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MULTICENTER OSTEOARTHRITIS STUDY

144-MONTH ACCELEROMETRY (OPAL) DATASET DESCRIPTION AND ANALYST NOTES

MARCH 2023

TABLE OF CONTENTS

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.

In healthy individuals, gait parameters are essentially symmetrical with only minor deviations. However, presence of musculoskeletal impairments leads to gait asymmetries in lower limb kinematic and kinetic parameters, such as stride time, stance time and swing time.

The Opal inertial system (APDM Inc.) was used to quantify spatial and temporal measures during over-ground walking (e.g., cadence, stride time, stride length, swing time, stride time variability, asymmetry). Three Opal monitors were worn simultaneously by the participant during the postural sway, 20-meter walk and the 6-minute walk: one on each ankle and one on the lower back. The Postural sway exam was performed first. Then the walks (2 trials of 20-meter and the 6-minute walk) were performed back-to-back, starting with the 20-meter walk. The data allows us to determine the left-right gait asymmetry. Gait complexity was also measured using the same monitors that were used to assess asymmetry.

Examiners responsible for conducting assessments using the Opal inertial system accelerometers during the postural sway, 20-meter and 6-minute walk test have undergone on-site training by an experienced investigator (Dr. Neil Segal, University of Iowa). Certification required demonstration of 100% agreement with the requirements of the protocol, focusing in particular on correct placement of the accelerometers. Examiners also demonstrated understanding of device charging and data downloading to participants' coded files as well as ability to problem-solve anticipated issues (e.g., battery or software issues and set-up of backup devices if primary devices malfunction). Examiners were also recertified midway through the examination cycle. Processing of the accelerometer data in order to extract the parameters of interest was performed by the Accelerometry Reading Center (ARC), supervised by Dr. Jeff Hausdorff, in his laboratory at Tel Aviv University.

See additional documentation "GaitBalanceActivityOutcomeVariables.pdf" for more information about the definition and calculation methods for derived variables and the Performance-Based Measurements.
Operations Manual available at
https://agingresearchbiobank.nia.nih.gov/studies/most/documents/?f=Manual_of_Procedures

2. DATA MANAGEMENT

Transfer of digital exam data to the UCSF Coordinating Center (CC). Digital examination data were transferred every 15 minutes from the clinics to the UCSF CC over the internet using a secure data transfer software and following data transfer SOPs detailing responsibilities of the sender and recipient.

Receipt of data at UCSF CC.
Basic quality control checks done by UCSF CC before transfer of the data to reading center

- Study identifiers on form match electronic file
- Study ID and Acrostic (second identifier) and date of exam (date of recording) must always match gold standard in master data system
- Confirm length of data is sufficient (determine using the file size)
- Confirm correct type of file export generated by clinic
- UCSF provided reading centers Zip files with this naming convention: MOSTID + acrostic + data export date

Transfer of data to the reading center. At the CC, receipt and completeness of data collection was evaluated against measurement acquisition tracking data recorded by the clinics in the study database (see above). The CC notified reading centers when data passed quality assurance checks and was ready for the reading center to download from the secure FTP site or other prearranged method.

Transfer of data from the reading center to the CC. Reading centers uploaded results of their analyses to the secure FTP server for integration into the study database.

A report on completeness of 144m Opal data collection and reading center processing is provided in Appendix 2.

3. OVERVIEW OF DATASETS

Reading Protocol: MOST_GaitBalanceActivityOutcomeVariables.pdf

144-month Opal 20-meter walk Dataset (V7OPAL20mWALK.SAS7BDAT)
Observations: 5140 (2573 participants; one record per trial; two trials per participant with a few exceptions)
Variable Guide: VariableGuide_V7OPAL20mWALK.pdf
Distributions: Distributions_V7OPAL20mWALK.pdf

144-month Opal 6MWT Dataset (V7OPAL6MWT.SAS7BDAT)
Observations: 2434 (2434 participants; one record per participant)
Variable Guide: VariableGuide_V7OPAL6MWT.pdf
Distributions: Distributions_V7OPAL6MWT.pdf

144-month Opal 6MWT Fatigability Dataset (V7OPAL6MWT_Fatigability.SAS7BDAT**)**
Observations: 2348 (2348 participants; one record per participant)
Variable Guide: VariableGuide_V7OPAL6MWT_Fatigability.pdf
Distributions: Distributions_V7OPAL6MWT_Fatigability.pdf

The Fatigability dataset contains gait parameters calculated for each minute of data acquired during the Six Minute Walk Test if recording contains at least 420 sec of data. The effect of participant fatigue on gait parameters can be estimated by comparing the parameter values over the time course of the Six Minute Walk. This inclusion criteria resulted in 86 Opal Six Minute Walk records that were not processed in the fatigability dataset: dataset V7OPAL6MWT, N=2434 ppts vs dataset V7OPAL6MWT_Fatigability, N=2348 ppts.

144-month Opal Sway Dataset (V7OPAL_SWAY.SAS7BDAT)
Observations: 3675 (1944participants; one record per trial; main exam: 213 participants with one trial and 1731 participants with two trials)
Variable Guide: VariableGuide_V7OPAL_SWAY.pdf
Distributions: Distributions_V7OPAL_SWAY.pdf

NOTE: SWAY exam started on the later time point as an addition to the 20-meter walk, therefore some participants' data was not collected.

See additional documentation "MOST_GaitBalanceActivityOutcomeVariables.pdf" for more information about the definition and calculation methods for derived variables.

4. IMPORTANT ANALYST NOTES

A. Dataset V7OPAL20mWALK

- To identify unique record, use variables #1 and #3 (MOSTID+walknumber).

- According to the MOST protocol, each participant completed two 20 meter walk trials. Most participants completed two trials. There are six 20-meter walk exams where only the first walk trial was processed by the Reading Center.

- Only valid trials are included in analytical dataset. If the Opal 20-meter walk data was unreadable, corrupted or not collected during the clinic visit, data is not included in V7OPAL20mWALK dataset.

- Variables #4 to #35 are parameters provided by ARC with units denoted in the labels (note: symbol [-] denotes parameter with no units). See the scoring protocol for definitions: MOST_GaitBalanceActivityOutcomeVariables.pdf.

- There are several 20-meter walk trials where there is a 5+ difference in the number of strides between the first walk trial and the second walk trial. Analysts are advised to use care when planning and using these trials in analyses.

- Coordinating center performed QA process - comparison between collection forms and ARC parameters. Walk time for the 20-meter walk was calculated using the cadence and number of steps using formula:
  calc_walktime=60*(NumberLeftLegSteps + NumberRightLegSteps)/Cadence

  Walk time calculated from the Opal recording (calc_walktime) compared to the walk time recorded by the clinic examiners from the stop watch (V7WALKT1 and V7WALKT2 in V7ENROLL dataset). There are some trials (generally in the second walk trial) with inconsistencies between these two variables (e.g., where the walk times between V7WALKT and calc_walktime are 10+ seconds different). The cadence results for these trials are almost always out of the valid range (80-150). Analysts are advised to use care when planning and using variables from these trials in analyses.

B. Dataset V7OPAL6MWT

- To identify unique record, use variable #1 MOSTID.

- Variables #3 to #36 are parameters provided by ARC with units denoted in the labels (note: symbol [-] denotes parameter with no units). See the scoring protocol for definitions: MOST_GaitBalanceActivityOutcomeVariables.pdf.

C. Dataset V7OPAL6MWT_Fatigability

- To identify unique record, use variable #1 MOSTID.

- Variables #4 to #172 are parameters provided by ARC with units denoted in the labels. See the scoring protocol for definitions: MOST_GaitBalanceActivityOutcomeVariables.pdf.

D. Dataset V7OPAL_SWAY

- To identify unique record, variables #1 and #3 (MOSTID+ sway_number).

- According to the MOST protocol, the sway exam was completed in the clinic starting on August 2016, and was completed just before the 20-meter walk exam. Only valid trials are included in analytical dataset. If the sway data was unreadable, corrupted or not collected during the clinic visit, this data is not included.

- Variables #4 to #39 are parameters provided by ARC. See the scoring protocol for definitions: MOST_GaitBalanceActivityOutcomeVariables.pdf.

5. REFERENCES

References are from the MOST proposal submitted in July 2014.

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APPENDIX 1: PERFORMANCE-BASED MEASUREMENTS OPERATIONS MANUAL (TABLE OF CONTENTS)

PERFORMANCE-BASED MEASUREMENTS
POSTURAL SWAY, 20-METER WALK AND 6-MINUTE WALK

TABLE OF CONTENTS

Operations Manual for the 144-month clinic visit protocol available at
https://agingresearchbiobank.nia.nih.gov/studies/most/documents/?f=Manual_of_Procedures

APPENDIX 2: OPAL DATA SUMMARY REPORT BY COHORT

MOST 144m 20-meter and 6MWT exam plus OPAL summary; data received between March 2016 and September 2018

Table 1. 20-meter walk exam status summary report - by cohort

	Original cohort		New cohort		Total	
	N	col%	N	col%	N	col%
Total CV	1309	100.0%	1525	100.0%	2,834	100.0%
20-meter walk status						
Done	1250	95.5%	1516	99.4%	2,766	97.6%
Not attempted, unable	1	0.1%	0	0.0%	1	0.0%
Attempted, unable to complete	0	0.0%	0	0.0%	0	0.0%
Participant refused	12	0.9%	2	0.1%	14	0.4%
Not done, reason unknown	12	0.9%	1	0.1%	15	0.5%
Exclusion:Q1:Feel unsafe to walk	32	2.4%	6	0.4%	38	1.3%

Table 2. 20-meter walk done: OPAL status summary report - by cohort

	Original cohort		New cohort		Total	
	N	col%	N	col%	N	col%
Total 20-meter walk done	1250	100.0%	1516	100.0%	2,766	100.0%
OPAL for 20-meter walk						
1:Data processed, stored	1146	91.7%	1427	94.1%	2,573	93.0%
2:RC unable to analyze	21	1.7%	12	0.8%	33	1.1%
C:Data not collected (see Table 3)	83	6.6%	77	5.1%	160	5.7%

Table 3. 20-meter walk done: Reason OPAL data not collected - by cohort

	Original cohort		New cohort		Total	
	N	col%	N	col%	N	col%
Total 20-meter no OPAL data	83	100.0%	77	100.0%	160	100.0%
Reason no OPAL data						
5:Only 1-2 monitor used	2	2.4%	7	9.1%	9	5.6%
6:Equipment failure	63	75.9%	63	81.8%	126	78.7%
7:Refused	1	1.2%	0	0.0%	1	0.6%
8:Data export failure	7	8.4%	2	2.6%	9	5.6%
9:Other reason not done	10	12.0%	5	6.5%	15	9.3%

Table 4. 6MWT exam status (includes only participants with 20-meter walk completed)

	Original cohort		New cohort		Total	
	N	col%	N	col%	N	col%
Total 20-meter walk done	1250	100.0%	1516	100.0%	2,766	100.0%
6MWT status						
6MWT completed	1121	89.7%	1468	96.8%	2,589	93.6%
Attempted, unable to complete	19	1.5%	4	0.3%	23	0.8%
Not attempted, safety concern	33	2.6%	2	0.1%	35	1.2%
Not attempted, refused	27	2.2%	6	0.4%	33	1.1%
Not attempted, excluded other	15	1.2%	1	0.1%	16	0.5%
Exclusion:Q2:Chest pain past 30D	35	2.8%	35	2.3%	70	2.5%

Table 5. 6MWT exam done: OPAL data status – by cohort

	Original cohort		New cohort		Total	
	N	col%	N	col%	N	col%
Total 6MWT attempted	1140	100.0%	1472	100.0%	2,612	100.0%
OPAL for 6MWT						
1:Data processed, stored	1049	92.0%	1385	94.1%	2,434	93.1%
2:RC unable to analyze	19	1.7%	8	0.5%	27	1.0%
C:Data not collected (see Table 6)	72	6.3%	79	5.4%	151	5.7%

Table 6. 6MWT exam done: reason OPAL data not collected – by cohort

	Original cohort		New cohort		Total	
	N	col%	N	col%	N	col%
Total 6MWT no OPAL	72	100.0%	79	100.0%	151	100.0%
Reason no OPAL data					9	5.9%
5:Only 1-2 monitor used	1	1.4%	8	10.1%		
6:Equipment failure	50	69.4%	63	79.7%	113	74.8%
7:Refused	0	0.0%	1	12.5%	1	0.6%
8:Data export failure	13	18.1%	3	3.8%	16	10.5%
9:Other reason not done	8	11.1%	4	5.1%	12	7.9%