Designation: ~~F3141 – 15~~ F3141 – 17

Standard Guide for Total Knee Replacement Loading Profiles[1]

This standard is issued under the fixed designation F3141; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 Motion path, load history and loading modalities all contribute to the wear, degradation and damage of implanted prosthetics. Simulating a variety of functional activities promises more realistic testing for wear and damage mode evaluation. Such activities are often called activities of daily living (ADLs). ADLs identified in the literature include walking, stair ascent and decent, sit-to-stand, stand-to-sit, squatting, kneeling, cross-legged sitting, into bath, out of bath, turning and cutting motions (**1-7**).[2] Activities other than walking gait often involve an extended range of motion and higher imposed loading conditions which have the ability to cause damage and modes of failure other than normal wear (**8-10**).

1.2 This document provides guidance for functional simulation that could be used to evaluate *in vitro* the durability of knee prosthetic devices under force control.

1.3 Function simulation is defined as the reproduction of loads and motions that might be encountered in activities of daily living but it does not necessarily cover every possible type of loading. Functional simulation differs from typical wear testing in that it attempts to exercise the prosthetic device through a variety of loading and motion conditions such as might be encountered *in situ* in the human body in order to reveal various damage modes and damage mechanisms that might be encountered throughout the life of the prosthetic device.

1.4 Force control is defined as the mode of control of the test machine that accepts a force level as the set point input and which utilizes a force feedback signal in a control loop to achieve that set point input. For knee simulation, the flexion motion is placed under angular displacement control, internal and external rotation is placed under torque control, and axial load, anterior posterior shear and medial lateral shear are placed under force control.

1.5 This document establishes kinetic and kinematic test conditions for several activities of daily living, including walking, turning navigational movements, stair climbing, stair descent, and squatting. The kinetic and kinematic test conditions are expressed as reference waveforms used to drive the relevant simulator machine actuators. These waveforms represent motion, as in the case of flexion extension, or kinetic signals representing the forces and moments resulting from body dynamics, gravitation and the active musculature acting across the knee.

1.6 This document does not address the assessment or measurement of damage modes, or wear or failure of the prosthetic device.

1.7 This document is a guide. As defined by ASTM in their "Form and Style for ASTM Standards" book in section C15.2, "A standard guide is a compendium of information or series of options that does not recommend a specific course of action. Guides are intended to increase the awareness of information and approaches in a given subject area. Guides may propose a series of options or instructions that offer direction without recommending a definite course of action. The purpose of this type of standard is to offer guidance based on a consensus of viewpoints but not to establish a standard practice to follow in all cases." The intent of this guide is to provide loading profiles and test procedures to develop testing that might be used for wear, durability or other types of testing of total knee replacements. As noted in this definition, a guide provides guidance on testing, but does not require specific testing. Thus, for example, if a user is unable to control one mode of force control given in the load profiles, that user is not required to perform that mode of loading.

1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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[2] The boldface numbers in parentheses refer to the list of references at the end of this standard.

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

~~**2. Referenced Documents**~~

~~2.1 *ASTM Standards:*[3]~~
~~E74 Practice of Calibration of Force-Measuring Instruments for Verifying the Force Indication of Testing Machines~~
~~E2309 Practices for Verification of Displacement Measuring Systems and Devices Used in Material Testing Machines~~
~~E2624 Practice for Torque Calibration of Testing Machines~~

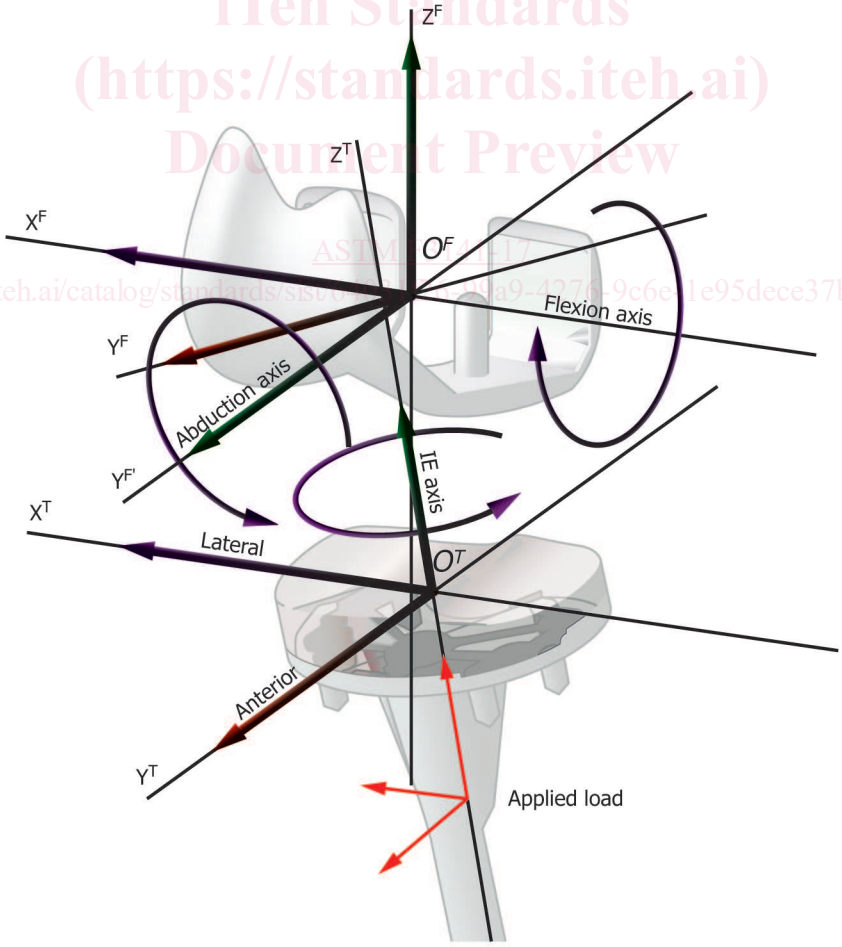
2. Reference Frame System (see Fig. 1)

2.1 Two right-handed coordinate systems are defined as reference frames; one with an origin at O^T fixed to the tibia and a second with an origin at O^F fixed to the femur.

2.2 Displacements (rotations and translations) shall mean displacements of the tibial component relative to the femoral component. The anatomical axes correspond to the mechanical axes described by Grood and Suntay (**11**).Table 1 shows the mechanical axes and abbreviations corresponding to each anatomical axis.

2.3 The orientation and location of the axes of the reference frames follow the approach defined by Pennock (**12**). However, to accommodate the simulator machine (versus anatomical) setting several modifications are made to the Pennock approach, as described in ~~3.4~~2.4.

2.4 The femoral reference frame defines three coordinate axes, X^F, Y^F, and Z^F all coincident at the origin O^F. The flexion axis, X^F, shall be defined as collinear with a line passing through the coordinates of the average center of curvature of the posterior 90 degrees of condylar arc. The average center of curvature shall be developed individually for the medial and lateral condyles based



Two righted-handed reference frames, O^F and O^T, are embedded in and move with the femur and tibia respectively. The coordinate system and signs are based on a right knee and forces and moments are considered to be applied to the tibia shaft with reaction forces acting at the joint articular surface.

FIG. 1 Reference Frame System

TABLE 1 Anatomical Meaning of Coordinate System Axes and Abbreviations

Anatomical Axis	Coordinate Axis	Abbreviations
Medial – Lateral	X^F	ML
Anterior – Posterior	Y^T	AP
Axial	Z^T	AX
Flexion – Extension	X^F	FE
Internal – External Rotation	Z^T	IE
Abduction – Adduction	$Y^{F'}$	AA

on regular increments of angle from 0 to 90 degrees of posterior arc (the transepicondylar line may be substituted for the average center of curvature if the manufacturer specifies that reference frame for surgical alignment purposes). The long axis of the femur, Z^F, lies on a line passing through the center of the femoral head which extends to the medial lateral midpoint of the trans-condylar line, lying on the X^F axis, connecting the most medial and most lateral points of the medial and lateral femoral condyles at their most distal projection. The Z^F axis shall be perpendicular to the X^F axis and the Y^F axis shall be defined as the cross product of the Z^F and X^F axes.

2.5 The tibial reference frame defines three coordinate axes, X^T, Y^T, and Z^T, all coincident at the origin O^T. The anatomical long axis of the tibia, Z^T, is defined by a line extending from the center of the tibial intercondylar eminence to the center of the ankle (**12**). This definition shall be adopted for this standard. The X^T, Y^T, axis shall be defined with the knee in full extension and in a neutral configuration. In that configuration the X^T axis shall be parallel to the femoral X^F axis and the Y^T axis will be coplanar with the plane of the Y^F and Z^F axes. The X^T and Y^T axes will be mutually perpendicular to the Z^T axis. The origin O^T of the tibial coordinate system shall be located such that the X^T axis is tangent to the most distal aspect of the tibial articular bearing surface.

2.6 Grood and Suntay describe the motions of the knee using the notion of a mechanical linkage that constrains rotation and translation axes in a way that is thought to be clinically relevant. To define this motion a floating axis, $Y^{F'}$ is utilized. This axis is labeled the abduction axis. The abduction axis remains perpendicular to both the X^F axis and the Z^T axis in all configurations. The abduction axis is rotated about the X^F axis by an arc equal to flexion-extension arc.

3. Terminology

3.1 *Definitions:*

3.1.1 *activity model, n*—an activity model provides a kinematic and kinetic description of a particular physiological activity. Each activity model shall provide a set of time series data that represents one cycle of the subject activity. The time series data provided by an activity model are used as inputs to control the motions and forces of the test machine. The time series data required to characterize each activity are: *(1)* axial force, *(2)* flexion-extension angle, *(3)* axial tibial torque, *(4)* anterior-posterior force, and *(5)* medial-lateral force. These torques or forces may result in the motion of the femur or tibial relative to the other. How these motions are described may be machine-dependent, as to whether it is a motion of the tibia relative to the femur or the femur relative to the tibia. The following descriptions are frequently described as motion of the tibia, but could also be described as motion of the femur.

3.1.2 *activities of daily living, ADLs, n*—these are the physiological activities to which a human knee may be subject during the course of normal living. Typical ADLs include: high frequency maneuvers such as walking and turning; navigational maneuvers such as cross over turning and pivot turning; deep knee flexion maneuvers such as squatting, stair ascent and descent; high loading maneuvers such as stumbling; and athletic activities.

3.1.3 *AP translation, d^T_{ap} or d^T_y [mm], n*—translation of the tibial component along the Y^T axis (anterior posterior axis); a positive displacement moves the tibia in the anterior direction. The magnitude of the displacement is expressed relative to the reference position.

3.1.4 *AP force, f^T_{ap} or f^T_y [N], n*—applied anterior or posterior force acting on the tibial component parallel to the Y^T axis. A positive AP force acts in the positive Y^T direction and will result in an anterior translation of the tibia.

3.1.5 *applied force, n*—applied force is that force acting on the joint originating from external sources (includes the musculature). When magnitude and direction are specified the applied force shall be considered to be acting on the tibial shaft with balancing reaction forces at the joint surface.

3.1.5.1 *Discussion*—

The forces acting across the knee are partitioned into applied and constraint forces while the constraint forces are further partitioned into joint reaction force and soft tissue constraint force. The applied force is comprised of the sum of the influences of gravitation, body dynamics, and the action of the active musculature. The joint reaction force is comprised of the influence of all of the mechanisms which contribute to the forces of contact acting on the articular joint surface. The soft tissue constraint force

is comprised of the sum of all of the influences of the passive soft tissue structure which is dominated by the elastic and viscoelastic response of the ligaments and capsular structure surrounding the joint.

3.1.6 *joint coordinate system, JCS, n*—the coordinate system and kinematic chain described by Grood and Suntay to represent the translational and rotational axes and motions of the knee.

3.1.7 *neutral position, n*—this is the position where the forces (or torques) are zero and corresponds to zero on the force (or torque) deflection graphs defining the constraint forces and torques.

3.1.8 *reference orientation, n*—the reference orientation is the relative alignment of the tibial and femoral components defined by the manufacturer as the desirable alignment at full extension and neutral IE rotation.

3.1.9 *reference position, n*—the reference position is determined with the prosthetic components aligned in the reference orientation. The reference position is that position on the AP and ML axis where an axial load results in no AP or ML reaction force. This may be determined experimentally in the test machine by applying 100 N of axial load and then exercising the machine through a range of AP or ML motion while recording the corresponding AP or ML reaction force and displacement. The midpoint of the minimum cusp of the force displacement curve is the reference position.

3.1.9.1 *Discussion*—

The reference position may be determined analytically or graphically as that point where, when in the reference orientation, the surface normal of contact points of the femoral and tibial components are collinear with the axial load axis.

4. Significance and Use

4.1 The purpose of this test guide is to provide load profile information on how ~~to~~ one could test a total knee replacement in order to evaluate *in vitro* its function and wear during several types of knee ~~motions.~~motions as described in 4.2 and 4.3.

4.2 This test guide may help characterize the magnitude and location of implant wear as an implant is repetitively moved according to specified load and displacement waveforms.

4.3 This test guide may also help characterize the functional limitations of a total knee replacement as its motion is guided by these waveforms. These limitations may be observed as impingement, subluxation or high loading in the soft tissue constraints, whether they are represented physically or virtually.

4.4 The motions and load conditions *in vivo* will, in general, differ from the load and motions defined in this guide. The results obtained from this guide cannot be used to directly predict *in vivo* performance. However, this guide is designed to allow for comparisons in performance of different knee designs, when tested under similar conditions.

5. Apparatus

5.1 A joint motion simulator machine is required for this testing.

5.2 Suggested cyclic frequency specified for each activity is given in Table 2. The cyclic frequency for each activity should be physiologically relevant. If an accelerated or other non-physiological rate is used, then a justification considering lubrication, thermal, and kinematic effects should be provided.

5.3 *Distribution of Activity Motions*—The testing system shall be equipped with a means to select and run different ensembles of reference waveforms representing various activities of daily living (ADLs). The six activities shall be performed in the order listed in Table 2. The percent of each activity is based on data from Glaister et al **(13)**, Grant et al **(14)**, and Morlock et al **(15)**. Some functional or wear testing may require only a subset of the activities in Table 2.

5.4 *Means of Mounting Specimen*—The system should include a means for repeatably mounting and dismounting specimens to maintain alignment and positioning to facilitate removal for gravimetric wear measurements and other wear evaluation and measurement processes if so tested in that manner.

TABLE 2 Distribution of Activities

Activity	Percent	Period (sec)	Suggested Frequency (Hz)
Straight walking	54%	1.16	0.86
Pivot turn	18%	1.20	0.83
Cross over turn	18%	1.20	0.83
Stair ascent	5%	1.28	0.78
Stair descent	5%	1.25	0.80
Sit stand sit	1%	2.45	0.41
Total cycles	100%		

5.5 *Control Method for Each Axis*—The system shall provide a means to control each axis of motion (Table 3). The required degrees of freedom and the control scheme for each degree of freedom are defined in (Table 3).

5.6 *Tracking Error*—The testing system shall be equipped with a means to measure the tracking error of each of the controlled degrees of freedom (Table 4). Data acquisition and storage requirements are discussed in ~~6.9~~5.9.

5.7 *Kinetic Measurement Instrumentation:*

5.7.1 The testing system shall be equipped with instrumentation to measure the forces and moments (Table 5). Those items indicated in the comments section as imperative are mandatory for the use of this guide; those items indicated optional are recommended but not required. Data acquisition and storage requirements are discussed in ~~6.9~~5.9.

5.7.2 Force and torque measurements ~~should~~shall be made with an accuracy of ~~±3%~~ ±5 % full scale range of the applied load.

5.8 *Kinematic Measurement Instrumentation:*

5.8.1 The testing system shall be equipped with instrumentation to measure the linear displacements and angular displacements (Table 6). Those items indicated in the comments section as imperative are mandatory for the use of this guide; those items indicated optional are recommended but not required. Data acquisition and storage requirements are discussed in ~~6.9~~5.9.

5.8.2 Linear displacements should be measured with an accuracy of ±0.2 mm and angular measurements with an accuracy of ±0.5°.

5.9 *Data Acquisition System:*

5.9.1 The testing system shall be equipped with a means to digitize and record measured and calculated values provided by the machine's instrumentation as discussed in sections ~~6.7~~5.7 and ~~6.8~~5.8. Each channel should be sampled at a minimum rate of 200 samples per second. A two-pole analog Butterworth filter (or similar) with a 100 Hz cutoff frequency should be provided for anti-aliasing. Data should be digitized with a minimum of 12 bits of digital resolution.

5.9.2 Recorded data should include the reference waveform for all controlled channels, the force and torque signals of section ~~6.7~~5.7, the displacement and angle signals of section ~~6.8~~5.8, and optionally the calculated error signals.

5.9.3 At least one time series sample with a duration of at least one waveform cycle should be saved for every instance that the reference waveforms are changed after the waveform has reached a steady state if the protocol allows it to reach steady state. Multiple samples should not be averaged as this occludes higher frequency content that may reveal vibration and jitter which can inadvertently elevate or diminish wear results. This sample should include the date, time, test identification information, and cycle count summary for the test protocol.

5.9.4 RMS error of the system tracking performance should be calculated periodically for each of the reference waveforms. RMS deviations of more than 5% of full scale should be flagged and corrective action should be taken. A record or log of proper operation based on RMS error should be maintained on a daily basis.

5.10 *Varus/Valgus Moment*—The testing system should be equipped with a means to adjust the varus/valgus moment to proportion the axial load between the medial and lateral compartments of the prosthetic component. The nominal ratio of load should be 57% medial to 43% lateral. Other ratios can be used if reported. This adjustment may be static; however, a means to monitor the load proportioning or moment should be available.

5.11 *IE Moment*—The testing system should include a means to allow the axis of IE rotation to float freely relative to the femoral component in the transverse plane. This center of rotation should adjust freely to accommodate the constraints provided by the articular surface contact kinetics and soft tissue.

5.11.1 *IE Motion Axes and Mounting Location*—The motion axes are shown in Fig. 1. The IE rotation axis should remain parallel to the tibial shaft and should not be constrained on either the AP or ML axes. IE rotation should be permitted to occur around an axis established by the natural constraints of articular contact and soft tissue constraint. This is particularly important with medial pivot designs which may undergo reduced torsional kinematics with a more laterally positioned axis of IE rotation.

5.11.2 If the testing system imposes position constraints on the IE rotation axis, then the IE axis should pass through the midpoint of the line segment joining the contact points of the medial and lateral condyles when the prosthesis is in the reference orientation and position.

TABLE 3 Control Scheme for Each Degree of Freedom

Anatomical Axis	Coordinate Axis	Control Method
ML	X^F	Force control
AP	Y^T	Force control
AX	Z^T	Force control
FE	X^F	Displacement control
IE	Z^T	Torque control
AA	$Y^{F'}$	Unconstrained

TABLE 4 Tracking Error Calculation Method

Anatomical Axis	Coordinate Axis	Error Method
ML	X^F	Constraint sum error
AP	Y^T	Constraint sum error
AX	Z^T	Force error
FE	X^F	Displacement error
IE	Z^T	Constraint sum error

TABLE 5 Kinetic Measurement Instrumentation

Anatomical Axis	Coordinate Axis	Comment
ML Force	X^F	Shall be measured
AP Force	Y^T	Shall be measured
AX Force	Z^T	Shall be measured
FE Moment	X^F	Optionally measured
IE Moment	Z^T	Shall be measured
AA Moment	$Y^{F'}$	Optionally measured

TABLE 6 Kinematic Measurement Instrumentation

Anatomical Axis	Coordinate Axis	Comment
ML Displacement	X^F	Shall be measured
AP Displacement	Y^T	Shall be measured
AX Displacement	Z^T	Optionally measured
FE Angle	X^F	Shall be measured
IE Angle	Z^T	Shall be measured
AA Angle	$Y^{F'}$	Optionally measured

6. Hazards

6.1 *Crushing Hazard*—Simulator machines produce crushing level forces. During operation the machines should be enclosed or equipped with automatic shut-off devices to prevent penetration into the operating space. During setup a low force mode of operation should be selected and used to mount and manipulate components. Operators shall be trained to understand the potential crushing hazard.

7. Number of Test Specimens and Cycles

7.1 A minimum of 3 test specimens of an implant design shall be tested.

7.2 The number of test cycles should be determined and justified by the user.

8. Calibration ~~and Standardization~~

~~9.1 *Force Measuring Instrumentation:*~~

~~9.1.1 All force and torque measuring instruments should be calibrated annually in accordance with ASTM E74 and ASTM E2624. As some machines utilize multi-axis force measurement transducers each channel of those transducers should be calibrated as above. If the instruments are not calibrated annually, the user should report when they were last calibrated.~~

~~9.1.2 Prior to every test of an implant all force measurement instruments should be verified by applying a known load using a secondary method of load measurement.~~

8.1 ~~*Displacement Measuring Instrumentation:*~~ Calibration of all force- and torque-measuring instruments and all displacement and angular displacement measuring instruments shall be performed according to the instrument manufacturer's recommendation.

~~9.2.1 All linear displacement and angular displacement measuring instrumentation should be calibrated annually using an NIST traceable secondary measurement device and calibration should follow ASTM E2309. If the instruments are not calibrated annually, the user should report when they were last calibrated.~~

~~9.2.2 Prior to every test all displacement measuring instruments should be verified using a secondary measurement instrument.~~

9. Loading, Alignment and Fixturing

9.1 The mounting or loading of specimens controls the alignment and relative position of specimens in the test machine which in turn significantly affects the kinematics and kinetics of the test. A means should be provided to ensure the accurate repeatable mounting of specimens through the use of appropriate fixturing. A measurement method should be used to document the position and alignment of the prosthetic components once mounted. Such measurement can be accomplished using calipers to determine positions of appropriate landmarks on the prosthetic components.

9.1.1 The reference orientation is the relative alignment of the tibial and femoral components defined by the manufacturer as the desirable alignment at full extension and neutral IE rotation.

9.1.2 The reference position is determined with the prosthetic components aligned in the reference orientation. The reference position is that position on the AP and ML axis where an axial load results in no AP or ML reaction force. This may be experimentally determined in the test machine by applying 100 N of axial load and then exercising the machine through a range of AP or ML motion while recording the corresponding AP or ML reaction force and displacement. The midpoint of the minimum cusp of the force displacement curve is the reference position. The 100 N force was selected to seat the femoral component into the tibial.

9.1.3 The reference position may be determined analytically or graphically as that point where, when in the reference orientation, the surface normal of contact points of the femoral and tibial components are collinear with the axial load axis.

9.1.4 *IE Motion Axes and Mounting Location*—The motion axes are shown in Fig. 1. The IE rotation axis should remain parallel to the tibial shaft and should not be constrained on either the AP or ML axes. IE rotation should be permitted to occur around an axis established by the natural constraints of articular contact and soft tissue constraint. This is particularly important with medial pivot designs which may undergo reduced torsional kinematics with a more laterally positioned axis of IE rotation.

9.1.5 If the testing system imposes positional constraints on the IE rotation axis, then the IE axis should pass through the midpoint of the line segment joining the contact points of the medial and lateral condyles when the prosthesis is in the reference orientation and position.

9.2 *Mounting Specimens*—The tibial component should be mounted with a posterior slope referenced to the axial load axis or the AP axis (see Fig. 1) in accordance with the manufacturer's recommendation. Mounting should include the tibial tray mechanism designed to retain the tibial bearing component in service.

10. Procedure

10.1 Verify force measurement instrumentation and displacement measurement instrumentation function.

10.2 Mount the femoral and tibial components on their respective fixtures in accordance with Sections ~~3~~2 and ~~10~~9.

10.3 Set up the machine program selecting the desired activities reference waveforms and the desired constraint characteristics. Create a verification program with the same waveforms and constraint characteristics that is programmed to provide only 200 cycles of motion for each activity waveform.

10.4 Verify the kinetics and kinematics with a throw-away sample of similar geometry in place in the machine. Tune the machine as necessary to achieve a suitable tracking performance.

10.5 Mount the test component fixtures in the machine.

10.6 Run the verification program and take data at the 150 cycle point of each of the reference waveforms. Verify that the kinetics and kinematics are consistent with the loading characteristics specified in Section ~~12~~11.

10.7 Start the test program.

10.8 Continue until the required number of cycles has been reached or evidence of failure is observed upon examination.

11. Loading Regimes for ADLs

11.1 The user shall use the heavy load curve unless the user can justify use of the mean loading curve. See Figs. 2-7.

12. Report

12.1 The report should include the following:

12.1.1 The identity of the test specimens; size; material type; manufacturer; method of sterilization; test medium; protein concentration of the test medium; and the time, date and duration of the testing.

12.1.2 A description of the test machine, numbers stations, control methodology, and calibration dates and traceability information for the system measurement instrumentation. Any changes to the control methodology, such as not using one or more modes of force control of a load profile, as allowed in 1.7, shall be noted in the report along with a justification.

12.1.3 A graphical representation of the series of the applied reference waveforms, and graphical representation of a typical measurement of the resulting kinetics and kinematics.

12.1.4 A quantitative representation of the RMS tracking performance over the course of the testing process.

12.1.5 A statement of results:

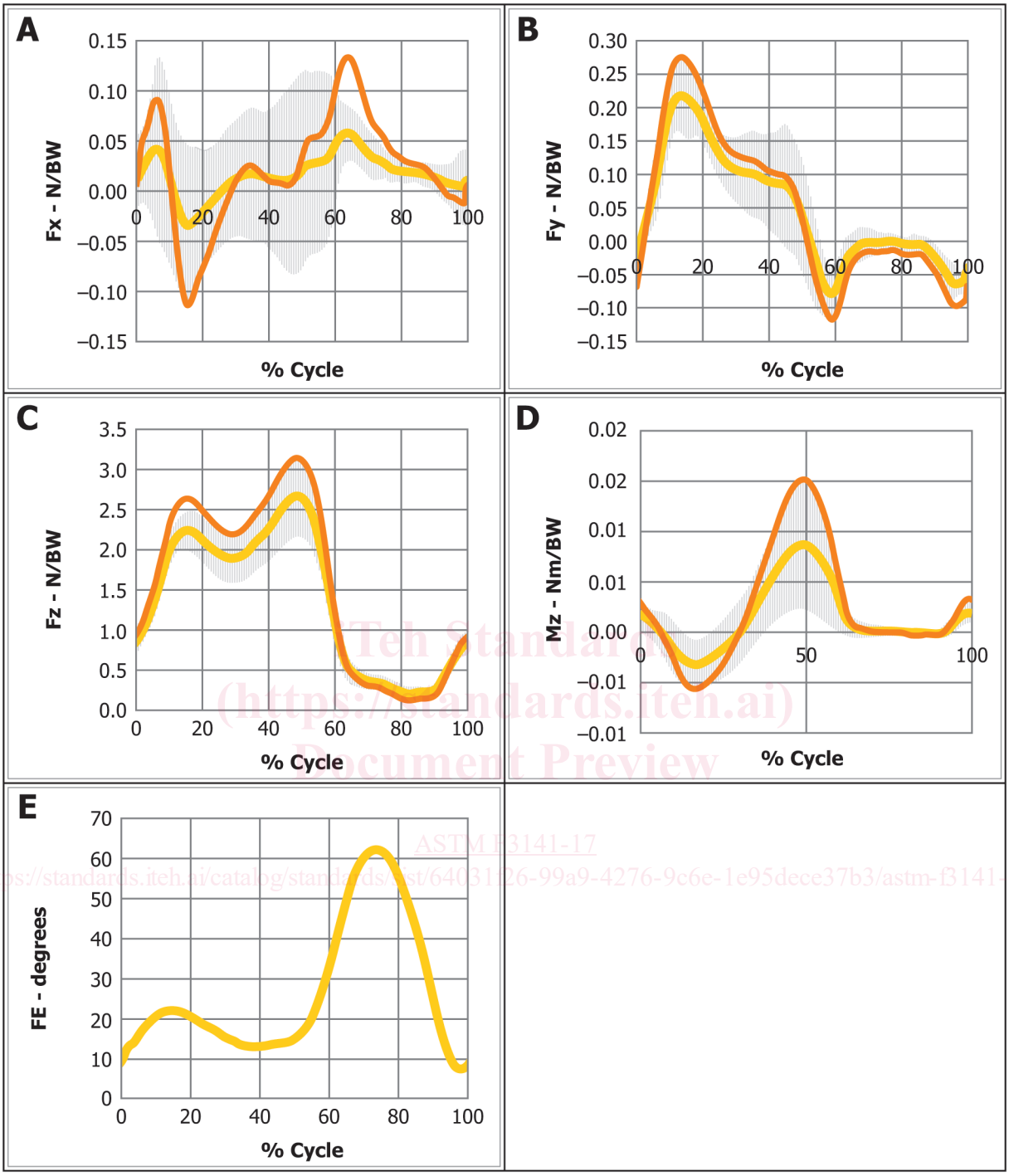
12.1.5.1 The total number of cycles applied,

12.1.5.2 The reason for terminating the test if less than the required number of cycles were reached, and

12.1.5.3 Any deviation from the standard testing approach.

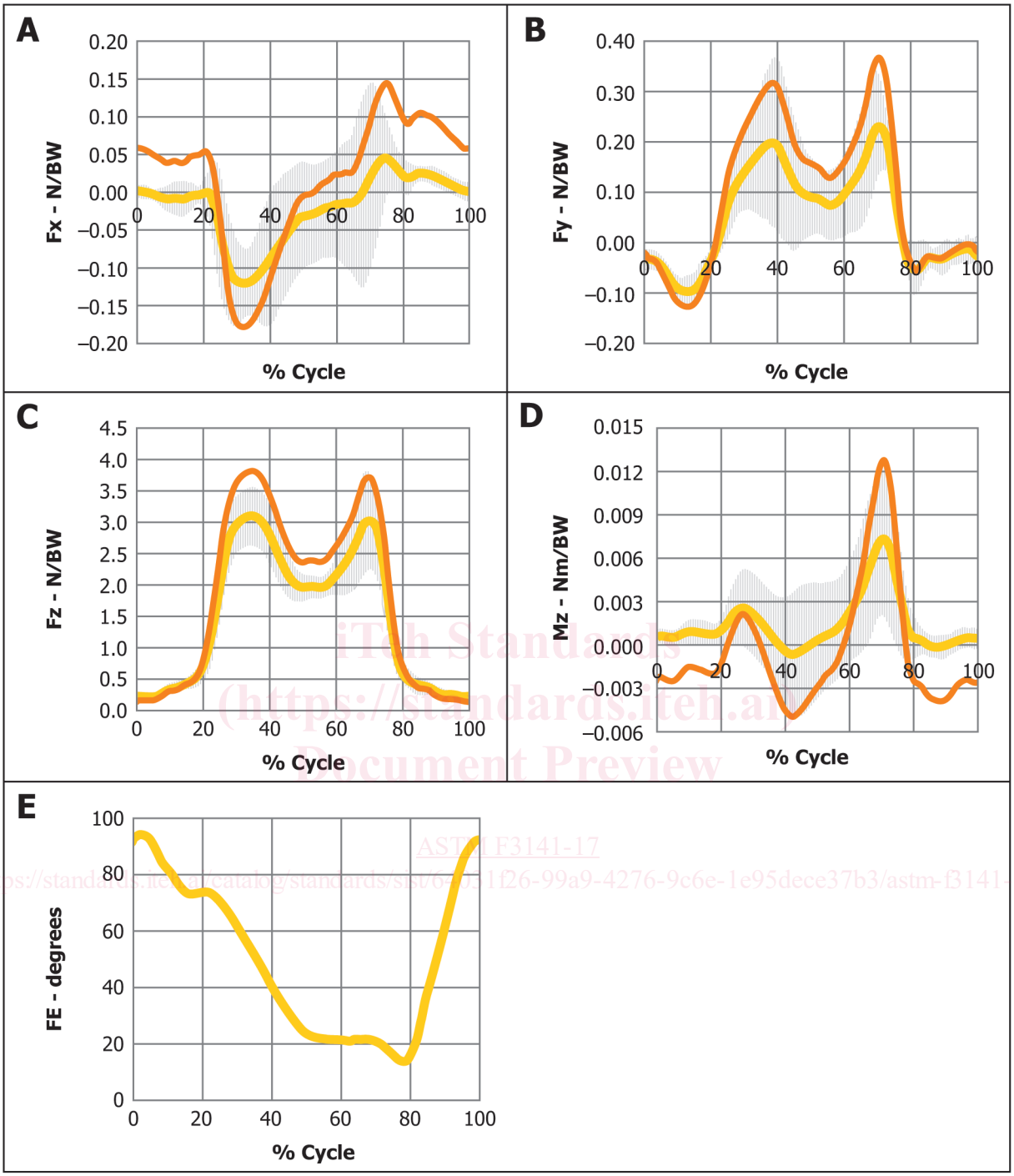
13. Keywords

13.1 arthroplasty; durability testing; knee prosthesis



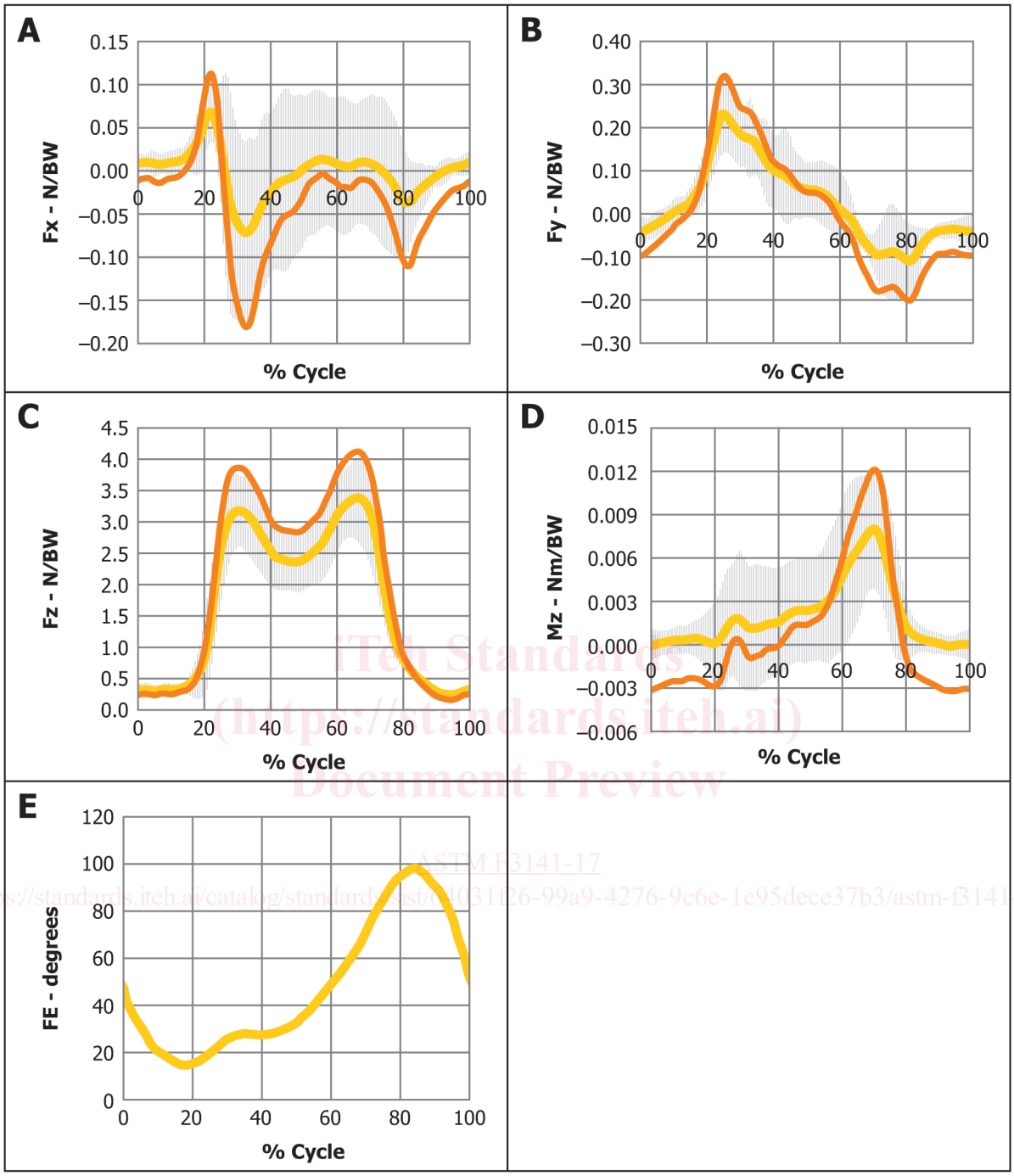
Loading curves produced from eight subjects in the Orthoload database, Bergmann et al., 2014 (**16**, **17**). Heavy loads were normalized in the y direction from the minimum of (Mean – 1 SD) to the maximum of (Mean + 1 SD). From left to right top to bottom the figures are the time series data corresponding to ML (Fx), AP (Fy), AX (Fz), IE (Mz) and FE (Flexion Extension) loads and motions. The horizontal axis is time expressed as a percent of the cycle duration. The vertical axis shows load in N or Nm for force or torque normalized to body weight and angle in degrees for flexion.

FIG. 2 Straight Walking Gait for Mean (light yellow) and Heavy (dark orange) Loading



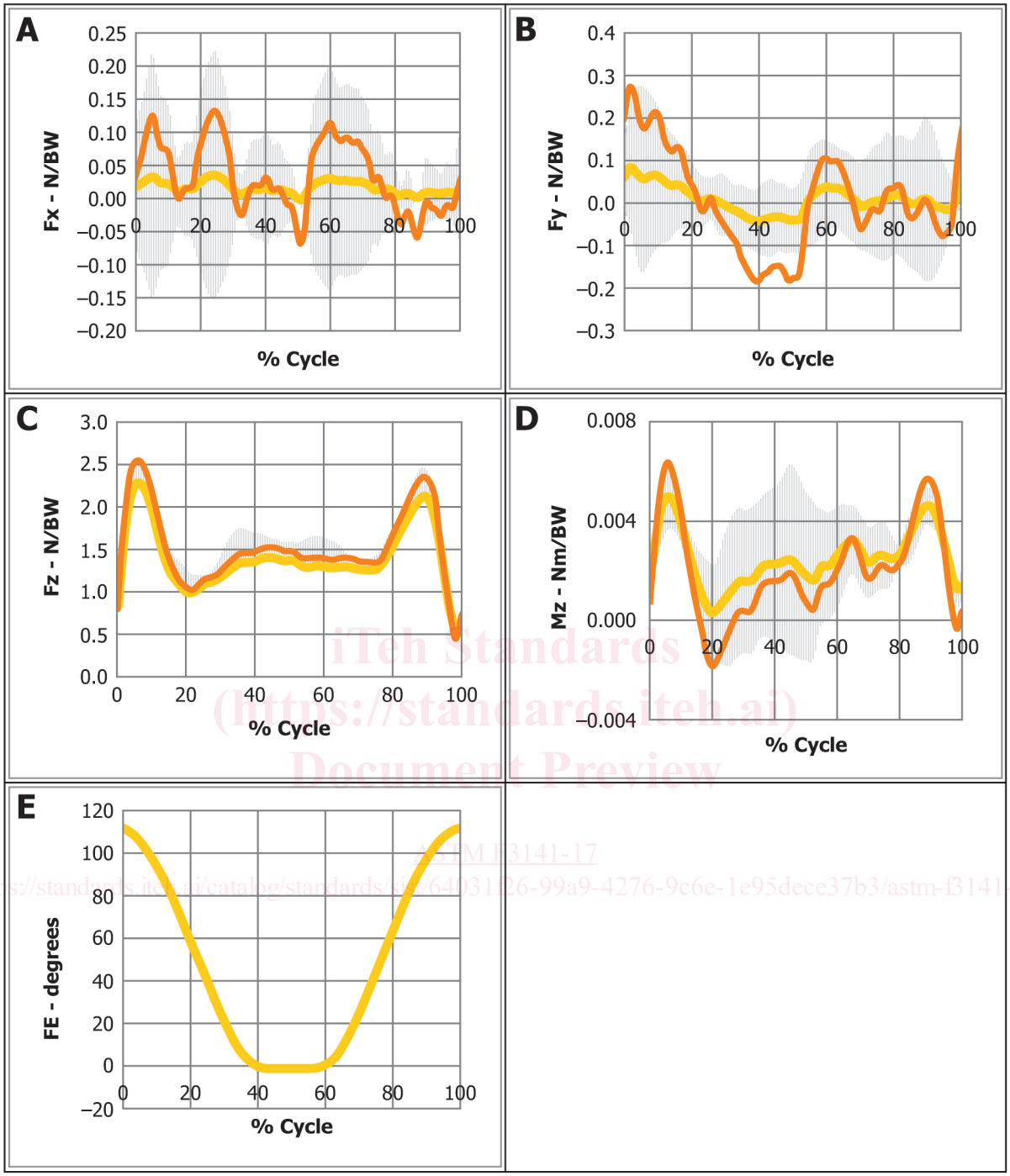
Loading curves produced from eight subjects in the Orthoload database, Bergmann et al., 2014 (**16**, **17**). Heavy loads were normalized in the y direction from the minimum of (Mean – 1 SD) to the maximum of (Mean + 1 SD). From left to right top to bottom the figures are the time series data corresponding to ML (Fx), AP (Fy), AX (Fz), IE (Mz) and FE (Flexion Extension) loads and motions. The horizontal axis is time expressed as a percent of the cycle duration. The vertical axis shows load in N or Nm for force or torque normalized to body weight and angle in degrees for flexion.

FIG. 3 Stair Ascent for Mean (light yellow) and Heavy (dark orange) Loading



Loading curves produced from eight subjects in the Orthoload database Bergmann et al., 2014 (**16**, **17**). Heavy loads were normalized in the y direction from the minimum of (Mean – 1 SD) to the maximum of (Mean + 1 SD). From left to right top to bottom the figures are the time series data corresponding to ML (Fx), AP (Fy), AX (Fz), IE (Mz) and FE (Flexion Extension) loads and motions. The horizontal axis is time expressed as a percent of the cycle duration. The vertical axis shows load in N or Nm for force or torque normalized to body weight and angle in degrees for flexion.

FIG. 4 Stair Descent for Mean (light yellow) and Heavy (dark orange) Loading



Loading curves produced from five subjects in the Orthoload database (17). Heavy loads were normalized in the y direction from the minimum of (Mean – 1 SD) to the maximum of (Mean + 1 SD). From left to right top to bottom the figures are the time series data corresponding to ML (Fx), AP (Fy), AX (Fz), IE (Mz) and FE (Flexion Extension) loads and motions. The horizontal axis is time expressed as a percent of the cycle duration. The vertical axis shows load in N or Nm for force or torque normalized to body weight and angle in degrees for flexion.

FIG. 5 Sit to Stand to Sit for Mean (light yellow) and Heavy (dark orange) Loading