Possibility Of Enhancement For The Pedicle Screw Fixations With HA Sticks (Hydroxyapatite Sticks) Augmentation: A Preliminary Report Of Clinical Results In Lumbar Reconstruction Surgery

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Citation

Abstract
Objectives: The purposes of this study are to elucidate the effect of HA stick on enhancement of PS fixation and to verify the safety of HA sticks in clinical use.

Method: One hundred thirty-eight pedicle screws (PS) are evaluated in 29 patients who underwent lumbar reconstruction surgery using PS. Forty-eight PS with HA sticks and 90 PS without HA in the patients with systems are evaluated on the loosening of PS by X-ray examinations.

Results: The clear zone around pedicle screws appeared on the X-ray at 2 or 3 month after the operations in nine PS in four patients with HA sticks and none in the patients without HA sticks (p=0.0088, Fisher's exact methods).

Discussion: The clear zone must be a space between bone and PS. When HA sticks were augmented in the pedicle holes, the interface between PS and bone was obstructed with HA granules. Then the HA granules around the PS caved in the space of cancerous bone influenced by continuous loading. Therefore we addressed that at this moment the enhancement of PS using HA sticks were questioned through the period.

INTRODUCTION
Spinal instrumentation surgery well developed in last three decades(1,2). Recently, however, osteoporosis is becoming a major problem which results in poor success of fusions in reconstruction surgery(3,4,5,6,7). In reconstruction surgery, pedicle screws (PS) play an important role to maintain the spinal alignment after surgery. On the initial stage, the screw-bone interface must be important, it is especially at risk for stripping during insertion or pull out of vertebrae after surgery especially in osteoporotic vertebrae (5,7). The osteoporotic vertebrae is also in dangers of collapse of the grafted bone, fractures caused by pedicle screws and the loosening of PS(5,7). Screw diameter, design, insertion technique and insertion site may also affect fixation strength (4,5,7,10,15,17,18). In recent literature, bioactive cement materials in vivo have been reported as a reinforcing materials for enhancement of PS fixation(3,5). The purposes of this study are to elucidate the effect of HA stick on enhancement of PS fixation and to verify the safety of HA sticks in clinical use.

PATIENTS AND METHODS
Twenty nine patients (12 male, 17 female), who were over 65 years old with osteoporosis, underwent lumbar reconstruction surgery with PS systems of Moss Miami (Deupuy Spine) since 2001 January to 2003 June. The average age is 71.5 (65-85) y.o. The grade of osteoporosis was evaluated before surgery on the X-ray examination. Single PLIF was performed in 21 cases, double PLIF in 4 cases and PLIF more than 3 levels in 2 cases. Anterior Spinal subtotal spondylectomy (ASS) with PS was performed in one case and PLF with PS (MOSS Miami) in one case (Table 1).
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Figure 1
Table 1: Group Comparison

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>HA (+) group</th>
<th>HA (-) group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>71.8 y.o.</td>
<td>71.4 y.o.</td>
</tr>
<tr>
<td>PS</td>
<td>48 PS</td>
<td>90 PS</td>
</tr>
</tbody>
</table>

Figure 2
Table 2: Patients with HA stick augmentation

<table>
<thead>
<tr>
<th>Case #</th>
<th>Sex</th>
<th>Age</th>
<th>Diagnosis</th>
<th>Operation</th>
<th>Number of PS inserted</th>
<th>Osteoporosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>71</td>
<td>L5spinaldecompression</td>
<td>L5/Facet L5/PF</td>
<td>4</td>
<td>2 grade 2</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>75</td>
<td>L5spinaldecompression</td>
<td>L4/PF + L5/PF</td>
<td>4</td>
<td>0 grade 2</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>68</td>
<td>L5spinaldecompression</td>
<td>L3/PF</td>
<td>4</td>
<td>0 grade 1</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>65</td>
<td>L5spinaldecompression</td>
<td>L4/PF + L5/PF</td>
<td>6</td>
<td>1 grade 1</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>74</td>
<td>L5spinaldecompression</td>
<td>L5/PF</td>
<td>4</td>
<td>0 grade 2</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>77</td>
<td>L5spinaldecompression</td>
<td>L4/PF + L5/PF</td>
<td>6</td>
<td>3 grade 1</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>76</td>
<td>L5spinaldecompression</td>
<td>L5/Burst + AGE</td>
<td>6</td>
<td>2 grade 2</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>76</td>
<td>L5spinaldecompression</td>
<td>L5/Burst + AGE</td>
<td>6</td>
<td>0 grade 1</td>
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<tr>
<td>9</td>
<td>F</td>
<td>66</td>
<td>L5spinaldecompression</td>
<td>L5/Burst + AGE</td>
<td>4</td>
<td>0 grade 1</td>
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<td>10</td>
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<td>L5spinaldecompression</td>
<td>L5/Burst + AGE</td>
<td>4</td>
<td>0 grade 1</td>
</tr>
</tbody>
</table>

Indication of the augmentation of HA sticks was made for the patients aged more than 65y.o. who operated during 2002 June –2002 December. And during the other periods (2001 Jan-2002 May, 2003 Jan-2003 June), HA sticks were not augmented in the screw holes. HA sticks were augmented in ten patients (2 male, 8 female). Nineteen patients (10 male, 9 female) were instrumented without HA sticks. The average age of HA+ group (HA+, PS with HA sticks, HA+; PS without HA sticks) was 71.4 y.o and 71.8 of HA+group (p=0.8308). Group comparison about screw fixations was done between the age matched groups. The degree of osteoporosis was evaluated by the Jikei scales for lumbar spine on the preoperative lumbar lateral X-p examination.

One hundred thirty eight PS are evaluated in 29 cases. Forty-eight PS with HA sticks in ten patients and 90 PS without HA are evaluated on the size, the diameter of screws and the total amount of HA stick for each pedicle hole. 40mm pedicle screws were inserted in 108 pedicles (diameter 6.0mm:46 pedicles, 7.0mm in 62 pedicles), 35mm screws in 30 pedicles (6.0mm in 8 pedicles, 7.0mm in 22 pedicles). Three HA sticks are augmented in 9 pedicles, two in 37 and one in 2 pedicles. Additional sublaminar hooks are applied in 6 cases (2 cases in HA+ , 1 case in HA-). The radiological changes were evaluated in two groups by X-ray examination. The PS fixations were evaluated by the X-ray examination at 1 month, 2 and 3 month after surgery until complete bony fusions are obtained. Fusions were considered as the consolidate length of trabeculae. The screw loosening was evaluated by the functional radiography. The HA sticks augmented in PS were evaluated on the extravasations into spinal canal and on the extent in vertebral body by MRI and/or CT at 3 month after operation.

SURGICAL PROCEDURE

Posterior interbody fusion (PLIF) was performed with Brantigan’s I/F cages and two or three bicortical bone grafts harvested from iliac crest. Posterior lateral fusion (PLF) was in one case and L3 subtotal spondylectomy was performed in one case with L3 burst fracture. Posterior instrumentations with polyaxial pedicle screws (MOSS Miami) were applied in all cases. Additional laminar hooks are applied in 4 cases. And two or three HA sticks (Fig.1a) were augmented into each pedicle hole with an adequate pressure with a pusher (Fig.1b) before screws were inserted.

Figure 3
HA STICK (HYDROXYAPATITE STICK)

HA stick (PENTAX Co. Japan) is a stick made of hydroxyapatite granules Ca_{10}(PO_4)_6(OH)_2. The pore size of the granules is ranged from 600 to 1000 µm which are high density granules with 15% volume-porosity. The length of the stick is 4mm~40mm (Fig.1a) and the weight of one stick is 1.5g of hydroxyapatite (\(^{(22,23,24)}\)). It spreads in the vertebral body and in the pedicle holes when augmented through an inserter with a pusher (Fig.1b). When pressurized with a pusher (Fig.1b), the HA granules are considered to work as an anchor of PS (Fig 2).
RESULTS
RADIOLOGICAL EVALUATIONS
The HA sticks were observed as a soft shadow around PS on the X-ray examinations (Fig.2ab) just after the operations. The clear zone around pedicle screws appeared on the X-ray at 2 or 3 month after the operations) in nine PS in four patients with HA sticks and none in the patients without HA sticks (p=0.0088, Fisher's exact methods). The clear zone was shown in Fig.4b. Apparent loosening of PS was not observed through the follow up. The complete bony fusions were obtained in all cases at 6 months without loss of correction.

EXTRAVASATIONS AND OTHER COMPLICATIONS WITH HA STICKS
Extravasations of HA granules were not observed in the spinal canal on postoperative MRI or CT examinations which were undertaken at 3 months. PS in sacrum was engaged with the anterior cortex for strengthening of the screw fixation, so that some HA granules spread in the front of sacrum in one case. No other complications (i.e. infection, the neural injury with HA sticks and leakage of granules into spinal canal) were encountered.

CASE
L5 spondylolisthesis with grade 2 osteoporosis. 71 y.o. female. She presented with difficulty in walking because of severe sciatica and severe numbness in both legs. The X-ray examination shows grade 2 osteoporosis (Fig.2a, b).

PLIF at L5/s and a partial laminectomy at L4/5 were performed with polyaxial PS and HA sticks. At the preparation with a pedicle probe, the resistance was actually weak because of the osteoporosis. Two HA sticks were augmented in the each pedicle hole through the inserter. Then the resistance of PS was enough at insertion. At two month on the X-ray examination (Fig.2ab), HA can be observed around PS, but at 3-month clear zone was observed around S1 pedicle screws (Fig.3, Fig.4b). Fig.4a showed the right S1 pedicle screw surrounded with HA granules at the 2nd month after surgery. Fig4.b demonstrated clear zone around the same screw at 3rd month.
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Figure 8

Figure 9
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**Figure 10**

At the end the anterior bony fusion was obtained at 6 month and maintained through follow up with clear zone around PS.

**DISCUSSION**

Instrumentation surgery well developed in lumbar spine in last three decades. Many authors reported good results of fusion rates in lumbar reconstruction surgery. The good fusion rate was supported by PS in reconstruction surgeries. Surgical reconstruction, however, should be careful in severe osteoporotic spines because of the poor quality. Many factors influence the holding strength of PS. Concerning about PS, the diameter and insertion technique were reported as effective methods for enhancement of screw fixation. However there is a limit of fixation force because of the poor bone quality. So that several techniques to enhance the fixation force are reported, for example additional laminar hooks and Polymethylmethacrylate(PMMA) augmentation. HA sticks are introduced as bioactive materials for enhancement of PS fixation. It is reported that the pull-out strength of PS with two HA sticks is approximately 180% of only PS in the experimental study. And hydroxyapatite is not only degradable but also bioconductive material. Hence the bone remodeling will proceed around screws and may reinforce the screw strength after surgery. In the actual clinical use, the clear zone often appeared around PS at some months after the surgery. The clear zone must be a space between bone and PS. When HA sticks were augmented in the pedicle holes, the interface between PS and bone was obstructed with HA granules. Then the HA granules around the PS caved in the space of cancerous bone influenced by continuous loading. The screw fixation seemed to be enhanced by the augmented HA granules due to increasing the insertion resistance. That was reported by the biomechanical pull-out experiments by Matsuzaki et al. These experiments didn't verify the continuous load which continued for more than 2 months after the surgery. PS with HA sticks were considered not to be enhanced until the anterior complete bony fusions were obtained. Instead of enhancement of PS at insertion, continuous loads would loosen PS surrounded with HA granules between bone and screw itself. Once the anterior column was stabilized with bony fusions, the clear zone might disappear because of osteoconduction around HA granules.

PS fixation is not possibly enhanced by the HA stick augmentation through the periods until the complete bony fusions are obtained, though PS fixation might be enhanced by the HA stick augmentation just at insertion. On the contrary, the existence of HA granule layers around PS may reduce PS fixations. In our study no cases had pseudarthrosis with PS loosening. The augmentation of HA sticks was discontinued at the 10th patient because the clear zone was often observed on the X-ray. We addressed that at this moment the enhancement of PS using HA sticks were questioned through the period.

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