to the body. Another concern of this design is that there is no way of locking the prosthesis to the desired length. By adding screw holes to each of the components of this device, we would be able to fix the device directly to the spine and thus address the problem of fixing the prosthesis to the desired length.

We have developed a second generation prosthesis which should be able to address the design limitations of inadequate and too small perforations. The new prosthesis eliminates the need for fixation plates, may

eliminate the micromotion seen in the initial design and will allow the locking of the prosthesis to the desired length.

Conclusion

Through developing this design and testing it in a pig model, we have become aware of certain deficiencies of the design of this prosthesis. We have been able to show that it is possible to bridge a vertebral gap in the spine by the use of a prosthesis which does give immediate initial stability through its mechanical properties and in the long term by the biologic process of bone growth.

The HA-coated prosthesis has been shown to stimulate bone production in the pig model. With the new prosthesis, we should be able to overcome the limitations of the initial design.

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