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Enhancement of pedicle screw stability using calcium phosphate cement in osteoporotic vertebrae: in vivo biomechanical study

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Abstract We conducted an experimental study using female beagles with and without ovariectomy-induced osteoporosis to determine the effect of calcium phosphate cement (CPC) on the mechanical stability of inserted pedicle screws. A drill hole was created from the base of the transverse process to the vertebral body; CPC was injected into the hole, and then a screw was inserted into the same hole. In the presence of osteoporosis evidenced by dual X-ray absorptiometry, the stability of the inserted screw augmented by CPC against pull-out and cephalocaudal forces were significantly greater by 28% and 54% at 1 week after operation, 48% and 71% at 2 weeks, and 56% and 68% at 4 weeks compared with those without CPC. The pull-out strength increased progressively with time after surgery, probably reflecting new-bone growth from the surrounding cancellous bone, which was in direct contact with the CPC, as shown in the histologic study. At each time point the cephalocaudal rigidity was similar and the pull-out strength greater than that for the screws inserted without CPC in nonporotic dogs. These findings suggest that CPC augments the stability of the inserted pedicle screws and increases the stiffness of fixed osteoporotic motion segments using instrumentation.

Key words Osteoporosis · Calcium phosphate cement · Pedicle screw · Spine · Biomechanics

Introduction

The combination system of pedicle screws and plates or rods has been used to stabilize unstable motion segments or to correct spinal deformities. Subsequently, the system has been used for segmental spinal fixation to promote graft incorporation in patients with some degenerative spinal disorders. However, instrumentation surgeries for the osteoporotic spine have been challenging.

The mechanical stability of inserted pedicle screws is affected by the bone mineral density (BMD).[2,3,15,17,20,22] Rigidity can be compromised and the screws can loosen in patients with osteoporosis. To investigate the stability of inserted pedicle screws, pull-out strength tests have been performed to optimize screw size, screw design, and the insertion depth and direction.[1,8,12,17,20,23] To improve the strength of the screw–bone interface, mechanical tests have been performed with augmentation using cancellous bone, hydroxyapatite (HA) grout, HA stick, and polymethylmethacrylate (PMMA).[11,16,20,21,25]

Calcium phosphate cement (CPC) (Biopex; Mitsubishi Materials, Tokyo, Japan) was developed by Hirano[4] based on the hydration reaction of α-tricalcium phosphate reported by Monma and Kanazawa[13] in 1976. CPC comes as a powder, the texture of which turns into that of a paste or soft clay when kneaded with liquid. It sets and hardens through a nonexothermic reaction. CPC enhances osteogenesis in the surrounding bone because of its osteoconductivity. In the long term, CPC is expected to be gradually replaced by bone as remodeling progresses.[24] CPC has been used to fill bone defects, and Shibata et al.[19] and Ikeuchi et al.[7] have reported that it increases the compressive strength of the vertebral body when injected into a void space in patients with osteoporosis. The use of CPC with pedicle screws may enhance the strength of the initial fixation, and Iai et al.[6] confirmed that the in vitro pull-out strength of screws can be increased with the use of CPC.

In the present study, the effects of CPC on the in vivo stability of inserted pedicle screws and sequential changes over 4 weeks were investigated using experimental osteoporotic dogs. This study is considered antecedent to the clinical use of CPC.

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Materials and methods

CPC

The CPC used in this study was produced using a powder consisting of 75 wt% α-tricalcium phosphate [α-TCP; $Ca_3(PO_4)_2$], 18 wt% tetracalcium phosphate [TeCP; $Ca_4(PO_4)_2O$], 5 wt% dicalcium phosphate dihydrate (DCPD; $CaHPO_4{\cdot}2H_2O$), 2 wt% HA [$Ca_{10}(PO_4)_6(OH)_2$], and a weakly basic hardening liquid consisting of 5 wt% sodium chondroitin sulfate, 12 wt% sodium succinate, and 83 wt% water. The handling and mechanical property of the CPC depend on the powder/liquid weight ratio. In this study, a powder/liquid weight ratio of 2.8 was used to permit easy injection using a syringe while maintaining sufficient strength.

Animals

Approval for this study was obtained from the Animal Experimentation Ethics Committee of Kochi Medical School. Nine female beagles (Nosan, Yokohama, Japan) aged 7.2–9.0 months (mean 7.8 ± 0.6 months) and weighing 7.9–9.7 kg (mean 8.7 ± 0.7 kg) were treated by transperitoneal bilateral ovariectomy and were fed a 250 g/day low-calcium diet (CLEA Japan, Tokyo, Japan) for 9 months to produce experimental osteoporosis (porotic dogs). At the end of the 9-month feeding period, the mean weight was 11.7 ± 1.2 kg (9.8–14.0 kg). Five female beagles aged 17.9–21.0 months (mean 19.4 ± 1.7 months) and weighing 10.0–11.9 kg (mean 11.0 ± 0.9 kg) that were not subjected to ovariectomy or given a low-calcium diet were used as healthy controls (nonporotic dogs).

Surgical preparation

All beagles were anesthetized with isoflurane. Each lamina from the first lumbar vertebra (L1) to the seventh lumbar vertebra (L7) was exposed by the posterior midline approach, and six holes were drilled to a depth of 12 mm from the base of the transverse process to the vertebral body alternately on the right and left sides of L1 to the L6 vertebra using a drill 3.5 mm in diameter. After about 2 min of kneading, CPC paste was injected into three of the six bone holes to fill the space using manual pressure with a syringe whose tip was 3.5 mm outside diameter. A stainless steel cancellous screw 26 mm in length, 12 mm in thread length, and 4.0 mm in major diameter (Stryker Japan, Tokyo, Japan) was then inserted into each hole to the same depth of 12 mm (CPC group). As a control, a screw was inserted into each of the remaining three holes to the same depth without CPC (non-CPC group).

BMD measurement and mechanical testing

At 1, 2, and 4 weeks after surgery, three porotic dogs and two nonporotic dogs (one nonporotic dog 2 weeks after surgery) were killed, and the spine from L1 to L7 was excised en bloc. In a water tank filled with physiological saline, the bone mineral density (BMD) value was measured on the lateral view of the vertebral body of the L7 vertebra, into which no screw had been inserted, by dual-energy X-ray absorptiometry (QDR-1000; Hologic, Waltham, MA, USA).

A total of 75 vertebrae were available for mechanical testing. The remaining vertebrae in which the screw had penetrated the spinal canal or anterior aspect of the vertebral body were not tested mechanically, but three of them from the CPC group were examined histologically. The vertebrae and screws in L1 to L6 were fixed in a custom-made holder, and mechanical testing was performed using Instron model 4466 (Instron, Canton, MA, USA).

A shank of the screw, 23.3 mm from the tip, was toggled by a specially designed connector of 7.0 mm inside diameter, producing a controlled wagging movement in the cephalocaudal direction. Five cycles of loading were applied perpendicular to the major axis of the screw at a crosshead speed of 3.0 mm/min with a maximal load of 9.8 N, which was within the elastic range of the screw–bone interface. A graph of force (newtons) versus displacement (millimeters) was recorded, and the cephalocaudal rigidity of the screw–bone interface was determined as the slope of the fifth load–deformation curve. The pull-out strength of the screw in the direction of the major axis was tested with a crosshead speed of 10 mm/min (Fig. 1). The cephalocaudal rigidity and pull-out strength in the CPC and non-CPC groups were compared.

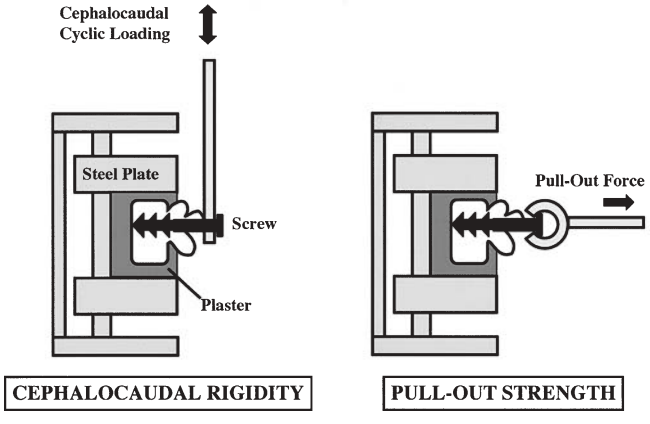

Fig. 1. Experimental setup. Five cycles of loading were applied perpendicular to the major axis of the screw. The cephalocaudal strength was calculated from the load–deformation curve. The pull-out strength of the screw in the direction of the major axis was tested

Histological study

Three vertebrae used for histological analysis were from the CPC group obtained 1, 2, and 4 weeks after surgery. The specimens were fixed in 20% neutral buffered formalin, embedded with polyester resin, sectioned along the screw axis using glass knives, and stained with toluidine blue.

Statistics

The strength between the CPC and non-CPC groups was compared by the Mann-Whitney U-test, and the differences between values 1, 2, and 4 weeks after surgery were compared by the Kruskal-Wallis test. Values were given as means ± SD and were considered significant at a probability (P) of <0.05.

Results

BMD

The BMD value of L7 was 0.43 ± 0.04 g/cm^2 (range 0.38–0.48 g/cm^2) in the porotic dogs and 0.59 ± 0.03 g/cm^2 (range 0.54–0.62 g/cm^2) in the nonporotic dogs. This difference was significant ($P < 0.01$), indicating that an experimental model of osteoporosis had been produced.

Biomechanical findings

Cephalocaudal rigidity

No looseness was observed by repeated loading perpendicular to the major axis of the screw. Load–deformation curves were generated to determine cephalocaudal rigidity.

Cephalocaudal rigidity in porotic dogs. The cephalocaudal rigidity in the CPC group of porotic dogs (Fig. 2) was 144.4 ± 36.8 N/mm ($n = 7$) 1 week after surgery, 163.4 ± 31.6 N/mm ($n = 9$) at 2 weeks, and 172.3 ± 38.2 N/mm ($n = 8$) at 4 weeks. The values in the non-CPC group were 93.8 ± 23.7 N/mm ($n = 9$) at 1 week, 95.6 ± 21.4 N/mm ($n = 9$) at 2 weeks, and 102.7 ± 32.3 N/mm ($n = 8$) at 4 weeks, showing no appreciable change. The cephalocaudal rigidity in porotic dogs was significantly higher at 1, 2, and 4 weeks after surgery in the CPC group than in the non-CPC group ($P < 0.01$), and it was higher by 53.9%, 70.9%, and 67.8%, respectively, in the CPC group than in the non-CPC group.

Cephalocaudal rigidity in nonporotic dogs. The cephalocaudal rigidity in the CPC group of nonporotic dogs (Fig. 3) was 234.3 ± 56.7 N/mm ($n = 4$) 1 week after surgery, 216.4 ± 78.3 N/mm ($n = 3$) at 2 weeks, and 240.8 ± 58.8 N/mm ($n = 6$) at 4 weeks. In the non-CPC group it was 143.4 ± 27.1 N/mm ($n = 4$) at 1 week, 149.2 ± 37.7 N/mm ($n = 3$) at 2 weeks, and 160.4 ± 28.9 N/mm ($n = 5$) at 4 weeks. The cephalocaudal rigidity was significantly higher in the CPC group than in the non-CPC group 1 and 4 weeks after surgery ($P < 0.05$) but not at 2 weeks.

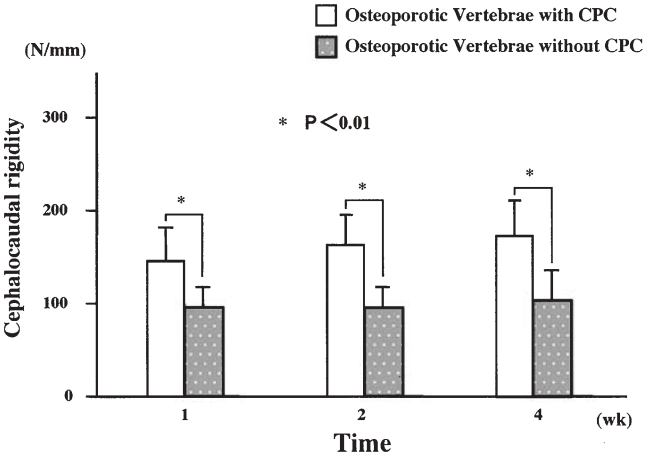

Fig. 2. Cephalocaudal rigidity of porotic dogs. Calcium phosphate cement (*CPC*) significantly enhanced the cephalocaudal rigidity of the screws in all experimental osteoporotic vertebrae examined in this study

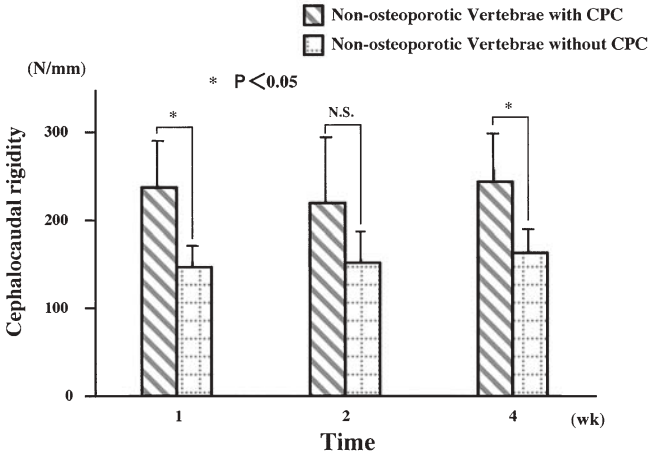

Fig. 3. Cephalocaudal rigidity of nonporotic dogs. Note that the rigidity was significantly higher in the CPC group than in the non-CPC group 1 and 4 weeks after surgery

Pull-out strength

Pull-out strength in porotic dogs. The pull-out strength in the CPC group of porotic dogs (Fig. 4) was 415.4 ± 69.6 N ($n = 7$) 1 week after surgery, 512 ± 91.2 N ($n = 9$) at 2 weeks, and 573.5 ± 92.1 N ($n = 8$) at 4 weeks, showing a tendency to increase with time after surgery

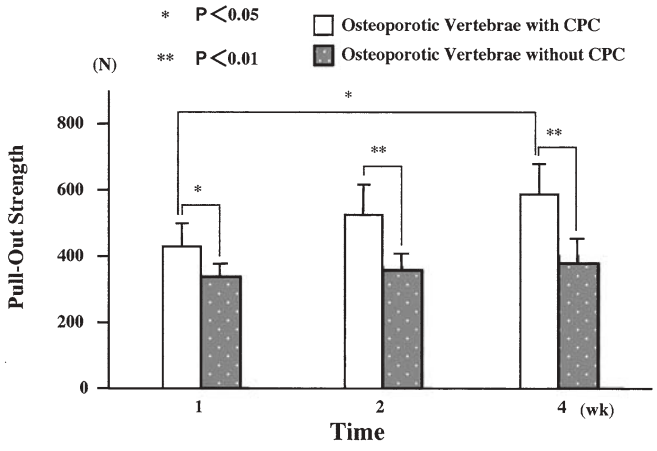

Fig. 4. Pull-out strength of porotic dogs. Note that the pull-out strength was gradually enhanced over time after screw insertion with the CPC. The value was significantly higher at 4 weeks than at 1 week

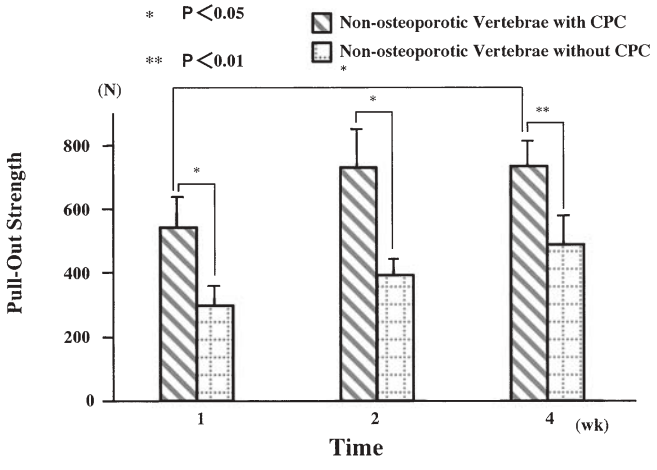

Fig. 5. Pull-out strength of nonporotic dogs. Note that the pull-out strength was significantly higher at 1, 2, and 4 weeks after surgery in the CPC group than in the non-CPC group

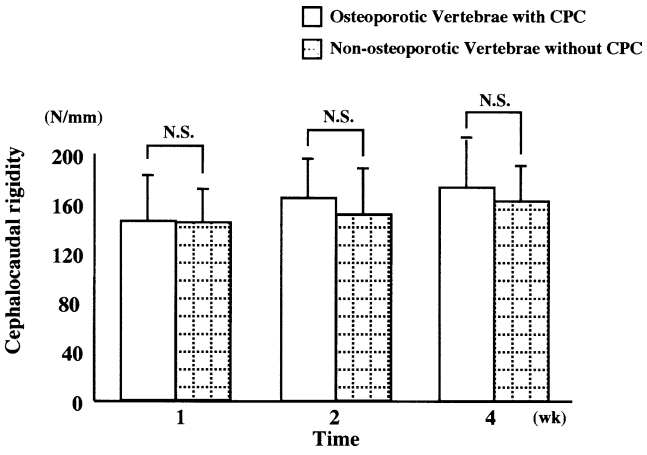

Fig. 6. Augmentation effect on cephalocaudal rigidity. Note that the rigidity in the CPC group of porotic dogs was similar to that in the non-CPC group of nonporotic dogs at all time stages

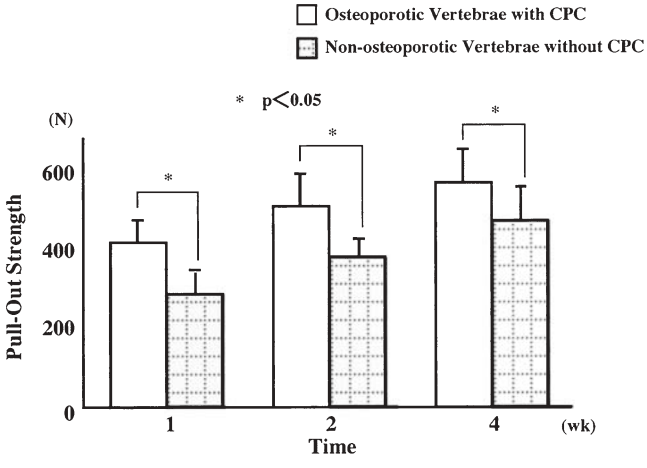

Fig. 7. Augmentation effect on pull-out strength. Even with osteoporotic bone, pull-out strength greater than that in normal bone can be achieved using the CPC, and the pull-out strength increases further over time

($P < 0.05$). The pull-out strength was significantly higher at 4 weeks than at 1 week ($P < 0.01$). In the non-CPC group the values were 324.4 ± 38.0 N ($n = 9$) 1 week after surgery, 346.0 ± 49.6 N ($n = 9$) at 2 weeks, and 366.8 ± 75.0 N ($n = 8$) at 4 weeks. These values were similar ($P > 0.6$). The pull-out strength in porotic dogs was significantly higher at 1 week ($P < 0.05$), 2 weeks ($P < 0.01$), and 4 weeks ($P < 0.01$) after surgery in the CPC group than in the non-CPC group; it was higher by 28.1%, 48.1%, and 56.3%, respectively.

Pull-out strength in nonporotic dogs. The pull-out strength in the CPC group of nonporotic dogs (Fig. 5) was 531.7 ± 96.2 N ($n = 4$) 1 week after surgery, 720.3 ± 120.3 N ($n = 3$) at 2 weeks, and 723.2 ± 79.5 N ($n = 6$) at 4 weeks, showing an increase over time, with a significant difference between 1 and 4 weeks ($P < 0.05$). The values in the non-CPC group were 285.2 ± 63.1 N ($n = 4$) 1 week after surgery, 381.2 ± 52.0 N ($n = 3$) at 2 weeks, and 478.2 ± 90.8 N ($n = 5$) at 4 weeks. The CPC group of nonporotic dogs showed a significantly higher pull-out strength at 1 week ($P < 0.05$), 2 weeks ($P < 0.05$), and 4 weeks ($P < 0.01$) after surgery than did the non-CPC group.

Compared to the non-CPC group of nonporotic dogs, the CPC group of porotic dogs had similar cephalocaudal rigidity ($P > 0.5$) and significantly higher pull-out strength at every time point after surgery ($P < 0.05$) (Figs. 6, 7).

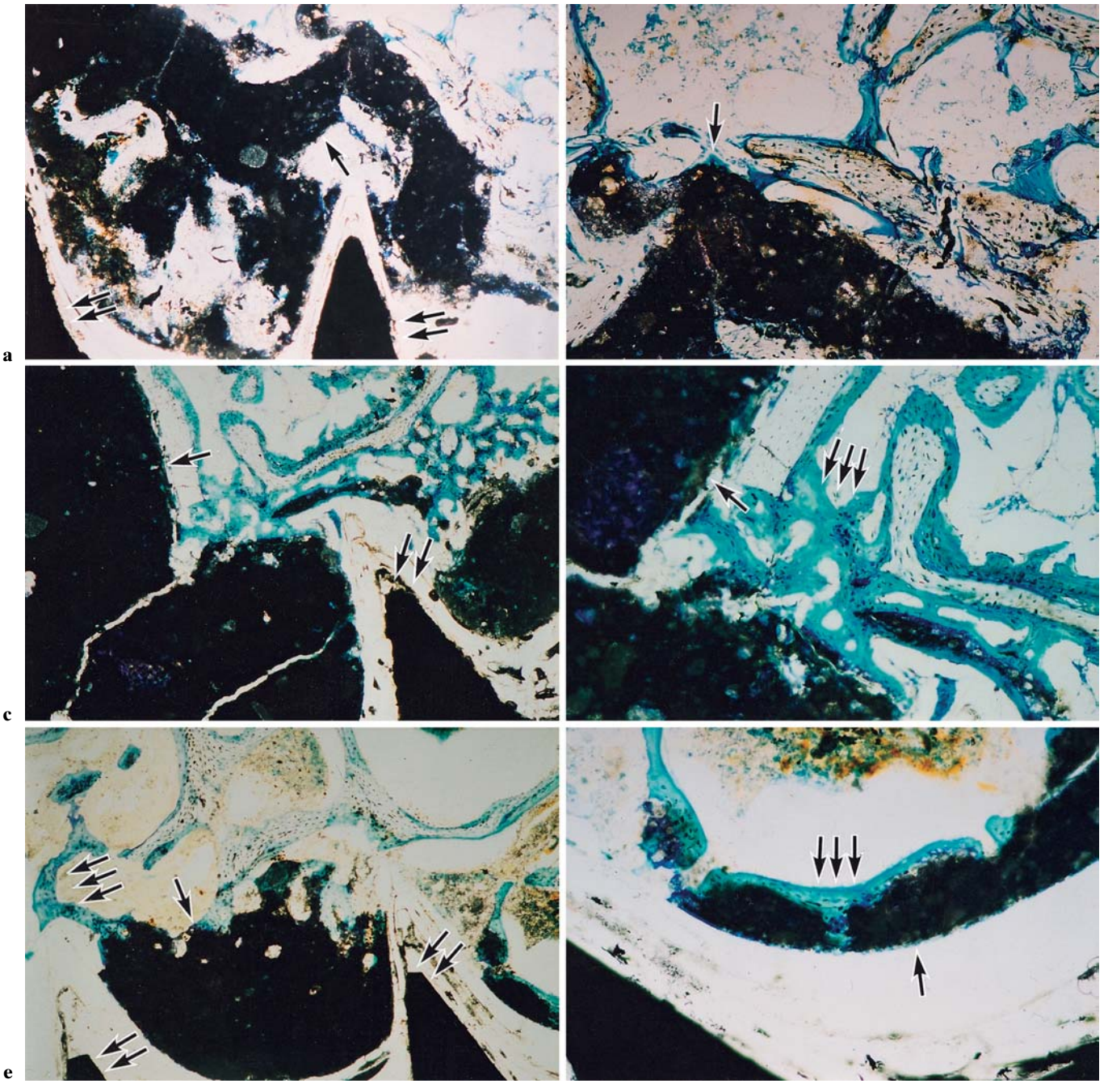

Fig. 8. Histological findings at 1, 2, and 4 weeks. **a,b** At 1 week after surgery, the CPC (*single arrow*) had infiltrated into the cancellous bone surrounding the screw (*double arrows*). There was no indication of foreign body reaction or intervening fibrous tissues. **c,d** At 2 weeks after surgery, partial osteoid formation and new bone formation (*triple arrows*) were observed around the CPC. **e,f** At 4 weeks after surgery, osteoid and newly formed bone were noted around the CPC, which had directly bonded to the surrounding bony trabeculae. **a–f** Toluidine blue. **a,c,e** ×50; **b,d,f** ×100

Histological findings

Histologically, CPC adequately filled the space between screw threads and remained in direct contact with the bone without a fibrous tissue interface 1 week after surgery (Fig. 8a). Osteoblasts with partial osteoid formation also were observed around the CPC (Fig. 8b). The osteoid layer thickened, and new bone was formed by 2 weeks after operation (Fig. 8c), when a thin layer of mesh-like osteoid with new bone formation filled the space between the CPC and the host bone, reflecting the osteoconductivity of the CPC (Fig. 8d). At 4 weeks after

surgery, the newly formed bone had thickened, and the CPC was directly bonded to the surrounding bony trabeculae (Fig. 8e,f).

Discussion

Bone mineral density is known to be an important factor affecting the strength of the screw–bone interface.[2,3,5,15,17,22] Insufficient rigidity and loosening of pedicle screws has been troublesome for spinal instrumentation surgery in elderly patients with osteoporosis.

A number of studies have looked at ways to improve the strength of the screw–bone interface. Soshi et al.[20] and Zindrick et al.[26] reported that the use of PMMA significantly increased the pull-out strength of pedicle screws, and Pfeifer et al.[16] found that pedicle screws augmented with PMMA had a 49% increase in pull-out strength. These studies showed that the combination of pedicle screws and PMMA significantly increased the pull-out strength. However, PMMA is a biotolerant material with no affinity for bone and remains an implanted foreign body. Injection of PMMA before screw insertion could injure the nerves by the heat of polymerization if the cement leaks into the spinal canal. In addition, toxicity of PMMA monomer with the use of this agent has been reported.[18]

To solve these problems, carbonated apatite cement (CAC) (Norian SRS; Norian, Cupertino, CA, USA) and HA-coated screws have been applied for this purpose, and mechanical tests have been performed on pedicle screws. Moore et al.[14] examined the pull-out strength of five kinds of reinserted pedicle screw augmented with CAC using human cadaveric vertebrae and found a 102% increase of pull-out strength on average. Yerby et al.[25] obtained a 1.5-fold higher pull-out strength with CAC using 7.0-mm pedicle screws inserted into the pedicles after removing 6.0-mm pedicle screws compared with that using no CAC. Lotz et al.[9] examined the pull-out strength and repeated load in the vertical directions of pedicle screws inserted into tapped holes where CAC had been injected and reported that the pull-out strength increased by 68% and the repeated load by 30%–63%. However, these studies were all based on in vitro experiments using cadavers, and the data cannot be directly translated to in vivo conditions, where the inserted materials interact with host bone.

Several in vivo studies have been reported. Spivak et al.[21] examined the effects of augmentation with HA grout on the screw placed in the lumbar vertebrae in adult mongrel dogs and reported that the pull-out strength of transpedicular screws with a poor initial fit insertion technique using an oversized pilot hole was significantly improved by HA grout at the sixth week. In mongrel dogs, Matsuzaki et al.[10] measured the twisting force of titanium alloy screws with and without HA coating inserted into the lumbar vertebrae and reported that the twisting force of HA-coated screws was 2.3 times higher than that of uncoated screws 8 weeks after insertion.

Our study differed from these studies in that it not only examined the effects of the newly developed CPC in an experimentally induced osteoporotic condition, it also investigated the time course of the augmentation effects under conditions that allowed interactions between the CPC and host bone.

The CPC used in the present study has been reported to maintain a compressive strength of about 80 MPa from 7 days onward at a powder/liquid weight ratio of 2.8 in in vitro simulated body fluid.[4] Moreover, unlike PMMA, it does not generate polymerization heat because it is created by a hydration reaction.

Our results indicate that the stability of the inserted pedicle screw, as demonstrated by the cephalocaudal loading test and the pull-out test, was enhanced by CPC injection into the vertebral body 1 week after insertion and increased further over time. The significant augmentation effect obtained during the early stage was probably due to self-hardening of the CPC that had efficiently infiltrated the cancellous bone surrounding the screws because of the pasty status. The subsequent increase in strength was a consequence of the progression of direct bonding of the CPC to surrounding cancellous bone, as suggested histologically. In fact, the CPC was in direct contact with the cancellous bone without a fibrous tissue interface 1 week after injection, which was followed by new bone formation that bonded the CPC to the surrounding bony trabeculae 4 weeks after injection.

In this study, the non-CPC group of nonporotic dogs simulated ordinary pedicle screwing without augmentation in normal-quality bone. The cephalocaudal rigidity was in the same range in both the CPC group of porotic dogs and the non-CPC group of nonporotic dogs throughout the 4-week experiment (Fig. 6), but the pull-out strength was significantly higher in the CPC group of porotic dogs at all time stages compared with the non-CPC group of nonporotic dogs (Fig. 7). Furthermore, the pull-out strength increased over time in the CPC group of porotic dogs, whereas that in the non-CPC group of nonporotic dogs did not. As these results show, even in osteoporotic bone, the initial stability of the inserted screw that is greater than that in normal bone can be achieved using CPC, and that the stability increases even more over time. Because spinal instrumentation is used for temporal stabilization of motion segments until bony union is completed, permanent fixation strength, which may be essential for fixation of artificial joints, is not required. Therefore, evaluation of

the short-term effects of augmentation on screw stability is sufficient for clinical purposes.

Of course, we cannot extrapolate from the results of a simplified mechanical testing involving only a single pedicle screw to what happens clinically with several screws connected by rods. Nevertheless, our results suggest that the CPC injection could be clinically useful to provide sufficient stability of screws inserted into the pedicle in patients with osteoporosis.

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