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ORIGINAL PAPER

Experimental periprosthetic fractures with collarless polished tapered cemented stems

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Abstract

Purpose After cemented total hip arthroplasty, the risk of periprosthetic fracture (PPF) of taper-slip stems is higher than that of composite-beam stems. We aimed to assess the conditions resulting in PPFs of taper-slip stems using a falling weight.

Methods Taper-slip stems were fixed to five types of simulated bone models using bone cement, and the fractures were evaluated by dropping stainless-steel weights from a predetermined height onto the heads. The periprosthetic fracture height in 50% of the bone models ($PPFH_{50}$) was calculated using the staircase method.

Results For the fixation with 0° of flexion, the values for $PPFH_{50}$ were 61 ± 11, 60 ± 13, above 110, 108 ± 49, and 78 ± 12 cm for the cobalt–chromium–molybdenum alloy, stainless steel alloy (SUS), titanium alloy (Ti), smooth surface, and thick cement mantle models, respectively; for the fixation with 10° of flexion (considering flexure), the $PPFH_{50}$ values were 77 ± 5, 85 ± 9, 90 ± 2, 89 ± 5, and 81 ± 11 cm, respectively. The fracture rates of the polished-surface stems were 78.6 and 35.7% at the proximal and distal sites, respectively ($p < 0.05$); the fracture rates of the smooth-surface stems were 14.2 and 100%, respectively ($p < 0.05$).

Conclusion The impact tests demonstrated that the conditions that were less likely to cause PPFs were use of Ti, a smooth surface, a thick cement mantle, and probably, use of SUS.

Keywords Bone cement · Falling-weight impact test · Periprosthetic fracture · Staircase method · Taper-slip stem

Introduction

Currently, "revisiting" cemented total hip arthroplasty (THA) is a worldwide trend, although many uncemented THAs has been performed around the world [1]. Cemented stems are preferable to uncemented stems in terms of the incidence of periprosthetic fractures (PPFs). In a large retrospective study of over 30,000 patients who underwent THAs at the Mayo Clinic [2], intraoperative PPF occurred up to three times more often in uncemented stems. According to the Nordic Arthroplasty Register Association database of 437,629 patients who underwent THAs, the incidence of PPF after two years of THA conducted using uncemented and cemented stems was 0.47 and 0.07%, respectively [3]. The American Joint Replacement Registry database of 10,277 patients who underwent revision THAs also reported that patients with uncemented stems were 2.6 times more likely to undergo early revision of PPF than those with cemented stems [4]. However, for cemented stems, some authors have reported that the risk of PPF of taper-slip stems was high compared to that of composite-beam stems [3, 5–9].

Regarding the mechanism of cement fixation, the design of a cemented stem is based on two ideas: the composite-beam or shape-closed design developed by Charnley and the taper-slip or force-closed design based on the Exeter stem [10]. These two types differ in terms of the location of the shear force, as the composite-beam stem and the bone cement behave as a single piece at the cement–bone interface, whereas the taper-slip stem slips on the bone cement because of its polished shape, and thus, applies a shear force to the stem–cement interface. This small degree of slipping of the taper-slip stem creates compressive hoop stress, which is thought to affect the long-term performance of the stem

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[11]. Although taper-slip stems are widely used and referred to as the gold standard for cemented stems, differences in cement fixation may lead to the occurrence of PPF.

Oe et al. reported some "atypical" PPFs of taper-slip stems that did not cause any trauma but resulted in excessive taper-slip [12]. Hirata et al. demonstrated that the effect of the surface appearance of the stem-cement interface differed for each metal, even if the roughness of the implant surface was equal [13]. Kaneuji et al. also performed dynamic loading tests using stainless steel alloy (SUS) and cobalt–chromium–molybdenum alloy (CoCr) stems of similar shapes and observed differences in the subsidence and forces at the bone–cement interface [14]. Their material and biomechanical studies suggested that a polished-tapered stem made of CoCr might cause excessive taper-slip on the cement, potentially resulting in PPF. However, PPF of taper-slip stems could be associated with other risk factors, including the surface roughness and thickness of the cement mantle. In this study, we aimed to identify the conditions resulting in PPF of taper-slip stems using a falling weight.

Materials and methods

Preparation of simulated bone models

The study design was not approved by the appropriate ethics review board because of no research involving human and animal subjects. An SC-stem (Kyocera Co., Kyoto, Japan) was used. The regular SC-stem had a curved triple-tapered design, was made of CoCr, and had a polished surface. The vertical stem length from the centre of the head to the stem tip was 135 mm (size: STD-3), and the horizontal off-set length from the centre of the head to the centre of the shaft was 38 mm. After rasping, the stem was fixed to the simulated bone (Sawbones-femur-medium-left; model number: 1121-3; Pacific Research Laboratories, Vashon, WA, USA) using bone cement (Ostron II; GC Co., Tokyo, Japan) with a centraliser. Under standard conditions, the cement-mantle thickness, which was calculated using the difference between the rasp and implant sizes, was 1 mm in the shaft and 3.1 mm in the calcar. After 30 min of bone–cement hardening, the stem was removed using an extraction tool. To mimic the wet conditions of the in vivo femoral environment, a stem wetted with normal saline was reinserted into the bone cement using the in-cement technique, without adding extra bone cement [15]. Because the stem–cement interface of a taper-slip stem is contaminated with liquid in clinical practice, the in-cement technique was used to reproduce this phenomenon. A 32-mm metal head was attached to the SC-stem (Fig. 1).

Conditions of simulated bone models

All implanted stems had the same shape (SC-stem; #STD-3). Five types of simulated bone models were prepared as follows: (1) standard conditions; CoCr, (2) SUS, (3) titanium alloy (Ti), (4) smooth surface, and (5) thick cement mantle

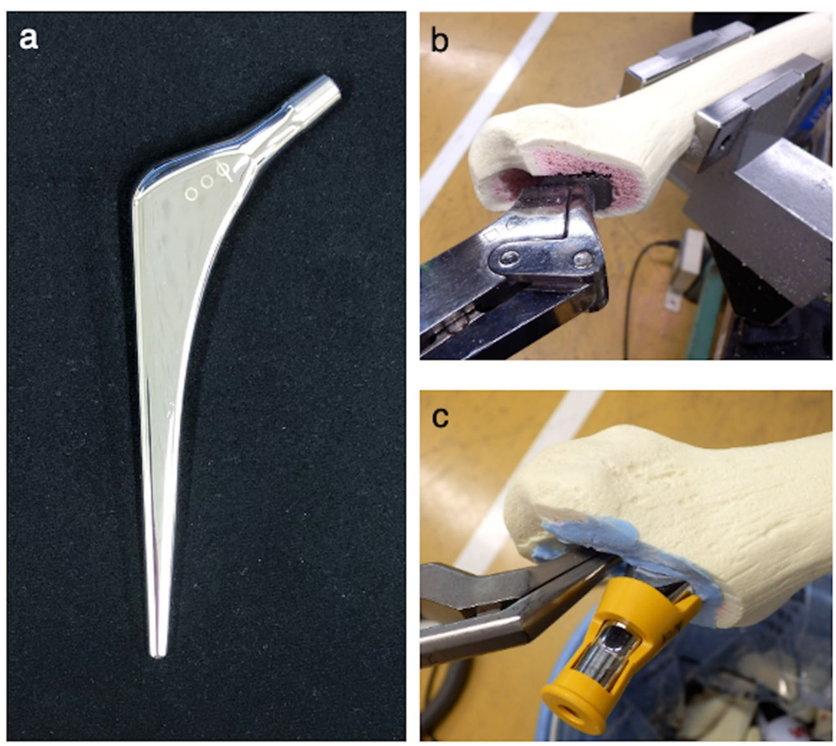

Fig. 1 Photographs of the stimulated bone model prepared for this study. **a** The SC-stem (size, #STD-3) has a curved triple-tapered design and is made of cobalt–chromium–molybdenum alloy. **b** The simulated bone is rasped using a broach. **c** The stem is fixed to the simulated bone using bone cement. Thereafter, the stem was removed, wetted with normal saline, and reinserted into the bone cement using the in-cement technique

Table 1 Conditions of simulated bone models

Conditions	Broach	Material	Surface roughness
Cobalt–chromium–molybdenum alloy	STD-3	CoCr	Polished
Stainless steel alloy	STD-3	SUS	Polished
Titanium alloy	STD-3	Ti	Smooth
Smooth surface	STD-3	CoCr	Smooth
Thick cement mantle	STD-4	CoCr	Polished

(Table 1). Commercially available SC-stems are made of both CoCr and Ti (Ti–15Mo–5Zr–3Al). Although polished CoCr stems are generally used, Ti stems with smooth surfaces are also available. The Kyocera company approved this study and provided "SUS" and "smooth-surface CoCr" stems, based on a computer-aided design. The SUS stem was made of SUS316. A stem with a smooth surface was fabricated using the glass bead blasting technique. Surface roughness was randomly measured at three points on each stem using a Formtracer Avant S3000 tester (Mitutoyo Co., Kanagawa, Japan). The mean surface roughness (Ra; μm) values were 0.006 ± 0.0006 under the standard condition (CoCr stem), 0.023 ± 0.006 for the SUS stem, 0.314 ± 0.0411 for the Ti stem, and 0.304 ± 0.0405 for the smooth surface stem. The thick cement mantle was created using a broach (STD-4).

Falling-weight impact test

The angle positions of the simulated bone models were determined using a digital inclinometer (DGL-C; Myzox Co., Aichi, Japan), and the simulated bone models were fixed within a metal box using bone cement (Ostron II; Fig. 2). After setting of the bone models, the fractures in the bone models were evaluated by dropping stainless-steel weights from a predetermined height onto the heads. The simulated bone models were fixed at two angles. In one condition, they were fixed at 0° flexion and 13° adduction, such that the head was at the vertical position of the fixed end of the simulated bone (Experiment 1). In the second condition, they were fixed at 10° flexion and 0° adduction, considering the flexure of the simulated bone models (Experiment 2). A 1.5-kg weight (65 mm in diameter × 57 mm) was used for Experiment 1, whereas a 3-kg weight (65 mm in diameter × 114 mm) was used for Experiment 2. For Experiment 1, a 2-kg weight was initially used, which was changed to a 1.5-kg weight because many fractures were observed. Regarding Experiment 2, a 1.5-kg weight could not break the simulated bone models pre-experimentally because, in the flexion position, the load point was outside the simulated-bone fixation position, and the impact was released owing to flexure of the simulated bone. Therefore, the weight was changed

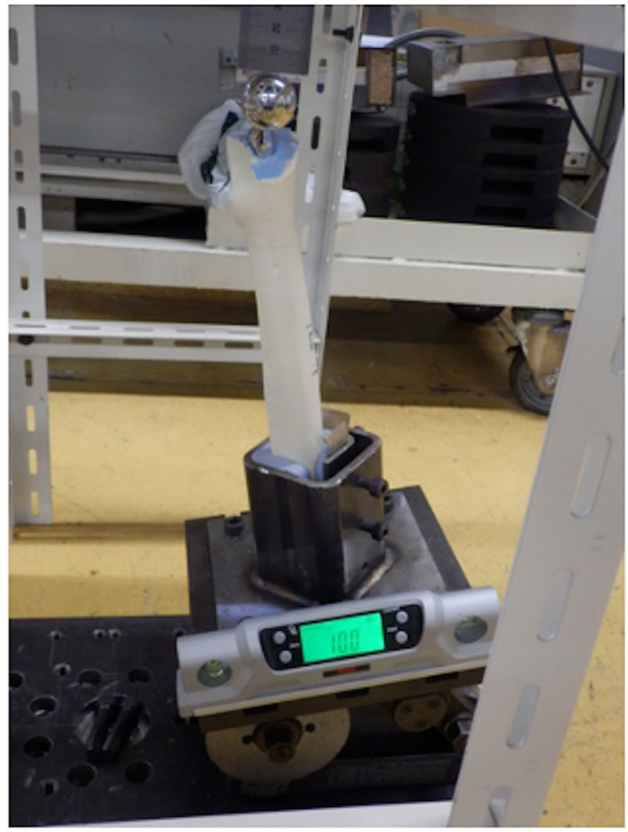

Fig. 2 Photograph showing fixation of the simulated bone model (Experiment 2: 10° of flexion and 0° of adduction). Angle positions of the simulated bone models were determined using a digital inclinometer (DGL-C; Myzox Co., Aichi, Japan). Subsequently, the simulated bone models were fixed within a metal box using a bone cement (Ostron II, GC Co., Tokyo, Japan)

to 3.0 kg. The weight was suspended by a string inside an acrylic pipe with an inner diameter of 68 mm at a predetermined height, and then, the weight was dropped by cutting the string (Fig. 3).

Fracture site characteristics

For Experiment 1, the weight was loaded vertically at the fixed end of the simulated bone, and thus, the bone was likely to be impacted because there was no route for escape from the loading. In Experiment 2, the fracture sites of the broken simulated bones were assessed because characteristic fractures were observed. The fracture sites were divided into two groups: proximal vertical and distal transverse fractures.

Statistical analysis

To assess the conditions influencing PPF of taper-slip stems, in each group, the periprosthetic fracture height in 50% of the bone models ($PPFH_{50}$) was calculated using the staircase

Fig. 3 Photographs of the falling-weight impact test. **a** The stimulated bone is fixed to a tester. **b** The weight is suspended by a string inside an acrylic pipe at a predetermined height. **c** The simulated bone models are fixed at two different angles (experiments 1 and 2)

method (sequential up-and-down technique) [16]. The procedure for the staircase method was as follows: (1) fractures in the bone models were evaluated by dropping a weight from a predetermined height; (2) if the specimen was broken, the next specimen was tested by placing it at a position 10 cm lower than the previous one, whereas if the specimen was not broken, the next specimen was tested by placing it at a position 10 cm higher than the previous one; and (3) this procedure was repeated ten times using ten bone models (Fig. 4). $PPFH_{50}$, which was calculated based on the number of fractured or non-fractured specimens at different heights, was defined as

$$PPFH_{50} = H_a + \Delta H(A/N \pm 0.5)$$

where H_a was the standard height, ΔH was the change in height, A was (the number of specimens with or without fracture at height Hi) + (the number of height changes), and N was the smaller number of specimens with or without fracture. After conducting preliminary tests, the height was predetermined to be 80 cm. Two-group comparisons were conducted using the Student's *t*-test. Statistical analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC, USA). A *p*-value of < 0.05 was considered statistically significant.

Results

Experiment 1: fixation at 0° of flexion and 13° of adduction

The $PPFH_{50}$ values are listed in Table 2. The conditions that were less likely to cause fracture were use of Ti, a smooth surface, and a thick cement mantle. No differences between the CoCr and SUS stems were observed.

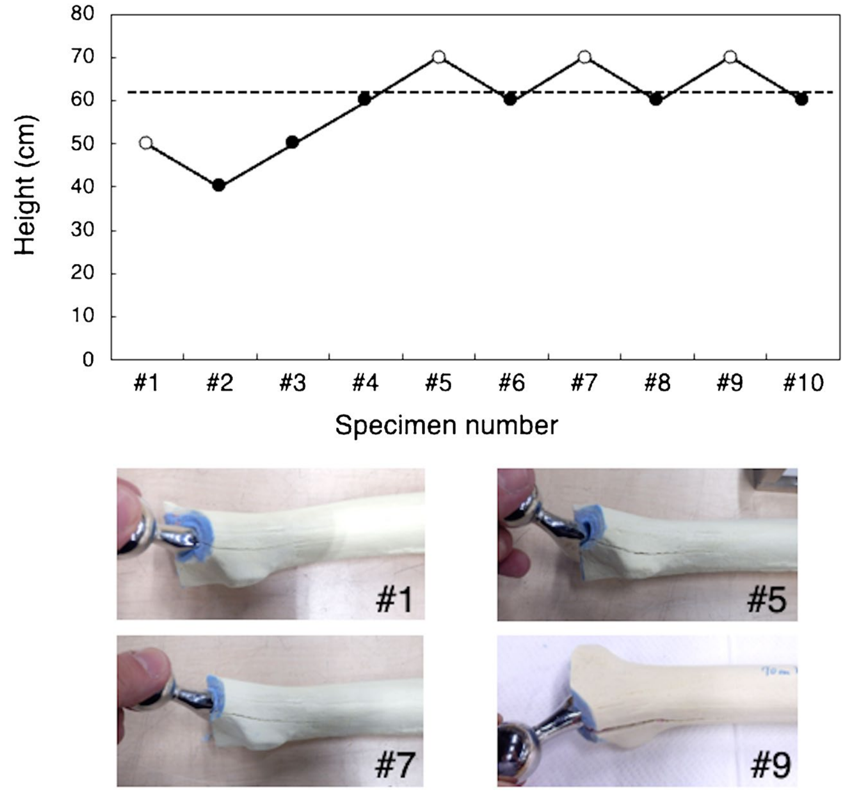

Fig. 4 Use of the staircase method for a representative condition (standard condition in experiment 1). The dotted line represents the calculated periprosthetic fracture height in 50% of the bone models. The white and black circles represent positive and negative responses, respectively. Photographs showing all the broken specimens

Table 2 $PPFH_{50}$ at 0°of flexion and 13° of adduction

Conditions	$PPFH_{50}$ (cm)
Cobalt–chromium–molybdenum alloy: Standard condition	61 ± 11
Stainless steel alloy	60 ± 13
Titanium alloy	Over 110
Smooth surface	108 ± 49
Thick cement mantle	78 ± 12

Data are presented as mean ± standard deviation

$PPFH_{50}$ periprosthetic fracture height in 50% of the bone models

Table 3 $PPFH_{50}$ at 10°of flexion and 0° of adduction

Conditions	$PPFH_{50}$ (cm)
Cobalt–chromium–molybdenum alloy: Standard condition	77 ± 5
Stainless steel alloy	85 ± 9
Titanium alloy	90 ± 2
Smooth surface	89 ± 5
Thick cement mantle	81 ± 11

Data are presented as mean ± standard deviation

$PPFH_{50}$ periprosthetic fracture height in 50% of the bone models

Experiment 2: fixation at 10° of flexion and 0° of adduction

The $PPFH_{50}$ values are listed in Table 3. The conditions that were less likely to cause fracture were use of Ti and SUS, a smooth surface, and a thick cement mantle. The taper-slip stems made of CoCr tended to fracture.

Fracture site characteristics

The fracture rates of the polished-surface stems were 78.6 (11/14) and 35.7% (5/14) at the proximal and distal sites, respectively ($p < 0.05$; Fig. 5a). In contrast, the fracture rates of the smooth-surface stems were 14.2 (1/7) and 100% (7/7) at the proximal and distal sites, respectively ($p < 0.05$; Fig. 5b).

Discussion

Although the incidence of PPF of cemented femoral stems is lower than that of uncemented femoral stems, a high failure rate is observed because of collarless, polished, tapered, and cemented stems [2–9]. Cemented stems have classically been categorised into two types based on the differences in the shear forces at the interface [10]. The PPF of cemented stems is likely caused by the material and surface roughness of the stems.

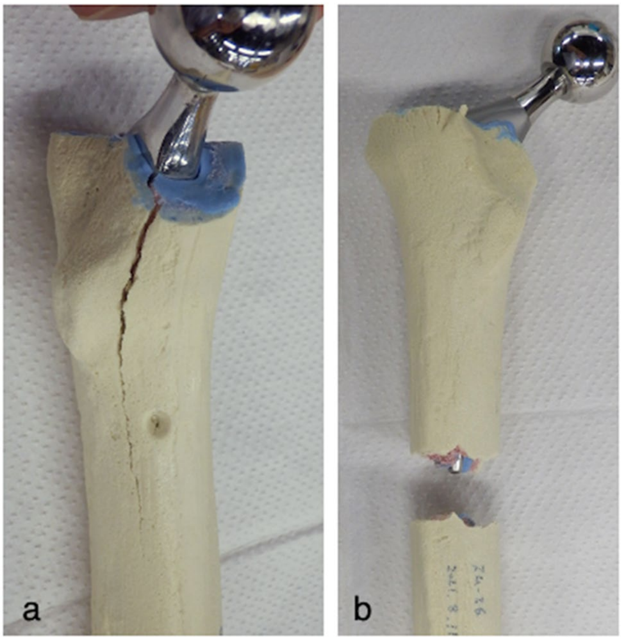

Fig. 5 Photographs of representative cases showing the fracture sites. **a** Proximal vertical fracture (standard condition; polished surface; drop height, 80 cm). **b** Distal transverse fracture (smooth surface condition; drop height, 100 cm)

Three materials are commonly used for synthesis of cemented stems: CoCr, SUS, and Ti. Taper-slip stems made of Ti are not favoured because they are associated with early failure and have two disadvantages: a stiffness of approximately 50% compared to that for CoCr and SUS stems and the susceptibility of the material to crevice corrosion [17]. Conversely, CoCr and SUS are considered to behave similarly because they have similar Young's modulus and Poisson's coefficient values. However, Tsuda concluded that CoCr and SUS showed different mechanical behaviours within the bone cement, and that this difference could be caused by a difference between surface wettability of the two materials [18]. Subsequently, Kaneuji et al. performed dynamic loading tests on SUS and CoCr stems and observed differences in subsidence and force at the bone–cement interface [14]. Moreover, Takegami et al. performed a compression–torsion test and observed that use of CoCr stem, polished surface, acute-square proximal form, and absence of a collar might be related to PPF [19]. Furthermore, Hirata et al. showed that CoCr had a lower surface wettability than SUS, and CoCr did not adhere to the bone cement; moreover, the surface roughness (Ra) of CoCr was 0.06 μm, and thus, the frictional coefficient of CoCr was lower than that of SUS [13]. The authors concluded that for CoCr stems, a low adhesive effect and a low frictional coefficient may result in excessive taper-slip. In the current study, use of Ti, and probably SUS, were associated with a low risk of fractures; however, the material-of-the-stem factor was inseparable from the surface-roughness factor.

Regarding the surface roughness of the stems, composite-beam implants generally have a "satin" or "matte" surface finish that maximises the mechanical strength of the cement mantle–stem bond, whereas the taper-slip stem is designed based on a dual- or triple-tapered stem geometry and typically has a "smooth" or "polished" surface finish, and thus, the implant is able to wedge into the cement mantle [20]. Among Ti-cemented stems, composite-beam stems with smooth surfaces result in excellent outcomes both in vivo and in vitro, although the low elastic modulus of the titanium alloy results in excessive stress on the proximal cement mantle, leading to micromovement and stem–cement debonding [21–23]. Our data also demonstrated that smooth surfaces prevented fractures, and the clinically low incidence of PPFs of composite-beam stems may be related to surface roughness. In addition, proximal vertical fractures were significantly more common in the polished-surface stems, whereas distal transverse fractures were significantly more common in the smooth-surface stems. This difference may be because the smooth-surface stem behaved similarly to a composite beam stem.

Clinically, there is a certain number of intraoperative cracks, although the incidence of PPF in cemented stems is low [3]. Some cracks may go undiagnosed because they are not directly visible, especially if the approach is limited or if they occur on the posterior surface of the femur during an anterior approach [24]. This study suggests that proximal cracks potentially exist and can propagate if not detected and diagnosed intraoperatively.

Our study has some limitations. First, to assess the conditions resulting in PPF of taper-slip stems, $PPFH_{50}$ was calculated using the staircase method. This method is a widely used statistical fatigue test, which provides highly accurate results; however, the accuracy of the standard deviation may be low [25, 26]. Second, the falling-weight impact test was not a cyclical loading test but a one-shot dynamic loading test. In addition, the falling-weight impact test could not be used to accurately assess the torque required for fracturing bones, although the flexure of the simulated bone was considered while performing Experiment 2. Third, the absence of radiographs prevented us from determining the exact position of the femoral stem, particularly concerning the risk of distal fractures [27, 28]. Fourth, this was a biomechanical study; therefore, the results may differ from those obtained in clinical practice. Although the conditions that cause PPF of taper-slip stems were replicated using the falling-weight impact test, PPF could be clinically caused by a variety of factors. Furthermore, fractures on cemented prostheses may occur in the long term due to osteolysis or osteoporosis, which can weaken the bone over time. Therefore, this study only addresses the risk of traumatic fracture of a cemented prosthesis.

Conclusions

Falling-weight impact tests demonstrated that a polished taper-slip stem made of CoCr with a thin cement mantle may be associated with a high risk of PPF. Additionally, proximal vertical fractures were significantly more common in the polished-surface stems.

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Author contribution All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Takuma Yagura, Kenichi Oe, Fumito Kobayasi, Shohei Sogawa, Tomohisa Nakamura, Hirokazu Iida and Takanori Saito. The first draft of the manuscript was written by Takuma Yagura and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Data availability The data that support the findings of this study are available on request from the corresponding author (KO).

Declarations

Ethics approval The study design was not approved by the appropriate ethics review board because of no research involving human and animal subjects.

Consent to participate Not applicable.

Consent to publish Not applicable.

Conflict of interest The authors declare no competing interests.

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