Peri-implant Bone Strains and Micro-motion Following In-Vivo Service: A Postmortem Retrieval Study of 22 Tibial Components from Total Knee Replacements

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Abstract

Biological adaptation following placement of total knee replacements (TKR) is known to affect peri-implant bone mineral density (BMD) and implant fixation. The goals of this project were to quantify the proximal tibial bone strain and implant-bone micro-motion for functioning postmortem retrieved TKRs and to assess the strain/micro-motion relationships with chronological (donor age and time in service) and patient (body weight and BMD) factors. Twenty-two tibial constructs were functionally loaded to one body weight (60% medial/40% lateral) and the proximal tibial bone strains and tray/bone micro-motion were measured using a digital image correlation system. Donors with more time in service had higher bone strains (p=0.044), but there was not a significant (p=0.333) contribution from donor age. Donors with lower peri-implant BMD (p=0.0039) and higher body mass (p=0.0286) had higher bone strains. Long term implants (> 11 years) had proximal bone strains (900 με) that were almost twice as high as short term (< 5 years) implants (570 με). Micro-motion was greater for younger donors (p=0.0161) and longer time in service (p=0.0008). Increased bone strain with long term in-vivo service could contribute to loosening of TKRs by failure of the tibial peri-implant bone.

Keywords

knee replacement; loosening; bone strain; postmortem; micro-motion

Introduction

Based on recent estimates of TKR burden in the United States (1), the lifetime probability of receiving a total knee replacement (TKR) is 7% for males and 9.5% for females. In addition, for those already with a primary TKR, the relative risk of revision at some point during the patient’s life has been estimated to be 15% for males and 17.5% for females. Clearly, efforts to reduce the risk of revision in this very large number of TKR recipients is warranted.
Substantial efforts have been made to improve implant design, materials, surgical techniques/alignment to improve the outcomes for TKR patients and to minimize the risk of revision. Information from retrospective and prospective clinical studies, implant registries, and retrieval studies provide vital ‘feedback’ to improve total joint function and longevity.

Clinical densitometry studies indicate that following TKR implantation there is a reduction in bone mineral density (BMD) in regions around the implant (2) in the short term. Over the longer term (eight years), bone density in the proximal tibia has been reported to decrease 36% (3) following TKR implantation. The authors report that this bone loss rate (~5%/year) is substantially greater than for osteoporosis patients in the same age group (~1–2%/year) and posit that the loss of mechanical support provided by the peri-implant bone could contribute to high bone strain and loosening of components over the long term. The general loss of bone around implants is thought to be due to a stress shielding phenomenon (4) where articular joint forces bypass bone and instead pass through the stiffer implant, thereby shielding the bone from physiologic stress. However, there is not a directly validated relationship between reduced BMD and high peri-implant strain in TKRs.

Based on these clinical observations, one might anticipate that bone strain would be higher for TKR constructs with more time in service (due to loss in BMD), and from older patients because of the natural loss of bone mass with age (5). To date, a link between chronological factors (time in service or age) with high peri-implant bone strain has not been made. It is also not possible to measure bone strain in-vivo for TKR patients using available tools. High patient mass and body mass index (BMI) have also been cited as factors that increase tibial component loosening rates (6; 7). However, other studies have found no direct linkage between high BMI and loosening (8; 9). High patient mass, coupled with low peri-implant BMD could result in higher bone strains that would put the supporting bone at risk of failure. The relationship between these patient factors (patient mass and peri-implant BMD) and bone strain has not been explored.

In contrast to the loss of peri-implant bone, loss of mechanical connection between implant and bone can occur and is often documented clinically by progressive radiographic lucencies at the bone-implant interface (10). Large inducible micro-motions and migration at the bone-implant interface have been related to increased risk of clinical loosening of tibial components (11; 12). However, to date, most laboratory studies have focused on quantifying the initial stability of components which represent the immediate postoperative situation, and few have explored the state of fixation after a period of in-vivo service (13; 14). Recent work (15) has shown that there is substantial loss of interlock between bone cement and trabecular bone with in-vivo service for cemented tibial components. The loss of interlock could result in increased micro-motion for TKR constructs. As with the peri-implant bone strains described above, it is not known whether TKR micro-motion is influenced by the chronological (age and time in service) and patient factors (peri-implant BMD and patient mass).

The goals of this project were to 1) quantify the proximal tibial bone strain and implant/bone micro-motion due to biomechanical loading using en bloc retrieved tibial components from cemented TKRs and 2) to assess the strain/micro-motion relationships with chronological
(donor age and time in service) and patient (body mass and peri-implant BMD) factors. Note that the implants were not obtained from revision surgery for a loose implant, but rather after death; thus the implants could be considered to be successful for the lifetime of the patient. We asked three research questions, guided by the clinical observations above: (1) are peri-implant tibial bone strains greater for implants with more time in service and from older donors?, (2) is tibial bone strain greater for constructs from donors with high body mass and lower peri-implant BMD?, and (3) are inducible micro-motions at the implant/bone interface also related to these chronological and patient factors?

METHODS

En bloc retrieved Total Knee Replacements

Twenty-one human knees with cemented total knee replacements were obtained from the SUNY Upstate Medical University Anatomical Gift Program. These implants were obtained en bloc, were not embalmed, and were frozen at −20 deg C until time of preparation and testing. Donor sex, age, body mass, BMI, and time in service were obtained from the Anatomical Gift Program (Table S1-supplemental). Anterior-posterior and lateral x-rays of the tibial component were used to score fixation status with three levels: well fixed, possibly loose, or loose by our arthroplasty surgeon (THI). One additional total knee construct was prepared in the laboratory using methods that simulated the operative procedure; this was included in the study as a ‘time zero’ construct where there would be no bony remodeling in response to the implantation procedure. All tibial components were metal-backed, the majority had a tibial stem or keel (n=18, one had an 80mm long stem), while four components did not have a stem. Wear of the articulating surface of the polyethylene insert was made using the scoring method described by Hood et al.(16).

Bone Densitometry

Clinical bone density scans (Lunar DPX-IQ, GE Healthcare, Waukesha, Wisconsin) were obtained of the proximal tibia with TKRs in the anterior-posterior direction. Bone mineral density (BMD) regions of interest were identified medial and lateral to the implant stem (peri-implant BMD), and for a region distal to the stem (distal to implant BMD) using the methods described by Abu-Rajab et al (17). An area-weighted total BMD was calculated for the composite of peri-implant and distal to implant BMD. When there was no implant stem, the peri-implant bone was defined as the region from the tibial tray surface to 35mm distal from the tray.

Mechanical Loading Protocol

The proximal tibiae were stripped of soft tissue and fixed in a rectangular pot 70 mm distal to the tibial component. The constructs were mounted in a mechanical test frame (MTS Renew, Eden Prarie MN) such that the tibial tray was perpendicular to the loading axis and axial compressive loads were applied to the tibia through the wear contact patches identified on each polyethylene insert. Non-destructive, donor specific, one body weight loads were applied with 60/40% medial to lateral distribution using a ramp (5 mm/min) loading pattern. Axial loads were chosen for this test in order to replicate the primary loading direction and magnitude found in instrumented knee replacements (18) and also to allow the tibia to
remain in a relatively fixed position required for the strain mapping measurement. Because repeated loading cycles were needed to perform all of the strain measurements, one body weight loading was used to ensure a non-destructive testing regime. All tests were performed in laboratory air at room temperature.

3-D Digital Image Correlation (DIC) Strain Mapping and Micro-motion Measurement

Strain and micro-motion measurements were made using a three-dimensional non-contacting digital image correlation (DIC) system. Black and white acrylic spray paint was applied to the bone surface to create texture for the DIC analysis. A pair of digital cameras (Diagnostic Instruments, Sterling Heights, Michigan) with 2–55mm telecentric lenses (Edmund Optics, Barrington, NJ) was mounted to a rigid aluminum stand. The cameras were spaced 37 cm apart and were focused on the bone surface (30 μm/pixel resolution) with an intersection angle of 60 deg between cameras (Fig. 1A). Field of view size was a maximum of 36 × 48 mm. MatchID (Catholic University College Ghent, Ghent, Belgium) 3-D DIC software was used to measure bone displacements and calculate strains. A normalized sum of squares difference (NSSD) approach was used for the DIC analysis with sub-regions of 20 pixels and step size of 10 pixels. Strain calculations used a bilinear quadrilateral interpolation (Q4) and the error in minimum compressive strain measurements were determined in a pilot calibration study (RMSE = 32.8 με, 95% confidence intervals 19 to 42 με).

Strain was measured over six regions of the bone surface (anterior (A), posterior (P), medial (M), lateral (L), postero-medial (PM), postero-lateral (PL)) (Fig 1B). For each region, the camera system was focused on the region of interest and the minimum principal strain (the most compressive strain) was determined. Strain data was collected moving from proximal to distal from the tibial tray surface (A, M, and L: 5 to 50mm; PM and PL: 5 to 15mm; P: 20–50mm)) using 5x10mm sampling regions in 5 mm increments. Examples of 5x10mm sampling regions are shown in Figure 1C&D. Loading was cycled between 1% BW and 100% BW with image collection after three preconditioning cycles. Proximal bone strain was calculated as the average of the minimum principal strains from the 5–15mm A-PM-PL-M-L regions. Peri-implant bone strain was calculated as the average of minimum principal strain measures from the 20 to 50mm A-P-M-L regions. A division between proximal and peri-implant strains was made based on bone morphology and strain distributions. Proximally there was large change in geometry and bone strain moving from proximal to distal, particularly over PM and PL regions. The PM and PL regions have been identified as strain ‘hot spots’ (19). The regional maximum strain was calculated as the maximum compressive strain magnitude from the five (A-PM-PL-M-L) proximal measurement regions.

Relative motion (micro-motion) between the metal tray and adjacent bone was also measured using the DIC system (error analysis from pilot accuracy study: RMSE = 1.1 μm, 95% CI: 0.54 to 1.16 μm) using a 2mm gage length between tray and bone sampling points (Fig 1B). The change in distance between the two sampling points for the 1% and 100% body weight load was calculated for the A, PM, PL, M, and L regions. Peak and average tray-bone micro-motion were calculated from the five sampling regions.
Statistical Methods

Descriptive statistics were calculated for all donor variables and for the biomechanical response (strain and micro-motion) to 1 body weight loading. Peri-implant bone strain and peak tray-bone micro-motion were chosen as the primary outcome variables to relate to the chronological and donor variables. Linear multiple regression was used to model the relationship between dependent variables (strain or micro-motion) and independent chronological variables (time in service and age) or donor variables (peri-implant BMD and mass).

RESULTS

Twenty-one biomechanical tests were completed successfully with collection of all bone surface strain and implant/bone micro-motion results. One biomechanical test (donor C) resulted in local failure of the bone directly under the tibial tray on the medial and lateral edges of the TKR due to an experimental error that caused 1 BW loading of just the medial and lateral plateau. For this donor, the micro-motion results and strain measures near the interface were excluded.

Peri-implant bone mineral density (BMD) spanned a wide range (0.07–1.16 gr/cm², mean: 0.61 gr/cm²) and was greater for the BMD distal to the implant (0.46–2.3 gr/cm², mean: 1.05 gr/cm²) (Table 1). The proximal bone strain (5 to 15mm from the tibial tray) was greater than the peri-implant bone strain (20 – 50mm from tibial tray) (Table 1). Proximally, bone surface strain was highest in the postero-medial (1120±803 (sd) μm) and postero-lateral (1270± 644 μm) regions, followed by medial (508±433 μm), lateral (426±644 μm), and anterior (362±267 μm) regions. Peri-implant regions, bone strain was greatest in the posterior region (567±654 μm), followed by medial (269±165 μm), lateral (263±243 μm), and anterior (240±143 μm) regions. Details of the distribution of bone strain and tray-bone micro-motion for all of the measured regions is provided in Figure S1 (supplemental).

Based on radiographic scoring (Table S1), there was substantial overlap of the peak tray-bone micro-motion between the ‘fixed’ group (range: 1.5 to 89 μm, median: 16.5 μm, n=16), ‘possibly loose’ group (range: 11.5 to 105 μm, median: 17.9 μm, n=5), and ‘loose’ group (87 μm, n=1). This indicates that radiographic scoring from x-rays alone is not very specific or sensitive to actual implant stability for this sample population of retrievals. Median tray/bone micro-motion for the five sampling regions were similar (anterior: 4.4 μm, postero-medial: 5.8 μm, postero-lateral: 4.1 μm, medial: 3.9 μm, lateral: 6.7 μm). In several retrievals, even though some regions of the implant/bone interface had relatively high micro-motions (>50 μm), there were always regions on the same retrieval with small micro-motions (<= 10 μm). There were few indications of vertical ‘liftoff’ where there was an increase in distance between the tray and bone; 4 cases of 22 had a region with liftoff greater than 3 μm, with the largest of 8.5 μm.

The results of the primary outcomes (peri-implant bone strain and peak micro-motion) are shown as a function of the chronological and patient factors (Figure 2). Using the linear regression models (Table 2), donors with more time in service had higher peri-implant bone strains (p=0.044), but there was not a statistically significant contribution (p=0.333) from
donor age. The axial distribution of bone strains (Figure 3) for time in service groups of 0 to 6, 7 to 11, and 12–22 years shows that the longest time in service group had higher bone strains both proximally and distally, compared to the shorter time in service groups. For the patient variables of BMD and body mass, donors with lower peri-implant BMD ($p=0.0039$) and higher mass ($p=0.0286$) had higher bone strains (Figure 2). Younger donors ($p=0.0161$) and longer time in service ($p=0.0008$) were correlated with greater peak interface micro-motion. However, tray-bone micro-motion was not significantly correlated with either peri-implant BMD ($p=0.455$) or body mass ($p=0.081$). Although not a primary research question, it is interesting to note that PE wear score was strongly correlated with time in service ($r^2=0.7$, $p<0.0001$).

**DISCUSSION**

The goal of the current study was to assess the influence of chronological (age and time in service) and patient (body mass and tibial bone density) factors on the bone strain patterns and micro-motion for functioning total knee replacements. In response to research question #1, bone surface strains were greater for donors with longer time in service, but did not depend on donor age for our sample population. Donors with short time in service (< 5 years) had proximal bone strains (mean: 570 $\mu$ε), but with longer time in service (> 11 years), proximal bone strains were almost twice as high (mean: 900 $\mu$ε) for 1 body weight (BW) loading. The short term proximal bone strains (<5 years) were similar to those reported for laboratory prepared TKR implantations in cadaver bone (520 $\mu$ε/BW) without remodeling (19), after normalizing to 1 BW loading. Medial and lateral bone strains reported for intact proximal tibia (20; 21) at 10 mm (125 $\mu$ε/BW), 25 mm (160 $\mu$ε/BW) and 50 mm (75 $\mu$ε/BW) from the articular surface (see Figure S1) were less than the strains (~200 $\mu$ε/BW) reported here for short term service (< 5 years), and much less than that for long term service (~500 $\mu$ε/BW). These findings suggest that the postmortem retrieved TKRs may not be strain shielded compared to intact tibia, and over the longer term may have higher than normal bone strain. Additional work comparing strain mapping in age/sex matched control cadaver tibia without implants is needed to confirm this observation.

Medial-midshaft tibial bone strain has been measured *in vivo* in humans performing a variety of activities (22–24) and compressive strains of 308 to 414 $\mu$ε have been reported during walking. These are similar to the bone strains measured at the most distal 50mm level in the current study (223, and 310 $\mu$ε for short and long term implantation) for 1 body weight loading. If this loading is scaled to gait levels (~2.6 BW) (18), and assume that bone strains scale linearly with load, strain magnitudes would increase to 580 to 805 $\mu$ε (short to long term), which approaches twice the strain magnitude measured *in vivo* for gait. This further supports the concept that the bone strains measured here may exceed normal *in vivo* levels.

The largest regional bone strain (3000 $\mu$ε) for one body weight loading was less than the yield strain reported for trabecular and cortical bone (~7000 $\mu$ε) (25; 26). If we scale to load levels for level walking (~2.6 BW), then three donors (C, E(R), O(R) from Table S1) would be estimated to exceed the yield strain for normal bone. Note that donor C was the bone that was overloaded on the medial and lateral margins when 1BW was applied to just the medial
and lateral plateaus. These results suggest that regional bone failure would be possible if larger loads were applied and is the subject of future investigation in our lab. It is also possible that the strain-loading response is not linear and higher loads do not result in proportional increases in bone strain. Increased peri-implant bone strains have been correlated with increased implant migration and component loosening (27).

In response to research question #2, bone strains were found to be higher for donors with lower BMD and higher body mass. Low BMD is associated with increased risk of bone fracture, but in the context of TKR there also may be less stress applied through the bone below the tibial tray due to stress shielding (28; 29). There does not appear to be clinical data that directly relates lower peri-implant BMD with increased risk of TKR loosening, but the work here supports the concept that low BMD constructs will have increased bone strain. There is also clinical data showing that bisphosphonates can maintain bone mass and reduce revision risk (30); maintaining bone mass may prevent an increase in bone strains thereby reducing risk of bone yielding. High body mass has also been shown to be a clinical factor associated with increased component migration and implant loosening (6). Thus, high body mass, coupled with lower BMD could result in an increased risk of failure due to higher peri-implant bone strains. Note that without BMD in the regression model, body mass (by itself) was not a predictor of bone strain ($r^2=0.01$). This may partially explain why some clinical studies have not reported a clear relationship between high mass or BMI and aseptic loosening. Adding BMD measures to clinical studies may be useful to help explore this issue. Finally, it is important to note that each construct was loaded with the donor’s body mass (one body weight), so that an equitable comparison between donors with high and low body mass could be made.

In response to research question #3, micro-motion was greater for younger donors and for donors with longer time in service. Loss of implant fixation resulting in increased micro-motion is a plausible failure scenario and is consistent with clinical data that shows that the revision rate for younger patients was greater than older patients, and that there is an increased risk of revision with time in service (31). However, it should be noted that the micro-motions measured here (peak median of 17 μm with a maximum of 105 μm) were relatively small compared to magnitudes known to result fibrous tissue formation with porous-surface implants (150 μm) (32). Micro-motion magnitude was similar to a recent study (13) of postmortem retrieved TKRs where 500N loads were applied to the medial and lateral plateaus and micro-motions were generally less than 20 μm with a maximum of 300 μm.

This project has several limitations. The loading was uni-axial and did not include forces experienced by the tibia during the entire gait cycle or other activities. However, axial loading represents, by far, the largest force component based on information obtained from instrumented knee replacements (18). This retrieval study included a variety of metal-backed tibial components from a number of different manufacturers. It is likely that implant design, as well as component alignment and cement distribution all contribute to the stability and stress distribution in the implant, interface, and bone. Of particular note were the four components that did not have a central stem. Presence of a stem was not a significant predictor in the regression models of peri-implant strain for the chronological (p=0.132) or
donor \((p=0.708)\) parameters. However, despite the variety of metal-backed implant types, our results showed that chronological and donor parameters could be correlated with micro-motion and bone strains.

Bone strain and micro-motion were only measured on the periphery of the construct. Internal bone strain, particularly bone strain near the distal tip of stem, is likely important in describing the load transfer from tibial tray to bone. Failure of trabecular bone supporting the tibial trays would also be an important component of the process. Micro-motion is likely lower in regions away from the periphery of the tray, because the periphery of the tray often show loss of interlock between cement and bone. Many of the specimens used in this study were from older donors \((80+\text{ years})\), and the mean age at implantation was \((69.5 \pm 10.4\text{ years})\). This is very similar to the registry data from Australia \((68.8 \pm 9.5\text{ years})\) \((33)\) suggesting that our retrievals are representative of a typical TKR age distribution.

Taking into account in-vivo changes to fixation and supporting bone, the results from this work suggest two possible scenarios for loosening of the tibial components in TKR. Younger, more active patients may load the implant/bone interface such that there is increased inducible micro-motion, and this could increase with time in service due to loss of interlock between cement and bone. The mechanism for this is not clear, but is likely related to morphology changes at the interface due to polyethylene debris \((34)\) or fluid induced lysis \((35)\). Older patients with long time in service may also have a higher risk of loosening due to failure of bone supporting the implant due to high bone strains. This may also be related to low peri-implant BMD and high body mass. Further work is needed to determine if high magnitude joint loading results in increased inducible micro-motion and clinically relevant component migration for these postmortem retrievals.

**Supplementary Material**

Refer to Web version on PubMed Central for supplementary material.

**Acknowledgments**

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**References**


Figure 1.
Strain and micro-motion measurements (A) were made using a two camera digital image correlation (DIC) system with an axial load of one body weight (BW) using 60/40% distribution applied to the medial/lateral plateau. Strain measurements were made at five regions (A, L, PL, PM, M) proximally (5–15 mm from tibial tray) and four regions (A, P, M, L) for regions 20 to 50 mm from the tibial tray (B). Micro-motion measurements were made using a 2mm gage length between the metal tray and bone at five locations (A, L, PL, PM, M). Example minimum principal strain maps are shown for PM (C) and lateral (D) regions. Nomenclature: A-anterior, P-posterior, M-medial, L-lateral, PM-postero-medial, and PL-postero-lateral.
Figure 2.
Contour plots of distal bone strain as a function of chronological factors (age and time in service) (A) and patient factors (body mass and peri-implant bone mineral density) (B) for 22 tibial components. Peak implant/bone micro-motion is shown as a function of chronological (C) and patient factors (D). Open circles indicate female TKR donors, filled circle indicate male TKR donors.
Figure 3.
Spatial distribution of bone strain as a function of years in service was divided into short term (0 – 6 years), medium term (7 – 11 years), and long term (12 – 22 year) groups. Mean and standard error of the mean shown.
Table 1

Descriptive statistics for TKR donor information, bone strain, and tray/bone micro-motion outcome measures (n=22).

<table>
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<th>Mean</th>
<th>Median</th>
<th>Std Dev</th>
<th>Min</th>
<th>Max</th>
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<tr>
<td>Age (years)</td>
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<td>84.5</td>
<td>11.0</td>
<td>54</td>
<td>90</td>
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<td>Age at Implantation (years)</td>
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<td>72.5</td>
<td>10.4</td>
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<td>Time in Service (years)</td>
<td>9.0</td>
<td>10</td>
<td>5.6</td>
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<td>Mass (kg)</td>
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<td>86</td>
<td>13.5</td>
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<td>BMI (kg/m²)</td>
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<td>29.1</td>
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<td>Peri-implant bone mineral density (g/cm²)</td>
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<td>0.51</td>
<td>0.29</td>
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<td>Distal to Implant bone mineral density (g/cm²)</td>
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<td>0.91</td>
<td>0.47</td>
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<td>Total bone mineral density (g/cm²)</td>
<td>0.77</td>
<td>0.65</td>
<td>0.34</td>
<td>0.28</td>
<td>1.57</td>
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<td>Proximal bone strain (5–15mm) (με)</td>
<td>743</td>
<td>733</td>
<td>369</td>
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<td>Peri-implant bone strain (20–50mm) (με)</td>
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<td>254</td>
<td>148</td>
<td>119</td>
<td>791</td>
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<td>Regional max bone strain (με)</td>
<td>1530</td>
<td>1390</td>
<td>828</td>
<td>342</td>
<td>3000</td>
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<td>Tray-bone peak micro-motion (μm)</td>
<td>32</td>
<td>17</td>
<td>31</td>
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<td>Tray-bone mean micro-motion (μm)</td>
<td>16</td>
<td>8</td>
<td>17</td>
<td>0.7</td>
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Table 2

Linear regression models for peri-implant bone strain and implant/bone micro-motion (dependent variables) due to 1 BW loading with chronological factors (donor age and time in service) and patient factors (peri-implant bone mineral density (BMD) and body mass) as independent variables.

<table>
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<th>Parameter Term</th>
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<th>Standard Error</th>
<th>P value</th>
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<td>Peri-implant bone strain (με), $r^2 = 0.30$, $p=0.033$, RMSE = 130.1 με</td>
<td>Intercept</td>
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<td>Time in service (years)</td>
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<td>Peri-implant BMD (gr/cm²)</td>
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<td>Mass (kg)</td>
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<td>Tray-bone peak micro-motion (μm), $r^2 = 0.50$, $p = 0.0019$, RMSE = 23 μm</td>
<td>Intercept</td>
<td>100.6</td>
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<td>Age (years)</td>
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<td>Time in service (years)</td>
<td>3.92</td>
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<td>Tray-bone peak micro-motion (μm), $r^2 = 0.19$, $p = 0.14$, RMSE = 29 μm</td>
<td>Intercept</td>
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<td>48.8</td>
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<td>Peri-implant BMD (gr/cm²)</td>
<td>-26.1</td>
<td>34.2</td>
<td>0.455</td>
</tr>
<tr>
<td></td>
<td>Mass (kg)</td>
<td>1.38</td>
<td>0.74</td>
<td>0.081</td>
</tr>
</tbody>
</table>