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Bone cement or bone substitute augmentation of pedicle screws improves pullout strength in posterior spinal fixation

S. L. EVANS*, C. M. HUNT
School of Engineering, Cardiff University, P.O. Box 925, The Parade, Cardiff, CF24 0YF, UK
S. AHUJA
University Hospital of Wales, The Heath, Cardiff, CF14 4XY, Wales, UK

Pedicle screws are widely used to fix posterior spinal implants. However, in some situations, such as at the ends of long constructs in scoliosis correction, the screws may pull out of the pedicles. This limits the use of pedicle screw fixation where bone quality is poor.

The aim of this study was to investigate the effect of using either a low-viscosity bone cement (Palacos LV) or a bone augmentation material (Cortoss) on the pullout strength of typical pedicle screws (5 mm USS Schanz screws).

Ten lumbar calf vertebrae were implanted with pedicle screws. One screw was inserted as normal, and the contralateral screw was augmented with Palacos LV or Cortoss. A plate was then cemented to the posterior surface of each pedicle and the screws were pulled out using a tensile testing machine.

The pullout strength of the non-augmented screws was 1203 $\pm$ 260 N, while the pullout strength of the augmented screws was 1970 $\pm$ 220 N (Palacos LV) and 2021 $\pm$ 342 N (Cortoss).

Both Palacos LV and Cortoss significantly increased the pullout strength ($p = 0.0213$ and $p = 0.0029$, respectively). There was no significant difference between the Palacos LV and Cortoss groups ($p = 0.79$).

1. Introduction

Posterior spinal instrumentation is used extensively in the treatment of many disorders, of the spine, including fractures, disc disorders, and scoliosis correction. Most posterior spinal implants are fixed by screws inserted into the pedicles to provide a mounting point for a structure that runs between two or more vertebrae. It has been found that in some situations (such as at the ends of long span constructs in scoliosis correction, or in the presence of osteoporosis) the pedicle screws can pull out, leading to clinical complications, and the use of hooks or other means of fixation is sometimes preferred in these situations [1, 2].

The aim of this study was to test whether the pullout strength of pedicle screws could be improved by augmenting their fixation with either a bioactive bone augmentation material (Cortoss, Orthovita Europe, Leuven) or a low viscosity bone cement (Palacos LV, Schering-Plough, Welwyn Garden City, UK). PMMA cements are used to reinforce osteoporotic vertebrae by injection vertebroplasty, and it has been found that this can greatly improve the pull out strength of pedicle screws [3]. PMMA and calcium phosphate cements have also been used to augment the fixation of anterior vertebral body screws, with substantial increases in pullout strength [4]. PMMA cements have been used clinically to augment the fixation of pedicle screws, and there is some pullout test data which confirms that cement augmentation can increase pullout strength [4, 5]. However, there are concerns about the effects of thermal necrosis due to the cement curing [6], which may affect both the bone and the adjacent neural structures, and also about monomer toxicity and possible adverse bone remodelling associated with the injection of substantial volumes of PMMA into the trabecular bone [4]. The use of a bioactive, resorbable material with a lower curing exotherm, and superior biocompatibility may help to avoid these problems.

Cortoss has been used to augment hip screws [7], where it provides similar pullout strength to PMMA bone cement, and has potential for improving the fixation of pedicle screws. It consists of a mixture of methacrylates (bisphenol-A glicydyl dimethacrylate, bisphenol-A ethoxy dimethacrylate and triethylene glycol dimethacrylate) together with combeite glass-ceramic particles which stimulate bone bonding and silica and barium boro-aluminosilicate glass particles which provide reinforcement and radiopacity. During curing it reaches a typical maximum temperature of 63 °C compared to around 90 °C for many PMMA cements, and hence there

* Author to whom all correspondence should be addressed.

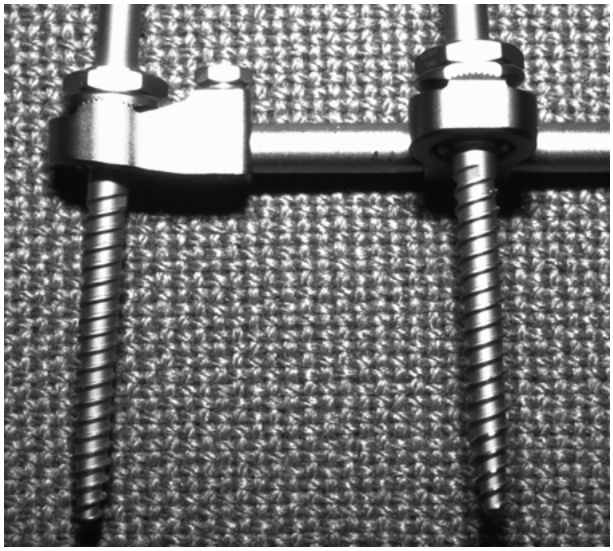

Figure 1 USS pedicle screws showing shallow thread with tapered core.

is a much reduced risk of thermal necrosis or neural damage. The problem of monomer toxicity which occur with PMMA are also much reduced due to its different chemistry and high degree of cross linking on curing.

2. Methods

The pedicle screws used in this study were 5 mm USS Schanz screws (Stratec Medical, Welwyn Garden City, UK), which are widely used for posterior spinal fixation. These screws have a shallow thread with a tapering core (Fig.1) which is intended to hold primarily in the cortex of the pedicle. The screws were inserted following standard surgical technique, using a blunt awl to find a path through the pedicle without damaging the cortex.

Cortoss is supplied in a dual cartridge and is mixed as it is dispensed through a disposable static mixer; the initial portion of cement was discarded to avoid any risk of incomplete mixing. The Palacos LV cement was hand mixed, taking care to avoid excessive air entrapment.

Five calf vertebrae (L4 or L5) were used to test each of the materials. An augmented screw was inserted into a randomly selected pedicle, and a non-augmented screw was inserted on the contralateral side, so that each augmented pedicle screw had its own paired, non-augmented control screw mounted in the same vertebra. For the augmented screws, the cement was inserted as deeply as possible into the screw holes by injecting through a rubber tube and the screw was then inserted, pressurizing the cement. Bone cement (Palacos R) was used to attach a loading plate to the posterior surface of each pedicle as shown in Fig. 2. The shafts of the screws were coated with PTFE tape to prevent the cement adhering to them. Once the vertebrae had been prepared the pedicle screws were pulled out using a Lloyd LRX tensile testing machine and the peak load at pullout was recorded.

The tests produced paired results for augmented and non-augmented pedicle screws. After testing, means and standard deviations were calculated for the cements and their non-augmented pairs. Paired, two-tailed Student's *t*-tests were then used to compare the augmented results with the paired non-augmented results. Two-tailed

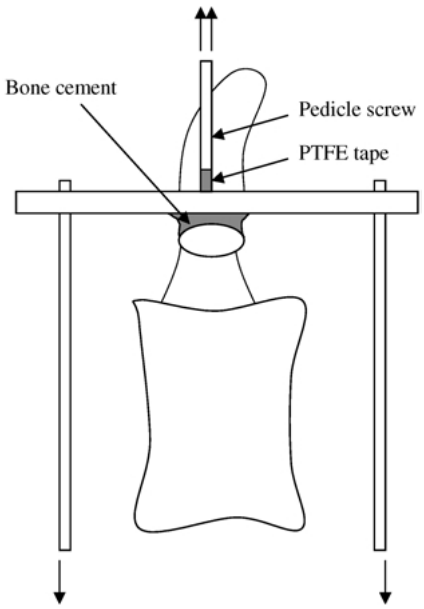

Figure 2 Loading of the pedicle screws for the pull out tests. A plate was cemented to the posterior surface of the pedicle, and PTFE tape was used to prevent the cement sticking to the screw.

unpaired *t*-tests were also used to compare the two types of cement and the two control groups.

3. Results

The results of the pullout tests are shown in Fig. 3. The pullout strength of the non-augmented screws was 1203 ± 260 N, while the pullout strength of the augmented screws was 1970 ± 220 N (Palacos LV) and 2021 ± 342 N (Cortoss).

Both Palacos LV and Cortoss significantly increased the pullout strength compared to the unaugmented contralateral screws ($p = 0.0213$ and $p = 0.0029$, respectively). There was no significant difference between the Cortoss and Palacos LV groups ($p = 0.79$). There was no significant difference between the two groups of spines used ($p = 0.41$).

4. Discussion

The results suggest that augmentation with Palacos LV or Cortoss can usefully increase the initial pullout strength

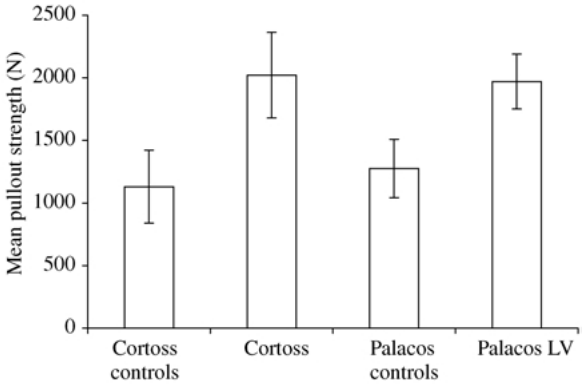

Figure 3 Mean pullout load for each group. The error bars show the standard deviations.

of pedicle screws, and this is probably due to penetration of the cement into the trabecular bone of the vertebral body and the deeper thread at the tip of the screw. The tip of the screw penetrates into the trabecular bone of the vertebral body but this has a very low density and is relatively weak [8], and so normally adds little to the strength of fixation of the screw. Bone cement injected into the screw hole is driven into the trabecular bone as the screw is inserted, giving much stronger fixation. The pedicles typically have a waisted shape, and the tapered screws hold mainly in the converging posterior part and cannot grip in the diverging anterior part of the cortex. Cement pushed into this region could provide extra fixation in this part of the pedicle, which is better shaped to resist screw pullout.

This technique may be beneficial in situations such as at the ends of long constructs for scoliosis correction, where there may be a risk of pullout. The technique could also be beneficial in cases where the bone quality is poor, for example, due to osteoporosis, and posterior fixation is currently difficult and hazardous. Possible limitations may be the difficulty of removing the screws in the event of complications, and the risk of cement extrusion through the pedicle walls resulting in nerve damage. No evidence of this complication was observed in the present series of tests, but further experimentation would be useful in assessing the risks posed by each of these problems. Other known problems such as thermal necrosis, monomer toxicity and adverse bone remodelling may be reduced by the use of Cortoss, and this gave similar initial pullout strength to Palacos LV.

No significant difference was found between the initial pullout strengths with each of the two materials. In the long term the Cortoss may stimulate bone growth, increasing bone density in the vicinity of the pedicle screw and increasing the pullout strength further, although, on the other hand, it might also be partially resorbed resulting in a loss of pullout strength. Clinical trials or *in vivo* testing would be required to resolve this question. The Palacos cement is effective in fixing hip prostheses and other implants over long periods and hence it is probable that its initial strength would be maintained, but bone remodelling may affect the pullout strength in the long term.

5. Conclusions

Augmentation of pedicle screw fixation using either Cortoss bioactive bone substitute or Palacos LV low viscosity cement resulted in increased pullout strength. This technique has potential for reducing the risk of screw pullout in long constructs or in cases where bone quality is poor. Augmentation with Cortoss gave similar initial pullout strength to conventional PMMA cement and may offer improved biocompatibility and reduced risk of thermal necrosis.

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