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Optimal screw orientation for the fixation of cervical degenerative disc disease using nonlinear C3-T2 multi-level spinal models and neuro-genetic algorithms

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Purpose: Anterior cervical discectomy and fusion is a common surgical procedure performed to remove a degenerative or herniated disc in cervical spine. Unfortunately, clinical complications of anterior cervical plate (ACP) systems still occur, such as weak fixation stability and implant loosening. Previous researchers have attempted to ameliorate these complications by varying screw orientations, but the screw orientations are mainly determined according to the investigator's experiences. Thus, the aim of this study was to discover the optimal screw orientations of ACP systems to achieve acceptable fixation stability using finite element simulations and engineering algorithms. Methods: Three-dimensional finite element models of C3-T2 multi-level segments with an ACP system were first developed to analyze the fixation stability using ANSYS Workbench 14.5. Then, artificial neural networks were applied to create one objective function, and the optimal screw orientations of an ACP system were discovered by genetic algorithms. Finally, the numerical models and the optimization study were validated using biomechanical tests. Results: The results showed that the optimal design of the ACP system had highest fixation stability compared with other ACP designs. The neuro-genetic algorithm has effectively reduced the time and effort required for discovering for the optimal screw orientations of an ACP system. Conclusions: The optimum screw orientation of the ACP system could be successfully discovered, and it revealed excellent fixation stability for the treatment of cervical degenerative disc disease. This study could directly provide the biomechanical rationale and surgical suggestion to orthopedic surgeons.

Key words: *cervical plate, insertion angle, fixation stability, optimization*

1. Introduction

Anterior cervical discectomy and fusion surgery has been widely used to treat cervical degenerative disc disease [1], [6], [23]. However, spinal decompression treatments with the use of the ACP system still face complications such as weak fixation stability and implant loosening [2], [13], [15], [20]. To improve the biomechanical outcomes of the ACP systems, many types of ACP systems with varied insertion angles of locking screws have been proposed. Past studies had investigated the influence of the screw orientations of the vertebral plate on the bone-implant interfacial strength [7], [8], but the fixation stability in terms of the screw orientation was unclear. In addition, the screw orientations of the vertebral plate systems determined in past studies are mainly based on the investigator's experiences. To our knowledge, no study has applied engineering algo-

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rithms to determine the screw orientations of ACP systems. In this study, three-dimensional finite element models of C3-T2 multi-level segments with an ACP system were first developed to calculate the fixation stability of the ACP systems with varied screw insertion angles. Both the Taguchi method and the artificial neural network were then applied to develop the surrogate model which was used to substitute the finite element model. In addition, the genetic algorithm was used to determine the optimum ACP system designs. Finally, one optimum ACP system and six ACP systems were tested and compared. The purpose of this study was to discover an ACP system with excellent fixation stability using the neuro-genetic algorithm and biomechanical tests.

2. Materials and methods

Finite element models

The solid models of C3-T2 spine with an ACP system were developed using SolidWorks 2013 (SolidWorks Corp., Concord, MA, USA). The C3-T2 spine models used in this study were scanned from a healthy volunteer, and each vertebra of the C3-T2 spine consisted of cortical bone, cancellous bone, and posterior elements. In addition, the solid models of the ACP system consisted of one cervical plate and four locking screws with real screw threads. The ACP system was implanted into the C5 and C6 vertebrae and one bone graft was inserted between the C5 and C6 vertebrae to simulate the anterior cervical discectomy and fusion surgery (Fig. 1). The bone graft was modeled as a brick, and the interface between the bone graft and the adjacent vertebral bodies was assumed to be a perfect bond. After implantation of the ACP system into the spine model, the solid models were converted into parasolid format and transferred to ANSYS Workbench 14.5 (ANSYS, Inc., Canonsburg, PA, USA). For the material properties of the numerical models, the ACP systems were considered as Titanium alloy and the materials of the C3-T2 vertebrae were referred to past study [11]. Both the bones and the implants were assumed to be linearly elastic isotropic material (Table 1). Five types of spinal ligaments were considered including anterior longitudinal ligament, posterior longitudinal ligament, interspinous ligament, ligamentum flavum, and capsular ligaments. These spinal ligaments were assumed to be linear tension-only spring elements. A free mesh was used to all solid models using 10-node tetrahedral elements (SOLID 187). To ensure the accuracy caused by the mesh quality, a convergent study was conducted by decreasing the element size. For the interface condition, the interfaces between the vertebrae and the locking screws of the ACP system were assumed to be contact with the use of CONTA 174 and TARGE 170 elements. A frictional force between the contact interfaces was neglected. In the loading condition, a body weight of 73.6 N and a flexion moment of 1.5 N-m were applied on the top surfaces of the C3 vertebra. The boundary conditions were restrained on the bottom surfaces of T2 vertebra. In the postprocessing, the total strain energy of the ACP systems was calculated to evaluate their fixation stability. The total strain energy was defined to be the sum of the element strain energy of the ACP system. The ACP system with lower total strain energy indicated that the fixation device had smaller deformation and better fixation stability [4].

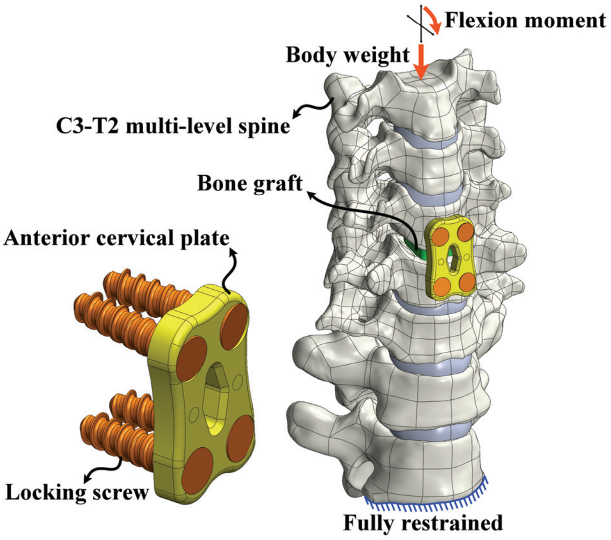

Fig. 1. The loading and boundary conditions of the numerical models

Table 1. The material properties of the finite element models

Material	Young's modulus (MPa)	Poisson's ratio
Cortical bone	10,000	0.29
Cancellous bone	100	0.29
Posterior elements	3,500	0.29
Annulus fibrosus	2.5	0.4
Nucleus pulposus	1.5	0.49
Bone graft	3,500	0.3
Anterior cervical plate	114,000	0.3
Locking screws	114,000	0.3

Design variables and their arrangements

Four design variables of the ACP systems were considered including the insertion angle with the locking screw inserted in the C5 segment in the superior-inferior direction (C5SI), the insertion angle with the locking screw inserted in the C5 segment in the medial-lateral direction (C5ML), the insertion angle with the locking screw inserted in the C6 segment in the superior-inferior direction (C6SI), and the insertion angle with the locking screw inserted in the C6 segment in the medial-lateral direction (C6ML) (Fig. 2a). Design spaces of each variable were determined based on the designs of the commercial products and the anatomy of the C3-T2 spine, and they were defined as follows: 5~15° for the C5SI, –5~10° for the C5ML, –5~15° for the C6SI, and –5~10° for the C6ML. To fairly arrange the design variables of the ACP systems, Taguchi methods which used a fractional factorial design to substitute a full factorial

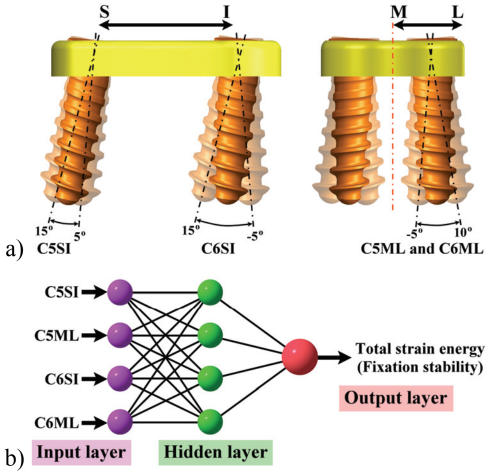

Fig. 2. (a) The design variables of the ACP system; (b) The structure of the artificial neural network

Table 2. The design combinations of the ACP systems for the learning process (from L-01 to L-25) and for the verification process (from V-01 to V-08) and discovered by Taguchi methods (OPT-TA) and genetic algorithms (OPT-GA)

Run	C5SI (°)	C5ML (°)	C6SI (°)	C6ML (°)	Total strain energy (mJ)	
					Finite element models	Artificial neural network models
L-01	5	–5	–5	–5	1.79	1.75
L-02	5	–1.25	0	–1.25	1.61	1.65
L-03	5	2.5	5	2.5	1.90	1.93
L-04	5	6.25	10	6.25	1.86	1.88
L-05	5	10	15	10	1.98	1.97
L-06	7.5	–5	0	2.5	1.79	1.77
L-07	7.5	–1.25	5	6.25	1.79	1.82
T-08	7.5	2.5	10	10	1.89	1.85
L-09	7.5	6.25	15	–5	1.94	1.92
L-10	7.5	10	–5	–1.25	1.93	1.92
L-11	10	–5	5	10	1.82	1.81
L-12	10	–1.25	10	–5	1.86	1.87
L-13	10	2.5	15	–1.25	1.92	1.95
L-14	10	6.25	–5	2.5	1.94	1.95
L-15	10	10	0	6.25	2.00	2.01
L-16	12.5	–5	10	–1.25	1.89	1.88
L-17	12.5	–1.25	15	2.5	1.95	1.95
L-18	12.5	2.5	–5	6.25	2.03	2.01
L-19	12.5	6.25	0	10	1.91	1.93
L-20	12.5	10	5	–5	2.00	1.99
L-21	15	–5	15	6.25	2.01	2.03
L-22	15	–1.25	–5	10	2.10	2.07
L-23	15	2.5	0	–5	1.89	1.88
L-24	15	6.25	5	–1.25	2.07	2.04
L-25	15	10	10	2.5	2.07	2.04
V-01	6.35	8.75	14.6	7.85	1.98	1.96
V-02	13.65	0.5	14.15	–0.95	1.99	2.04
V-03	8.15	8.5	–3.6	0.6	1.90	1.88
V-04	11.1	6.75	–4.2	2.9	1.94	1.93
V-05	13.6	1.65	–3.7	5.35	1.93	1.90
V-06	14.1	–2.6	–3.95	8.7	1.93	1.91
V-07	10.6	–3.8	6.1	–3.65	1.83	1.80
V-08	6.1	2.75	13.3	–3.9	1.99	2.02
OPT-TA	5	–1.25	0	–1.25	1.61	–
OPT-GA	5	–5	0	–5	1.56	1.59

design were used. In the present study, the L_{25} orthogonal array was selected and it could arrange six design variables at five levels. The matrix experiments were conducted based on the arrangements of the L_{25} orthogonal array (Table 2). A lower total strain energy obtained from the numerical model represented better fixation stability of the ACP system. Thus, the total strain energy was transformed into a the-smaller-the-better signal-to-noise (S/N) ratio. Except for the arrangement of design variables, Taguchi methods could also discover an optimum variable-level combination which was based on the factor levels corresponding to the maximum S/N ratio. The optimum design obtained using the Taguchi method was named "OPT-TA".

Artificial neural networks

The first part of the neuro-genetic algorithms was the artificial neural networks (ANNs). In the present study, the ANNs were developed to substitute the finite element models in order to reduce their computational time. Thus, the ANN model was used as a fitness function to predict the fixation stability of the ACP systems. The ANN model was formed in three layers including the input layer, hidden layer, and output layer. There are four neurons which represented four design variables of the ACP systems (C5SI, C5ML, C6SI, and C6ML) in the input layer. The number of neurons was four in the hidden layer. The total strain energy of the ACP system was predicted in the output layer, and a sigmoid function was used as the activation function (Fig. 2b). Two groups of data were prepared to construct a feasible ANN model including the learning data and verification data. In the present study, twenty-five ACP designs provided by the Taguchi method were used as the learning data to create the ANN model, and eight ACP designs were randomly selected as the verification data to validate the feasibility of the ANN model (Table 2). To achieve the accurate ANN models, the learning cycle was set to be 6,000. In addition, the learning rate and the momentum term were 0.5 and 0.55, respectively. The computer program for the ANN was developed with the use of Microsoft Visual Basic (Microsoft Corp., Redmond, WA, USA).

Genetic algorithms

After the development of the ANN model, genetic algorithms were the second part of the neuro-genetic algorithms (GAs). The GAs were inspired by Darwin's theory of evolution and invented by John Holland in 1975 [17]. In the present study, the lower total strain energy of the ACP system, which represented the better fixation stability, was expected during design optimization. Thus, the total strain energy of the ACP system should be minimized. To accurately discover a global optimum solution, the crossover rate and mutation rate were 90% and 1%, respectively. In addition, the genetic algorithm was stopped when 2,000 populations were produced. In this study, each population had ten ACP designs and each design variable had five strings. The computer program for the GA was also developed using Microsoft Visual Basic. The optimum design obtained using the genetic algorithm was named "OPT-GA". The workflows of the two decision-system procedures were showed (Fig. 3).

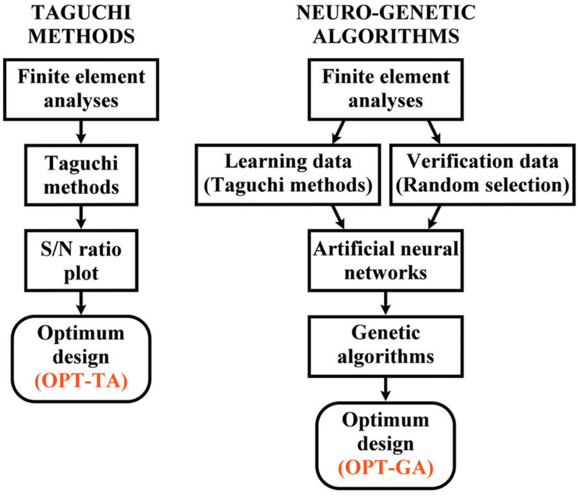

Fig. 3. The workflows of two decision-system procedures

Biomechanical tests

Five types of the ACP systems (the L-01, the L-06, the L-11, the L-16, and the L-21), which were selected from the L_{25} orthogonal array, one optimum ACP system (the OPT-TA), which was obtained by the Taguchi methods, and one optimum ACP system (the OPT-GA), which was obtained by neuro-genetic algorithms, were manufactured. High molecular-weight polyethylene cylinders were used instead of human vertebrae to prevent breakage and eliminate the inter-specimen variability during biomechanical testing. One bone plate and four locking screws were implanted into two polyethylene cylinders. A compression force of 80N which caused by a body weight was considered using a cable wire, pulleys, and counterweights. A flexion movement was applied on the specimens at a loading rate of 2.5 mm/min (Fig. 4). The load and displacement of each ACP system were recorded. Seven types of the ACP systems were repeated six times. The yielding strength, which was defined using 0.2% offset method, was obtained to represent the fixation stability. A one-way ANOVA followed by LSD post-hoc tests was used to evaluate the yielding strength among the experimental groups. *P values* less than 0.05 were considered to indicate statistically significant differences.

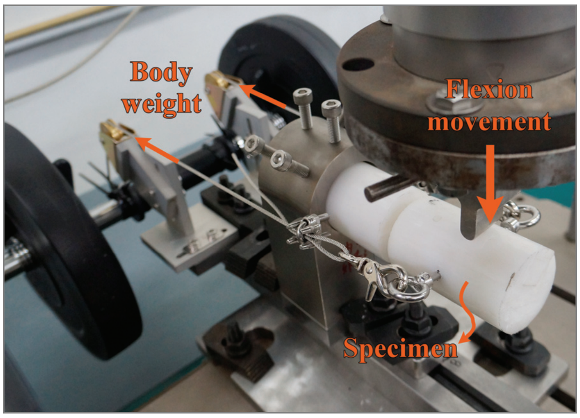

Fig. 4. The experimental setup

3. Results

Finite element models

Thirty-five finite element models of the C3-T2 spine with the ACP system were constructed including twenty-five ACP models arranged by the Taguchi method (the learning data for the ANNs), eight ACP models selected by a random method (the verification data for the ANNs), the optimum design discovered using the Taguchi method (the OPT-TA), and the optimum design discovered using the genetic algorithm (the OPT-GA). All finite element models were successfully meshed. The total number of elements ranged from 550,000 to 600,000 and the total number of nodes ranged from 890,000 to 950,000. The computational time ranged from 8 h to 10 h. In the convergent analyses, the total strain energy of the ACP systems was converged properly, and the differences between two neighboring data were less than 5%. The maximum total strain energy of the ACP system occurred at the central part of the ACP and the proximal part of the locking screws (Fig. 5).

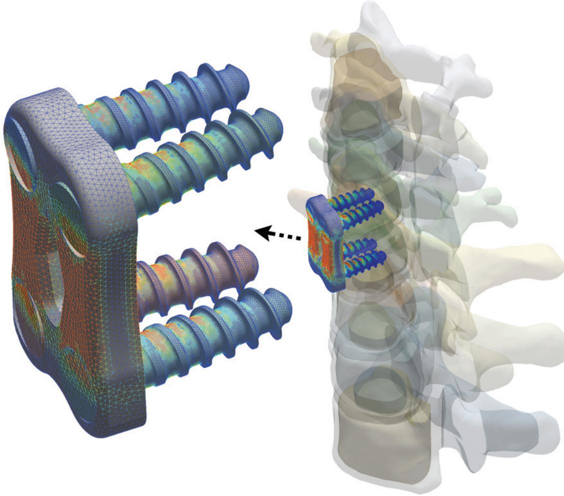

Fig. 5. The strain energy distribution of the ACP system

Taguchi methods

The total strain energy of the twenty-five ACP systems was obtained (Table 2). The L-02 design had lowest total strain energy (1.61 mJ) compared to the ACP designs of the L_{25} orthogonal array, but the L-24 and L-25 designs showed highest total strain energy (2.07 mJ). According to the results of the S/N ratio plat for the total strain energy, the optimum variable-level combination of the ACP system was $C5SI_1C5ML_2C6SI_2C6ML_2$ (the OPT-TA design) (Fig. 6). This optimum ACP design corresponded to a C5SI of 5°, C5ML of –1.25°, C6SI of 0°, and C6ML of –1.25°. In fact, the OPT-TA design was the same as the L-02 design. In addition, the OPT-TA design was superior to the designs of the L_{25} orthogonal array in all aspects.

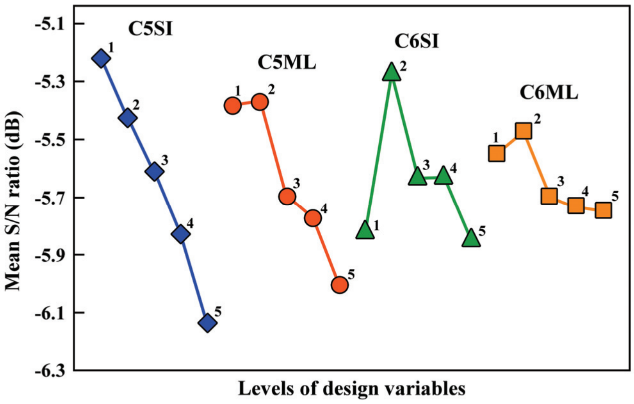

Fig. 6. The S/N ratio plot of the total strain energy

Artificial neural networks

Both learning data and verification data are necessary to develop an ANN model. In the present study, the twenty-five ACP results and eight ACP results were used as the learning data and the verification data, respectively. In the learning process, the mean absolute error was 1.1%, and the correlation coefficient between the finite element models and the ANN models was 0.98. In the verification process, the mean absolute error was 1.4%, and the correlation coefficient between the finite element models and the ANN models was 0.96 (Table 2). The above results demonstrated that the ANN model developed in the present study was accurate. Thus, it could be used to substitute the finite element models during the optimization study.

Genetic algorithms

The optimum ACP system design had been successfully discovered with the use of the genetic algorithm (the OPT-GA). The total strain energy of the OPT-GA was 1.56 mJ. This optimum design was superior to the designs of the learning group and verification group (Table 2). In addition, the total strain energy of the OPT-GA was also superior to that of the optimum design obtained using the Taguchi method (the OPT-TA) (Fig. 6). The design values of the OPT-GA were a C5SI of 5°, C5ML of –5°, C6SI of 0°, and C6ML of –5°. These design values indicated that the locking screws should be inserted convergently in the medial-lateral direction. However, the locking screws should be perpendicular to the ACP in the superior-inferior direction.

Biomechanical tests

Two optimum ACP systems and five ACP systems were successfully tested. All of the ACP systems have a permanent deformation, and the main deformation occurred at the screw-plate junction. In the load deformation curves, the load went up on the curve as the displacement went up. However, the curve became horizontal when the loading continued. The OPT-GA design showed the highest yielding strength of 921 ± 72 N compared with the other six designs (717 ± 55 N of the L-01, 750 ± 80 N of the L-06, 639 ± 72 N of the L-11, 690 ± 72 N of the L-16, 587 ± 64 N of the L-21, and 807 ± 40 N of the OPT-TA). The yielding strength of the OPT-GA design was significantly higher than those of the L-01, the L-06, the L-11, the L-16, the L-21, and the OPT-TA designs ($p < 0.05$). The total strain energy determined using the finite element models was closely related to the yielding strength obtained from the experiments, featuring a high correlation coefficient of –0.93 (Fig. 7).

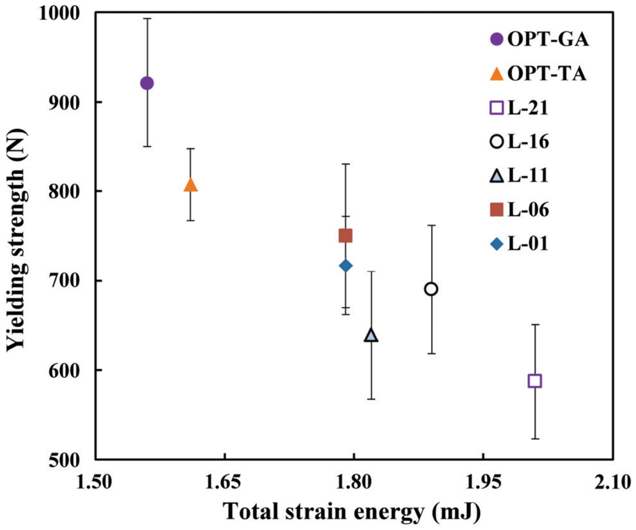

Fig. 7. The correlation study of the ACP systems

4. Discussions

Finite element analyses have been widely used to evaluate orthopaedic biomechanics [9], [14], [21]. Past studies had developed cervical spine models to evaluate the biomechanical performances of ACP system. Palepu et al. [18] developed an experimentally validated intact C5-C6 finite element model to investigate the load sharing ability of a novel dynamic plate design. However, only the C5 and C6 segments were considered. Hussain et al. [11] developed a three-dimensional finite element model of a C3-T1 motion segment to evaluate the stability of fusion constructs with three different multi-level reconstruction techniques. Although the C3-T1 multilevel spine model with real bone geometry was considered, the geometry of the anterior screws was assumed to be axisymmetric. In this study, both the bone and the ACP system were constructed according to the real geometries, especially for the cervical locking screws of the ACP system. Thus, the present study simultaneously considered the real geometries of both the bone and the ACP systems. To our knowledge, there has been very little research which considered the real geometries of both the bone and the implants at the same time. The total strain energy was used as an objective performance. Two reasons could explain this assumption. First, both the displacement and the total strain energy have the same tendency. In fact, a correlation coefficient between them was 0.99. Second, the difference of the total strain energy of each ACP system is larger than that of the displacement. Thus, the total strain energy was used instead of the displacement as an objective performance.

Engineering methodologies and algorithms can effectively discover an optimum design of orthopaedic implants [3], [10]. In the present study, the optimum ACP design could be obtained by either the Taguchi method or the genetic algorithm. The OPT-TA was the optimum ACP design discovered using the Taguchi method. This optimum design was based on the factor levels corresponding to the maximum S/N ratio. Thus, the design values were limited to discrete levels. It implied that an optimum ACP design obtained using the Taguchi method might fall into a local optimum solution [19]. Compared to the Taguchi method, the genetic algorithm, which was an evolutionary algorithm, could search all possible combinations. Thus, the genetic algorithm might avoid falling into a local optimum solution [12]. This opinion was also verified in the present study, because the OPT-GA design was superior to the OPT-TA design. In addition, the OPT-GA design was also superior to all learning and verification data in all aspects.

The genetic algorithm had been demonstrated to have excellent performance to discover a global optimum solution compared with the Taguchi method in the present study. Except for the search ability of engineering algorithms, the correctness of an objective function is another important part. In fact, the objective function used in this study was not a finite element model but an ANN model. The reason for applying the ANN model was to decrease the simulation time of the finite element models [5]. However, it should be ensured that the ANN model could accurately predict the results of the finite element models. In the present study, the mean absolute error between the ANN models and the finite element models was sufficiently small (error < 1.4%). Besides, the predicted outcomes calculated using the ANN models were closely related to those calculated using the finite element models with a high correlation coefficient of 0.98 for the learning group and 0.96 for the verification group. Thus, the optimum ACP design obtained using the genetic algorithm was reliable and accurate.

An ACP system that includes four individual locking screws was quite complicated to determine the best screw orientations. Past study has tried to determine the screw orientations of anterior vertebral plate systems to improve clinical performances. Di Paola et al. [8] evaluated the influence of screw orientation and plate design on screw pullout strength. However, the screw orientation of their study was mainly based on the experiences of the investigators. In addition, only some of the vertebral plate designs were selected and tested. Thus, a bias may exist for determining the screw orientations of the vertebral plates. Fortunately, a contrived bias caused by past study could be minimized using engineering algorithms. In the present study, the optimum screw orientation of the ACP systems could be determined using the genetic algorithm. All possible combinations of the screw orientations of the ACP system designs could be considered. Thus, the present study has higher chance to discover a global optimum design of the ACP systems.

High molecular-weight polyethylene cylinders were used instead of human vertebrae in the present study. The reasons for using the polyethylene cylinders were that they could prevent breaking bones and reduce the interspecimen variability during biomechanical testing [16], [22]. Although the polyethylene cylinders could not represent real geometries and materials of human vertebrae, they may be suitable to be used for evaluating the yielding strength of different ACP systems. A custom-made jig, which could fix the specimens and apply both a body weight and a flexion movement, was designed and manufactured. The concept of this experimental jig was to simulate the biomechanics of human spine. Fortunately, the correlation study indicated that the total strain energy determined using the finite element models was closely related to the yielding strength obtained from the experiments with a high correlation coefficient of –0.93. Thus, the experimental setup used in the present study may be reasonable.

This study had the following limitations. First, linear elastic isotropic materials were assumed for the numerical models of the C3-T2 multi-level segments with the ACP system. This ideal assumption might impede the numerical models to predict the actual clinical performance. Second, the spinal ligaments considered in this study were simulated using linear tension-only spring elements. However, the biomechanical behavior of the spinal ligaments may be nonlinear. Third, the optimum screw orientation of the ACP systems was determined by applying a flexion moment and a body weight on the top surfaces of the C3 vertebra. However, the actual loading conditions, such as extension, lateral bending, and axial rotation, may also need to be considered. Thus, the optimum ACP system design may depend on the loading condition. Finally, only one of the clinical performances, the fixation stability, was considered as the objective function for discovering the optimum ACP system design. However, other clinical performances should also be considered as the objectives, such as the bone-implant interfacial strength and stress of vertebral bone around ACP systems.

In conclusion, the optimum ACP system design obtained using the neuro-genetic algorithm showed excellent fixation stability compared to the other ACP system designs. The neuro-genetic algorithm can accurately and effectively determine the global optimum solution compared with the Taguchi method. The biomechanical result of the present study could help surgeons to clearly understand the fixation stability of ACP systems in terms of screw orientations.

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