

MULTICENTER OSTEOARTHRITIS STUDY

144-MONTH FORCE OF HEEL STRIKE ASSESSMENT DATASET DESCRIPTION AND SCORING PROTOCOL

MARCH 2023

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1. Introduction

The Multicenter Osteoarthritis Study (MOST) is a longitudinal, prospective, observational study of knee osteoarthritis (OA) in older Americans with knee OA disease or at increased risk of developing it.

Force of Heel Strike (FHS) exams for force plate data analysis were acquired during clinic visits for the Original Cohort (144-month follow-up visit) and the New Cohort (baseline visit).

To accurately measure the rate of impact loading, we used an AccuGait force platform (AMTI, Inc) with an analog signal sampled at 1000 Hz. The force plate was recessed within a raised AccuGait walkway (40 mm. high with tapered ends). Participants completed a minimum of 5 walking trials per side (10 total). Each walking trial consisted of ~5 steps with the 3rd footfall landing on the centrally placed platform within the 5.3-meter-long walkway.

FHS exam procedures are described in MOST Force of Heel Strike Examination Operations Manual (Appendix 1). Staff are trained and certified before conducting this exam with MOST participants.

2. Data Management

The Templo software stores the video and force plate data in multiple file formats. The exam details are saved by Templo software in a Microsoft Access *.mdb file, and each trial was saved as a video *.avi file and a matching *.adc file recorded the force plate information. The MS Access database file and any new *.avi and *.adc files were automatically transferred via sFTP to the Coordinating Center on a set schedule directly from the exam computer at least daily using Fling File Transfer software (NCH Software).

A separate exam tracking form was also submitted via a web-based system (REDCap) for each exam that recorded the completion of each exam, which sides and how many trials were completed. Cases where the exam was never started due to safety concerns or ended early were also recorded. The tracking form is used to reconcile the receipt of the video and force plate data.

Force of heel strike exam is comprised of video of participants walking and force plate measurements. The force plate data was exported from the Templo software as a serial set of force measurements in a text file to facilitate analysis in other software. One text file was exported per trial. There is no function to bulk export to a text file so each exam was exported separately. The video files were not transformed into any other formats although they were exported into a single "package" of files per participant so the videos could be measured by the Reading Center.

In June 2016, it was discovered that the force plate data appeared to have discontinuities, or tiny slices of "dropped" data, randomly in the force plate data. The Coordinating Center contacted zFlo (Templo software was purchased via zFlo), who then consulted with the Contemplas company, which developed the Templo software. Contemplas investigated and provided updated software to the clinics and the Coordinating Center. The Templo software was simultaneously upgraded at both clinics to version 2016.1.400 on July 2016. After the software upgrade, test trial data from each clinic was collected and reviewed at the Coordinating Center and no evidence of dropped data was found. Data for 1971 trials (273 participants) were excluded from analysis because of this "dropped" data issue (Appendix 2, table 2).

The Coordinating Center at UCSF exported each trial from the Templo software for analysis by the BU Reading Center. The original force plate data was saved to an *.adc file for each trial which is only viewable within the Templo software. The export process generates a text (*.txt) file which contains a series of force measurements in a single file. The Coordinating Center uploaded the MOST .txt files in

batches of approximately 50 onto the UCSF secure FTP server. At the Reading Center, the raw data from each *.txt is analyzed, and the summary results are saved to a text file with the same file name as the raw data file. This similarity in names facilitates reconciliation between the raw and analyzed files.

3. Force of Heel Strike Exam Scoring

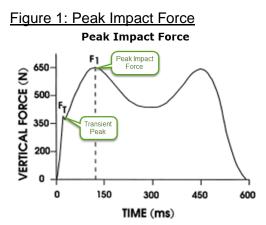
Dr. Cara Lewis of the Boston University Human Adaptation Lab processed raw force plate data contained within each .txt file. Using a custom written MATLAB algorithm (MathWorks, Inc), the following variables were calculated from the vertical component of the ground reaction force (Fz) shortly after impact (see Figures 1-3):

- Peak Impact Force, measured at the 1st peak in the bimodal Fz tracing
- Average Loading Rate, measured between heel strike and the peak vertical impact force
- Maximal Loading Rate, also measured between heel strike and the peak impact force

Between initial contact with the force plate (defined as the moment when Fz exceeds a minimum threshold) and 50% of stance, the peak magnitude of Fz as <u>Peak Impact Force</u> was identified. <u>Average Loading Rate</u> was defined as Fz peak magnitude divided by the time taken from initial heel strike to that point. To determine <u>Maximum Loading Rate</u>, the instantaneous slope (first order derivative) of the force versus time curve was calculated, and its maximum value during the period between initial heel strike and peak impact force was identified. Measured values for each foot were recorded for 5 trials, and expressed in Newtons (N) for Peak Impact Force, and Newtons per second (N/sec) for Average and Maximum Loading Rate.

Figures 1-3. Variables to be measured from the force plate tracings.

Three force variables were targeted for measurement during the first 50% of stance phase: 1) Peak Impact Force, 2) Average Loading Rate at Impact, and 3) Maximum Loading Rate at Impact. Five values per limb are expected.



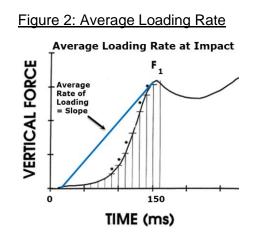
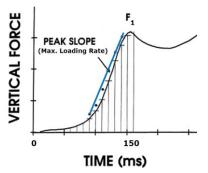


Figure 3: Maximum Loading Rate

Maximum Loading Rate at Impact



Force of Heel Strike scoring will have the following output for each trial:

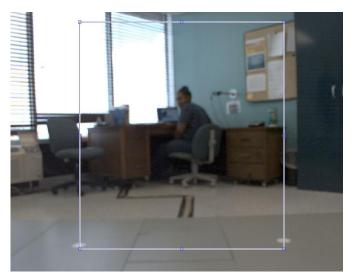
| Reading Parameters: | Description |
|--------------------------------------|---|
| PIF (N) | Peak impact force |
| ALR (N/s) | Average loading rate |
| MILR (N/s) | Maximum instantaneous loading rate |
| AILR (N/s) | Average instantaneous loading rate |
| Violation flags (data not released): | Description |
| Center of pressure (COP) violation | Indicates center of pressure on force plate near edge of plate (may indicate contact that extends beyond edge of force plate) |
| Valley violation | Indicates atypical load curve shape (insufficient / no valley between the two peaks) |
| Loading violation | Indicates atypical loading (may indicate bad initial contact) |
| Unloading violation | Indicates atypical unloading (may indicate bad final contact) |
| Timing violation | Indicates atypical location of peaks (may indicate bad contact) |
| Double differential violation | Indicates atypical force data (may indicate dropped force data) |
| Plateau violation | Indicates atypical peak curvature (may indicate flattened peak) |
| Empty violation | Indicates no change in force data detected (may indicate trial not collected / no foot contact) |
| Autopeak violation | Indicates atypical load curve shape (no detectable double peaks) |
| Onsetoffset violation | Indicates force value at start or end of trial unusually high (may indicate recording began late / stopped early) |
| Manually defined | Indicates values were manually defined and not autodefined |
| Manually accepted | Indicates trial was flagged for review and was accepted |
| Manually rejected | Indicates trial was flagged for review and was rejected |
| Comments | Comments |
| Knee/side corrected from video | =1 if knee/side value corrected based on video |
| 2 feet seen on video | =1 if 2 feet seen stepping on force plate on video |

4. Gait Speed measurement Protocol

Protocol developed by Dr. Cara Lewis

A. Process Gait Speed for Each Trial (process one batch at a time)

- Open MATLAB software.
- Right click on the desired batch folder and rename the folder from "processing_batch(batch #)" to "processing" (e.g. processing_batch1 → processing). This will need to be done each time you begin to process a new batch.
- Open "Load_AVIs_For_WalkTime.m" in the left panel and click "Run" in the top panel.
- When prompted, chose the folder labeled "processing". The first video of the batch will automatically open in its own video window.
- Use the "Draw Rectangle" feature on the bottom tab of the video window to connect the two dots located in the video and extend the rectangle upward (see below). You will use these lines to determine the participant's start and stop times for their gait speed.



Use your cursor on the bottom tab of the video window to play through a trial. You should see a white dot on the participant's hip. When the participant's dot falls in line with the first dot, click the "Walk Start" button in the bottom tab of the video window (see below). When the participant's dot falls in line with the second dot, click the "Walk End" button in the bottom tab of the video window (see below). This will determine the gait speed for a given trial in the "Walk Time:" box.



- Add a comment (from the list of comments below) in the "Comments:" box if there is anything notable that occurs during the trial. If more than one comment applies, add a comma in between each.
- Click the "Save Results" button on the bottom panel of the video window.
- Click "File" and "Close" in the video window.
- The next video in the batch will automatically open.

Available list of comments to be selected:

- "2 footfalls" → both of the participant's feet step on the force plate
- "Arm obscuring marker" → the participant's arm is blocking the marker on their side during the time of "Walk Start" and/or "Walk End"
- "Toes off plate" \rightarrow the participant's toes cross the end of the force plate
- "Toes at edge of plate" → the participant's toes land along the edge of the end of the force plate
- "Heel off plate" \rightarrow the participant's heel strikes the ground before the start of the force plate
- "Heel at edge of plate" → the participant's heel strikes the ground along the edge of the start of the force plate
- "Foot at side of plate" → the participant's foot lands along the side edge of the force plate
- "Marker missing" → the participant does not have a marker on their side
- "Marker displaced" → the participant's marker has moved too far forward or back from the original side position
- "Gait altered" → the participant stumbles or falls

5. Reading Center Dataset and Analyst Notes

Dataset: V7FHS.sas7bdat Observations: 23,253 records Documentation:

- DatasetDescription_V7FHS_ScoringProtocol.pdf
- Distributions_V7FHS.pdf
- VariableGuide_V7FHS.pdf

Notes to analyst:

- Variables #1 to #4 are based on the MOST force of heel strike data tracking. The unique combination is (MOSTID + Visit + Knee + Recordnum). According to the protocol, there were 1 trial for practice and 4 trials for analysis however, final number of trials for analysis may vary.
- Variables #5 to #8 are provided by the Reading Center (Dr. Cara Lewis). See MOST FHS Scoring Protocol above.

NOTE: trials with missing parameters (PIF_N, ALR_N_s, etc) are dropped from the analytical dataset.

- Variables #9 and to 10 provide information about the corresponding video file (processed at the Coordinating Center). Variable #10 (trial_status) is 1 if processed with video or 2 if processed without video (i.e., no matching AVI video file available).
- Variable#11 is provided by Reading Center (Dr. Cara Lewis, Dr. Kerri Graber) and is the result of the video file parameters for gait speed.

• Variable #12 (gaitspeed) is calculated using the formula:

GaitSpeed = 1.1032m/WalkTimeCalculated (sec).

<u>Important Note:</u> White "x" markers placed at measured lengths along the walkway to assist the trained video readers at Boston University in calculating the participant's walking velocity during each trial. The markers are placed similarly for both clinics in the center of the two walkway sections sandwiching the central force plate section. From the operations manual for FHS, the force plate section width is 503.2 mm and we can infer all the other sections are 600 mm in width. That means that perfectly placed markers result in (503.2 + 600 mm) = 1103.2 mm. Coordinating Center confirmed this distance by reviewing video files and markers on the floor for both clinics.

 Variable #13 (Exclude_from_Video_Analysis) summarizes review/evaluation of video files. Exclude_from_Video_Analysis =1 identifies trials with known video files marked as corrupted or other video issues based on video review of ground reaction force data by Coordinating Center and Reading Center. If parameter gait speed was not measured (gaitspeed=. missing) the flag also marked as 1.

Recommendation for analysis

#1 – [if speed being used] drop records without valid speed measurements

- (Exclude_from_Video_Analysis =1)
- #2 calculate the N of trials per side
- #3 keep only participants/sides with 3+records

#4 – restrict analysis further only for the eligible participants and eligible side (based on the hypothesis)

If there are only 1 or 2 valid records per ID+side, those parameters are not consistent according to the MOST protocol may be used with caution in secondary or sensitivity analysis.

6. References

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Appendix 1. Force of Heel Strike Operations Manual (Table of Contents)

Operations Manual available at

https://agingresearchbiobank.nia.nih.gov/studies/most/documents/?f=Manual_of_Procedures Force of Heel Strike Examination

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Appendix 2. Force of Heel Strike Data Summary Report by Cohort

MOST 144m Force Heel Strike (FHS) exam summary; data received between March 2016 and September 2018

| Table 1 . FHS exam status summary report - by cohort |
|---|
|---|

| | Original cohort New cohort | | | | Total | |
|----------------------------------|----------------------------|--------|------|--------|-------|--------|
| | Ν | col% | Ν | col% | Ν | col% |
| Total CV | 1309 | 100.0% | 1525 | 100.0% | 2,834 | 100.0% |
| Exam attempted | 1147 | 87.6% | 1453 | 95.3% | 2,600 | 91.7% |
| Not attempted, equipment failure | 9 | 0.7% | 3 | 0.2% | 12 | 0.4% |
| Not attempted, safety concern | 4 | 0.3% | 4 | 0.3% | 8 | 0.2% |
| Not attempted, refused | 4 | 0.3% | 1 | 0.1% | 5 | 0.1% |
| Not attempted, excluded other | 20 | 1.5% | 29 | 1.9% | 49 | 1.7% |
| Not done, reason unknown | 26 | 2.0% | 5 | 0.3% | 31 | 1.0% |
| Exclusion:Q1:consent | 7 | 0.5% | 22 | 1.4% | 29 | 1.0% |
| Exclusion:Q2:walker | 16 | 1.2% | 1 | 0.1% | 17 | 0.5% |
| Exclusion:Q3:cane | 53 | 4.0% | 3 | 0.2% | 56 | 1.9% |
| Exclusion:Q4:knee brace | 2 | 0.2% | 2 | 0.1% | 4 | 0.1% |
| Exclusion:Q5:amputation | 1 | 0.1% | 0 | 0.0% | 1 | 0.0% |
| Exclusion:Q6:leg surgery/injury | 3 | 0.2% | 2 | 0.1% | 5 | 0.1% |
| Exclusion:Q7:stroke | 1 | 0.1% | 0 | 0.0% | 1 | 0.0% |
| Exclusion:Q8:safety concern | 16 | 1.2% | 0 | 0.0% | 16 | 0.5% |

Table 2. FHS exam processing status summary report - by cohort

| | Original cohort | | New cohort | | Total | |
|--|-----------------|--------|------------|--------|-------|--------|
| | Ν | col% | Ν | col% | Ν | col% |
| Total FHS exam attempted | 1147 | 100.0% | 1453 | 100.0% | 2,600 | 100.0% |
| FHS data processing status | | | | | | |
| 1:Data processed bilateral | 845 | 73.7% | 1442 | 99.2% | 2,287 | 88.0% |
| 2:Data processed unilateral | 4 | 0.3% | 3 | 0.2% | 7 | 0.3% |
| 3.Data collected – invalid (s/w issue) | 273 | 23.8% | 0 | 0.0% | 273 | 10.5% |
| 4. Data collected – not readable | 9 | 0.8% | 0 | 0.0% | 9 | 0.3% |
| C:Data not collected (see Table 3) | 16 | 1.4% | 8 | 0.6% | 24 | 0.9% |

Table 3. FHS data not collected: summary report - by cohort

| | Original | Original cohort | | New cohort | | Total | |
|--------------------------|----------|-----------------|---|------------|----|--------|--|
| | N | col% | Ν | col% | Ν | col% | |
| Total with no FHS data | 16 | 100.0% | 8 | 100.0% | 24 | 100.0% | |
| Reason no FHS data | | | | | | | |
| 3:Participant discomfort | 1 | 6.3% | 0 | 0.0% | 1 | 4.1% | |
| 6:Equipment failure | 2 | 12.5% | 0 | 0.0% | 2 | 8.3% | |
| 7:Participant refused | 1 | 6.3% | 0 | 0.0% | 1 | 4.1% | |
| 8:Data export failure | 0 | 0.0% | 0 | 0.0% | 0 | 0.0% | |
| 9:Other reason-data lost | 12 | 75.0% | 8 | 100.0% | 20 | 83.3% | |

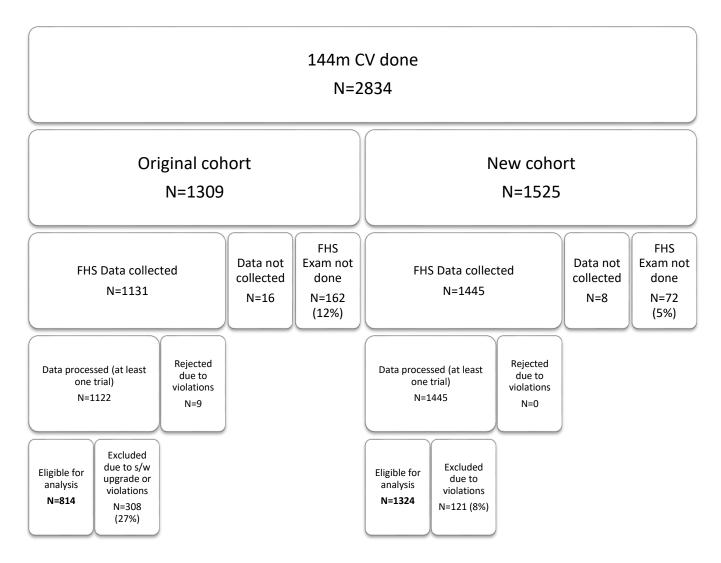


Figure 1. Flow chart of FHS exam status and data processed (person level).

Table 4. Demographic characteristics by inclusion/exclusion in the analytical dataset.

| Characteristic at 144m visit | N (col %) or mean[median](sd) | 144m CV completed | Eligible for analysis* | Excluded due to s/w upgrade | Exam not done or data not | p-value |
|---------------------------------|----------------------------------|----------------------|---------------------------|--------------------------------|------------------------------|---------|
| | nobs | 2834 | 2138 | or violation 438 | collected | |
| A = - | | | | | | . 0001 |
| Age | mean[median](sd) | 64.0[64.0](10.6) | 62.2[63.0](9.9) | 68.7[68.0](10.4) | 70.4[70.5](11.4) | <.0001 |
| sex | Female | 1620 (57.2%) | 1204 (56.3%) | 246 (56.2%) | 170 (65.9%) | 0.0121 |
| | Male | 1214 (42.8%) | 934 (43.7%) | 192 (43.8%) | 88 (34.1%) | |
| site | Site=1 | 1356 (47.8%) | 899 (42.0%) | 255 (58.2%) | 202 (78.3%) | <.0001 |
| | Site=2 | 1478 (52.2%) | 1239 (58.0%) | 183 (41.8%) | 56 (21.7%) | |
| cohort | Original cohort | 1309 (46.2%) | 814 (38.1%) | 317 (72.4%) | 178 (69.0%) | <.0001 |
| | New cohort | 1525 (53.8%) | 1324 (61.9%) | 121 (27.6%) | 80 (31.0%) | |
| Race/Clinic | W_UI | 1424 (50.2%) | 1191 (55.7%) | 179 (40.9%) | 54 (20.9%) | <.0001 |
| | W_UAB | 849 (30.0%) | 585 (27.4%) | 163 (37.2%) | 101 (39.1%) | |
| | AA_UAB | 466 (16.4%) | 279 (13.0%) | 88 (20.1%) | 99 (38.4%) | |
| | AA_UI | 22 (0.8%) | 21 (1.0%) | 1 (0.2%) | 0(0.0%) | |
| | other | 73 (2.6%) | 62 (2.9%) | 7 (1.6%) | 4 (1.6%) | |
| Hip Replacement | 0:None | 2715 (95.8%) | 2074 (97.0%) | 406 (92.7%) | 235 (91.1%) | <.0001 |
| | 1:Unilateral | 84 (3.0%) | 41 (1.9%) | 25 (5.7%) | 18 (7.0%) | |
| | 2:Bilateral | 35 (1.2%) | 23 (1.1%) | 7 (1.6%) | 5 (1.9%) | |
| Knee Replacement | 0:None | 2643 (93.3%) | 2063 (96.5%) | 366 (83.6%) | 214 (82.9%) | <.0001 |
| | 1:Unilateral | 175 (6.2%) | 73 (3.4%) | 68 (15.5%) | 34 (13.2%) | |
| | 2:Bilateral | 16 (0.6%) | 2 (0.1%) | 4 (0.9%) | 10 (3.9%) | |
| BMI | mean[median](sd) | 29.5[28.8](5.7) | 28.9[28.3](5.3) | 31.1[30.1](6.4) | 31.7[30.6](6.6) | <.0001 |
| WOMAC pain (max in 2 knees) | mean[median](sd) | 3.1[2.0](3.3) | 2.6[2.0](3.0) | 4.1[3.0](3.7) | 5.1[4.0](4.2) | <.0001 |
| WOMAC function score | mean[median](sd) | 10.1[7.0](10.6) | 8.5[5.0](9.4) | 14.1[13.0](11.5) | 17.2[16.0](13.3) | <.0001 |

*Eligible for analysis are participants with trials flagged as Exclude_from_Video_analysis=0