Abstract: A posterior stabilized type of total knee replacement (TKR) device was used to assess the impact of material of tibial tray and varying posterior tibial slopes on the periprosthetic bone region. Two type of tray material viz. all-polyethylene (AP) metal-backed (MB) and four posterior tibial slopes (0°, 3°, 5° and 7°) were considered in a subject-specific finite element full tibia bone model. The strain responses in periprosthetic bone region due to tibial material and over the length of tibial tray keel was investigated under peak axial loads of walking and stair descending/ascending. The anticipated increment in bone density owing to implantation for the cases considered was additionally displayed. The impact of stress shielding on the periprosthetic bone was found to be more fundamentally affected by the material used than its geometry. Considerably higher stress shielding was observed in MB cases than on its AP equivalent, especially in the region underneath the baseplate. Hence, the effect of material is found to have greater impact on the regions assessed than the posterior tibial slopes considered.

Subjects: Biomaterials; Biomechanics; Joint Replacement

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PUBLIC INTEREST STATEMENT
Total knee replacement is the most common surgical treatment for acute knee pain. Each surgical procedure is unique since each patient’s knee joint damage is different both qualitatively and quantitatively. Factors such as knee condition prior to surgery play a crucial role during surgical planning and the variables to be considered at the time of joint replacement. One such factor is the tibial slope of knee. This article compares the various tibial slopes of the knee and its effect on stress and strains generated in the bone. Understanding these effects prior to surgery leads to better planning and the life of implants, post-surgery. Exploration of various factors gives a clear idea to the surgeon regarding operative variables to be considered for better patient satisfaction and reduce the need for revision surgery.
1. Introduction
Total knee arthroplasty (TKA) is the most effective and successful intervention (Saleh, Santos, Ghomrawi, Parvizi, & Mulhall, 2006) for knee osteoarthritis, with various types of implant types used over the years with a good success rate. TKA reduces pain in the knee and assists in restoration of its mobility in an arthritic knee (Yassin et al., 2015). The essential goal of TKA is to reduce knee joint pain and maintain the range of motion to assist in the patients’ ability to perform daily activities. With advancements in modern day technology, success of TKA is evaluated based on knee kinematic scores and extended range of motion. However, owing to premature implant failure due to poor results post-TKA, revision surgeries may be required. It has been widely reported in studies that more than 20% TKA failures were due to malposition and malalignment which can be evaded with careful surgical technique (Abdel et al., 2014). Changes in contact kinematics has been found to be the main factor causing wear in TKA, further leading to necessity of revision surgery (Zimmerman, Miller, Cleary, Izant, & Mann, 2016). Furthermore, loosening of components, often starting from the tibial surface also is an equally critical mode of failure initiation (Song et al., 2017).

Posterior tibial slope (PTS) is defined as the posterior inclination of the tibial plateau, in patients undergoing TKA. It influences the kinematics of the knee and the postoperative stability of cruciate-retaining (CR) and posterior stabilized (PS) knees in both the sagittal and coronal planes, in turn impacting the flexion angle of the knee (Nedopil, Howell, & Hull, 2017). PTS on the tibial surface created during resection of tibia in TKA has been considered as an important factor effecting the kinematics of knee post-TKA (Kaper, Smith, Bourne, Rorabeck, & Robertson, 1999). Reflecting its significance, the PTS was adopted by the American Knee Society to evaluate the tibial component sagittal alignment. Loosening of posterior cruciate ligaments may occur due to excessive tibial slope, hence there exists an understanding of an optimal tibial slope to be considered prior to TKA, without which the range of motion may be hampered leading to stiffness in the knee (Kelly & Clarke, 2002). An ideal tibial slope of 3°–9° have been previously reported in other studies (Lee, Kim, Kang, Kim, & Park, 2012; Schnurr, Eysel, & König, 2012). However, the extent of tibial slope may vary based on patient needs, age group and ethnicity (Grupp et al., 2017).

Anterior cruciate ligament along with posterior one, bilateral collateral ligaments and other soft tissues in the knee assist in maintaining the normal knee dynamic balance (Nicoll & Rowley, 2010). The regular knee kinematic patterns change post-TKA leading to a new dynamic knee balance (Garling, Kaptein, Nelissen, & Valstar, 2007). Gap balancing is also considered to be an important issue during TKA. This can be achieved by balancing of the soft tissues to yield a rectangular gap tension between the lateral and medial sides and maintaining equal gap lengths during flexion-extension (Suero et al., 2015). In case of cruciate retaining TKA, tight flexion gaps occur in seldom, which leads to impeded knee range of motion due to tightness if posterior cruciate ligament (Eisenhuth, Saleh, Cui, Clark, & Brown, 2006). Alternately, in posterior stabilized (PS) type of TKA, removal of the posterior cruciate ligament leads to increase in flexion gap by 7–10 m, thereby assisting in maintaining the balance between flexion-extension gaps (Kelly & Clarke, 2002). Flexion gap maintenance is perceived to be largely assisted using a reduced posterior tibial slope, mainly in PS type of TKA. Many surgeons have confidence in the fact that PTS in TKA has a positive effect on the postoperative knee flexion angles. A few experimental studies proposed that PTS helped in knee flexion enhancement prior to tibiofemoral impingement occurrence (Collier, Engh, McAuley, & Engh, 2007) and leads to reduced posterior cruciate ligament loading during flexion (Suero et al., 2015). However, few surgeons prefer a PTS at 0° or 3°, which is lower in comparison with the natural slope of an intact knee (Yoo, Chang, Shin, Seong, & Kim, 2008). Nevertheless, majority of previous studies being retroactive, the extent of effect of PTS angle on the flexion gap remains uncertain. The flexion gap being influenced by many factors in addition to the PTS, it is therefore hard to analyze the independent influence of the PTS on the flexion gap using those study designs.
Many experimental studies, both clinical and cadaveric have tried to determine an optimal PTS, but wide variations due to errors in cutting plane during surgery have resulted in inconclusive results. An error in the range of 2° have been reported in 30% cases between planned and actual PTS even while using a combination of computer-assisted navigation and conventional alignment guides (Shen, Li, Fu, & Wang, 2015; Weinberg, Gebhart, & Wera, 2017). Retrieval studies have shown that excessive PTS to be detrimental to wear and deformation at the anterior portion of tibial post in PS-TKA (Gamada et al., 2008; Shen et al., 2015; Vince, 2003). It has been suggested from previous studies that PTS needs to be parallel to the preoperative anatomical PTS (Harman, Banks, Kirschner, & Lützner, 2012). Evidences also point out that PTS of more than 8° leads to rotational, varus/valgus and anteroposterior laxities and loosening of posterior cruciate ligament (Fantozzi et al., 2004; Lotke & Ecker, 1977).

In the current study, detailed finite element analyses were performed to evaluate the response of periprosthetic bone region and keel of the tibial implant tray upon varying PTS (0°, 3°, 5° and 7°) and the effect of implant material. This study was limited to a posterior stabilized prosthesis design, considering the above factors and subsequent trends in stress shielding and bone-density variations, considering axial compressive loads during level walking and stair ascending scenarios. The advantage of computational simulation with a single subject is that we can determine the effects of component alignment within the same subject without any effect of variables such as weight, height, bone geometry, ligament properties and component size.

2. Materials and methods

2.1. Bone-implant model acquisition and reconstruction

The TKA prosthesis used for current study is a commercially available posterior stabilized type implant system, DePuy SIGMA (DePuy Orthopaedics, Warsaw, IN, USA). The 3D geometries of implant components were scanned using a 3D scanner (Geomagic Capture, 3D systems, USA) and reverse engineered using Geomagic Design X (3D systems, USA) and ANSYS Spaceclaim (ANSYS Inc, USA) to generate a 3D model. A 3D FE model of an intact tibia was developed from the CT images (Pixel size = 0.976562 mm, slice thickness = 0.625 mm) of a 36-year-old male, using MIMICS (Materialise, Leuven, Belgium). Full tibia (length = 375 mm) is considered for current study, to closely resemble the actual response of the bone-implant system. Resection and virtual implantation of bone was done in ANSYS Spaceclaim, perpendicular to the mechanical axis as per standard surgical technique consistent with DePuy surgical guide (DePuy, 2010). Figure 1 shows the isometric and sectional view of bone-implant assembly and Figure 2 shows the cross-sectional view of bone implant system at different posterior tibial slopes considered.

2.2. Meshing

Bone and implant components were imported in Hypermesh (Hyper works, Altair University) and initial surface meshing was done for all components with an element size ranging from 0.3 to 1.5 mm. The element size of different surfaces was chosen, considering the master-slave contact surface relation of the solver and desired precision in results at critical areas of bone-implant system. Triangular surface meshes were converted to volume mesh using tetrahedral C3D10 and C3D4 element types for implant system and bone, respectively. Mesh quality check and optimizations were performed considering: Jacobian 0.8–1, skew angle of less than 40°, tet-collapse greater than 0.5 and aspect ratio of less than 5, as parameters for fine mesh, based on previous studies and by using an iterative approach for meshing (El-Zayat et al., 2016; Shen et al., 2015; Steinbrück et al., 2014).

2.3. Material properties and boundary conditions

Linear elastic and isotropic properties were assumed for implant components and cement mantle layer. The material properties used in present study are listed in Table 1.
Figure 1. (a) Bone-implant assembly, (b) sectional view of assembly and exploded view with constituent parts.

Figure 2. Representation of posterior tibial slope (a) neutral alignment, (b) 3° PTS, (c) 5° PTS and (d) 7° PTS.

| Component                | Young’s Modulus | Poisson’s ratio | No. of elements |
|--------------------------|-----------------|-----------------|-----------------|
| Titanium tray (Zhang, Cossey, & Tong, 2016a) | 11.7 GPa         | 0.3             | 2,27,004        |
| AP tray (Kurtz, 2015)    | 0.835 GPa       | 0.4             | 2,27,004        |
| Tibial insert            | 0.835 GPa       | 0.4             | 2,46,000        |
| Tibial tray screw        | 0.835 GPa       | 0.4             | 49,890          |
| Cement mantle (Technique, 2013) | 3.36 GPa      | 0.3             | 2,22,354        |
| Bone                     | 48 MPa-14.8 GPa | 0.3             | 10,33,205       |
Meshed bone was imported to MIMICS (Materialise, Leuven, Belgium) and calibrated with CT images for assigning its heterogeneous properties. Fifteen different sections were considered for property assignment. The correlations between Hounsfield units and bone apparent density (g/cm$^3$) (Zhang et al., 2016a) are:

\[ \rho = 1.037 \times 10^{-4} \, (HU + 1000) \text{ for } -135 \leq HU \leq 138 \] (1)

\[ \rho = 1.011 \times 10^{-3} \, (HU - 2000) \text{ for } HU > 138 \] (2)

And subsequently for Young's modulus (MPa) are:

\[ E = 2003 \rho^{1.56} \text{ for } 0 \leq \rho \leq 0.778 \] (3)

\[ E = 2875 \rho^{3.0} \text{ for } \rho > 0.778 \] (4)

The range of Young's modulus values obtained from Eqs. (3) and (4) is from 48 MPa to 14.8 GPa, which is inside the typical scope of bone properties in the knee (Miller, Terbush, Goodheart, Izant, & Mann, 2017; Zhang et al., 2016a).

The interface between polyethylene insert—titanium tray, cement mantle layer—titanium tray and bone-cement were assumed to be fully bonded, as per available literatures and other similar studies carried out. The lower part of full tibia bone was fully fixed by constraining all its degrees of freedom.

For each set of simulation, MB and AP components were separately considered. Properties of titanium and polyethylene were considered for MB and AP implant components, respectively, for the tibial tray. Neutral position of implantation was considered for all arrangements, wherein, neutral position alludes to a tibial level cut made at 0° back incline and 90° to the mechanical pivot of tibia.

Maximum axial compressive loads of 3360 N, 4108 N and 4261 N during level walking, stair ascending and stair descending activity, respectively were considered, for a high body weight of 100 Kg (“Database: OrthoLoad,” n.d.). The ratio of axial forces was assigned as 50:50 and 55:45 on medial and lateral surfaces of polyethylene insert for level walking and stair ascending and descending, respectively (Carr & Goswami, 2009; Martin et al., 2017; Taylor, 2007; Zhang et al., 2016a). The nonimplanted and implanted tibial models, consisting of C3D10 elements in implant components and C3D4 type of element in bone with about 16,00,000 elements, with sizes ranging from 0.5 to 2.0 mm, were entered to Abaqus 6.14 (Dassault Systems, USA) for numerical analysis.

The response of a 20mm layer in the periprosthetic region of bone to stress shielding was evaluated using three conditions, viz: (i) volume of bone at risk of resorption (ii) anticipated volume of bone under the risk of failure. For case (iii) volume of bone undergoing increase in density. The difference in strain energy density (SENER) between the nonimplanted and implanted tibia was a measure of potential reduction of bone degradation, post-TKR (Zhang et al., 2016a). Bone resorption was perceived to occur if decrease in SENER is above $s$

\[ \frac{1 - \text{SENER}_{\text{implanted}}}{\text{SENER}_{\text{intact}}} \geq s \]

To assess the influence of implant material on the strain response in the periprosthetic area, percentage of volume of bone at risk of resorption, for the considered conditions was computed. Bone density was expected to increase for case (ii) when,

\[ \frac{\text{SENER}_{\text{implanted}}}{\text{SENER}_{\text{intact}}} - 1 \geq s \]
For case (iii), bone failure was expected to happen when either the maximum or minimum absolute principal strain falls outside the range of 0.7–1%.

A total of 16 set of simulations were carried out for the considered combinations of MB and AP configurations and three load steps of level walking (LW), stair ascending (SA) and stair descending (SD) activity.

3. Results and discussion
Stress shielding is known to be the primary factor and initiator for implant loosening, causing aseptic loosening in the bone-implant region, thus resulting in revision of TKA. To analyze the regions of high stress area, analyses were carried out for four different PTS (0°, 3°, 5° and 7°) for both MB and AP systems. Figure 3 demonstrates a correlation of appropriations of the predicted maximum principal absolute strains in the bone for the above-mentioned cases, for level walking condition.

The obtained strains generated in the bone vary from 280 to 460 micro strains for different PTS considered. Bone implanted with MB components was found to have 45% more strains in the same region, i.e. keel of the tray. Analyzing the obtained strains, it is clear that AP components fare much better than MB components. Also, the neutral positioning of the tibial tray (0° MB and AP) is more beneficial in comparison with enhanced PTS. Hence, it suggests that MB tray significantly modified the strain distribution and response in the periprosthetic bone, due to the compressive stress concentrations in the distal tibia caused due to major load being carried by the keel of the tray.

The stresses generated as shown in Figure 4 relates to the surface level stress in bone-tibial tray adjoining surface. It can be observed that AP components generate very low stresses both in the flange region and the end of keel region, compared to MB component. Stress shielding was also observed to be more predominant in MB cases in the flange region on the tibial surface. Higher stress in the range of 4.5–7 MPa in the anterior region of the keel was observed in MB components. This suggests that AP components are more beneficial than MB ones. However, PTS of above 3° leads to higher stress in the regions considered. Thus, based on stress analysis 3° PTS may be considered rather than 5° or 7°. This conclusion of superior performance of AP components have been reported in literature elsewhere (Nouta, Pijls, & Nelissen, 2012; Scott et al., 2017).

Based on the obtained strains in Figure 5 it is clear that AP components strain lower than MB components. As the PTS increases, it was observed that strain increases proximally in the posterior region. Also, 5° and 7° PTS with MB components were observed to strain 73% higher than AP cases.
The full tibia and the volume of interest (VOI) were additionally analyzed under maximum axial loads for three load cases, and the rates of the bone volume influenced for (a) in danger of resorption and (b) increase in bone density. Obviously, MB components are shown to have higher level of bone resorption in both the full tibia and in the VOI, especially in the latter, between 40% and 60% bone resorption was found rather than under 20% for AP parts. The most noteworthy bone resorption is predicted in the VOI for MB segment (59.7%) for 7° PTS. The evaluated bone-density increase in the entire tibia seems to support AP and independent of PTS even though in the VOI essentially higher increase in bone density are found in AP than those of MB parts.

In the present investigation, the outcomes uncover that impact of tibial tray material is much more than that of polyethylene insert thickness for the cases considered. Although, higher stress shielding has been observed in MB segments cases. Most past examinations essentially considered just 100–150 mm of bone length and featured mainly on the stress-strain variations in the periprosthetic bones (Completo et al., 2010; Godest, Beaugonin, Haug, Taylor, & Gregson, 2002; Innocenti et al., 2014; Villa, Migliavacca, Gastaldi, Colombo, & Pietrabissa, 2004). Such investigations are prone to anomalies and not illustrative of the full bone-implant framework reaction. We inspected the entire tibia bone and incorporated predicted percentage level of bone volume with resorption chance, which gives a superior quantitative measure to the potential danger of bone resorption, bringing about upgraded evidence about the impact of stress shielding on the periprosthetic bone in proximal tibia and over the keel length of tibial tray, post-TKR considering commonly used PTS.

Current implant systems are known to have high success rates with minimal revisions in short to medium terms. With progressively more youthful patients accepting knee substitutions, the effect of such implants on bone quality cannot be thought little of. Even though a couple of side effects may perhaps arise clinically following a successful TKR, the impact of implant materials on the periprosthetic bone region after considerable time post-TKR, is largely unknown and the potential to study the same is quite significant.
4. Conclusions
The strain distribution in the periprosthetic bone post-TKR, considering two implant materials and four different PTS were analyzed. MB components have been found to have significant consequences for stress shielding (68% volume of bone in the flange region under reduced stresses for MB vs only 10% volume in AP) than those of AP components for the three load cases considered. Similarly, the impact of PTS (63% variation in stress patterns around the flange and keel region) on stress shielding appears to be of secondary or less significance in comparison with the implant material. AP material seems to reduce the effect of stress shielding to a large extent (60% reduction in stress shielding), compared to MB trays. Our inference, for the said loading conditions and observed strain distribution pattern, that neutral position or a 3° PTS for AP trays may be preferred have also been widely reported by clinicians and other FE studies.

5. Limitations
The tibial FE model developed in the current study was based on the CT images of a healthy male person, aged 36 years, hence, validation of the model was not tried. Despite this, the trends of obtained results were reasonable with other similar studies considering 100–150 mm of tibia bone. The articular ligament and menisci were not considered for analyses. Completely tied conditions were considered between bone–implant and cement-plate interfaces, and the residual stresses within the cement because of the exothermic response of cement polymerization were not considered. The static examinations were completed assuming normal axial joint contact forces during typical walking and stair ascending and descending while the impacts of physiological dynamic load cases were not considered.

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