



Software User's Guide

Software Version 1.4

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TL-HEX Software User's Guide: Software version 1.4

The applicable End User License Agreement can be found at <http://tlhex.com/policies/Eulapolicy.html>

The applicable privacy policy can be found at <http://tlhex.com/policies/privacypolicy.html>

Security Precautions:

User is advised to clear the browser history (temporary Internet files, cookies, etc.) after logging out of the TL-HEX application.

Computer System Requirements

Display Settings:

Screen resolution of 1024 x 768 Pixel or higher.

Supported Browsers:

Microsoft Internet Explorer®: Version 8 or 9

Microsoft and Internet Explorer are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries

Internet Connection:

High-speed Internet connectivity is recommended.

Language Setting:

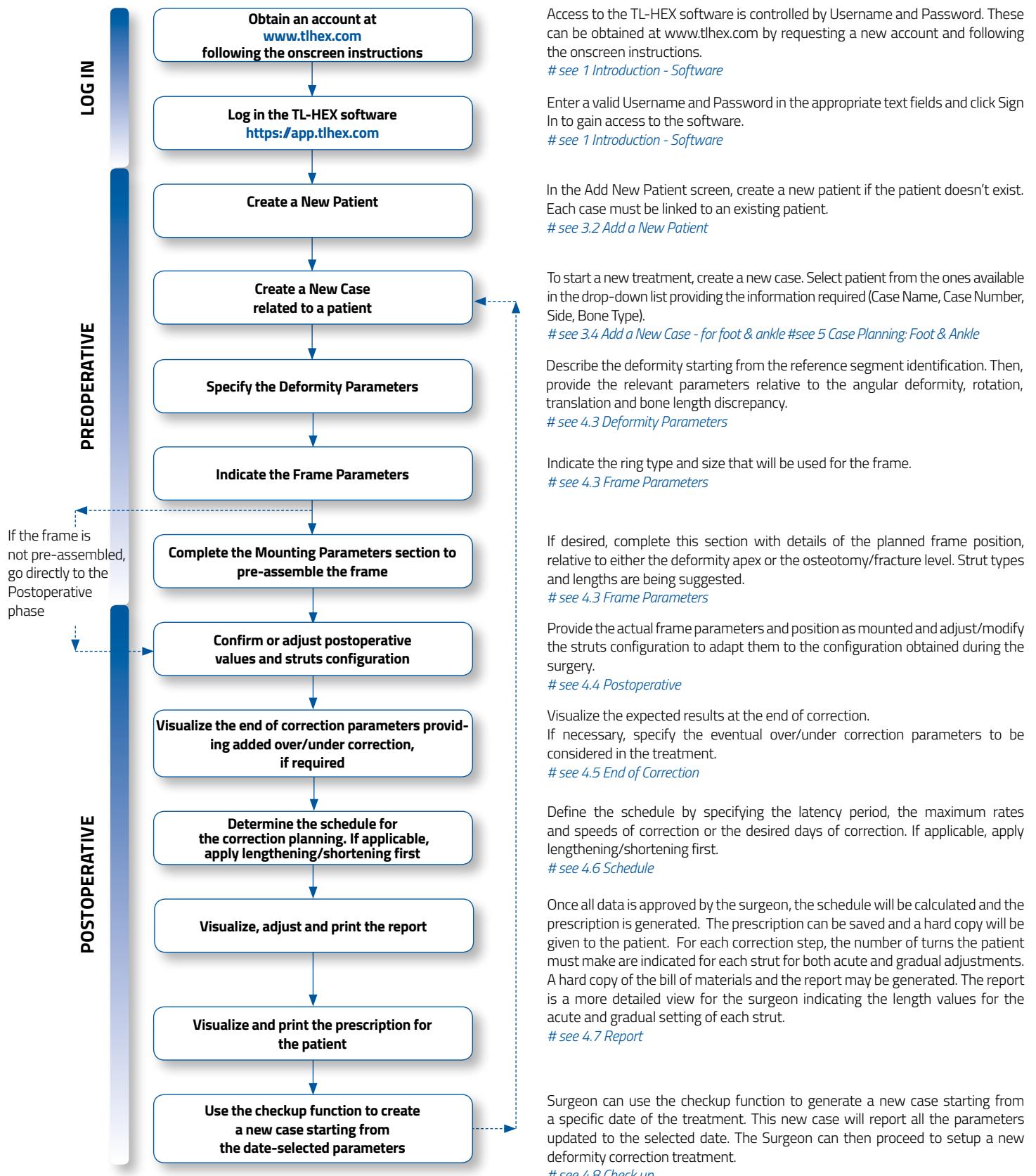
Select the "Language" setting in the Internet Explorer browser for the country of origin. This will provide the correct date setting.

My Username: _____

My Password: _____

My Email Address: _____

The following provides a sequential overview of the process for a case management with TL-HEX software



1. Introduction

HARDWARE

The TL-HEX is a circular external fixator based on Ilizarov principles. This frame consists of a hexapod made up of two rings (circular external supports - Fig.1), one ring and one foot plate (U shaped plate for foot deformity correction - Fig.2) or two foot plates with the opening in opposite directions and six variable-length struts. The relative strut lengths determine the position of the rings in space. Because the rings are attached to bone segments or to a bone segment and foot, their position indirectly determines the position of the bone segment.



Fig.1



Fig.2

Fig.1 TL-HEX standard application with two rings and 6 variable length struts

Fig.2 TL-HEX application with one ring, one foot plate and 6 variable length struts (foot deformity correction)

Struts

TL-HEX struts (Fig. 3) consist of two telescoping aluminum tubes which can be locked together at various length. The rod translates relative to the inner tube when the knob is rotated providing a gradual changes of overall strut length in 0.5-mm increments.

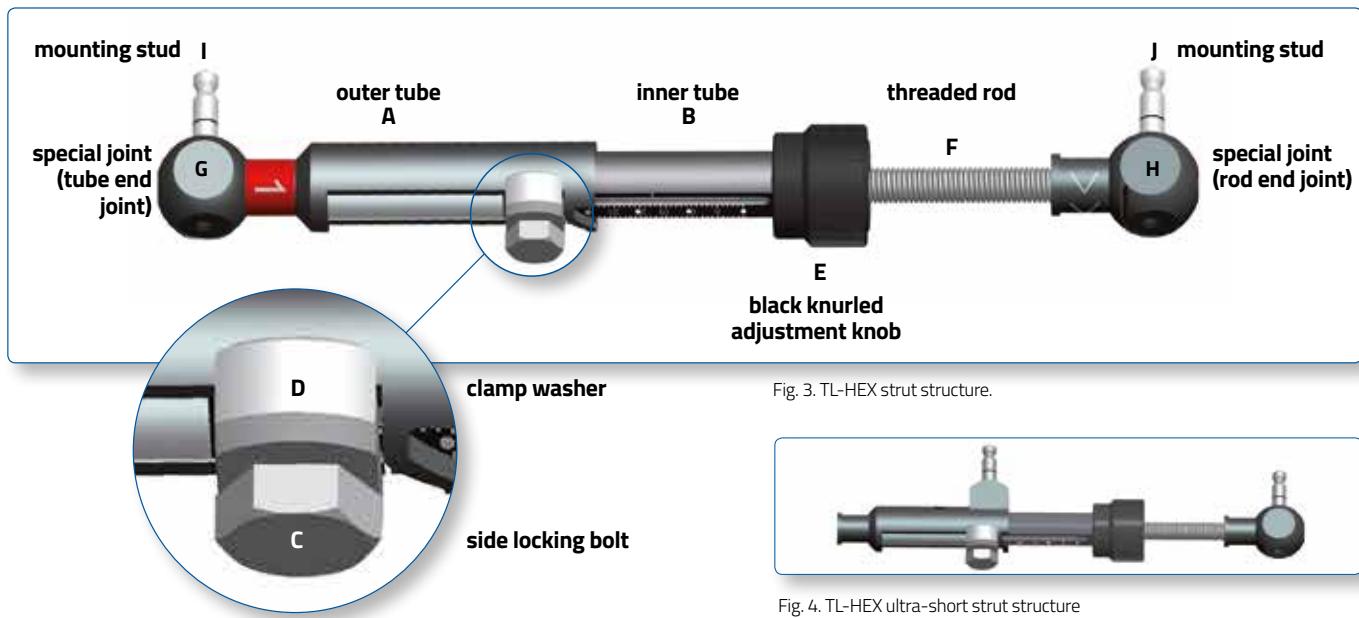


Fig. 3. TL-HEX strut structure.



Fig. 4. TL-HEX ultra-short strut structure

The UltraShort strut has a different design in order to be applied in special cases (very severe angular deformity, extreme Equinus foot, etc.) but the most important features (two telescoping tubes, the adjustment knob and the locking bolt) have been preserved. (Fig. 4)

The TL-HEX struts allow performing **acute** and **gradual** adjustment of the strut length.

The acute adjustment is achieved by untightening the side locking bolt, sliding the inner tube relative to the outer tube to the desired length and re-tightening the locking bolt. Acute adjustment is indicated by the inner tube scale in 1-mm increments relative to the orange-line mark on the outer tube (Fig.5 a).

The gradual adjustment is achieved by pulling and rotating the adjustment knob resulting in a noticeable detent (tactile click) every 0.5 mm of adjustment. Gradual adjustment is indicated by the same scale relative to the green-line mark on the end of the threaded rod (Fig.5 b).

The direction of adjustment is indicated by the direction clips. The arrow of the direction clips is oriented according to the prescription (see details in General Principles of TL-HEX Frame Assembly, TL-1405-OPT-E0).

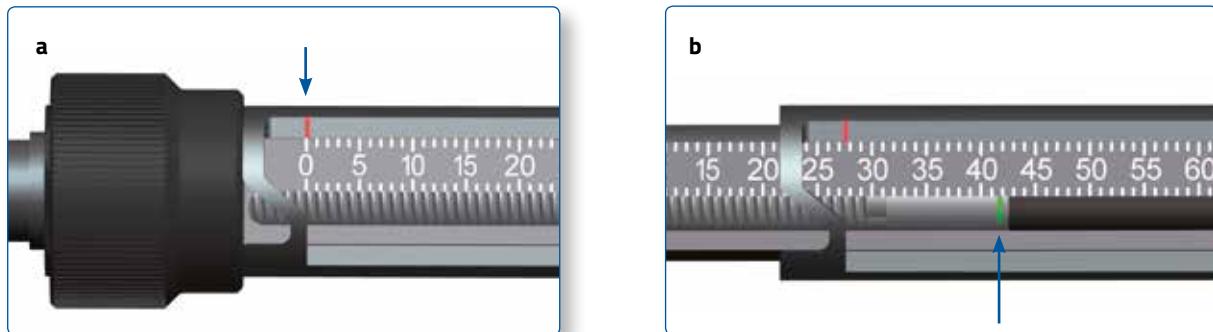


Fig. 5. Indicators for acute (a) and gradual (b) adjustments on the TL-HEX struts.

Rings & Footplates

The struts are attached to full rings, 5/8 rings or foot plates in pairs using special angulated tabs around the circumference of the external support.

Each full ring or foot plate has:

- 3 working tabs, which will have struts attached to them
- 3 non-working tabs.

Each 5/8 ring has 3 working and 2 non-working tabs.

The 3/8 component allows for transforming a 5/8 into a full ring. It has one tab, working or non-working depending on the case.

How to mount the frame

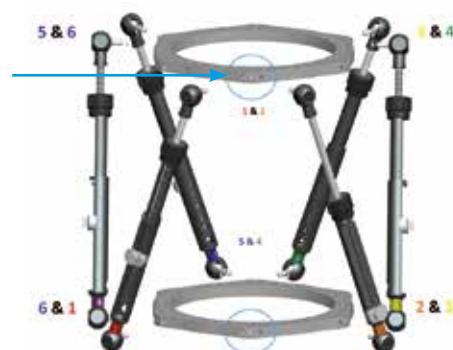
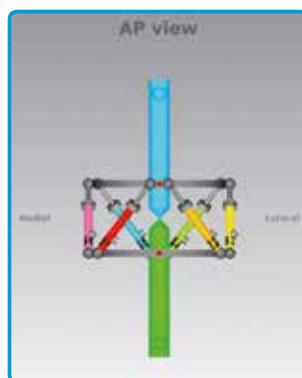
For proper identification, the struts are numbered using color number clips. The clips are numbered from 1 to 6 and color coded as **red** (1), **orange** (2), **yellow** (3), **green** (4), **blue** (5), and **purple** (6).

The following rules apply to every TL-HEX frame in order to be consistent with the software graphical representation:

Full Rings or 5/8 Rings open posteriorly

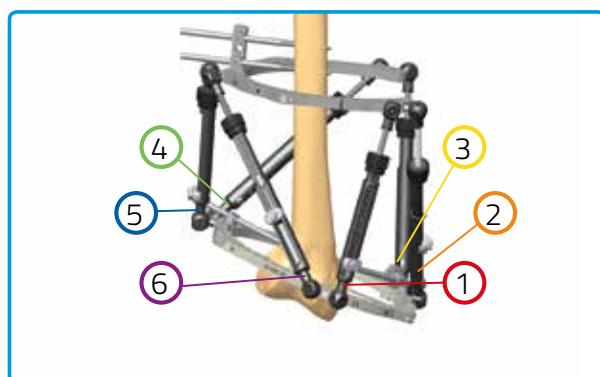
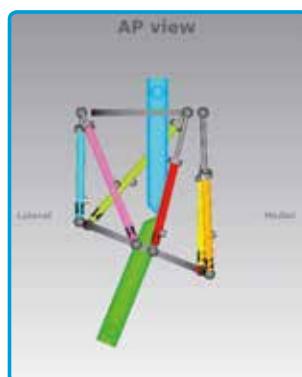
- The ring orientation tab is always placed on the anterior aspect of the limb

- The Ring Orientation tab is the one from which struts 1 and 2 originate
- It is always on the proximal ring, regardless of which segment is chosen as the reference segment

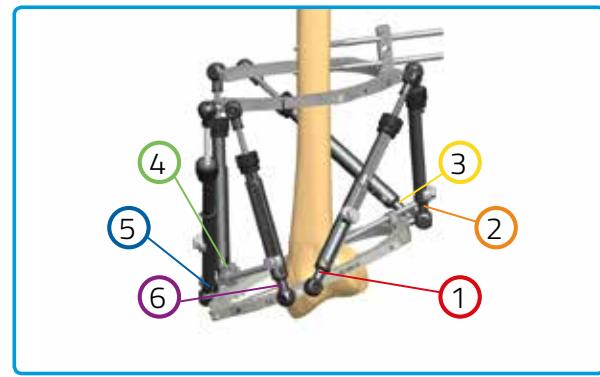
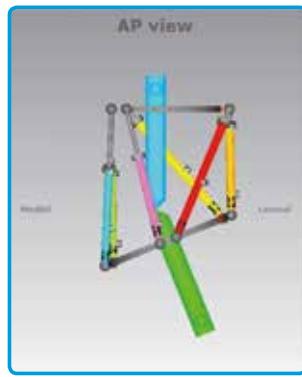


5/8 Rings open medially

- In this case, when there is no rotational deformity, according to the software convention, the ring orientation tab is the nearest tab that is anti-clockwise from the anterior point of the limb.
- Being this rotation always anti-clockwise for both right and left limbs, for the left limb there is an "external" rotation value and for the right limb there is an "internal" rotation value.
- The rotational values are automatically calculated.



Right femur application



Left femur application

SOFTWARE

The Software, starting from the initial fracture or deformity, is able to calculate a prescription for surgeon's review and approval, indicating direction and daily amount of adjustment in length for each strut in order to achieve the treatment goals.

Obtaining Access & information

Access to the TL-HEX software is controlled by Username and Password that can be obtained at www.tlhex.com by requesting a new account from the Home Page and following the onscreen instructions.

Once the request has been received by Orthofix, it will be validated to confirm whether the applicant has undergone the necessary training to use the system safely and responsibly. Once approved, the surgeon's user account will be activated, and Username and Password will be emailed to the applicant.

For further information and support, please, send an email to tlhexcustomercare@orthofix.com.

Getting Started... How to login

Go to: <http://app.tlhex.com>

This location provides the login screen (Fig. 6) after the selection of the user's country.

NOTE: the releases 1.2 and 1.3 will be maintained to serve the countries where the new version 1.4 has not been approved yet.



Fig. 6. TL-HEX software Login Page.

Patient ID	Initials	Gender	Last Case Created	Active Cases	Actions
PATIENT A	PA	Male	17/03/2014	12	Modify Patient Delete Patient
RECEIVED_CASES	RC	N/A	13/03/2014	0	Delete Patient
PATIENT B	PB	Female	12/03/2014	2	Modify Patient Delete Patient
PATIENT C	PC	Male	12/03/2014	1	Modify Patient Delete Patient

Fig. 7. TL-HEX software Home Page, i.e. the list of patients

2. Nomenclature

Reference segment : Proximal or Distal

In the description of the fracture or deformity, one of the bone segments is defined as the **reference segment** and the other one as the **moving segment**. In the software views, the **reference segment** is indicated as a **blue** segment, and the **moving (non-reference)** segment as **green**. The surgeon chooses a reference segment, either the proximal or distal.

Choosing **proximal reference** means that:

- the frame and the deformity are oriented relative to the axis of the proximal segment
- the deformity parameters (what the bone looks like) should be described accordingly
- the translation and rotation of the distal segment are described in relation to the proximal segment.

If the **distal segment** is chosen as the reference segment:

- the frame and the deformity are orientated relative to the axis of the distal segment
- the measurements would need to be taken in relation to this orientation
- the translation and rotation of the proximal segment are described in relation to the distal segment.

For example, in case of a distal reference segment, medial translation of the distal bone segment would be described as lateral translation because the proximal segment would be translating laterally in relation to the distal (reference) segment (Fig. 8). In the description of foot cases, the software views represents the deformity following the same rules as above but with a dedicated graphic (Fig. 9).

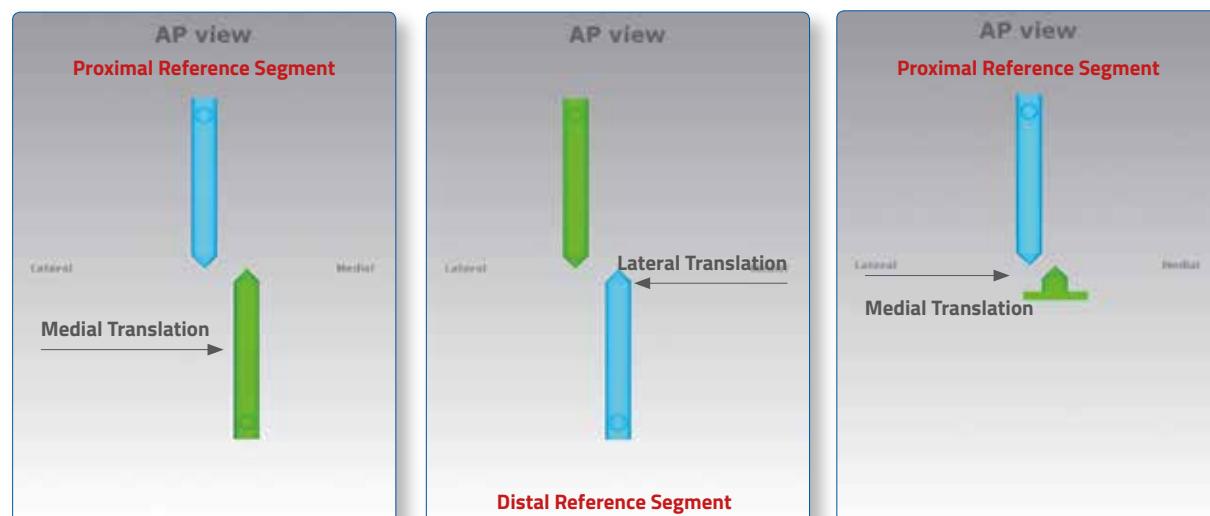


Fig. 8. Description of moving segment translation depending on proximal or distal location of the reference segment

Fig. 9. For foot deformity, the proximal segment is almost always used for referencing

It is important to realize that changing from proximal to distal referencing will change direction of translation in both AP and ML views and the direction of rotation in the Axial view, but will not change length or angulation parameters because these are mathematically independent of the point of reference.

To minimize measurement errors on the x-rays, the shortest segment should be used as a reference segment. For example, if a correction was performed around a proximal tibial osteotomy or fracture, the proximal segment should be used for referencing. If the surgeon is dealing with a distal femoral fracture or deformity, the distal segment should be used as the reference segment, if the surgeon works with foot deformity, (for example Equinus foot) the proximal segment is almost always used for referencing.

There are three pictures in the software. The first is the AP view diagram corresponding to the standard AP x-ray of the limb. The second is the ML view diagram representing the standard ML x-ray of the limb. There are orientation keys on these two views that indicate the medial/lateral and anterior/posterior aspects, respectively. The third picture is the Axial view representing the view we would have when looking either up or down the limb from the reference segment. On this view, the orientation keys are anterior, posterior, medial, and lateral (Fig. 10).

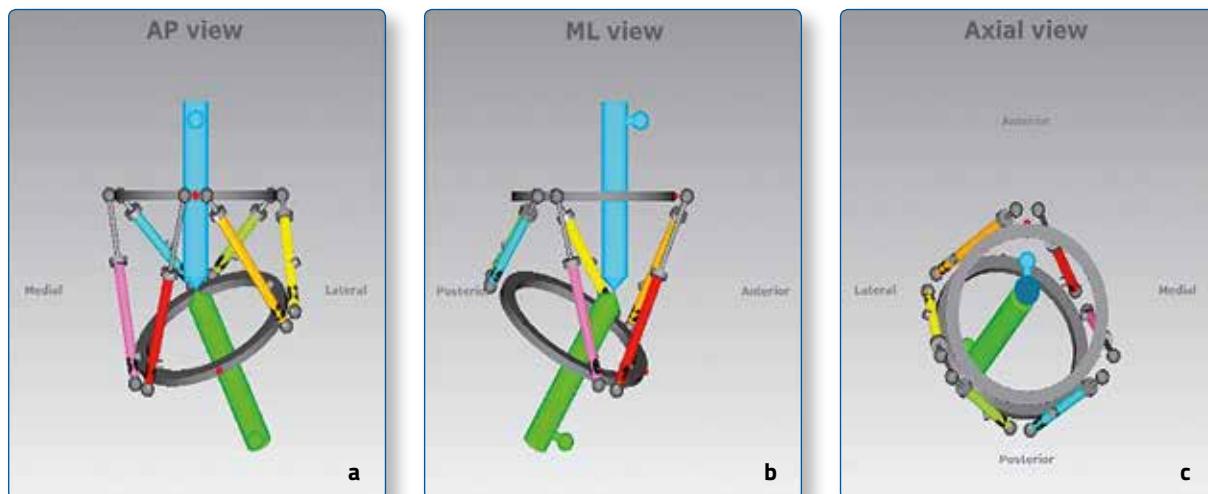


Fig. 10. Standard AP view (a), ML view (b) and Axial view (c) representations of a long bone deformity in the software. The proximal (reference) segment is indicated in **blue** and the distal (moving) segment in **green**. There is valgus-procurvatum deformity of the limb as evidenced by the direction of angulation on the AP and ML views. The frame is comprised of two rings interconnected by 6 struts. In all three views, the ring orientation is marked with **red dots**.

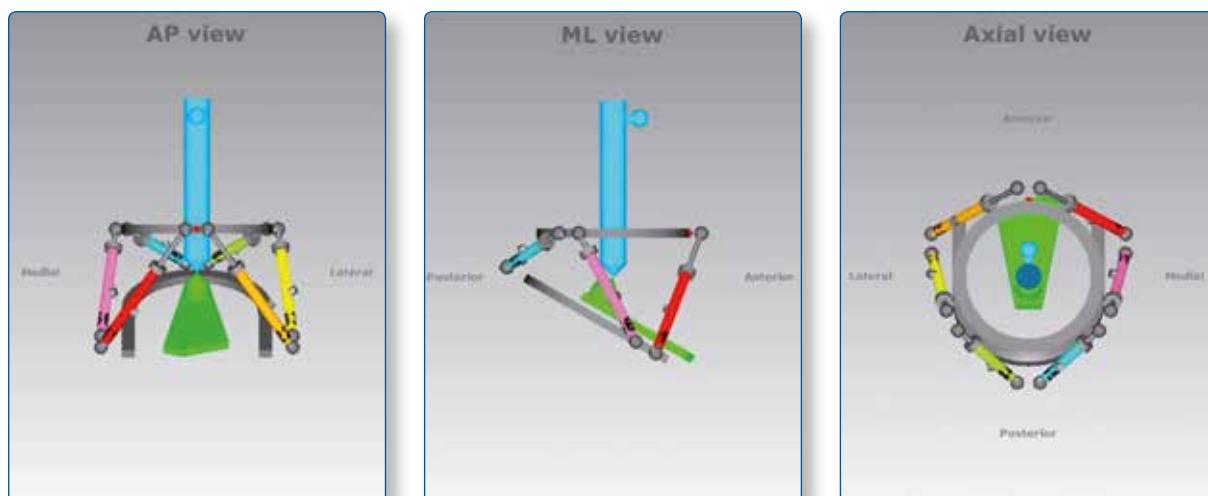


Fig. 11. Standard AP view (a), ML view (b) and Axial view (c) representations of a foot and ankle deformity in the software. The proximal (reference) segment is indicated in **blue** and the distal (moving) segment in **green**. There is procurvatum deformity of the foot as evidenced by the direction of angulation with the axis of talus on the ML view. The frame is comprised of one ring and one foot plate. In all three views, the ring orientation is marked with **red dots**.

3. Patient and Case Management

3.1 Menu Structure

- Patient** and **Case** menus include a list of patients or cases and allow the surgeon to add a new patient or case, respectively. - All cases are related to a patient
- At least one patient must be present prior to start any case
 - There are no restrictions on the number of cases that can be associated with each patient

The figure consists of two screenshots of the TL-HEX software interface. Both screenshots show a top navigation bar with the 'Patient' tab selected, followed by 'Case', 'Account', and 'About'. The 'Patient' menu includes 'List of Patients' and 'Add New Patient'. The 'Case' menu includes 'List of Cases' and 'Add New Case'. Below the menu is a table listing patients or cases.

Screenshot 1 (Patient Management):

Patient ID	Initials	Gender	Last Case Created	Active Cases	Actions
RECEIVED_CASES	RC	N/A	23/09/2014	0	Delete Patient
PATIENT A	PA	Male	23/09/2014	1	Modify Patient Delete Patient
PATIENT B	PB	Female	23/09/2014	6	Modify Patient Delete Patient
PATIENT C	PC	Male	23/09/2014	3	Modify Patient Delete Patient

Screenshot 2 (Case Management):

Patient ID	Case Number	Case Name	Status	Side	Date Created	Days Left	Actions
RECEIVED_CASES	Case from user1.tl...	Case from user1.tlhex@gmail.com	Received	Left	23/09/2014	0	View Delete
PATIENT A	1	tibia	Active	Left	23/09/2014	0	Modify View Send Archive Delete
PATIENT B	2	foot	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT C	1	blount's deformity	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT C	3	femur valgus	Active	Left	22/09/2014	0	Modify View Send Archive Delete
PATIENT C	2	equinus	Active	Left	18/09/2014	0	Modify View Send Archive Delete
PATIENT B	1	femur	Active	Left	09/09/2014	0	Modify View Send Archive Delete



Fig. 13. Patient and Case management menus and structure.

3.2 Add a New Patient

Patient → Add New Patient

A new patient can be entered using:

- the **Add New Patient** menu
- the **Add New Patient** button (either in List of Patients or List of Cases screen)

For each new patient (Fig. 14), surgeon should assign a Patient ID, insert Patient Initials (or other reference associated with this patient) and select patient Gender. Optionally user can associate to a patient specific "Prescription Notes" and a "Prescription Address" expanding the "Prescription Preferences" menu (Fig. 15) (see 6.2 Prescription Preferences for details about setting addresses). Clicking on "Save Patient" will complete the creation process and open the "List of patients" screen, which will include all previously entered patients as well as the newly created one.

On the other hand, clicking on "Save & Create Case" will save the new patient and will open a new ready-to-use case already associated to the newly created patient (Fig. 16).



Fig. 14. Add New Patient screen.

Patient ID: PATIENT A

Patient Initials: PA

Gender: Male Female

Warning: You are not allowed to enter or provide any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.). Please use only an internal confidential code to identify your patient record when using this Software.

Prescription Preferences

Prescription Notes (Optional):

Select Prescription Address:

- Dr. test test
University Clinic
Main Street
London, London UK E11 1NR
08956845
- Dr. test test
Hospital Name
Hospital Street
Dallas, Texas US 23443
123456789
0346789000

Preview

Cancel Save Patient Save & Create Case

Fig. 15. Add New Patient Screen with Expanded Prescription Preferences Section

Patient ID: PATIENT A

Case Number

Case Name

Planning Created: 23/09/2014

Side: Left Right

Bone Type: Long Bone Foot and Ankle

Warning: You are not allowed to enter or provide any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.). Please use only an internal confidential code to identify your patient record when using this Software.

Notes History

>

Fig. 16. New Case associated to the Brand New Patient

Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon shall never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

3.3 List of Patients

Patient → List of Patients

List of patients can be reached:

- by clicking List of Patients from Navigation menu

Clicking on one of the patients of the list (Fig. 17. a), will expand the list of cases related to him. (Fig. 17. b)

Patient ID	Initials	Gender	Last Case Created	Active Cases	Actions
RECEIVED_CASES	RC	N/A	23/09/2014	0	Delete Patient
PATIENT A	PA	Male	23/09/2014	1	Modify Patient Delete Patient
PATIENT B	PB	Female	23/09/2014	6	Modify Patient Delete Patient
PATIENT C	PC	Male	23/09/2014	3	Modify Patient Delete Patient

Page size: 10 4 items in 1 pages

Fig. 17. a. List of Patients screen

Case Number	Case Name	Status	Side	Date Created	Days Left	Actions
1	tibia	Active	Left	23/09/2014	0	Modify View Send Archive Delete
PATIENT B	PB	Female		23/09/2014	6	Modify Patient Delete Patient
PATIENT C	PC	Male		23/09/2014	3	Modify Patient Delete Patient

Page size: 10 4 items in 1 pages

Fig. 17. b. List of Patients screen with relative list of cases expanded

Expand the Search Bar to search the content based on a specified criteria. Enter the search criteria in the relevant field and press **Search** button.

User can search by Patient ID, Status, Case Number, Side, Case Name, Bone type and Data Created (using the "This Date", "After This Date" or "Before This Date" logic). To remove any filter, click the **Clear** button (Fig. 18).

Patient ID	Initials	Gender	Last Case Created	Active Cases	Actions
RECEIVED_CASES	RC	N/A	23/09/2014	0	Delete Patient
PATIENT A	PA	Male	23/09/2014	1	Modify Patient Delete Patient
PATIENT B	PB	Female	23/09/2014	6	Modify Patient Delete Patient
PATIENT C	PC	Male	23/09/2014	3	Modify Patient Delete Patient

Fig. 18. Search Section Expanded

The List of Patients can also be sorted in ascending or descending order by clicking on any of the headers except Actions (Fig. 18).

Actions that can be performed on a patient are "modify patient" or "delete patient" (if it has been created by the current user). If it has been received from another user it can be viewed or deleted but not modified (see 3.6 Send a Case for details on sending cases).

3.4 New Case

Case → Add New Case

A new case can be added using one of the following methods:

- selecting **Add New Case** from the **Case** menu
- clicking **Add New Case** in the List of Cases screen
- clicking **Add New Case** in the List of Patients screen
- clicking **Save & Create Case** after a new patient creation process

NOTE: At least one patient must be present, if not, the Patient ID drop-down selector will be empty and an error message will be displayed

For each new case (Fig. 19), the surgeon should assign a Case Number and a Case Name (reference associated with this case). Select gender, left/right side, bone type (long bone or Foot and Ankle) and the planning date, followed by entering Notes associated with this case (optional).

Proceed to the next step in the treatment planning process by clicking on the "next" arrow to the right hand side..

The screenshot shows the 'Case Data' tab selected in the top navigation bar. The main form contains the following data:

- Patient ID: PATIENT A
- Case Number: 2
- Case Name: blount's disease
- Planning Created: 26/09/2014
- Side: Left
- Bone Type: Long Bone
- New Notes: Notes about this case

A warning message box is displayed, stating: "Warning: You are not allowed to enter or provide any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.). Please use only an internal confidential code to identify your patient record when using this Software." A red arrow points to the right 'next' button.

Fig. 19. Add New Case screen.

Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon shall never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

3.5 View Cases

Case → List of Cases

All cases for all patients in the **List of Cases** are sorted by the latest date created (Fig. 21). The List of Cases can be also sorted by clicking on any of the headers a part from Actions.

A case can be in "Active", "Received" or "Archived" status (Fig. 20).

CASE STATUS	MEANING	ACTIONS
ACTIVE	Open and Modifiable	view delete modify archive send
RECEIVED	Sent by Another User	view delete
ARCHIVED	Read-Only	view delete send

Fig. 20. Table Summarizing the Actions Performable Depending on Case Status

Patient ID	Case Number	Case Name	Status	Side	Date Created	Days Left	Actions
RECEIVED_CASES	Case from user1.tl...	Case from user1.tlhex@gmail.com	Received	Left	23/09/2014	0	View Delete
PATIENT A	1	tibia	Active	Left	23/09/2014	0	Modify View Send Archive Delete
PATIENT B	2	foot	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT C	1	blount's deformity	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT C	3	femur valgus	Active	Left	22/09/2014	0	Modify View Send Archive Delete
PATIENT C	2	equinuus	Active	Left	18/09/2014	0	Modify View Send Archive Delete
PATIENT B	1	femur	Active	Left	09/09/2014	0	Modify View Send Archive Delete

Fig. 21. List of Cases screen

3.6 Send a Case

User can send to another user a case in read-only mode:

- 1- go to List of Cases
- 2- find the case you want to send
- 3- click on "Send" link in the "Actions" field related to this case
- 4- enter the "Receiving UserName" i.e. the registration username (email) of the receiver
- 5- click on **Send** (Fig. 22)



Fig. 22. Send Case Pop Up Window

Patient ID	Case Number	Case Name	Status	Side	Date Created	Days Left	Actions
RECEIVED_CASES	Case from user1.tl...	Case from user1.thex@gmail.com	Received	Left	23/09/2014	0	View Delete
PATIENT_A	1	tibia	Active	Left	23/09/2014	0	Modify View Send Archive Delete
PATIENT_B	2	foot	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT_C	1	blount's deformity	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT_D	3	femur valgus	Active	Left	22/09/2014	0	Modify View Send Archive Delete
PATIENT_E	2	equinus	Active	Left	18/09/2014	0	Modify View Send Archive Delete
PATIENT_F	1	femur	Active	Left	09/09/2014	0	Modify View Send Archive Delete

Fig. 23. Received Case Listed in the List of Cases Screen

3.7 Archive a case

To Archive a case user should click on "Archive" in the "Actions" field of a case. A warning pop up reminds that the action cannot be reverted, once a Case has been Archived it cannot be modified (Fig. 24 and Fig. 25).

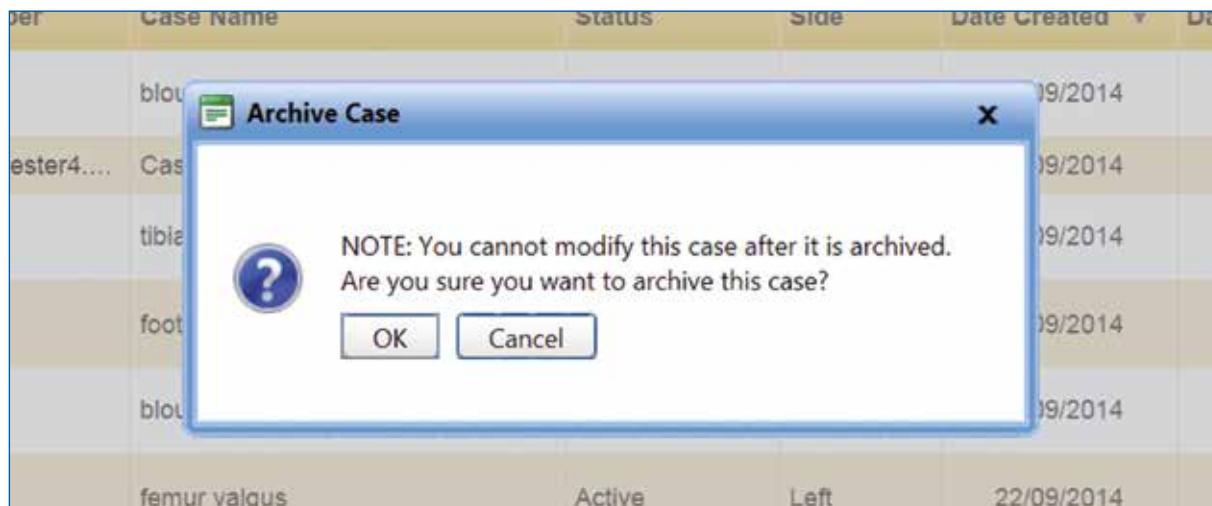


Fig. 24. Warning Pop Up

Patient ID	Case Number	Case Name	Status	Side	Date Created	Days Left	Actions
PATIENT A	2	blout's disease	Active	Left	26/09/2014	0	Modify View Send Archive Delete
RECEIVED_CASES	Case from user1.tl...	Case from user1.tlhex@gmail.com	Received	Left	23/09/2014	0	View Delete
PATIENT A	1	tibia	Active	Left	23/09/2014	0	Modify View Send Archive Delete
PATIENT B	2	foot	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT C	1	blout's deformity	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT C	3	femur valgus	Archived	Left	22/09/2014	0	View Send Delete
PATIENT C	2	equinus	Active	Left	18/09/2014	0	Modify View Send Archive Delete
PATIENT B	1	femur	Active	Left	09/09/2014	0	Modify View Send Archive Delete

Fig. 25. Performable Actions on an Archived Case. An Archived Case cannot be modified.

As per the List of Patients, user can expand the "search" bar in order to search the content based on a specific criteria. Enter the search criteria in the relevant field and press **Search** button. User can search by Patient ID, Status, Case Number, Side, Case Name, Bone Type and Data Created (using the "This Date", "After This Date" or "Before This Date" logic). To remove any filter, click the **Clear** button (Fig. 26).

Patient ID	Case Number	Case Name	Status	Side	Date Created	Days Left	Actions
PATIENT_A	2	blount's disease	Active	Left	26/09/2014	0	Modify View Send Archive Delete
RECEIVED_CASES	Case from user1.tl...	Case from user1.tlhex@gmail.com	Received	Left	23/09/2014	0	View Delete
PATIENT_A	1	tibia	Active	Left	23/09/2014	0	Modify View Send Archive Delete
PATIENT_B	2	foot	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT_C	1	blount's deformity	Active	Right	23/09/2014	0	Modify View Send Archive Delete
PATIENT_C	3	femur valgus	Archived	Left	22/09/2014	0	View Send Delete
PATIENT_C	2	equinus	Active	Left	18/09/2014	0	Modify View Send Archive Delete
PATIENT_B	1	femur	Active	Left	09/09/2014	0	Modify View Send Archive Delete

Fig. 26. Search Section Expanded

The List of Cases can also be sorted in ascending or descending order by clicking on any of the headers except Actions (Fig. 21).

Upgrade from previous versions to 1.4

Case Version Management

Cases created with a prior software version will be migrated in read-only mode in version 1.4. If surgeon wants to modify one of these cases, he should create a brand new case with the new software release entering all the relevant parameters from the prior version case (deformity, frame and post-operative).

4. Case Planning - Long Bone

4.1 Case Data

Case data includes Patient ID, Case Number, Case Name (reference associated with this case), Anatomical site (left or right), Bone Type (long bone or foot and ankle), New Notes and Date of Planning (see 3.4 Add a New Case for details). The software needs three sets of parameters to calculate correction:

	Deformity Parameters	Frame Parameters	Mounting Parameters
DEFINITION	What the deformity or fracture displacement looks like	The size and the shape of the frame that is to be used	Where the frame's reference point is in relation to the fracture or deformity area
SOURCE	AP & ML X-rays, clinical assessment	Rings (full or 5/8+3/8), footplates, 5/8 rings (in mm)	Position, translation and angulation of the rings
SOFTWARE SCREEN	Deformity Parameters	Frame Parameters	Preoperative Mounting Parameters Section OR Postoperative

4.2 Deformity Parameters

Move to the Deformity Parameters screen to enter parameters associated with the deformity (Fig. 27 and 28)

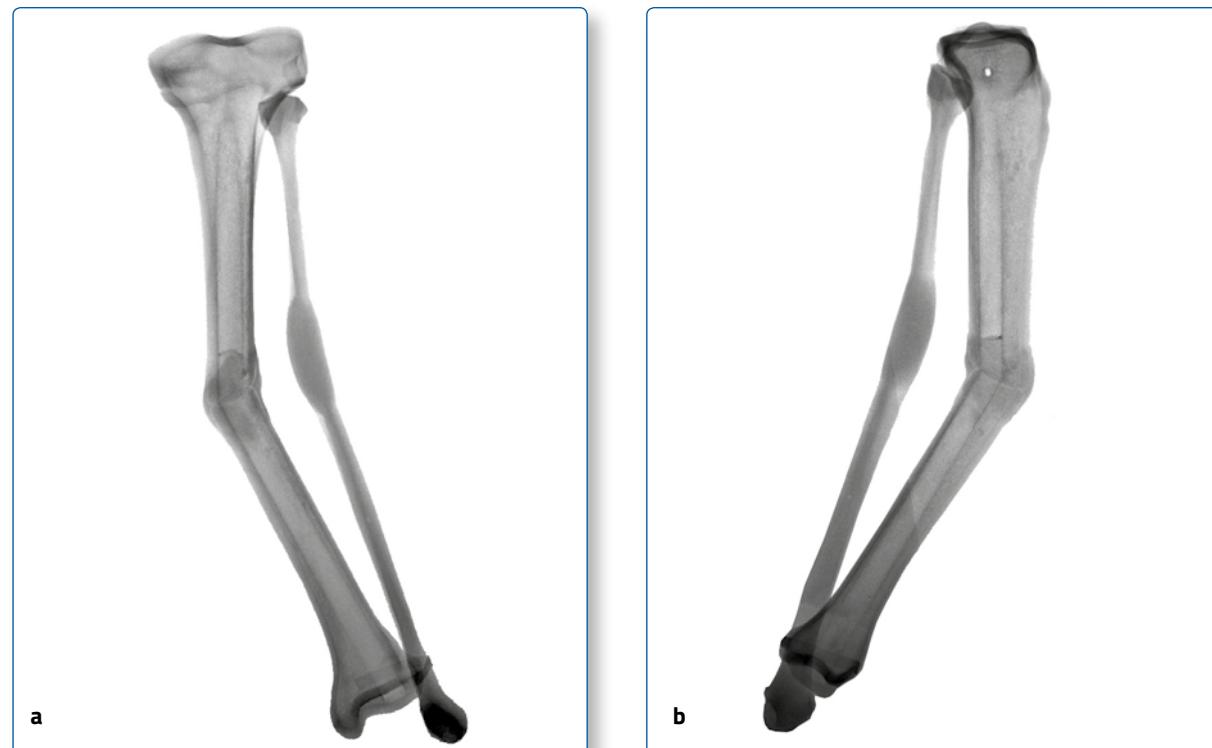


Fig. 27. AP view (a) and ML view (b) radiographs of oblique plane midshaft tibial deformity (valgus - procurvatum).

The first step is to choose the reference segment (Fig. 28). The surgeon is free to choose either the *proximal* or *distal* segment as the reference segment depending on the clinical scenario (see 2. Nomenclature for details).

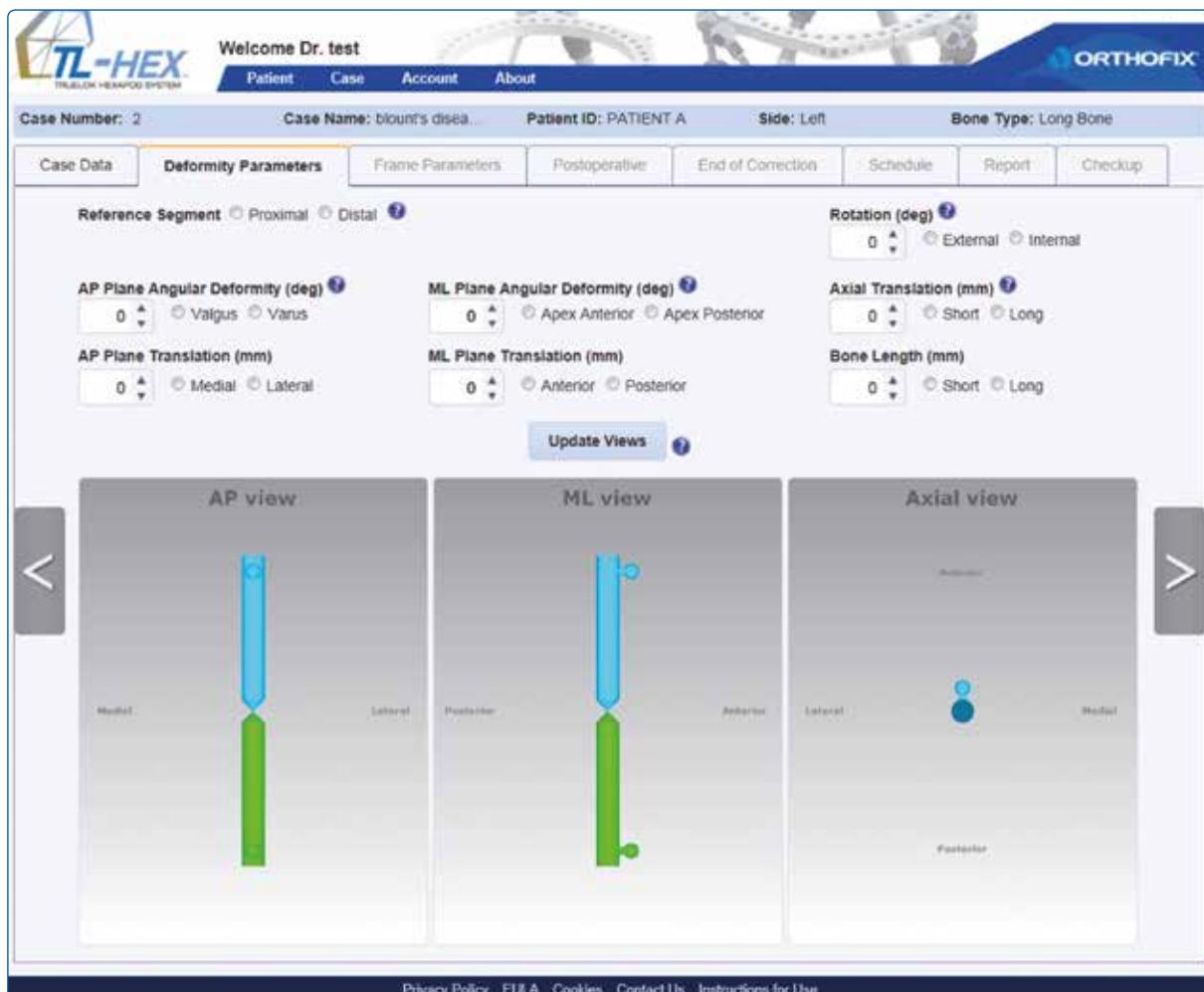
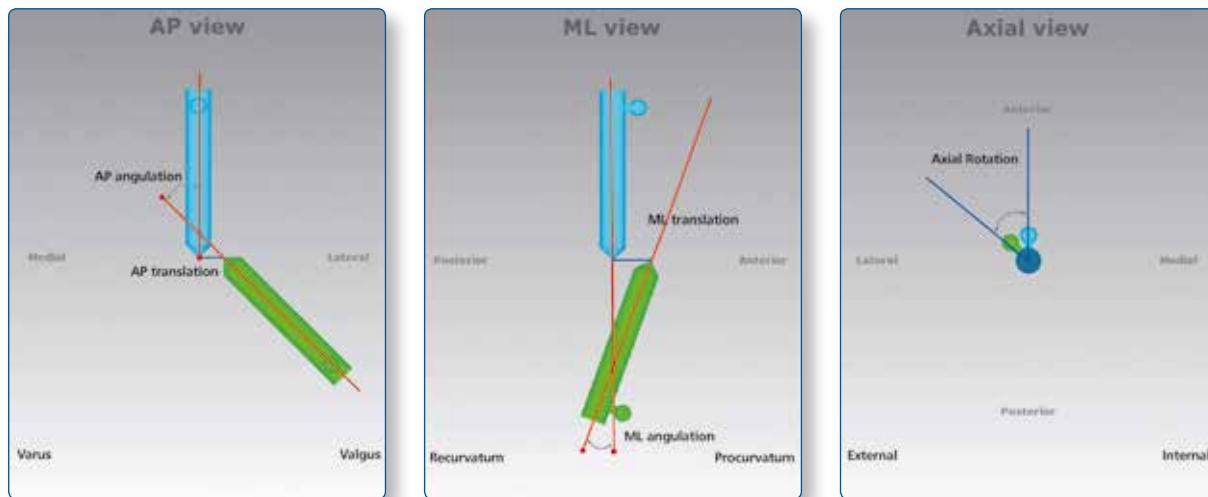


Fig. 28. Default Deformity Parameters screen.



Example: Left long bone - Proximal Reference Segment

AP Plane Angular Deformity (deg)

Coronal plane angulation can be either varus or valgus, depending whether the distal segment is deviated medially or laterally to the reference segment.

AP Plane Translation (mm)

In the *coronal plane*, the translation can be medial or lateral. Medial translation, for example, means that the moving segment is translated medially relative to the reference segment.

ML Plane Angular Deformity (deg)

Sagittal plane angulation will be described as either apex anterior (procurvatum) or apex posterior (recurvatum).

ML Plane Translation (mm)

In the *sagittal plane*, the translation can be anterior or posterior.

Rotation (deg)

Horizontal plane angulation can be described as internal or external rotation. With external rotation, for example, the distal segment is rotated laterally around its longitudinal axis. Because the rotation is difficult to measure radiologically, this parameter will be most commonly established clinically.

NOTE: All angulations are described in degrees. Their direction is independent regardless of whether proximal or distal referencing is chosen.

NOTE: All translations are described in millimeters in relation to the reference segment and direction of translations will change depending on whether proximal or distal referencing is used (see 2. Nomenclature for details).

The third type of translation occurs along the longitudinal axis of the limb. In the software, the *axial translation* is described in millimeters as short or long. The first option (short) is used when the moving bone segment is translated (compressed) towards the reference bone segment. The second option (long) is used when the moving bone segment is translated (distracted) away from the reference bone segment (Fig. 29).

In addition, the "Bone Length" is included in the description of the deformity parameters. Again, the software allows to indicate whether the bone is short or long and supports the entry of the relevant amount of bone length discrepancy in millimeters.

NOTE: The bone length is a clinical parameter indicating limb length discrepancy relative to contralateral limb and will not change bone segment orientation in the software diagrams.

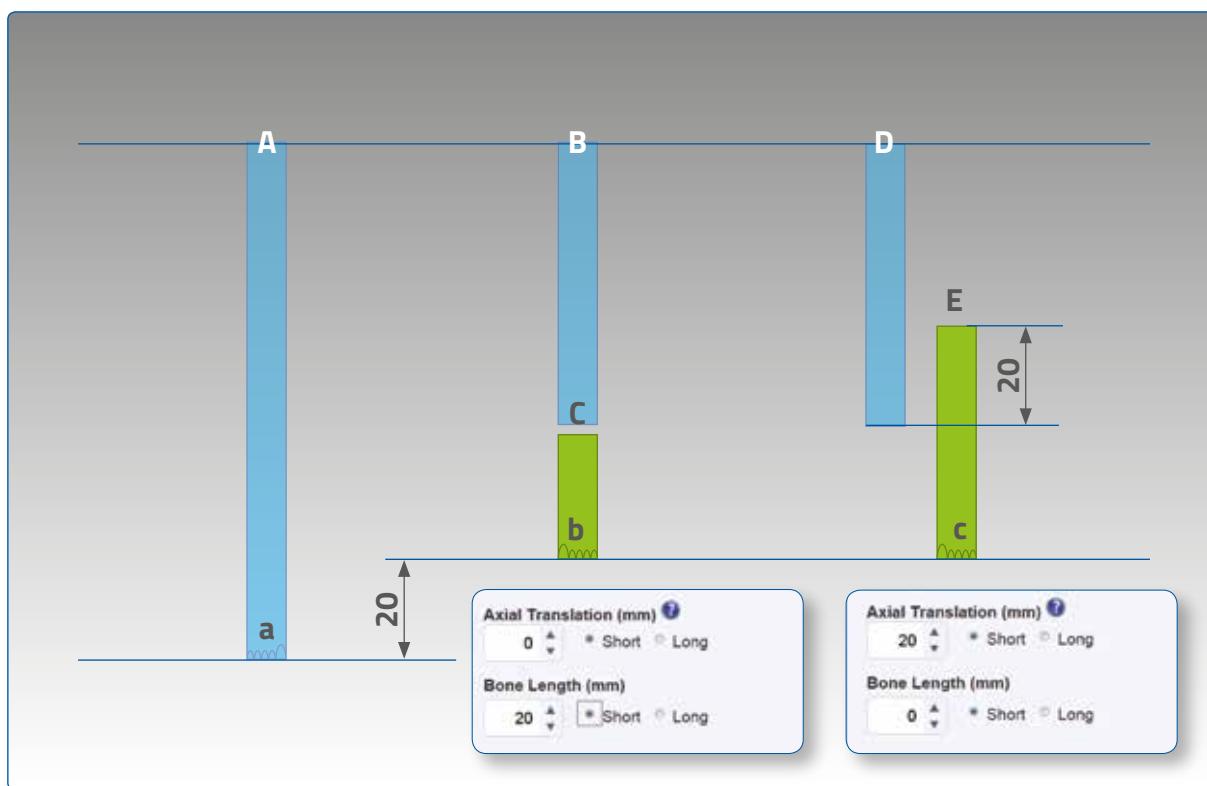


Fig. 29. Description of translation along the longitudinal axis and bone length: (a), contralateral (normal) limb; (b), short limb as result of bone shortening without axial translation; (c), short limb due to axial translation of bone segments. Note that the combined length of bone segments B and C is shorter than the length of contralateral bone segment A. The combined length of segments D and E, however, is equal to the length of contralateral bone segment A.

Click **Update Views** at any time to refresh the display according to the parameters entered (Fig. 30).

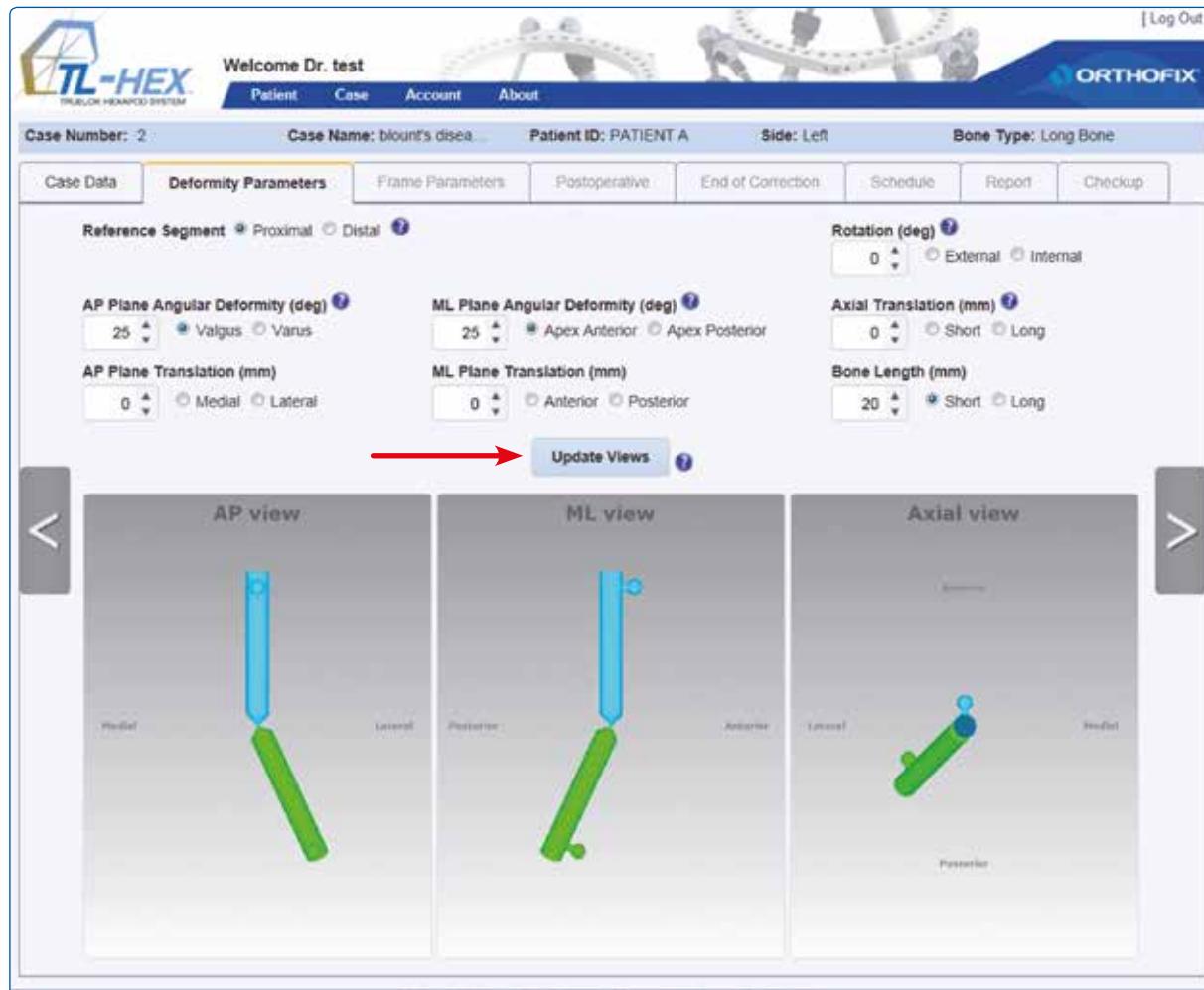


Fig. 30. Updated Deformity Parameters screen.

NOTE: It is an important safety mechanism to check whether the diagrams on the software correspond to the deformity that is seen on the patient's x-rays and/or clinically. Click **Update Views** after any changes or updates to deformity parameters.

Once satisfied with the deformity parameters that have been entered, click on the 'next' arrow to the right hand side to go to the Frame Parameters screen, or click on the Frame Parameters tab, if it is active (darker font).

4.3 Frame Parameters

Frame Parameters screen (Fig. 31) consists of two drop-down menus for each of the proximal and distal external supports (ring type and ring size) and an optional section “Preoperative Mounting Parameters” that can be expanded/collapsed as desired. (Fig. 32)



Fig. 31. Frame Parameters screen and Preoperative Mounting Parameters section collapsed.

In the example shown, 180 mm full rings have been selected (Fig. 32). Should an open external support be chosen (i.e., a 5/8 ring), the relevant ring orientation (open posteriorly, open medially, open anteriorly) should be selected from the drop-down menu (Fig. 33). The software will automatically change the orientation offset of the 5/8 ring in the Reference Ring Rotation field with the relevant read-only value. This value can be overridden in the Postoperative Screen.

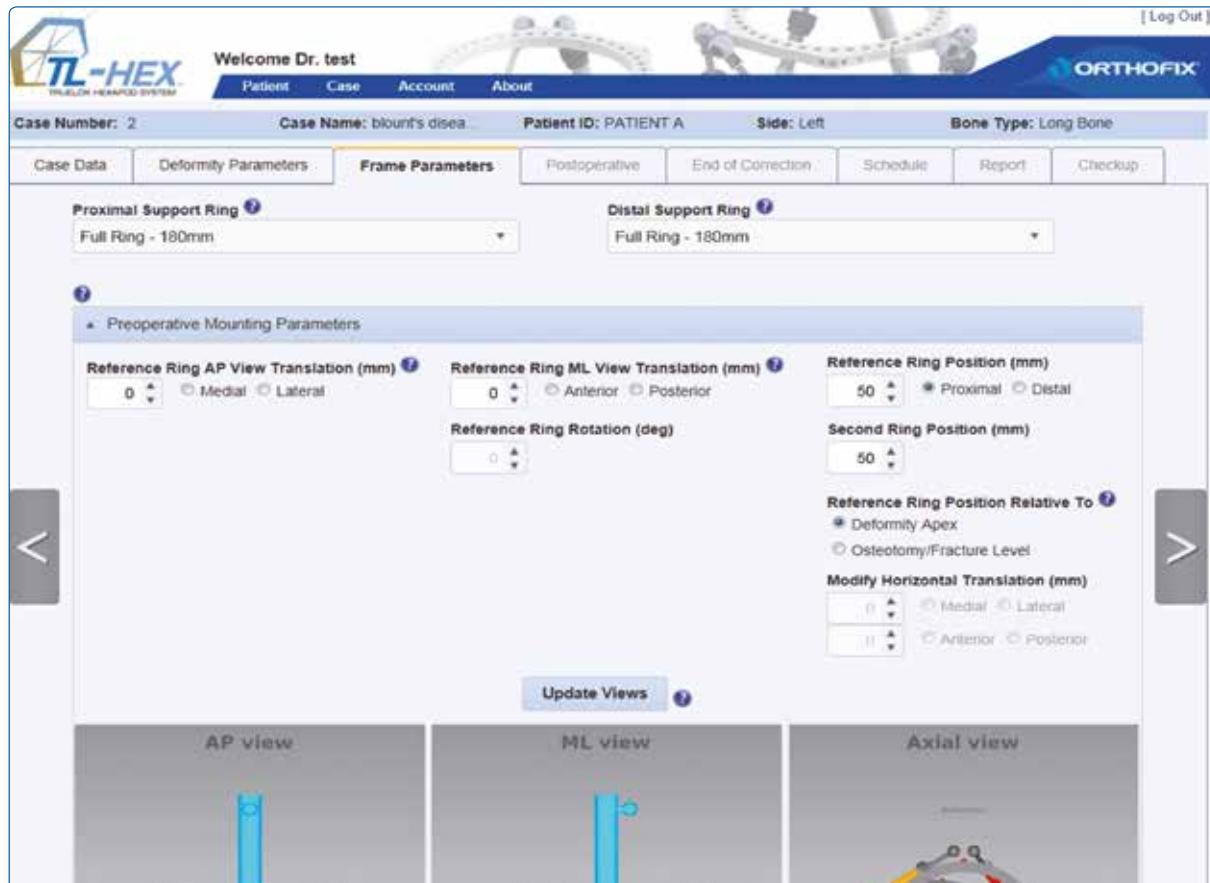


Fig. 32. Preoperative Mounting Parameters section Expanded

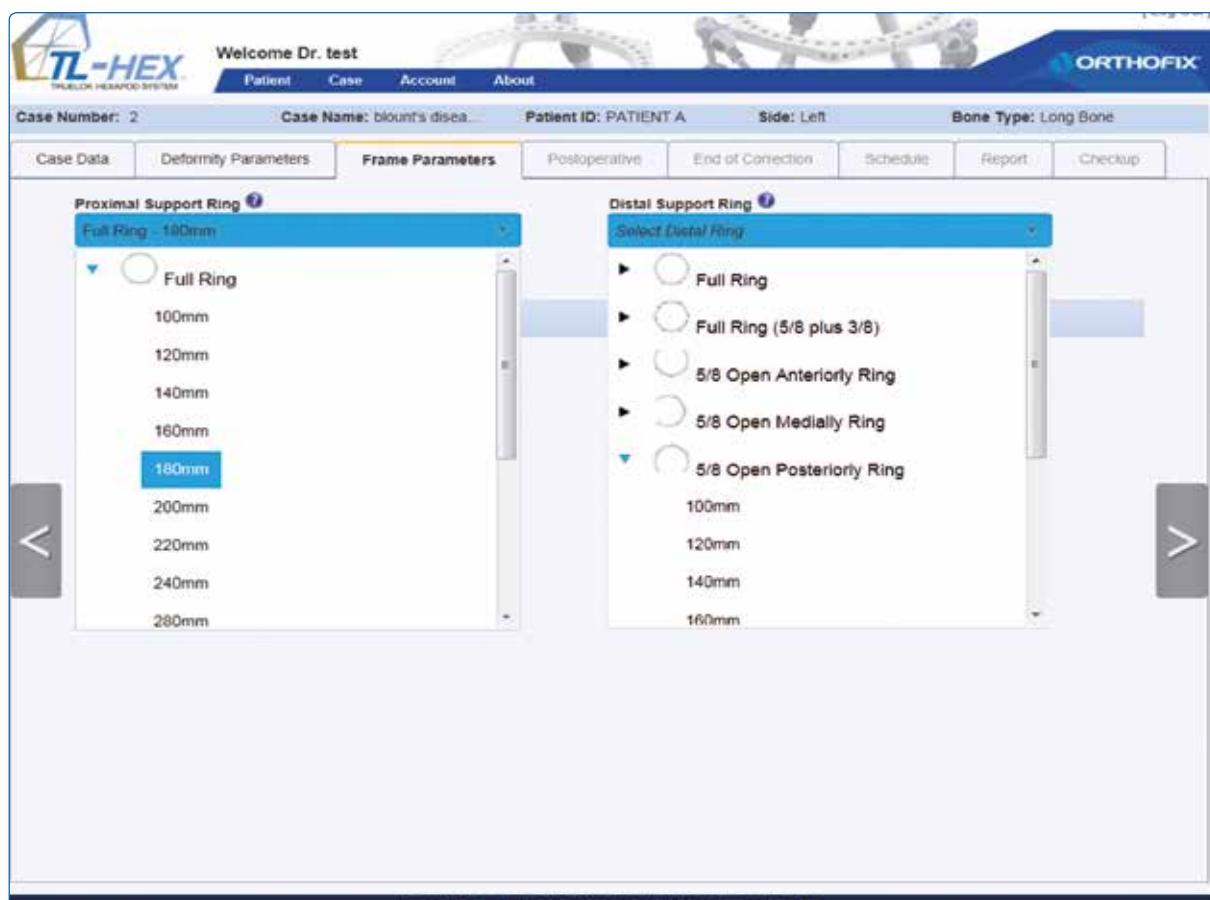


Fig. 33. Frame Parameters screen.

The optional **Preoperative Mounting Parameters** section appears underneath the external support selection drop-down menus (Fi. 32).

The default assumptions at this stage are:

- proximal and distal external supports are perpendicular to the corresponding bone segment axis
- both are located at 50mm distance from the deformity apex or osteotomy/fracture level.

The screen provides the capability to adjust:

- **Reference Ring AP View translation:** the position of the reference ring in the coronal plane. Described in millimeters as the translation medial/lateral of the center of the reference ring in relation to the longitudinal axis of the reference bone segment.
- **Reference Ring ML View translation:** the position of the reference ring in the sagittal plane. Described in millimeters as the translation anterior/posterior of the center of the reference ring in relation to the longitudinal axis of the reference bone segment.
- **Reference Ring Position:** described in millimeter as a distance along the longitudinal axis of the reference bone segment (proximal/distal) from the center of the reference ring to the deformity apex or osteotomy/ fracture level.
- **Second Ring Position:** described in millimeter as a distance along the longitudinal axis of the NON reference bone segment (proximal/distal) from the center of the second ring to the deformity apex or osteotomy/ fracture level.

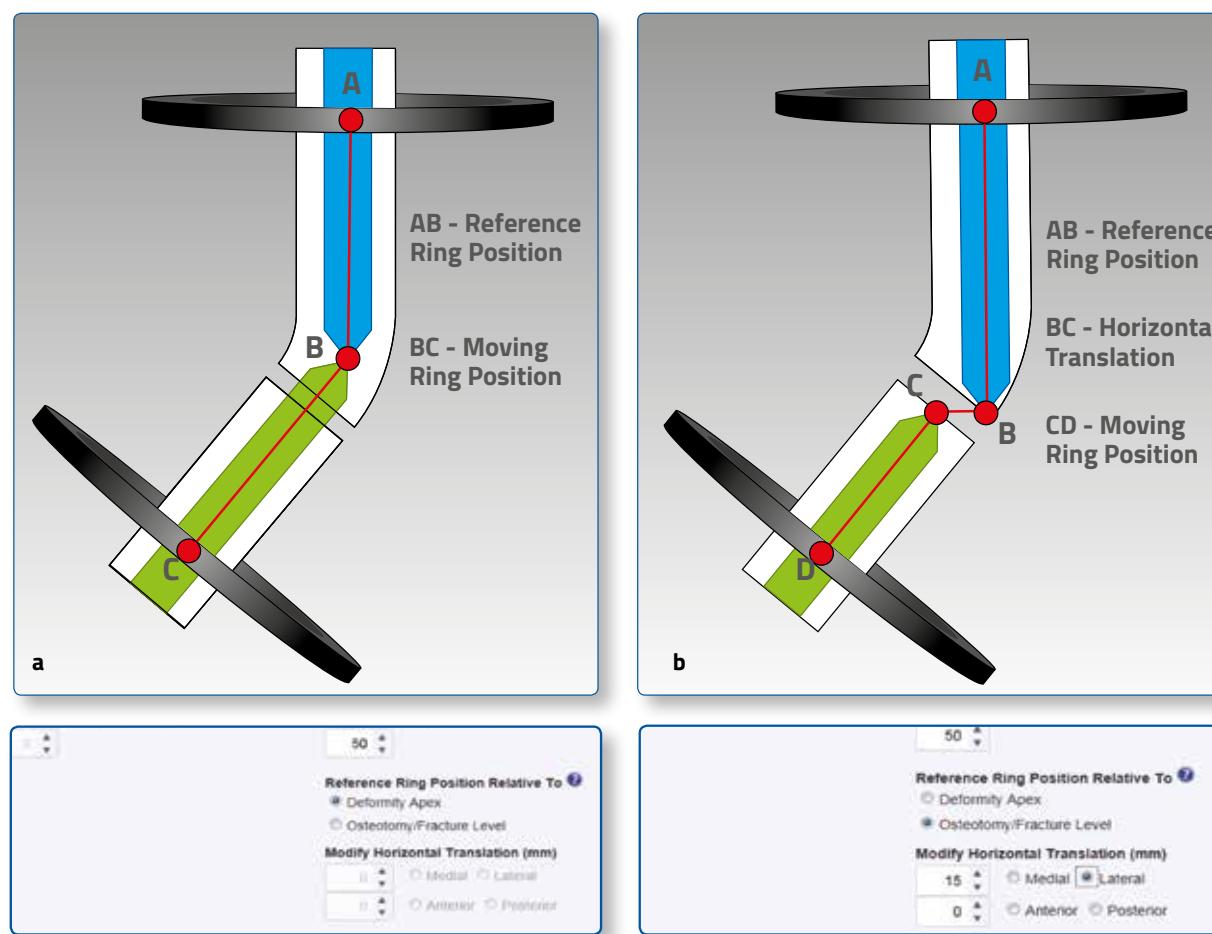


Fig. 34. Description of Reference Ring Box relative to deformity apex (a) or osteotomy/fracture level (b).

Either the apex of the deformity or the level of the osteotomy/fracture can be chosen as point of interest (Fig. 34) If the point of interest is "Osteotomy/Fracture Level" the two fields below are editable and surgeon can enter (in millimeters) the horizontal fragments translation of the osteotomy/fracture (anterior/posterior and medial/lateral).

If "Deformity Apex" is selected the two fields are grayed out.

If the AP or ML translation was entered into the deformity parameters section, the osteotomy/fracture level is automatically chosen as point of interest. The surgeon has the ability to adjust previously entered horizontal segment translation depending on the distance between the point of interest and deformity apex.

Reference Ring Rotation is a not editable parameter in preoperative and it is automatically calculated on the basis of ring selection.

Preoperative Mounting Parameters section allows preassembly of the frame before surgery to mimic the patient's deformity. Clicking the **Update Views** button after entering the mounting parameters will reveal the preassembled frame construct and render an optional set of strut sizes and lengths that will result in the required frame (Fig. 35).



Fig. 35. Updated Frame Parameters screen.

Check the bottom of the screen for struts that are out of range (indicated by a red number). An out of range strut can be addressed by modifying the mounting parameters of the [Frame Parameters](#) screen (remember to Update Views after any change). When satisfied, the surgeon may proceed to [Postoperative](#) screen.

Preoperative Mounting Parameters portion of frame parameters can be skipped if the surgeon doesn't want to pre-build a frame or doesn't have the possibility to do a pre-plan of the surgery; in this case he can proceed directly from choosing the support rings to [Postoperative](#) screen.

Note: Although the surgeon can skip the Pre-Operative Mounting Parameters section, it is suggested that the surgeon completes the Preoperative section. This simplifies the overall data entry and then the application suggests the optimal strut sizes and lengths.

Note: The feasibility of the solutions suggested by the preoperative planning must be verified especially in extreme cases (rings too oblique or overlapping each others) until the generation of a prescription providing all the needed data. In case the frame is not realizable, then the surgeon must change some parameters in preoperative screen (such as the distance between the rings) or contact tlexcustomercare@orthofix.com for support.

Note: If choosing two 5/8 rings, the openings can now be oriented in the same direction (e.g., both open anteriorly, posteriorly, medially). The proposed solution may not be applicable on a patient due to the position of the struts that can pass through the soft tissues.

The surgeon must check the real feasibility of the frame during all the treatment period before applying on the patient. These points can be anyway overcome by adding a 3/8 ring. This component allows in fact to transform a 5/8 ring into a full ring, so, using this technique it's possible to apply two 5/8 rings with the opening on the same side (very useful in trauma cases).

4.4 Postoperative

In the **Postoperative** screen (Fig. 36) no assumptions are made on the positioning of the frame and the parameters are entered in order to reproduce accurately the positioning of the rings and the values of the struts after the surgery.

Similarly to the Preoperative Mounting Parameters section in the Frame Parameters screen, the position of the reference ring relative to the reference bone segment is described in the coronal (medial/lateral), sagittal (anterior/posterior) and axial planes.

Three more parameters relative to reference ring angulation in AP, ML and Axial views are added to Postoperative screen. These parameters reflect angular deviation of the reference ring orientation in the coronal (AP view), sagittal (ML view) and horizontal (axial view) planes from the orthogonal position relative to the reference bone segment.

The position of the second (moving) ring at this stage is not needed since it can be fully retrieved knowing the parameters of the reference ring and the values of the struts.

If proximal referencing was chosen, the ring orientation tab related to the proximal ring will determine the rotational offset. If distal referencing was chosen, the ring orientation tab related to the distal ring will determine the rotational frame offset (Fig. 37).

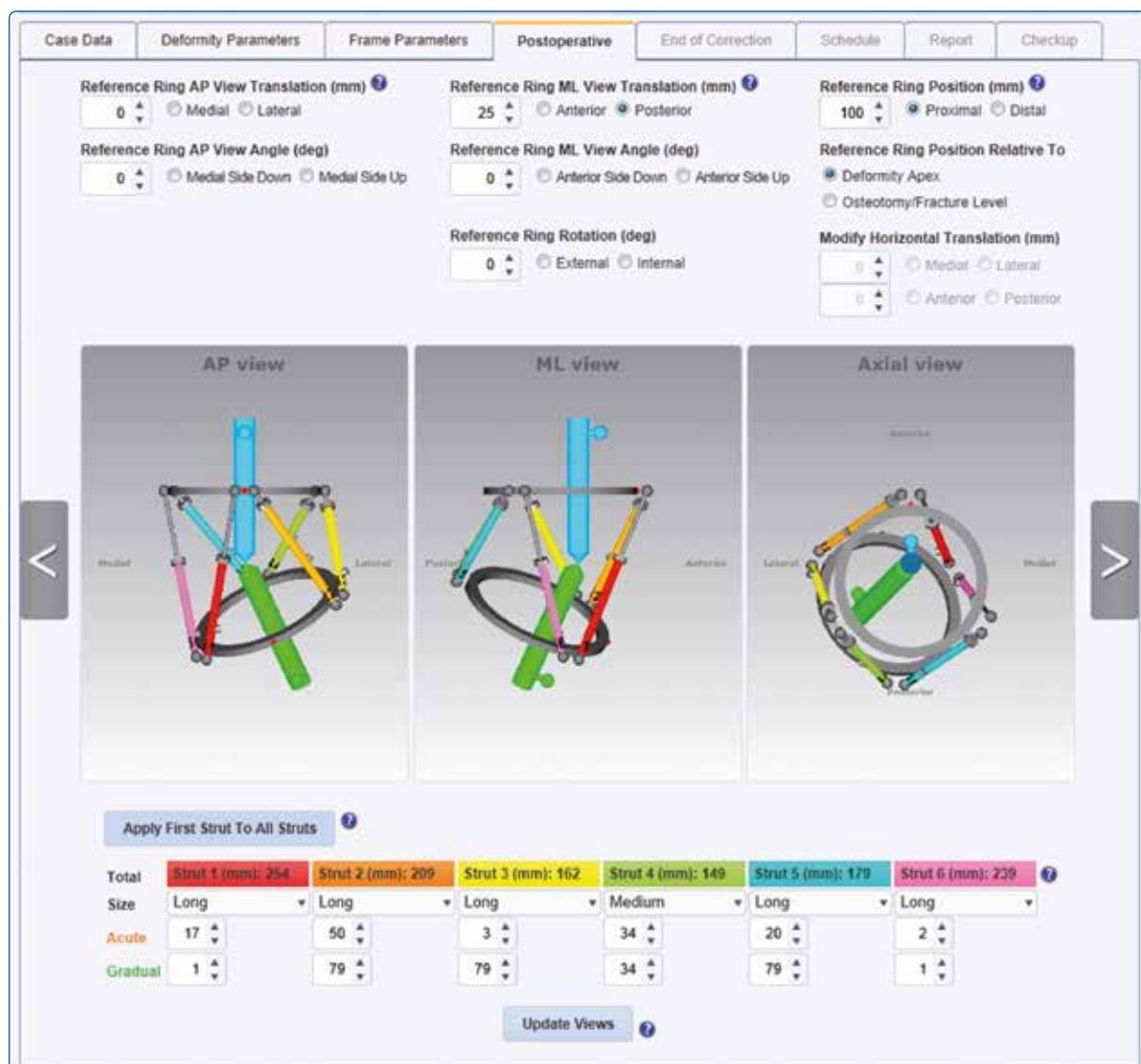


Fig. 36. Postoperative screen.

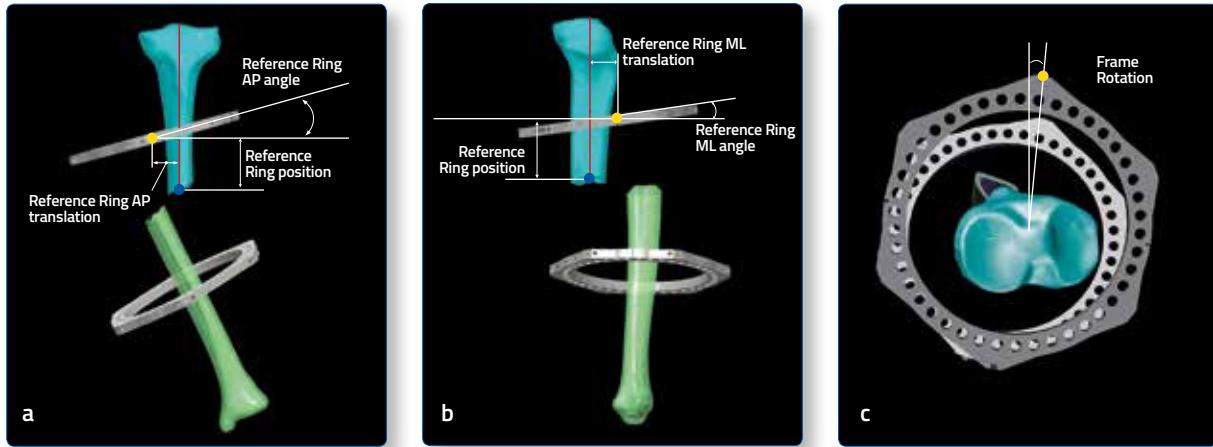
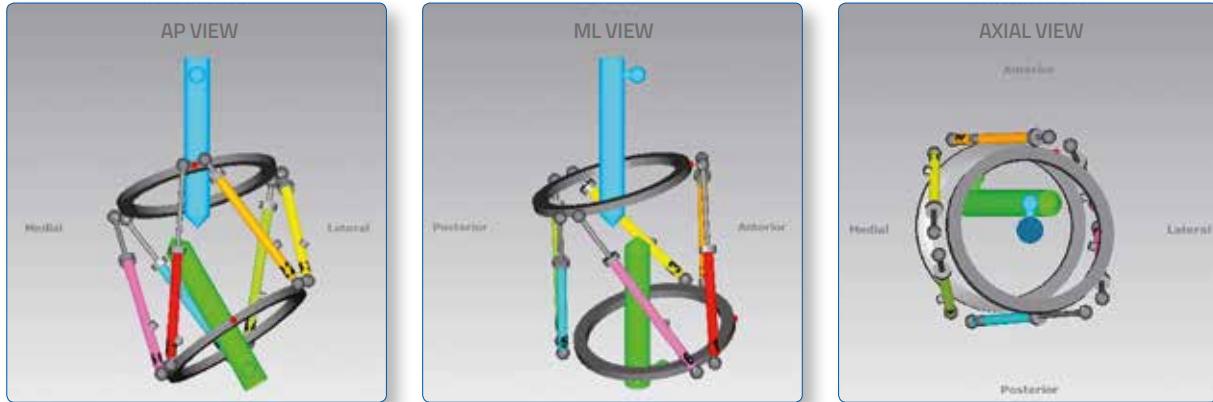


Fig. 37 How to take the measurements of the mounting parameters from the X-Rays. The yellow dot represents the reference



Realistic Software representation with angulation in two planes (AP and ML)

Reference Ring AP View Translation:

the position of the reference ring in the coronal view. Described in millimeters as the translation medial/lateral of the center of the reference ring in relation to the longitudinal axis of the reference bone segment.

Reference Ring AP View Angle:

This is the angle between the reference ring orientation in the coronal view and the reference ring projection orthogonal to the reference bone segment longitudinal axis. Described in degrees with the medial side of the ring either up or down.

Reference Ring ML View Translation:

the position of the reference ring in the sagittal view. Described in millimeters as the translation anterior/posterior of the center of the reference ring in relation to the longitudinal axis of the reference bone segment.

Reference Ring ML View Angle:

This is the angle between the reference ring orientation in the sagittal view and the reference ring projection orthogonal to the reference bone segment longitudinal axis. Described in degrees as an angle between the projection of the ring and the axis of the bone segment with the anterior side of the ring either up or down.

Reference Ring Position:

the position of the reference ring relative to deformity apex or osteotomy/fracture level. Described in millimeter as a distance along the longitudinal axis of the reference bone segment (proximal/distal) from the center of the reference ring to the specific point of interest.

Reference Ring Rotation:

This is the angle between the sagittal plane and the plane passing through the reference ring orientation in the axial view. Described in degrees as external or internal rotation.

At the bottom of the screen (Fig. 38), the strut mounting parameters are entered for all six struts.

Each strut is described by three fields:

- strut size (e.g. ultra short, short, medium, long)
- acute length (in millimeters) relative to the orange mark
- gradual length (in millimeters) relative to the green mark

Clicking on the "Apply First Strut To All Struts" button, the strut size, acute and gradual length selected for the first strut will be applied automatically to all the other struts.

If preoperative planning was performed previously, all data (including frame mounting parameters and strut lengths) is transferred automatically to the corresponding fields of the **Postoperative** screen. The Surgeon should confirm the data or adjust them if necessary. Strut type (ultra short, short, medium and long) as well as both acute and gradual adjustment lengths recorded at the end of the surgery should be confirmed or adjusted in the corresponding fields.

We suggest, in order to collect easily the data, to use the Patient ID form you can download by accessing the reserved area of the TL-HEX site (click on Instruction for Use on the footer of the software and provide your registration email address).

These adjustments will describe not only the final shape and orientation of the frame, but also where it is located in relation to the bone segments. Clicking on the **Update Views** at this point will render software generated diagrammatic models that reflect the bone deformity and frame position on the x-rays. In case of a discrepancy, the surgeon should go back and check all the variables before proceeding to the next step.

If changes are made in the **Postoperative** screen followed by changes to deformity parameters, frame parameters section should be skipped over assuming that the frame is already placed on the patient and the surgeon is just modifying deformity parameters or frame position relative to reference bone segment. The Healthcare Professional will then need to update views on the **Post Op** screen to reflect the deformity modification.

In the software, the strut length entries are validated against the type (size) of struts selected. If the entered value exceeded the range for any given strut, an error is indicated and the strut size/length should be corrected prior to proceeding to the next step (Fig. 38).

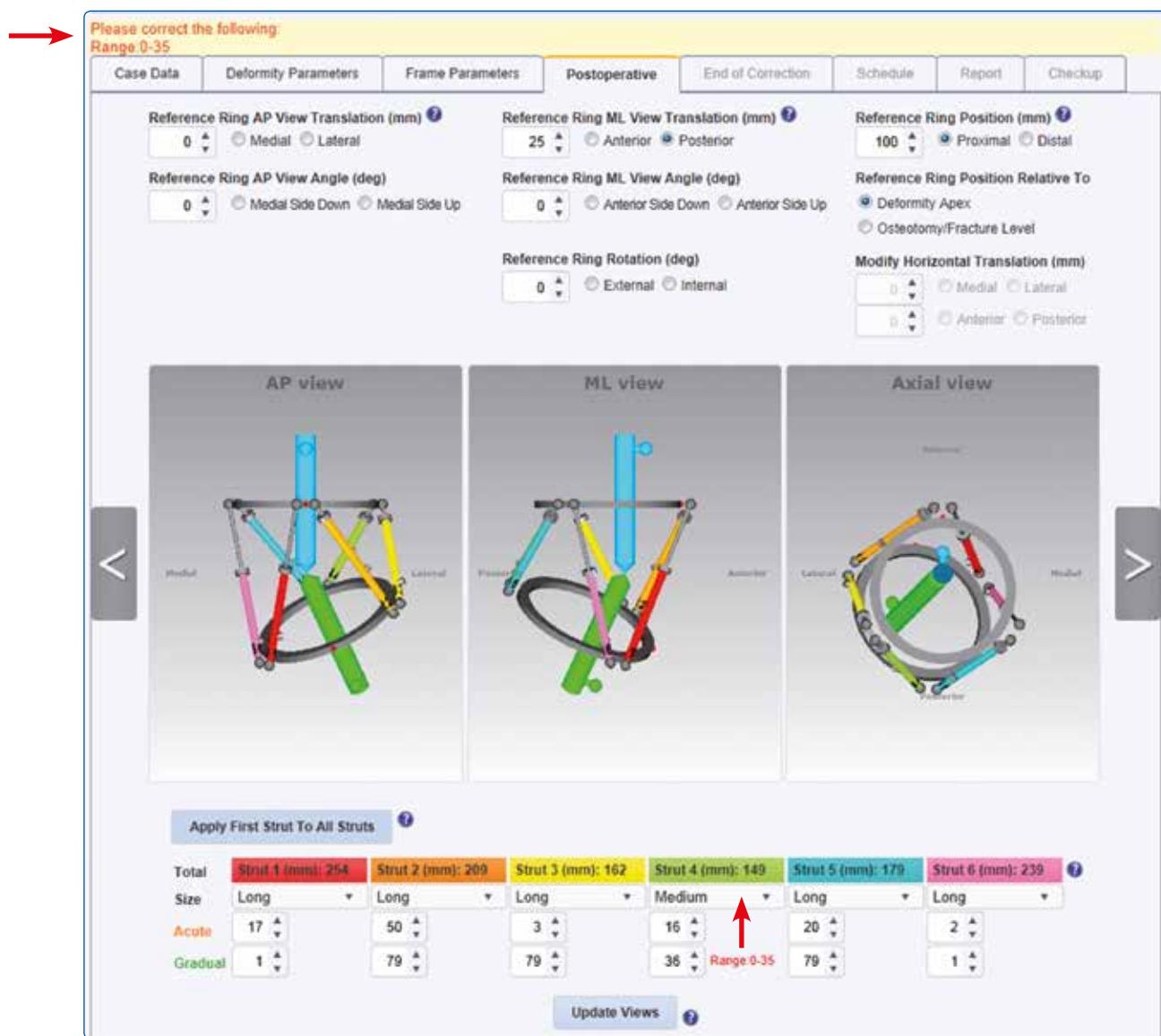


Fig. 38. Updated Postoperative screen, with errors related to incorrect strut lengths.

4.5 End of Correction

The [End of Correction](#) screen (Fig. 39) displays the position of the bone segments and the frame at the end of the treatment (deformity correction). The software assumes that, at the end of deformity correction, the bone segments should be in perfect alignment with no limb length discrepancy (amount of lengthening / shortening will be equal to the amount of limb length discrepancy value entered at the [Deformity Parameters](#) screen).

For foot application, the software assumes that the end of correction should be achieved when the two segments are perpendicular. The screen, however, provides the surgeon the opportunity to override the default position as desired. Additional adjustments include: coronal plane ([AP view](#)) and sagittal plane ([ML view](#)) angulation and translation and horizontal plane ([Axial view](#)) internal/external rotation. The values entered represent the desired bone segment position at the end of deformity correction. This is useful if an overcorrection or undercorrection is desired at the end of deformity correction (e.g., Blount's deformity correction, where a 10-degree overcorrection is desired).



Fig. 39. End of Correction screen.

Click on **Update Views** to check the final struts length.

NOTE: The [Report](#) should be referenced for final strut position (acute and gradual) and strut size.

4.6 Schedule

The **Schedule** screen (Fig. 40) allows the surgeon to enter specific parameters related to bone segment movement during the deformity correction. Those parameters include:

- **Daily Correction Rate in mm/day:** maximum rate of bone segment translation, distraction, compression speed (combination of all the linear speeds)
- **Angular Max Speed in degrees/day:** maximum rate of bone segment angular correction speed (varus-valgus correction)
- **Rotate Max Speed in degree/day:** maximum rate of bone segment rotation correction speed (external-internal rotation)
- **Days of Correction:** desired days of correction

Treatment start date may be adjusted using **Latency Period** (days) and **Correction time** may be selected in the appropriate box. The correction rates and the days of correction are correlated and, therefore, the surgeon can determine the prescription calculation either choosing a speed parameter or choosing the Days of Correction. It is necessary to enter a values in the "Calculate By" box and "Correction Time(s)" box prior to clicking **Calculate**. A warning message will appear if no value was chosen in either of these boxes.

Once the "Calculate by" parameter is determined by the surgeon, the other parameters are automatically calculated by the software. The software is able to come up with a solution using also decimals.

NOTE: Surgeon has to carefully review the calculation to ensure it is accurate.

The Correction Times table provides the flexibility to have the prescription calculated for one or more adjustments during each treatment day (up to 4 different correction times per day can be selected).

Apply lengthening/shortening first

Clicking the checkbox "**Apply lengthening/shortening first**", will allow the deformity correction to be performed in two stages: in the first stage only axial shortening or lengthening will be implemented, and then in the second stage the remaining deformity will be corrected. This will generate two reports.

Fig. 40. Schedule screen.

If continuing to the **Report** screen with struts that will potentially move out of range, then once the 'next' arrow at the right hand side is clicked, the surgeon will be advised via a pop-up window that struts are out of range.

4.7 Report

The **Report** screen displays the adjustment schedule for the patient resulting from the previously entered parameters plus acute and gradual adjustment values in millimeters for each strut (fig. 41). These values should be checked by the surgeon, especially in extreme cases.

The screenshot shows the 'Report' tab selected in the top navigation bar. The main area displays a table titled 'Strut Length A/Acute / G/Gradual' with 41 rows of data. The columns represent different struts (Strut 1 to Strut 6) and their corresponding length parameters (A, G, and various adjustment values like 'med', '2', '1', etc.). The table includes columns for 'Actions' (Delete, Adjust, Check), 'Print' (button), and 'Checkup' (button). The top of the table has a red highlight over the 'Strut 5: Purple' row.

No.	Day	Date-Time	Strut 1: Red			Strut 2: Orange			Strut 3: Yellow			Strut 4: Green			Strut 5: Blue			Strut 6: Purple			Actions		
			No.	A	G	No.	A	G	No.	A	G	No.	A	G	No.	A	G	No.	A	G			
0	sat	04/10/2014 09:00	long	17	1	long	50	70	long	3	79	med	34	34	long	29	79	long	2	1	Delete	Adjust	Check
1	sat	04/10/2014 09:00	long	17	1	long	50	72	long	3	78	med	34	32	long	29	78	long	2	1	Delete	Adjust	Check
2	sat	04/10/2014 29:00	long	17	2	long	50	70	long	3	76	med	34	34	long	29	76	long	2	1	Delete	Adjust	Check
3	sun	05/10/2014 09:00	long	17	2	long	50	77	long	3	74	med	34	28	long	29	76	long	2	1	Delete	Adjust	Check
4	mon	05/10/2014 29:00	long	17	2	long	50	76	long	3	72	med	34	26	long	29	74	long	2	1	Delete	Adjust	Check
5	sun	06/10/2014 09:00	long	17	2	long	50	75	long	3	78	med	34	24	long	29	72	long	2	1	Delete	Adjust	Check
6	sun	06/10/2014 29:00	long	17	3	long	50	75	long	3	68	med	34	22	long	29	72	long	2	0	Delete	Adjust	Check
7	mon	07/10/2014 09:00	long	17	4	long	50	74	long	3	67	med	34	20	long	29	70	long	2	0	Delete	Adjust	Check
8	mon	07/10/2014 29:00	long	17	4	long	50	74	long	3	63	med	34	18	long	29	68	long	2	0	Delete	Adjust	Check
9	mon	08/10/2014 09:00	long	17	4	long	50	74	long	3	63	med	34	16	long	29	67	long	2	1	Delete	Adjust	Check
10	mon	08/10/2014 29:00	long	17	5	long	50	72	long	3	62	med	34	14	long	29	66	long	2	1	Delete	Adjust	Check
11	sun	09/10/2014 09:00	long	17	5	long	50	72	long	3	60	med	34	12	long	29	64	long	2	1	Delete	Adjust	Check
12	sun	09/10/2014 29:00	long	17	6	long	50	72	long	3	58	med	34	10	long	29	63	long	2	1	Delete	Adjust	Check
13	mon	10/10/2014 09:00	long	17	6	long	50	71	long	3	56	med	34	8	long	29	62	long	2	1	Delete	Adjust	Check
14	mon	10/10/2014 29:00	long	17	6	long	50	70	long	3	54	med	34	6	long	29	60	long	2	1	Delete	Adjust	Check
15	sat	11/10/2014 09:00	long	17	7	long	50	70	long	3	52	med	34	4	long	29	58	long	2	1	Delete	Adjust	Check
16	sat	11/10/2014 29:00	long	17	8	long	50	69	long	3	50	med	34	2	long	29	56	long	2	2	Delete	Adjust	Check
17	sun	12/10/2014 09:00	long	17	8	long	50	68	long	3	48	long	24	19	long	29	56	long	2	2	Delete	Adjust	Check
18	sun	12/10/2014 29:00	long	17	8	long	50	68	long	3	47	long	24	17	long	29	56	long	2	2	Delete	Adjust	Check
19	sun	13/10/2014 09:00	long	17	9	long	50	68	long	3	45	long	24	15	long	29	54	long	2	4	Delete	Adjust	Check
20	sat	13/10/2014 29:00	long	17	9	long	50	67	long	3	43	long	24	13	long	29	53	long	2	2	Delete	Adjust	Check
21	mon	14/10/2014 09:00	long	17	10	long	50	66	long	3	42	long	24	11	long	29	52	long	2	2	Delete	Adjust	Check
22	mon	14/10/2014 29:00	long	17	11	long	50	66	long	3	40	long	24	9	long	29	50	long	2	2	Delete	Adjust	Check
23	mon	15/10/2014 09:00	long	17	12	long	50	65	long	3	38	long	24	7	long	29	49	long	2	2	Delete	Adjust	Check
24	mon	15/10/2014 29:00	long	17	12	long	50	64	long	3	36	long	24	5	long	29	48	long	2	2	Delete	Adjust	Check
25	sun	16/10/2014 09:00	long	17	12	long	50	64	long	3	34	long	24	3	long	29	46	long	2	3	Delete	Adjust	Check
26	sun	16/10/2014 29:00	long	17	13	long	50	64	long	3	32	long	24	1	long	29	45	long	2	3	Delete	Adjust	Check
27	mon	17/10/2014 09:00	long	17	14	long	50	63	long	3	31	long	24	54	long	29	44	long	2	4	Delete	Adjust	Check
28	mon	17/10/2014 29:00	long	17	14	long	50	62	long	3	29	long	24	54	long	29	42	long	2	4	Delete	Adjust	Check
29	sun	18/10/2014 09:00	long	17	15	long	50	62	long	3	28	long	24	54	long	29	42	long	2	4	Delete	Adjust	Check
30	sun	18/10/2014 29:00	long	17	16	long	50	61	long	3	26	long	24	52	long	29	40	long	2	4	Delete	Adjust	Check
31	mon	19/10/2014 09:00	long	17	16	long	50	61	long	3	24	long	24	50	long	29	38	long	2	4	Delete	Adjust	Check
32	mon	19/10/2014 29:00	long	17	17	long	50	61	long	3	22	long	24	48	long	29	38	long	2	4	Delete	Adjust	Check
33	sun	20/10/2014 09:00	long	17	18	long	50	60	long	3	20	long	24	48	long	29	36	long	2	5	Delete	Adjust	Check
34	mon	20/10/2014 29:00	long	17	18	long	50	60	long	3	19	long	24	44	long	29	36	long	2	6	Delete	Adjust	Check
35	mon	21/10/2014 09:00	long	17	19	long	50	60	long	3	17	long	24	42	long	29	34	long	2	6	Delete	Adjust	Check
36	mon	21/10/2014 29:00	long	17	20	long	50	59	long	3	16	long	24	39	long	29	33	long	2	6	Delete	Adjust	Check
37	mon	22/10/2014 09:00	long	17	20	long	50	59	long	3	14	long	24	37	long	29	32	long	2	6	Delete	Adjust	Check
38	mon	22/10/2014 29:00	long	17	22	long	50	58	long	3	12	long	24	36	long	29	30	long	2	7	Delete	Adjust	Check
39	mon	23/10/2014 09:00	long	17	22	long	50	58	long	3	10	long	24	33	long	29	28	long	2	8	Delete	Adjust	Check
40	mon	23/10/2014 29:00	long	17	23	long	50	58	long	3	9	long	24	31	long	29	28	long	2	8	Delete	Adjust	Check
41	mon	24/10/2014 09:00	long	17	23	long	50	58	long	3	8	long	24	31	long	29	28	long	2	8	Delete	Adjust	Check

Fig. 41. Report screen view before starting adjustments.

The “Select Print Option” drop down allows to choose which pdf file to print: Prescription, Report and BOM.

NOTE: If the option "Apply lengthening/shortening first" has been selected on the previous screen (schedule) the report will appear divided into two tables. The first one is for the lengthening/shortening stage, the second one is for the remaining deformity correction.

The prescription, instead, will remain a unique table and pdf.

The "Prescription" pdf file displays the adjustment schedule for the patient, each row describes the strut adjustment to be made by the patient for each deformity correction step as specified in the schedule (Fig. 42, Fig. 43 and Fig. 44). This document must then be printed and the hard copy must be issued to the patient and can also be saved for the record. The print-out should be checked for correctness and readability and the patient should be instructed to contact the surgeon in case the prescription becomes lost or damaged.

NOTE: All information must be reviewed by the surgeon before completing and printing the prescription to ensure that it is accurate.

Fig. 42. Prescription PDF file describing the struts adjustment to be made by the patient - page 1

Dr. test test	Print Date: lunedì 29 settembre 2014	Page 2												
Hospital Name	Case Number: 2													
Hospital Street	Case Name: blount's disease													
Dallas Texas US 23443	Patient ID: PATIENT A													
123456789	Side: Left													
0346789000	Bone Type: Long Bone													
Strut Adjustment in 'CLICKS' (a)														
No	Day	Date-Time	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE
11	gio	09/10/2014 08:00	1	2	3	4	5	6	1	2	3	4	5	6
12	gio	09/10/2014 20:00	0	+1	+4	+4	+3	0	5	72	60	12	64	1
13	ven	10/10/2014 08:00	-1	+1	+3	+4	+3	0	6	72	58	10	63	1
14	ven	10/10/2014 20:00	-1	+2	+4	+5	+3	0	6	71	56	8	62	1
15	sab	11/10/2014 08:00	-1	+1	+4	+4	+2	0	7	70	52	4	60	1
16	sab	11/10/2014 20:00	-1	+1	+3	+4	+3	0	8	69	50	2	58	1
17	dom	12/10/2014 08:00	-1	+1	+4	0	+3	-1	8	68	48	79	56	2
18	dome	12/10/2014 20:00	-1	+1	+3	+4	+2	0	8	68	47	77	56	2
19	lun	13/10/2014 08:00	-1	+1	+4	+4	+3	0	9	68	45	75	54	2
20	lun	13/10/2014 20:00	-1	+1	+4	+5	+2	-1	10	67	43	73	53	2
21	mar	14/10/2014 08:00	-2	+1	+3	+4	+3	0	10	66	42	71	52	2
22	mar	14/10/2014 20:00	-1	+2	+4	+4	+3	0	11	66	40	69	50	2
23	mer	15/10/2014 08:00	-1	+1	+3	+4	+2	-1	12	65	38	67	49	2
24	mer	15/10/2014 20:00	-1	+1	+4	+4	+3	0	12	64	36	65	48	2
25	gio	16/10/2014 08:00	-1	+1	+3	+5	+2	-1	12	64	34	62	46	3
26	gio	16/10/2014 20:00	-1	+1	+4	+4	+3	0	13	64	32	60	45	3

Fig. 43. Prescription PDF file describing the struts adjustment to be made by the patient - page 2

Dr. test test	Print Date: lunedì 29 settembre 2014	Page 3												
Hospital Name	Case Number: 2													
Hospital Street	Case Name: blount's disease													
Dallas Texas US 23443	Patient ID: PATIENT A													
123456789	Side: Left													
0346789000	Bone Type: Long Bone													
Strut Adjustment in 'CLICKS' (a)														
No	Day	Date-Time	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE
27	ven	17/10/2014 08:00	1	2	3	4	5	6	1	2	3	4	5	6
28	ven	17/10/2014 20:00	-2	+1	+3	+4	+2	-1	14	63	31	58	44	4
29	sab	18/10/2014 08:00	-1	+1	+3	+4	+2	-1	14	62	29	56	42	4
30	sab	18/10/2014 20:00	-1	+1	+4	+5	+3	0	15	62	28	54	42	4
31	dom	19/10/2014 08:00	-2	+1	+3	+4	+2	-1	16	62	26	52	40	4
32	dom	19/10/2014 20:00	-1	0	+4	+4	+2	0	16	61	24	50	39	4
33	lun	20/10/2014 08:00	-2	+1	+3	+4	+3	-1	17	61	22	48	38	4
34	lun	20/10/2014 20:00	-1	+1	+3	+4	+2	-1	18	60	20	46	36	5
35	mar	21/10/2014 08:00	-1	+1	+4	+4	+3	0	18	60	19	44	36	6
36	mar	21/10/2014 20:00	-2	+1	+3	+5	+2	-1	19	60	17	42	34	6
37	mer	22/10/2014 08:00	-1	+1	+3	+4	+2	-1	20	59	16	39	33	6
38	mer	22/10/2014 20:00	-2	+1	+4	+4	+3	-1	20	58	14	37	32	6
39	gio	23/10/2014 08:00	-1	0	+3	+4	+2	-1	22	58	12	35	30	7
40	gio	23/10/2014 20:00	-2	+1	+3	+4	+2	0	23	58	9	31	28	8
41	ven	24/10/2014 08:00	0	0	+1	+1	+1	-1	23	58	8	31	28	8

Fig. 44. Prescription PDF file describing the struts adjustment to be made by the patient - page 3

Adjustment for each strut is represented by number of clicks (1/2 rotation of the strut adjustment knob that is 1/2 mm) and can be positive (if strut length increases) or negative (when the strut length decreases). In addition, in the report file, the gradual adjustment scale value in millimeters is displayed as a reference for each strut.

The direction clips are then applied to the rod end joints according to the prescription. If strut elongation is required (positive numbers in the prescription), the arrow on the clip should point in the same direction as the reference arrow on the adjustment knob (Fig. 45 a). If strut shortening is required (negative numbers in the prescription), the clip should be applied with the arrow pointing in the opposite direction of the arrow on the adjustment knob (Fig. 45 b).

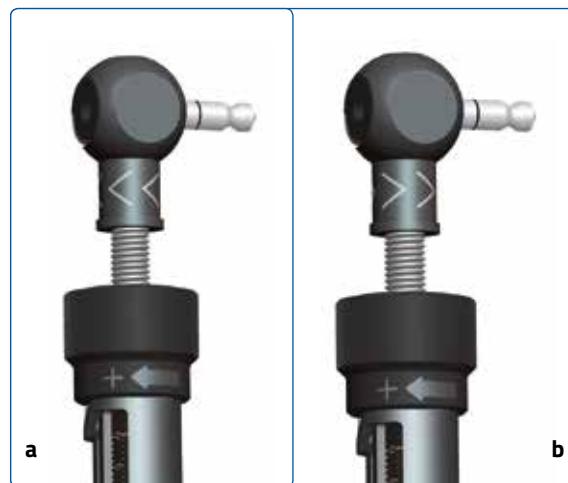


Fig. 45. Orientation of direction clips for strut elongation

Strut Adjustments direction change

In most of the cases, the orientation of direction clips remains the same throughout the treatment. In some cases with a rotational deformity correction, the direction of strut adjustments in the prescription may change from positive to negative or from negative to positive. In this situation, the surgeon should instruct the patient about the day the change of direction occurs and either schedule a clinic visit for the orientation change of the direction clip or instruct the patient on how to make this orientation change to the direction clip.

In addition, the direction of strut adjustment may change from positive to negative in cases of extreme elongation of the long strut (acute adjustment indicates 80 mm and gradual adjustment indicates 0 mm left on the strut scale) even though additional strut elongation is still required. This situation may occur when external supports are placed too far from each other and maximal elongation of the longest available strut is not enough to achieve the desired amount. The surgeon should review the acute/gradual indication numbers in the [Report](#) screen either preoperatively to adjust the ring separation distance or postoperatively to schedule frame modifications on time.

Strut readjustment/exchange

The prescription row will be highlighted when strut readjustment (shaded **blue**) or exchange (shaded **red**) are required (Fig. 42, Fig. 43 and Fig. 44). The rows of lighter shading indicate the allowable range of days that are suitable for the re-adjustment/exchange; the heavier shaded row indicates the last possible day for the strut change.

If the strut re-adjustment/exchange occurs on the last day (marked by the solid color blue/red box), the existent prescription can be used. If the strut readjustment/exchange occurs prior to the last day, a new prescription must be generated from that date. The [Checkup](#) screen can be used to create a new case.

The Acute and Gradual values of the new strut, if the exchange /adjustment occurs prior to the last day of possible re-adjustment/exchange, can be found using the conversion tables available online clicking on "Instructions for Use" link on the footer of the www.tlhex.com site.

If strut exchange is required shortly after the beginning of correction and correction has not yet started, the surgeon should return to the [Postoperative](#) screen and move through the End of Correction to re-generate a prescription.

NOTE: Please review all information before completing and printing the prescription to ensure that it is accurate.

The Prescription Preferences previously entered and associated to a patient will be printed in the upper left corner of this file (see section 6.2 "Prescription Preferences" for details). Prescription file has been optimized for black and white printing. In order to distinguish between blue and red shaded rows, a black contour has been added to the red cells. This document must then be printed and the hard copy must be issued to the patient and can also be saved for the record. The print-out should be checked for correctness and readability and the patient should be instructed to contact the surgeon in case the prescription becomes lost or damaged.

The "Print BOM" button produces a "Bill Of Material" file listing the materials that only cover the TL-HEX components needed for the treatment. This includes rings, foot plates and struts (Fig. 46).

Case Number: 2	Case Name: blount's disease	Patient ID: PATIENT A	Side: Left	Bone Type: Long Bone	Bill of Material Print Date: lunedì 29 settembre 2014	Page 1
Initial Construct						
Item	Description			Quantity	Item Number	
Strut	Long			5	60-10400	
Strut	Medium			1	50-10300	
Distal Ring	Full Ring 180mm			1	56-20040	
Proximal Ring	Full Ring 180mm			1	56-20040	

Fig. 46. Bill of Material PDF

The "Print Report" button generates a pdf file of the report screen and it is intended for the doctor to print and maintain a hard copy as a permanent record for the patient's file. Similar to prescription pdf file, the report row will be highlighted when strut readjustments (shaded **blue**) or exchanges (shaded **red**) are required. The rows of lighter shading indicate the allowable range of days that are suitable for the readjustment/exchange; the heavier shaded row indicates the last possible day for the readjustment/exchange.(Fig. 47 and Fig. 48).

Also Report file, as the prescription pdf file, has been optimized for black and white printing.

Case Number: 2	Case Name: blount's disease	Patient ID: PATIENT A	Side: Left	Bone Type: Long Bone	Print Date: lunedì 29 settembre 2014	Page 1		
No	Day	Date-Time	1: A G	2: A G	3: A G	4: A G	5: A G	6: A G
0	sab	04/10/2014 00:00	long 17 1	long 50 79	long 3 79	med 34 34	long 20 79	long 2 1
1	sab	04/10/2014 08:00	long 17 1	long 50 78	long 3 78	med 34 32	long 20 78	long 2 1
2	sab	04/10/2014 20:00	long 17 2	long 50 78	long 3 76	med 34 30	long 20 76	long 2 1
3	dom	05/10/2014 08:00	long 17 2	long 50 77	long 3 74	med 34 28	long 20 76	long 2 1
4	dom	05/10/2014 20:00	long 17 2	long 50 76	long 3 72	med 34 26	long 20 74	long 2 1
5	lun	06/10/2014 08:00	long 17 2	long 50 76	long 3 70	med 34 24	long 20 72	long 2 1
6	lun	06/10/2014 20:00	long 17 3	long 50 75	long 3 68	med 34 22	long 20 72	long 2 0
7	mar	07/10/2014 08:00	long 17 4	long 50 74	long 3 67	med 34 20	long 20 70	long 2 0
8	mar	07/10/2014 20:00	long 17 4	long 50 74	long 3 65	med 34 18	long 20 68	long 2 0
9	mer	08/10/2014 08:00	long 17 4	long 50 74	long 3 63	med 34 16	long 20 67	long 2 1
10	mer	08/10/2014 20:00	long 17 5	long 50 72	long 3 62	med 34 14	long 20 66	long 2 1
11	gio	09/10/2014 08:00	long 17 5	long 50 72	long 3 60	med 34 12	long 20 64	long 2 1
12	gio	09/10/2014 20:00	long 17 6	long 50 72	long 3 58	med 34 10	long 20 63	long 2 1
13	ven	10/10/2014 08:00	long 17 6	long 50 71	long 3 56	med 34 8	long 20 62	long 2 1
14	ven	10/10/2014 20:00	long 17 6	long 50 70	long 3 54	med 34 6	long 20 60	long 2 1
15	sab	11/10/2014 08:00	long 17 7	long 50 70	long 3 52	med 34 4	long 20 60	long 2 1
16	sab	11/10/2014 20:00	long 17 8	long 50 69	long 3 50	med 34 2	long 20 58	long 2 1
17	dom	12/10/2014 08:00	long 17 8	long 50 68	long 3 48	long 24 79	long 20 56	long 2 2
18	dom	12/10/2014 20:00	long 17 8	long 50 68	long 3 47	long 24 77	long 20 56	long 2 2
19	lun	13/10/2014 08:00	long 17 9	long 50 68	long 3 45	long 24 75	long 20 54	long 2 2
20	lun	13/10/2014 20:00	long 17 10	long 50 67	long 3 43	long 24 73	long 20 53	long 2 2

Fig. 47. Report PDF file describing the acute and gradual adjustments to be made during the treatment - page 1

Print Date: lunedì 29 settembre 2014												Page 2								
No	Day	Date-Time	1:	A	G	2:	A	G	3:	A	G	4:	A	G	5:	A	G	6:	A	G
21	mer	14/10/2014 08:00	long	17	10	long	50	66	long	3	42	long	24	71	long	20	52	long	2	2
22	mer	14/10/2014 20:00	long	17	11	long	50	66	long	3	40	long	24	69	long	20	50	long	2	2
23	mer	15/10/2014 08:00	long	17	12	long	50	65	long	3	38	long	24	67	long	20	49	long	2	2
24	mer	15/10/2014 20:00	long	17	12	long	50	64	long	3	36	long	24	65	long	20	48	long	2	2
25	gio	16/10/2014 08:00	long	17	12	long	50	64	long	3	34	long	24	62	long	20	46	long	2	3
26	gio	16/10/2014 20:00	long	17	13	long	50	64	long	3	32	long	24	60	long	20	45	long	2	3
27	ven	17/10/2014 08:00	long	17	14	long	50	63	long	3	31	long	24	58	long	20	44	long	2	4
28	ven	17/10/2014 20:00	long	17	14	long	50	62	long	3	29	long	24	56	long	20	42	long	2	4
29	sab	18/10/2014 08:00	long	17	15	long	50	62	long	3	28	long	24	54	long	20	42	long	2	4
30	sab	18/10/2014 20:00	long	17	16	long	50	62	long	3	26	long	24	52	long	20	40	long	2	4
31	dom	19/10/2014 08:00	long	17	16	long	50	61	long	3	24	long	24	50	long	20	39	long	2	4
32	dom	19/10/2014 20:00	long	17	17	long	50	61	long	3	22	long	24	48	long	20	38	long	2	4
33	lun	20/10/2014 08:00	long	17	18	long	50	60	long	3	20	long	24	46	long	20	36	long	2	5
34	lun	20/10/2014 20:00	long	17	18	long	50	60	long	3	19	long	24	44	long	20	36	long	2	6
35	mer	21/10/2014 08:00	long	17	19	long	50	60	long	3	17	long	24	42	long	20	34	long	2	6
36	mer	21/10/2014 20:00	long	17	20	long	50	59	long	3	16	long	24	39	long	20	33	long	2	6
37	mer	22/10/2014 08:00	long	17	20	long	50	58	long	3	14	long	24	37	long	20	32	long	2	6
38	mer	22/10/2014 20:00	long	17	22	long	50	58	long	3	12	long	24	35	long	20	30	long	2	7
39	gio	23/10/2014 08:00	long	17	22	long	50	58	long	3	10	long	24	33	long	20	30	long	2	8
40	gio	23/10/2014 20:00	long	17	23	long	50	58	long	3	9	long	24	31	long	20	28	long	2	8
41	ven	24/10/2014 08:00	long	17	23	long	50	58	long	3	8	long	24	31	long	20	28	long	2	8

Fig. 48. Report PDF file describing the acute and gradual adjustments to be made during the treatment - page 2

The "Actions" column allows, for each row, three different actions: "Details", "Adjust" and "Checkup".

By clicking on the "Details" link for any day in the report table, the system will generate a pop up window with a view of the bone segments and frame orientation of that particular day as well as the corresponding struts length with Acute/Gradual values (Fig. 51 and Fig. 52).

By clicking on the "Adjust" link, the system will show a pop up window (Fig. 49) with the length, size and acute/gradual values of each strut for that time of day. Clicking the "Propose strut" button, allows the software to suggest the optimized acute and gradual values for the selected strut. The proposed solution takes the current Strut Direction into consideration to calculate the Strut Proposal. In the event the Selected Strut is changing directions the HCP may want to adjust the Acute Length and Gradual Length Values to eliminate any Acute Changes introduced in the newly adjusted report.

The surgeon can also input directly the acute and gradual values for a strut given its current length. This functionality allows the HCP to print the new prescription with the changed values without passing through checkup.

NOTE: Once the struts are adjusted at the report screen, the case is no longer modifiable, but the HCP can still view the previously entered parameters, in read-only mode, using the "View" button.

The HCP can reset the changes made so far on the report using the "Reset" button. All the adjustments will be lost and the report will go back to the initial one.

Strut Length A-Acute / G-Gradual									
No	Day	Date-Time	Strut 1: Red	Strut 2: Orange	Strut 3: Yellow	Strut 4: Green	Strut 5: Blue	Strut 6: Purple	Actions
			Total: Strut 1 (mm): 248	Strut 2 (mm): 219	Strut 3 (mm): 190	Strut 4 (mm): 181	Strut 5 (mm): 200	Strut 6 (mm): 239	
			Size: Long	Long	Long	Medium	Long	Long	
			Acute: 17	50	3	34	20	2	
			Gradual: 8	69	50	2	58	1	
			<button>Propose Strut 1</button>	<button>Propose Strut 2</button>	<button>Propose Strut 3</button>	<button>Propose Strut 4</button>	<button>Propose Strut 5</button>	<button>Propose Strut 6</button>	
									<button>Apply Changes</button> <button>Cancel Changes</button>

Fig. 49. Adjusting report window

Case Number: 2 Case Name: Blount's disease... Patient ID: PATIENT A Side: Left Bone Type: Long Bone			Adjusted Report																																																																																																																																																																																																																																																																																																																																																																																																																																									
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<table border="1"> <thead> <tr> <th rowspan="2">No</th> <th rowspan="2">Day</th> <th rowspan="2">Date-Time</th> <th colspan="3">Strut 1: Red</th> <th colspan="3">Strut 2: Orange</th> <th colspan="3">Strut 3: Yellow</th> <th colspan="3">Strut 4: Green</th> <th colspan="3">Strut 5: Blue</th> <th colspan="3">Strut 6: Purple</th> <th rowspan="2">Actions</th> </tr> <tr> <th>Size</th> <th>A</th> <th>G</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>sab</td> <td>04/10/2014 00:00</td> <td>long</td> <td>17</td> <td>1</td> <td>long</td> <td>50</td> <td>79</td> <td>long</td> <td>3</td> <td>79</td> <td>med</td> <td>34</td> <td>34</td> <td>long</td> <td>20</td> <td>79</td> <td>long</td> <td>2</td> <td>1</td> <td>Details Adjust Checkup</td> </tr> <tr> <td>1</td> <td>sab</td> <td>04/10/2014 08:00</td> <td>long</td> <td>17</td> <td>1</td> <td>long</td> <td>50</td> <td>78</td> <td>long</td> <td>3</td> <td>78</td> <td>med</td> <td>34</td> <td>32</td> <td>long</td> <td>20</td> <td>78</td> <td>long</td> <td>2</td> <td>1</td> <td>Details Adjust Checkup</td> </tr> <tr> <td>2</td> <td>sab</td> <td>04/10/2014 20:00</td> <td>long</td> <td>17</td> <td>2</td> <td>long</td> <td>50</td> <td>78</td> <td>long</td> <td>3</td> <td>76</td> <td>med</td> <td>34</td> <td>30</td> <td>long</td> <td>20</td> <td>76</td> <td>long</td> <td>2</td> <td>1</td> <td>Details Adjust Checkup</td> </tr> <tr> <td>3</td> <td>dom</td> <td>05/10/2014 08:00</td> <td>long</td> <td>17</td> <td>2</td> <td>long</td> <td>50</td> <td>77</td> <td>long</td> <td>3</td> <td>74</td> <td>med</td> <td>34</td> <td>28</td> <td>long</td> <td>20</td> <td>76</td> <td>long</td> <td>2</td> <td>1</td> <td>Details Adjust Checkup</td> </tr> <tr> <td>4</td> <td>dom</td> <td>05/10/2014 20:00</td> <td>long</td> <td>17</td> <td>2</td> <td>long</td> <td>50</td> <td>76</td> <td>long</td> <td>3</td> <td>72</td> <td>med</td> <td>34</td> <td>26</td> <td>long</td> <td>20</td> <td>74</td> <td>long</td> <td>2</td> <td>1</td> <td>Details Adjust 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Fig. 50. Adjusted report



Fig. 51. Details at the beginning of the treatment



Fig. 52. Details at the end of the treatment

By clicking on the Checkup link in the Report table the Checkup screen will be launched for the selected day and time.

4.8 Checkup

The **Checkup** screen (Fig. 53) provides the position of the bone segments and the frame with corresponding strut adjustment values at any particular day of treatment (deformity correction). When the **Checkup** screen is opened, it defaults to the Treatment Start Date or the treatment date from which the Checkup has been launched from the Report Screen. If necessary, use the Calendar to select the date the new case should begin. Click **Create New Case** and a new case will be generated using the parameters of the bone segment position and the strut length values (from the date selected) as starting point. The **Create New Case** screen is used in the following situations:

- Changes in parameters of strut adjustment
- Unplanned strut readjustment or exchange
- Residual correction is required
- Next treatment phase for the staged correction

Before clicking on **Create New Case**, the new case number and new case name can be entered into the corresponding fields. Clicking on **Create New Case** will open **Case Data** screen for the newly generated case. All the deformity and frame parameters will be transferred from the previous case at the date of check-up.

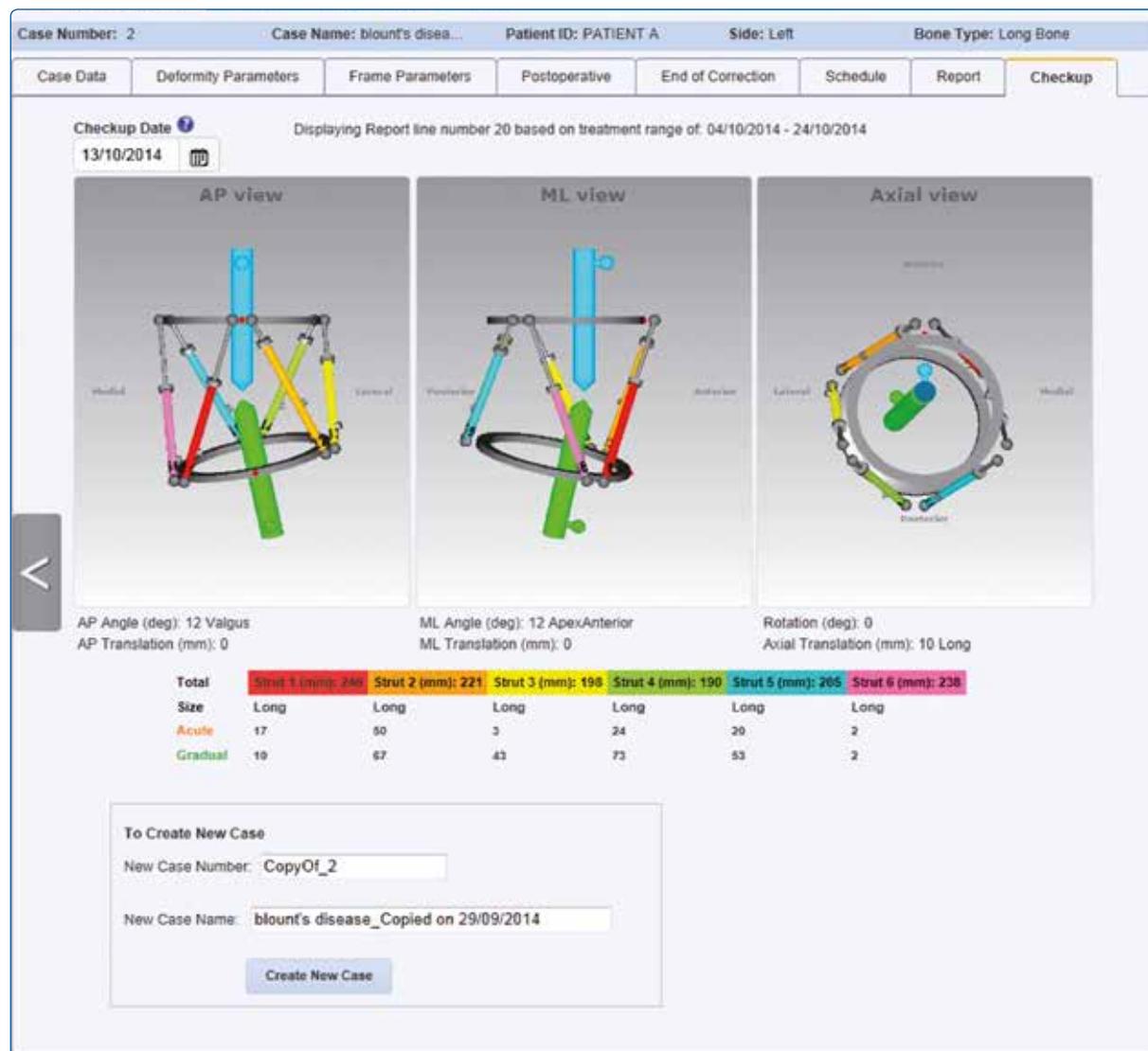


Fig. 53. Checkup screen.

The standard software steps are now followed to complete the new planning from this starting point (Fig. 54). The surgeon should check and adjust Deformity Parameters if necessary (Fig. 55). The Frame Parameters section should be skipped and the surgeon should proceed to the Postoperative section where mounting parameters and strut parameters should be verified and adjusted if necessary. This will result in a new prescription for the patient, based on the starting point as chosen from the Checkup screen.

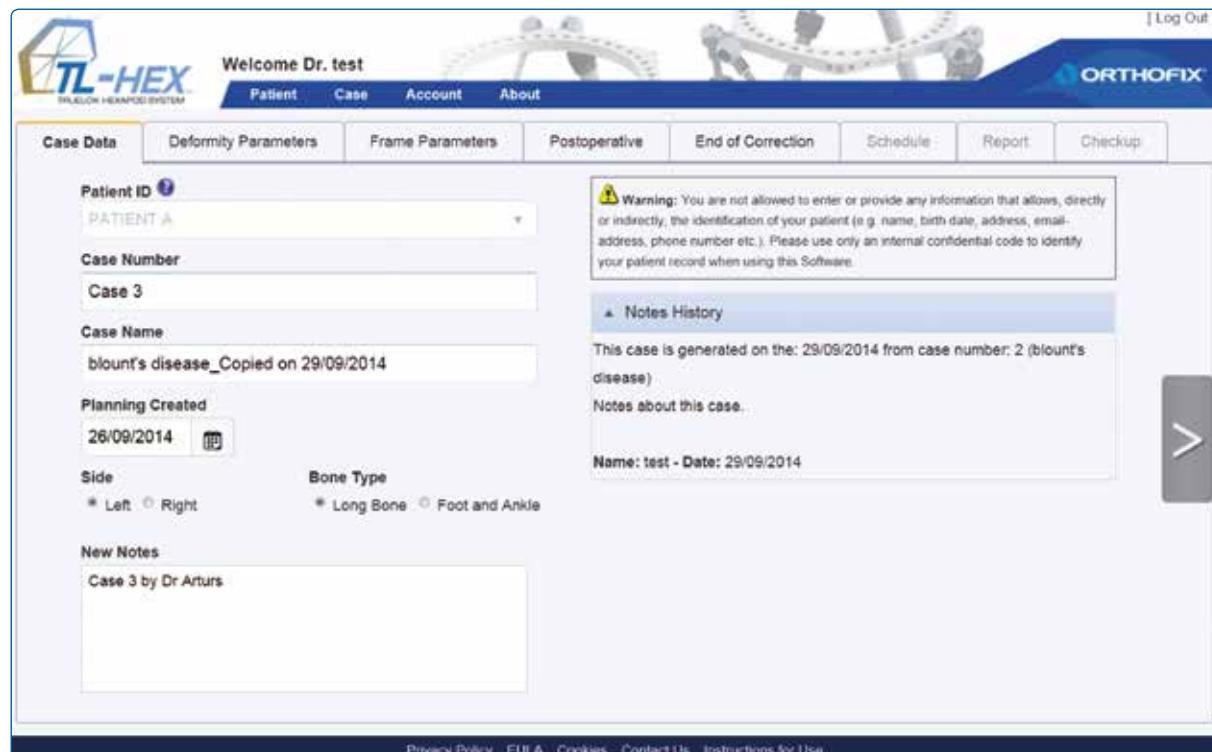


Fig. 54. Create New Case screen.

NOTE: The surgeon should verify and if needed, re-enter the parameters (bone length or over/under correction).

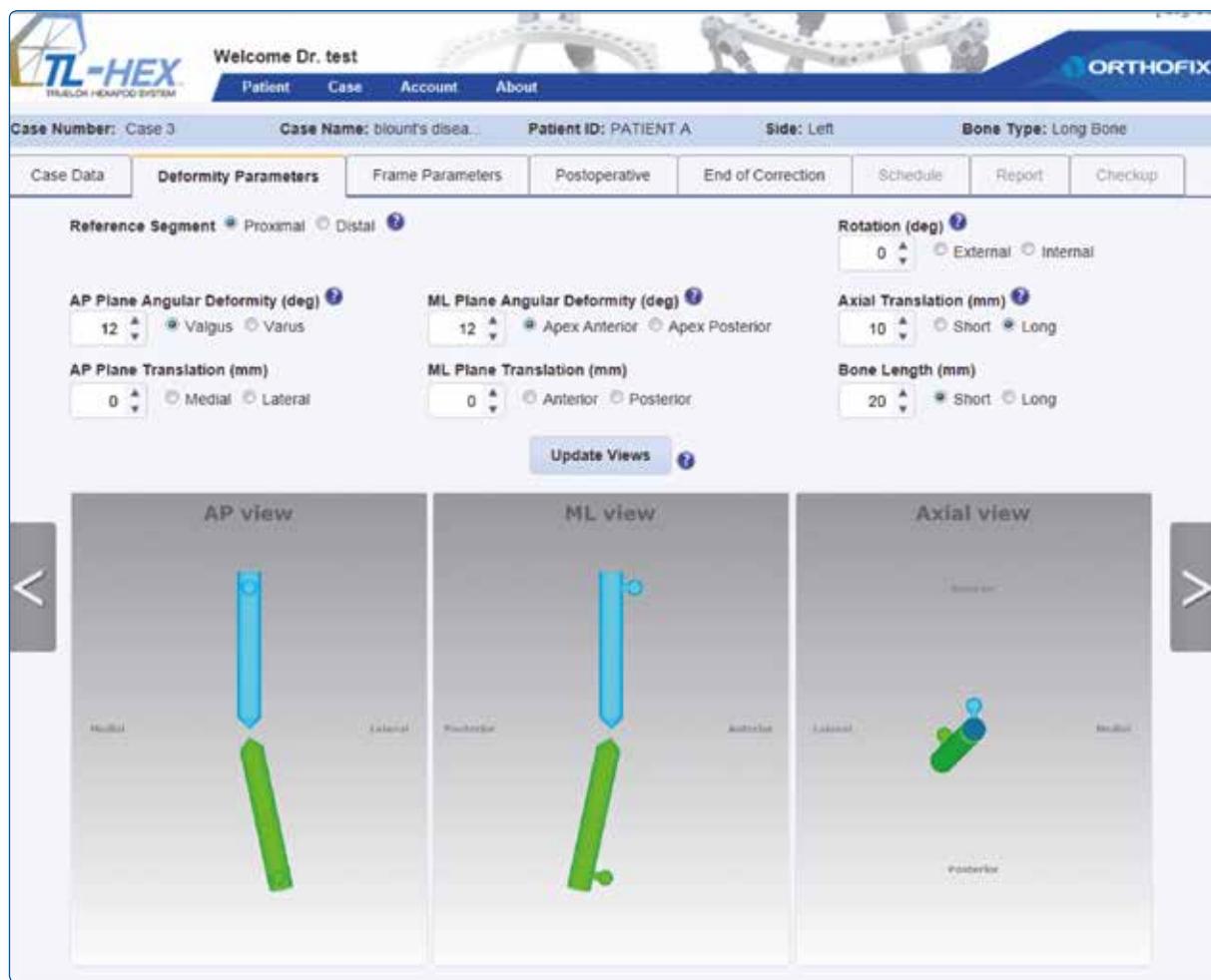


Fig. 55. Verify deformity parameters.

5. Case Planning - Foot and Ankle

Selecting the Foot and Ankle option in the Case Data screen, a new case with Foot and Ankle dedicated graphic will be presented. Starting from the x-ray of the patient (Fig. 56) the surgeon will input deformity, frame and mounting parameters (see 4 case planning - long bone for further details).

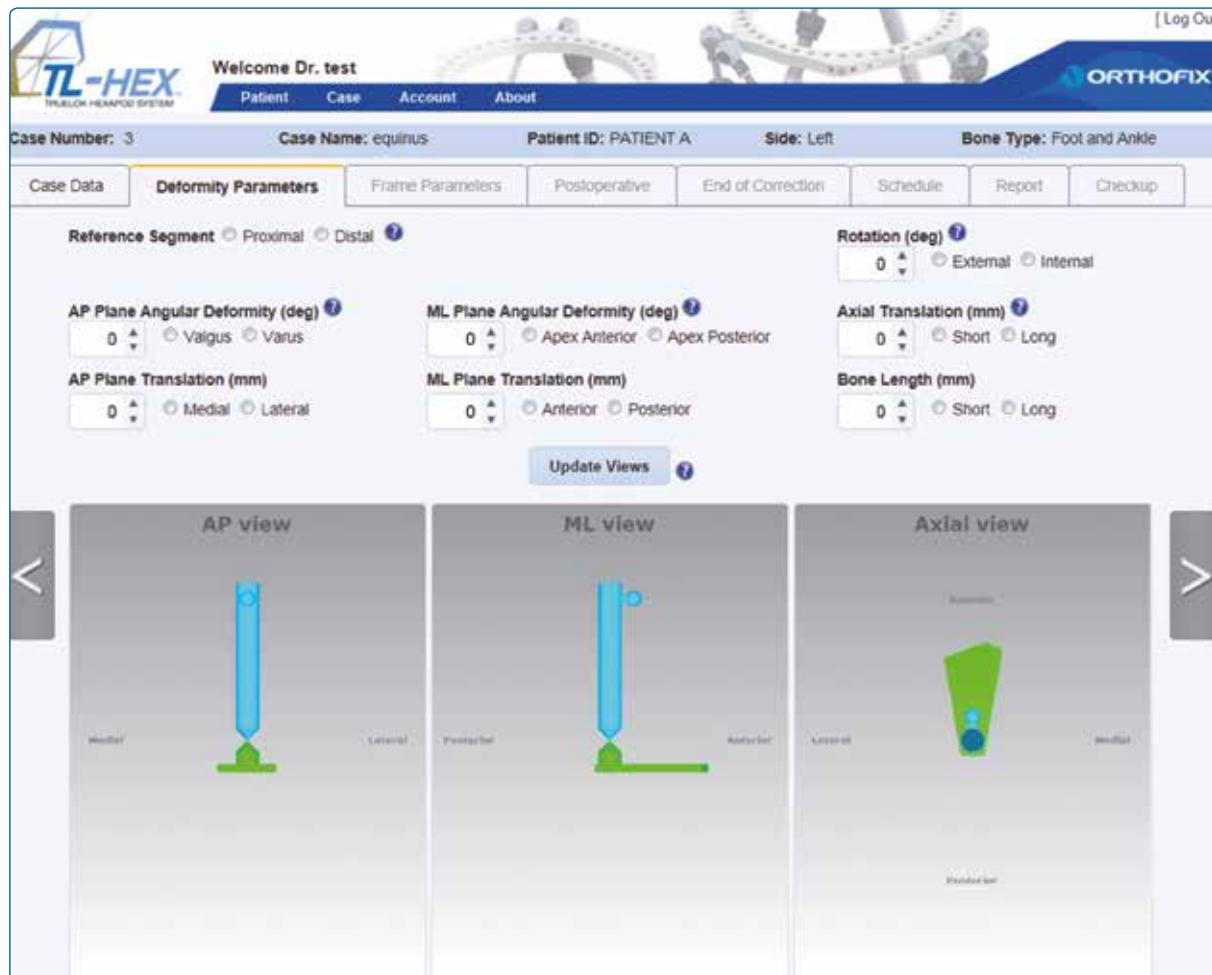


Fig. 56. Foot and Ankle deformity parameters screen

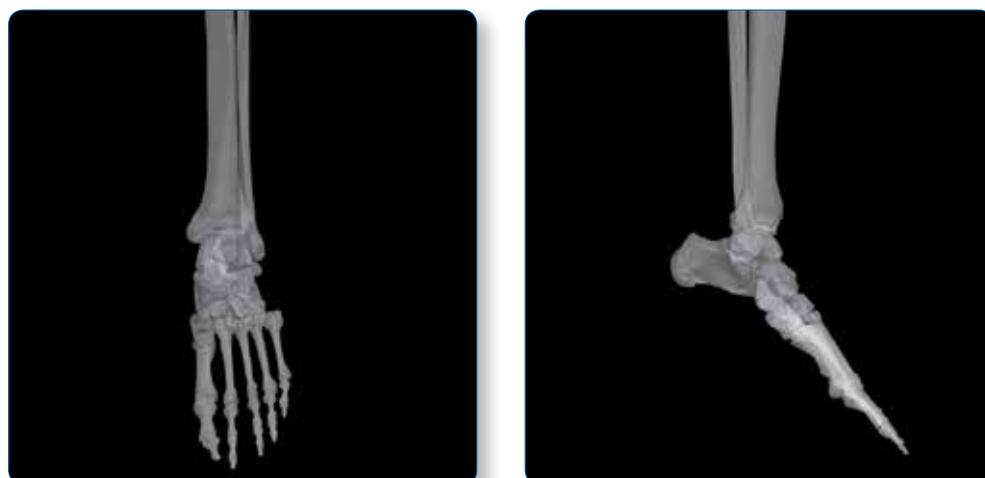


Fig. 57. AP view (a) and ML view (b) radiographs of an Equinus foot

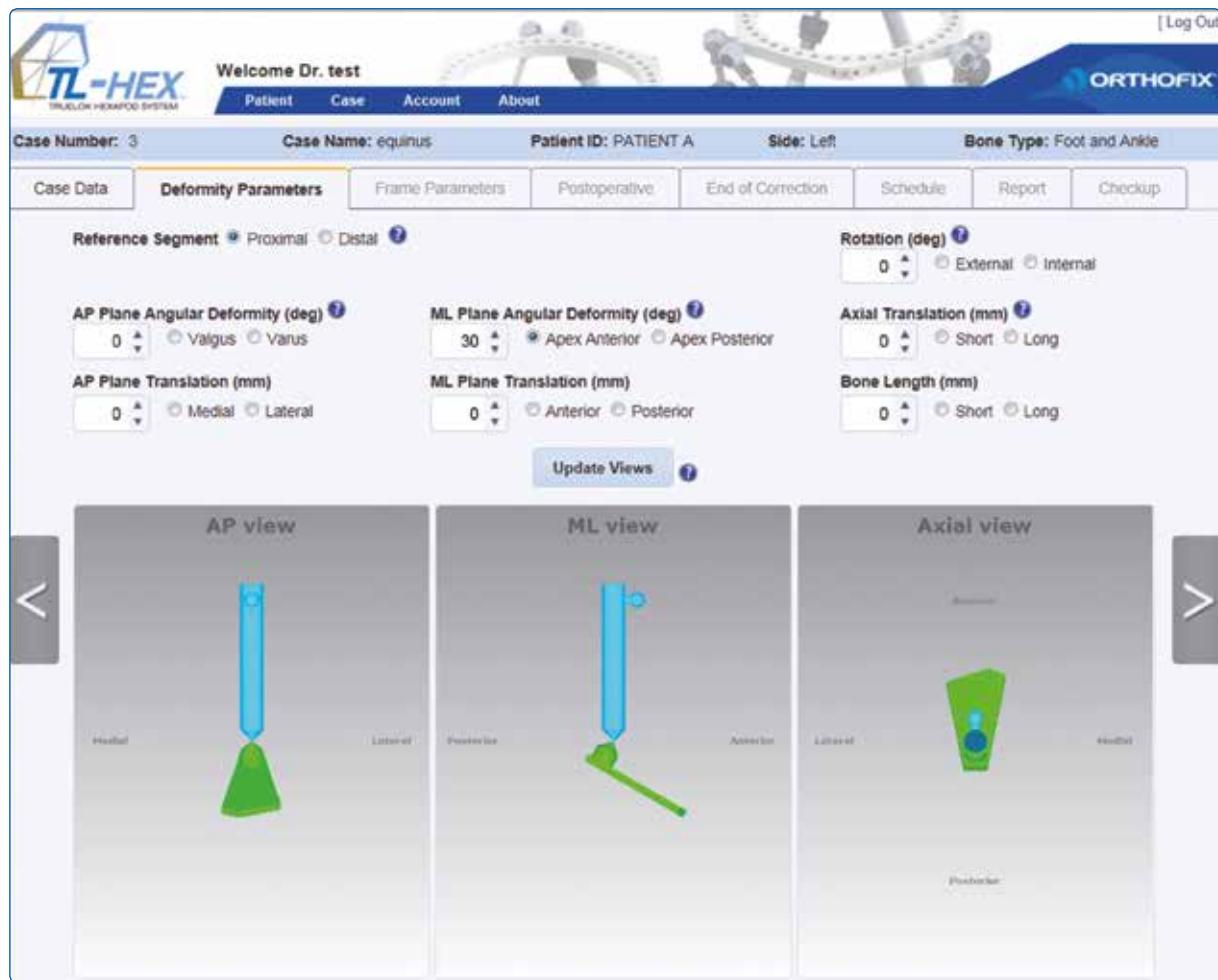


Fig. 58. Foot and Ankle updated deformity



Fig. 59. Foot and Ankle frame parameters screen

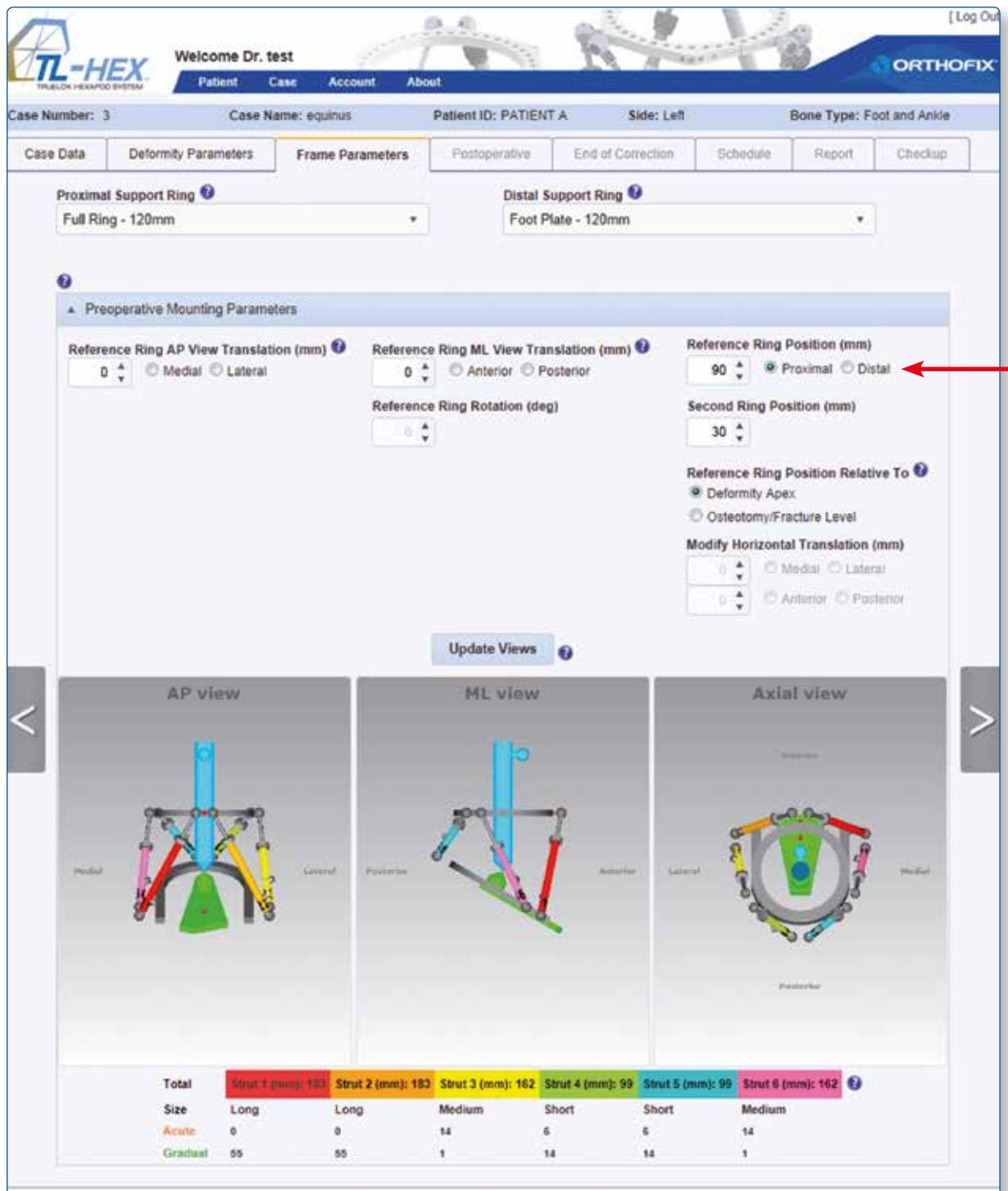


Fig. 60. Foot and Ankle preoperative updated



Fig. 61. Foot and Ankle postoperative screen

6. Website Navigation

- Online help is available by clicking on the question mark icons present in every screen of the software, the HCP will be able to view context relevant help information.
- In general, it is good practice to click the **Update Views** after making any changes to the on screen parameters. This will provide visual confirmation that the changes are as intended. User can click on each image to enlarge it in a pop up window (Fig. 62).

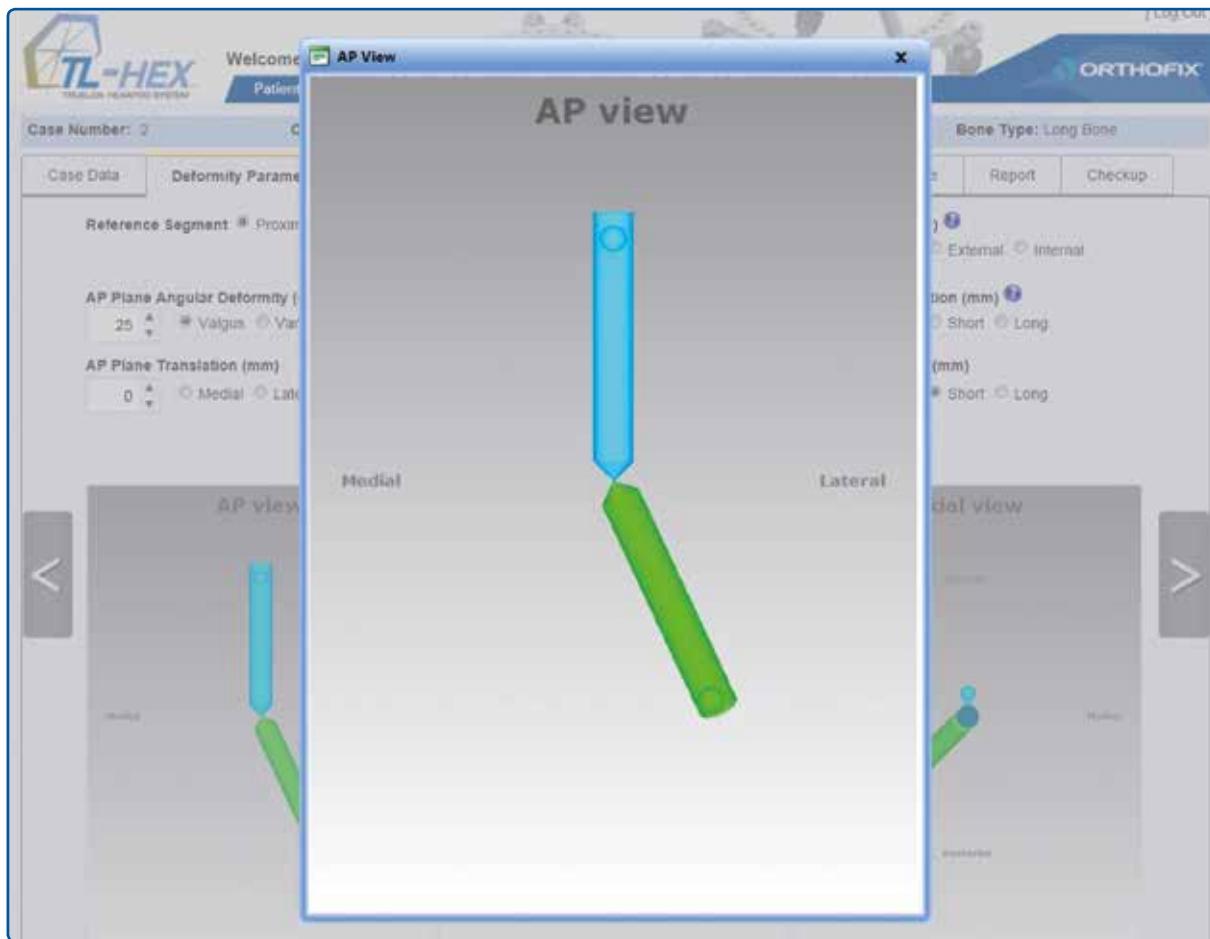


Fig. 62. Enlarge image in a pop up window by clicking on it

- Regardless of whether the **Update Views** is clicked after changing one or more parameters, the new parameters will be saved once either the 'next' arrow to the right hand or one of the function tabs are clicked.
- When a new case is initiated, the flow is from left to right. To go back to a previous tab during a case creation process, click the arrow to the left hand of the screen or one of the function tabs. Note: These actions will not actually save the new parameters. A warning pop up window will advise the user (Fig. 63).
For example, the user begins with the **Case Data** tab, followed by **Deformity Parameters** tab, etc. Tabs that are not appropriate to the next step of the case planning process are grayed out. Once the case is completed, the user can navigate freely between tabs.

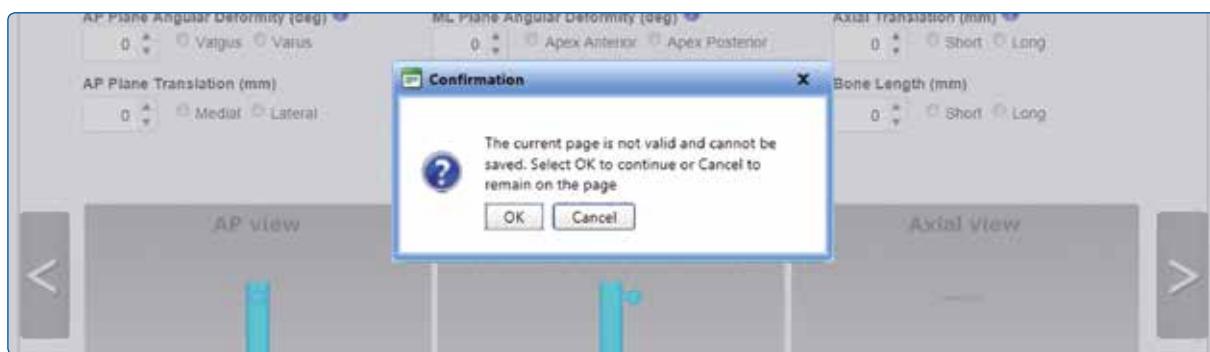


Fig. 63. Warning pop up window when the arrow to the left hand of the screen is clicked during a case creation process

- The TL-HEX software is designed for minimal response (wait) time. However, in the event of Internet transmission delays, a three dots loading animation is displayed while the user's PC is waiting for a response from the TL-HEX server (Fig. 64).
- In certain situations (such as a ring size change), recalculation of the strut lengths is required. In these situations, the popup window appears on the screen (Fig. 65).
- In case of temporary loss of Internet connection and/or when done for the day (by logging off), the surgeon should close the Internet Browser, then reopen browser, clear the browser history, open TL-HEX application and login.
- The session will automatically time out after 30 minutes. The surgeon should close the Internet Browser, then reopen browser, clear the browser history, open TL-HEX application and login.
- The "about" menu item contains general information about the product and its website. The site footer links provide legal information (about Cookies, Eula, Privacy) and contact/support information ("Contact us" to reach our Customer Care and "Instruction for use" for accessing all needed support material and literature).

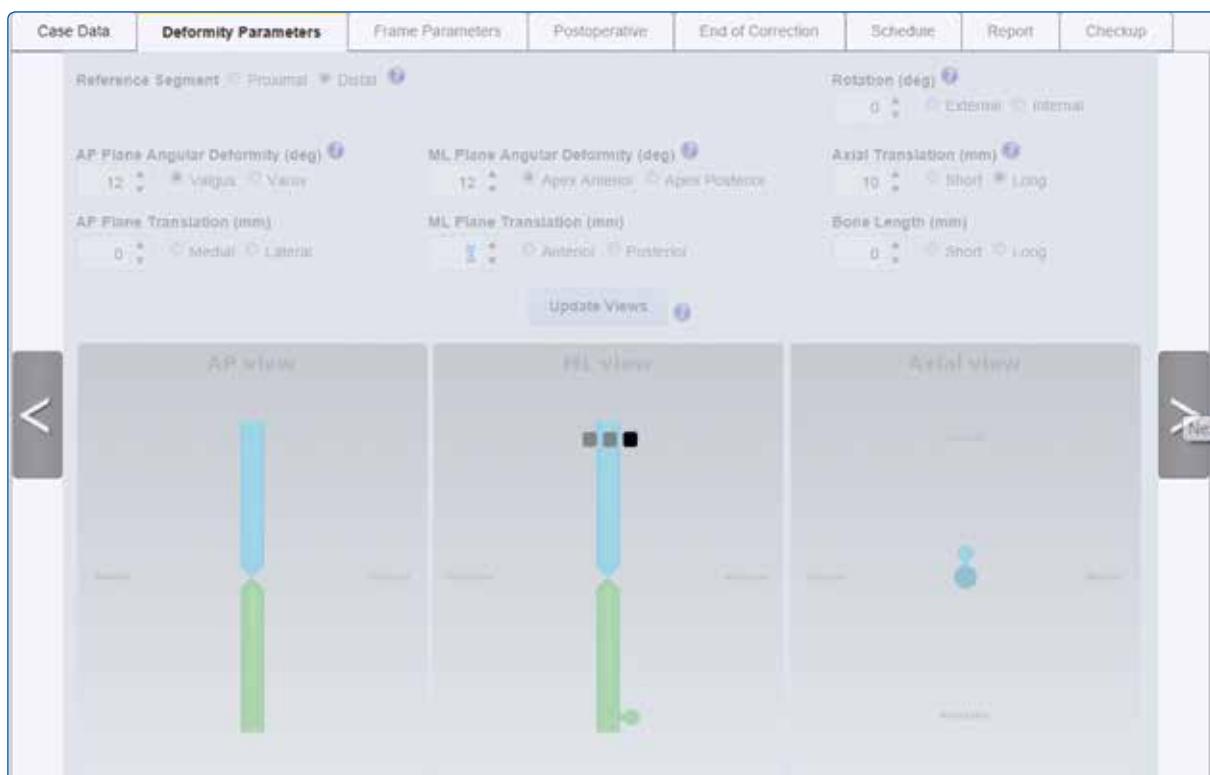


Fig. 64. Three dotted loading animation

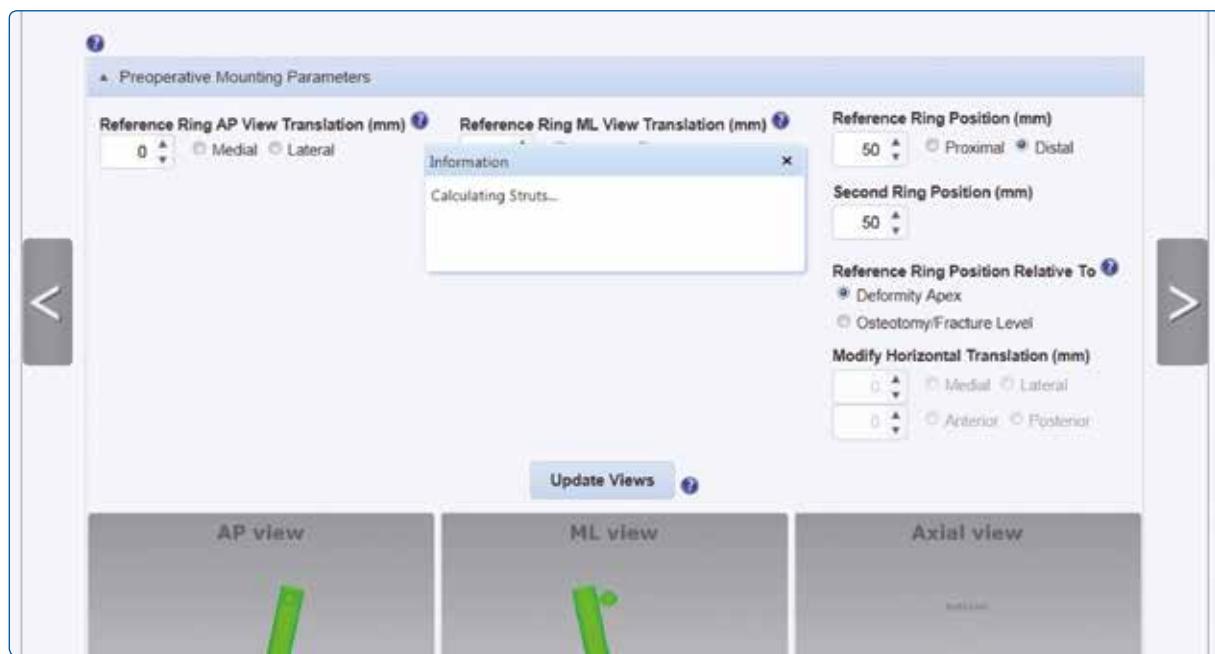


Fig. 65. Popup window for calculation of strut lengths

6.1 Change Password

It is recommended that the user change the password during the first login and periodically thereafter. The **Change Password** screen (Fig. 66) appears by clicking on the **Account** pull down. Simply enter the current password, followed by entering and confirming the new password, then click **Change Password**. Passwords must be 6 or more characters and is case sensitive.

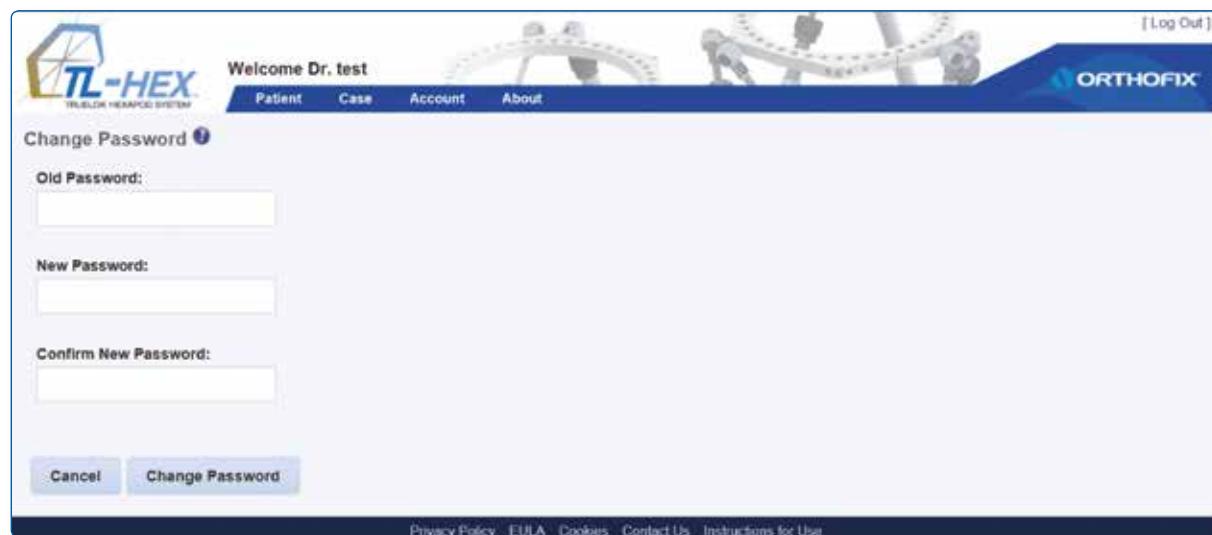


Fig. 66. Change Password screen.

It is important to remember that the surgeon remains ultimately responsible for the confidentiality of the information entered into the software. One of the ways to ensure confidentiality is to ensure password integrity by changing it at regular intervals and by keeping the password as secure as possible.

Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon should never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

6.2 Prescription Preferences

The Prescription Preferences screen appears after prescription preferences is chosen from the Account pull down (Fig. 67). User can optionally add default prescription notes and/or enter addresses different from the first entered during registration phase. At the beginning of the patient creation process the HCP can link to a new patient any of the addresses previously created using this menu. The link between address and patient can always be modified using the "modify" action in the "List of patients" menu and selecting a new preference.

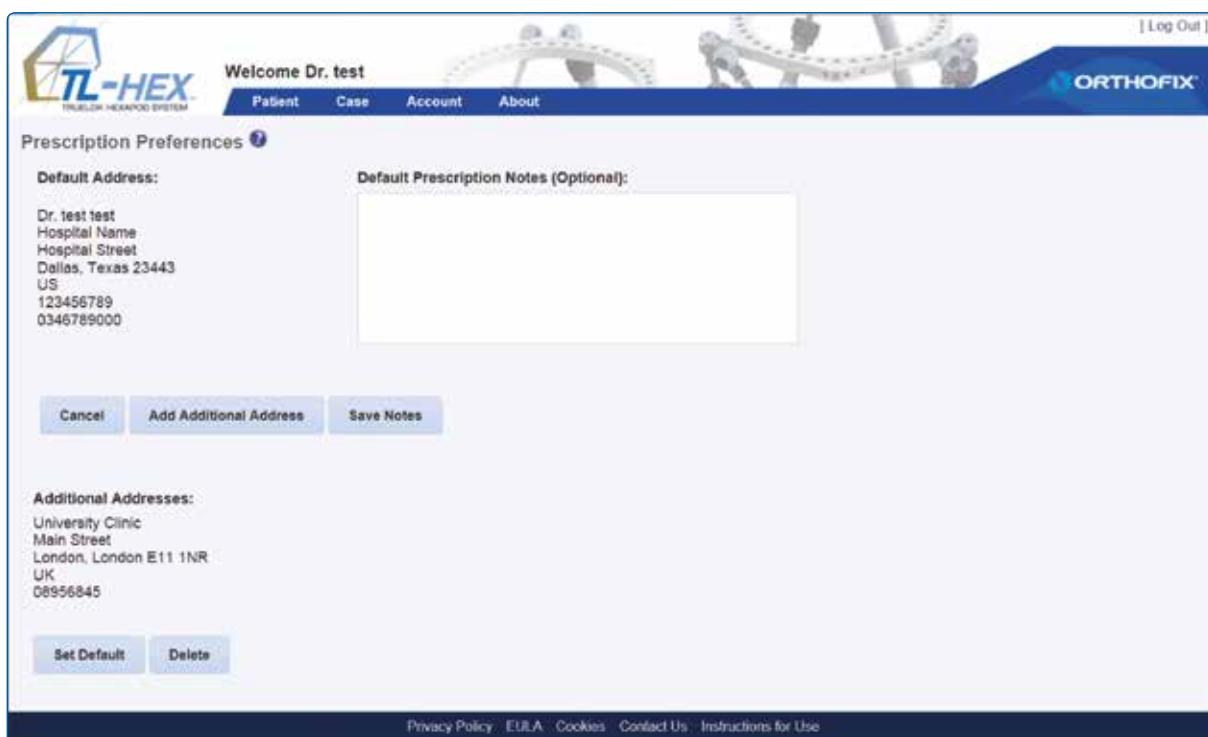


Fig. 67. Prescription Preferences screen

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