



Long-term survival of fully cemented stem in re-revision total knee arthroplasty performed on femur with diaphyseal deformation due to implant loosening

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Abstract

Purpose The study aims to analyze long-term clinical and radiographic results, and survival of re-revision total knee arthroplasty (TKA) using fully cemented stems performed on femurs with diaphyseal deformation.

Methods Thirty-seven re-revision TKAs using fully cemented stems performed in femoral diaphyseal deformations, characterized as diaphyseal canal enlargement and cortex deformation due to aseptic loosening of previously implanted stems, between 2003 and 2015 were retrospectively reviewed. The mean follow-up period was 10.0 years. Clinically, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and range of motion (ROM) were evaluated. Radiographically, mechanical axis (MA) and component positions were measured. Complications and survival rates were also analyzed.

Results Clinically, the WOMAC significantly improved at final follow-up (61.2 vs 47.2, $p < 0.001$), but not the ROM (95.5 vs 102.5, $p = 0.206$). Radiographically, the MA and component positions were appropriate, with no changes in component positions from immediately post-operative to final follow-up, but with MA change from varus 2.9° to 3.7° ($p = 0.020$). Two cases (5.4%) with history of previous infections developed periprosthetic joint infection (PJI). Debridement with polyethylene insert exchange following antibiotic suppression were performed in those cases because of concern for difficult implant-removal. The five and ten year survival rates were 100% and 93.2%, respectively.

Conclusion Fully cemented stems are viable in providing long-term satisfactory survival after re-revision TKA in patients with femoral diaphyseal deformation. However, it should be used carefully for those with previous infections.

Keywords Knee · Arthroplasty · Re-revision · Diaphyseal deformation · Cemented stem

Introduction

As life expectancy and the number of primary total knee arthroplasties (TKAs) performed on younger patients increase, more patients would eventually require a re-revision TKA [1, 2]. Stable and durable fixation of implant are bound to be of principal interest in re-revision TKA, because of fairly severe bone defects and compromised soft

tissues [3, 4]. Accordingly, using the stem, thereby improving mechanical stability, is an important issue in re-revision TKA [5, 6].

Aseptic loosening is reported as main failure mode of revision TKA [6]. When the femoral component with the stem loosens, it can damage the diaphysis over time, leading to canal enlargement and cortical deformation (Fig. 1). Hybrid stem fixation, which requires robust diaphyseal purchases, would be difficult when there is diaphyseal deformation [5, 7]. A fully cemented stem has been applicable in this situation [2]. However, no studies have reported long-term results of re-revision TKA with fully cemented stems performed on femoral diaphyseal deformations.

This study aimed to analyze clinical and radiographic results, and survival of re-revision TKA using fully cemented stems performed on the femur with diaphyseal deformation with a minimum and mean follow-up period of five and ten years, respectively. It was hypothesized that the

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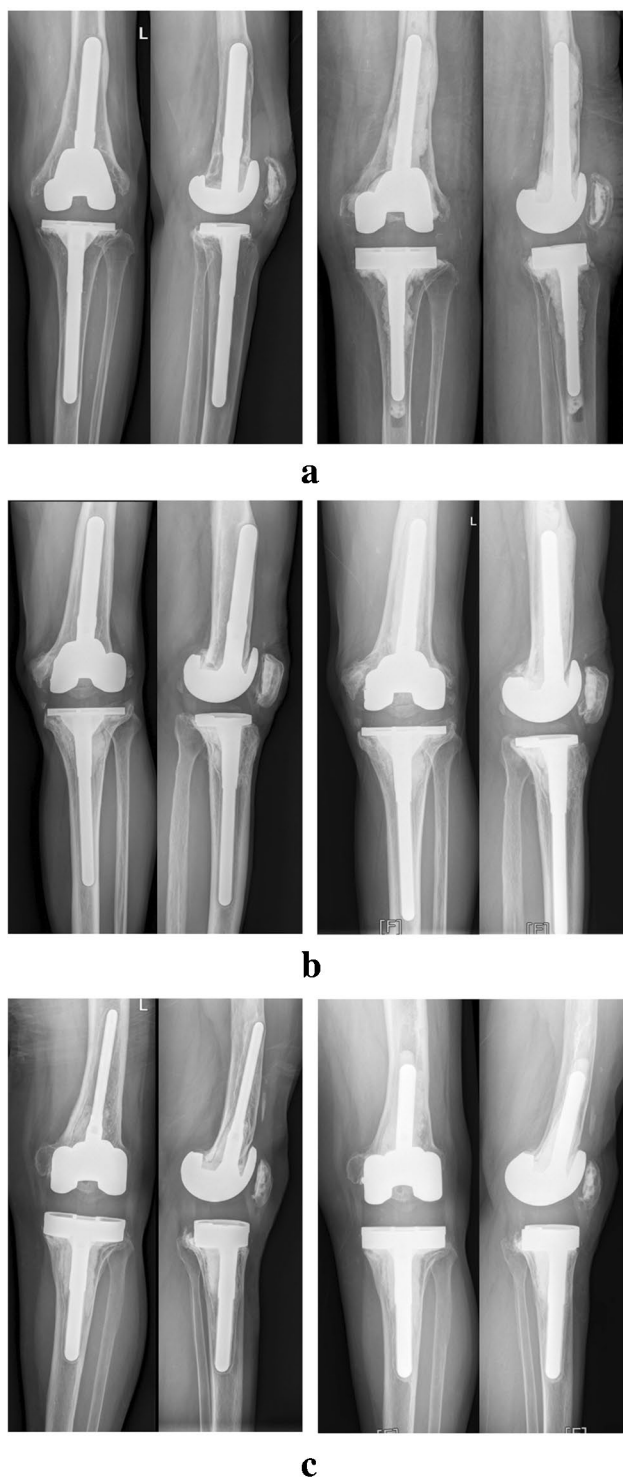


Fig. 1 Re-revision total knee arthroplasties (TKAs) using fully cemented stems performed on femurs with diaphyseal deformation due to aseptic loosening of the previously implanted stem. **(A)** Fully cemented stems of same length to the previous stem at the seventh post-operative year. **(B)** Fully cemented stems of same length to the previous stem at the 12th post-operative year. **(C)** Fully cemented stems of shorter length to the previous stem at the seventh post-operative year

Table 1 Demographic data

	Number of subjects, or mean \pm standard deviation (range)
Total cases	37
Age (years)	69.4 \pm 6.8
Sex (female/male)	32/5
Body mass index (kg/m ²)	26.3 \pm 3.4
Laterality (right/left)	15/22
Revision cause	15 PJI, 9 PE wear, 8 aseptic loosening, 3 osteolysis, 2 instability
Period between revision and re-revision TKAs (year)	8.2 \pm 4.7 (2.2–18.6)
Follow-up period after re-revision (year)	10.1 \pm 3.5 (5.3–17.3)

PJI periprosthetic joint infection, *PE* polyethylene

fully cemented stems would provide satisfactory long-term outcomes.

Materials and methods

Patients

Consecutive re-revision TKAs performed in our hospital between April 2003 and December 2015 were retrospectively reviewed. All procedures were performed with the Press Fit Condylar (PFC) Sigma® (Depuy Synthes, Warsaw, IN, USA) prostheses by a senior surgeon with surgical experience of > 100 cases of revision TKA and > 30 cases of re-revision TKA.

Initially, 51 re-revision TKAs were identified. Among them, re-revision TKA (1) with femoral component change using fully cemented stem; (2) which were performed on the femur with diaphyseal deformation; (3) with at least five years of follow-up; and (4) available pre-operative and post-operative radiographs were included. Femoral diaphyseal deformation was identified in radiograph as canal enlargement and cortical deformation due to aseptic loosening and motion of previously implanted femoral stems (Fig. 1). Cases of re-revision TKA due to periprosthetic joint infection (PJI) or periprosthetic fracture after revision were excluded.

According to the inclusion criteria, 37 patients with re-revision TKA were selected. The demographics at re-revision TKA are presented in Table 1. The mean post-operative follow-up period was 10.0 years. The mean period from revision to re-revision TKAs was 8.2 years (2.2–18.6 years). The cause of revision TKA prior to re-revision was PJI, polyethylene insert wear, aseptic implant loosening, osteolysis,

and instability in 15, 9, 8, 3, and 2 cases, respectively. The PFC posterior stabilized (PS) prostheses with femoral stem were used in all cases during revision TKA; hybrid and fully cemented stems were used in 34 and 3 cases. This study was approved by the appropriate institutional review board. Informed consent was obtained from all patients.

Surgical techniques

Re-revision TKAs were performed using the prior midline skin incision with a medial parapatellar approach, with rectus snip if necessary. The patella was either everted or subluxated following complete synovectomy. The previous implant and cement were removed with minimal bone loss as possible. The femoral and tibial components were re-revised in 29 cases, whereas in eight cases, only the femoral component was re-revised.

Based on the Anderson Orthopaedic Research Institute (AORI) classification [8], all cases had femoral bone defects > F2. The original joint line was restored via augmentation of the various bone defects, thereby ensuring accurate rotation of an appropriately sized femoral component, without unnecessary release of contracted soft tissue or unnecessary placement of over-thick polyethylene inserts or constrained prostheses. The 30 cases received bulk allografts on the femur. Appropriate metal augmentation was also performed in all cases.

The femoral stem was used with a full-cement technique. Stems with a diameter and length of 14 mm (range, 12–16 mm) and 125 mm (range, 90–130 mm), respectively, and with similar or shorter lengths to previous stems were mainly used (Fig. 1). When fixing the femoral component and stem, the cement was sufficiently injected into the femoral diaphyseal deformation site using a cement gun, and pressure was applied from the metaphysis to compress the cement. The stem to which the cement was sufficiently applied was slowly inserted, and press-fixed in the cement. The simplex P (Howmedica, Mahwah, USA) was used. Cefazolin (1 g) was added per 40-g cement pack. PS and constrained condylar knee (CCK) prostheses were applied in 26 and 11 cases, respectively.

Isometric exercises using the extensor and flexor muscles were initiated shortly after the operation. The drain was removed on the second or third postoperative day, followed by the initiation of active and assisted ROM exercise. Full weight-bearing ambulation was started at four to five days to the extent that the patient's condition permitted.

Clinical evaluation

Clinically, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and ROM were evaluated

before re-revision and at the last follow-up [9]. The ROM was measured using a long-armed goniometer.

Radiographic evaluation

The radiographic parameters were measured pre-operatively, post-operatively (1 month after re-revision), and at the last follow-up. True anteroposterior (AP) and lateral radiographs, as well as ortho-roentgenograms (full-length standing AP radiographs), were taken under weight-bearing conditions.

The mechanical axis (MA) was defined as the angle between the femoral and tibial mechanical axes on ortho-roentgenograms [10]. Detailed analyses of AP and lateral radiographs were performed to evaluate the positions of components with α , β , γ , and δ angles by the Knee Society radiological evaluation method [11]. The canal filling ratio (CFR), which was defined as the diameter of the stem divided by the endosteal diameter near the stem tip, was also measured in both AP and lateral radiographs (Fig. 2) [12].

Component loosening was investigated with reference to AP and lateral radiographs from post-operative and last follow-up visits. Component loosening was determined according to conventional radiographic criteria: a progressive radiolucent line with width of ≥ 2 mm at the bone-cement or bone-implant interface, a significant change in component positions including subsidence, or a visible fracture of the surrounding cement [13].

The quality of radiographs was improved by standardization in the knee position and the distance between the X-ray beam and cassette [14]. The images were transferred

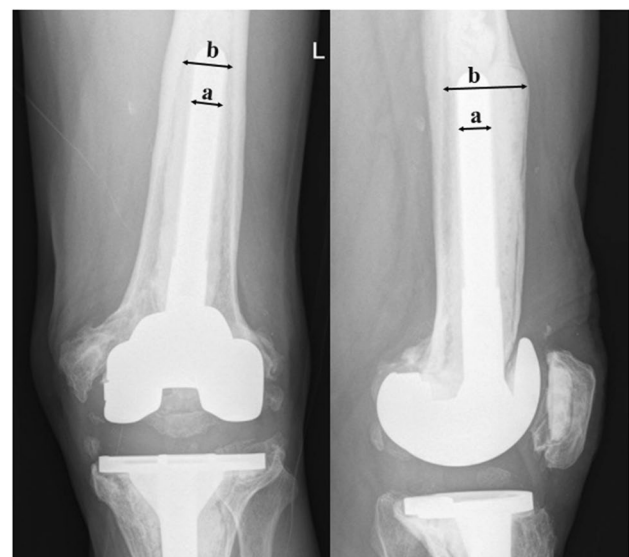


Fig. 2 Canal filling ratio. *a* Diameter of the stem, *b* endosteal diameter near the stem tip, a/b canal filling ratio (CFR). (A) CFR in the anteroposterior radiograph. (B) CFR in the lateral radiograph

digitally to a picture archiving and communication system (PACS) (Infinit HealthCare, Seoul, South Korea). The PACS software was capable of detecting a minimum difference of 0.1° in angle and 0.1 mm in length [15].

To minimize observation bias, two independent investigators performed all radiographic measurements. The inter-observer reliabilities of the MA measurements, component position, and CFR were assessed using intraclass correlation coefficients (ICC), which were all > 0.8 . Thus, the average values of the two investigators were used. Regarding component loosening, the evaluations of the two investigators were consistent.

Incidence of complications

Any complications were investigated with reference to the standardized list and definition of complications suggested by the Knee Society [16].

Statistical analysis

The pre-operative and post-operative or post-operative and last follow-up results were compared using paired *t*-tests. A survival analysis was conducted using the Kaplan–Meier method. Success was defined as a TKA prosthesis without any problem throughout the study period. Failure was defined as implant removal due to any reason or debridement with polyethylene (PE) insert exchange due to PJI after re-revision. Patients who were lost to follow-up were censored. The follow-up period was determined by the date of implant removal, debridement with PE exchange, or last follow-up visit. Statistical analyses were performed using SPSS (version 18.0; Chicago, IL, USA), with *p*-values < 0.05 considered statistically significant.

A power analysis was performed to determine the minimum sample size required for sufficient statistical power, with the failure rate as the primary outcome. Using a significant failure rate, alpha, and power of 10%, 0.05, and 90%, respectively [12], > 3 cases were required to ensure sufficient statistical power. Thus, it was determined that our study was adequately powered.

Results

Clinically, WOMAC scores significantly improved at last follow-up, but with less than the minimal important change which was reported to be 17 points [17] (Table 2). There was no significant difference in the ROM between pre-operatively and at the last follow-up (Table 2). Radiographically, the MA was corrected from varus 10.3 to varus 2.9 and all of the component positions also corrected appropriately after re-revision (Table 3). The average post-operative CFR of

Table 2 Clinical results

	Pre re-revision	Last follow-up	<i>p</i> -Value
WOMAC score	61.2 ± 12.3	47.2 ± 21.1	< 0.001
Range of motion ($^\circ$)	95.5 ± 37.3	102.5 ± 28.9	0.206

Data are presented as means \pm standard deviations

WOMAC Western Ontario and McMaster Universities Osteoarthritis Index

the femoral stem was < 0.85 , which was criteria for appropriate canal filling, in both AP (0.62 ± 0.11) and lateral (0.59 ± 0.09) radiographs [7, 18]. At the last follow-up, there was no significant change in all of the component positions, but a slight varus change in MA was observed compared to immediate post-operative (Table 3).

There was no aseptic component loosening. Radiolucent lines between bone-cement interfaces were observed around the fully cemented femoral stem in 17 cases at last follow-up, which were a non-significant line with width of < 2 mm; additionally, these all cases had no clinical symptoms. Two cases (5.4%) developed PJI during the follow-up period. Both cases had undergone revision TKA due to infection. Debridement with PE insert exchange following antibiotic suppression was performed because a two-staged operation involving replacement of the whole implant was too complex because of difficult removal, and because both patients were aged > 80 years. The five and ten year Kaplan–Meier survival rates were 100% and 93.2%, respectively (Fig. 3).

Discussion

The most important finding of the present study was that re-revision TKA using fully cemented femoral stems performed on femoral diaphyseal deformations showed satisfactory survival at average ten years and minimum five years of follow-up.

Stem extension is critical for stable implant fixation in revision or re-revision by offloading stress at the metaphyseal bone defect and providing additional prosthetic fixation surface [12, 19]. Failure rates within five years reached 66% and 8% without and with stems in revision TKA, respectively [20]. Stems can be fixated by full cementation or a hybrid method using a press-fit cementless stem, in which cement is applied on the undersurface and metaphyseal portion of the articular components, but not around the diaphyseal portion [5]. Recently, the hybrid method become universal due to a significant concern over difficulty of implant removal in situation that the removal should be required [12]. Further, a previous meta-analysis has reported a similar or superior mechanical stability of hybrid stems, compared to fully cemented stems [5].

Table 3 Radiographic results between the well-balanced group and the group with mid-flexion laxity

	Pre re-revision	Post re-revision*	<i>p</i> -Value ^a	Last follow-up	<i>p</i> -Value ^b
Mechanical axis (°)	Varus 10.3 ± 6.5	Varus 2.9 ± 3.3	<0.001	Varus 3.8 ± 4.5	0.020
Component positions (°)					
α	91.7 ± 2.3	93.2 ± 3.8	0.001	94.1 ± 2.2	0.272
β	86.7 ± 6.5	89.8 ± 1.4	0.009	89.5 ± 1.7	0.092
γ	6.1 ± 5.9	4.0 ± 3.2	0.034	4.0 ± 3.7	0.902
δ	85.0 ± 7.4	87.3 ± 2.4	0.037	87.3 ± 2.2	0.936

*Post re-revision, 1 month after re-revision TKA

^a*p*-Value between pre- and post-re-revision TKA^b*p*-Value between last follow-up and post re-revision TKA

However, using hybrid stems on femoral diaphyseal deformation sites with canal enlargement and cortical deformation are difficult. For stable fixation of hybrid stems, a stem length that enables sufficient diaphyseal engagement (> 4 cm) is required [18]. A longer stem should be required for sufficient diaphyseal engagement in the femur with diaphyseal deformation, but the optimal implant position and femoral shaft bowing would make it challenging (Fig. 1B) [18]. Proper canal filling for stable hybrid fixation (generally, CFR > 0.85) is also difficult to achieve because of diaphyseal canal enlargement [7]. Lastly, there might be a risk of breakage of deformed cortex when the stem is inserted with the press fit technique [5].

The use of fully cemented stems will be a convenient method for immediate stable fixation of implants in the re-revision situation with femoral diaphyseal deformation, as it can provide flexibility to the positioning and fixation of the stem and implant in altered geometry of the diaphyseal canal, and the availability of short stems with the cemented technique can further increase the flexibility [2, 19]. The risk of fractures of the deformed femoral cortex in during stem preparation is also low [2].

However, there are some related concerns. The cement fixation may be impaired in the enlarged diaphyseal canal because of compromised pressurization of the cement, possibly leading to implant loosening [21]. Additionally, removal of the implant-cement composite, if necessary (especially in PJI cases), is difficult [2, 3]. Complex and aggressive surgical techniques, including osteotomy, will be required for thorough removal of the cement [3]. Unintentional fractures may occur during the removal [2].

The present study showed the long-term satisfactory survival of re-revision TKAs using the fully cemented stems performed on the femur with diaphyseal deformation. There is no aseptic implant loosening due to insufficient cement fixation, possibly owing to our surgical technique of sufficiently cement injection to enlarged canal by the cement gun, and applying pressure from metaphysis to compress the cement. Additionally, robust

reconstruction of metaphysical bone defects, proper selection for the constraint level of insert, and appropriate postoperative limb alignment and component position could contribute to the long-term success.

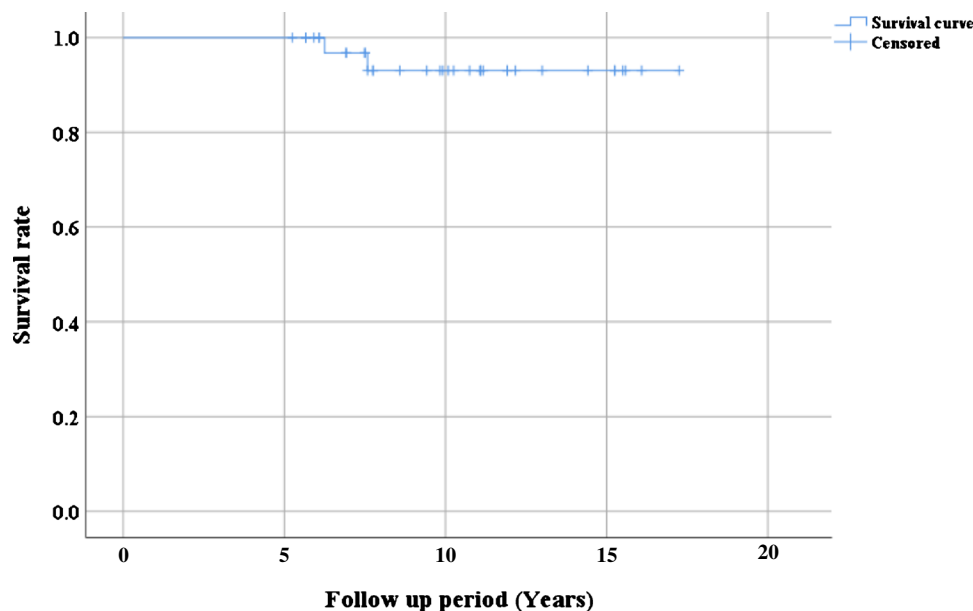
Two cases developed PJI after re-revision TKA, despite the antibiotic mix with the cement. Although re-revision was performed due to aseptic loosening, both cases had history of PJI after primary TKA. Debridement and polyethylene insert exchange following antibiotic suppression was performed, as aggressive removal of the prosthesis in elderly patients with comorbidities is burdensome. Considering the difficulty for implant removal, care should be taken when removing fully cemented stems for patient with previous infections, even if antibiotics were mixed.

Our long-term clinical results after re-revision TKA did not seem to be satisfactory. It is clearly expected that re-revision TKA in elderly patients would produce less satisfactory clinical results when compared with primary or revision TKA [1]. This was an additional practical reason why we decided not to perform a two-stage operation with prosthesis removal for our PJI cases.

Using a fully cemented stems will be a viable option in re-revision situation with femoral diaphyseal deformation which makes it difficult to use a hybrid stem. Satisfactory survival of fully cemented stems can be expected when proper surgical techniques, including appropriate cementation, are performed. It is necessary to explain to the patients with previous infections that implant and cement removal is very difficult with recurring infections. Additionally, a frozen biopsy should be performed perioperatively, when considering using the fully cemented stems.

The present study has several limitations. First, this is a retrospective study with a small sample size. However, it is practically difficult to conduct a prospective study with a large cohort regarding re-revision TKA in a single institute. Second, two types of polyethylene insert, PS and CCK, were used in the included cases although the single prosthesis (PFC) was used. Since the stress on a prosthesis and cement can be different according to the constraint level of

Fig. 3 Kaplan–Meier survival curve. The 5- and 10-year Kaplan–Meier survival rates were 100% and 93.2%, respectively



the insert, it would have been better if the study was conducted with a single constrained level of insert [22]. Third, patients with follow-up loss may have received additional surgery due to failure at another institute. However, additional surgical procedures are very difficult and complicated, with a possible reason being that another hospital (especially non-tertiary centers) did not readily perform it. Fourth, the study period was more than ten years; hence, there may be performance bias due to change of surgical technique over time. However, the surgeon had sufficient experience in revision and re-revision before the study period, and the surgical technique had already been standardized. Therefore, the change in technique over time is not considered as significant. Last, re-revision procedures were performed by an experienced surgeon in a tertiary center with a single prosthesis. Caution should be taken when generalizing our findings.

Conclusion

Fully cemented stems are viable in providing long-term satisfactory survival after re-revision TKA in patients with femoral diaphyseal deformation. However, it should be used carefully for those with previous infections.

Author contribution The following authors have made substantial contributions to the followings: (1) the conception and design of the study (S. J. S., C. H. P.), provision of study materials or patients (D. K. B.), acquisition of data (H. W. L., C. H. P.), analysis and interpretation of data (S. J. S., H. W. L., and C. H. P.), (2) drafting the article (S. J. S., H. W. L., D. K. B., and C. H. P.), (3) revision of the article (S. J. S., H.

W. L., D. K. B., and C. H. P.), and (3) final approval of the version to be submitted (S. J. S., H. W. L., D. K. B., and C. H. P.).

Declarations

Ethics approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by Institutional Review Board of Kyung Hee University Medical Center.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent for publication There is no any individual person's data in any form.

Competing interests The authors declare no competing interests.

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