INTRODUCTION:
The incidence of hardware problems associated with pedicle screw instrumentation, including screw breakage, loosening at the bone-screw interface and difficulties in system assembly have been significantly reduced over the last two decades. However, the loosening and back-out of pedicle screws resulting from failure of screw fixation remains a significant clinical problem, particularly in patients with poor vertebral bone quality. When screw loosening occurs, one surgical option for manipulating the bone-screw interface may be the use of matchstick or milled bone allograft or the injection of polymethylmethacrylate (PMMA) or bone mineral cement.

The injection of PMMA has been shown to dramatically improve pull-out strength. However, it can have serious intraoperative and long-term complications including neural damage from the exothermic nature of PMMA and complications in revision surgery. PMMA can cause cement and bone cement augmentation to interface problems that may result in nonunion or loss of corrections. It is of clinical importance to develop a method to revise a failed screw or to prevent the failure of screw fixation. In this study, biomechanical pull-out tests were performed to investigate the effectiveness of a new injectable CaP for improving pedicle screw fixation strength as well as the effect of cement injection timing and method. This study has limitations that are common in in vitro studies. For example, tested cases represent only immediate postoperative conditions and it was not possible to investigate the resorption characteristics of CaP over time. Although the pedicle screws are known to experience various types of loads in vivo, the screw fixation strength was tested in pullout directions only in this study.

Despite of these limitations, well-controlled biomechanical tests were performed in this study and results measured from the intact specimens showed a good agreement to the results of previous studies in the literature. Results of this study also suggested clinically relevant conclusions as follows. The injection of CaP was found to improve the PS over the intact strength when injected before failure regardless of injection method. CaP injection along the entire length of the screw was also found to improve the PS when injected into a failed pedicle. Thus, when using CaP to revise the failed pedicle screw (REV case), the CaP injection along the entire screw length is recommended for stronger fixation. In addition, CaP injection at the time of initial screw insertion may be an effective method to prevent the screw failure in patients with higher potential for screw failure in order to reduce the incidence of fixation failure and the need for costly revision surgery as well. Thus, CaP may be a good alternative to PMMA for screw augmentation before and after failure considering the isothermic and bioerosorbable characteristics of CaP although in vivo studies should be performed prior to the clinical application of CaP.

RESULTS:
No pedicle or lamina fractures were seen during the pull out tests. No statistical significance was seen in the mean BMD among the injection groups (range from 0.58 to 0.61 gm/cm²). There was a significant correlation between BMD and PS of the INT case (R² = 0.57). The average pull-out strength of each group is shown in Table 1. No significant difference was found in the PS of the intact cases among the injection groups. In the CaP-1 group, no significant PS improvement was found in REV over INT, but the PS of the AUG case was significantly higher than the INT case (p<0.0005). The CaP-2 group had significantly higher PS in both REV and AUG cases as compared with the INT case (p<0.0005). The PMMA group had significantly higher PS in both REV and AUG cases than the INT case (p<0.0005). When comparing the effect of CaP injection methods, the PS of the REV case in the CaP-2 group was significantly larger than that of the CaP-1 group (p=0.001), whereas no significant PS difference was found between the CaP-1 and CaP-2 groups in case of AUG (p=0.198). In both REV and AUG cases, PMMA group showed a significantly greater PS than both CaP-1 and Cap-2 groups (p<0.01).

DISCUSSION:
Loosening and back-out of pedicle screws are significant clinical problems that may result in nonunion or loss of corrections. It is of clinical importance to develop a method to revise a failed screw or to prevent the failure of screw fixation. In this study, biomechanical pull-out tests were performed to investigate the effectiveness of a new injectable CaP for improving pedicle screw fixation strength as well as the effect of cement injection timing and method. This study has limitations that are common in in vitro studies. For example, tested cases represent only immediate postoperative conditions and it was not possible to investigate the resorption characteristics of CaP over time. Although the pedicle screws are known to experience various types of loads in vivo, the screw fixation strength was tested in pullout directions only in this study.

Despite of these limitations, well-controlled biomechanical tests were performed in this study and results measured from the intact specimens showed a good agreement to the results of previous studies in the literature. Results of this study also suggested clinically relevant conclusions as follows. The injection of CaP was found to improve the PS over the intact strength when injected before failure regardless of injection method. CaP injection along the entire length of the screw was also found to improve the PS when injected into a failed pedicle. Thus, when using CaP to revise the failed pedicle screw (REV case), the CaP injection along the entire screw length is recommended for stronger fixation. In addition, CaP injection at the time of initial screw insertion may be an effective method to prevent the screw failure in patients with higher potential for screw failure in order to reduce the incidence of fixation failure and the need for costly revision surgery as well. Thus, CaP may be a good alternative to PMMA for screw augmentation before and after failure considering the isothermic and bioerosorbable characteristics of CaP although in vivo studies should be performed prior to the clinical application of CaP.

Table 1: Average pull-out strength in Newtons.

<table>
<thead>
<tr>
<th>Tested Groups</th>
<th>Intact (N)</th>
<th>Revision (N)</th>
<th>Augmented (N)</th>
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</thead>
<tbody>
<tr>
<td>CaP-1 (n = 19)</td>
<td>1032 ± 453</td>
<td>895 ± 422</td>
<td>1617 ± 448</td>
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<tr>
<td>CaP-2 (n = 20)</td>
<td>839 ± 514</td>
<td>1571 ± 656</td>
<td>1852 ± 574</td>
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<tr>
<td>PMMA (n = 13)</td>
<td>910 ± 513</td>
<td>2496 ± 1083</td>
<td>2797 ± 796</td>
</tr>
</tbody>
</table>

REFERENCES:

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