Omega-wire Stabilization System for the Spine

Yeon Soo Lee, Geun Soo Song

Abstract—This study has investigated mechanical deformation characteristics of a newly developed screwless omega-wire dynamic system for stabilization of posterior spinous processes. The omega-wire spring stabilization system was tested under tension, compression loads. In addition, its bending deformation was compared to that of a spiral-wire spring system, using the finite element analysis. The model whose hanger inter-center distance is 60 mm showed the ultimate tensile stress 3981.7N at the displacement of 3.61 mm and the ultimate compressive load of 535.6N at the displacement of 2.16 mm. In the finite element analysis, the omega-wire spring system showed more flexible bending characteristics than the spiral-wire spring system.

Keywords— Lumbar, Posterior spinous process, Omega-wire spring, Dynamic stabilization system

I. INTRODUCTION

Recent computer and internet environment makes people sit on chair for longer timer and bring higher intervertebral compression. With elongated life expectancy, there may be more number of spine patients. An increase abnormally high disc pressure or degenerative spinal stenosis could develop into disc failure or severe spinal cord injury [1].

Treatments for the spinal diseases include conservative methods such as drug medication, physical exercise, and orthotic support, while surgical methods such as laminectomy, medial facetectomy, and foraminotomy [2]. Alternative treatments using spinal implants have also been performed. As one of the implanting methods, the rigid fixation fusion using rods and pedicle screws has been widely performed. However, the rigid fixation does not allow relative movement and brings periprosthetic failure, and may result in degeneration of vertebral bones and intervertebral discs [3, 4].

To fix the limitation of the rigid fixation system, the dynamic stabilization system like Bio-flex (Bio-Spine system, Seoul, Korea) has been developed. The dynamic stabilization system provides the spinal bony flexible range motion as well as stabilization. It is a screw and spiral-wire spring system composed of pedicle screws and spiral-wire springs [5]. In spite of the flexibility due to the spring, it still has a possibility of bone fracture around pedicel screws since pedicle screws have to be inserted into vertebrae. Screwing to spine body also give patients psychological inconvenience. Therefore, recently new stabilization systems which do not bring about those problems have been developed [6-8].

Fig. 1 The pedicle screw spiral-wire spring posterior stabilization system and the screwless omega-wire spring posterior stabilization system incorporated with a polyethylene spacer (UHMWPE)

Fig. 1 shows a pedicle screw & spiral-wire stabilization system and the screwless omega-wire system (Kang and Park Medical Co., Korea) where no pedicle screw is used. It is made of Nitinol where Titanium and Nickel are mixed with 55:45 ratio (9). When it is cooled by cool water of 0℃, it can be easily deformed, while inside body of about 36.7℃ it returns to its designed shape for stable placement. It is expected to control abnormally large movement due to vertebral degeneration or dislocation. With combination with Ultra-High Molecular Weight Polyethylene (UHMWPE) spacer, it is designed to decrease intervertebral compression as well as to accommodate stabilization.

The current study aims to evaluate mechanical characteristics of the screwless omega-wire dynamic stabilization system, as a stabilization system for posterior spinal processes.

II. MATERIALS AND METHODS

2.1 Materials

The specimens were Screwless Omega-wire System...
Kang&Park Medical Co., Korea) which has 4 models with inter-ring distances of 45mm, 50mm, 55mm, and 60 mm, respectively (Fig. 2). The material of the specimens is Nitinol (Table I).

![Fig. 2 Dimensions of the screwless omega-wire spring posterior stabilization system](image)

Jig for fixing the specimens to quasi mechanical tester is made of stainless steel. A jig for dynamic fatigue test was also machined of UHMWPE by ASTM F1717 standard.

![Fig. 3 Finite element model and loading conditions](image)

### Table I Mechanical properties of NITINOL

<table>
<thead>
<tr>
<th>0.2% offset yield stress (MPa)</th>
<th>Ultimate tensile strength (MPa)</th>
<th>Modulus (GPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>307.2</td>
<td>1053.6</td>
<td>14622.8</td>
</tr>
</tbody>
</table>

2.2 Quasi static tensile and compressive tests

For quasi static tensile and compressive mechanical tests were performed to assess the deformation characteristics of the omega-wire spring models. The used testing machine was a universal mechanical tester, i.e. Instron 5582 (Instron Co., U.S.A.). The loading was controlled with displacement speed of 25 mm/min, and 6 trials were performed for each specimen.

2.3 Finite element analysis

To compare the compressive bending characteristics of the screw and spiral-wire spring system) and screwless Omega-wire spring system, finite element analysis were performed. The analysis were performed using Ansys Workbench 12.1. As shown in Fig. 3, X and Z directions were fixed, while Y direction is set free. Vertical load passing through the cylinder centers of UHMWPE blocks was applied up to 20N (Fig. 3).

![Fig. 4 The stress distribution and deformation of finite element models of omega-wire spring (left-hand) and the spiral-wire spring (right-hand)](image)

### III. RESULTS

3.1 Quasi static tensile and compressive tests

Among the specimens of inter-ring distances of 45mm, 50mm, 55mm, and 60mm, 60 mm specimen showed the lowest tensile and compressive stiffness as well as the lowest tensile and compressive ultimate loads. The ultimate tensile load and the ultimate tensile displacement were mean 3981.7 N and mean 86.74 mm, respectively. The ultimate compressive load and the ultimate tensile displacement were mean 536.6 N and mean 2.11 mm, respectively.

3.2 Finite element analysis (FEA)

Fig. 4 demonstrated stress distribution and deformation of a spiral-wire spring and an omega-wire Nitinol springs, through finite element analysis. The maximum stress at the implant was 75 M Pa for the spiral-wire spring at the compression of 20N, while it was 270 M Pa mm for omega-wire spring (Fig. 5).
Fig. 5 Maximum stress and displacement of spiral-wire spring and Omega-wire spring, calculated from the finite element analysis.

IV. CONCLUSIONS

In conclusion, the screwless omega-wire spring of inter-ring distance 60 mm was revealed to safe when used over 5 million cycles under compressive bending displacement of 8–9 mm, from ASTM F1717 test.

From FEA results, the omega-wire spring showed more flexible deformation compared to the spiral-wire spring. The omega-wire spring dynamic stabilization system is considered as an excellent dynamic stabilization system for the posterior spinal process to minimize vertebral bony loss and enable simple plantation without screw insertion, utilizing temperature-dependent shape flexibility and memory features of Nitinol.

The study has several limitations. The 1st limitation is that the compressive bending tests does not mimic real vertebral structure which includes intervertebral discs and posterior ligaments. For more realistic test, a polyethylene spacer between vertebrae should be used in the fatigue test and finite element analysis. Hence, ASTM F1717 testing method need to be update to consider the spacer effect. Furthermore, since UHMWPE suggested in ASTM F1717 can show different mechanical characteristics compared to real vertebral bones.

ACKNOWLEDGMENT

This work was supported by the National Research Foundation of Korea Grant funded by the Korean Government (MEST)" (NRF-2012-0001655).

REFERENCES