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Research article

Decreased stress shielding with poly-ether-ether-ketone tibial implant for total knee arthroplasty - A preliminary study using finite element analysis

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A B S T R A C T

In total knee arthroplasty (TKA), the mechanical mismatch between cobalt-chromium (CoCr) alloy tibial implant and bone has been implicated in stress shielding and subsequent implant failure and bone resorption. This study investigates the biomechanical advantages of poly-ether-ether-ketone (PEEK) tibial implant, which exhibit properties analogous to those of the surrounding bone. A finite element analysis (FEA) was employed to assess and compare the biomechanical performances of PEEK and CoCr tibial implants in patients with and without osteoporosis. Four FEA models were constructed with PEEK and CoCr alloy implants in normal and osteoporotic tibias. Based on previous literature and our clinical experience, stresses measurements were taken at 16 points on the tibial plateau and 8 points on the two surfaces which were 10 mm and 20 mm apart from the tibial plateau, with specific regions quantified for stress shielding. The results showed significant differences in stress distribution between PEEK and CoCr implants. The PEEK implants exhibited higher equivalent stresses on the tibial plateau in all models (normal bone: 0.22 ± 0.07 MPa vs. 0.13 ± 0.06 MPa, $p < 0.01$; osteoporotic bone: 0.39 ± 0.06 MPa vs. 0.17 ± 0.07 MPa, $p < 0.01$). In non-osteoporotic models, the mean equivalent stresses on proximal tibial surfaces were similarly elevated for PEEK implants (0.29 ± 0.13 MPa vs. 0.21 ± 0.08 MPa, $p = 0.02$). The CoCr implants demonstrated more stress shielding across all measured regions (tibial plateau: 23.47% vs. 2.73%; surface 1: 15.93% vs. 1.37%; surface 2: 10.71% vs. 6.56%). These disparities were even more pronounced in osteoporotic models in the CoCr group (tibial plateau: 32.50% vs. 8.36%). The maximum equivalent stresses on the tibial plateau further supported this trend (normal bone: 1.02 MPa vs. 0.52 MPa; osteoporotic bone: 1.43 MPa vs. 0.67 MPa). These data confirm the hypothesis that a PEEK tibial implant can reduce peri-prosthetic stress shielding, suggesting that PEEK implants have the capability to distribute loads more uniformly and maintain a closer approximation to physiological conditions.

1. Introduction

Total Knee Arthroplasty (TKA) had been established as a markedly efficacious remedy for patients grappling with the debilitating effects of degenerative knee joint conditions. Its long-term viability is supported by commendable survival rates; however, a non-

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negligible subset of recipients ultimately faces revision surgeries. Primarily, aseptic loosening poses a significant threat to the endurance of the implanted prostheses. The latest insights from the Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) 2020 report placed primary TKA at the lower end of the revision spectrum relative to alternative knee replacement interventions. Nineteen years subsequent to primary TKA for osteoarthritis, the cumulative percentage of revision procedures stood at 9.0% [1]. Within this revision cohort, the cause of revision due to implant loosening was notably significant, accounting for 24.7% of cases. This stark statistic underscores the crucial need to innovate and implement strategies to mitigate implant loosening, thereby enhancing the overall efficacy and durability of TKA interventions.

Aseptic loosening represents a pivotal failure mode in the domain of TKA, attributable predominantly to two distinct mechanisms. The deterioration of the interface between the prosthetic implant and the bone cement or direct bone resorption underneath the implant trigger these failures [2,3]. Debonding at the implant-bone cement juncture had emerged as a critical concern. Investigations into this impairment prioritize implant design parameters and the rheological characteristics of bone cement, particularly high viscosity, which may precipitate interface integrity loss [4]. Concurrently, tibial bone resorption surfaces as a complex phenomenon influenced by multifactorial etiologies: stress shielding, thermal injuries secondary to exothermic cement polymerization, and devascularization compromising osseous vitality [2]. Technological strides in implant configuration and manipulation of bone cement viscosity may offer partial redress for these issues. Nonetheless, the intrinsic biomechanical discordance between the substantial rigidity of cobalt chrome implants and the more compliant osseous structures, especially in the milieu of osteoporotic bone, presents enduring challenges. Such disparities might render complete abrogation of bone resorption an elusive goal in TKA longevity.

The panorama of orthopedic surgery is witnessing a paradigm shift with the advent of biomimetic materials, designed to surmount the constraints conferred by conventional Cobalt–Chromium (CoCr) alloys. The surge of interest in poly-ether-ether-ketone (PEEK) underscores its burgeoning potential as an alternative material with significant advantages. Critical investigations accentuated PEEK's elastic modulus, which closely mirrors that of bone, augmenting biomechanical compatibility and promoting osteointegration [5–7]. The robust biocompatibility of PEEK coupled with its osteogenic induction attributes heralds a new dawn in material sciences for

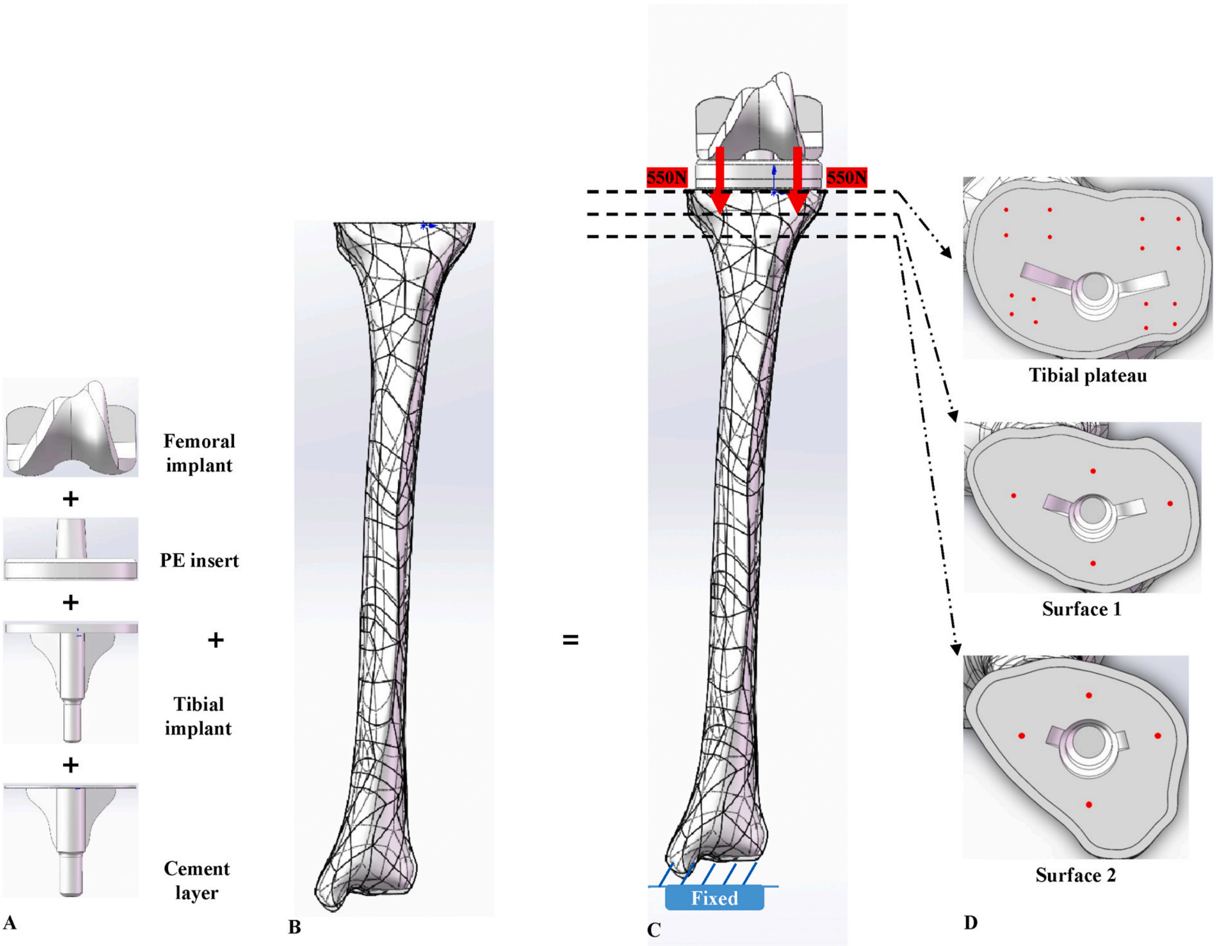

Fig. 1. The finite element model including tibial component and 3D model of lower limb. A. Tibial component; B. The assembled model; C. Stress of 550 N was applied to the medial and lateral tibial plateau respectively, and the distal tibia was fixed; D. The stress measuring points on tibial plateau and proximal tibia.

surgical applications. To date, PEEK's utilization extends across various orthopedic devices, encompassing intervertebral lumbar cages, fixation screws, and cranial reconstruction patches [8]. Notably, in the realm of TKA, the deployment of a PEEK femoral component demonstrates promising computational outcomes. Early models predicted a beneficial modulation of periprosthetic bone remodeling stimulus and a decrease in stress shielding effects, thereby preserving bone health adjacent to the implant [9–11]. Nonetheless, the adoption of PEEK as a tibial component in TKA has yet to be fully elucidated, with ambiguity surrounding its influence on periprosthetic bone remodeling and stress shielding mechanisms. Furthermore, the efficacy and reliability of PEEK-based tibial implants in the context of osteoporotic bone remain subjects ripe for research.

This study aims to compare the biomechanical properties of PEEK and CoCr alloy tibial implants after implantation in patients with and without osteoporosis. The assessment is conducted using a finite element analysis (FEA) to simulate and analyze the mechanical behavior of the implants.

2. Materials and methods

2.1. CAD model

A high-fidelity three-dimensional (3D) tibial model was derived from computed tomography (CT) scans of a non-pathological subject. The participant, a 20-year-old female of 165 cm stature and 50 kg mass, provided informed consent for the utilization of her CT images. The modeling process commenced with the extraction of geometric data from CT slices, each 0.8-mm in thickness, accumulating to a total of 1142 slices. Imaging parameters were meticulously controlled, with the electrical current and potential set at 156 mA and 120 kV, respectively.

The generated data were initially processed using Mimics 21.0 software (Materialise NV, Leuven, Belgium) to craft the initial 3D representation of the tibia. The ensuing model was thereafter subjected to refinement processes through Geomagic Studio 12.0 (3D Systems, Inc., North Carolina, USA), ensuring structural optimization and verisimilitude to the native anatomy. The culminating model was then transitioned into the SolidWorks 2016 (Dassault Systems SolidWorks Corp., Waltham, Massachusetts, USA) where a virtual analogue of the tibial resection—characteristic of prosthetic implantation and situated 9 mm proximal to the tibial plateau—was executed.

The tibial component consists of a baseplate and a posterior-stabilized fixed-bearing ultra-high molecular weight polyethylene (UHMWPE) insert. The geometries of the PEEK and CoCr alloy tibial baseplates were obtained through direct measurement (Fig. 1A). The PEEK models utilized knee implants from Suzhou SinoMed Biomaterials Co., Ltd., China, while the CoCr alloy models used implants from Smith & Nephew Orthopedics, USA. The insert was 9 mm in thickness with a rounded-top and a flat-inferior surfaces. A 2 mm thick cement layer was employed to securely fix the tibial tray into the resected tibia. The tibial component was positioned perpendicular to the tibial mechanical axis. The assembly of all components was performed using SolidWorks software (Fig. 1B).

2.2. Finite element simulation

The biomechanical analysis of models was presented using ANSYS Workbench 17 software (Swanson Analysis Systems, Inc., Houston, Pennsylvania, USA). After importing the three-dimensional (3D) models constructed in the previous steps, the mechanical properties of the component materials were defined (Table 1) [11–13]. To simulate a secure union between the implant, bone cement, and bone, the contact behaviors among them were modeled as bonded [14]. Linear elastic isotropic materials were assigned to all implant components [15]. A total load of 1100 N, equivalent to 2.2 times the body weight, was applied in a 1:1 ratio between the medial and lateral tibial plateaus [16]. The distal tibia's inferior surface was fixed in all directions to simulate the anatomical conditions (Fig. 1C). Referring to previous literature, the study implemented conservative values for the damage stress of cancellous bone (2.8 MPa) and assessed possible bone resorption using a resorption threshold of 0.1 MPa [17].

2.3. Finite element analysis

To evaluate their performance under varying conditions, four FEA models were created: PEEK and CoCr alloy implants inserted in

Table 1
The performance of component materials in each model.

Material	E (MPa)	v
Cortical bone	17,000	0.3
Cancellous bone	700	0.3
Cortical bone (osteoporosis)	17,000	0.3
Cancellous bone (osteoporosis)	155	0.3
UHMWPE (tibial insert)	2300	0.25
Cobalt-chrome alloy (tibial implant)	248,000	0.3
PMMA (cement)	2270	0.46
PEEK (tibial implant)	3700	0.362

UHMWPE: ultra-high molecular weight polyethylene; PMMA: Polymethyl methacrylate; PEEK: poly-ether-ether-ketone.

Table 2
Equivalent stresses at 16 points on the medial and lateral tibial plateaus (MPa).

Tibial plateau		Anteromedial area				Posteromedial area				Anterolateral area				Posterolateral area				Mean	sd	p
		Point 1	Point 2	Point 3	Point 4	Point 5	Point 6	Point 7	Point 8	Point 9	Point 10	Point 11	Point 12	Point 13	Point 14	Point 15	Point 16			
Non-osteoporosis	CoCr alloy	0.20	0.16	0.13	0.10	0.19	0.24	0.16	0.27	0.09*	0.06*	0.14	0.11	0.16	0.24	0.22	0.27	0.17	0.07	<0.01**
	PEEK	0.37	0.37	0.31	0.33	0.43	0.40	0.35	0.39	0.30	0.35	0.41	0.39	0.50	0.47	0.48	0.45	0.39	0.06	
Osteoporosis	CoCr alloy	0.20	0.11	**0.09***	**0.05***	0.15	0.22	0.13	0.21	**0.04***	**0.03***	0.10	**0.06***	0.13	0.17	0.15	0.21	0.13	0.06	<0.01**
	PEEK	0.20	0.20	0.15	0.14	0.27	0.33	0.21	0.29	0.12	0.13	0.21	0.17	0.25	0.28	0.27	0.31	0.22	0.07	

The "*" means the equivalent stress was less than 0.1 MPa. The "**" means the results have significant statistical difference. Sd: standard deviation; CoCr: cobalt-chromium; PEEK: poly-ether-ether-ketone.

both normal and osteoporotic tibias. Based on previous literature and our clinical experience, stresses measurements were taken at 16 points on the tibial plateau and 8 points on two surfaces which were 10 mm (surface 1) and 20 mm (surface 2) apart from the tibial plateau (Fig. 1D). Additionally, the extent of stress shielding was quantified as a percentage of the tibial plateau and proximal tibia. Statistical analyses were conducted using SPSS version 22 (SPSS Inc., Chicago, IL, USA), utilizing a paired Student's t-test to compare stress differences between the models, with a significance level set at $p < 0.05$.

3. Results

3.1. Equivalent stresses on tibial plateau

Equivalent stresses at 16 points on the medial and lateral tibial plateaus were shown in Table 2. The results showed that the PEEK groups exhibited stress levels within the normal range (0.1–2.8 MPa), while the CoCr alloy groups displayed lower equivalent stresses in the anterolateral area of the tibial plateau (<0.1 MPa). Furthermore, the mean equivalent stresses on the tibial plateau were significantly higher in the PEEK groups than the CoCr alloy groups, irrespective of the presence or absence of osteoporosis (0.22 ± 0.07 MPa vs. 0.13 ± 0.06 MPa, $p < 0.01$; 0.39 ± 0.06 MPa vs. 0.17 ± 0.07 MPa, $P < 0.01$).

3.2. Equivalent stresses on proximal tibia

In non-osteoporosis models, the mean equivalent stress on (surface 1 and surface 2) was significantly higher in the PEEK group compared to the CoCr alloy group (0.29 ± 0.13 MPa vs. 0.21 ± 0.08 MPa, $p = 0.02$). However, no significant difference in stress level was observed on proximal tibia between the two materials in models with osteoporosis (0.19 ± 0.08 MPa vs. 0.17 ± 0.06 MPa, $p = 0.15$) (Table 3).

3.3. Stress shielding area

In non-osteoporosis models, the use of CoCr alloy implants resulted in larger stress shielding areas on the tibial plateau, surface 1, and surface 2 compared to PEEK implants (Fig. 2 and Table 4). In osteoporosis models, the extent of stress shielding was more pronounced with CoCr alloy implants than with PEEK alloy implants in tibial plateau (32.50% vs. 8.36%). However, no significant difference was observed on surface 1 and surface 2 between the two materials (15.88% and 16.12% vs. 16.88% and 15.87%).

3.4. Maximum stress in the tibial medullary cavity distal to the implant

The equivalent stress in the tibial medullary cavity distal to the implant were shown in Fig. 3. In non-osteoporosis models, the maximum equivalent stresses in the tibial medullary cavity distal to the implant were 1.43 MPa with the use of CoCr alloy implants and 0.67 MPa with the use of PEEK implants. In osteoporosis models, the maximum equivalent stresses in the tibial medullary cavity distal to the implant were 1.02 MPa with the use of CoCr alloy implants and 0.52 MPa with the use of PEEK implants.

4. Discussion

Despite being an emerging material in clinical application for knee implants, PEEK had shown promising results in preliminary clinical trials, exhibiting satisfactory short-term outcomes [18]. The present study extended the investigation into the biomechanical ramifications of PEEK implant utilization within TKA. Our findings elucidate a heightened stress response on the tibial plateau and proximal tibia with the adoption of PEEK, relative to the stresses encountered with CoCr alloy-based implants. However, a notable reduction in the area of stress shielding was observed on the tibial plateau and proximal tibia, indicating improved load transfer and potential preservation of bone integrity. Similar results were also observed on the tibial plateau in osteoporotic models, indicating the potential benefits of PEEK implants in these challenging cases. Nonetheless, the proximal tibia in osteoporotic models did not exhibit the significant reduction of stress shielding area as seen in non-osteoporotic models.

As the field of orthopedic surgery evolves, the quest for enhanced durability and functionality of joint implants remains paramount. The long-term efficacy of CoCr alloy implants in TKA has been extensively documented, showcasing their reliable performance over

Table 3
Equivalent stresses at 8 points on the proximal tibia (MPa).

		Surface 1				Surface 2				Mean	sd	p
		Point 1	Point 2	Point 3	Point 4	Point 1	Point 2	Point 3	Point 4			
Non-osteoporosis	CoCr alloy	**0.07***	0.25	0.25	0.27	0.10	0.29	0.17	0.26	0.21	0.08	**0.02****
	PEEK	0.12	0.38	0.40	0.47	0.11	0.28	0.21	0.33	0.29	0.13	
Osteoporosis	CoCr alloy	**0.08***	0.20	0.18	0.21	**0.09***	0.23	0.13	0.21	0.19	0.08	0.15
	PEEK	**0.07***	0.25	0.25	0.28	**0.08***	0.20	0.14	0.22	0.17	0.06	

The "*" means the equivalent stress was less than 0.1 MPa. The "**" means the results have significant statistical difference. Sd: standard deviation. Sd: standard deviation; CoCr: cobalt-chromium; PEEK: poly-ether-ether-ketone.

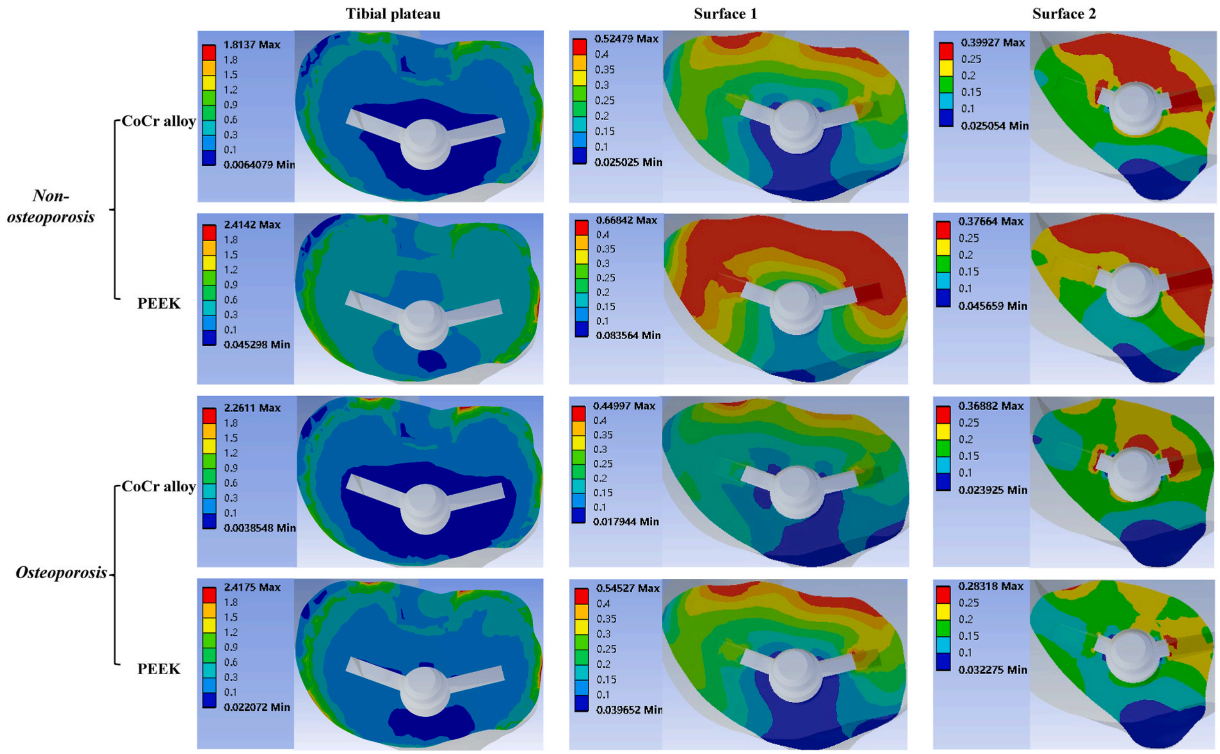

Fig. 2. Nephogram of equivalent stress distribution of tibial plateau and proximal tibia in each model. The blue areas represent stresses of less than 0.1 MPa.

Table 4
The percentage of the area with equivalent stresses less than 0.1 MPa to the tibial plateau or proximal tibia.

		Tibial plateau	Surface 1	Surface 2
Non-osteoporosis	CoCr alloy	23.47%	15.93%	10.71%
	PEEK	2.73%	1.37%	6.56%
Osteoporosis	CoCr alloy	32.50%	15.88%	16.12%
	PEEK	8.36%	16.88%	15.87%

CoCr: cobalt-chromium; PEEK: poly-ether-ether-ketone.

extended periods. A comprehensive systematic review and meta-analysis conducted by Evans et al. [19] revealed an impressive survival rate, with approximately 82% of TKA implants enduring up to a quarter-century. Further confirmation of these favorable statistics is found in the annual report of the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), which reported a 9.0% cumulative percent revision rate for primary TKA at 19 years after surgery [1]. Notably, implant loosening emerged as the principal factor in approximately one-quarter of all revision surgeries, underscoring its significance as a complication warranting further scrutiny. It is imperative to acknowledge, though CoCr alloy implants are associated with long-term success, the pursuit of perfection in TKA remains unceasing, with particular emphasis on combating implant loosening. The past decades have heralded the advent of robotic-assisted TKA, a technology poised to refine surgical precision, notably in implant alignment, a critical determinant of implant survivorship. Comparative analyses comparing robotic-assisted procedures with traditional surgical techniques have posited an advantage in favor of robotic assistance, yielding improved accuracy in component placement [20,21]. Nonetheless, the implications of such technological intervention on the long-term incidence of implant loosening are not yet fully delineated.

Traditional knee implants, particularly those made of CoCr alloy, exhibit a large difference in elastic modulus compared to human bone. This mismatch in modulus can lead to stress shielding, whereby the load is inadequately transmitted to the periprosthetic bone, resulting in bone resorption and potentially compromising the long-term stability of the implants [22]. Studies have shown significant bone resorption in well-fixed metal baseplate implants retrieved from patient's post-mortem after several years of service [23,24]. Although clinical failures were not observed at the time of patient death, the long-term implications of these bone losses on implant stability and future revisions cannot be overlooked. Tibial tray malalignment has been associated with abnormal medial-lateral force distribution, which can overload the bone-implant interface and the bone itself, exacerbating stress shielding and potentially leading to implant loosening [25].

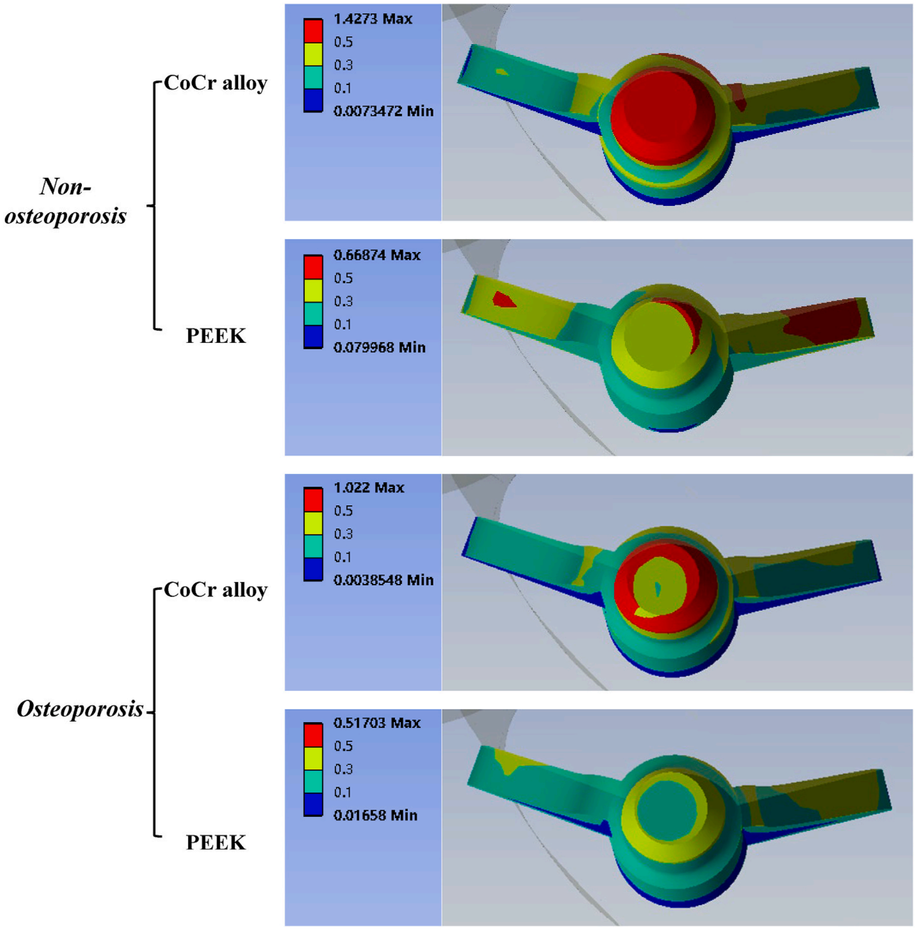

Fig. 3. Nephogram of equivalent stress distribution of distal cancellous bone of tibial implant in each model.

PEEK, a high-performance polymetric compound, has emerged as a leading biomaterial, displaying distinct advantages over metallic counterparts within the domain of orthopedic prosthetics. It is recognized for its reduced allergenic potential, lighter weight, enhanced fatigue resistance, and chemical inertness, properties that are particularly suited to the rigorous demands of orthopedic applications [26,27]. The utility of PEEK has been substantiated in the crafting of femoral components, total hip replacements, and hip resurfacing procedures [28]. Notably, PEEK femoral implants have been shown to attenuate peri-prosthetic stress shielding, a common biomechanical issue associated with implant-bone interactions [11]. However, the specific influence of PEEK tibial implant on stress response within the subjacent bone remained uncharacterized until now. In this study, we positioned the tibial component perpendicular to the mechanical axis of the tibia and analyzed the stress distribution patterns associated with CoCr alloy and PEEK tibial implants. The results demonstrated that CoCr alloy implants led to large areas of stress shielding at the anterior side of the tibial plateau. Conversely, the use of PEEK tibial implants significantly reduced the stress shielding area. These findings emphasize the potential of implant material selection to mitigate stress shielding effects and enhance long-term implant stability.

The present investigation provides a novel insight into the biomechanical performance of PEEK in the context of tibial implants. In our comprehensive analysis, we observed an increase in equivalent stress within the tibial plateau and proximal tibia under the placement of a PEEK implant, yet it simultaneously manifested a significant reduction in the extent of stress shielding within these crucial regions as compared to the conventional CoCr alloy implants. These observations are consistent with the documented benefits of diminished stress shielding phenomena gleaned from the deployment of femoral PEEK implants. Additionally, our study revealed that, in contrast to PEEK implants, CoCr alloy implants confer a higher equivalent stress within the tibial medullary cavity distal to the implant, suggesting localized stress concentration. In comparison, PEEK implants showcased a more favorable biomechanical phenomenon of stress dispersion and homogeneous load transmission.

Osteoporosis is characterized by a reduction in trabecular bone density and separation of the trabecular architecture, which diminishes the local mechanical support structure. Such alterations correlate with an increased susceptibility to structural impairment and bone resorption postoperatively, particularly in the context of stress exerted during TKA procedures [29,30]. In light of these observations, our study probes the biomechanical implications of implant material selection in osteoporotic conditions. Through the lens of osteoporotic tibial models, we have discerned distinct differences between the CoCr alloy and PEEK implants. The use of a CoCr alloy knee implant was associated with a more pronounced occurrence of stress shielding within the tibial plateau, suggesting a decrement in mechanical load bearing, which is crucial for maintaining bone density and strength. In contrast, the implementation of PEEK implants was linked with a tangible diminution of stress shielding, intimating improved mechanical load dispersion and a potential for enhanced postoperative bone integrity.

Given that the stress shielding area of the proximal tibia revealed no significant disparities between the two materials, the results of our investigation accentuate the relevance of implant composition on stress distribution within osteoporotic tibiae. The comparatively heightened incidence of stress shielding observed with CoCr alloy implants ratifies the urgency for an advanced mechanical assessment, aimed at reevaluating implant designs for this vulnerable patient population. On the converse, PEEK implants emerge as a propitious alternative, presenting a biomechanical profile that could favor better long-term orthopedic outcomes for those suffering from osteoporosis undergoing TKA. The reduced stress shielding associated with PEEK not only endorses its potential as a substitute for traditional metal alloys but also directs future research to elucidate the clinical ramifications of material selection in orthopedic implants.

This study has several limitations. Firstly, this study only compared the PEEK and CoCr alloy implants with a single design. Further studies should consider evaluating the impact of other prosthetic designs on stress shielding in TKA patients. Secondly, the models used in this study were based on a healthy young patient without any deformity. This may not accurately represent the factors present in real patients requiring TKA. However, we attempted to mimic the conditions in elderly patients by defining the model based on appropriate parameters such as bone elasticity modulus and Poisson's ratio. Thirdly, this study only considered the use of fixed platforms and did not investigate the influence of mobile platforms. The inclusion of different types of platforms could provide a more comprehensive understanding of their applicability and potential impact on stress shielding. Lastly, during the initial stage after TKA, the bone cement and tibial implant, as well as the bone cement and the tibia, are expected to maintain an ideal lock. While the connection conditions in this study were set as bonded, there may be micromovements between them. Despite these limitations, this study provides preliminary evidence supporting the potential use of PEEK knee implants in reducing stress shielding and improving load distribution in TKA patients.

5. Conclusions

This FEA study provides valuable insights into the potential of PEEK tibial components in reducing periprosthetic bone stress shielding in TKA procedures. Although increased the mean equivalent stresses, the findings suggest that PEEK implants have the capability to distribute loads more uniformly and maintain a closer approximation to physiological conditions. Further research, including clinical trials and imaging evaluations, is warranted to validate these findings and establish the long-term performance of PEEK knee implants.

Ethics approval and consent to participate

The radiographic results, according to the ethical guidelines of the Helsinki Declaration, were approved by the Human Ethics Committee of Honghui hospital (NO. 2021-008-001). Written informed consent was obtained from individual or guardian participants.

Data availability statement

Has data associated with your study been deposited into a publicly available repository?No. All data was included in article/supp. material/referenced in article.

CRediT authorship contribution statement

Guanghui Zhao: Writing – original draft, Methodology, Investigation. **Jing Luo:** Visualization, Software. **Jianbing Ma:** Writing – review & editing, Software. **Jianpeng Wang:** Writing – review & editing, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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