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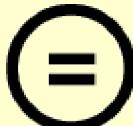
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Optimization of tibial stem geometry
in total knee arthroplasty using design of experiments:
a finite element analysis

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Optimization of tibial stem geometry in total knee arthroplasty using design of experiments: a finite element analysis

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ABSTRACT

Optimization of tibial stem geometry in total knee arthroplasty using design of experiments: a finite element analysis

Introduction: Total Knee Arthroplasty (TKA) relies on the stability of the tibial component, particularly the tibial stem, to prevent aseptic loosening, a major cause of TKA failure. Common tibial stem designs have improved implant stability but require further optimization to reduce stress shielding and bone resorption. This study uses Design of Experiments (DOE) to evaluate key design parameters, aiming to develop an optimized tibial stem that enhances long-term implant stability and patient outcomes.

Methods: The study employed the "Cylinder with wing" tibial stem design, enhanced with an anterior wing concept. A 3D finite element model of the knee was created from CT images of a 62-year-old female. Key design parameters—stem length, diameter, wing angle, and M/L ratio—were defined and analyzed. The DOE methodology was utilized to optimize these parameters, focusing on minimizing aseptic loosening and stress shielding.

Results: The study established boundaries for key design parameters and developed a new tibial stem model, which ranked competitively in both minimum principal stress and strain energy compared to conventional models. DOE screening identified stem diameter and length as dominant factors, leading to further optimization. The final optimized model, with a stem diameter of 12mm, length of 40mm, M/L ratio of 0.61, and wing angle of 60°, demonstrated a significant improvement in performance.

Conclusion: The study identified stem diameter as a more critical factor than stem length in reducing stress shielding and aseptic loosening. The exclusion of the wing angle and anterior wing from further optimization was supported by their minimal impact on biomechanical performance. This optimized design effectively addresses the trade-offs between key factors, enhancing the long-term success of TKA implants.

Key words : tibial stem geometry, aseptic loosening, stress shielding, design of experiments, finite element analysis

1. INTRODUCTION

TKA is a widely performed surgical procedure aimed at alleviating pain and restoring function in patients suffering from severe knee joint disorders, such as osteoarthritis¹. The long-term success of TKA largely depends on the stability and durability of the tibial component, particularly the tibial stem, which is a critical element in the overall prosthesis design². Tibial stems serve to enhance the fixation of the tibial baseplate to the bone, thereby reducing the risk of aseptic loosening—a leading cause of TKA failure³.

Various tibial stem designs have been employed to address the challenges associated with TKA, with the two most common being the "cross-shaped" and "cylinder with wing" designs. While these designs have been successful in improving implant stability, there remains a significant need to optimize these designs further to minimize stress shielding and bone resorption while ensuring the long-term stability of the implant. In particular, the "cylinder with wing" design has gained widespread clinical use due to its balance of mechanical stability and ease of implantation. However, the biomechanical implications of various design parameters within this configuration are not fully understood, necessitating a systematic approach to design optimization.

In this study, we employ DOE methodology to systematically investigate the effects of key design parameters on the biomechanical performance of the tibial stem in TKA. The parameters analyzed include stem length, stem diameter, wing angle, and the addition of an anterior wing, which is a novel design feature inspired by the cross-shaped design. By conducting a series of DOE-based simulations and analyses, we aim to identify an optimized tibial stem design that achieves a balance between minimizing stress shielding and reducing the risk of aseptic loosening.

The findings from this research are expected to contribute to the development of more effective tibial components for TKA, potentially improving patient outcomes and extending the lifespan of the prosthesis. Ultimately, the optimized tibial stem design derived from this study could lead to a significant advancement in the field of orthopedic implant design.

2. METHODS

2.1. Conventional design analysis

There were two common types of stem design which are ‘Cross shape’ and ‘Cylinder with wing’ type among conventional TKA (Fig. 1). In this study, ‘Cylinder with wing’ design, more commonly used in the surgery, was selected. Also, we apply anterior wing concept from cross shape type.

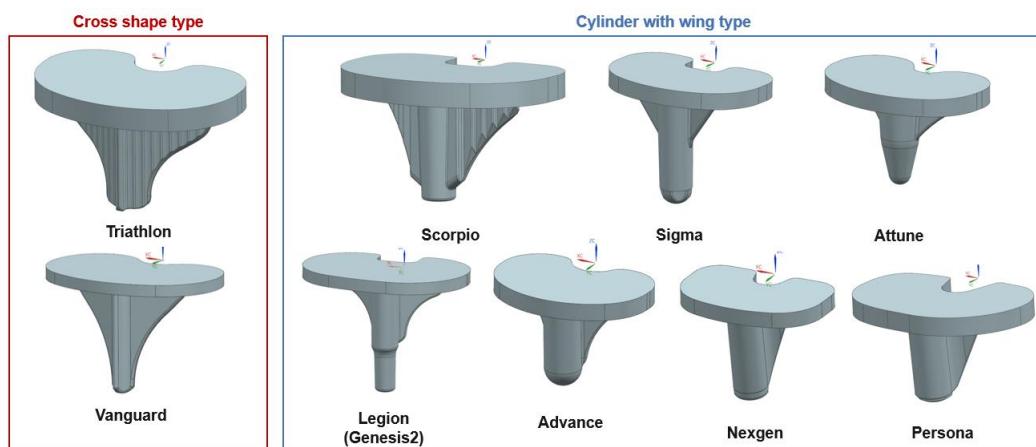


Fig. 1 Types of stem design: Cross shape type versus Cylinder with wing type.

In this study, the following design parameters in Fig. 2 were defined for tibia stem design, and each design parameter of commercial TKA implant products (Scorpio, Triathlon, Sigma, Attune, Vanguard, Genesis 2, Advance, Nexgen, Persona) were analyzed. From analysis, generic model that has four parameters (stem length, stem diameter, wing angle, stem M/L ratio) was created. Anterior wing concept added as a new parameter as three levels (none, half, full).

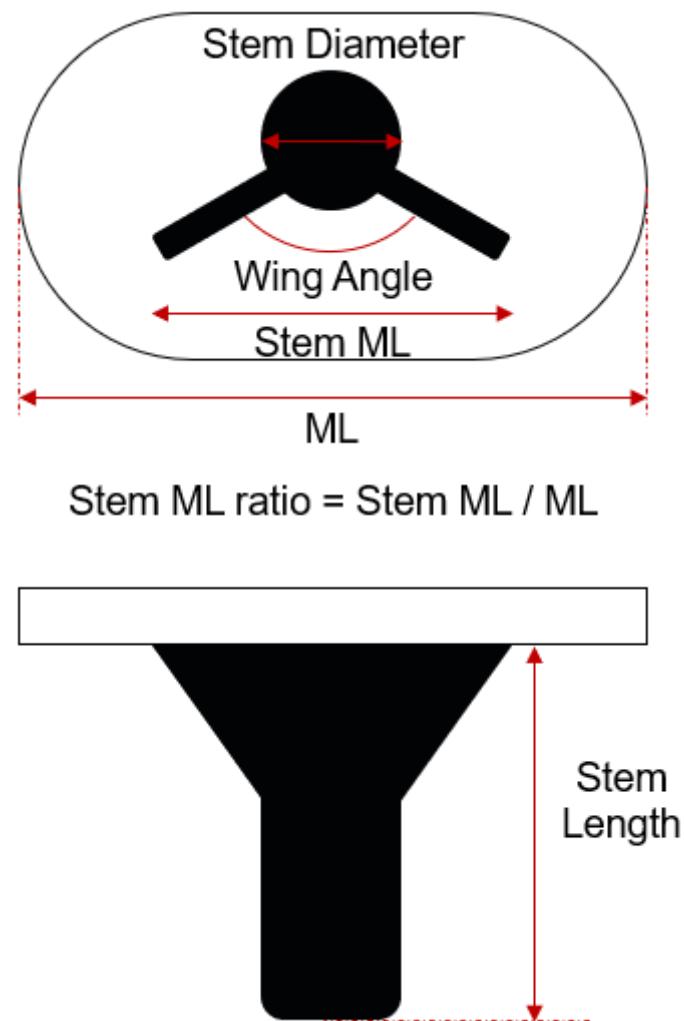


Fig. 2 Definition of design parameter for the stem design of conventional TKA implants.

ML Mediolateral, TKA Total Knee Arthroplasty

2.2. Intact model

Three-dimensional (3D) geometry of a linear finite element (FE) model of the knee was constructed based on the computed tomography (CT) images of a 62-year-old Asian female. The contours of the tibia were reconstructed from CT images using the commercially available software Mimics 17.0 (Materialise Ltd., Leuven, Belgium). CT images were obtained using a 64-channel CT

scanner (Somatom Sensation 64; Siemens Healthcare, Erlangen, Germany). CT was performed with 0.1-mm slice thicknesses. The study protocol was approved by our institutional review board.

2.3. Material properties

Material properties of Cortical bone, Cancellous bone and tibial tray and were used from literature. Though we use CoCr for tibial tray, use of titanium will have a same tendency of result cause our FEM model is linearly elastic. The material properties used in this study are listed in Table 1.

Table 1. Material properties

Material	Elastic modulus (MPa)	Poisson's ratio
Cancellous bone⁴	-	449
Cortical bone⁵	-	15,250
Tibial tray⁴	CoCr	210GPa

Mpa Megapascals

2.4. Loading & boundary conditions

In this study, three loading conditions were included: two for the validation of the FE model and one for model predictions for clinically relevant loading scenarios. First, the walking loading conditions from our previous study were applied to validate the FE model⁴. Second, the FE model was validated by applying stand-up loading conditions corresponding to activities of daily living for a 0° flexion angle of the knee⁶. Third, a compressive loading condition corresponding to clinical relevance was used to evaluate the effect of the three stem lengths on various bone defects. Each bearing forces (lateral:870N, medial:1160N) were applied, considering that three times the load was applied in the late stance phase when a 70 kg adult walks. The compressive load on the tibial base is shown in Fig. 3. The distal end of the tibial bone is fully constrained.⁴

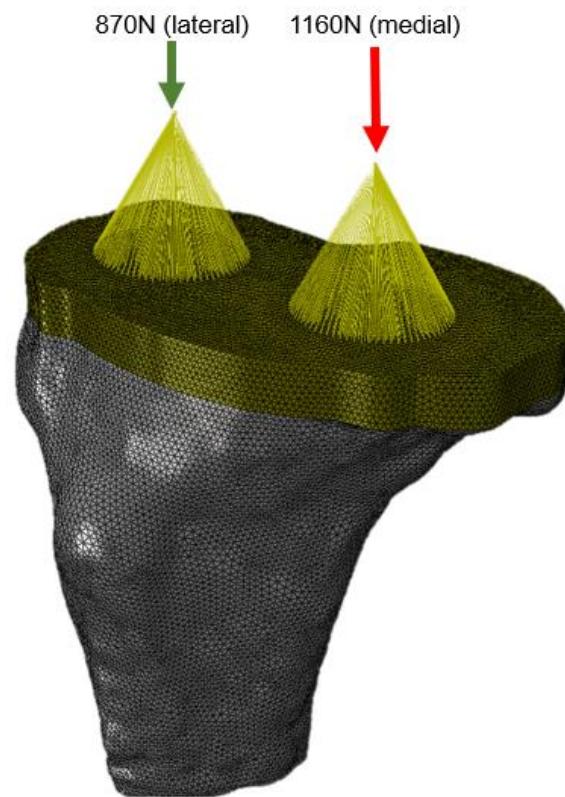


Fig. 3 Loading conditions in the study. Lateral (870N) and medial (1160N) bearing forces applied, reflecting three times body weight load in late stance phase of a 70 kg adult.

2.5. Mesh convergence

The convergence of the FE model was investigated. Mesh convergence was defined as the maximum displacement on trabecular bone were within 95% of the pressure of the next two smaller mesh sizes.⁷ This criteria were met by a mesh size of 0.5 mm on stem region, 0.8mm on stem-around region and 1.0 mm on other region.

2.6. Finite element model

The bone models were imported into commercial CAD software (SolidWorks 2021, Dassault Systèmes, France) and were appropriately positioned using surgical techniques. The FE

model was generated using Hypermesh 11.0 (Altair Engineering, Inc., Troy, Michigan). and analyzed using ABAQUS (version 6.11; Simulia, Providence, RI, USA), and the following surgical techniques were applied to the FE model. The stress and strain distributions on the trabecular bone depend on the position and shape of the cortical bone. The tibial axis was defined as the connection between the center of the tibial plateau and the center of the sphere that fits the talocrural joint. The proximal tibia was cut perpendicular to the tibial shaft with a posterior slope of 5° , and the cutting level was set at 8 mm from the highest side of the tibial plateau (all lateral condyles in this study, Fig. 4). During implant insertion, the anteroposterior position was aligned with the anterior border, and the mediolateral position was positioned in the middle. The rotation of the tibial components was aligned to the line between the center of the posterior cruciate ligament footprint and the medial third of the tibial tubercle. For equivalent ML length of tibial plate, all conventional model's ML length was changed to 68mm (only for significant difference, change stem ML length either). The same insertion protocol was applied to all models.

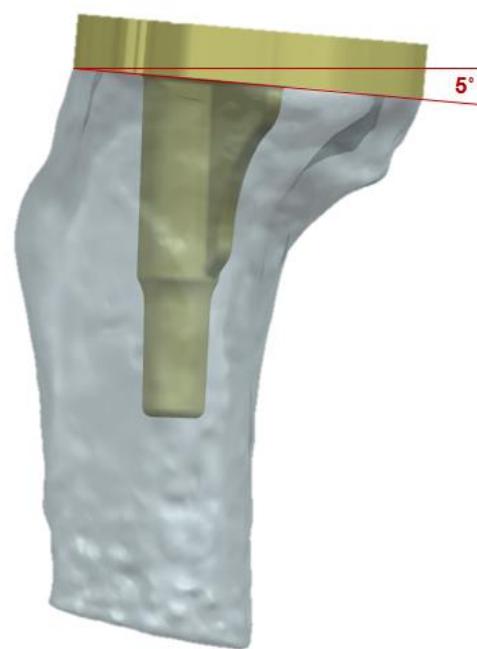


Fig. 4 Tibia-component-implanted 3D model for TKA
TKA Total Knee Arthroplasty

2.7. Design of experiments (DOE)

Design parameters and level were determined in this study. Design of experiment was conducted using orthogonal arrays. We performed DOE 3 times to define the design parameters.

2.8. Criteria for design optimization

There can be two significant factors to evaluate performances of tibia stem, aseptic loosening and stress shielding. We classified each factor according to the short- and long-term effects as follows; aseptic loosening (short term) and stress shielding (long term). In a view of aseptic loosening, minimum principal stress was used as a criterion to follow literature. In a view of stress shielding, strain energy was used as a criterion to follow literature.⁸

To optimize two responses with a trade-off relationship, we define multi-objective responses using weight and normalization. In addition, the weight factor of minimum principal stress, related aseptic loosening loosening, was 0.7 because we considered early failure more seriously.^{2, 9-11} The objective function in DOE 2 and DOE 3 for optimization was set as follows.^{12, 13}

$$\text{response} = 0.7 * \frac{x1 - PMiPS_{min}}{PMiPS_{max} - PMiPS_{min}} + 0.3 \frac{x2 - SE_{min}}{SE_{max} - SE_{min}}$$

$x1$: The current value of minimum principal stress (PMiPS), which is associated with aseptic loosening.

$x2$: The current value of strain energy (SE), which is linked to stress shielding.

$PMiPS_{min}$ and $PMiPS_{max}$: Minimum and maximum values of the principal stress in the data set.

SE_{min} and SE_{max} : Minimum and maximum values of the strain energy in the data set.

Finite element models were assessed of which conventional tibial plate and minimum principal stress and strain energy were calculated.

3. Results

3.1. Conventional design analysis

Using dimensions of Conventional TKA, we set boundaries in stem length, stem diameter, wing angle as shown in Table 2. We have created new stem model within these boundaries to ensure safety.

Table 2. Dimensional boundaries for design parameters of tibia stem

	Lower limits	Upper limits
Stem length (mm)	23.4	50.3
Stem diameter (mm)	11.5	19.8
Wing angle (°)	67.3	90
Stem ratio	0.53	0.73

Comparison between base model and conventional tibia in minimum principal stress was conducted and base model was ranked 6 within 10 models in minimum principal stress rank. Comparison between base model and conventional tibia in strain energy was conducted and base model was ranked 2 within 10 models in strain energy rank. Therefore, we considered that our base model was competitive.

3.2. DOE 1 – screening

Stem diameter and stem length were dominant variables for each response. Wing angle has significant different only on strain energy. Therefore, wing angle was excluded for further DOE. There was trade-off relationship between two responses of dominant parameters (stem diameter, stem length, Fig. 5)

Table 3. Design parameters and levels for DOE 1

Parameter	Level			Explanatory
Stem diameter	12	14	16	Within conventional boundaries
Stem length	40	45	50	Within conventional boundaries
Wing angle	60	75	90	Within conventional boundaries
anterior wing	modeled	half	none	Within conventional boundaries
M/L ratio	0.68			Within conventional boundaries

DOE 1 Design of Experiments 1, M/L ratio Mediolateral ratio

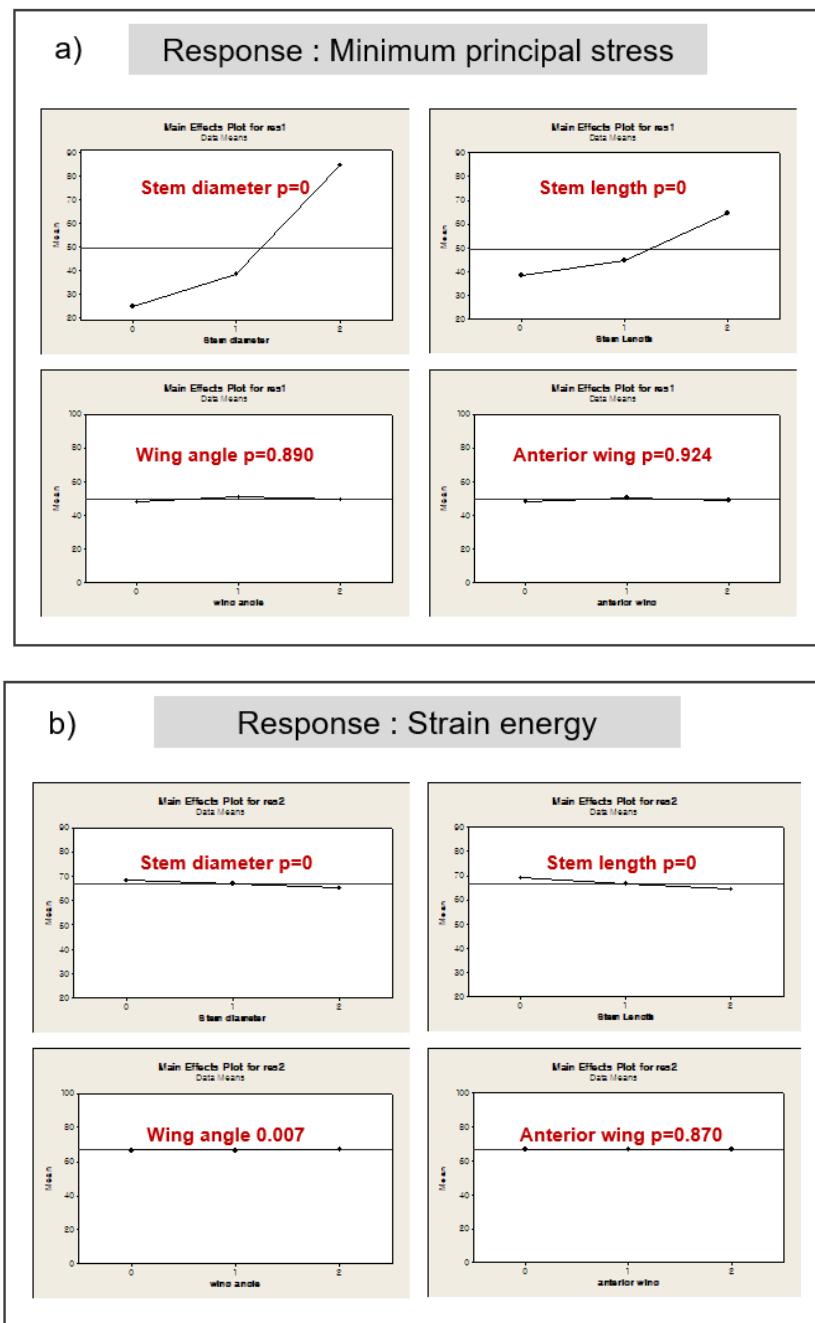


Fig. 5 Response by design parameter in DOE1: a) minimum principal stress b) strain energy
DOE 1 Design of Experiments 1

3.3. DOE 2 – stem length and stem diameter

In Fig. 6, there was no significant effect of stem length on response that a value was determined in case of minimum responses and there was significant effect of stem diameter on response that we decided further DOE.

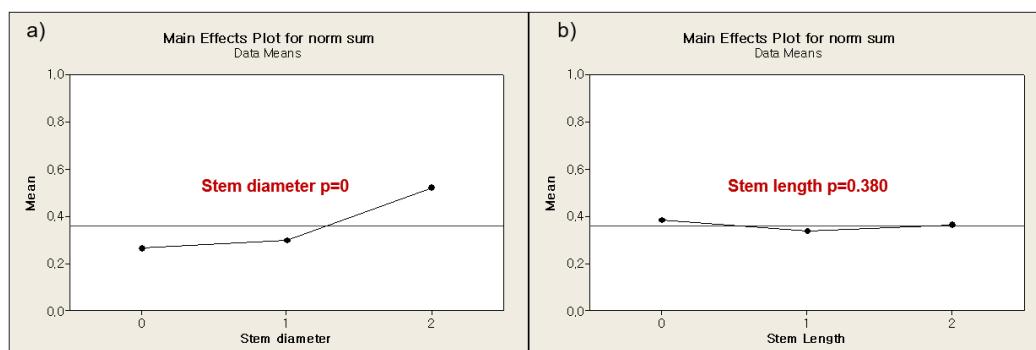


Fig. 6 Multi-objective response by a) by stem diameter b) stem length

Table 4. Design parameters and levels for DOE 2

Parameter	Level	Explanatory
Stem diameter	12 13 14 15 16	Within conventional boundaries
Stem length	45	Minimum response
Wing angle	60	Minimum response
anterior wing	none	Minimum response
M/L ratio	0.68	Within conventional boundaries

DOE 2 Design of Experiments 2, M/L ratio Mediolateral ratio

In Fig. 7, third order polynomial regression curve was calculated using RMSE approach (R-square=0.9949). Regression curve validation was conducted in a point near optimum value. The difference between real and estimated value was 0%. The response of the optimized model with diameter 12 was 25.6% improve than the base model shown in Table 5.

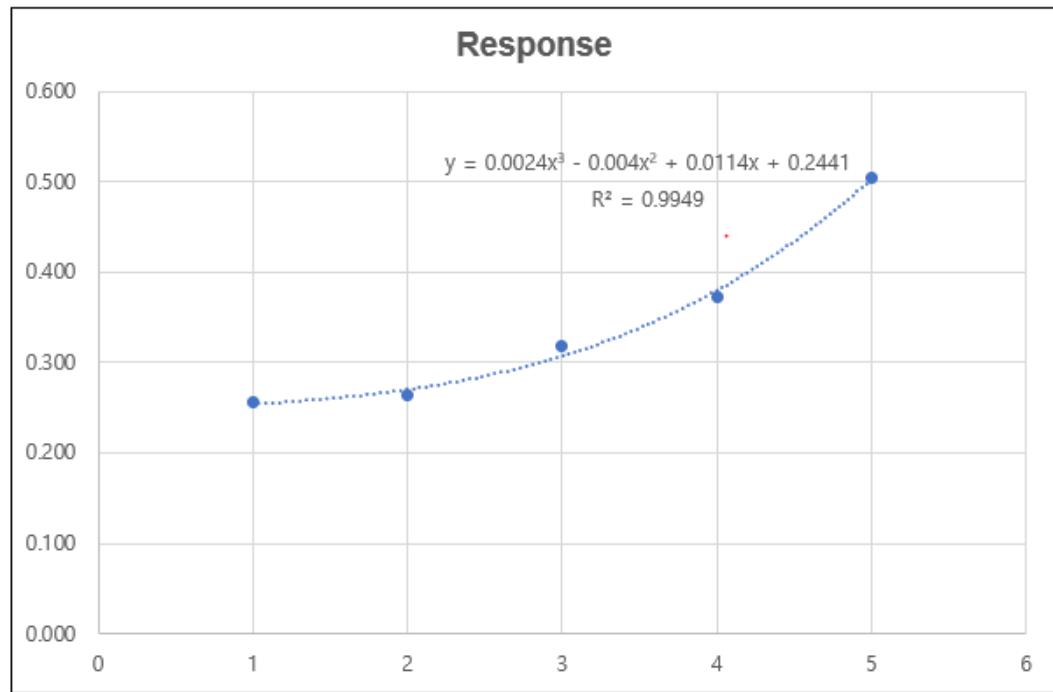


Fig. 7 Regression curve for DOE 2

DOE 2 Design of Experiments 2

Table 5. Validations results of DOE 2

Validation			
Diameter	Real	Estimated	Error
12.5	0.261	0.260	0%

DOE 2 Design of Experiments 2

Table 6. Comparison for the multi-objective response of base model and optimized model in DOE 2

Multi-objective response	
Base model	Optimized model

0.33	0.256
------	-------

DOE 2 Design of Experiments 2

3.4. DOE 3 – M/L ratio

In a view of bone preservation (minimal bone resection), further DOE was conducted. There were no significant effect of Stem length and M/L ratio on response. Stem length 40 and M/L ratio 0.61 was determined as a minimal bone resection. Analysis of variance for multi-objective using two parameters, stem length and M/L ratio, was conducted and each p-values of parameters were 0.857 and 0.723, respectively.

Table 7. Design parameters and levels for DOE 3

Parameter	Level	Explanatory
Stem diameter	12	Minimum response
Stem length	40	Minimum resection (no significant different)
Wing angle	60	Minimum response
anterior wing	none	Minimum response
M/L ratio	0.61	Minimum resection (no significant different)

DOE 3 Design of Experiments 3, M/L ratio Mediolateral ratio

3.5. Final model

Finally, design parameter was determined as follows: stem diameter 12mm, stem length 40mm; stem M/L ration 61% and stem wing angle 60°. Optimized model was analyzed using FEA. And optimized model has smaller M/L ratio, stem diameter which minimize bone resection. In addition, the final model had a low response, indicating that both of the two main factors, aseptic loosening and stress shielding effecting tibia stability of TKA, were satisfied to good performance. Below table shows rank of M/L ratio, Stem diameter, Response.

Table 8. Verification of the final model: rank of M/L ratio

Rank	Product	M/L ratio
1	<i>Persona</i>	0.53
2	<i>Sigma</i>	0.55
3	<i>Nexgen</i>	0.56
4	<i>Advance</i>	0.58
5	<i>Opt model</i>	0.61
6	<i>Attune</i>	0.63
7	<i>genesis2</i>	0.63
8	<i>Vanguard</i>	0.68
9	<i>Scorpio</i>	0.69
10	<i>Triathlon</i>	0.73

M/L ratio Mediolateral ratio, Opt model Optimized model

Table 9. Verification of the final model: rank of stem diameter

Rank	Product	Stem diameter
1	<i>Scorpio</i>	11.5
2	<i>Opt model</i>	12
3	<i>genesis2</i>	12.2
4	<i>Sigma</i>	13.4
5	<i>Persona</i>	14.5
6	<i>Advance</i>	15.2

7	<i>Nexgen</i>	<i>15.3</i>
8	<i>Attune</i>	<i>19.8</i>

Opt model Optimized model

Table 10. Verification of the final model: rank of response

<i>Rank</i>	<i>Product</i>	<i>Response</i>
1	<i>Sigma</i>	<i>0.163</i>
2	<i>Opt model</i>	<i>0.256</i>
2	<i>Advance</i>	<i>0.256</i>
4	<i>Attune</i>	<i>0.347</i>
5	<i>Vanguard</i>	<i>0.374</i>
6	<i>Genesis2</i>	<i>0.377</i>
7	<i>Scorpio</i>	<i>0.387</i>
8	<i>Triathlon</i>	<i>0.503</i>
9	<i>Nexgen</i>	<i>0.506</i>
10	<i>Persona</i>	<i>0.596</i>

Opt model Optimized model

4. Discussion

The optimization of the tibial stem design in TKA is crucial for enhancing implant stability, reducing stress shielding, and minimizing the risk of aseptic loosening. This study systematically investigated the effects of various design parameters using the DOE methodology to identify an optimized tibial stem configuration.

During knee movement, flexion and extension occur within the sagittal plane, accompanied by additional femoral external rotation and roll-back on the tibia during flexion.¹⁴⁻¹⁶ These movements generate forces such as compression, tension, axial torque, varus/valgus moments, and shear, all of which must be resisted by the components of a TKA to ensure stability.¹⁷ To mitigate these forces at the interface between the tibial component and the proximal tibia, projections like stems, pegs, or keels/wings can be integrated into the underside of the tibial component (Fig. 1). These projections help reduce shear forces and axial displacement (lift-off) caused by varus-valgus moments.¹⁸ Stems also limit micromotion at the bone/cement interface, thereby reducing the risk of aseptic loosening.¹⁹ However, the presence of a stem introduces new shear forces between the stem and the proximal tibia. In this study, to implement the optimized model, four parameters were screened in DOE1 to measure their responses in terms of minimum principal stress and strain energy. The results from DOE 1 indicated that stem diameter and length are dominant factors influencing both the minimum principal stress and strain energy. The optimization process in DOE 2 showed that a smaller stem diameter (12 mm) combined with a stem length (40 mm) with the minimum amount of bone resection produced favorable outcomes in terms of both stress shielding and aseptic loosening. The regression analysis further validated these findings, demonstrating that the optimized model significantly outperforms the base model in multi-objective responses, with improvements in stress distribution and strain energy. As a key difference from previous studies⁵, in DOE 2 there was no significant effect of stem length on response that a value was determined in case of minimum responses and there was significant effect of stem diameter on response that we decided further DOE. This is likely because, under the optimized model conditions, variations in stem diameter have a more significant impact on stress shielding and other related responses compared to changes in stem length.

Stems enhance the stiffness of the tibial construct and offer resistance to bending.^{20, 21} When tibial stems are sufficiently long, they engage the cortical bone as the metaphyseal flare tapers into the

diaphysis. This engagement is more pronounced in press-fit stems, which are designed for bone ongrowth or ingrowth, compared to long stems with a smooth or polished surface. This configuration directs load directly from the stem to the cortical bone, causing stress to concentrate in this area and leading to stress shielding of the proximal metaphysis.²¹ Even without direct cortical contact, the length of the stem correlates with the extent of stress shielding that occurs.²² This stress shielding reduces bone density in the unloaded regions, increasing the risk of implant subsidence (tibial migration), loosening, and periprosthetic fractures. Another potential downside of longer stems is pain at the implant tip, where stress concentration happens.²³ In primary TKA with short-stem designs, load transfer and stress shielding are influenced by the implant's geometry, material, tibial coverage, and the use of cement. Previous studies have predominantly focused on analyzing the impact of stem length on the outcomes of tibial constructs, as mentioned above. However, in this study, we developed a new response model by assigning different weight values to key factors influencing early and late failures after TKA. Specifically, minimum principal stress was identified as a critical factor in early failure, while strain energy was linked to late failure. This approach provided a new perspective, suggesting that in addition to stem length, stem diameter should also be considered when evaluating tibial geometry.

Contrary to initial expectations, the wing angle had a minimal impact on biomechanical responses, leading to its exclusion from further optimization stages. Similarly, the anterior wing design, inspired by the cross-shaped configuration, did not significantly reduce the minimum principal stress, indicating that its inclusion may not be necessary in the final design.

The DOE 3 analysis focused on minimizing bone resection by varying the M/L ratio and stem length. The findings revealed that there were no significant effect of stem length and M/L ratio on response. The final model, with a stem length of 40 mm and an M/L ratio of 0.61, was determined to achieve minimal bone resection while maintaining mechanical stability. This configuration effectively balances the need to preserve bone stock during implantation with the necessity of ensuring sufficient implant stability to prevent complications like aseptic loosening and stress shielding. The study found that reducing both the M/L ratio and stem length minimized bone resection without compromising the mechanical integrity of the implant, making it an ideal choice for enhancing long-term outcomes in TKA. Research on the M/L ratio of tibial stems in knee replacement surgery is somewhat limited, but it is a relevant factor in optimizing implant design and stability. The M/L ratio, which refers to the width of the stem relative to the width of the tibial component, plays a

significant role in ensuring proper load distribution and reducing the risk of stress shielding or implant migration.⁵ Several studies have touched on aspects of tibial stem design, including length, diameter, and surface finish, which all interact with the M/L ratio to influence the biomechanics of the implant. A balanced M/L ratio is important for maintaining stability, especially in cases where the tibial bone structure is compromised, such as in patients with osteoporosis or large bone defects. A well-chosen M/L ratio can help in achieving better alignment and fixation, thereby reducing the risks of loosening or subsidence.²⁴ While specific studies on the M/L ratio alone are scarce, related research indicates that this parameter, along with stem length and diameter, needs careful consideration during the design and selection of implants to ensure long-term success in TKA. Additionally, while this study primarily focused on primary TKA, it is important to consider its implications for revision surgeries. Revision TKA presents unique challenges due to bone loss and the need for more robust fixation. The findings from this study, particularly regarding the significance of stem diameter in stress distribution, could inform future research aimed at optimizing tibial stems specifically for revision procedures. Further studies are warranted to evaluate how the optimized design might perform under the more demanding conditions of revision TKA, where additional fixation methods and stem modifications may be required to address the complexities of bone quality and implant stability.

This study also has several limitations. First, the exclusion of bone-cement interface from this study represents a significant limitation, as the interaction between bone and cement plays a critical role in the overall stability and long-term success of implants. The lack of consideration for this factor may lead to an incomplete understanding of the biomechanical behavior of the tibial stem, potentially affecting the generalizability of the findings to clinical settings where cemented fixation is commonly used.⁵ Future research should incorporate bone-cement interference to provide a more comprehensive analysis of implant performance under realistic conditions. Second, in this study the previously verified normal knee joint model (62-year-old Asian female) was used to implant the TKA prosthesis for calculation and analysis. If the knee models of end-stage osteoarthritis or other deformity were also selected for finite element analysis of TKA prosthesis implantation, the analysis results could have yielded results in more diverse situations. Third, because the analysis was conducted in a controlled experimental setting, the results may vary when applied to in-vivo conditions, where host and surgical factors are involved. For example, stress shielding might also be influenced by the specific bone quality of the patient around the implant. Lastly, the most

important aspect to consider in this study is the subjectivity of the weight setting. The weight factors (0.7 for minimum principal stress in early failure and 0.3 for strain energy in late failure) are determined based on the researcher's subjective judgment of the importance of each factor. If the weight is not appropriately balanced, it may lead to suboptimal results in other criteria, such as long-term stress shielding. Also trade-off management in response formula combines both objectives into one, which can oversimplify the relationship between the conflicting goals. There could be cases where improving one objective (e.g., reducing aseptic loosening) significantly worsens the other (e.g., increasing stress shielding), but this isn't always clearly captured by a simple weighted sum. In conclusion, while the formula effectively captures the trade-off between early failure and long-term implant stability, the limitations regarding subjectivity in weighting and potential oversimplification of complex relationships should be carefully considered.

5. Conclusion

Optimizing the tibial stem design in TKA to enhance implant stability, reduce stress shielding, and minimize the risk of aseptic loosening. The study systematically evaluated various design parameters using the DOE methodology. Stem diameter and length were identified as critical factors influencing minimum principal stress and strain energy. The optimized model features a stem diameter of 12 mm, a stem length of 40 mm, an M/L ratio of 0.61, and a stem wing angle of 60°. This configuration minimizes bone resection while maintaining mechanical stability, balancing the preservation of bone stock with sufficient implant stability to prevent complications. Contrary to initial expectations, stem length had less impact on response than stem diameter. The wing angle had minimal impact on biomechanical responses, leading to its exclusion from further optimization stages. Similarly, the anterior wing design, inspired by a cross-shaped configuration, did not significantly reduce minimum principal stress. Overall, the optimized tibial stem design developed through this study demonstrates improved performance by effectively managing the trade-offs between aseptic loosening and stress shielding, contributing to the long-term success of TKA implants.

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versus Standard Configuration in Total Knee Arthroplasty: A Biomechanical Assessment According to Bone Properties. *Medicina*. 2022;58(5):634.

Abstract in Korean

실험계획법을 적용한 인공 슬관절 전치환술에서의 경골 주대 형태의 최적화 : 유한요소해석

서론: 슬관절 인공관절 전치환술에서는 무균성 해리를 방지하기 위해 경골치환물 주대의 안정성에 중점을 두고 있다. 경골 주대의 형태는 통상적으로 치환물의 안정성을 개선하는 방향으로 고안되었지만, 응력 차폐 및 골 흡수를 줄이기 위한 추가적인 최적화가 필요하다. 본 연구는 실험 계획법을 활용하여 주요 설계 매개변수를 평가하고, 장기적으로 치환물의 안정성과 환자 결과를 향상시키는 최적의 경골 주대 형태를 개발하고자 하였다.

방법: 본 연구에서는 전방의 개념이 추가된 "양익 원통형" 경골 주대 설계를 사용하였다. 또한 아시아인 62세 여성의 CT 영상을 기반으로 무릎의 3D 유한 요소 모델을 생성하였다. 주대 길이, 직경, 날개 각도, 경골치환물 직경 대비 주대 직경 비율과 같은 주요 설계 매개변수의 정의와 분석을 통해 무균성 해리 및 응력 차폐를 최소화하는 데 중점을 두고 실험 계획법을 활용하여 매개변수를 최적화하였다.

결과: 주요 설계 매개변수의 범위를 설정하고, 기존 상용 치환물들과 비교하여 최소 주응력 및 변형 에너지에서 경쟁력 있는 값을 가지는 새로운 경골 주대 모델을 고안하였다. 실험 설계법을 활용한 선별검사를 통해 주대 직경과 길이가 주요 요인으로 확인되었으며, 이를 기반으로 최적화를 진행하였다. 최종 최적화 모델은 주대 직경 12mm, 길이 40mm, 경골치환물 직경 대비 주대 직경 비율 0.61, 날개 각도 60°로 예측되었다.

결론: 응력 차폐 및 무균성 해리를 줄이는 데 있어 주대 직경이 주대 길이보다 중요한 요인임을 확인하였다. 날개 각도와 전방의 개념은 생체역학적 결과에

미치는 유의미한 영향이 없었다. 최적화된 설계는 주요 요인 간의 균형된 트레이드-오프를 통해 슬관절 인공관절 전치환술 치환물의 장기적인 결과 향상을 얻을 수 있을 것으로 생각된다.

핵심되는 말 : 경골 주대 형태, 무균성 해리, 응력 차폐, 실험 계획법, 유한요소해석