Published in final edited form as:

J Biomech. 2016 July 5; 49(10): 2068–2075. doi:10.1016/j.jbiomech.2016.05.014.

Damage in Total Knee Replacements from Mechanical Overload

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Abstract

The mechanical loads acting across the knee joint following total knee replacements (TKR) during activities of daily living have recently been measured using instrumented TKRs. Using a series of postmortem retrieved TKR constructs we investigated whether these mechanical loads could result in damage to the implant bone interface or supporting bone in the tibia. Eighteen cemented *en bloc* tibial components (0 to 22 years in service) were loaded under axial compression in increments from 1 to 10 times body weight and digital image correlation was used to measure bone strain and interface micromotion during loading and unloading. Failure was considered to occur when micromotion exceeded 150 μm or compressive bone strain exceeded 7300 $\mu\epsilon$. The results show that all retrieved specimens had sufficient bone strength to support most activities of daily living, but ~40% would be at risk under larger physiologic loads that might occur secondary to a higher impacts such as jogging or a stumble. The tray-bone micromotion (regression model $R^2=0.48$, $p=0.025$) was greater for donors with lower age at implantation ($p=0.0092$). Proximal bone strain (model $R^2=0.46$, $p=0.03$) was greater for donors with longer time in service ($p=0.021$). Distal bone strain (model $R^2=0.58$, $p=0.005$) was greater for donors with more time in service ($p=0.0054$) and lower peri-implant BMD ($p=0.049$). High mechanical overload of a single or

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Contributions: William Zimmerman performed specimen preparation, the experimental methods, and assisted in manuscript preparation. Mark Miller performed the experimental methods, digital image correlation analysis, and assisted in manuscript preparation. Richard Cleary assisted with statistical design, analysis, and contributed to manuscript preparation. Timothy Izant assisted with radiographic assessment, clinical input and rationale, and manuscript preparation. Kenneth Mann designed experiments, performed statistics, and contributed to manuscript preparation. All authors have read and approved the final submitted manuscript.

Conflict of Interest Statement

William Zimmerman has no conflicts of interest, directly or indirectly related to this manuscript.

Mark Miller has no conflicts of interest, directly or indirectly related to this manuscript.

Richard Cleary is a paid consultant of Modern Energy Inc of Tully, NY for activities unrelated to this manuscript.

Timothy Izant is a paid consultant of Stryker Orthopaedics, for activities unrelated to this manuscript.

Kenneth Mann has no conflicts of interest, directly or indirectly related to this manuscript.

repetitive nature may be an initiating factor in aseptic loosening of total joint arthroplasties and should be avoided in order to prolong the life of the implant.

Keywords

Total Knee Replacement; Aseptic Loosening; Postmortem Retrievals; Bone damage; Micromotion

INTRODUCTION

Total knee replacement (TKR) utilization continues to grow at a rapid pace in the US with nearly 1 million primary knee replacements predicted to be implanted in 2015 (Kurtz et al., 2014). Unfortunately, revision surgery to replace failed primary arthroplasties also continues to grow in number. Cumulative results from a large series of joint registries indicate that revision rates are 6% at 5 years and 12% after 10 years of in vivo service (Labek et al., 2011). Aseptic loosening continues to be the predominant mechanism of failure (Lombardi et al., 2014; Sharkey et al., 2014), but it is acknowledged that this is a rather broad descriptor and the underlying mechanisms leading to loosening are not fully understood.

Recent *in vivo* studies using instrumented total knee replacements have shown that the loading magnitude applied across the knee joint can vary considerably depending on activity (Bergmann et al., 2014; D'Lima et al., 2012; D'Lima et al., 2011). In addition, infrequent high demand loading situations such as stumbling (Bergmann et al., 2004) could potentially damage the fixation of TKRs and this might lead to eventual clinical loosening. However, it is not known whether the load magnitudes associated with the more aggressive activities of daily living or stumbling would damage the TKR construct. Mechanical overload could cause the supporting bone beneath the cemented tibial tray to mechanically yield resulting in subsidence of the implant. Excessive loads could also induce large relative motions between the implant and bone (micromotion) resulting in loss of mechanical fixation. The overall goal of this study is to assess the ability of functioning knee replacements to support high mechanical loads without damage to the implant-bone interface or supporting bone bed. Testing of high load scenarios is not possible in patients because of the obvious risk of causing damage to the TKR construct. However, *en bloc* postmortem retrieved knee replacements, that have functioned for the life of the donor, could be used to directly assess the effects of mechanical overload for the scenarios of supporting bone damage and increased induced micromotion.

Clinically, the risk of aseptic loosening is known to be higher for younger TKR patients and revision risk increases for implants with longer time in service (Julin et al., 2010). Younger patients are likely to be more active and may generate larger loads on their knee replacement, while implants with long time in service may be associated with a reduction in the amount of bone supporting the knee replacement due to stress shielding (Huiskes et al., 1987; Levitz et al., 1995; Li and Nilsson, 2000) and loss of mechanical interlock between the implant and bone (Goodheart et al., 2014; Miller et al., 2014). It is possible that the overload damage scenarios described above may also depend on donor factors such as age at implantation, time in service, and amount of peri-implant bone. Using the tibial components

from postmortem retrieved TKRs, we asked two primary research questions: 1) do high (but clinically relevant) mechanical loads result in damage to the implant-bone interface or supporting trabecular bone? and 2) is there greater micromotion and bone strain for donors with younger age at implantation, longer time in service, or lower peri-implant bone mineral density in cases in which there is mechanical overload?

METHODS

Total Knee Replacements Following In Vivo Service

Seventeen human knees with cemented total knee replacements (TKRs) were obtained from eleven donors (6 were bilateral pairs) from the SUNY Upstate Anatomical Gift Program. The components were retrieved *en bloc* and were frozen at -20°C until time of testing. Constructs were radiographed in the anterior-posterior and medial-lateral planes, and radiolucencies along the implant-bone interface were scored as: well fixed (no radiolucencies), possibly loose (peripheral radiolucencies), and loose (extensive radiolucencies). Peri-implant bone mineral density (BMD) was obtained using clinical dual-energy x-ray absorptiometry (DXA) (Lunar DPX-IQ, GE Healthcare, Waukesha, WI). An additional ‘time 0’ construct was created in the lab using a fresh cadaver knee using conditions that simulated the clinical operative environment to represent a case with no bone remodeling. Summary statistics for donor information are shown in Table 1. All tibial components ($n=17$ postmortem retrieval +1 ‘time 0’) were metal backed and were cemented in place. Fourteen of the eighteen implants had stems or keels, while four did not. Details for each donor TKR are included in Supplemental Table 1. The polyethylene insert wear was documented using the scoring method described by Hood (Hood et al., 1983).

Mechanical Loading Procedure

The tibiae were cemented in a pot 70mm below the tibial tray using PMMA and fixed to a mechanical test frame (MTS Systems, Eden Prairie, MN), such that the tray was orthogonal to the loading axis. Axial compressive loads were applied to the center of wear patches on the articulating polyethylene insert using distributed loading pads (20 by 24mm) with a 60% medial/40% lateral load distribution (Figure 1A). Axial compression was chosen as this represents the primary loading direction acting on the tibia as determined from instrumented knee replacement studies (Kutzner et al., 2010). The loading regime consisted of axial compressive loads applied in displacement control (5 mm/min, equivalent to ~ 0.75 BW/s) to load limits from 1 to 10 body weight (BW) in 1BW increments. Once the load limit was reached, the test was reversed until the tibia was unloaded (Figure 1B). Testing was stopped if there was frank compressive failure of the construct. Loading was limited to a maximum of 10BW, because this was considered to be an upper limit of what might be anticipated during any ambulatory activities including stumbling, but excludes impact loading due to falls or automobile accidents.

Digital Image Correlation (DIC) Strain and Micromotion Measurements

A pair of CCD cameras (Diagnostic Instruments, Sterling Heights, MI) with telecentric lenses (55mm, Edmund Optics, Barrington, NJ) was used to capture images (0.053 mm/pixel) of the posterior and medial surface of proximal tibia during loading. Digital image

correlation (DIC) software (MI-2D, MatchID, Merelbeke, Belgium) was used to quantify horizontal (u) and vertical (v) displacement components (Figure 1A) for sampling zones on the tray and bone surface. A normalized sum of squares difference (NSSD) with subregions of 35 pixels and step size of 17 pixels was used for the DIC analysis. The axial (v) component, shear (u) component, and the vector sum ($\sqrt{u^2 + v^2}$) of micromotion across the tray-bone interface (gauge length, $Y_2 - Y_1 \approx 5\text{mm}$) were calculated. Axial (eg. $v/(Y_3 - Y_2)$) and shear strain (eg. $u/(Y_3 - Y_2) + v/(X_3 - X_1)$) measurements were made using a 'virtual extensometer' approach (gauge length, $Y_3 - Y_2 \approx 24\text{mm}$). At the peak load for each loading step, the *total* tray-bone micromotion/bone strain was measured relative to the initial unloaded state (Figure 1B). After unloading, the *permanent* micromotion and bone strain was measured relative to the initial unloaded state. At each load step, total and permanent tray/bone micromotion, and total and permanent bone strain were used as the primary outcome measures. The error in DIC micromotion (RMSE=1.0 μm , 95% confidence intervals 0.6-1.1 μm) and DIC strain measurements (RMSE=53 $\mu\epsilon$, 95% confidence intervals 19-64 $\mu\epsilon$) was determined in a pilot calibration study.

Bone strain was compared to the known range of yield strain of tibial trabecular bone ($-7300 \pm 600\mu\epsilon$) (Morgan and Keaveny, 2001). If the measured bone strain exceeded $-7300\mu\epsilon$, the supporting bone of the construct was considered damaged. To assess sensitivity of the risk of damage to variability in yield strain of bone, results were also compiled for yield strains that were ± 2 standard deviations of the mean (6100-8500 $\mu\epsilon$). This range of bone strain also spans compressive yield strain values for tibial cortical bone (Leng et al., 2009) for young (8200 $\mu\epsilon$, age: 53 ± 2 years) and elderly (7110 $\mu\epsilon$, age: 83 ± 6 years). Similarly, a micromotion limit of 150 μm was used as an indicator of an implant-bone interface that would be unable to sustain stable fixation (Jasty et al., 1997). A range of $\pm 50\mu\text{m}$ was used to assess the sensitivity of the micromotion limit; while the 150 μm limit is often quoted in the literature, in vivo experiments where micromotion is applied over relatively narrow ranges has not been performed.

Statistics

Descriptive statistics were calculated for the donor and strain/micromotion outcome measures. Because of the wide range of biomechanical responses, whisker plots were used to plot outcome measures as a function of load level (BW). Regression models were used to relate the donor factors (time in service, age at implantation, peri-implant bone mineral density (BMD)), and the maximum (magnitude) micromotion and strain. A cumulative frequency distribution plot was used to assess the relationship between load magnitude and risk of fracture for the sample population. Two sample t-tests were used to test whether implant micromotion or bone strain were different for donors with evidence of radiographic loosening and absence of a keel and stem in the tibial component.

RESULTS

Fifteen specimens completed the full 10BW loading regime without gross failure; two had frank bone failure at 8BW and one failed at 9BW. There was axial 'closing' micromotion across the tray-bone interface that increased with larger applied BW (Figure 2A). The axial

micromotion component was generally larger than the shear component (Table 1). However the magnitude of total micromotion was quite variable. With 6BW applied, total micromotion ranged from 14 to 215 μm with a median of 54 μm . The location of the largest micromotion did not occur in a consistent region with 38% occurring in the medial region, 33% in the posterolateral region, and 28% in the posteromedial region. After unloading of the implant, the axial permanent micromotion across the tray bone interface generally had a positive value indicating that there was increased ‘opening’ with larger applied loads (Figure 2B). After 6BW loading, permanent micromotion ranged from 4 to 102 μm with a median of 19 μm . To explore the mechanism causing the opening displacement after unloading, the axial migration of the tray and bone adjacent to the tray were measured relative to the base of the bone (Figure 3A-B). These results show that there is a net distal migration of the tray and bone after removal of the applied load and this migration increases with larger applied loads. The observation that the bone migrates more than the tray indicates that there is some ‘spring-back response of the tibial tray’ relative to the adjacent bone, while there is permanent damage to the underlying bone.

Total axial compressive strain in the peri-implant bone (Figure 4A-B) region of the tibia increased with larger applied BW, and strain magnitudes were larger for the proximal zone compared to the distal zone (median: $-3840/-2550\mu\epsilon$ for proximal/distal at 6BW, $p=0.0004$). For the minimum (most compressive) strain values shown in Figure 4, there was a wide range of bone strain magnitudes. The location of the largest compressive strain was not consistently in the same region with 50% occurring in the medial and posterior aspects of the proximal tibia. Total proximal shear strain magnitude (Table 1) (median: 531 $\mu\epsilon$ at 6BW, $\sim 15\%$ of axial strain) was significantly lower than the axial compressive strain ($p<0.0001$) for the axial loading scenario used in this study. Given the relatively small shear strain component, the contribution of shear to bone yielding would be limited based on a super-ellipsoidal yield criterion for human trabecular bone (Bayraktar et al., 2004). Therefore, only axial strains were considered further in the analysis. Permanent axial compressive strain also increased with applied load (Figure 5A-B) and had a larger magnitude for the proximal zone compared to the distal zone (median: $-830/-350\mu\epsilon$ for proximal/distal at 6BW, $p=0.0042$). There was a strong positive correlation (median: $r=0.88$, 95% confidence intervals: 0.61–0.92) between the magnitude of implant micromotion and the strain in the supporting bone when loaded from 1 to 10BW. This suggests that greater damage to the supporting bone is related to increased tray/bone micromotion.

A cumulative frequency distribution plot was created for the sample population to indicate the fraction of the population at risk of supporting bone damage (Figure 6A), using the compressive bone strain yield limit of $-7300\pm 1200\mu\epsilon$ (2 SD) (Morgan and Keaveny, 2001). None of the sample population had supporting bone damage at 4 BW, but further increases in applied load resulted in a larger fraction of the population with bone damage. Altering the yield limit from 6100 to 8500 $\mu\epsilon$ varied the frequency distribution generally less than 10% of the nominal value case (7300 $\mu\epsilon$). Using a micromotion limit of $150\pm 50\mu\text{m}$ as a condition that would prevent stable fixation (Jasty et al., 1997), a corresponding cumulative frequency distribution plot (Figure 6B) for ‘interface failure’ was generated. There were two donor knees with excessive total micromotion ($>150\mu\text{m}$) even at low load magnitudes (2BW). However, loads of 8BW or greater were needed to cause any of the other knees in the sample

population to exceed the 150 μ m micromotion limit. Altering the micromotion limit by 50 μ m had a substantial effect on the frequency distribution plot.

For the donor bones that were possibly loose based on tray/bone radiolucencies, there was much greater ($p=0.0064$) micromotion (Figure 7, data shown for 6BW) compared to implants that appeared to be well fixed. The maximum bone strains for the two groups were not statistically different ($p=0.26$). In this study there were four donor implants that had no keel or stem. Comparing the response to the population with a keel or stem did not show any difference for micromotion at the tray/bone interface ($p=0.28$) or maximum strain in the supporting bone ($p=0.84$).

Multiple regression models (Table 2) were used to explore relationships between the outcome measures (micromotion, bone strain) and patient factors (age at implantation, time in service, peri-implant BMD). Because specimens in the bilateral pairs had, in most cases, substantially different times in service, these were treated as independent samples. The tray-bone total micromotion (regression model $R^2=0.48$, $p=0.0025$) increased with lower age at implantation ($p=0.0059$), but not time in service ($p=0.61$), or peri-implant BMD ($p=0.44$). Total proximal bone strain (model $R^2=0.46$, $p=0.03$) increased with longer time in service ($p=0.021$), but not age at implantation ($p=0.29$) or peri-implant BMD ($p=0.18$). The total distal bone strain (model $R^2=0.58$, $p=0.005$), increased with time in service ($p=0.0054$) and lower peri-implant BMD ($p=0.049$), but not age at implantation ($p=0.45$).

DISCUSSION

Using a sample population of postmortem retrieved knee replacements that were incrementally loaded to large load magnitudes, all would appear to have sufficient proximal tibial bone strength to support most activities of daily living such as walking and stair descent. Only one donor would be at risk of bone damage from more aggressive natural loading from sport; but this 85-year-old donor would be unlikely to participate in rigorous sporting activities like running or downhill skiing. However, a large fraction of the sample population (~40%) may be at risk of bone damage if they were to stumble and generate large compressive loads ($7\text{--}9 \times \text{BW}$) across the knee joint. Two of the implants had large micromotion magnitudes, even with applied loads consistent with less rigorous activities of daily living. Both implants were from the same donor (K), who was young (age 54 years) with 10 and 12 years of service. Loads of 8 or greater BW were needed to induce micromotion of greater than 150 μ m for the rest of the sample population. Note that this work only explores a single cycle of mechanical overload as a mechanism leading to clinical loosening. Cyclic loading from activities of daily living, following single cycle overload could result in progression of the loosening process.

With application of large loads to the TKRs, donors with longer time in service had higher bone strains in the proximal tibia and donors with a younger age at implantation had greater micromotion. These findings are consistent with clinical registry data indicating that younger age at implantation and longer time in service both are associated with higher risk of revision (Julin et al., 2010). Donors with lower peri-implant BMD had higher bone strains for the more distal strain measurement, but not for the proximal strain measurement. With

longer time in service, there may be reduced quantity of bone surrounding the implant due to stress shielding (Chong et al., 2011) and general loss of bone due to aging (Hannan et al., 2000). Younger patients may be more at risk of losing fixation at the cemented tray/bone interface, presumably from increased activity and magnitude of force application. Morphology changes at the interface between cement and bone including loss of trabecular interlock (Miller et al., 2014) have been documented in postmortem retrievals, but the mechanism responsible for this loss of fixation is not known. It is possible that younger and more active patients generate more polyethylene debris resulting in localized lysis at the interface (Fisher et al., 2010). Another possibility is that local micromotion between the trabeculae and cement results in fluid pumping along the interface causing fluid induced lysis (Fahlgren et al., 2010).

An interesting finding from the current study was the phenomenon of a residual opening displacement between the implant and adjacent bone after unloading from a large applied load cycle. It is not clear if the opening displacement results in a small ($\sim 10\mu\text{m}$ at 10BW) gap between the tray and cement or cement and bone. But any residual gap could serve as a conduit for debris or fluid pumping when the joint is reloaded. Small gap formation, coupled with continued cyclic loading could result in fibrous tissue formation between the cement and bone. It should also be noted that there is a strong positive correlation between the magnitude of interface micromotion and supporting bone strain, and there is likely an interaction between damage to the supporting bone and damage to the interface.

In this study, postmortem retrieved total knee replacements were used that were functioning for the patient at the time of death. Compared to cadaver studies in which the implants are placed in the lab, postmortem retrievals include all remodeling processes that occur from the time of implantation including changes to the supporting bone structure and the fixation at the interface. As such, they serve as an ideal platform to test the biomechanics of TKR fixation (Gebert de Uhlenbrock et al., 2012). However, because the implants were from retrievals obtained from an anatomical gift program, there was not a prospective study design with control of factors such as implant design, component alignment, or cementing technique.

The age at implantation (69.0 ± 10.8 years) was similar to the age at implantation for large national registries (68.8 ± 9.5) (Australian NJR-(2009)). A much larger sample population would be needed to separate out specific implant or surgical factors. For example, four of the donor TKRs had cemented tibial trays without keels or stems. One might anticipate that this group would respond to overload differently compared to keeled designs. But this was not found to be the case (Figure 7). Because the sample size was relatively small, analyses were restricted to a few independent variables (age at implantation, time in service, peri-implant BMD), and the variables were chosen based on clinical data suggesting that each was a parameter related to risk of loosening. Extending this work to a much larger sample size would give more confidence to the risk of bone damage or high micromotion for activities of daily living.

Due to the available donor population (age: 69 ± 11 years), the results may not translate to younger patients with limited TKR time in service. It is interesting to note that the response

of the youngest donor (age 54, bilateral implants with 10 and 12 years in service) had total bone strains that were very similar to the mean response of the rest of the population. The bone strain and implant micromotion measurements were only made on the exterior surface of the construct and will not fully reflect the internal strain/micromotion response. It is likely that some internal strains/micromotions are higher than what is measured on the bone/implant surface. The micromotion measures could not be used to identify if the source of damage was local damage in bone directly beneath the interface or loss of fixation of tray-cement and cement-bone interfaces.

Loading was applied in a 60/40% medial/lateral distribution without a shear or axial torsion component. Failure loads would be expected to decrease if loading was concentrated on the medial condyle and if additional shear and torsional loads were included. However, data from instrumented implants shows that medial/lateral loading can remain with a 60/40% distribution with stumbling and internal torque and A/P shear can be quite small for a variety of loading conditions (Bergmann et al., 2014). Load was applied through the center of the wear patches on the articulating surfaces. While this may be reasonable to recapitulate the common load transfer location for a particular patient, it may not represent loading during extreme load cases, such as edge loading (Taylor and Barrett, 2003). Muscle and ligament loads acting on the proximal tibia were also not considered. Further work is needed to address the relative contribution of these factors in failure mechanics of the proximal tibia constructs. Finite element modeling work that captures the local damage mechanics of the interface and trabecular bone bed could be useful to provide a fuller understanding of the distribution of damage and micromotion within the implant system. Larger scale musculoskeletal modeling could also be combined with finite element model efforts to assess the effects of variation in construct loading due to the factors described above.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGEMENTS

The research reported in this publication was supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health under Award Number AR42017. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The authors would like to acknowledge the assistance of Dan Jaeger for providing the postmortem retrievals and tissue from the SUNY Upstate Anatomical Gift Program.

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Clinical Relevance

Compressive loads across the knee joint in TKR vary considerably depending on activity, and some situations can result in load magnitudes that are many times a patient's body weight. This work directly measured damage to the fixation interface and proximal tibia for donors with functioning postmortem retrieved TKRs. These results show that cemented joint replacement constructs are able to withstand load magnitudes that occur from most activities of daily living without excessive damage to TKR fixation. But higher loads, such as jogging and unusually high loads such as from stumbling, were of sufficient magnitude to result in permanent damage to the supporting bone beneath the tibial tray and caused high micromotion between the implant and bone. Mechanical overload could be an initiation event in the loosening process of patients with total joint replacement, and efforts to reduce risk of very high load application could reduce risk of aseptic loosening.

Figure 1.

Digital image correlation (DIC) sampling zones were used on the posterior and medial views of the proximal tibia during loading (A). An axial compressive load was applied in increments from 1 to 10 times body weight (BW) with loads distributed to the medial (60%) and lateral (40%) regions of the polyethylene insert. Image sets were captured at the peak of each load increment to document total micromotion and strain and after unloading to document permanent micromotion and strain (B).

Figure 2.

Whisker plots of peak total micromotion (**A**) and permanent micromotion (**B**) between the metal tray and adjacent bone for load application ranging from 1 to 10 body weights (BW). Results for axial, shear, and axial plus shear (vector addition) components are shown. Sign convention with tensile (+) and compressive (–) axial strain, opening (+) and closing (–) axial micromotion was used. The median value of the measure is shown as the central line in the shaded box. The upper and lower boundaries represent the 25 to 75% of the sample population, while the extended whiskers are calculated as 1.5 times the interquartile range. If the data does not extend to this value, the whisker is truncated at the data value. Additional outliers are shown as single data points.

Figure 3.

Axial migration of the tibial tray and bone at the cement-bone interface for the posterior (**A**) and medial (**B**) views of the proximal tibia as a function of applied load. Median values and standard error of the mean bars are shown. Negative values indicate migration in the distal direction.

Figure 4.

Whisker plots of minimum total axial strain (most compressive) in the proximal (A) and distal (B) regions of the peri-implant bone for load application ranging from 1 to 10 body weights (BW). Confidence intervals (95%, mean $\pm$ 2SD) for compressive yield of bone from the proximal tibia are shown as dashed lines. Negative values represent compressive strain. Individual data points that have strain values that extend beyond the scale are indicated with an arrow.

Figure 5.

Whisker plots of minimum permanent axial strain (most compressive) in the proximal (A) and distal (B) regions of the peri-implant bone for load application ranging from 1 to 10 body weights (BW). Negative values represent compressive strain. Individual data points that have strain values that extend beyond the scale are indicated with an arrow.

Figure 6.

The fraction of the sample population ($n=18$ implants) that exceed the compressive yield strain of trabecular bone (7300 ± 1200 (2SD) $\mu\epsilon$) (**A**) or high interface [axial + shear] micromotion (150 ± 50 μm) (**B**) as a function of applied load magnitude in body weights (BW). Representative peak loads across the knee joint for various activities of daily living are also shown using data collected from instrumented knee replacements (a-stationary bike, golf, ski (D'Lima et al., 2011), b-walking, stair descent (Kutzner et al., 2010), c-jog

(Bergmann et al., 2014), d-stumble (Bergmann et al., 2004)). The stumbling load is shown only as an estimate based on similar data collected at the hip.

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Figure 7. Total micromotion and proximal bone strain at 6 BW loading stratified by radiographic fixation status and presence of a keel or stem. P values from two sample t-tests are shown.

Table 1

Descriptive statistics for TKR donor information, total (with load applied) and permanent (after load removed) tray/bone micro-motion and bone strain measures at 3 and 6 times body weight (BW) (n=18). Sign convention with tensile (+) and compressive (–) axial strain, opening (+) and closing (–) axial micromotion was used. Shear micromotion and strain reported as positive values. Data represent micromotion with largest magnitude and minimum (most compressive) bone strain for each donor.

	<i>Applied Load (BW)</i>	<i>Mean</i>	<i>Median</i>	<i>Std Dev</i>	<i>Min</i>	<i>Max</i>
<i>Age (years)</i>		78.9	85	11.2	54	90
<i>Age at Implantation (years)</i>		69.0	72.5	10.8	42	82
<i>Time in Service (years)</i>		9.9	10	5.3	0	22
<i>Mass (kg)</i>		83.3	85	14.3	53	100
<i>BMI (kg/m²)</i>		29.0	29	3.92	22.7	36.5
<i>Peri-implant bone mineral density (gr/cm²)</i>		0.63	0.54	0.27	0.07	1.16
<i>Total tray-bone micromotion [axial] (μm)</i>	3	–53	–35	51	–175	–6
	6	–67	–48	57	–176	–12
<i>Permanent tray-bone micromotion [axial] (μm)</i>	3	12	9	12	2	46
	6	20	13	19	1	81
<i>Total tray-bone micromotion [shear] (μm)</i>	3	16	15	10	6	42
	6	25	17	27	6	142
<i>Permanent tray-bone micromotion [shear] (μm)</i>	3	12	8	12	1	38
	6	16	10	15	1	63
<i>Total tray-bone micromotion [axial + shear] (μm)</i>	3	57	39	50	9	176
	6	77	54	62	14	215
<i>Permanent tray-bone micromotion [axial + shear] (μm)</i>	3	17	13	16	2	59
	6	28	19	24	4	102
<i>Total proximal bone strain [axial] (μɛ)</i>	3	–2030	–2000	860	–4150	–850
	6	–4400	–3840	2390	–10900	–2000
<i>Permanent proximal bone strain [axial] (μɛ)</i>	3	–610	–470	570	–2670	–140
	6	–1110	–830	930	–3360	–150
<i>Total proximal bone strain [shear] (μɛ)</i>	3	419	290	350	39	1183
	6	507	531	375	11	1614
<i>Permanent proximal bone strain [shear] (μɛ)</i>	3	199	135	174	31	590
	6	296	255	229	14	1016
<i>Total distal bone strain [axial] (μɛ)</i>	3	–1550	–1230	940	–4440	–670
	6	–3050	–2550	1790	–8430	–1560
<i>Permanent distal bone strain [axial] (μɛ)</i>	3	–200	–140	240	–730	140
	6	–470	–360	280	–1010	–110

Table 2

Linear regression models for implant/bone micromotion and tibial axial bone strain due to 6 BW loading with age at implantation, time in service, and peri-implant bone mineral density (BMD) as independent variables (n=18). Maximum magnitude values for the response term are used.

<i>Response Term</i>	<i>Parameter Term</i>	<i>Estimate</i>	<i>Standard Error</i>	<i>P value</i>
<i>Tray-bone Total Micromotion [axial + shear] (μm), $R^2 = 0.48$, $p=0.025$, $\beta = 0.86$, $\text{RMSE} = 34.4 \mu\text{m}$</i>	<i>Intercept</i>	256	79	0.0063
	<i>Age at Implantation (years)</i>	-2.85	0.88	0.0059
	<i>Time in service (years)</i>	0.85	1.64	0.61
	<i>Peri-implant BMD (gr/cm^2)</i>	-27.6	34.9	0.44
<i>Proximal tibial axial bone strain ($\mu\epsilon$), $R^2 = 0.46$, $p = 0.03$, $\beta = 0.83$, $\text{RMSE} = 1930\mu\epsilon$</i>	<i>Intercept</i>	7500	4500	0.117
	<i>Age at Implantation (years)</i>	-54.3	49.5	0.29
	<i>Time in service (years)</i>	239	92	0.021
	<i>Peri-implant BMD (gr/cm^2)</i>	-2760	1970	0.183
<i>Distal tibial axial bone strain ($\mu\epsilon$), $R^2 = 0.58$, $p = 0.005$, $\beta = 0.96$, $\text{RMSE} = 1270\mu\epsilon$</i>	<i>Intercept</i>	4575	2940	0.14
	<i>Age at Implantation (years)</i>	-25.4	32.4	0.45
	<i>Time in service (years)</i>	198	60.3	0.0054
	<i>Peri-implant BMD (gr/cm^2)</i>	-2770	1290	0.049