Chapter 4
Effect of Cement Augmentation

It is difficult to stabilize the spine of patients with poor bone quality by normal pedicle screws. To increase the holding strength of screw, different designs and solutions had been found such as expandable and cannulated pedicle screws. Cement augmentation through the cannulated screws increase the pullout strength significantly [17]. In this section, the studies which are concentrated on curing effect of cement, cement types, amount, and application techniques were reviewed.

4.1 Cement Types

Several materials are being used as different cement types [22]. PMMA had been shown as gold standard. On the other hand the bioresorbable materials like calcium phosphate, calcium sulfate also increase the pullout strength significantly when compared to normal pedicle screws without augmentation.

4.1.1 PMMA Augmentation

As mentioned before PMMA had been shown as gold standard of cement material for augmentation. PMMA increases significantly the pullout strength more than any other cement materials [4, 6, 7, 8, 9, 10, 13, 16, 23, 24, 26, 27, 29, 33, 35, 36, 39, 40].

For instance, PMMA was used for cement augmentation in Cook et al.'s [14] study. Non cemented expandable pedicle screw was compared with the cemented EPS on fresh human vertebrae from thoracolumbar spine. Bone mineral densities (BMD) of vertebrae were measured before testing and divided into two groups as osteoporotic and severely osteoporotic. As a result, the mean pullout strength of cemented EPS was two and half times higher than non-cemented EPS for severely osteoporotic bones.

T. Demir and C. Başgül, *The Pullout Performance of Pedicle Screws*,
SpringerBriefs in Computational Mechanics, DOI 10.1007/978-3-319-16601-8_4

Moreover, effectiveness of PMMA augmentation in long term was in vivo investigated in Sawakami et al.'s [32] study. Mean follow up period was chosen as 31 months. PMMA augmented screws compared with non-cemented screws. PMMA augmentation increased the incidence of clear zones and fusion rate, as well as decreased the correction loss and back pain of patient.

4.1.2 Calcium Based Cement Augmentation

Although PMMA augmentation has been shown as the gold standard, there are disadvantages like the danger of osteonecrosis because of its exothermic reaction as a synthetic material. Calcium based materials for cement augmentation could be an alternative to PMMA as being osteo-conductive and bioresorbable [12, 15, 19, 37]. Some researches had proved that there was no interface between calcium based cement material and bone tissues after 12 weeks [14]. Calcium phosphate, calcium sulfate and the mixture of them are mostly used as calcium based cement types [3, 12, 29, 30].

For instance, Choma et al. [12] tested CP, calcium sulfate (CS) and mixture of CP and CS augmented pedicle screws' pullout properties and compared with non-augmented group. All types of augmented pedicle screws pullout strengths' were higher than control (non-augmented) group. CP showed the highest pullout strength between all augmented groups. CS followed CP and the mixture of them showed the lowest pullout strength.

In Rohmiller et al.'s [30] study axial pullout tests were performed for non-cemented, cemented with PMMA and cemented with CS pedicle screws on lumbar cadaveric vertebrae. The pullout strength of the pedicle screws cemented with either calcium sulfate paste or PMMA were significantly higher than the non-cemented screws. As calcium sulfate showed similar fixation strength to PMMA, it could be a useful alternative in spinal surgery.

In the same manner, Yi et al. [39] investigated the advantages of calcium sulfate augmentation. Pedicle screws were divided into 3 groups: non augmented, PMMA augmented, CS augmented. Axial pull out and histological tests were done after; 24 h, 6 or 12 weeks. There was no significant difference between 24 h, 6 and 12 weeks on pullout strength for all test groups. Maximum pullout strength was significantly higher for PMMA than CS augmented screws and CS augmented PS than control group. However, CS was completely resorbed after 12 weeks. Resorption of CS also had histologically shown by the thicker bone walls around the screws. As an important result, CS increased the pullout strength over non augmented screws and maintained that effect even after 12 weeks when CS was totally resorbed.

Moreover, Taniwaki et al. [34] investigated the post-operative period of CP augmented and non-augmented groups to show the bioresorbable effect of calcium phosphate augmentation. Post-operative period was specified as 1, 2 and 4 weeks. The vertebrae of living animals that are used in study were osteoporotic. The

pedicle screws with augmentation with more period of post operation achieved more pullout strength, which points out the advantages of bioresorbable cement materials.

On the other hand, granular types of calcium based cement augmentation are also used as cement augmentation [20]. The viscosity of the granular cement is higher than normal cement so that the danger of leakage is less than normal cement augmentation. For instance, Hashemi et al. [20] studied granular calcium phosphate as bone augmentation material. Augmented with granular CP pedicle screws and non-augmented pedicle screws were tested for pullout values on polyurethane foams. To demonstrate the osteoporotic and normal incidents, two different densities of blocks were used. The PSs were firstly pulled out and then secondly inserted with cement augmentation to test the effect of cement augmentation for failed screws by pullout. Finally the results showed that the granular CP increases the pullout strength for both failed screws and osteoporotic bones. However for normal bones CP decreased the pullout strength in the short term.

4.1.3 Hydroxyapatite and Cyanoacrylate Augmentation

The effect of hydroxyapatite (HA) augmentation was investigated for patients with osteoporosis in Jang et al.'s [21] study. Radiologic parameters (segmental lordosis, disc height, screw angle, L4 screw angle, and L5 screw angle) were compared between post-operative periods 1 day and 3 months follow up and 1 day and 2 months follow up. To induce the effect of leakage to the spinal canal augmentation to only the distal end of the screw was used for augmentation with a special method. There was no significant changes in radiologic parameters for HA augmented group. On the other hand, there were significant changes in several radiologic parameters for non-augmented group. As the results of this study, HA augmentation could be viable option to decrease the risk of angular displacement of screws and augmentation only at the distal end of the pedicle screw could be a sufficient method without damaging the spinal canal.

In another previous study written by Zhu et al. [41], a novel bioactive bone cement including particles of strontium and hydroxyapatite (Sr-HA) and PMMA were compared for the pullout strength of pedicle screws on osteoporotic human cadaveric vertebrae. Increment of PMMA augmented screws pullout strength was slightly significant. However Sr-HA covered more surface of the pedicle screw than PMMA. So, Sr-HA could be a better option by allowing new bone formation and better osteo-integration in long term.

Finally, Milcan et al. [26] compared the pullout strength of pedicle screws of Butyl-2-cyanoacrylate and PMMA augmentations. Although Butyl-2-cyanoacrylate is a bioresorbable material, there was no statistically difference between non-augmented and cyanoacrylate augmented group. PMMA augmented pedicle screws

showed significantly higher pullout strength compared to the native bone or cyanoacrylate augmented group as mentioned before.

4.2 Effect of Cement Amount

As many researches had already proved, cement augmentation increases the pullout strength. The idea first comes to the mind is that increasing the amount of cement will provide higher pullout strength. However, the higher amount of cement, the higher the risk of cement leakage through spinal canal [38].

For instance, to investigate the proper amount of cement, osteoporotic human thoracic and lumbar vertebrae were subjected to pullout force and extraction torque by Paré et al. [27]. The amounts used for thoracic spine were 0.5, 1, 1.5 cc and for lumbar spine were 1.5, 2, 2.5 cc. PMMA augmentation increased pullout force for both thoracic and lumbar spine than standard pedicle screw without augmentation. The highest pullout force achieved for thoracic spine was with 1 cc cement and for lumbar spine with 1.5 cc. Thereby, the idea of higher pullout strength provided by higher cement amount was refuted.

Similar results were obtained by Frankel et al. [18]. They investigated the vertebroplasty augmentation in two different volumes a low-cement group ($\leq$2.8 ml/pedicle) and a high-cement group ($\geq$5.5 ml/pedicle) through a novel fenestrated bone tap which prevents the back flow the cement on human cadaveric specimens. PMMA augmented and non-augmented groups were than subjected to axial pullout tests. However there was no significant difference on pullout strength between those two different volumes.

On the other hand, limiting the cement amount with screw design is another option, which was studied [24]. A new designed screw which allows to partial augmentation was compared with full augmentation. Mechanical properties were measured for both groups and control group (non-augmented). Partial and full augmentation with PMMA significantly increased the pullout strength than non-cemented pedicle screws, so partial augmentation could be used to decrease the leakage risk and allow more interface between bone and screw by providing reasonable pullout strength.

4.3 Effect of Curing

Curing of cement is crucial for all types of polymer based mixtures which needs time. Curing time must be known by the surgeons to manage the timelines of surgery.

Cho et al. [11] investigated the effect of curing by inserting the pedicle screws into cadaveric bones after 2, 4 and 6 min from cement (CP) injection. Also primary and secondary pullouts were done to demonstrate the revision surgery. Primary pullout was first done, then for calculating the effect of curing, cement

was injected for secondary pullouts. Secondary pullout strength was significantly higher than primary pullout strength which showed the effect of using CP. Pullout strength due to the timing of augmentation increased from 0 to 4 min and decreased after 6 min. However there was no significant difference between fixation strengths of pedicle screws caused by curing time.

Furthermore, Linhardt et al. [23] tested soft cement, cured cement and control groups on human cadaveric specimens to see the effect of curing in kyphoplasty augmentation. Despite the soft cemented group achieved the highest pullout strength, the difference between soft and cured cemented group was not significant. Non cemented group's pullout strength was significantly lower than cemented group. As a result, cured cement was also a sufficient method when kyphoplasty augmentation is chosen.

Masaki et al. [25] also investigated the timing of the cement by augmenting the cement after 2, 5 or 10 min. Cement augmented group and control group (non-augmented) were pulled out from human cadaveric vertebrae. CP cement augmented screws showed 77 % higher than non-augmented group. Although pullout strength was the highest for pedicle screws pulled out after 5 min, the difference between time groups were not significant. Nevertheless, it is important to make adjustments on PS with augmentation before the cement hardens.

Finally, Ying et al. [40] investigated how to change PMMA augmented pedicle screws depths after 24 h of cement augmentation. The groups upon their depths were unchanged, 3 threads in and 3 threads out. Mean pullout for augmented pedicle screws showed significantly higher than non-augmented pedicle screws. Pullout strength of unchanged PS was significantly higher than screws inserted 3 threads out and screws inserted 3 threads in. As a result it could be seen that adjustment of the pedicle screw following 24 h after cement augmentation significantly decreased the pullout strength.

It can be concluded that curing time do not affect pullout strength significantly, but it is important for the surgeons to make adjustments before cement hardens.

4.4 Cement Application Techniques

Cement can be injected before screw insertion to the pedicle for non-cannulated screw applications. Additionally, cement can also be injected through the cannula for cannulated screws after the screw insertion [23].

For instance, Chao et al. [7] tested those different types of cement application techniques to compare the pullout strengths of these applications. Cannulated screws with cement augmentation divided into two groups as cement filled before screw insertion and cement injected after screw insertion. There was also a non-cemented control group. Pullout strengths of pre-filled and injected after screw insertion groups did not differ statistically from each other, although both of them were significantly higher than control group. However, pre-filled cannulated screws showed lower extraction torque and higher pullout strength than screws

with cement injected after insertion, which is useful information for revision surgeries.

Along similar lines, Chen et al. [9] compared solid screws with prefilled cement and cannulated screws with PMMA injection during perforation on polyurethane blocks demonstrating the severe osteoporosis. However, to see the effect of cement application techniques in different screws, conical and cylindrical cored screws were used in tests. Cement prefilling increased significantly the initial fixation strength than injection during perforation for both conical and cylindrical cored screws.

Moreover, Chang et al. [6] made an in vivo research on cannulated pedicle screws with PMMA augmentation on human vertebrae. Visual Analog Scale (VAS) pain scale, ODI and screw migration were recorded for the patients operated with cannulated screws and the results were compared with those reported with the needle injection method mentioned with details in another Chang et al.'s [5] study. These two different techniques were also tested on synthetic bones for their pullout strengths, insertional and back out torques. Clinical results of both techniques were sufficient enough and the difference was not significant. Pullout strength and back out torque for needle injection technique was significantly higher. However as an important result, the cannulated pedicle screw augmented with PMMA decreased the operation time and cement leakage probability.

On the other hand, Renner et al. [29] investigated how the cement distribution affects the pullout strength as an application method. The same amount of cement (PMMA or CP) injected either to the distal part or entire length of the pedicle screw. CP and PMMA augmented screws' pullout values were significantly higher than initial pedicle screws'. CP augmented to the entire length of the screw achieved higher pullout value than only distal end augmented screws, this result can be explained by more interface between cement and the screw for the entire length injected screws. However, the risk of cement perforation through spinal canal must be taken into account for entire length injections.

Osteoporotic vertebral fractures become problematic especially if the spine of patient must be fused with pedicle screws. In those situations, kyphoplasty augmentation is generally used which aims regaining the height of vertebral body, correcting the kyphotic distortion, and forming a gap into which bone cement can be injected with the help of specially designed inflatable or expandable cannulas [4, 28].

For instance, Derincek et al. [16] compared kyphoplasty and transpedicular PMMA augmentation for revision of the failed pedicle screws on osteoporotic calf vertebrae. Pullout strength of kyphoplasty augmentation group was significantly higher than the transpedicular augmentation group. Thereby, kyphoplasty could be an effective method for the revision of failed pedicle screws for the patients with osteoporosis.

In a same manner, Burval et al. [4] compared transpedicular and kyphoplasty augmentation (PMMA) techniques on pedicle screws on osteoporotic human vertebrae. Pullout tests were conducted either before or after cyclic loading. Both techniques showed higher pullout strength than non-augmented pedicle screws on

osteoporotic vertebrae. Augmentation with kyphoplasty technique showed significantly higher pullout strength than transpedicular technique. Also PS with kyphoplasty augmentation showed higher pullout strength than PS inserted into normal bones without augmentation.

Differently, Benson et al. [2] investigated three different cement augmentation techniques (kyphoplasty, kyphoplasty through a fenestrated tap and direct injection) on human cadaveric vertebrae by using the advantage of kyphoplasty and the novel tap which reduces the cement leakage risk. The vertebrae, inserted with screws were then subjected to cyclic loading and after that total vertical displacement of screw's head was measured. The pedicle screws tapped with novel fenestrated tap for augmentation was less durable to cyclic loading than the screws augmented with other two techniques. However, decreasing the cement leakage risk through nerves is really beneficial. As a result, Kyphoplasty augmentation using the novel tap with more viscous cement could be an option as being safe and efficient.

Vertebroplasty is another augmentation technique used in vertebral compression fractures due to the vanishing bone mineral density and also to stabilize the spine with pedicle screws on those patients [28].

For example, Becker et al. [1] tested cannulated and standard PS augmented with three different cement augmentation techniques. Osteoporotic human vertebrae were inserted with PS and cement material was PMMA. Cannulated PS and standard PS both with vertebroplasty augmentation showed significantly higher pullout strength than control (non-augmented) group. On the other hand, leakage was observed in some cases with CPS insertion. Kyphoplasty augmentation technique was not significantly higher than control group. Additionally, there was no significant difference between these three different augmentation techniques.

Finally, Sarzier et al. [31] tested vertebroplasty augmentation with PMMA on human cadaveric vertebrae. The vertebrae divided into three groups according to Jekei scale. Vertebroplasty augmentation with PMMA significantly increased the pullout strength than non-augmented group.

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