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# Correlation between the Computed Tomography Values of the Screw Path and Pedicle Screw Pullout Strength: An Experimental Study in Porcine Vertebrae

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**Study Design:** Biomechanical study.

**Purpose:** To assess the correlation between the computed tomography (CT) values of the pedicle screw path and screw pullout strength.

**Overview of Literature:** The correlation between pedicle screw pullout strength and bone mineral density has been well established. In addition, several reports have demonstrated a correlation between bone mineral density and CT values. However, no previous biomechanical studies investigated the correlation between CT values and pedicle screw pullout strength.

**Methods:** Sixty fresh-frozen lumbar vertebrae from 6-month-old pigs were used. Before screw insertion, the CT values of the screw path were obtained for each sample. Specimens were then randomly divided into three equal groups. Each group had one of three pedicle screws inserted: 4.0-mm LEGACY (4.0-LEG), 4.5-mm LEGACY (4.5-LEG), or 4.5-mm SOLERA (4.5-SOL) (all from Medtronic Sofamor Danek Inc., Memphis, TN, USA). Each screw had a consistent 30-mm thread length. Axial pullout testing was performed at a rate of 1.0 mm/min. Correlations between the CT values and pedicle screw pullout strength were evaluated using Pearson's correlation coefficient analysis.

**Results:** The correlation coefficients between the CT values of the screw path and pedicle screw pullout strength for the 4.0-LEG, 4.5-LEG, and 4.5-SOL groups were 0.836 ($p$<0.001), 0.780 ($p$<0.001), and 0.873 ($p$<0.001), respectively. Greater CT values were associated with greater screw pullout strength.

**Conclusions:** The CT values of the screw path were strongly positively correlated with pedicle screw pullout strength, regardless of the screw type and diameter, suggesting that the CT values could be clinically useful for predicting pedicle screw pullout strength.

**Keywords:** Lumbar vertebrae; Pig; Prosthesis failure; Computed tomography; Pedicle screws

## Introduction

Recent advances in spinal surgical techniques have led to an increase in the proportion of patients undergoing instrumented spinal surgery [1]. Instrumented spinal surgery using pedicle screws is one of the most common

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methods for correcting spinal instability. However, the relatively poor bone quality in older adult patients' results in decreased pedicle screw anchorage, potentially resulting in failure at the bone–screw interface [2,3]. The pedicle screw loosening rate in patients with osteoporosis reportedly ranges from 0% to 62.8% [4]. When pedicle screw fixation failure occurs, revision surgery may be required; therefore, achieving adequate pedicle screw anchorage is a major concern.

Spinal stability after treatment with instrumentation depends mainly on the stability of the pedicle screws and the vertebral bodies [3]. The stability of pedicle screws is affected by many factors, namely, screw design [5], pedicle morphology [6], and vertebral bone mineral density (BMD). Several studies have demonstrated a strong correlation between pedicle screw pullout strength and the BMD of human vertebral bodies [3,7], and a recent radiological study reported a correlation between the pedicle screw pullout strength and the pedicle BMD measured using dual-energy computed tomography (CT) [8]. Currently, BMD is assessed mainly with dual-energy X-ray absorptiometry (DXA), which is the only diagnostic method included in the World Health Organization's definition of osteoporosis [9]. Furthermore, DXA is reportedly a powerful predictor of bone degradation and fracture risk [10]; however, this technique has limitations because it can be used only in the lumbar spine and the proximal femur, and is inaccurate in patients with lumbar scoliosis or degenerative changes [11].

There is current interest in using CT values to assess BMD. Some studies have reported a correlation between CT values and BMD, and proposed that CT values are a suitable alternative to DXA when measuring BMD [12,13]. Therefore, we hypothesized that the CT values of the screw path may be correlated with pedicle screw pullout strength. However, to our knowledge, based on an English-language literature review, no previous biomechanical studies have investigated this relationship. Thus, we performed an axial pullout test of pedicle screws from the lumbar vertebrae of porcine specimens. The aim of the present study was to assess the correlation between the CT values of the screw path and the pedicle screw pullout strength, and to confirm the validity of using the CT values of the screw path to predict pedicle screw pullout strength.

## Materials and Methods

### 1. Ethical approval and consent to participate

The present study did not involve human participants or experimental animals, so ethical approval was not required.

### 2. Screw types

Three types of compliance engineering-certified monoaxial pedicle screws (Medtronic Sofamor Danek USA Inc., Memphis, TN, USA) were used: 4.0-mm LEGACY (4.0-LEG; diameter, 4.0 mm; length, 30 mm; thread pitch, 2.75 mm), 4.5-mm LEGACY (4.5-LEG; diameter, 4.5 mm; length, 30 mm; thread pitch, 2.75 mm), and 4.5-mm SOLERA (4.5-SOL; diameter, 4.5 mm; length, 30 mm; thread pitch, 2.0 mm in the cortical zone and 4 mm in the cancellous zone) (Fig. 1).

### 3. Specimen preparation

A total of 60 fresh-frozen lumbar vertebrae from various lumbar levels (cut into halves through the spinous processes) were obtained from 6-month-old pigs (Tokyo Shibaurazouki Co. Ltd., Tokyo, Japan) that had been slaughtered domestically for edible use (and so were not experimental animals). Porcine specimens were chosen because of their easy availability and use in previous studies [14,15]. In preparation for biomechanical testing, the specimens were thawed at room temperature; carefully cleaned of muscle, ligament, and connective tissue; and separated into indi-

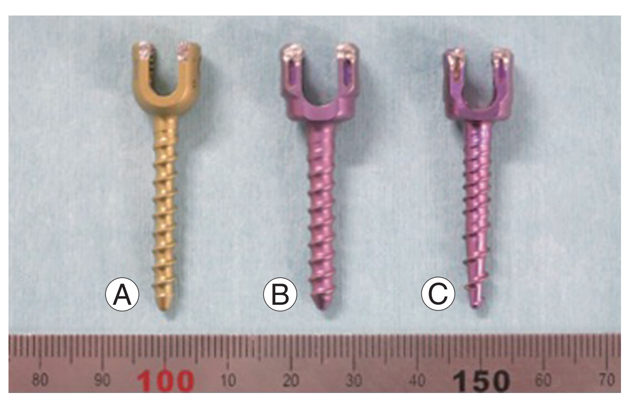


**Fig. 1.** Photographs showing the screw types used in the present study. **(A)** 4.0-LEG (LEGACY; diameter, 4.0 mm; length, 30 mm), **(B)** 4.5-LEG (LEGACY; diameter, 4.5 mm; length, 30 mm), and **(C)** 4.5-SOL (SOLERA; diameter, 4.5 mm; length, 30 mm).

vidual vertebrae. These 60 vertebrae were randomly divided into three equal groups, one group for each screw type. Just prior to testing, the discs and cartilaginous endplates were resected. Screws were then inserted perpendicularly to the resection plane into pilot holes that had been predrilled with a 2.0-mm drill bit, which was smaller than the inner diameter of the screw tip. Pedicle screws were inserted directly into the vertebrae in the cranial–caudal direction, rather than transpedicularly, to eliminate the effects of the cortical bone surrounding the pedicle and the pedicular morphology. Tapping was not performed prior to screw insertion. All screws were inserted through a 2-mm-thick washer with a consistent 30-mm thread length, and all screws were inserted by a single researcher to eliminate technical bias (Fig. 2A).

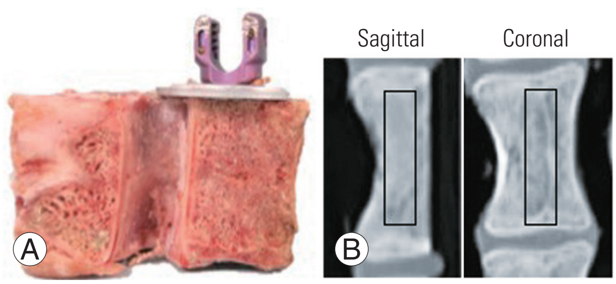


Fig. 2. Images of the porcine vertebrae. (A) Photograph of a 30-mm-long screw inserted through a 2-mm-thick washer. (B) Computed tomographic image showing the 10×30-mm rectangular region of interest (enclosed by the black lines); cortical margins were excluded to prevent volume averaging.

### 4. Radiographic analysis

Before screw insertion, we measured the CT (Aquilion 16SX; Canon Medical Systems Corp., Otawara, Japan) value of the screw path in each specimen. The CT parameters included a slice thickness of 1.0 mm, tube voltage of 120 kVp, tube current of 300 mA, and a bone reconstruction algorithm (window width/window level: 3,000/400). A picture archiving and communication system (EV Insite R; PSP Corp., Tokyo, Japan) was used to calculate the average CT value for a region of interest (ROI) that was confined to the trabecular area. ROIs were measured using sagittal and coronal images. For each measurement, a 10×30-mm rectangular ROI was drawn without using any special device; the cortical margins were excluded to prevent volume averaging (Fig. 2B). The CT values from the two planes were averaged to obtain a mean value, and ROIs were selected by two researchers to evaluate the intra- and inter-observer variabilities of the CT values using the interclass correlation coefficient (ICC) values.

### 5. Biomechanical testing and analysis

To ensure that the screw tracts were parallel to the pullout axis, specimens were placed in a custom-made stainless steel device that enabled capturing of the screw head and specimen for biomechanical testing (Fig. 3A–C). This device had a rectangular shape with a screw hole at the

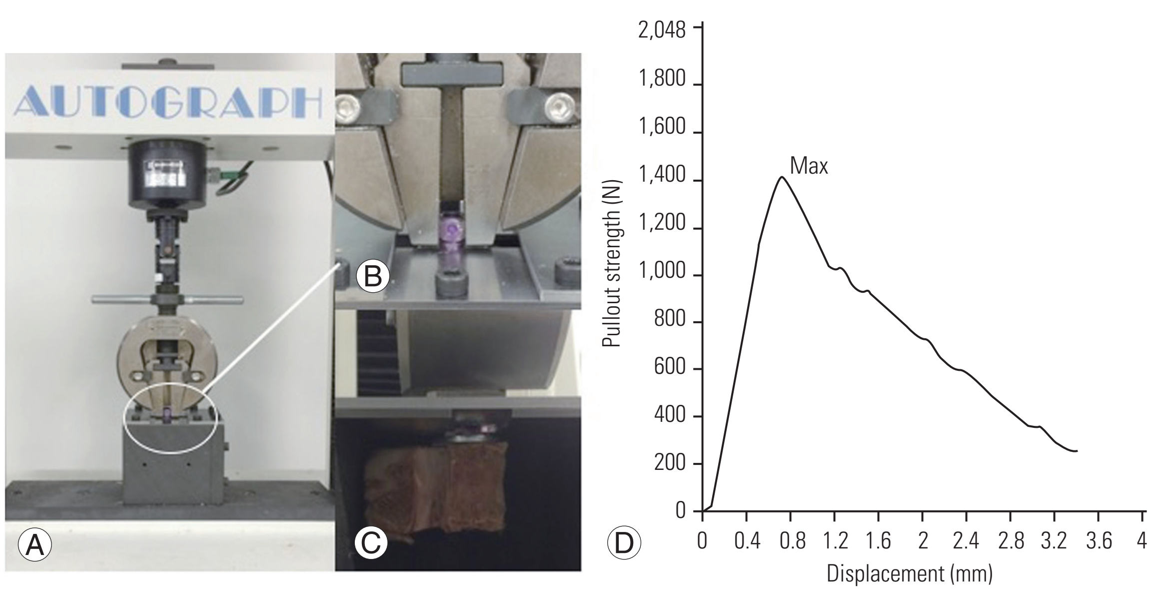


Fig. 3. Biomechanical testing. (A) The autograph used to determine pullout strength (N) at a displacement rate of 1.0 mm/min. (B) A screw head attached to the testing machine. (C) The bone–screw complex fixed inside the metal box. (D) Typical load–displacement curve for screw axial pullout.

bottom for rigid fixation within the lower part of the testing machine (Fig. 3A). On the upper side, the device had a rectangular hole through which only the pedicle screw head could pass, allowing the pullout force applied by the machine to be transmitted directly to the specimen (Fig. 3B). The screw heads were attached to the testing machine, and a constant pullout displacement rate of 1 mm/min was applied in line with the screw axis.

The maximum pullout strengths of the pedicle screws were determined using a mechanical testing machine (Autograph AG-I; Shimadzu Corp., Kyoto, Japan). The load cell capacity of this system was 5,000 N, and the screw–bone complex was pulled until failure occurred. Data collected using TrapeziumX ver. 1.3.0 (Shimadzu Corp.), were used to calculate the ultimate failure load of each screw–bone complex. The maximum pullout strength (N) was determined as the maximum point on the strength–displacement curve where failure occurred (Fig. 3D). Finally, we assessed the correlations between the CT values of the screw paths and the pullout strengths of the three pedicle screws.

### 6. Statistical analysis

Intra- and inter-observer reliability calculations were performed using the ICC values, and were reported as scores between 0 and 1 (0, no agreement; 1, perfect agreement) [16]. ICC values of 0.75–0.89 were defined as indicating good reliability, while values of 0.90–0.99 were defined as excellent reliability. Differences between the CT values and pedicle screw pullout strengths in each group were evaluated with one-way analysis of variance followed by a Tukey multiple comparison test. Correlations between the CT values of the screw path and the pedicle screw pullout strengths were evaluated using Pearson's correlation coefficient. Analyses were performed with JMP software ver. 10 (SAS Institute Japan Ltd., Tokyo, Japan). Two-sided $p$-values <0.05 were considered to indicate statistically significant differences.

## Results

### 1. Computed tomography values and pullout strengths

As shown in Table 1, the CT values of the screw paths did not differ significantly among the three groups (4.0-LEG versus 4.5-LEG, $p$=0.10; 4.0-LEG versus 4.5-SOL, $p$=0.78; 4.5-LEG versus 4.5-SOL, $p$=0.32). However, the 4.5-LEG and 4.5-SOL screws had significantly greater pullout strengths than the 4.0-LEG screw (4.0-LEG versus 4.5-LEG, $p$=0.01; 4.0-LEG versus 4.5-SOL, $p$=0.03; 4.5-LEG versus 4.5-SOL, $p$=0.87).

**Table 1.** Computed tomography values and pullout strengths for each screw type

| Pedicle screw | CT value [a] (HU) | Pullout strength [a] (N) |
|---|---|---|
| 4.0-LEG | 412.9±107.5 | 757.7±379.7 |
| 4.5-LEG | 470.1±82.0 | 1,157.0±275.0 [b] |
| 4.5-SOL | 432.5±96.8 | 1,085.9±532.8 [b] |

Values are presented as mean±standard deviation. 4.0-LEG: LEGACY; diameter, 4.0 mm; length, 30 mm; thread pitch, 2.75 mm; 4.5-LEG: LEGACY; diameter, 4.5 mm; length, 30 mm; thread pitch, 2.75 mm; 4.5-SOL: SOLERA; diameter, 4.5 mm; length, 30 mm; thread pitch, 2.0 mm in the cortical zone and 4 mm in the cancellous zone.
HU, Hounsfield units.
[a] Groups were compared using one-way analysis of variance followed by the Tukey multiple comparison test. [b] $p$<0.05 for 4.0-LEG vs. 4.5-LEG and 4.5-SOL.

### 2. Correlation between the computed tomography value of the screw path and the pullout strength

The correlation between the CT value of the screw path and pedicle screw pullout strength was evaluated separately for each screw type (Fig. 4). The correlation coefficients ($r$) for the 4.0-LEG, 4.5-LEG, and 4.5-SOL screws were 0.836, 0.780, and 0.873, respectively. The CT values of the screw path were significantly positively correlated with pullout strength for all three pedicle screws ($p$<0.001). In all groups, greater CT values were associated with greater screw pullout strength.

### 3. Reliability

The ICCs for intra- and inter-observer variability were 0.962 and 0.957, respectively, indicating excellent reliability of the CT value measurements.

## Discussion

Correlations between the BMD of human vertebral bodies and the pedicle screw pullout strength, and between the BMD and CT values have been proven [3,7,12,13]; however, the association between pedicle screw pullout strength and CT values has not yet been discussed. To our

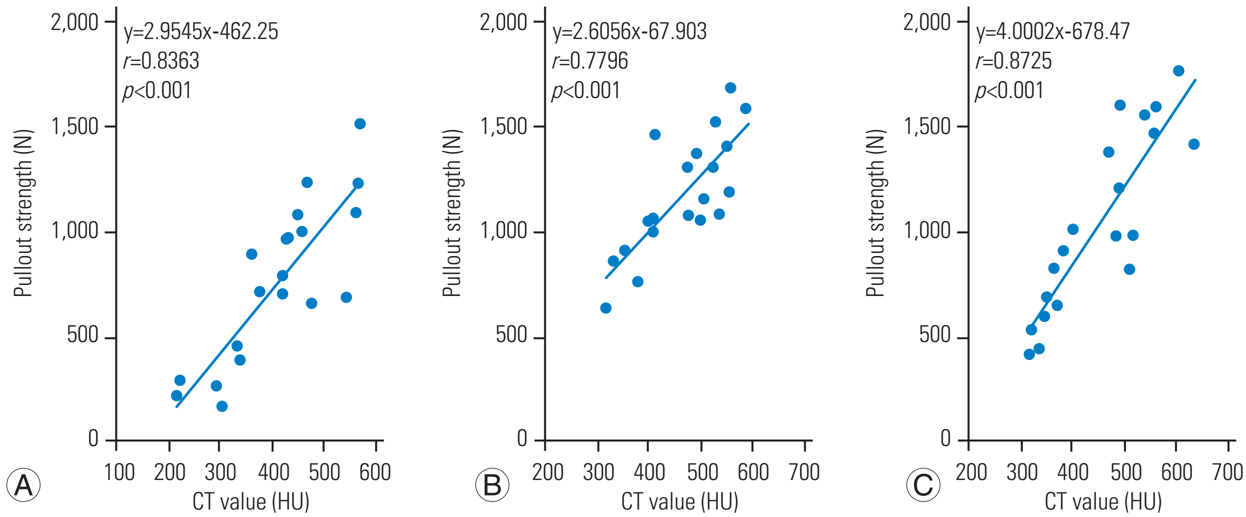


**Fig. 4.** Relationships between the CT values and pullout strengths (N) of **(A)** 4.0-LEG (LEGACY; diameter, 4.0 mm; length, 30 mm), **(B)** 4.5-LEG (LEGACY; diameter, 4.5 mm; length, 30 mm), and **(C)** 4.5-SOL (SOLERA; diameter, 4.5 mm; length, 30 mm) screws. The CT values were significantly positively correlated with the pullout strengths (N) of all pedicle screws ($p$<0.001). CT, computed tomography; HU, Hounsfield units.

knowledge, the current study is the first to evaluate the association between pedicle screw pullout strength and CT values, and we found a strong correlation between the CT values of the screw path and the pedicle screw pullout strength, regardless of the screw type and diameter (Fig. 4). Our results indicate that the CT values of the screw path may be useful in predicting pedicle screw pullout strength, which may help spine surgeons develop better treatments.

Some studies have reported a strong correlation between implant stability and CT values. In dentistry, the correlation between CT values and implant stability has been shown *in vitro* and *in vivo*, and normal CT values have been reported for specific regions of the mandible and maxilla [17,18]. In orthopedic surgery, Aichmair et al. [19] demonstrated a trend towards a greater pullout strength with a greater vertebral BMD measured using CT values. However, their research had two drawbacks: BMD was evaluated in the ellipsoidal regions of the vertebral body (not the screw path), and the pullout strength was compared among only three subgroups divided according to CT values [19]. Therefore, to further clarify the effect of CT values on pullout strength, we investigated the correlation between the CT values of the screw path and the pullout strength of the pedicle screw. Matsukawa et al. [20] used the CT value of the screw path as a BMD measurement and showed that the CT value correlated with the pedicle screw insertional torque. However, the authors also stated that insertional torque, which represents the holding power in the axial direction, closely approximates but is not identical to the pullout strength [20]. Furthermore, the relationship between insertional torque and pullout strength remains controversial [21,22], and screw pullout occurs occasionally, clinically [2,23]. Thus, in the current study, we focused on the relationship between the CT values of the screw path and the pedicle screw pullout strength. In addition to the strong positive correlation between the CT values of the screw path and pedicle screw pullout strength in our study, the correlation coefficients (0.836, 0.780, and 0.873 for the 4.0-LEG, 4.5-LEG, and 4.5-SOL groups, respectively) were comparable with the correlation coefficient reported in a previous study ($r$=0.80) demonstrating a correlation between the pedicle screw pullout strength and the pedicle BMD measured using dual-energy CT [8].

CT values, expressed in Hounsfield units (HU), are standard measurements representing the relative densities of body tissues according to a calibrated grayscale based on the values for air (−1,000 HU) and water (0 HU). Schreiber et al. [12] reported that participants with normal bone density, osteopenia, and osteoporosis had mean lumbar CT values of 133.0 HU, 100.8 HU, and 78.5 HU, respectively. The authors also showed correlations between CT values and the T-scores cited in the World Health Organization's guidelines for diagnosing osteoporosis, and concluded that CT values can be used for fracture risk assessment, and for the diagnosis and early initiation of the treatment of osteoporosis [12]. Additionally, microarchitectural studies have reported that CT values can approximate microarchitectural parameters such as bone surface density [24], and that bone surface density is the most effective tool to predict pedicle screw pullout strength [25]. In addition, CT values can be measured easily in any form by drawing an ROI on the captured CT image (Fig. 2B). However, the reproducibility of ROI selection is an important concern. In the present study, two spine surgeons manually placed ROIs on the images of 60 porcine lumbar vertebrae. The ICCs for intra- and interobserver variabilities were 0.962 and 0.957, respectively, which were similar to values reported in previous studies [12,13,20] showing excellent reliability of CT value measurements in the spine region. Although there is room for improvement via the development of software applications to automatically select optimal ROIs, CT values can be measured simply and accurately without a specialized device.

CT values have advantages over DXA for determining screw stability. A study published in 2009 reported that only 44% of spine surgeons use DXA to preoperatively assess BMD [26]. DXA incurs additional cost and radiation exposure (a typical total-body DXA examination exposes patients to 0.96 mSv) [27], and the technique can be used only to assess the lumbar spine and the proximal femur. In contrast, CT scans are always performed preoperatively to evaluate the morphology of the vertebral body and pedicle (especially the pedicular diameter) to determine the appropriate screw size, and can be obtained for any vertebra in which screw placement is planned. Therefore, we considered CT values to be more suitable for estimating pedicle screw pullout strength than DXA, particularly for clinical use.

In the present study, we excluded the cortical margins when selecting the ROIs. A previous cadaver study reported that the mean percentage of the cortical bone contacting the screw inserted in the vertebral pedicle was only 2.7%, and that the cortical bone of the vertebral pedicle was not an important contributing factor in the fixation of implants [28]. Although part of the pedicle screw pullout strength may be attributed to its interface with the cortical margins of the pedicle, we considered that the association between the pedicle screw and cancellous bone was more critical for evaluating screw stability.

The present study had several limitations that should be noted. First, the BMD of porcine bone is greater than that of human bone [29]. We used porcine vertebrae because our cultural background makes it difficult to obtain cadaveric spinal specimens. However, many studies have documented the utility of porcine bone as a model [14,15]. Furthermore, porcine vertebrae are similar to human vertebrae in terms of their nutritional make-up, bone structure, and mineral metabolism [30], and the microarchitectural ratios of cortical bone and cancellous bone in porcine vertebrae are similar to those of human vertebrae [24]. Although a cadaveric study using human bones of varying quality would be ideal, the goal of the present study was to determine the relationship between the CT values of the screw path and pedicle screw pullout strength, specifically. Second, there are currently no reference CT values for the vertebrae, and our results only demonstrate a correlation between the CT values of the screw path and pedicle screw pullout strength. Ideally, reference values for clinical use should be determined in future studies.

## Conclusions

We introduced a novel application of CT values as a simple measurement that was significantly positively correlated with pedicle screw pullout strength. Our findings suggest that the CT values of the screw path can be used to predict pedicle screw pullout strength, and may be a reasonable substitute for BMD measured by DXA. However, our findings must be confirmed in a larger cadaveric study.

## Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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## Author Contributions

Atsushi Ikeura: conception and design, data acquisition, analysis of data, drafting of the manuscript, funding acquisition; Taketoshi Kushida: data acquisition, critical revision; Kenichi Oe: drafting of the manuscript, critical revision; Yoshihisa Kotani: critical revision; Muneharu Ando: critical revision; Takashi Adachi: administrative support; and Takanori Saito: supervision.

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