

FORCE OF HEEL STRIKE**TABLE OF CONTENTS**

1.	Background and rationale.....	2
2.	Equipment and facilities.....	2
2.1	Suppliers and maintenance contacts	3
2.2	Cleaning	3
2.3	Hardware installation.....	4
2.4	Software installation and preferences	4
3.	Exam room preparation	4
4.	Safety and exclusions	6
4.1	Exclusion criteria	6
4.2	Stopping rules.....	6
5.	Participant preparation.....	6
5.1	Ask exclusions questions at the start of the exam	6
5.2	Identify knee braces, and /or assistive walking devices	7
5.3	Algorithm for exclusion based on knee brace or assistive walking device dependency.....	7
5.3.1	Questioning triggered by observed use of cane or knee brace.....	7
5.4	Footwear and clothing during testing	8
5.4.1	Customary walking shoes.....	8
5.4.2	Shoe hardness assessment	8
5.4.3	Secure velcro belt with markers to participant’s pelvis	8
6.	Administration	11
6.1	Practice walking trial and ideal starting line.....	11
6.2	Step by step measurement procedures.....	12
7.	Data transfer.....	31
8.	Quality assurance.....	31
8.1	Training and certification	31
8.2	Certification requirements	31
8.3	Quality assurance checklist	31
9.	Data collection forms	32
	Appendix 1 Data Processing	33

1. Background and rationale

Given the importance of mechanical loading to osteoarthritis (OA) etiology, repeated exposure to impact loads during gait could increase OA risk. For weight-bearing joints like the knee, each footfall imparts a sudden vertical force that is transmitted up the limb as a shockwave. Animal experiments suggest that even moderate loads, comparable in magnitude to the forces incurred at heel strike during walking, when applied suddenly and repeatedly, can soon exceed the time-dependent ability of joint tissues to accommodate, resulting in pathological changes that parallel those of early OA.

In MOST, we will measure the forces that are generated when the foot impacts the ground during self-paced walking. Our primary interest is in characterizing the *rate* at which the vertically directed forces rise to an early peak immediately following a left or right footfall. We posit that an excessively rapid rate of impact loading may damage the load-bearing tissues of the knee, leading over time to OA.

2. Equipment and facilities

1. Equipment from AMTI, Inc.

- a. Optimized AccuGait Force Platform ([ACG-O-NF](#))
 - i. Dimensions: 45.5 h X 502 w X 502 l mm.
 - ii. Interface: USB 2.0 to personal computer (no need for separate power source)
 - iii. Sampling speed: 1000 Hz (datasets per sec)
 - iv. Parameters measured (channels): Forces (Fx, Fy, Fz), Moments (Mx, My, Mz)
 - v. Capacity: Fz 300 lb (1334 N), Fx and Fy 100 lb (450 N)
 - vi. Installation: On level floor, surrounded by, but not touching, AccuGait walkway
 - vii. Calibration: Pre-calibrated at factory. Recalibration not required
 - viii. AccuGait Walkway ([ACG-WALK](#))
 - ix. Dimensions: .040 h X .600 w X 5.3 l meters. Height is tapered at ends to meet floor.
 - x. Installation: 9 interlocking segments positioned on level floor

2. Equipment from Zflo, Inc. (distributor)

- a. TEMPLO Motion Analysis Software
 - i. Version: [8.2.358](#)
 - ii. Additional software module: Force plate module
 - iii. Manufacturer website: www.contemplas.com
- b. Basler Video Camera
 - i. Model: Ace [acA1300-60gc](#) with tripod mount
 - ii. Dimensions: 42 l x 29 w x 29 h mm.
 - iii. Frame rate: 60 Hz
 - iv. Resolution: 1.3 megapixels
 - v. Pixels: 1280 h × 1024 v color pixels

- vi. Output: GigE
 - vii. Interface: Ethernet to personal computer (computer's native Ethernet port)*
 - viii. Lens: [Computar M0814-MP2](#) 8mm focal length with locking focus and iris
 - ix. Manufacturer website: www.baslerweb.com/en
3. Equipment from Fowler, Inc.
 - a. Fowler Shore A Portable Durometer
 - i. Item#: [537621010](#)
 - ii. Purpose: Measure shoe hardness
 4. Additional Equipment from Clinic
 - a. Laptop or Desktop Computer
 - i. Operating System: Windows 7
 - ii. Memory: \geq 4GB RAM, 1.7 GHz
 - iii. Ports: USB 2.0 (\geq 3), Ethernet (\geq 2, or 1 with adapter)
 - iv. Drives: CD
 5. Video Camera Tripod and Lighting
 - a. Polaroid Travel Tripod: expandable 22" – 42"
 - b. Westcott [uLite](#) Umbrella Kit:
 - i. 250W Floodlight
 - ii. 81 cm white umbrella
 - iii. 1.98 m high stand
 6. Accessories
 - a. External USB hub
 - b. Ethernet extension cable
 - c. AC surge protector power strip
 - d. Desk for computer
 - e. 1/2" vinyl Gardner Bender electrical tape in 5 assorted colors ([#GTPC-550](#))
 - f. Two plastic cord protectors

2.1 Suppliers and maintenance contacts

Advanced Mechanical Technology, Inc. (AMTI) warrants all transducers in the force platform to be free from defects. AMTI agrees to repair or replace any defective platform within five years after date of shipment. Moreover, force platforms are factory calibrated prior to shipping, and if used appropriately will not require recalibration at any time during the MOST study.

2.2 Cleaning

The AccuGait walkway consists of a high density foam covered with an aluminum skin that is painted with gray textured polyurethane paint. The same textured paint covers the surface of the force platform, and serves to minimize reflections. The walkway and force platform surfaces should all be periodically swept clean in order to maintain a reasonably sanitary environment

for shod testing. While liquids should be kept safely away from the electrical components of the force platform, a damp rag can be used to wipe the surface clean of any dirt that cannot be easily swept.

2.3 Hardware installation

Onsite setup of all equipment, pre-configuration of the TEMPLO software, and training and certification of the UAB and UI staff for execution of the study protocol will be provided by MOST study investigator. See section 8 for training and certification information.

2.4 Software installation and preferences

Initial preferences were set up during installation of the software. Unneeded data fields were removed and additional data fields were added in order to simplify use of the software by clinic examiners. Please notify the study coordinator immediately if you find that any of the preferences have been inadvertently changed during the course of the study.

3. Exam room preparation

A quiet room with a hard, smooth, and reasonably *level* (not sloping) and *even* (not undulating) floor measuring at least 6.5 meters in length and 4.2 meters (13.8 feet) in width to accommodate:

1. Force platform positioned on level and even floor to avoid rocking or tilting when force is applied, and so that all parts of its surface remain flush with the surrounding walkway.
2. Walkway is 1.20 meters (3.94 feet) wide, and 5.30 meters (17.40 feet) long.
3. Video camera is positioned on tripod at a distance of 2.4 to 3.0 meters (8 to 10 feet) from lateral edge of walkway.

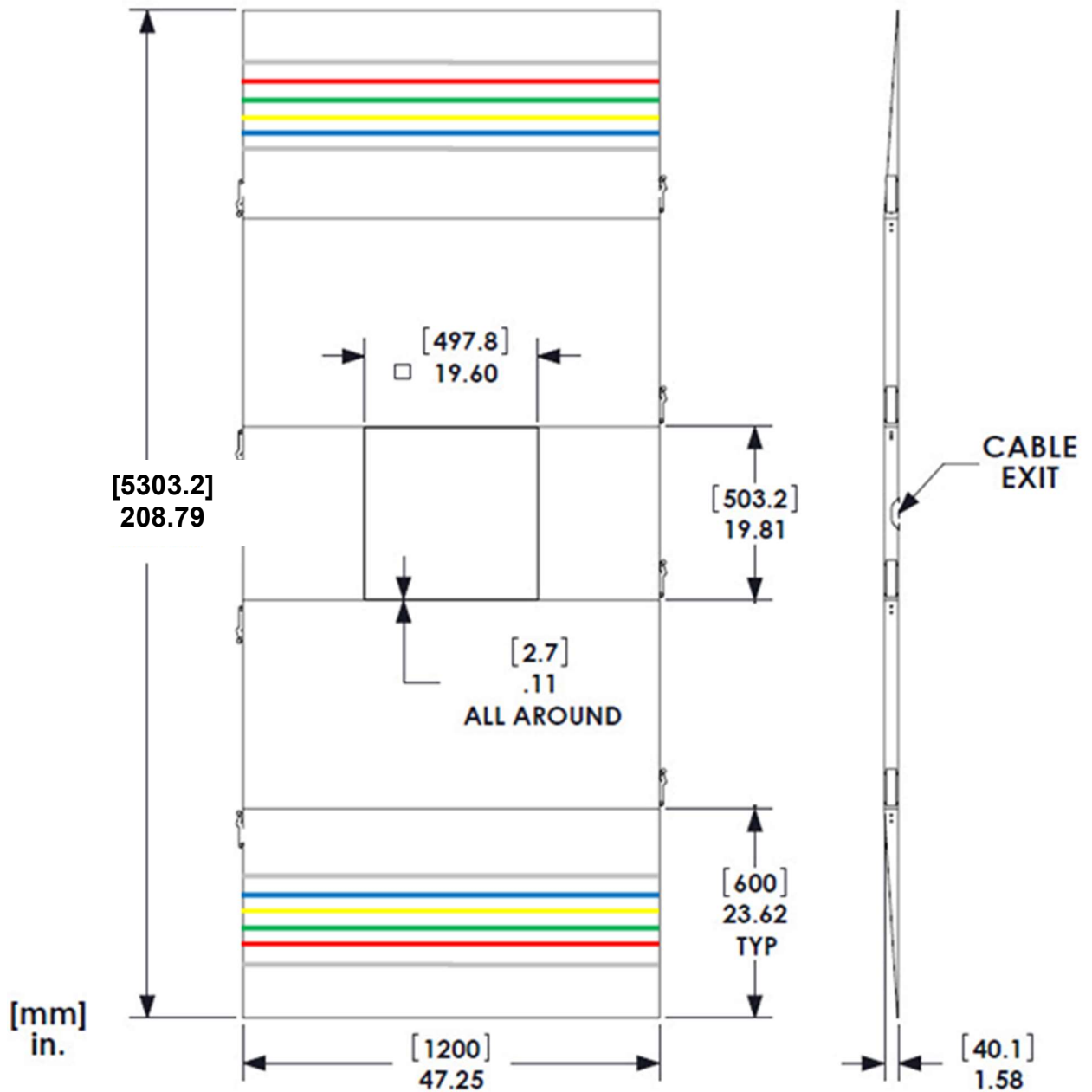


Figure 1. Diagram of walkway. 9 interlocking sections (only 5 shown) surround the force platform. Colored tape on either end mark possible starting lines for initiation of a walking trial.

4. Safety and exclusions

4.1 Exclusion criteria

1. Participant does not consent to videotaping.
2. Participant brings a walker or crutches to the clinic visit (see Figure 2B) and reports an inability to walk safely over short distances without using their walker or crutches.
3. Participant brings a cane or walking stick to the clinic visit (see Figure 2A) and reports an inability to walk safely over short distances without using their cane or walking stick.
4. Participant wears an orthotic knee brace (not including neoprene sleeves or patellar straps) to the clinic visit (see Figures 3A and 3B) and reports inability to walk safely over short distances without using their orthotic knee brace.
5. Surgery or an injury to the legs in the past 6 weeks that caused the participant to restrict weight bearing for a week or longer.
6. Any amputation of the lower extremity other than the toes.
7. Difficulty walking or standing upright because of a stroke, Parkinson's disease, or other neurological condition whose onset was less than 6 months ago.
8. Exhibits signs of vision, gait, or balance impairment, or signs of severe joint pain suggesting a possible safety risk *and*, when questioned, expresses uncertainty in the ability to safely walk short distances.

4.2 Stopping rules

1. If the participant develops chest pain or dizziness during the test, do not complete testing.
2. If the participant says that they cannot continue due to severe knee, foot, or back pain do not complete testing.

5. Participant preparation

5.1 Ask exclusions questions at the start of the exam

Exclusion questions can be seen on the Force of Heel Strike data collection form.

If the exam is not performed for any reason, indicate on the Force of Heel Strike data collection form that the exam was not attempted. Force of Heel Strike data collection form. Also, record a reason why the test was not attempted on the Follow-up Clinic Visit Procedure Checklist.

5.2 Identify knee braces, and /or assistive walking devices

The following algorithm is used to determine whether to exclude a participant from the Heel Strike Force exam based on habitual use of an assistive walking device or orthotic knee brace. The algorithm requires the examiner to distinguish canes and walking sticks from crutches and walkers, and orthotic knee braces from neoprene knee sleeves and patellar tendon straps. Figures 2A, 2B, and 3A, 3B will assist the examiner in making these distinctions.

5.3 Algorithm for exclusion based on knee brace or assistive walking device dependency

Participants who bring a walker or crutches with them to the clinic (see Figure 2B) are excluded from testing (see exclusion criteria). Participants who *bring* a cane or walking stick (see Figure 2A) or *wear* an orthotic or ligament support knee brace (see Figure 3A) are questioned to determine the extent of their dependency on the device. Note that the participant must be *wearing* the knee brace in order to trigger the following questions. These questions are not triggered if the participant is wearing a neoprene knee sleeve or patellar tendon strap (see Figure 3B).

5.3.1 Questioning triggered by observed use of cane or knee brace

Script: "Are you able to walk safely over short distances without using your cane/knee brace?"

If NO for either the cane or the knee brace, exclude from testing.

If YES for both the cane and knee brace, perform exam without the device.



Figures 2A (left) and B (right). Assistive walking devices. Canes and walking sticks (Figure 2A, left) are distinguished from crutches and walkers (Figure 2B, right). Participants arriving with crutches or walkers (B) are excluded. Participants arriving with a cane or walking stick (A) are questioned about dependency.



Figures 3A (left) and B (right). Knee braces. Orthotic knee braces, including realigning and ligament support braces (Figure 3A, left) are distinguished from Neoprene sleeves and patellar tendon straps (Figure 3B, right). Participants wearing an orthotic knee brace (A) are questioned about dependency.

5.4 Footwear and clothing during testing

During the heel strike exam, the participant must be shod in their own customary walking shoes (see below) and wearing short pants that do not cover the knee. If a participant's shorts are of a "Bermuda" length, then the examiner may need to assist in rolling up the hemline so that neither knee is obscured from view.

5.4.1 Customary walking shoes

Participants are examined wearing their own "customary walking shoes." During scheduling, participants are instructed:

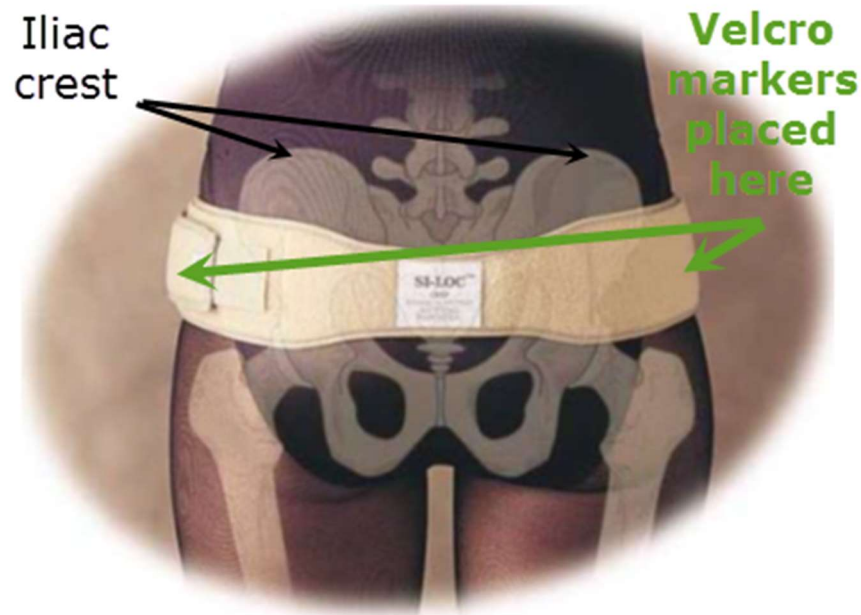
Script: "Bring with you the walking shoes or sneakers that you would typically wear if you knew that you were going to be on your feet for a prolonged period of time, such as when shopping, taking a walk, or waiting in a long line."

5.4.2 Shoe hardness assessment

An assessment of shoe hardness using a handheld Shore A durometer will take place during the height and weight examination, when participants have removed their customary walking shoes. The procedures for completing this assessment are detailed in Operations Manual Chapter 3Q.

5.4.3 Secure velcro belt with markers to participant's pelvis

An elastic belt with two brightly colored removable Velcro markers will be available in the exam room. This elastic belt will be fastened to the participant's pelvis, just below the iliac crest in the location shown:



Once fastened in the appropriate location on the pelvis, the two Velcro markers can then be adhered to the belt over the right and left ilium. The purpose of the markers is to clearly indicate the location of the pelvis so that its position during walking can be determined from the video recording.

Note: Because similar elastic belts are often prescribed to pregnant women in order to improve the stability of pelvic joints during the last trimester of pregnancy, we are confident that our belts can be appropriately situated on the pelvis even in the presence of moderate obesity or a large abdominal pannus. However, where severe obesity or the presence of an unusually large abdominal pannus does interfere with accurate placement of the belt or markers, the participant can be excluded from this portion of the exam, and the examination can proceed without an elastic belt.

To properly position the elastic belt and situate the Velcro markers, please perform the following steps:

1. Move abdominal pannus out of the way.

If the participant has an extremely large abdominal pannus (overhanging belly) that is completely obscuring the anterior pelvis, please instruct them:

Script: “Put both hands on your belly, like Santa Claus does when he laughs, and lift your belly up towards the ceiling and away from your belt line.”

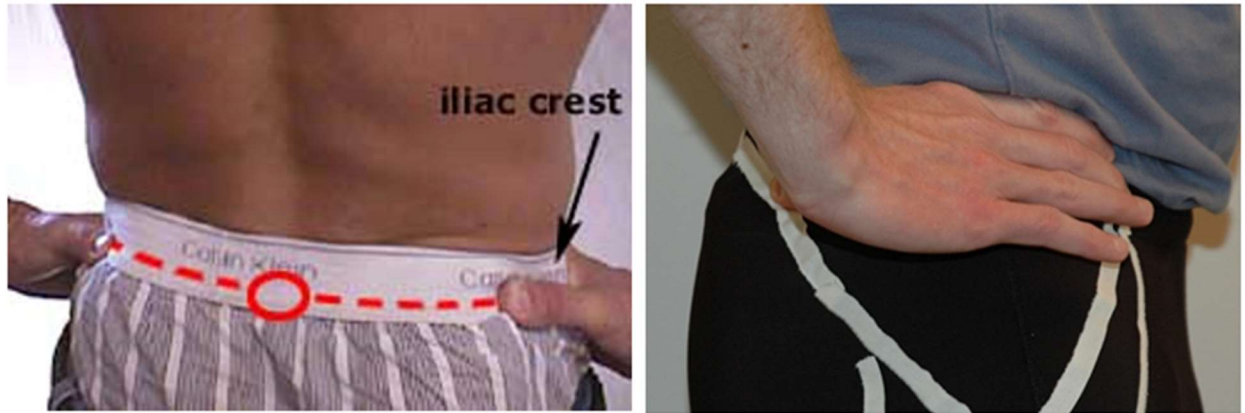
With the abdominal pannus now safely out of the way, you can fasten the elastic belt around the pelvis, just below the level of the iliac crests.

2. Locate the iliac crests and fasten elastic belt around pelvis just below the iliac crests.

The iliac crests are prominent crests of bone at right and left sides of the pelvis at the approximate level of the waist line. If you have trouble locating the iliac crests, tell the participant:

Script: “Please rest your hands on your hips.”

A person resting “hands on hips” generally places the hands directly on the right and left iliac crests of the pelvis, as shown below



3. Adhere the Velcro markers to the right and left lateral sides of the belt, just below the iliac crests of the pelvis.

Properly placed, the markers will be visible to the video camera, allowing video readers to track the position of pelvis during walking (see Figure 4 below).

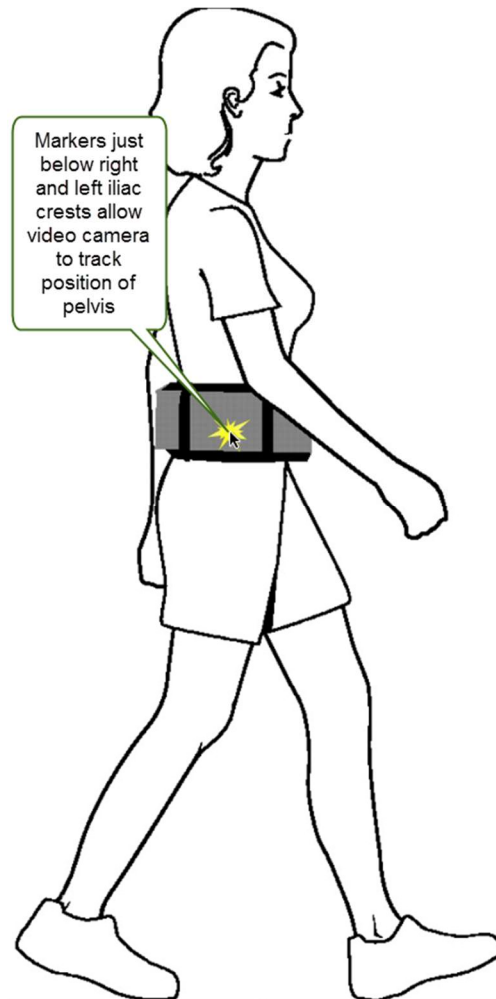


Figure 4

6. Administration

6.1 Practice walking trial and ideal starting line

The heel strike exam will begin with a single practice trial. The purpose of the practice trial is to establish an optimal starting line from which to initiate all subsequent test trials.

To begin the practice trial, the participant is instructed to stand at the center of the force platform and face a visual target that has been placed at eye-level on the wall located at the far end of the walkway. On the examiner's command, the participant will then walk in their usual manner towards that end of the walkway.

Script: "Please stand here at the center of this square platform and face that target at the far end of the walkway. When I instruct you, please walk towards the target over the full length of the walkway. Keeping your attention on the target, you should walk in your usual way, at a pace that feels comfortable and unhurried to you."

“Begin walking.”

Take note of whether it is the left or right foot that initiates the practice walking trial, and where along the length of the walkway the 3rd footfall lands. Colored strips of vinyl tape, oriented perpendicular to the walkway at measured distances from the platform center, provide convenient markers to assist in identifying the approximate location of the 3rd footfall (see colored lines on Figure 1). Participants will then be instructed to turn around and initiate all subsequent test trials using this same colored strip of tape as their starting line. After walking the length of the walkway in one direction during the first test trial, the participant will then turn around and initiate the second test trial using the same color of tape as a starting line to walk in the opposite direction down the length of the walkway.

6.2 Step by step measurement procedures

Five trials with clean single force plate strikes will be collected from left and right limbs of each participant. Values impact loading rate will be averaged across the 5 trials.

1. Turn on the umbrella floodlight

There is a plastic on / off switch on the power cord. Switch it to the “on” position.



2. Log on to the computer

To log-on to the university network requires that each examiner have their own personal User Name and Password provided by the local university. In addition, a single User Name and Password has been issued to the clinic supervisor which will allow administrative privileges on this machine.

After logging on, you will see the desktop.

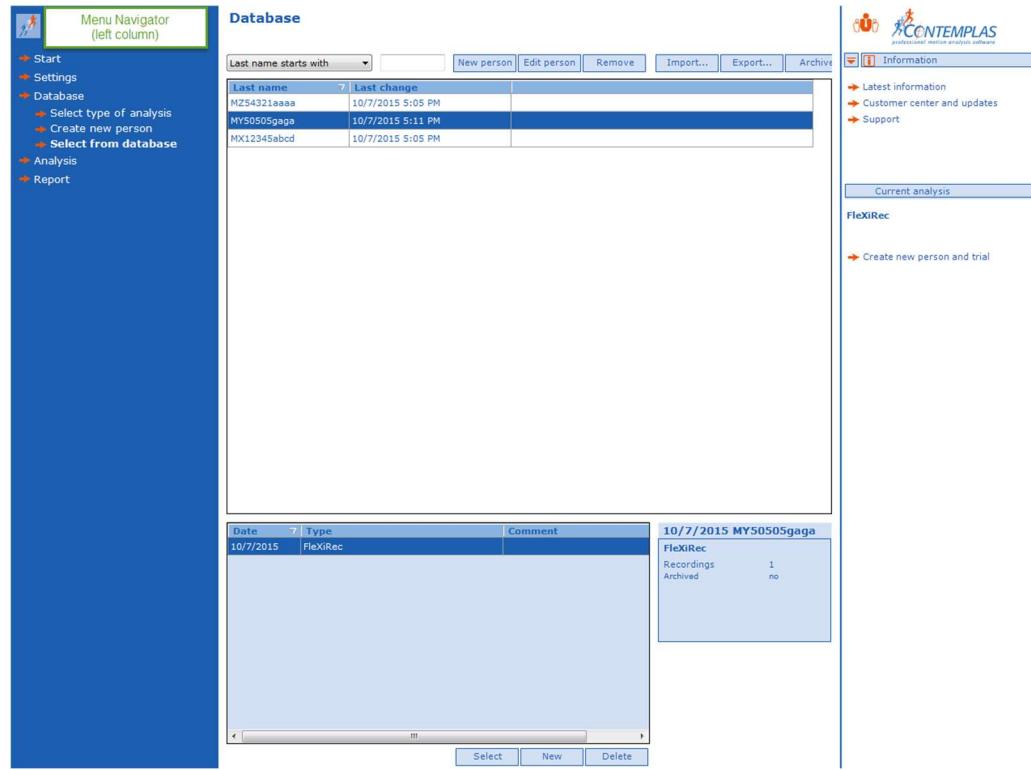
3. Launch the TEMPLO software. Double click on the TEMPLO Desktop Shortcut:

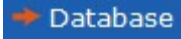


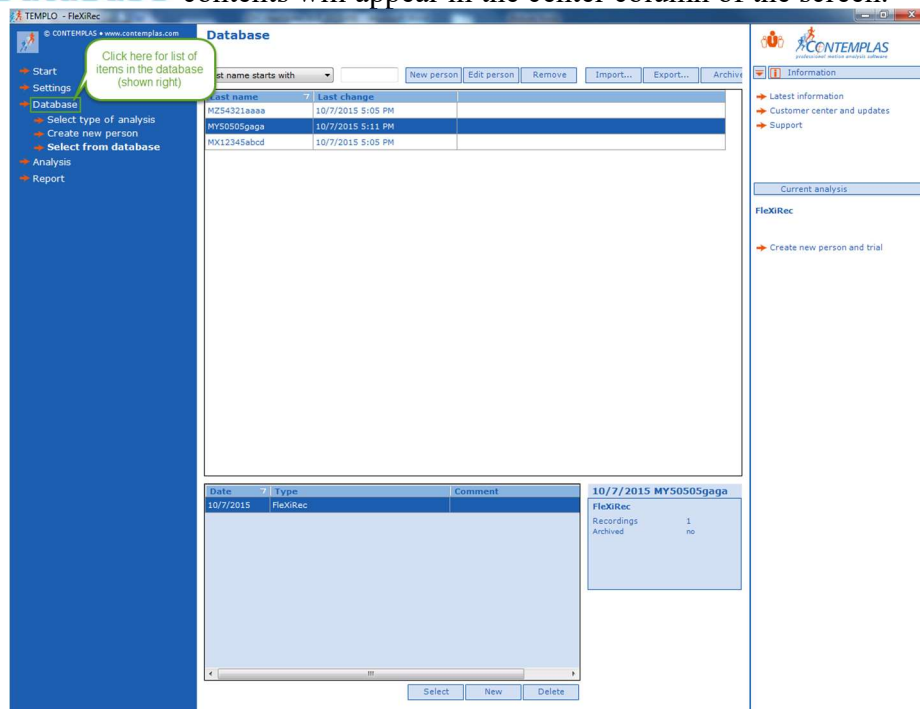
4. Click through the Start Screen to the User Interface Screen. Left click to pass through the Start Screen:



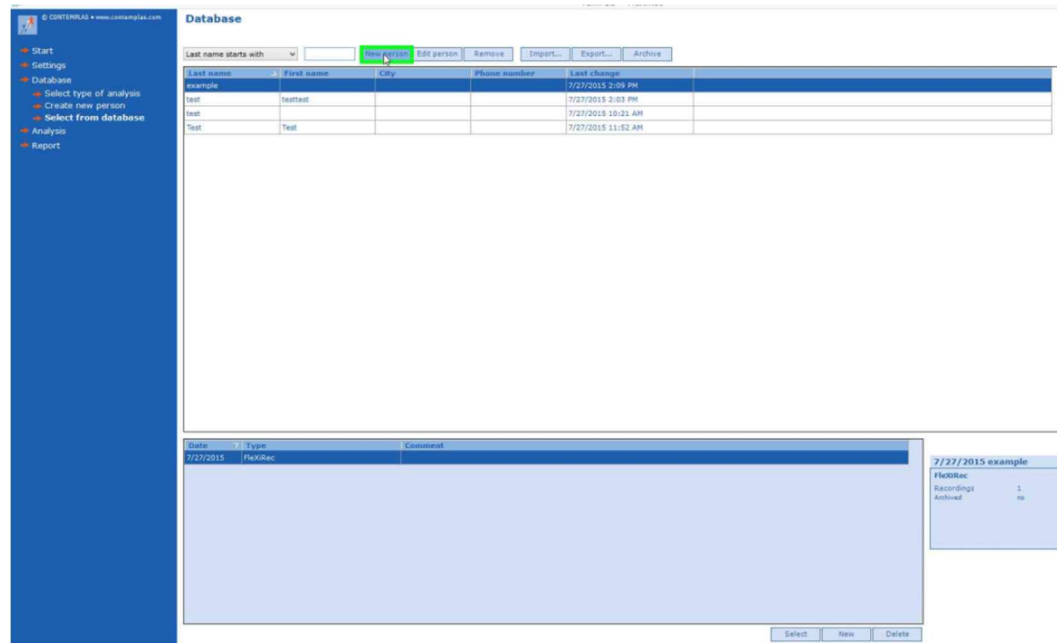
Arrive at the User Interface screen. Find the Menu Navigator in the left column:



5. If not already visible in the center column, click on  Database in the Menu Navigator. A list of the **Database** contents will appear in the center column of the screen.



6. Create a New Person in the database by clicking on the New person box at the top of the center column.



7. Enter the MOST Participant ID and Acroscopic in the field titled Last name. After confirming that you've entered this ID correctly, use your mouse to highlight and copy your entry.

In the field labeled “Last name”, enter the Participant ID with Acroscopic. This entry should take following form, with no spaces or underscore marks between these three elements (TEMPLO software will identify the ID as “Subject ID”):

Subject ID naming scheme:

- a. Enter “MI” if at the Iowa site, or “MB” if at the Birmingham site.
- b. Enter the five number ID
- c. Enter the **FOUR** letter Acroscopic (in UPPER CASE letters)

Leave all other fields blank.

Create new person

The screenshot shows a web form titled "Create new person" with the following fields: Gender (dropdown), Last name (text input containing "MI12345AAAA"), first name (text input), Birth date (text input), Phone number (text input), Street (text input), ZIP (text input), City (text input), and Email (text input). At the bottom are "Add" and "Cancel" buttons. A green callout box points to the "Last name" field with the text: "Enter Subject ID (MI or MB followed by five numbers and 4 letters)".

After taking a moment to confirm that you've entered the MOST Participant ID correctly, use a right click of your mouse to highlight and copy your entry. You will save time and minimize the chance of errors by pasting (rather than re-typing) this same Participant ID entry into another data field later.

Create new person

Gender

Last name

first name

Birth date

Phone number

Street

ZIP

City

Email

MPF4221777

Undo

Cut

Copy

Paste

Delete

Select All

Right to left Reading order

Show Unicode control characters

Insert Unicode control character

Open IME

Reconversion

Add

Cancel

After copying the subject ID, click Add

Right click of your mouse to copy subject ID

After copying the Participant ID, click

Add

8. You will be taken back to the **Database** screen. If not already highlighted in the list, click on the person that you just created in the database in order to highlight that row. Then, select

New

at the bottom of the screen to create a new recording for that person.

Database

Last name starts with

Last name	Last change	
MB54321ZZZ	11/2/2015 11:31 AM	
MIS4321ZZZ	11/2/2015 12:01 PM	
MB12345AAA		
MI12345AAA	11/2/2015 11:30 AM	
MX12345abcd	10/7/2015 5:05 PM	
MZ54321aaaa	10/7/2015 5:05 PM	
MY50505gaga	10/7/2015 5:11 PM	

Highlight the new person in the database

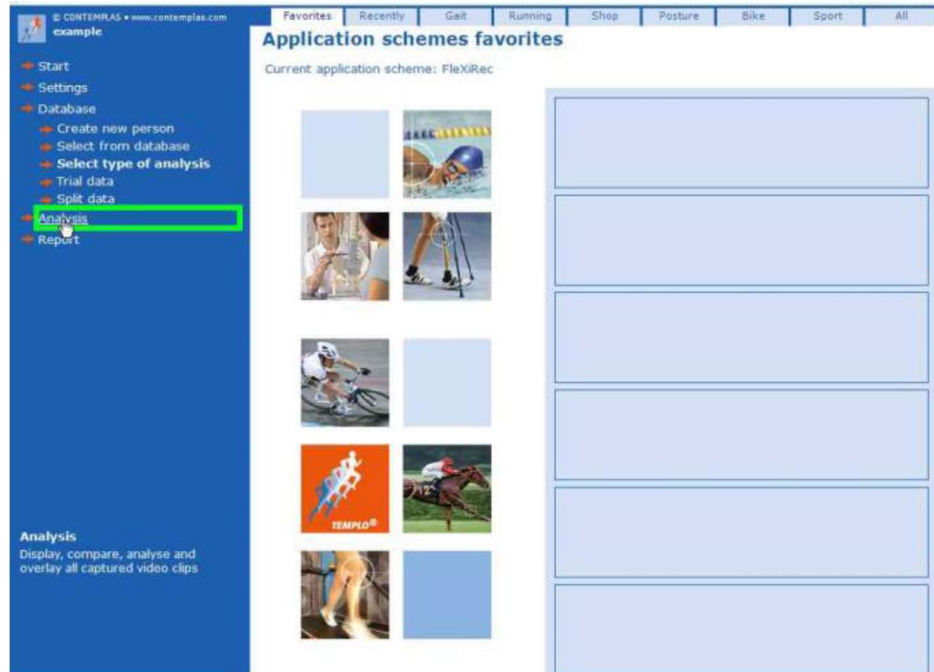
Date	Type	Comment
------	------	---------

Select Delete

Then, click "New" to create a new recording for that person

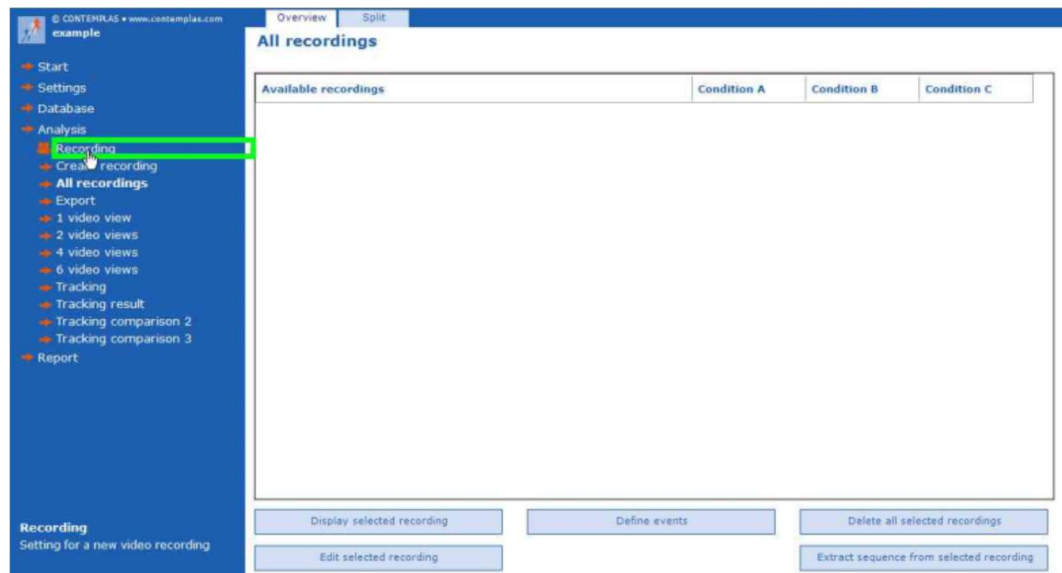
9. Verify that, by default, the current application scheme is set to “FlexiRec” (at the top of the center column it should say: **Current application scheme: FlexiRec**). Then click

Analysis in the Menu Navigator at the left.



10. You will be brought to a list of **All recordings** for this participant. If this is your first recording for this new participant, the list will still be unpopulated.

Click on **Recording** in the Menu Navigator to create a new recording.



11. Create a file name for the new recording by completing the following four sub-steps:

The screen will initially appear as follows:

Recording

Label for next recording:

Automatically create name of recording

Use as file name

Subject ID

R/L Trial#

Date

a. Check *both* of the following boxes (if not already checked):

Automatically create name of recording

Use as file name

b. Paste the Subject ID that you previously copied into the Subject ID field here.

Having previously copied the Subject ID that you entered into the Database, you can now save time and minimize errors by using a right click of your mouse to paste this same Subject ID into the **Subject ID** field on this screen. This will serve the purpose of ensuring that the file name of each recording clearly identifies the ID of the MOST participant to which that recording pertains.

Label for next recording:
 MI##### - Right 1 -

Automatically create name of recording

Use as file name

Subject ID: MI#####

R/L Trial#: Right 1

Date:

Use pre-defined person group

Paste Subject ID (previously copied)

Context menu options: Undo, Cut, Copy, Paste, Delete, Select All, Right to left Reading order, Show Unicode control characters, Insert Unicode control character, Open IME, Reconversion.

Note, if you failed to copy the Subject ID previously, you will need to re-type it here according to same naming scheme that was previously used to enter this Subject ID into the database:

Subject ID naming scheme (no spaces between):

- i. Enter “MI” if at the Iowa site, or “MB” if at the Birmingham site.
- ii. Enter the five number ID
- iii. Enter the **FOUR** letter acronym (in UPPER CASE letters)

For example:

Subject ID: MI12345AAAA

- c. In the field titled **R/L Trial#**, use the dropdown menu to identify the trial as either a **Right or Left footfall, and according to whether it is the first (1), second (2), third (3), fourth (4) or fifth (5) such trial for that foot.**

Recall that whichever foot initiates a walking trial (right or left) should also be the foot that makes the 3rd footfall onto the force platform.

R/L Trial# Right 1

Date

Right 1

Right 2

Right 3

Right 4

Right 5

Left 1

Left 2

Left 3

Left 4

Left 5

d. In the field titled **Date**, enter the current date using the following format: “yyymmdd”.

For example, if the current date is November 4, 2015, you would enter “20151104” into the data field titled **Date**.

MOST ID MI12345AAAA

R/L Trial# Right 1

Date 20151104

12. Confirm that a “**Label for next recording**” has been automatically created at the top of the screen using the information that you just entered.

Label for next recording:

MI12345AAAA - Right 1 - 20151104

Next

Automatically create name of recording

Use as file name

Subject ID MI12345AAAA

R/L Trial# Right 1

Date 20151104

A file name is automatically created for the recording based on the information entered

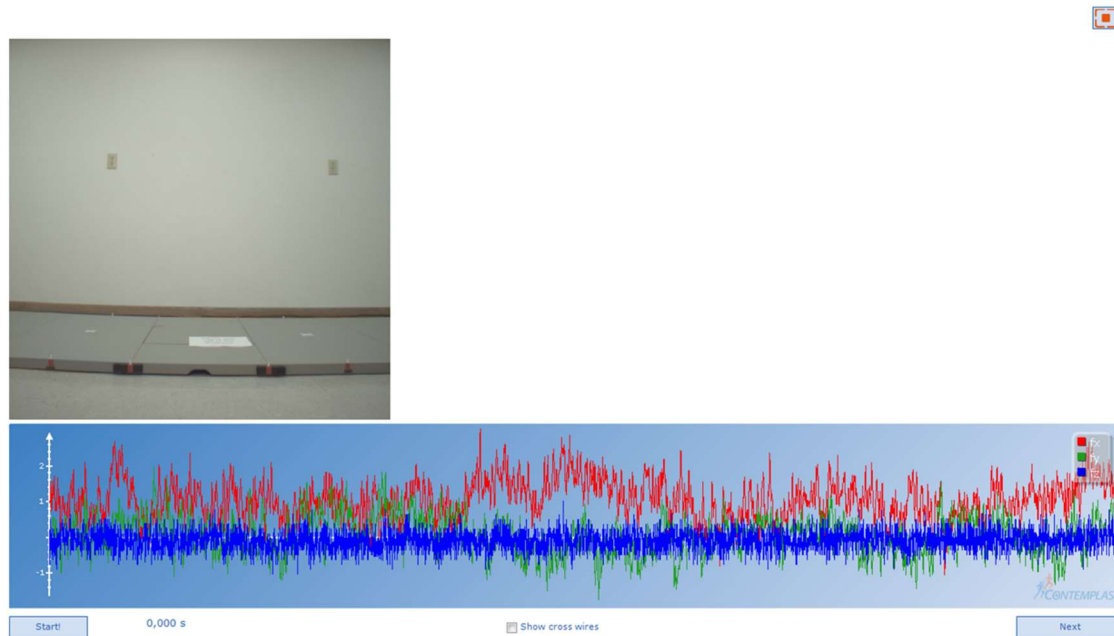
Next

If the data has been entered correctly, click

13. You will see a preview from the video camera alongside a graph of the force plate recordings.

The video image should be a perpendicular view of the force platform. The force plate tracing will register some “noise”.

MI12345AAAA - Right 1 - 20151104




14. Instruct the participant to begin a walking trial.


Script: “When I instruct you, please take a step forward with your right / left foot and continue walking all the way to end of the walkway. As you walk, keep your attention on the target at the end of the walkway. Walk in your usual manner and at a pace that feels comfortable and unhurried to you.”

“Ready?”

“Begin walking.”

15. As the participant begins walking, initiate recording by clicking  at the bottom left corner of the screen.

A timer in the bottom left corner of the screen (**0,000 s**) indicates the amount of time that has elapsed since the Start button was activated. Once activated, the Start button immediately

converts into a  button that, when clicked, will stop recording.

If the recording is not stopped by the examiner before 10 seconds have elapsed, the recording will stop automatically.

16. Observe the participant as they walk in order ensure that the 3rd footfall of the walking trial lands squarely within the boundaries of the force platform. If it does not, the trial is considered unsuccessful and must be either repeated or edited.

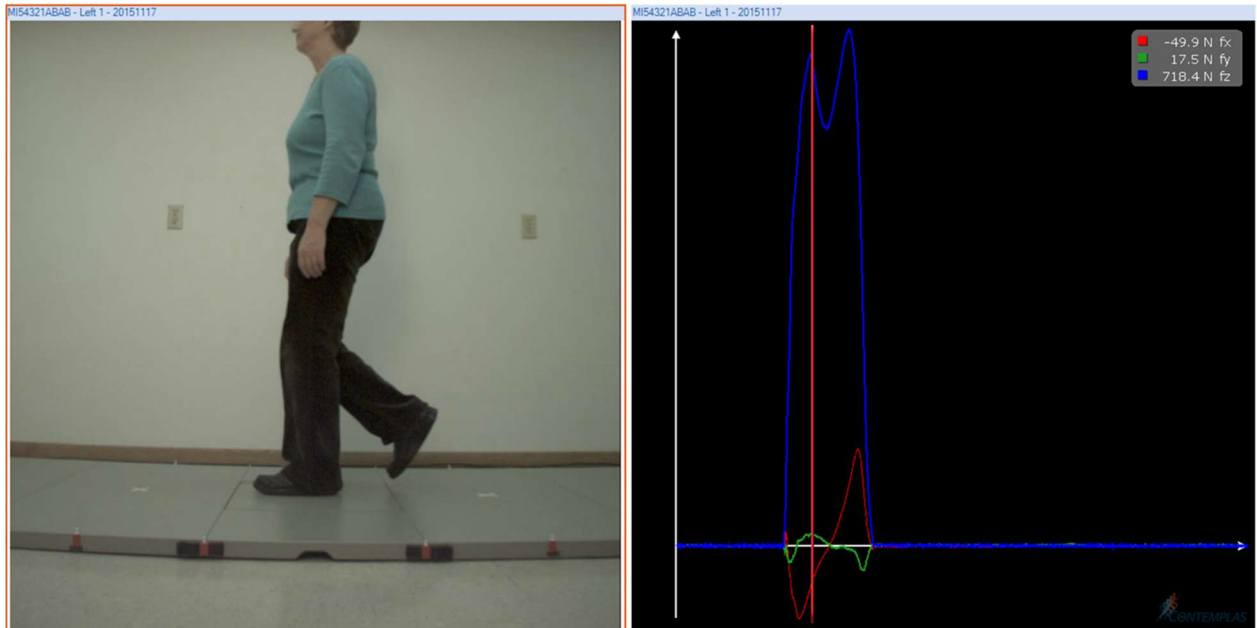




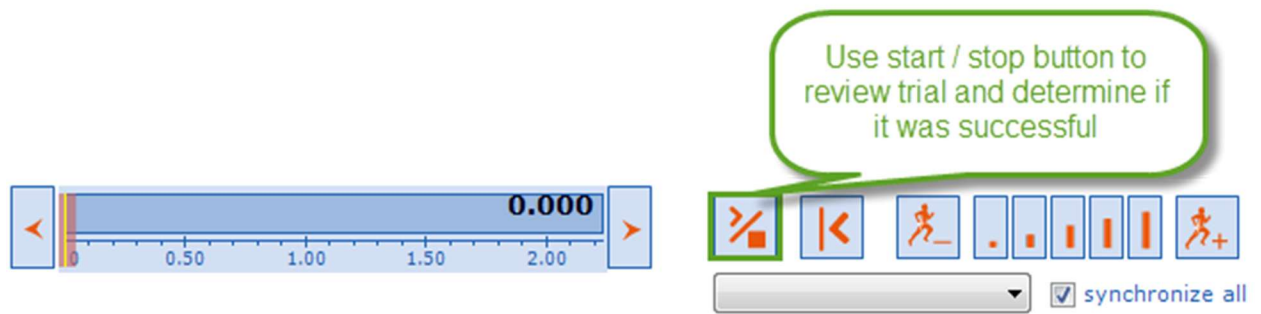
Figure 5. Successful Trial. The video shows the 3rd footfall landing entirely within the boundaries of the force platform (left), and the force tracing (F_z , in blue) has the expected “double hump” shape (right).

Recall that whichever foot initiated the walking trial (right or left) should also be the foot that makes the 3rd footfall onto the platform. If it is the opposite foot that lands within the boundaries of the force platform, or if neither foot lands within the boundaries of the force platform, the trial is considered initially unsuccessful, and must be either edited or deleted from the database before a repeat trial is attempted (see Step 20).

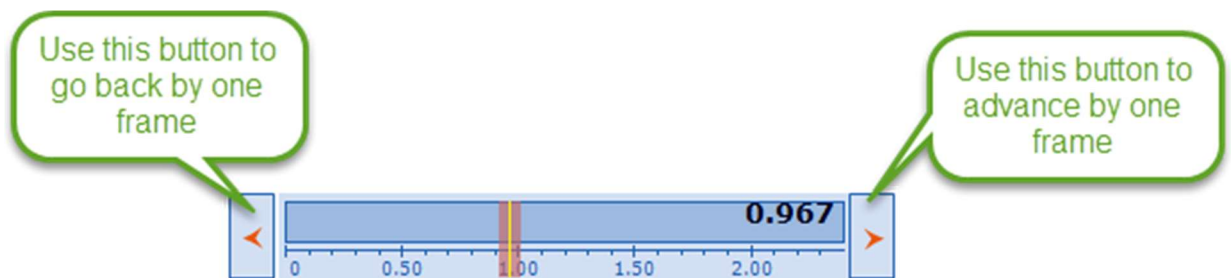
17. To end the recording, click . The “Stop” button has supplanted the “Start” button at the bottom left corner of the screen.

Once the “Stop” button is clicked, controls will appear to allow you to simultaneously review both the video (left side of screen) and the force plate tracing (right side of screen).

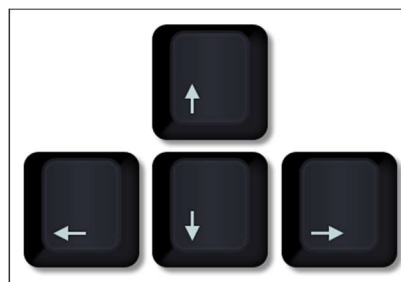
18. Use the  button to review the trial if you are uncertain about whether or not it was successful.



To facilitate your review of the trial, you have the option of advancing or going back by one video frame at a time.



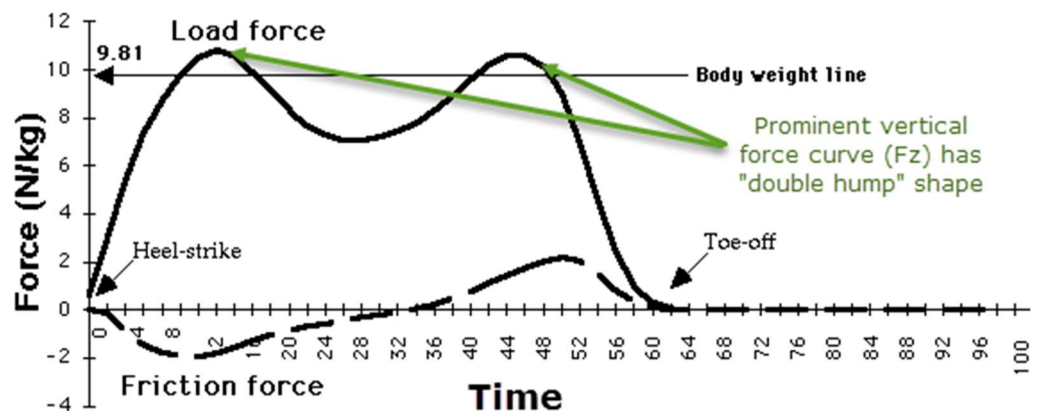
Alternatively, you can use the arrow keys on your keyboard to advance one frame at a time (right arrow) or rewind one frame at a time (left arrow). The up key will advance the video 10 frames at a time, while the down arrow on your keyboard will rewind the video 10 frames at a time:



In addition to the video recording, the force plate tracing can also give an indication of whether or not a trial was successful (see Criteria for a Successful Trial below).

The force tracing for a successful recording has the features shown below, including the characteristic “double hump” shape of the prominent vertical force curve (Fz, shown in blue in Figure 5). An example of a successful force tracing is shown in Figure 5 on the right.

Graphic of a Successful Force Tracing



3 Criteria for a Successful Trial:

1. Only one footfall landed on the force platform
2. That one footfall was contained within the boundaries of the force platform with no part of the foot extending beyond those boundaries*.
3. That one footfall was the intended foot (left or right).

* NOTE: If it is only the toes, and not any part of the forefoot that extends beyond the boundary of the force platform, the footfall may still be considered successful if the “double hump” form of the force tracing (Fz) is preserved.

19. IF THE TRIAL MEETS ALL 3 CRITERIA FOR A SUCCESSFUL TRIAL (listed above), click **Recording** in the Menu Navigator to prepare for the next walking trail. To execute the next walking trial, repeat steps 11-18 above until 5 successful trials have been recorded for the right foot, and 5 successful trials have been recorded for the left foot.

When 5 successful trials have been recorded for each foot, skip to Step 22.

20. IF THE TRIAL DOES NOT MEET ALL 3 CRITERIA FOR A SUCCESSFUL TRIAL (listed above), click **All recordings** in the Menu Navigator in order to edit or delete that unsuccessful recording.

a) Determine if the unsuccessful recording can be edited.

An initially unsuccessful recording can be edited and retained in the database if it meets the following 3 criteria:

3 Criteria for when an Initially Unsuccessful Recording can be Edited:

- a. Only one footfall landed on the force platform
- b. That one footfall was contained within the boundaries of the force platform with no part of the foot extending beyond those boundaries.
- c. That one footfall was *not* the intended foot (left or right).

These criteria would be met if, for example, the participant fails to abide by your instructions regarding whether to initiate the trial with their right foot or their left foot. In that instance, the 3rd footfall may still land cleanly within the boundaries of the force platform, but having initiated the trial with the unintended foot, the 3rd footfall onto the platform may also be made by the unintended foot.

b) **STEPS TO EDIT A TRIAL: If the unsuccessful recording meets the 3 criteria for editing (listed above), complete the following steps to edit it:**

- 1) Highlight the recording within the list of **Available recordings**

2) Click 

All recordings

Available recordings	Subject ID	R/L & Trial#	Date
MI12345AAA - right 1 - 20151104	MI12345AAA	right 1	2015





- 3) On the **Edit recording** screen, in the field titled **R/L & Trial#**, use the dropdown menu to select the *correct* side and trial number for the footfall.

Edit recording

MI12345AAA - right 1 - 20151104

Automatically create name of recording

Use as file name

Subject ID

R/L & Trial#

Date

Use pre-defined person group

- right 1
- right 2
- right 3
- right 3
- right 4
- right 5
- left 1
- left 2
- left 3
- left 4
- left 5

In this unsuccessful trial, the right foot was intended, but the left foot actually made the successful footfall

When the correct side and trial number have been selected, this information will replace the original information in the file name of the recording.

MI12345AAA - left 1 - 20151104

Automatically create name of recording


Use as file name

Subject ID

R/L & Trial#

Date

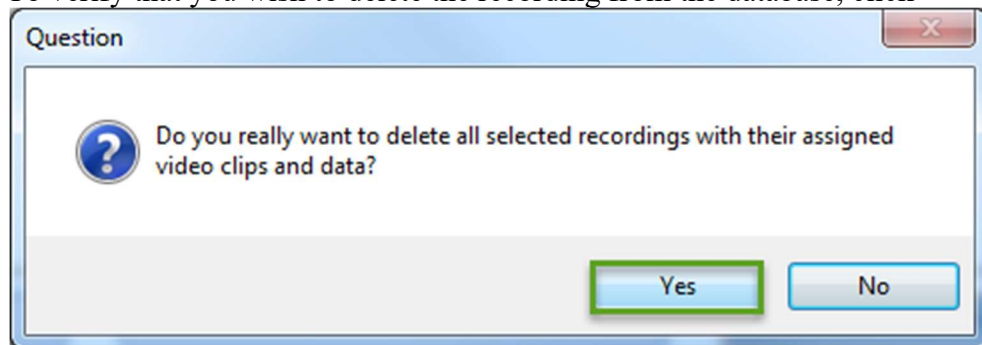
The selected side and trial # now appear in renamed file

- 4) Click  to return to the list of all **Available recordings** for this participant. The changes that you've made to the labeling of this trial name will be saved automatically.
- 5) **STEPS TO DELETE A TRIAL.** If the unsuccessful recording does not meet the 3 criteria for editing (listed above), complete the following Steps to delete it:

a. Highlight the recording within the list of **Available recordings**

b. Click .

c. To verify that you wish to delete the recording from the database, click



21. Repeat Steps 10-19 until 5 successful trials have been recorded for the right foot and 5 successful trials have been recorded for the left foot.

22. Before exiting the TEMPLO software, click  to confirm that 10 successful recordings have been included in the database for that participant.

Database

Last name starts with

Last name	Last change
MB54321ZZZ	11/2/2015 11:31 AM
MI54321ZZZ	11/4/2015 6:12 PM
MB12345AAA	11/4/2015 2:38 PM
MI12345AAA	11/4/2015 6:17 PM
MX12345abcd	10/7/2015 5:05 PM
MZ54321aaaa	10/7/2015 5:05 PM
MY50505gaga	10/7/2015 5:11 PM

Highlight Current Subject



Current date of recordings

Confirm 10 recordings on this date

Date	Type	Comment
11/4/2015	FlexiRec	

11/4/2015 MI12345/AA	
FlexiRec	
Recordings	10
Archived	no

Select New Delete

23. Exit by clicking  to return to the Start Screen if there are more participants expected on that day. Or, exit TEMPLO entirely by clicking  at the top right corner of the screen when there are no more participants to be seen on that day.

7. Data transfer

At the end of the day when force of heel strike data have been acquired the operator will need to check that the computer is left switched on so that the files can be synchronized to the UCSF ftp server overnight. This is done by clicking on an icon in the bottom right of the screen. See section 4 of the MOST Secure Data Transfer Operations Manual.

8. Quality assurance

8.1 Training and certification

Dr. Gross will provide onsite training to the staff at each clinic.

The examiner requires no special qualifications or experience to perform this assessment.

Training should include:

- Observing execution of study protocol by an experienced examiner
- Reading MOST operations manual with goal of understanding:
 - The proper use of equipment
 - Exclusions and safety considerations
 - Detailed testing procedures
- Practicing on colleagues and “naïve” volunteers
- Attending training session

8.2 Certification requirements

- Completion of training requirements
- Recitation of exclusion criteria and stopping rules
- Performance of exam on two volunteers under the observation of clinic QC officer
 - According to protocol, as demonstrated by completed QC checklist

8.3 Quality assurance checklist

- Exclusion questions asked and recorded on data collection form
- Assistive device, brace, and orthotics questions asked from data collection form
- Participant information correctly entered on computer
- Visit information correctly entered on computer
- Script correctly and clearly delivered for walking tests
- Practice test administered properly, start line determined
- 5 walking trials starting with right foot

- 5 walking trials starting with left foot
- Additional walking trials are performed as needed to replace deleted recordings
- Participant asked pain questions and responses recorded on data collection form
- Reviews data collection form for completeness
- Correctly completes data collection form
- Data archived and transferred properly

9. Data collection forms

Please see the Overview of the 144-month Follow-up Visit Operations Manual for an overview of the data collection forms, information on whether each form is in REDCap or Teleform, and where the forms can be accessed on the study website.

Appendix 1 Data Processing

1a. Overview of Data Collection

To accurately measure the rate of impact loading in MOST, we will employ an AccuGait force platform (AMTI, Inc.), the analog signal from which we will sample at 1000 Hz. The force platform will be recessed within a raised AccuGait walkway (40 mm. high with tapered ends). Participants will complete a minimum of 10 walking trials over the 5.3 meter long walkway, landing the 3rd footfall of each trial on the centrally placed platform. To ensure that the 3rd footfall lands squarely within the boundaries of the force platform, the exam will begin with a single practice trial. The purpose of the practice trial is to establish an optimal starting position from which to initiate all subsequent test trials. To begin the practice trial, the participant will stand at the center of the force platform. They will then walk in their usual manner towards one end of the walkway. The examiner will take note of whether it is the left or right foot that initiates the practice walking trial, and where along the length of the walkway the 3rd footfall lands. Colored strips of vinyl tape, oriented perpendicular to the walkway at measured distances from the platform center, will provide convenient markers to assist the examiner in identifying the approximate location of the 3rd footfall. Participants will then be instructed to turn around and initiate all subsequent test trials using this same colored tape strip as a starting line.

During each of 10 test trials, a participant will be instructed to walk the full length of the walkway in their “usual manner, at a pace that feels comfortable and unhurried”. During the first 5 test trials, the participant will initiate walking with the same foot (right or left) that was used to initiate the practice trial. In alternate step walking, the same foot that initiates the walking trial can also be expected to make the 3rd footfall onto the force platform. After 5 footfalls on the force platform have been successfully collected from one foot, the examiner will then instruct the participant to initiate the remaining 5 walking trials with the opposite foot. To minimize the risk that participants begin “targeting” the force platform, or otherwise modifying their natural gait pattern, participants are asked to fix their gaze and walk towards an eye-level target that has been placed on the wall at either end of the walkway.

Using TEMPLO motion analysis software (Contemplas, Inc.) installed on a desktop computer with connections to the force plate and to a camera, we will synchronize collection of all force plate tracings with simultaneous recording of high-speed video (60 Hz; 1280×1024 pixels). A Basler (Ace model acA1300) video camera with a perpendicular view of the force platform will remain fixed on a tripod alongside the walkway in order to capture the sagittal plane position of the ankle at the moment of heel strike. In addition, small colored markers placed at measured lengths along the walkway will assist trained video readers at Boston University (led by Dr. Gross) in calculating the participant’s average walking velocity during each trial. Throughout the exam, participants will wear their own customary walking shoes. Elsewhere during the same clinic visit, measurements will be acquired of the cushioning / hardness characteristics of these shoes so that comparisons can be made to the measured rate of impact loading during this shod walking exam.

1b. Overview of Data Transfer

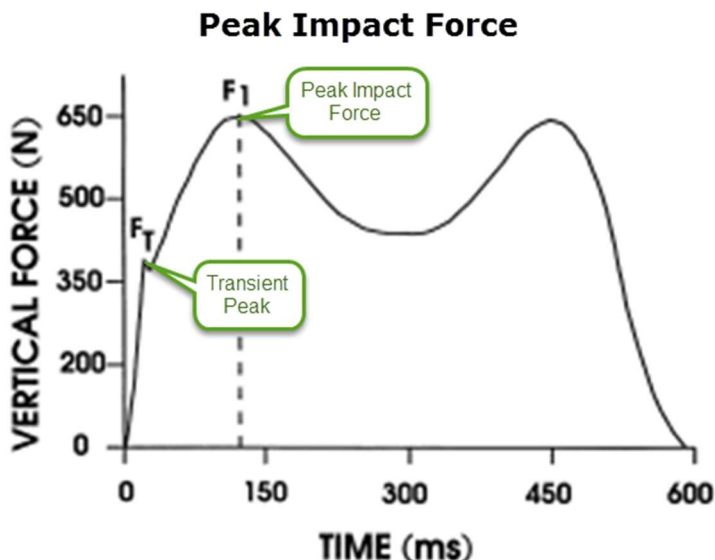
All unprocessed force plate tracings and video recordings will be organized and stored within designated folders that are recognizable to the TEMPLO software database. At the end of each week, the clinic site manager will use the software's "archive" function to make a back-up copy of this database. The back-up copy will be stored in a secure folder on the local university network. In addition, the contents of the designated folders that are accessed by the TEMPLO database will be transferred daily via secure ftp to the UCSF Coordinating Center. This is done by clicking on an icon in the bottom right of the screen, as described in Section 4 of the MOST Secure Data Transfer Operations Manual. Using their own TEMPLO software, the UCSF Coordinating Center will then periodically review the contents of the database in order to identify and correct any errors in the entry of Subject IDs or exam dates. Once all errors have been corrected, the Coordinating Center will create a clean archived copy of the weekly database to be transferred to the BU Reading Center. In addition, the Coordinating Center will use the software's "export" function to export from the cleaned weekly database a set of .txt files containing unprocessed data from the force plate. Since force data from each walking trial will be contained within its own unique .txt file, it will be necessary to export a set of 10 .txt files for each participant (one for each of 10 walking trials completed by a participant). To facilitate correct identification of each .txt file by the BU Reading Center, we have pre-configured the TEMPLO software so that the file name of each .txt file will correctly identify: 1) the MOST Participant ID, 2) the limb (right or left) and trial number (1-5), and 3) the date of the exam (using the format "yyyymmdd").

1c. Overview of Data Processing

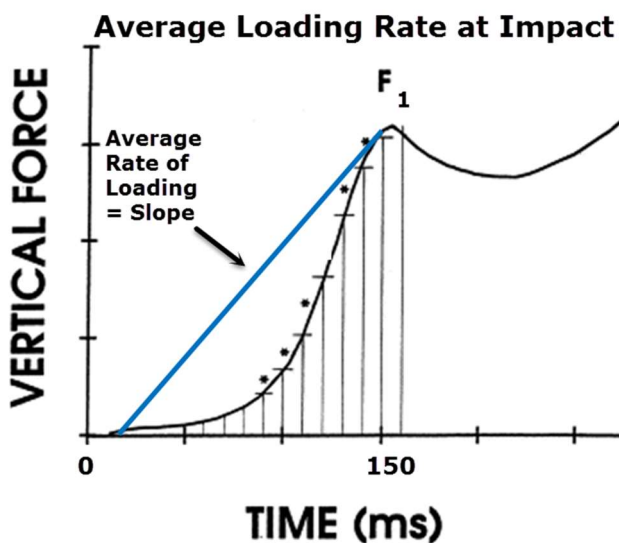
At the BU Reading Center, Dr. Doug Gross will lead efforts to read the videos for the following measured variables: 1) Average Walking Velocity, and 2) Ankle Angle at Heelstrike. Elsewhere at the Reading Center, Dr. Cara Lewis will lead efforts to process the raw force plate data that is contained within each .txt file. Using a custom written MatLab algorithm (MathWorks, Inc.), the following variables will be calculated from the vertical component of the ground reaction force (F_z) shortly after impact: 1) Peak Impact Force, measured at the 1st peak in the bimodal F_z tracing; 2) Average Loading Rate, measured between heel strike and the peak vertical impact force; and 3) Maximal Loading Rate, also measured between heel strike and the peak impact force (see Figure 1 below).

Between initial contact with the force plate (defined as the moment when F_z exceeds a minimum threshold) and 50% of stance, we will identify the peak magnitude of F_z as Peak Impact Force. Average Loading Rate will be defined as F_z peak magnitude divided by the time taken from initial heel strike to that point. To determine Maximum Loading Rate, we will calculate the instantaneous slope (first order derivative) of the force versus time curve, and identify its maximum value during the period between initial heel strike and peak impact force. Measured values for each foot will be averaged across 5 trials, and expressed in units of body weight (BW) for Peak Impact Force, and body per second (BW/sec) for average and maximum Loading Rate.

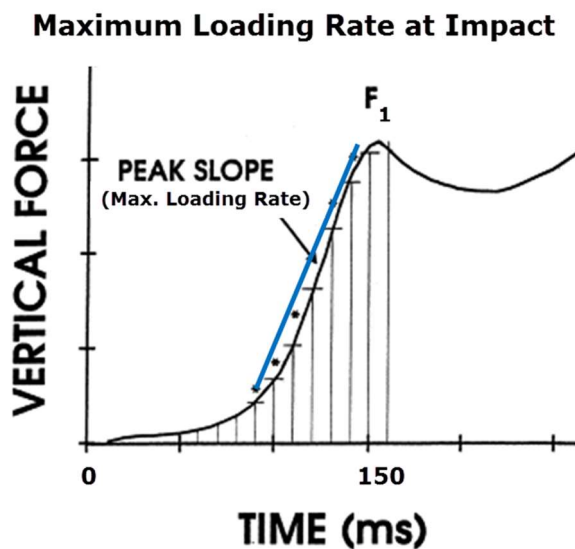
a. Peak Impact Force



b. Average Loading Rate



c. Maximum Loading Rate



Appendix 1, Figure 1. Variables to be measured from the force plate tracings. Three force variables will be targeted for measurement during the first 50% of stance phase by the BU Reading Center under the leadership of Dr. Cara Lewis: a) Peak Impact Force, b) Average Loading Rate at Impact, and c) Maximum Loading Rate at Impact.