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RESEARCH

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Metaphyseal sleeve and straight stem fixation with or without screws for bone defect in complex primary total knee arthroplasty in Eastern Asian populations

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Abstract

Background Massive bone defects present significant challenges in complex primary total knee arthroplasty (TKA). Previous studies with limited sample sizes have demonstrated the potential of metaphyseal sleeves (MS) in addressing such defects. This study mainly aimed to assess the clinical outcomes and survivorship of MS utilized for reconstructing bone defects in complex primary TKA among East Asian patients, with a secondary focus on the use of scews for tibial residual bone defect.

Methods A total of 3,672 primary TKAs were performed between January 2016 and December 2020, of which 106 procedures (87 patients) utilized MS in conjunction with straight stems to address bone defects. Among these, 55 (46 patients) incorporated screws for tibial residual bone defect, while 51 (41 patients) were performed without screws. The mean follow-up period was 57.86 months, during which demographic data, operative details, clinical and radiographic outcomes, complications, and implant survivorship were recorded and analyzed.

Results All cases demonstrated successful osteointegration, with both the endpoint reoperation and revision implant survival rates reaching 100%. The mean Hospital for Special Surgery (HSS) score significantly improved from 56.98 to 82.36 at the final follow-up, resulting in an overall excellent and good outcome rate of 95.40%. Knee conditions were notably worse in the screw group compared to the non-screw group; however, the clinical and radiographic outcomes between the two groups were comparable. Postoperative tibial end-of-stem pain was reported in 9.8% of the non-screw group, while none (0%) in the screw group, reflecting marginal significance ($P = 0.0548$).

Conclusion The application of metaphyseal sleeves with straight stems represents a promising strategy for addressing massive bone defects in complex primary TKA among East Asian patients. The cement-screw technique, providing potential biomechanical advantages, emerges as a safe and effective solution for managing residual defects surrounding MS placement in tibial site.

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Keywords Metaphyseal sleeve, Straight stem, Screw, Eastern Asian, Complex primary total knee arthroplasty, Bone defect

Background

Massive bone defects present a formidable challenge for surgeons performing total knee arthroplasty (TKA), particularly in revision TKA and complex primary TKA, the latter of which often arise from diverse etiologies such as rheumatoid arthritis (RA), post-traumatic arthritis, Charcot knee arthropathy, and others [1]. In cases of complex primary TKA where substantial bone defects exist in the epiphysis and metaphysis, coupled with significant deformities, eroded ligaments, severe osteoporosis (OP), flexion contractures, and other atypical complications, the surgical interventions closely resemble those of revision surgeries rather than routine primary procedures typically performed for common osteoarthritis. In such instances, specialized surgical techniques, metal augments, and modular prosthesis components for revision TKA must also be considered to address the challenges posed by massive bone defects. The concept of "zonal fixation" (zone 1: epiphysis, zone 2: metaphysis, zone 3: diaphysis), introduced by Haddad et al. [2], emphasizes the necessity of fixation that spans at least two zones to ensure the long-term survival of the revision implant. This strategy has gained widespread acceptance [3–6] and is also applicable to complex primary TKA procedures.

Currently, porous-coated metaphyseal sleeves (MS) are increasingly utilized for the reconstruction of significant bone defects during revision TKA, demonstrating several advantages [7–9], including rapid achievement of weight-bearing and rotational stability in metaphysis (zone 2), a stepped structure designed to minimize shear forces, favorable conditions for bone integration, reduced bone resorption, and a straightforward standardized operation mode. To our knowledge, there are currently few reports assessing the mid- to long-term follow-up outcomes of MS in complex primary TKA within East Asian populations, especially large sample studies; most existing literature predominantly stems from Caucasian cohorts, such as studies in Spain (Martín-Hernández C et al. [10], 2018) and the Netherlands (Van Rensch et al. [11], 2022), which indicate that MS can significantly enhance early and mid-term joint function, quality of life, and radiographic metrics for patients with complex knee etiologies.

It is well established that knee prostheses and components are generally designed based on Caucasian knee anatomy [12, 13]. Several studies have identified notable differences in knee anatomy between East Asian populations and Caucasians [14–20]. Specifically, MS is often employed alongside a straight stem, and the ideal positioning of the "MS-straight-stem" system should be centrally placed to ensure optimal bone contact in all directions. However, the location of the tibial axis in East Asian individuals differs significantly from that in Caucasian populations [14]. Thus, a critical question arises: can the off-the-shelf "MS-straight-stem" system, designed based on Caucasian anatomical principles, achieve the intended "central position" placement in East Asian individuals while ensuring sufficient tibial plateau coverage and satisfactory clinical outcomes? We noted that one study involving Chinese patients reported excellent mid-term outcomes of MS with straight stems in complex primary TKA, suggesting its potential application in this context [21]. However, the sample size of primary TKA in that study was limited (seven cases), underscoring the need for comprehensive cohort studies with larger sample sizes to evaluate the feasibility and survivorship of MS for bone defect repair in this population.

Furthermore, previous reports on the application of MS for bone defect repair in both revision TKA and complex primary TKA have mainly concentrated on fixations in zones 2 and 3, where MS and cemented or press-fit stems are used in combination to achieve adequate stability [7–11]. However, one or more relatively small peripheral defects may frequently persist in zone 1 despite MS placement in complex primary TKA cases, necessitating additional repair procedures [22]. While bone grafts (autologous or allograft) have been considered for addressing the "residual defects" in revision TKA characterized by a well-vascularized cancellous base, it may not be easy to realized in complex primary TKA, where osteosclerosis typifies the base of these defects (Fig. 1), requiring significant modifications to facilitate osseointegration between the graft and host bone. The preliminary treatment of bony osteosclerosis at the defect site, along with graft trimming and fixation, presents several technical challenges and is often time-consuming. What is more, studies have raised the risks of bone resorption and collapse associated with grafting [5, 23, 24].The optimal approach for addressing these defects warrants further investigation. Bone cement and screws, representing a useful, simple, and cost-effective technique for repairing minor defects in both primary and revision TKA [25, 26], may offer a viable solution to these challenges; however, a comparative study addressing this issue is currently lacking.

Therefore, the objective of the present study is to evaluate the clinical outcomes and survivorship of MS used for reconstructing massive bone defects in complex primary TKA among East Asians, with or without the utilization of screws.

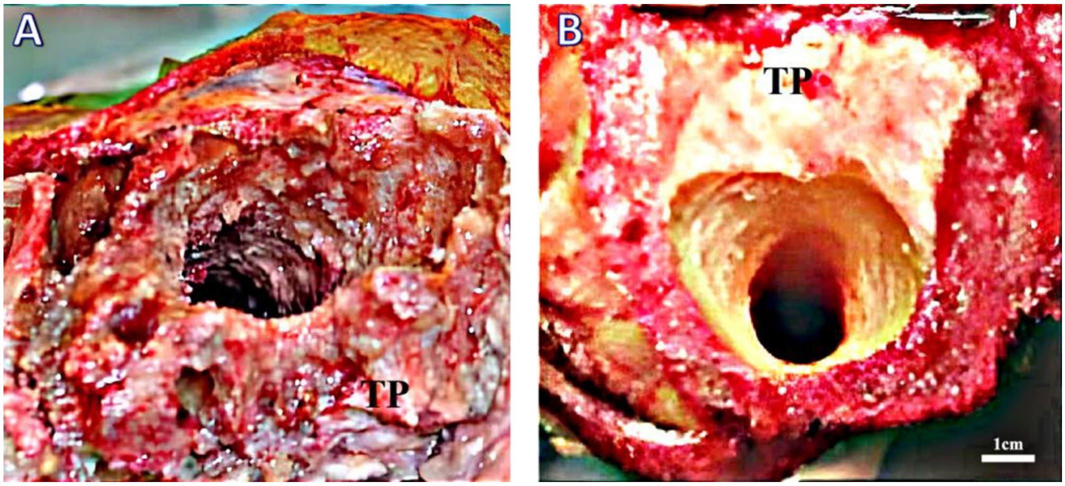

Fig. 1 The comparison of the "residual defects" surrounding MS placement between revision TKA **(A)** and primary TKA **(B)** TP: tibial plateau

Materials and methods

Study design

This retrospective analysis examined the hospitalization and follow-up data of patients utilizing MS for the reconstruction of significant bone defects during primary TKAs at a large academic urban center. The study spanned from January 2016 to December 2020, with the patient selection process illustrated in Fig. 2. The analysis included multiple surgeons and received approval from the ethics committee of Guangzhou First People's Hospital (ethics number: K-2021-036-02). Written informed consent was obtained from all patients.

Inclusion criteria encompassed: (1) patients who underwent unilateral or bilateral massive bone defect reconstruction using MS during primary TKAs; (2) a minimum follow-up period of three years post-surgery. Exclusion criteria included: (1) patients with oncological diagnoses; (2) incomplete hospitalization and follow-up data; (3) knees that received bone grafts (either autologous or allograft) during the TKA procedures; and (4) cases in which MS was utilized for bilateral bone defects but screws were employed in only one knee.

Preoperative assessment

All patients presented with significant preoperative pain and functional impairment, severely compromising their quality of life. Conservative treatment lasting at least six months proved ineffective, leading to a strong desire for surgical intervention. X-ray examinations revealed severe bone destruction in all cases. Dual-energy X-ray absorptiometry (DEXA) scans were routinely performed to evaluate bone quality, and CT or MRI imaging was conducted when necessary for a comprehensive assessment of bone and soft tissue conditions.

The evaluation of significant bone defects primarily used the Anderson Orthopedic Research Institute (AORI) classification [1], which categorizes bone defects into three types: type 1 refers to minor or contained defects in the epiphysis; type 2 is divided into type 2 A, involving metaphyseal bone damage and cancellous bone loss in one femoral condyle or tibial plateau, and type 2B, involving similar damage in both femoral condyles and tibial plateau; type 3 indicates extensive cancellous bone loss affecting a substantial portion of either the femoral condyle or tibial plateau, occasionally accompanied by collateral ligament damage.

Indications for the use of MS included: (1) AORI type 3 bone defects of any etiology; (2) AORI type 2 bone defects in specific conditions characterized by extremely poor bone quality, particularly in zones 1 and 2, such as rheumatoid arthritis, post-traumatic arthritis, and Charcot knee arthropathy.

Surgical procedures

The surgical procedure was performed under general or spinal anesthesia through a midline incision extending from the superior patella to the medial tibial condyle, providing access to the joint. The joint was meticulously cleared of pathological synovium and osteophytes. Following tibial canal expansion, sleeve tibial preparation was conducted using a broach, with subsequent leveling of the tibial platform and selection of an appropriate tibial tray based on measured data. After opening the femoral canal, adjustments were made to the femoral condyles, and appropriate measurements for the femoral distal data were obtained. Osteotomies were then performed on the anterior and posterior condyles, the anterior sloping surface, and the intercondylar area. Additional expansion of the femoral canal was executed, followed by sleeve femoral preparation (if necessary) and selection of suitable femoral components, ensuring the balance of flexion-extension gaps and joint stability. All

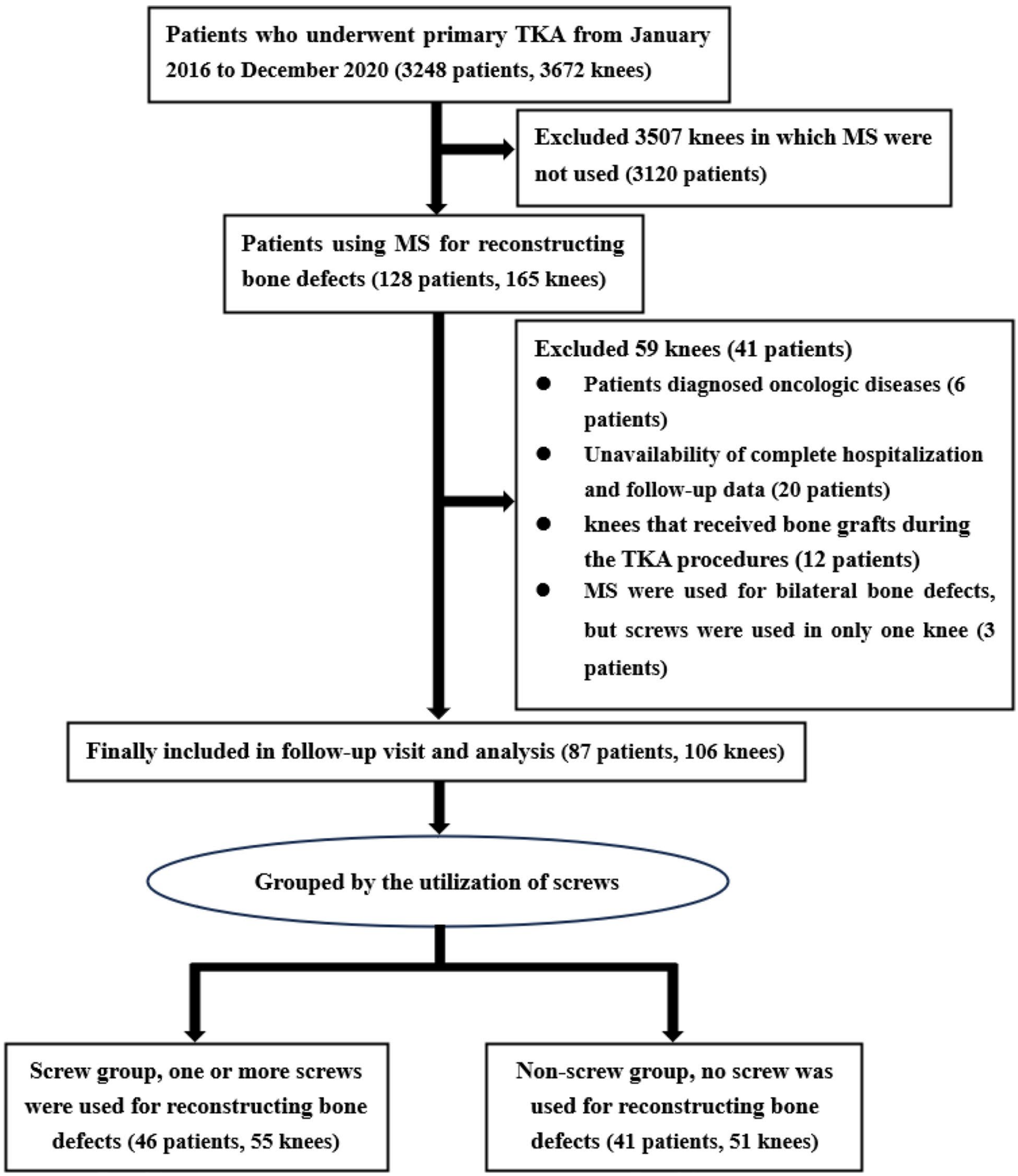

Fig. 2 Flow chart of patient selection

prosthetic components were assembled based on trial results, with all patients receiving implants from DePuy Synthes Inc., Warsaw, Indiana.

In cases where the residual defects surrounding the metaphyseal sleeve were considerable (mainly in tibial sites in the present study), and filling with cement alone was inadequate, the cement-screw technique was employed. The definitive tibial tray, connected to a metaphyseal sleeve and a straight stem, alongside the femoral components (also connected to a metaphyseal sleeve and a straight stem if indicated), and a rotational polyethylene liner, were installed. Cement was applied to the undersurfaces of the tibial tray and femoral component, avoiding use on the surface of the MS. Drains were routinely placed, and the incision was closed with the knee joint flexed at 30 degrees. A schematic overview of the procedure is presented in Fig. 3.

Perioperative management and follow-up

Postoperative care included side-specific knee joint ice packs and elastic bandage wrapping. Routine treatments such as antimicrobial prophylaxis, pain medication, and prevention of lower limb deep vein thrombosis were provided. Patients with OP were given routine pharmacologic treatment once the diagnosis was ensured in the perioperative and follow-up period. The drainage tube was removed within 24 h after surgery. On the first day after surgery, ankle pumps, quadriceps muscle strength training, and knee joint flexion-extension exercises were initiated. Early mobilization was encouraged with partial weight-bearing using assistive devices. Gradual weaning from assistive devices for walking was initiated 2–4 weeks postoperatively. Long-term lifelong follow-up was scheduled, and routine outpatient visits

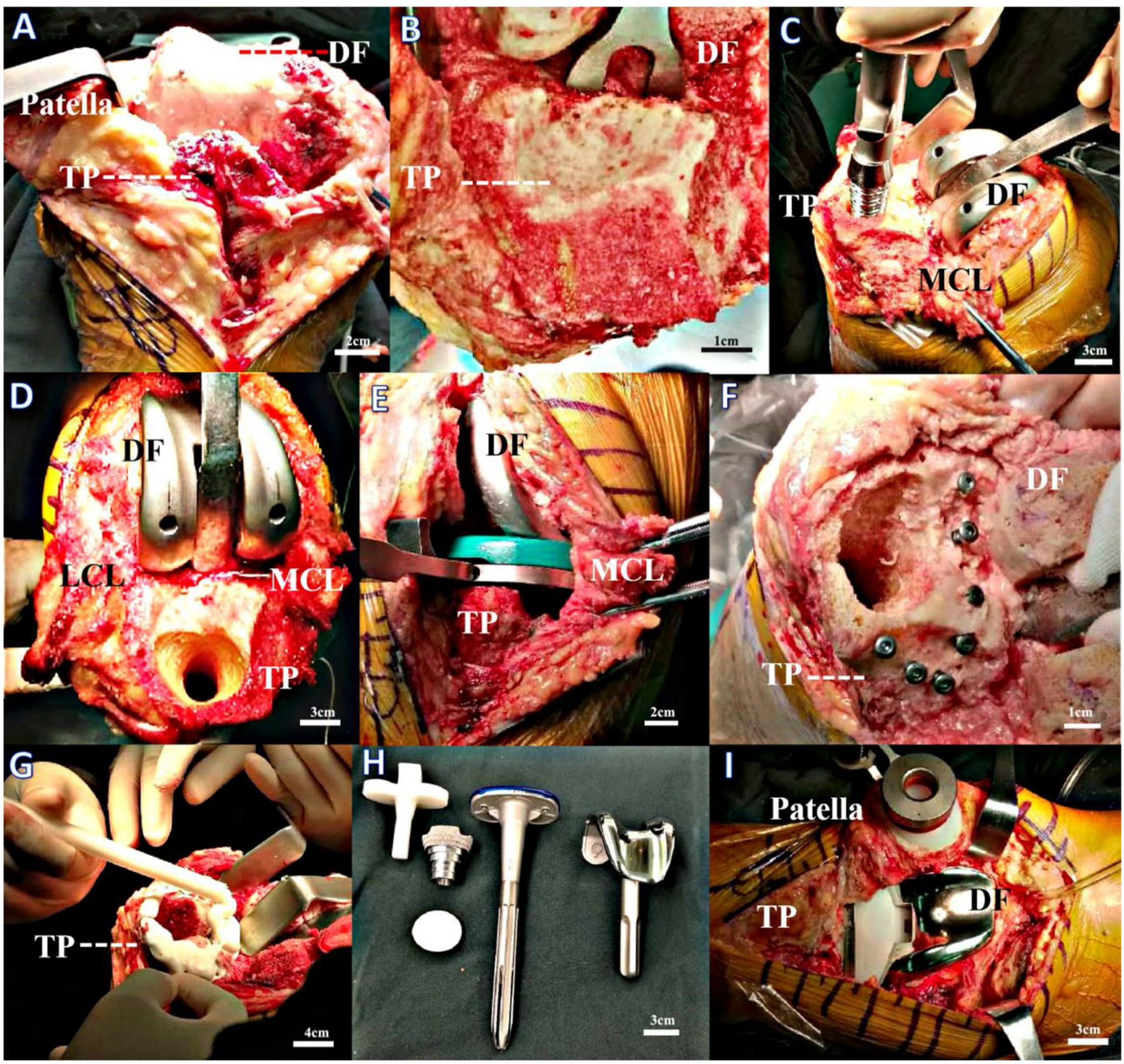

Fig. 3 Schematic representation of repairing a massive bone defect using a metaphyseal sleeve-straight stem system and cement-screw technique in a 61-year-old male patient with advanced RA undergoing primary TKA. **(A)** Exposure of the surgical site. **(B)** Assessment and preliminary treatment of the extensive bone defect in the right tibial plateau. **C-D)** Reaming and broaching of the epiphysis and metaphysis of the right tibia. **E)** Reconstruction of the joint line. **F)** Insertion of screws into the residual bone defect regions adjacent to the planned site for the metaphyseal sleeve-straight stem implant. **G)** Application of bone cement to the surfaces of the screws and the affected bone defect areas. **H)** Components of the implant to be utilized. **I)** Installation of the prosthesis. DF: distal femur; TP: tibial plateau; MCL: medial collateral ligament; LCL: lateral collateral ligament

were conducted to guide patients in standardized postoperative rehabilitation.

Preoperative assessments and routine follow-up included measurements using the numerical rating scale (NRS) for pain (0–10 scale, where 0 indicates no pain and 10 indicates the worst pain), the range of motion (ROM) of the knee, and the Hospital for Special Surgery (HSS) knee score [27]. Anteroposterior, lateral, and standing full-length lower limb X-ray images were obtained preoperatively and during routine follow-ups. The hip-knee-ankle (HKA) angle was measured, amd the absolute value of HKA was recorded as HKA deviation (HKAD, HKAD=|HKA|). Monitored complications included intraoperative fractures, DVT, cardiac events, pulmonary complications, postoperative wound issues, periprosthetic joint infection (PJI), joint instability, aseptic loosening of the prosthesis, and end-of-stem pain.

Standard measurement of HKA can be referred to the study of Cooke et al. [28]. Osteointegration was defined as an increase in osteosclerosis at the bone-prosthesis interface without radiolucent lines between the host bone and prosthesis [29]. Joint instability was defined as as any abnormal or excessive displacement of the articular elements that leads to clinical failure of the arthroplasty [30], while prosthetic loosening was defined as displacement or radiolucent lines exceeding 2 mm around the prosthesis [31].

Data analysis

Data entry and statistical analyses were performed using SPSS version 13.0. Descriptive statistics are presented as means ± standard deviations (SD) for continuous variables and as n (%) for categorical variables. Group comparisons were conducted using a two-sample independent t-test or a general linear model for continuous variables, a chi-square test, continuous calibration chi-square test, or Fisher's exact test for unordered categorical variables, and a Mann-Whitney U test for ordered categorical variables. Statistical significance was defined as $P < 0.05$.

Results

Patients' demographics and preoperative conditions

A total of 87 patients (106 knees) undergoing MS reconstruction for substantial bone defects in primary TKAs were included in the study. Among these, 46 patients (55 knees) received screws for the repair of tibial residual bone defects, while 41 patients (51 knees) did not. The distribution of knee etiologies included 53 patients with RA, 25 with post-traumatic arthritis, 6 with osteoarthritis, and 3 diagnosed with Charcot knee arthropathy. The demographics and preoperative conditions of the included patients are detailed in Table 1. Patients who received screws exhibited poorer bone quality ($t = 3.095$, $P = 0.003$), and a higher prevalence of osteoporosis was observed in the screw group ($\chi^2 = 5.892$, $P = 0.015$).

Table 1 Patients' demographics and preoperative conditions

Demographics/Preoperative conditions	Screw group	Non-screw group	statistic	*P*
Patient included, n (knee)	46 (55 knees)	41 (51 knees)		
Female, n (%)	33 (71.74%)	25 (60.98%)	$\chi^2 = 0.288$	0.288
Age, years (mean ± SD)	67.44 ± 5.84	68.08 ± 4.15	t=-0.648	0.519
Height, cm (mean ± SD)	159.23 ± 5.62	159.45 ± 4.72	t=-0.212	0.833
Weight, kg (mean ± SD)	65.72 ± 4.99	66.80 ± 5.46	t=-1.060	0.292
BMI, Kg/cm^2 (mean ± SD)	25.81 ± 2.35	26.27 ± 1.85	t=-1.129	0.261
Smokers, n (%)	10 (21.74%)	5 (12.19%)	$\chi^2 = 1.384$	0.239
History of operation in knee, n (%)	8 (14.55%)	14 (27.45%)	$\chi^2 = 2.680$	0.102
Distribution of etiologies			$\chi^2 = 2.646$	0.450
Rheumatoid arthritis, n (%)	30 (65.22%)	23 (56.10%)		
Post-traumatic arthritis, n (%)	10 (21.74%)	15 (36.59%)		
Osteoarthritis, n (%)	4 (8.70%)	2 (4.88%)		
Charcot knee arthropathy, n (%)	2 (4.35%)	1 (2.44%)		
Length of stay, days (mean ± SD)	10.49 ± 1.49	10.61 ± 1.15	t=-0.450	0.654
Follow-up, months (mean ± SD)	57.36 ± 8.38	58.39 ± 10.58	t=-0.557	0.579
Preoperative HKA axis			$\chi^2 = 1.333$	0.248
Neutral, -3°≤HKA ≤ 3°, knees (%)	0(0%)	0(0%)		
Varus, HKA<-3°, knees (%)	44(80.00%)	45(88.24%)		
Valgus, HKA>3°, knees (%)	11(20.00%)	6(11.76%)		
-Bone density (-T, mean ± SD)	2.32 ± 0.49	1.97 ± 0.58	t = 3.095	**0.003**
Co-morbid with osteoporosis, n (%)	31 (67.39%)	17 (41.46%)	$\chi^2 = 5.892$	**0.015**

Note: the significant differences in the comparison are highlighted in bold

Operation details

A total of 138 metaphyseal sleeves and 140 straight stems were utilized in the TKA procedures. Intraoperative assessments revealed that knees in the screw group presented with more severe bone defects (Z=-3.590, $P<0.001$). Additionally, the screw group demonstrated a statistically significant increase in operative time ($t=3.024$, $P=0.003$), a higher utilization of femoral MS ($\chi^2=12.641$, $P<0.001$), greater use of femoral stems ($\chi^2=12.118$, $P<0.001$), and an increased frequency of constrained prostheses (Z=-2.423, $P=0.015$). Detailed intraoperative data are included in Table 2.

General survivorship and outcomes

Overall, all cases included in the study displayed successful integration of the prostheses with the host bone, as evidenced by postoperative X-rays that indicated effective healing of the bone defect at the metaphysis. Implant survival rates, measured by endpoints of reoperation and revision for any reason, were both recorded at 100% during the mean follow-up period of 57.86 months (ranging from 39 to 80 months, SD: 9.47). The mean NRS for pain significantly decreased ($P<0.05$) from 6.83 preoperatively to 1.67 postoperatively, while the mean HKAD reduced from 24.02 preoperatively to 2.75 postoperatively. Additionally, both ROM and HSS scores significantly improved ($P<0.05$) at the final follow-up, measuring 103.09° and 82.36 respectively, compared to preoperative values of 58.80° and 56.98. Based on HSS scores, 35 participants were categorized as excellent, 48 as good, and 4 as fair at the last follow-up, resulting in an excellent and good rate of 95.40% in terms of knee function. Representative cases are illustrated in Fig. 4 (screw group) and Fig. 5 (non-screw group).

Comparison between the two groups in clinical and radiographic outcomes

Specifically, knees that received screws exhibited poorer preoperative ROM ($F=11.670$, $P<0.001$), diminished knee function ($F=8.289$, $P=0.005$), and significantly greater preoperative deformities ($F=34.761$, $P<0.001$) compared to knees without screws, indicating a worse initial condition for the screw group. Nonetheless, postoperative outcomes revealed that the screw group attained comparable knee ROM, functional status, and radiographic alignment to the non-screw group ($P>0.05$). Detailed comparisons of clinical and radiographic outcomes between the two groups are presented in Table 3, with trends illustrated in Fig. 6.

Complications

Tibial end-of-stem pain appeared in five cases in the non-screw group, while none of the screw group developed such discomfort, the incidence of the pain occurs

Table 2 Operation details of the two groups

variables	Screw group	Non-screw group	Statistic	*P*
TKA side			$\chi^2=0.827$	0.661
Left, n, (%)	20 (43.48%)	14 (34.15%)		
Right, n, (%)	17 (36.96%)	17 (41.46%)		
Bilateral, n, (%)	9 (19.57%)	10 (24.39%)		
Type of bone defect (AORI classification)			Z=-3.590	**<0.001**
2 A, knees (%)	30(54.55%)	44(86.27%)		
2B, knees (%)	18(32.73%)	6(11.76%)		
3, knees (%)	7(12.73%)	1(1.96%)		
Length of incision, cm (mean ± SD)	15.31 ± 0.97	15.51 ± 0.89	t=-1.152	0.252
Operative time, minutes (mean ± SD)	129.36 ± 14.60	122.00 ± 9.80	t = 3.024	**0.003**
Using femoral MS, knees (%)	25(45.45%)	7(13.73%)	$\chi^2=12.641$	**<0.001**
Using tibial MS, knees (%)	55(100%)	51(100%)		
Total use of MS	80	58		
Using femoral stem, knees (%)	26(45.45%)	8(13.73%)	$\chi^2=12.118$	**<0.001**
Using tibial stem, knees (%)	55(100%)	51(100%)		
Total use of stems	81	59		
Fixation of stems			$\chi^2=3.524$	0.172
Press-fit, knees (%)	38(69.1%)	40(78.4%)		
Hybrid, knees (%)	11(20.0%)	10(19.6%)		
Cemented, knees (%)	6(10.9%)	1(2.0%)		
Constraint of prostheses			Z=-2.423	**0.015**
PFC sigma PS, knees (%)	16(29.1%)	25(49.0%)		
PFC sigma TC3, knees (%)	33(60.0%)	25(49.0%)		
S-ROM Noiles RHK, knees (%)	6(10.9%)	1(2.0%)		

Note: the significant differences in the comparison are highlighted in bold

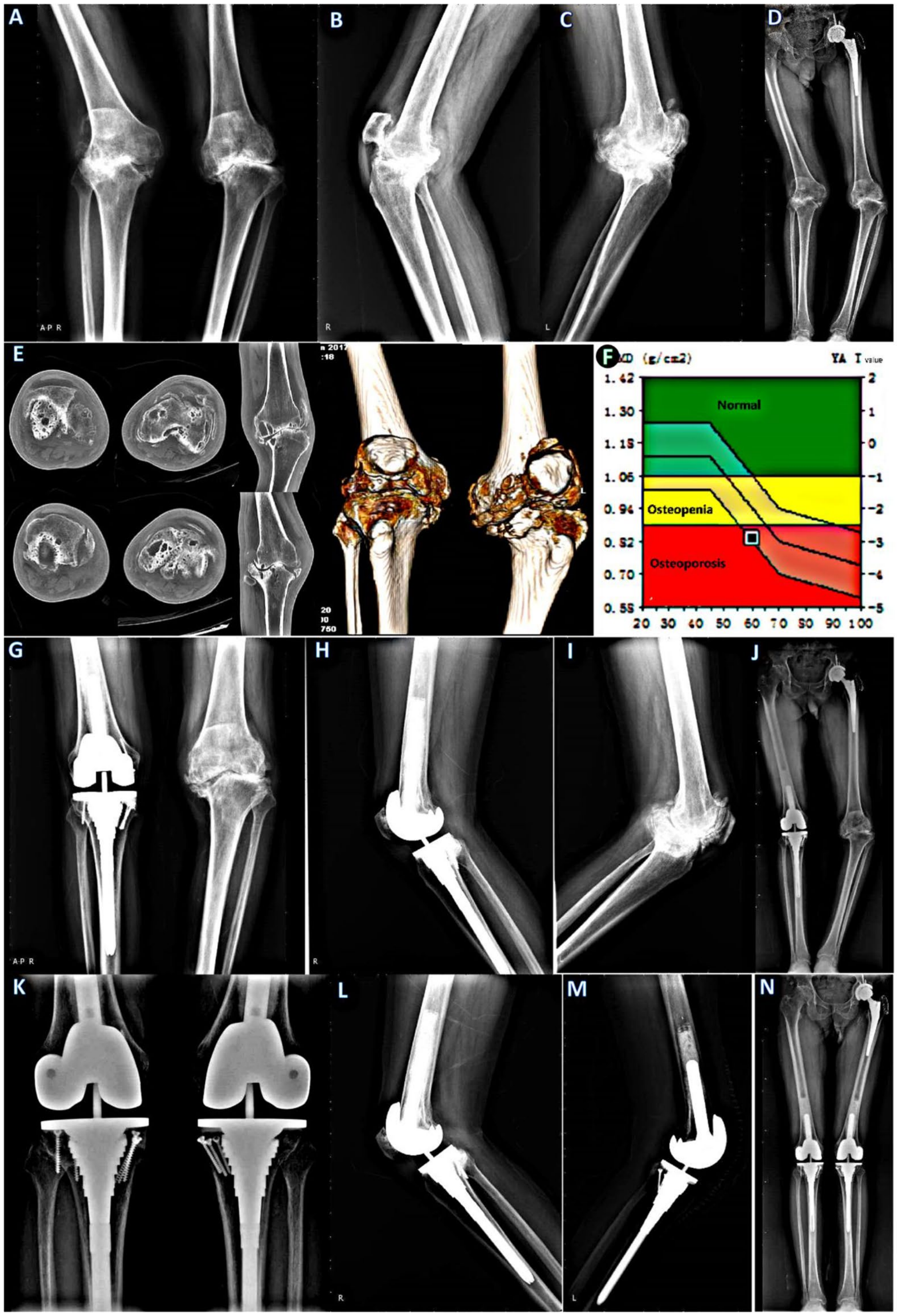

Fig. 4 Representative imaging data from the screw group. A patient with RA was admitted to the hospital due to persistent knee pain, severe knee deformity, and difficulty walking. **A-D)** Preoperative X-rays revealed characteristic windswept deformities of the knees. **E)** A preoperative CT scan indicated significant degeneration and massive bone defects in both knees. **F)** A preoperative DEXA scan showed severe osteoporosis that was not commensurate with his age and gender. **G-N)** A staged bilateral TKA strategy was employed, utilizing MS combined with screws to reconstruct the bone defects in both knees. Excellent radiographic outcomes for both knees were achieved at the last follow-up (6 years postoperatively)

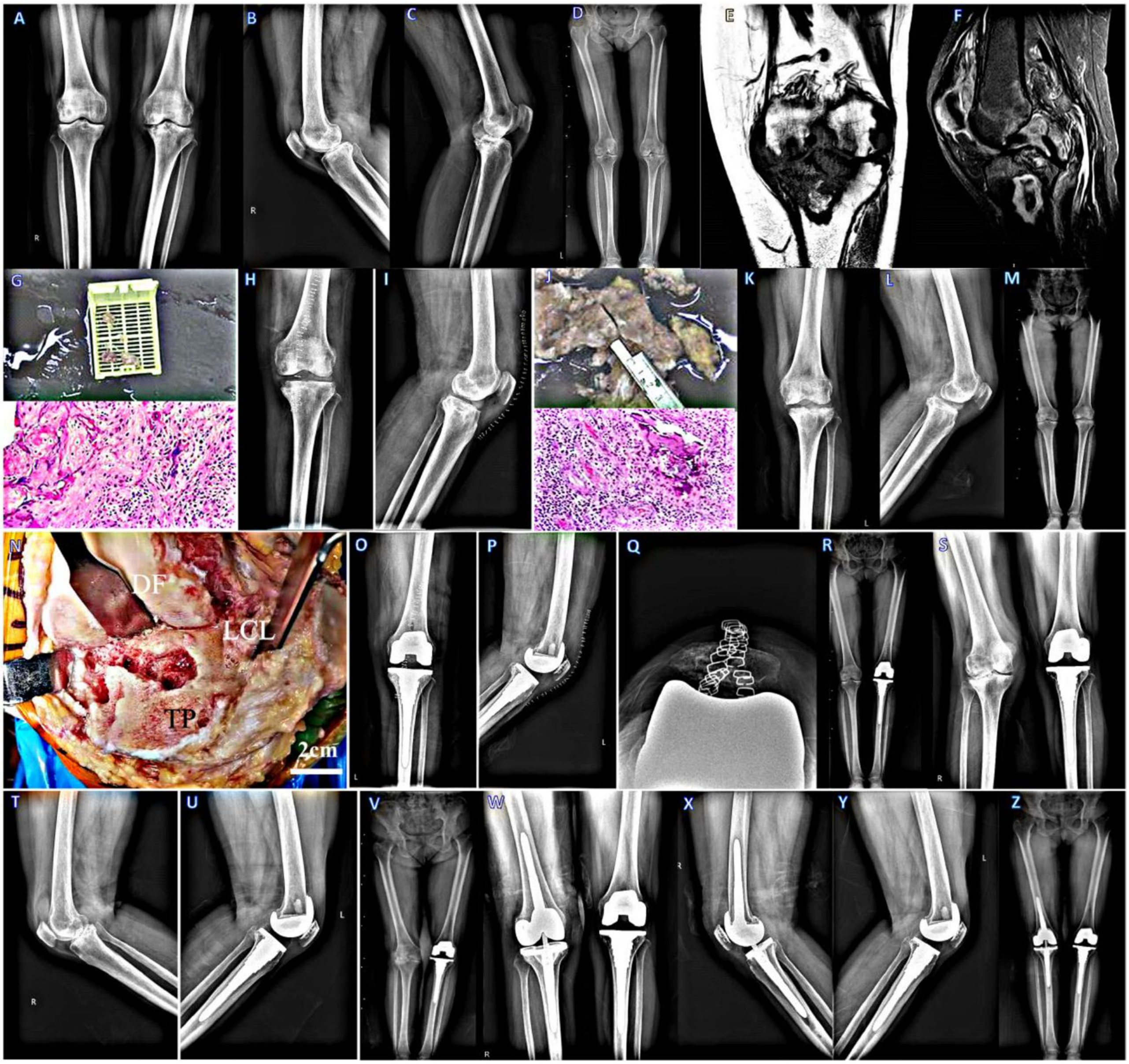

Fig. 5 Representative imaging data from the non-screw group. A patient with RA was hospitalized due to escalating knee pain, redness and swelling, and difficulty walking. **A-D)** X-rays demonstrated significant impairment in the left knee, with a shift in the center of gravity attributed to severe pain in the left knee. **E-F)** MRI scans revealed extensive lesions in the metaphysis of the left tibial plateau, as well as erosion of the medial collateral ligament. **G)** Pathological results from joint aspiration showed neutrophil infiltration and necrosis. Although bacterial cultures were negative, she was diagnosed with infection due to the typical clinical manifestations and pathological findings. **H-I)** Debridement was performed, and a spacer was implanted. **J)** A substantial amount of proliferative synovial tissue was excised, with pathological results confirming the infection. **K-M)** The patient's symptoms improved; however, imaging indicated progressive joint damage, necessitating TKA in the left knee. **N-R)** Surgical findings validated massive bone defects in the metaphysis and erosion of the medial collateral ligament (MCL), with MS utilized to achieve stable fixation of the left knee. **S-V)** Excellent radiographic outcomes for the left knee were achieved at the 3-month postoperative mark. Subsequently, she developed mild end-of-stem pain in the left knee, along with increasing pain and deformity in the right knee, which required another TKA. **W-Z)** Excellent radiographic outcomes for both knees were achieved at the last follow-up (5 years postoperatively), with complete resolution of end-of-stem pain in the left knee. DF: distal femur; TP: tibial plateau; LCL: lateral collateral ligament

relatively more frequently in the non-screw group (9.8% VS 0%, $\chi^2 = 3.688$, $P = 0.0548$, marginal significance). Patients suffering from this mild pain did not show radiolucency or loosening at the follow-up (Fig. 5), and the pain can be relieved by routine NSAID and generally disappeared at about 3–6 months after the surgery.

Incision liquefaction occurred in seven knees (four cases in the screw group and three cases in the non-screw group) postoperatively, but all cases resolved

Table 3 Detailed clinical and radiographic outcomes of the two groups

Variables	Group	Pre-operative	Post-operative 1 year	Post-operative 2 year	Last follow-up	F	P
NRS	Total	6.83 ± 0.57	1.81 ± 0.78	1.72 ± 0.67	1.67 ± 0.63		
	Screw group	6.85 ± 0.45	1.76 ± 0.84	1.67 ± 0.70	1.64 ± 0.65	745.503	**< 0.001**
	Non-screw group	6.82 ± 0.68	1.86 ± 0.72	1.78 ± 0.64	1.71 ± 0.61	665.124	**< 0.001**
	MD, 95% CI	0.031(-0.190,0.252)	-0.099(-0.401,0.203)	-0.112(-0.370,0.147)	-0.070(-0.312,0.173)		
	F	0.077	0.423	0.733	0.322		
	P	0.782	0.517	0.394	< 0.572		
ROM (°)	Total	58.80 ± 1010	99.89 ± 5.98	102.13 ± 5.86	103.09 ± 5.77		
	Screw group	55.73 ± 9.27	99.76 ± 5.96	101.87 ± 6.26	102.85 ± 6.14	318.500	**< 0.001**
	Non-screw group	62.12 ± 9. 99	100.02 ± 6.02	102.41 ± 5.45	103.35 ± 5.38	223.473	**< 0.001**
	MD, 95% CI	-6.390(-10.100, -2.681)	-0.256(-2.572,2.060)	-0.539(-2.807,1.729)	-0.498(-2.730,1.733)		
	F	11.670	0.048	0.222	0.196		
	P	**0.001**	0.827	0.638	0.659		
HSS	Total	56.98 ± 6.99	79.76 ± 4.45	81.55 ± 4.38	82.36 ± 4.34		
	Screw group	55.02 ± 7.15	79.46 ± 4.67	81.43 ± 4.90	82.24 ± 4.73	260.475	**< 0.001**
	Non-screw group	59.17 ± 6.17	89.10 ± 4.22	81.68 ± 3.76	82.49 ± 3.90	170.788	**< 0.001**
	MD, 95% CI	-4.149(-7.014, -1.284)	-0.641(-2.548,1.266)	-0.248(-2.127,1.631)	-0.937(-2.112,1.615)		
	F	8.289	0.447	0.069	0.070		
	P	**0.005**	0.506	< 0.794	0.791		
HKAD (°)	Total	24.02 ± 6.71	2.50 ± 0.61	2.60 ± 0.63	2.75 ± 0.73		
	Screw group	27.24 ± 5.30	2.45 ± 0.63	2.58 ± 0.57	2.78 ± 0.74	344.310	**< 0.001**
	Non-screw group	20.55 ± 6.36	2.55 ± 0.58	2.62 ± 0.68	2.71 ± 0.73	168.653	**< 0.001**
	MD, 95% CI	6.687(4.438,8.937)	-0.094(-0.328,0.139)	-0.030(-0.213,0.273)	0.076(-0.207,0.359)		
	F	34.761	0.642	0.060	0.284		
	P	**< 0.001**	0.425	0.807	0.596		

Note: the significant differences in the comparison are highlighted in bold

following dressing changes and infrared therapy, without the need for additional surgery. Two patients required a postoperative blood transfusion of 200 ml; however, this did not affect their length of hospital stay or time to suture removal. One readmission involved a patient with Charcot knee arthropathy who developed DVT, which was successfully treated with routine anticoagulation. Throughout the perioperative period and follow-up, no intraoperative fractures, cardiac events, pulmonary issues, joint instability, aseptic loosening, radiolucency, or PJI were reported.

Discussion

The main findings of this study are as follows: (1) MS is effective for reconstructing significant bone defects in complex primary TKA among East Asian populations, demonstrating satisfactory short- to mid-term implant survivorship; and (2) the use of screws proved beneficial in addressing tibial "residual defects" around the MS placement, potentially reducing the risk of postoperative end-of-stem pain in complex primary TKA utilizing the MS-stem system.

In typical cases of primary TKA, osteoarthritis is the chief underlying condition, accounting for over 90% of cases [25]. However, in the current study, the distribution of etiologies among patients undergoing complex primary TKA with MS was as follows: rheumatoid arthritis, post-traumatic arthritis, osteoarthritis, and Charcot knee arthropathy, with more than 90% of patients presenting conditions other than osteoarthritis. This notable distribution reflects the unique and complex nature of the cases included in this study. These patients often exhibit more significant bone defects, poorer bone quality, more challenging deformities, and worse soft tissue conditions compared to the majority of primary TKA recipients. These special factors may occur either individually or in combination among the individuals enrolled in the study. Given these complexities, we speculated that conventional approaches to primary TKA are likely insufficient to address the aforementioned challenges, and employing standard repair techniques might lead to suboptimal outcomes, such as surgical failure and the need for early revision. Consequently, we opted for the use of MS, which incorporates a metaphyseal metal augmentation strategy to address these issues.

As a new modular prosthetic component designed for revision TKA, the suitability of MS for complex primary TKA in East Asian populations remains uncertain and warrants rigorous retrospective evaluation. It is well established that current TKA prostheses and component designs are mainly based on anatomical data from Caucasians; however, numerous studies [12–20] indicate significant anatomical differences between Caucasian and East Asian knee joints. Research [16] has shown that

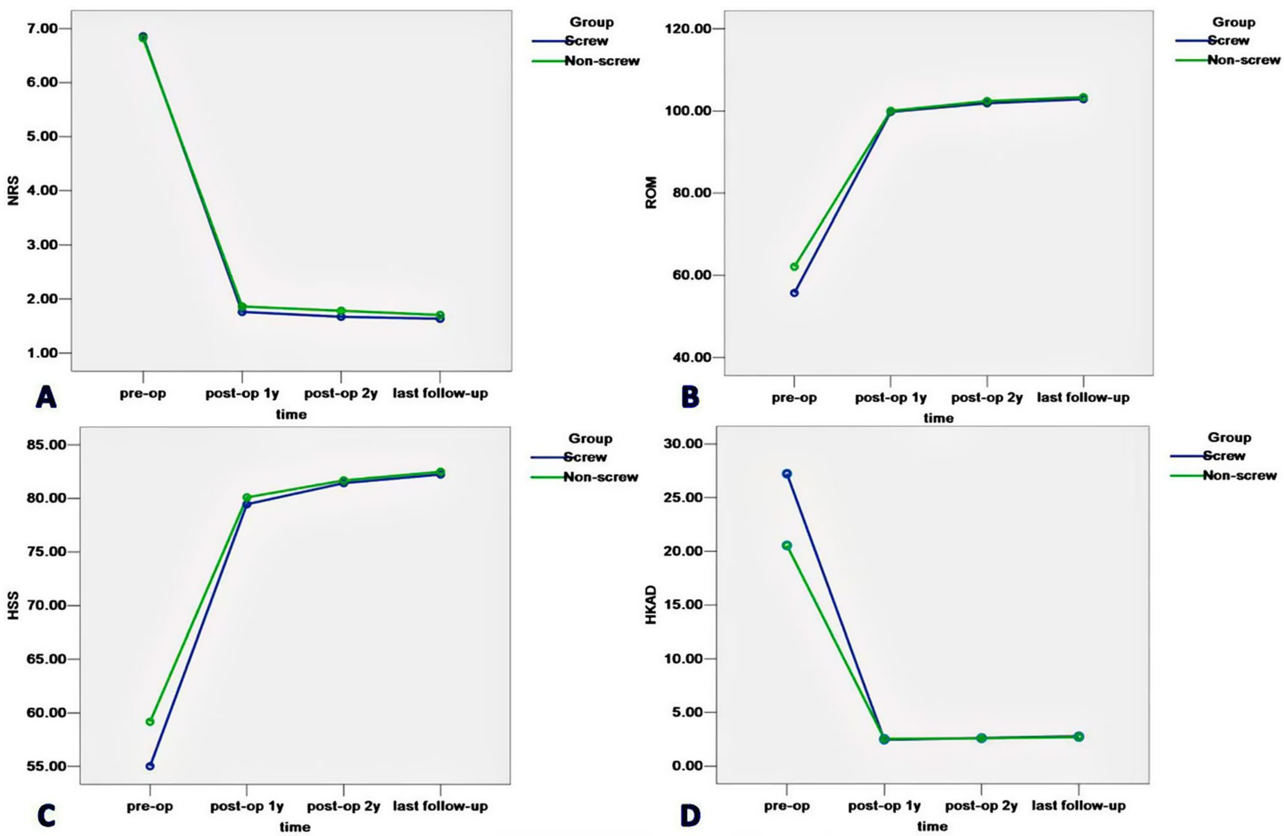

Fig. 6 The change tendency of NRS**(A)**, ROM**(B)**, HSS**(C)** and HKAD **(D)** of the two groups

Caucasians exhibit a higher tibial torsion angle, lower varus angle, and larger valgus angle compared to Japanese individuals. Furthermore, Caucasians have larger measures for distal femur and proximal tibia diameters as well as a higher femoral-tibial ratio compared to Chinese individuals [17]. Some scholars have suggested that existing knee prosthesis designs may not adequately match the anatomy of East Asians [17].

Particularly, metaphyseal sleeves are often used in combination with straight stems, which are commonly employed in complex primary TKAs or revisions to help resolve anatomical mismatches, reduce malalignment, and improve gap balancing. The ideal placement of a MS-straight-stem system should be central to ensure optimal bone contact in all directions [32]. Failure to achieve these objectives may significantly increase the risk of surgical failure [32]. While studies suggest the tibial axis in East Asian individuals is consistently anterolateral to the plateau center [14], Caucasian populations exhibit less anterolateral offset [14] and may even demonstrate anteromedial positioning [18–20]. Theoretically, the use of off-set stems in complex knee surgeries in East Asian populations may enhance tibial plateau coverage; however, this raises questions about potential mismatches when applying MS-straight-stem systems in this demographic. Therefore, the ability of off-the-shelf, Caucasian-based MS-straight-stem systems to achieve ideal "central" placement and deliver satisfactory mid to long-term clinical outcomes in East Asian individuals necessitates validation through clinical studies involving larger patient samples.

The results of this study compellingly demonstrate that the use of MS in complex primary TKA for managing bone defects in East Asian populations yields early to mid-term clinical outcomes that are comparable to those reported in Caucasian patients [10, 11]. Radiographic evaluations (Figs. 4 and 5) indicated optimal "central position" placement of the implants, satisfactory coverage of the tibial plateau, and significant improvement in the correction of the gravity line.In a prospective study conducted by Matin-Hernandez et al. in Spain [10], which involved 25 patients with post-traumatic arthritis of the knee undergoing primary TKA using MS, the authors reported that the mean Knee Society Score improved from 29 preoperatively to 78 postoperatively. Additionally, the Western Ontario and McMaster Universities Osteoarthritis Index pain score improved significantly from 12 preoperatively to 3 postoperatively. Notably, all patients achieved osseous integration at a mean follow-up of 79 months, with a survival rate of

100%. Similarly, a cohort study conducted by Van Rensch et al. in the Netherlands [11], which included 28 primary TKA recipients following high tibial osteotomy and tibial plateau fractures, demonstrated favorable outcomes with the use of MS. With a final follow-up surpassing 2 years, the study reported significant improvements in overall health scores and the NRS, with scores increasing from 63 preoperatively to 70 postoperatively, and from 8 preoperatively to 3 postoperatively. The implant survival rate for all reasons was reported at 96.4% at the 2-year follow-up.

In the present study, all 87 patients (106 knees) exhibited significant improvements in the NRS for pain, ROM, and HSS at the final follow-up after surgery. Notably, the HKAD declined dramatically from 24.02 preoperatively to 2.75 at the last follow-up, with no knees demonstrated varus or valgus deformities exceeding 4° at postoperative 2 year. During a mean follow-up period of 4.8 years, we reported no cases of joint instability, aseptic loosening, PJI, or the need for revision surgery, resulting in an excellent and good rate of 95.40% based on HSS. Furthermore, both the overall survival rates with respect to reoperation and revision endpoints were 100% at the final follow-up. Our study represents the first focused observation of MS utilized in complex primary TKA, with a sample size exceeding 100 knees (87 cases, 106 knees). The findings indicate that metaphyseal sleeves, with or without accompanying screws, demonstrate encouraging early to mid-term clinical effectiveness in addressing significant bone defects in complex primary TKA among East Asian patients, showcasing excellent applicability and implant survivorship.Importantly, as the MS positioning is guided by an intramedullary guide and the metaphyseal bone is gradually removed based on the sinking of the MS, the potential impact of tibial shaft axis offset variations - including those associated with anatomical differences - may be partially mitigated. This approach facilitates optimal tibial tray coverage while demonstrating particular advantages in complex primary TKA scenarios requiring straight extended stems. The intramedullary-guided bone resection combined with progressive MS settling appears to minimize anatomical variability challenges, representing a previously unreported benefit of sleeve implementation that merits further exploration.

Another notable aspect of this study is that it is the first to describe the role of screws for tibial "residual bone defects" in the complex primary TKA procedure using MS. The concept of using bone cement and screws to repair bone defects during total knee arthroplasty was first introduced by Freeman [33] in 1982. Since then, this method has been widely adopted in clinical practice and has demonstrated effectiveness and cost-efficiency for independently addressing small bone defects [25, 26], specifically those with a depth of less than 10 mm. However, in the case of substantial bone defects exceeding 30 mm in depth, cement screws are typically employed as an adjunct to primary reconstruction techniques, such as bone grafting, metal augmentation, and constrained prostheses.

During the surgical procedure, following the implantation of the MS-stem system in zones 2 and 3, successful reconstruction of the central region and the main body of substantial bone defects is typically achieved. Nevertheless, some patients are left with irregular small peripheral bone defects in zone 1 [22], and there is currently no dedicated research addressing the repair of these "residual defects" It has been suggested that in revision cases, bone grafting (either autologous or allogenic) may be employed to address these residual defects. In revision TKA cases, the bone defects left after implant removal (including the aforementioned residual defects) typically expose well-vascularized cancellous bone, making it conducive to successful bone grafting that provides reliable support. Conversely, in primary TKA cases, the base of the residual defects often exhibits sclerosis. Unless further interventions, such as freshening or osteotomy, are performed on these defects, they may hinder the graft's viability, resulting in higher risks of graft failure, bone resorption, or collapse [5, 23, 24]. These complications can adversely affect joint function and the long-term survival of the prosthesis. The use of bone cement and screws offers a reliable approach to rapidly fill small bone defects and provide long-term support, addressing these challenges effectively.

In this study involving 87 patients (106 knees) of primary TKA with bone defects reconstructed using MS, 46 patients (55 knees) employed bone cement and screws to repair the residual defects. The clinical outcomes and prosthesis survival rates in these patients were comparable to those of the group that did not use screws (41 patients, 51 knees), demonstrating the feasibility and efficacy of this approach. Additionally, this study indicates that, compared to the non-screw group, the screw group presented with significantly greater preoperative deformity angles, more severe bone defect conditions, and poorer bone density differences that were anticipated. After the MS was placed in the central metaphysis, patients with worse knee conditions were more likely to have small residual defects needing further repair, necessitating more operation time, more MS and stems in the distal femur, and more implant constraint. The differences in bone density may also be attributed to the higher proportion of RA patients within the screw group, as it is well-known that individuals with RA are at a significant risk for OP due to the disease's invasiveness and the effects of corticosteroids [34, 35].Poor bone quality, especially severe osteoporosis is a strong indication for screw in these cases.

An unexpected finding of this study was that none of the patients in the screw group experienced end-of-stem pain, whereas five knees in the non-screw group reported mild tibial end-of-stem pain; the incidence of end-of-stem pain in the screw group was less than that in the non-screw group, with a strong tendency towards statistical significance (0/55 vs. 5/51, $P = 0.0548$). Although radiography conducted during follow-ups (ranging from 3.2 to 6.4 years) for these patients experiencing pain did not reveal signs of implant subsidence, periprosthetic radiolucent line, or distal stem displacement, the patients still required intermittent analgesic use to manage their discomfort, which is noteworthy.

End-of-stem pain is relatively common in revision cases involving MS, with an incidence ranging from 10 to 23% [36]. In a previous study by Matin-Hernandez et al. [10], the incidence of end-of-stem pain in primary TKA cases utilizing MS was documented at 3.7% (1/27).It is generally believed that this discomfort is associated with the use of stems during TKA, which can result in stress shielding in the proximal tibia and potentially induce bone resorption; furthermore, the use of stems may concentrate stress around the distal tip, potentially leading to para-stem pain and an increased risk of fracture [37–40].

In this study, the overall incidence of end-of-stem pain was found to be 4.72% (5/106), which aligns with the findings of Matin-Hernandez et al. [10], despite a significantly higher utilization of stems. Notably, we observed no occurrences of end-of-stem pain in the screw group, a result that deviates from expectations. Patients in the screw group exhibited considerably worse knee pathology and theoretically had a greater risk of postoperative complications; however, the incidence of end-of-stem pain in this group was lower than that observed in the non-screw group. We hypothesize that this outcome may be attributed to the screws enhancing the biomechanical performance of the stems. An experimental biomechanical study has indicated that strain concentration occurs at the tip of the stem for both cemented and press-fit stems used in primary TKA [40]. The biomechanical advantage conferred by screws is their ability to provide support to the tibial platform prosthesis from above while anchoring within the cancellous bone of the medial tibial plateau below. This design may facilitate the transmission of joint loads to the cancellous bone, potentially mitigating the stress shielding effect associated with the stem and thereby lowering the risk of distal pain. Nevertheless, this hypothesis necessitates further validation through clinical studies involving larger sample sizes and extended follow-up periods.

In our study, no intra-operative fractures, aseptic loosening, or PJI were observed during the follow-up. The mean length of stay (LOS) was 10 days (minimum 7 days), which is comparable to the typical LOS for general TKA recipients at our institution. Furthermore, the incidence of readmission for complications within 90 days was relatively low (0.94%, 1/106). The sole readmission case involved a patient with Charcot knee arthropathy who developed DVT; her readmission may be partially attributed to prolonged immobilization aimed at preventing early aseptic loosening. Perioperative period and follow-up did not reveal any cases of cardiac events and pulmonary issues despite the medically frail patient population being at high risk for perioperative complications.

Another main perioperative complication identified in our study was fat liquefaction at the incision site, occurring in seven knees (6.60%, 7/106) without bacterial growth, which resulted in delayed wound healing and extended LOS. We believe this type of complication primarily affects obese individuals, those with hypoproteinemia, and patients with diabetes. In our study, all cases of delayed wound healing were successfully treated with conservative management, and no additional surgeries were required for wound-related complications. Two patients required postoperative blood transfusions, both of whom had preoperative anemia. A retrospective review by Morse KW et al. demonstrated a correlation between postoperative blood transfusion and prolonged LOS [41]; however, in our study, transfusions did not affect LOS or time to suture removal. Considering the complexity of the surgical procedures, a staged replacement strategy was employed for the 19 participants requiring bilateral arthroplasty, which we believe contributed to favorable short-term outcomes and a reduced incidence of surgical complications.

Limitation of the present study

The most significant limitation of this study is its retrospective design. As a clinical investigation, the challenges of randomizing and prospectively grouping patients restrict our ability to fully evaluate the effectiveness of metaphyseal sleeves and screws in complex primary TKA. While we did perform several complex primary TKA procedures utilizing metaphyseal sleeves and bone grafts for reconstructing bone defects, these cases were not included in the current analysis due to the small sample size (12 patients), as illustrated in Fig. 2. Consequently, further investigation is needed to compare the efficacy of bone grafts versus cement-screws in addressing residual defects around the sleeve-stem placement in complex primary TKA procedures. Additionally, the relatively short follow-up period have surely limited our ability to detect some complications that have been reported in the literature. As a result, there may be observation bias, and comprehensive survival analyses could not be conducted.

Conclusions

Given the excellent feasibility, encouraging outcomes, high survival rates, and low complication rates observed in our study, we believe that metaphyseal sleeve is a safe and effective option for reconstructing substantial bone defects in complex primary TKA in Eastern Asian populations. The cement-screw technique represents a viable solution for addressing tibial "remaining defects" surrounding the placement of metaphyseal sleeves, particularly in cases with significant deformity and poor bone quality. However, the potential benefits of this technique in improving load transfer and reducing stress shielding need further exploration through larger studies with extended follow-up periods.

Abbreviations

TKA	Total knee arthroplasty
RA	Rheumatoid arthritis
OP	Osteoporosis
MS	Metaphyseal sleeve
ROM	Range of motion
HSS	Hospital for Special Surgery
HKA	Hip-knee-ankle angle
HKAD	Hip-knee-ankle angle deviation
DEXA	Dual-energy X-ray absorptiometry
SD	Standard deviations
MD	Mean difference
BMI	Body mass index
LOS	Length of stay
DVT	Deep vein thrombosis
PJI	Periprosthetic joint infection
NRS	Numerical rating scale
AORI	Anderson Orthopedic Research Institute
PS	Posterior stabilized knee
TC3	Total condylar III knee
RHK	Rotating hinge knee
S-ROM	Sivash-range of motion
DF	Distal femur
TP	Tibial plateau
MCL	Medial collateral ligament
LCL	Lateral collateral ligament

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Author contributions
WK Zheng. and WD Xiao designed the study; WK Zheng, JF Tang and JY Huang collected the clinical data; XL Wang and WD Xiao performed the surgeries; WK Zheng and JF Tang performed statistical analysis; WK Zheng and JF Tang wrote the manuscript; WD Xiao revised the paper. All authors reviewed and approved the final manuscript.

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Data availability
The data and materials during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study was conducted in accordance with the Declaration of Helsinki and with approval from the Ethics Committee of the First People's Hospital of Guangzhou (Ethics number: K-2021-036-02), and written consent was obtained from the patients.Clinical trial number: not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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