The syndrome of herniated intervertebral disc (HIVD) is the neurological symptom that the protrusion of nucleus pulposus (NP) compressed the nerve root in the spinal canal or the intervertebral foramen. The minimally invasive operations of HIVD included the endoscopic (or percutaneous) nucleotomy and discectomy. Nevertheless, the recurrence of HIVD after aggressive surgery is frequently observed due to recurrent leakage of NP through the injured annulus fibrosus (AF). Recently, the tissue engineered AF and NP, a cell-based extracellular matrix, is implanted into the disc to biologically repair the injury. In this study, instead of regenerating the AF tissue, we try to induce the scar formation in the AF. We hope the scar developed in the AF would seal the disc and hold the disc integrity. Quantitative discomanometry (QD) was a reproducible technique that measures the volume injected and pressure developed in the disc. QD studies can be used to quantify the disc integrity, and hence to evaluate the degree of disc injury and degeneration.

The in vivo porcine model was used for study. Four biocompatible materials were implanted into the injured disc to increase the healing process than the natural course. The functional integrity of disc using QD was evaluated after two months of implantation to find the feasibility of the proposed innovative treatment.

MATERIAL AND METHOD

Surgery Protocol. Four mini pigs were used. Pigs were 3-months old during surgery, and 5-months old when sacrificed. The average weight of pigs was 15 kg. The two month discs were used and vaccines used to produce AF injury. The discography was applied to insure the leakage of disc. Six groups of discs, including four implantation materials, in addition to the sham (injured disc, no implantation) and intact (no injury, no implantation) groups were randomly assigned. Two discs in each group, and a total 12 discs were used in each pig. The four implantation materials are Tissue Glue (NBCA Glue, Histocryl, Ingenon, Paris, France), Platinum Coil (VORTX, Fibered Platinum Coil-18, Boston Scientific Corp Ltd., Cork, Ireland), Bone Cement (CMW 1 Radiopaque, DePuy CMW, Johnson-Johnson company, Lancashire FY4 4QG, England), and Gelfoam (Absorbable gelatin sponge, USP, Pharmacia & Upjohn Company, A subsidiary of Pharmacia Corporation, Kalamazoo, MI 49001, USA). The six groups of disc are abbreviated as Glue, Coil, Bone Cement, Gelfoam, Sham, and Intact hereafter. The four groups were used to examine the functional integrity of disc using QD. The specimens were imaged and measured. The disc images were used to compare the disc integrity of the injured discs in each group.

Apparatus. Two months after the surgery, the pigs were sacrificed. The excised discs were dissected and prepared for analysis. The disc columns were dissected preserving the osteoligamentous structure. Two discs in each group, a total 12 discs were used in each pig. The four implantation materials were used to evaluate the effectiveness of the treatment. The data were collected and analyzed using the one-way analysis of variance (ANOVA). The data were then compared using the post hoc analysis for ANOVA.

RESULTS

The QD was found a significant parameter (p>0.000) in evaluating the disc function of six group. The rank order of LP as follows; Sham, Gelfoam the second, Sham the third, Coil and Bone Cement the fourth, and Glue the lowest (Figure 1). The Gelfoam is the best candidate among the four implantation materials. The LP of Gelfoam is smaller than the intact, no significant different with Sham, but higher than the other three materials (Table 1).

Table 1. The significances of post hoc test on the leakage pressure within implantation materials, sham and intact group.

<table>
<thead>
<tr>
<th>Material</th>
<th>p-value</th>
<th>Glue</th>
<th>Coil</th>
<th>Bone Cement</th>
<th>Gelfoam</th>
<th>Intact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sham</td>
<td>0.002**</td>
<td>0.915</td>
<td>0.835</td>
<td>0.425</td>
<td>0.000***</td>
<td></td>
</tr>
<tr>
<td>Glue</td>
<td></td>
<td>0.089</td>
<td>0.148</td>
<td>0.000***</td>
<td>0.000***</td>
<td></td>
</tr>
<tr>
<td>Coil</td>
<td></td>
<td></td>
<td>1.000</td>
<td>0.036*</td>
<td>0.000***</td>
<td></td>
</tr>
<tr>
<td>Bone Cement</td>
<td></td>
<td></td>
<td></td>
<td>0.018**</td>
<td>0.000***</td>
<td></td>
</tr>
<tr>
<td>Gelfoam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.013*</td>
<td></td>
</tr>
</tbody>
</table>

DISCUSSION

Two major finding in this study; first the percutaneous disc injury cannot be recovered even after two months of healing. Second, the Gelfoam may be the best material as the substrate to induce the AF scar formation comparing to the three others.

Advantages. The principle of available artificial NP is to maintain the disc height and mobility of motion segment without consideration of "pump" function of disc that provide the nutrition. The idea of the current study is to find a material that will induce a scar in the injury site, hence, seal the fissure of AF, and hold the disc integrity. The implantation materials are limited to the one that can be delivered by percutaneous technique for the possibility of minimal invasive surgery. Only the no cell-based implantation materials are considered in this study. The materials implanted in the current study are widely and safely used on other treatment, e.g., platinum coil for embolization, bone cement for the enhancement of porous bone, glue and Gelfoam for hemostasis during surgery. Hence no worry of unexpected neoplasm would be generated with the current idea. The morphological, biochemical observation of the growth factor G/P1 and calcium polyphosphate substrate have been validated. The in vivo animal results showed the changes of disc height and percentage of PG synthesis. However, these evaluations cannot reveal the biomechanical function of disc. The current study used QD to validate the essential disc anatomical function. It is believed that the QD is one of the best, if not the best, procedure to evaluate the effectiveness of treatment of the disc.

Limitations. The current study found that the injury of disc cannot be recovered even after two months of healing. We are not sure of permanent injury were occurred in the disc, since only two months of healing is applied in this study. The age of the tested pigs was from 3 to 5 months old, which is comparable to the 10 to 15 years old young juvenile. It is expected that injury within this period should recovered faster than a fully matured or aged adult. The two months recovery time in pigs is long enough to simulate the chronic stage of healing process in human.

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Figure 1. Effect of implantation material, sham and intact group on the disc leakage pressure after two months of healing. Sham: injured disc, no implantation, Intact: no injury, no implantation.

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