



HEX-ray

Software User's Guide

A module of the TL-HEX software version 2.3



HEX-ray Software User's Guide: A module of the TL-HEX software version 2.3

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 1280 x 768 pixels or higher.

Supported Browsers:

Microsoft Internet Explorer® Version 11 or higher

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

Safari® 13 or higher

Safari is a trademark of Apple Inc., registered in the U.S. and other countries. HomeKit is a trademark of Apple Inc.

Google Chrome™ Browser 79 or higher

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Mobile Safari® 13 or higher

Safari is a trademark of Apple Inc., registered in the U.S. and other countries. HomeKit is a trademark of Apple Inc.

Other Requirements:

Web Graphics Library (WebGL) availability and minimum screen resolution are checked at login time in order to provide access to Hex-ray.

NOTE: for an optimal navigation experience, Annex A provides instruction on how to configure the browser.

Internet Connection:

Minimum required internet connectivity speed is 512kbps.

Recommended internet connectivity speed is 3mbps or higher.

My Username:

My Password:

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Getting Started with HEX-ray module

The HEX-ray module adds an optional support for the acquisition of the required TL-HEX deformity / fracture and mounting parameters using patient's x-rays.

TL-HEX software maintains the ability to directly input the required parameter values. Users may also access the HEX-ray module that supports the acquisition of parameter values from patient images already calibrated into the system and fill the values in the related parameter fields of the TL-HEX software. The user may switch from TL-HEX to the HEX-ray module way of working freely during any stage of planning or treatment.

Using either the inherent deformity or fracture displacement as a starting point, the TL-HEX software will calculate a comprehensive treatment plan for the operating surgeon's approval. Elements of the plan will include the frequency, direction and extent of adjustment for each strut.

NOTE: Although possible to mix HEX-ray and TL-HEX data, keeping a consistent singular input flow is recommended.

The formulation of the treatment plan is independent of the method of parameter input. The software is equally capable regardless of values being manually inputted or acquired automatically by the analysis of radiographs using HEX-ray.

The HEX-ray module introduces the following features:

- Support of **Deformity** and **Fracture cases**
- Support of both **preoperative** and **postoperative** mounting stages
- It is optimized to work with the **bone anatomical axis** and **TL-HEX hardware**
- In both deformity and fracture cases, the **translation values are automatically calculated** relative to either the osteotomy level or fracture site
- To perform radiographic assessments of lower limb deformities, tools such as **Line** and the **Goniometer** are provided
- *X-ray images uploaded and processed*
Upload of x-ray images, and application of **basic image processing** (flip, rotation, brightness, contrast and crop), to **calibrate** the images
- *Deformity Analysis*
Deformity or trauma assessment and the acquisition of the related parameter values to be used for the TL-HEX treatment plan calculation
- *Correction definition*
Desired **End Of Correction definition** and the acquisition of the related parameter values to be used for the TL-HEX treatment plan calculation
- *Preplanning with TL-HEX hardware*
TL-HEX frame preplanning, closely matched to real surgical application, in order to provide initial recommended struts data set
- *Mounting assessment of TL-HEX hardware*
Acquisition of the TL-HEX mounting parameter values to be used for TL-HEX treatment plan calculation.

Work Flow Overview

The following flow chart provides a sequential overview of the **6 case management steps** within HEX-ray software.

NOTE: It is recommended to follow the flow sequentially even if it is possible to go back and forth.

Step 1: HEX-Ray computer System requirements

- **Supported Desktop Browsers:** Microsoft Internet Explorer® 11 or higher, Safari® 12 or higher, Google Chrome™ Browser 79 or higher, Mobile Safari® 12 or higher
- **Display Settings:** Screen resolution of 1280 x 768 pixels or higher.
- **NOTE:** Web Graphics Library (WebGL) availability and minimum screen resolution are checked at login time in order to provide access to HEX-ray.
- **NOTE:** For an optimal navigation experience, Annex A provides instructions on how to configure the browser.

Step 2: X-ray Image requirements

For the HEX-ray module to be effective:

- The Reference Segment in the x-ray image must be perpendicular to the beam in both views.
- Orthogonal (90°) x-ray images are required.
- Two x-ray images are required to be uploaded and calibrated in order to activate the work flow.

X-ray images must not contain any information that allows, directly or indirectly, the identification of a patient (e.g. name, birth date, address, email-address, phone number etc.). Refer to local image tools to ensure radiographs are appropriately stripped of patient identifiable data.

NOTE: It is the surgeon's responsibility to ensure that all the above requirements are met with equal consideration given to data protection as X-ray images must be anonymized before uploading into HEX-ray.



Step 3: Image Upload & Calibration Workflow

User can upload the x-ray images in three ways: **Browsing from File System, Drag & Drop and Copy & Paste.**

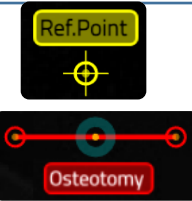
When the user has successfully uploaded an x-ray image, the **workflow** will automatically start for both:

1. user will be asked to confirm or change the x-ray image orientation, by rotating it along its vertical axis (180°).
2. user will be asked to **calibrate with Line or Circle tool. The calibration step is critical.** The precision of HEX-ray measurements is highly effected by the accuracy of the calibration. To improve measurement accuracy, use a marker and superimpose the HEX-ray calibration tool carefully on it.

Load

Calibrate

3. According to the **Case Type** and **Operative Phase** user will be asked to:
 - Deformity Case, Preoperative Phase: Reference the images with the **Reference Points**.
 - Deformity Case, Postoperative Phase: Reference the images with the **Osteotomy**.



NOTE: Image referencing is critical; it allows HEX-ray to correlate the images in both views.

PREOPERATIVE: in Deformity Analysis tab to permit consistent coordination of the Osteotomy line between the views, the Reference Points should be at the same level on both views. For this reason, the reference points must be placed with care on the same point in both images.

POSTOPERATIVE: the **Osteotomy line** should be positioned as desired, paying attention to match the bone cortices, permitting HEX-ray to suggest the axial bone length to avoid segment impingement during treatment.



Step 4: Deformity or Fracture Analysis

Deformity Cases:

For Deformity cases, the APEX represents the point from which translations are calculated and corrections (angular and translational) applied.

Preoperative Case only:

The **Osteotomy line** should be positioned as desired, paying attention to match the bone cortices, permitting HEX-ray to suggest the axial bone length to avoid segment impingements during treatment. Any alteration of the Osteotomy position in one view will result in a coordinated move in the orthogonal plane in accordance with the Reference Points set in the Image Tools tab (step 3).

Fracture Cases:

For Fracture cases, the central point of the ending dashed line on the Reference axis is the point from which translations are measured and corrections (angular and translational) applied. Select the reference value for the Axial Translation and insert the clinical evaluation result of the Axial Rotation.



Step 5: End of Correction Analysis

The axial bone length suggested by HEX-ray to avoid segment impingements during the treatment considers: **Angular Deformity, Osteotomy length, inclination angle, distance from the APEX, Default EoC position.**

The suggested bone length value is calculated based on both AP/Dorsal and Lateral views, and the highest value is shown.

If the Osteotomy is not perfectly perpendicular to the bone axis, this value might be overestimated.

It is recommended to review the value with the End of Correction analysis before continuing.



Step 6: TL-HEX ring positioning**Postoperative assessment.**

Since the Reference Ring movements are coordinated between the views, the task is **to match the HEX-ray 3D ring model to the Reference Ring on the x-ray images simultaneously on both views.**

In case the HEX-ray 3D model will not match perfectly the actual x-ray image on both views it is possible to overcome this situation allowing for independent movement of the Reference Ring models between both views and match the Reference Ring independently in each view.

**Others**

HEX-ray supports both Preoperative and Postoperative stages. The work done in the Preoperative Planning, if present, will be available to determine if the positioning needs review and adjustment.

According with the working step, handles are visible and selectable only for enabled tools, to simplify the HEX-ray user. In addition, relevant user actions and selections are highlighted with a blue background.

TL-HEX and HEX-ray integration

The diagram demonstrates the interaction between HEX-ray module and the TL-HEX software in acquiring anatomical, correction and mounting parameters from patient x-rays; the green represents the path for preoperative planning and yellow the path for postoperative assessment.

The software provides the flexibility to access the HEX-ray module at any point within the TL-HEX Deformity or Mounting tabs, depending on the x-ray images uploaded.

When accessing HEX-ray, the user is asked to indicate the x-ray image type as either preoperative or postoperative. This information opens the appropriate HEX-ray Mounting tools and logic for struts within the TL-HEX.

Along the case life cycle, the user can upload both preoperative and postoperative x-ray images. However, TL-HEX permits only one working dataset, therefore, the last activity performed in HEX-ray will overwrite any prior TL-HEX Deformity and Mounting parameter value.

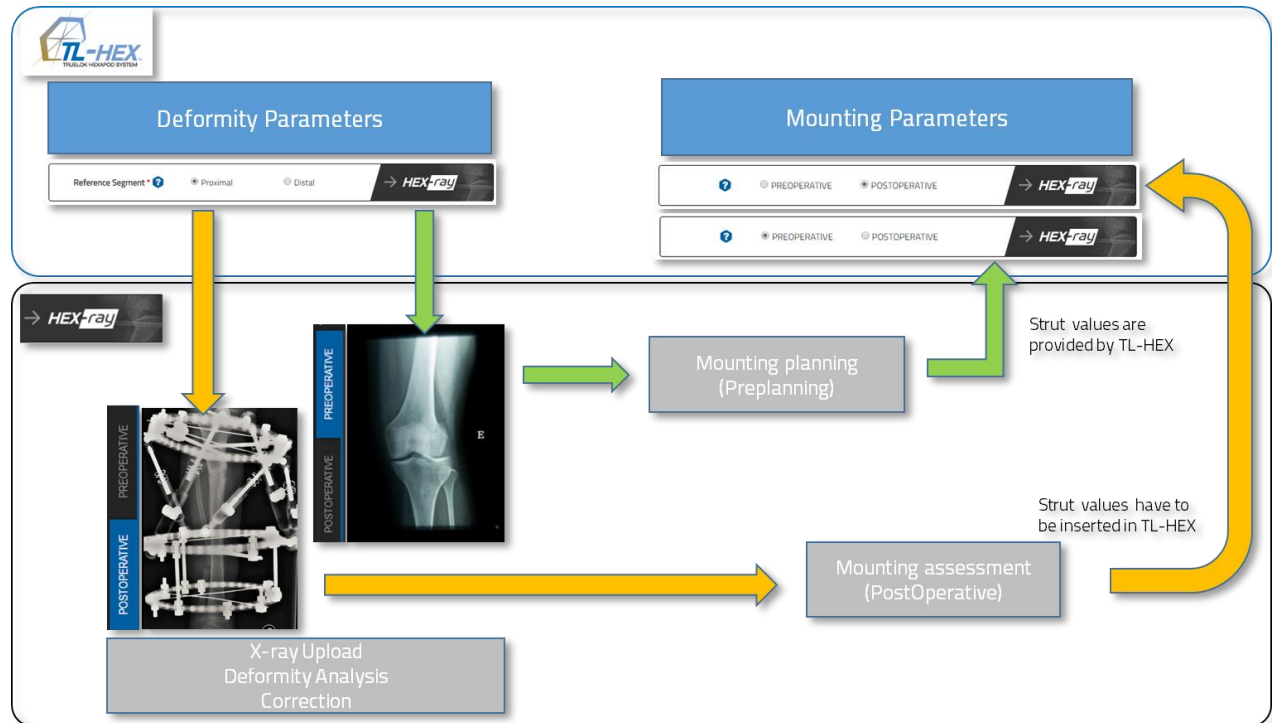
Any updated value on TL-HEX or HEX-ray may be saved before continuing. In TL-HEX it is possible to save modifications by pressing on the

Save & Update

button and in HEX-ray with



icons.



First, be aware of how some selections in TL-HEX Case Data tab have an effect on HEX-ray setup. The table below describes the integration between TL-HEX and HEX-ray during case management:

Case Type: Deformity or Fracture

The Case Type selection permits access to the appropriate HEX-ray tools and calculation options; it also eases case organization.

Bone Type:

The appropriate selection of the bone type sets up the HEX-ray tools accordingly.

NOTE: Since these selections are crucial to perform the analysis in HEX-ray and might affect the correctness of the data, any subsequent saved changes to Case Type, Side or Bone Type resets any HEX-ray analysis already performed.

The screenshot displays the 'Case Data' tab of the TL-HEX software interface. It features several input fields and selection options:

- Case Type:** A dropdown menu with 'Deformity' (selected) and 'Fracture' options. A 'Trial' checkbox is also present.
- Patient ID:** A dropdown menu showing 'SW User's Guide'.
- Frame ID:** A row of buttons labeled A through I, with 'A' selected.
- Case ID:** A text input field.
- Case Description:** A text input field.
- Planning Created:** A date picker showing '1/30/2019'.
- Side:** Radio buttons for 'Left' (selected) and 'Right'.
- Bone Type:** A row of buttons labeled 'Long Bone', 'Femur' (selected), 'Tibia', 'Ankle', 'Forefoot', and 'Hindfoot'.
- New Notes:** A text area for entering notes.

After selection of the Reference Segment, the Deformity Parameters page is refreshed with images and the HEX-ray icon is enabled.

After returning to TL-HEX from HEX-ray, the parameters will be transferred and locked to avoid undesired modification.

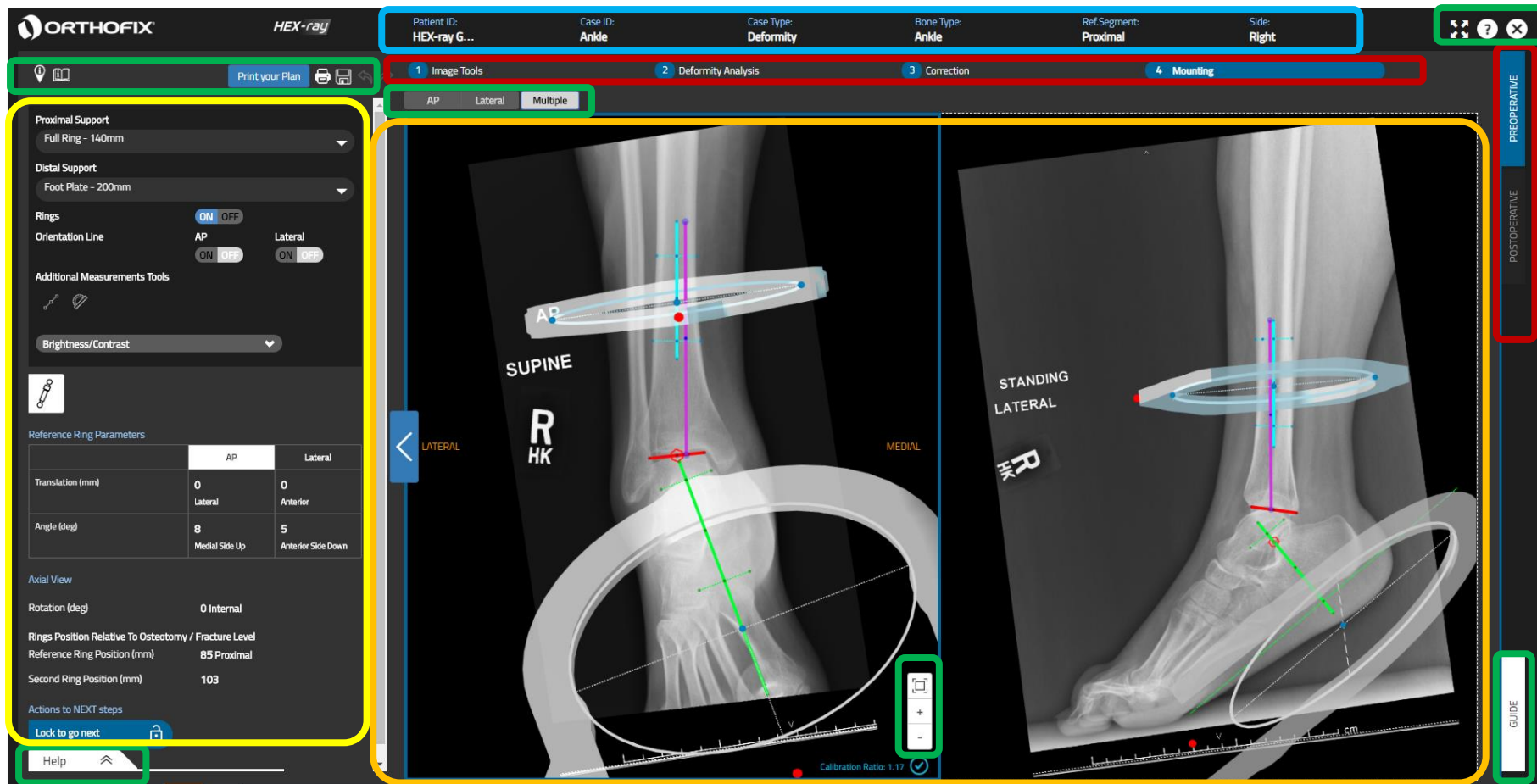
You can unlock and make the TL-HEX parameters editable by clicking on them.

NOTE: Keeping a consistent singular input flow is recommended.

Although possible to mix data flows, the surgeon must be aware that any alteration in TL-HEX will have a potentially conflicting result in HEX-ray.

HEX-ray DESKTOP

The picture below shows the HEX-ray desktop:



- The HEX-ray tabs to manage the work flows
- Work area, with the x-ray images and tools

- Work area tools and calculation results
- Common functions available in each tab

- Relevant Case information

Work Flow tabs

In accordance with the correction or trauma stage and the type of x-ray images uploaded, the tabs in the picture above permit the user to switch between Preoperative and Postoperative flow.

HEX-ray is organized into 4 main tabs (red areas):

1 Image Tools	2 Deformity Analysis	3 Correction	4 Mounting
<h3>Image Tools</h3> <p>In this tab the user may:</p> <ul style="list-style-type: none"> upload x-ray images (preoperative and/or postoperative), apply basic image processing (flip, rotation, brightness, contrast and crop) calibrate the images (Preoperative deformity) place the reference points (Postoperative deformity) overlap osteotomy on the real one on the X-ray images. 	<h3>Deformity Analysis</h3> <p>In this tab the user may:</p> <ul style="list-style-type: none"> assess the deformity or fracture characteristics acquire the related parameter values to be used for the TL-HEX treatment plan calculations (Preoperative deformity) place osteotomy to pre-plan their case. 	<h3>Correction</h3> <p>In this tab, the user may:</p> <ul style="list-style-type: none"> define the desired End Of Correction acquire the related parameter values to be used for TL-HEX treatment plan calculations. 	<h3>Mounting</h3> <p>In this tab the user is provided with different options in relation to the treatment stage:</p> <p><u>Preoperative planning</u> with TL-HEX hardware</p> <ul style="list-style-type: none"> The user may pre-plan surgery with the TL-HEX frame at a time close to real surgical application <p>Postoperative assessment with TL-HEX hardware</p> <ul style="list-style-type: none"> The user may acquire the TL-HEX mounting parameter values to be used for the TL-HEX Treatment plan calculations.

Common functions



SAVE & CLOSE HEX-ray

User can save the work completed so far and return to TL-HEX. All HEX-ray data is imported into TL-HEX.



HELP OVERLAY

User can see contextual help explaining the meaning of the different on-screen options.



FULL SCREEN

User can view the software using the entire screen.



UNDO - REDO

User can undo - redo actions performed after data was last saved.



ZOOM IN/OUT

X-ray image and tools are zoomed in or out.



GUIDE

Contextual guide where the user can find instructions related to the tab and case type.



SAVE

User can save the work completed so far.



GUIDED TOUR HELP

User can see step by step help showing the basic operations to be performed to use the software.



INSTRUCTIONS FOR USE

User can access the Instructions for Use section with all the documents and materials about TL-HEX product.



PRINT

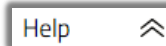
User can print all data and the views of the tab.

NOTE: To prevent your summary from being cut off when you print it, print it in landscape format. See Annex B for more instructions.



FIT TO VIEW

X-ray image and tools are zoomed to fit the view.



HELP

User is provided with information related to the tab and bone type being worked on.



User can select which view to show or see them side by side using the Multiple option.

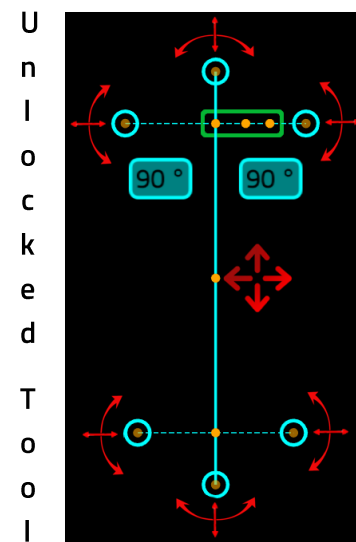
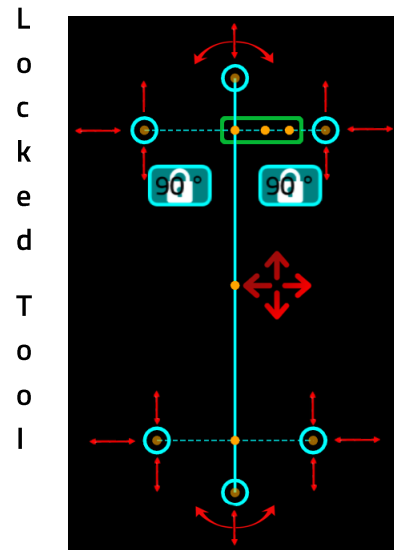
Tools interaction

Below is a list of the tools that are available to use in the main working area:





Tool type / Name	Color	On screen label	On screen values
Calibration Line	Blue		
Calibration Circle	Blue		
Reference segment	Light Blue	Reference	Anatomical or user angles
Moving segment	Light Green	Moving	Anatomical or user angles
Osteotomy line	Red	Osteotomy	
Fracture line	Red	Fracture Level	
Free Line	Purple		Length value
Goniometer	Purple		Length and angle values
Crop area	Orange		
Reference Ring	Light Blue		
Second Ring	Gray		
Orientation Line	Yellow	Orientation Line	Length between orientation line and reference ring Length between orientation line and osteotomy

Tool for Deformity/Fracture analysis

The image below demonstrates how to interact with a tool. The described interaction is applicable to all available desktop tools:



NOTE: According to the bone type, in Lateral View the user will be able to switch the tool axis position. Hovering the mouse over the yellow dots (green area of the image), will make the icons **1/2**, **1/3**, **1/5** pop up. Pressing on them will change the axis position of the tool.

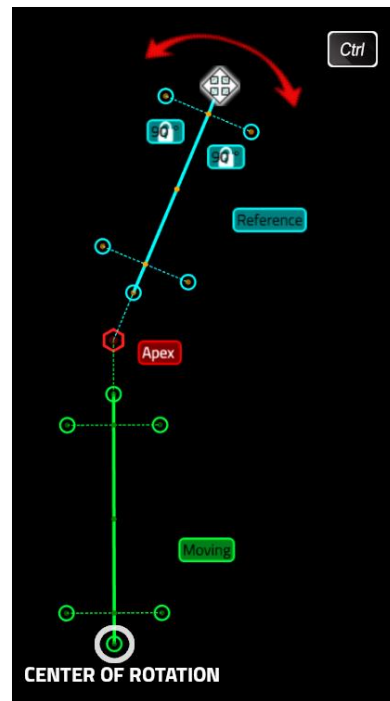
- Hover the handle points to activate it and drag it to move the tool across the view. The mouse pointer will become .
- Drag the **Center** point to move the whole tool inside the view.
- On the labels with angles, the  icon means that the angles are not modifiable and dragging the handle points will not change the angles. Click on the label to unlock the angles; dragging the handles will change the angles accordingly. In order to **manually type** a different angle number: click again on the unlocked label; the  icon will appear, and user can input the value using the keyboard.
- User can move the image in the view with left mouse button when the pointer changes to .

Synchronized movement of the axes

When in the Deformity Analysis tab, it is possible to rotate or translate both the Axes tools simultaneously, according to the selected axes tool handle.

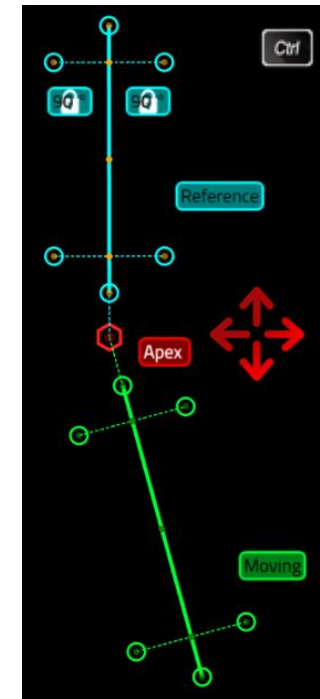
ROTATE

Hold CTRL key and select with Left mouse button one of the axes tool extremity handles: the tool rotates on the opposite extreme handle.



TRANSLATE

1) Hold CTRL key and select with Left mouse button any handle apart from the axes tool extremity handles; the tools translate together in any direction.
2) Alternatively, select deformity apex with Left mouse button



X-ray Image Requirements

For the HEX-ray module to be effective:

- **The Reference Segment in the x-ray image must be perpendicular to the beam, in both views**
- **Orthogonal (90°) x-ray images are required**
- **Two x-ray images are required** to be uploaded and calibrated in order to activate the work flow.

NOTE: At this stage, the surgeon is reminded to ensure that no patient identifiable data is uploaded by use of local anonymization tools.

X-ray images **must not** contain any information that allows, directly or indirectly, the identification of a patient (e.g. name, birth date, address, email-address, phone number etc.). X-ray images must be anonymized before uploading in HEX-ray.

User is asked to confirm the x-ray image doesn't contain any personal information of the patient

HEX-ray

DO NOT UPLOAD files that contain any information that allow, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.).
Please anonymize your x-ray image before uploading when using this Software.

Accept

Decline

After the disclaimer is accepted, the user must declare the x-ray images treatment stage as either Preoperative or Postoperative.

HEX-ray

Do you want to upload Preoperative or Postoperative x-ray images?

Preoperative

Postoperative

IMAGE TOOLS

Within Image Tools the HEX-ray module will enable the user to:

- Upload x-ray image
- Calibrate the uploaded image
- Apply basic processing like image crop, brightness and contrast fine tuning
- Review image orientation
- Delete or substitute an uploaded image
- **PREOPERATIVE DEFORMITY**: place reference points
- **POSTOPERATIVE DEFORMITY**: place osteotomy

Image loaded **IMAGE LOADED**
User can see the uploaded image file name for reference



BROWSE FOLDER
User can browse folders to identify the x-ray image to be uploaded



DELETE IMAGE
User can delete the image in the active view



ROTATE
User can rotate the image in the active view to a desired orientation



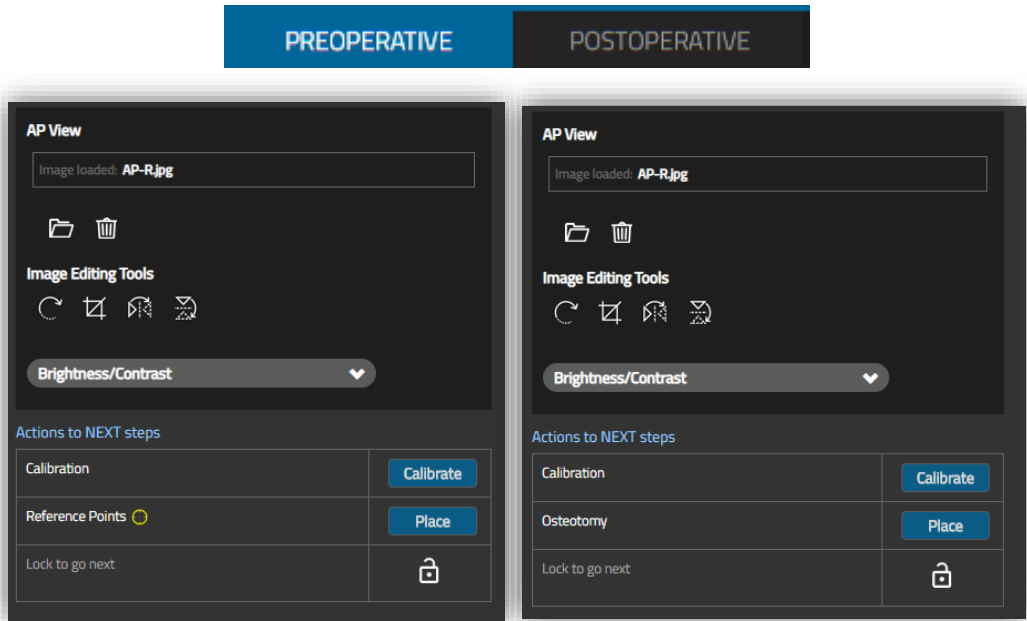
CROP
User can crop the image in the active view to the desired size



FLIP IMAGE HORIZONTALLY
User can horizontally flip the image in the active view



FLIP IMAGE VERTICALLY
User can vertically flip the image in the active view



BRIGHTNESS
User can fine tune the brightness of the image in the active view



CONTRAST
User can fine tune the contrast of the image in the active view



CALIBRATION
User can calibrate the image in the active view with a linear or circular calibration tool




REFERENCE POINTS/OSTEOTOMY PLACEMENT
User can place reference points or osteotomy to correlate the images

Image Upload

The supported x-ray image formats are **JPG** and **PNG**, with maximum file size of 5MB.

To start the image upload & calibration workflow:

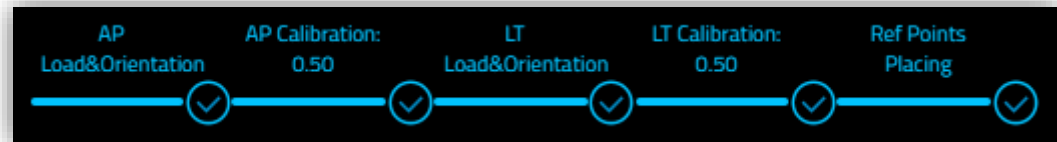
- Select image from file with  button
- Copy and Paste using Ctrl+V (not available for Internet Explorer)
- Drag and Drop the image on a view

Upload and Calibration Workflow

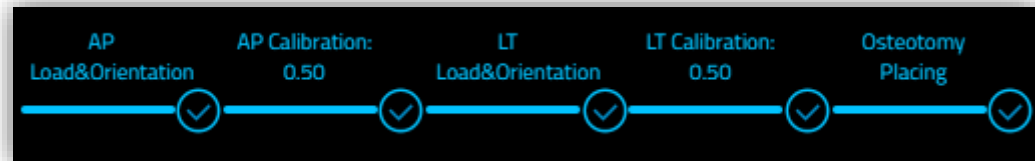
To ease the process, the user is guided with a step-by-step workflow and an intuitive on-screen feedback of the progress of the mandatory activities needed to proceed to next steps.

The process is tailored to the type of program chosen:

Deformity Preoperative



Deformity Postoperative



Fracture (Preoperative/Postoperative)

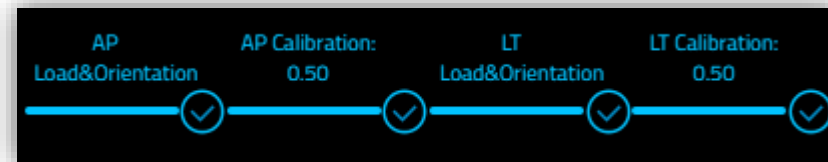


Image Orientation

It is possible to review the image orientation and characteristics any time. It is recommended to review and confirm the image orientation after uploading because any modifications could impact the work completed in the following HEX-ray steps.

AP/Dorsal x-ray image upload

When the upload of the AP/Dorsal image is completed, the image is visible on the desktop and the **relevant anatomical labels** are shown to support the correct image orientation. In addition, the user is asked to review the proposed **orientation**.



Lateral x-ray image upload

When the upload of the Lateral image has completed, the image is visible on the desktop and the relevant anatomical labels are shown to support the correct image orientation.

In addition, the user is asked to review the proposed orientation.

Image Orientation

Make sure the image has the following orientation:
Proximal segment above, Distal segment below.

Is the image orientation correct?

Image Orientation

Make sure the image has the following orientation:
Posterior on the left side, Anterior on the right side.

Is the image orientation correct?

Image Calibration

X-ray image **calibration** can be performed with one of the two available tools: *line* or *circle*.

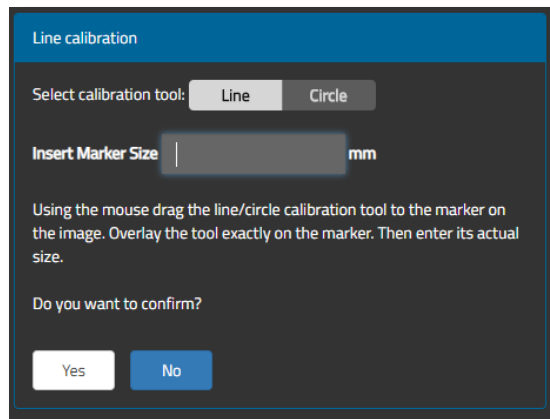


Select the preferred tool and it will appear inside the selected view

1. Position it on an object or scale marker of known dimension.

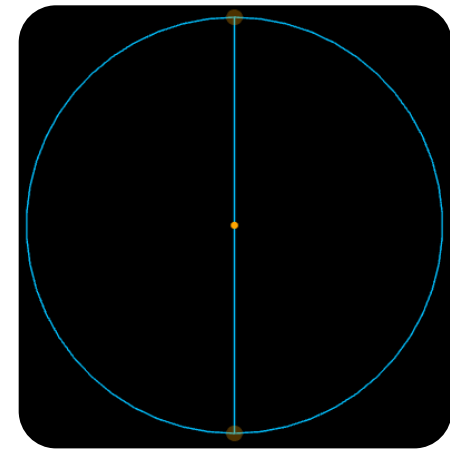
NOTE: To improve measurement precision, it is recommended to use a marker and to accurately superimpose the HEX-ray calibration tool on it.

2. Insert the dimension value (mm) in the Insert Marker Size box



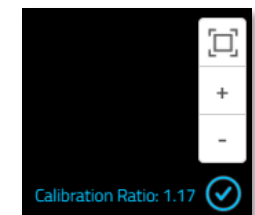
3. Confirm by pressing *Yes* when completed for calibration.

After this confirmation, all measurements will be scaled accordingly to the marker and value provided.



A reminder that calibration has been performed and the calibration ratio will be seen:

- On the workflow progress bar in the Image Tools screen
- In the bottom-right corner of the view in each screen.



NOTE: after calibration of both images, if the difference between values of the two ratios is greater than one, HEX-ray shows a pop up message highlighting the two ratios as in the example pictured on the right. User may need to review and check the performed calibration.

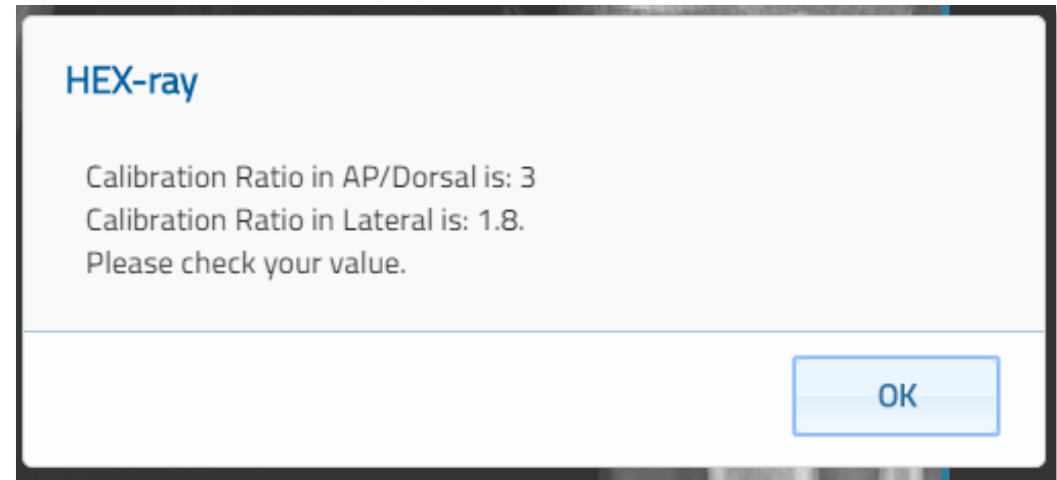


Image Referencing

Deformity case

In the workflow, after calibration of both images, HEX-ray shows the views side by side and prompts the user to place:

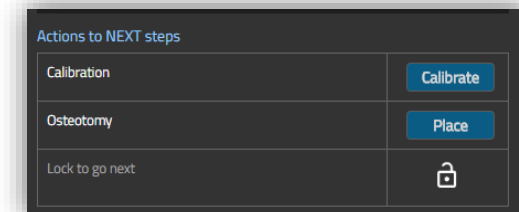
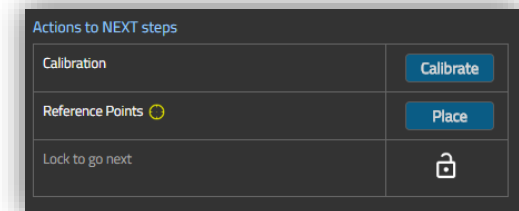
- Reference points for preoperative cases
- Osteotomy for postoperative cases

Alternatively, if user has not used the workflow or wants to place referencing tools again, user can press the Place button.

PREOPERATIVE: Reference Points can be placed everywhere in each view, but they should be at the same level on both views to permit consistent coordination.

POSTOPERATIVE: surgery has already been made and the Osteotomy Line is our "Reference Point" between the views.


In Image Tools, after calibration of both images, user must place **Osteotomy Line overlapping the real one in both views, paying attention to match the bone cortices**, permitting HEX-ray to suggest the axial bone length to avoid segment impingements during treatment.



NOTE: To avoid any risk of misalignment and preventing accidental displacement of already placed reference points/osteotomy, the Image Editing Tools are switched off. User can always turn them on again, if needed, but they will be warned that this action will result in requiring the reference points/osteotomy to be placed again.

Fracture case –Preoperative/Postoperative

For Fracture cases, the Fracture Level of the tools should be placed on each side of the fracture in Deformity Analysis. The Fracture level will work as a reference, resulting in no need to place any reference object at this stage.

User will need to calibrate and, when completed, press on the Lock icon to go to next tab, Deformity Analysis. The icon will change to  and the arrow to proceed will appear on the right.

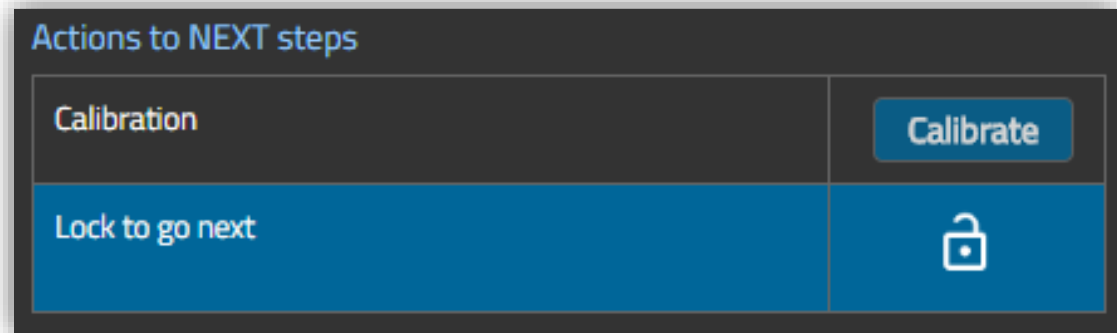
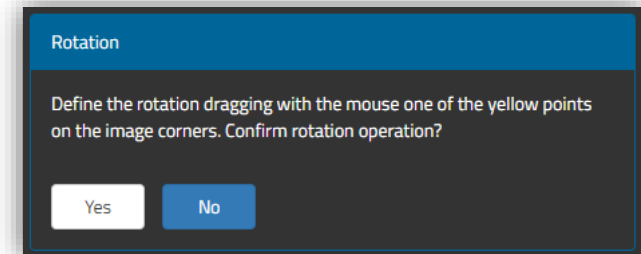


Image Editing Tools

Rotation and Flipping

Image Rotation and **Horizontal/Vertical Flip** are applicable in order to correctly orientate the image, according to Reference Segment position and on-screen desktop labels.

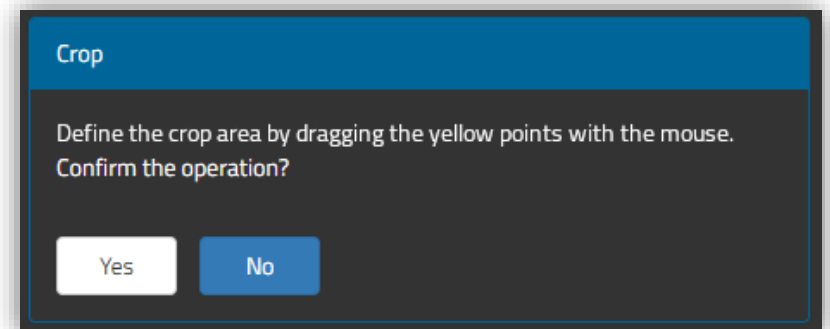
Horizontal and Vertical Flip buttons work directly on the image in the view, while the Rotation button starts a workflow permitting the user to review the image rotation and confirm it to complete the flow.



Crop and Brightness / Contrast

Image Crop and Brightness / Contrast review are applicable.

Brightness and Contrast controls work directly on the image in the view, while the Crop button starts a workflow permitting the user to review the image dimension and confirm it to complete the flow.



DEFORMITY ANALYSIS

There are two sets of tools depending on the Case Type selection present in the TL-HEX Case Data tab:
Deformity or **Fracture**.




Deformity case

Within Deformity Analysis the HEX-ray module will enable the user to:


- **Position the axes tools** according to the deformity, on both views
 - The HEX-ray identifies the **Deformity APEX** in the AP/Dorsal and Lateral views and provides numerical Angular Deformity values in the side table
- **Insert clinical evaluation** results of the **Axial Rotation** and **Translation**
- **View the Suggested Bone Length**
- **Declare completion of the deformity analysis** and data entry secondary to clinical evaluation.
- For Deformity Preoperative cases, **Position the Osteotomy line** on both views



 **NOTE:** Any translation values inserted into TL-HEX prior to the setting of an osteotomy site will be recalculated by HEX-ray once the osteotomy site has been positioned and will be shown in the Deformity Analysis tab.


When considering Deformity cases HEX-ray will automatically calculate the secondary translation values resulting from the deformity apex and the osteotomy site. HEX-ray will not provide a graphical reference of translation. On return to TL-HEX, the translation values will be recorded together with a pure graphic representation of the deformity.

Deformity Analysis tools and value areas for Deformity cases:




BONE SEGMENT AXES SHOW / HIDE
User can hide or show the axes tools anytime


DOWELS SHOW / HIDE
User can show or hide the TL-HEX dowels




LINE
A Line tool the user may use to evaluate lengths of interest. It is possible to use up to 7 tools at the same time



GONIOMETER
A Goniometer tool the user may use to evaluate angles and lengths of interest. It is possible to use up to 7 tools at the same time



DELETE SELECTED OBJECT
When a Line or Goniometer is selected, Delete icon appears permitting to remove the object from the active view



BRIGHTNESS/CONTRAST
User can fine tune the brightness/contrast of the image in the active view

Angular Deformity

Translation

Suggested Bone Length

Rotation

Translation

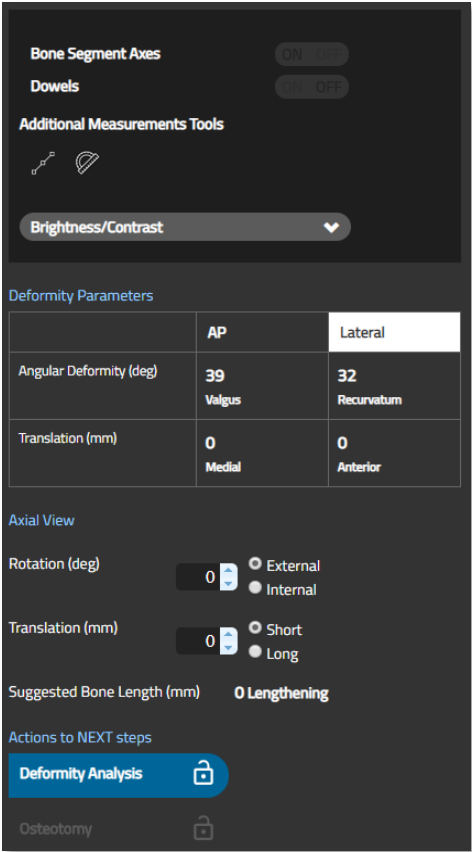
AP/DORSAL AND LATERAL ANGULAR DEFORMITY
AP/Dorsal and Lateral Angular Deformity (degrees) are automatically provided by HEX-ray when the axis tools have been set in the views

AP/DORSAL AND LATERAL TRANSLATION
AP/Dorsal and Lateral Translation (mm) are automatically provided by HEX-ray when the Osteotomy tool has been positioned in the views.

SUGGESTED BONE LENGTH
After the Osteotomy line has been positioned, the Suggested Bone Length is automatically provided by HEX-ray to avoid bone segment impingement during treatment

AXIAL ROTATION
Axial Rotation (degrees) is manually inserted by the user to complete the set of TL-HEX Deformity parameters required to describe the deformity. The rotation value is obtained by the surgeon secondary to clinical evaluation

AXIAL TRANSLATION
Axial Translation (mm) is manually inserted by the user to complete the set of TL-HEX Deformity parameters required to describe the deformity. The translation value is obtained by the surgeon secondary to clinical evaluation.



DEFORMITY ANALYSIS LOCKED / UNLOCKED

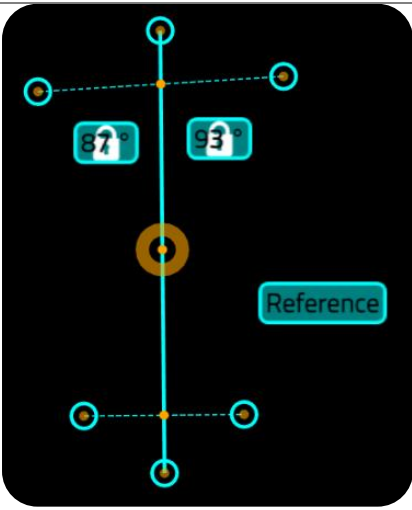
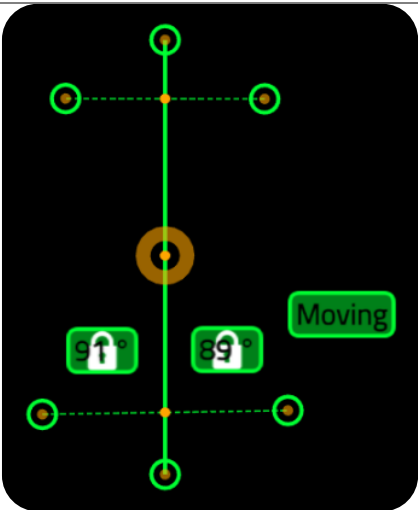
Locking the Deformity Analysis declares completion of the analysis and data entry secondary to clinical evaluation.

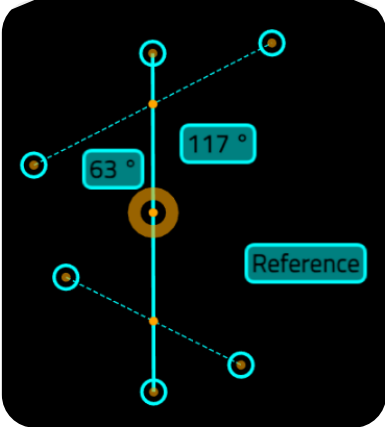
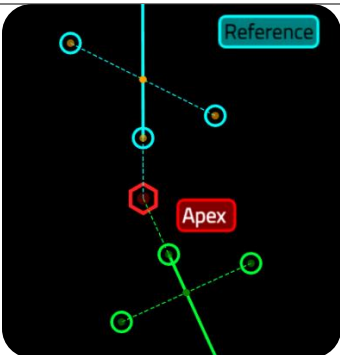
(Preoperative only) OSTEOTOMY LOCKED / UNLOCKED

Locking the Osteotomy declares completion of the preplanning of the osteotomy. When one (Postoperative) or both (Preoperative) are locked the user can access the Correction tab

Axis tool description


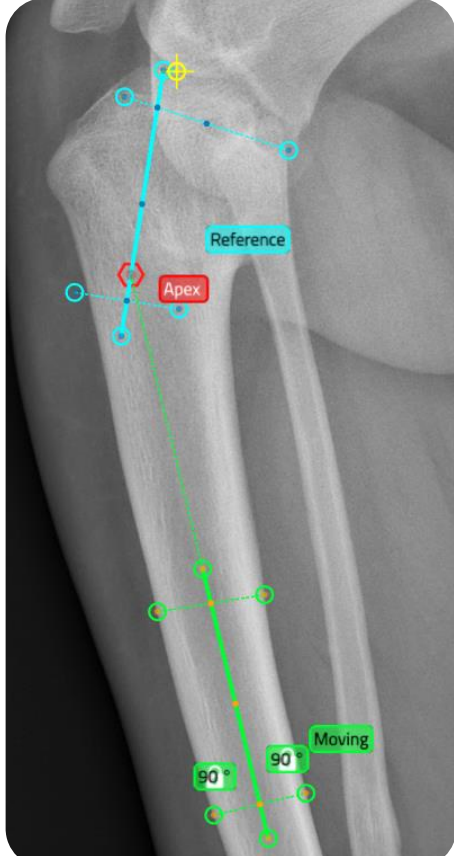
The table below provides additional information about the Axis tool:



<div>Axis Tool</div> <p>The Axis tool has 9 handle points for manipulation.</p> <p>Tools interaction</p> <p>The <i>light blue</i> is the Reference axis tool to be placed on the Reference Segment and the <i>green</i> is the Moving axis tool to be placed on the Moving Segment. A label identifies the axis tool type (Reference or Moving).</p> <p>For Femur and Tibia bone types, the Axis tool is set with the typical <u>anatomical angles</u> of the axis with the corresponding joint line in AP and Lateral views (e.g. in the images Left Tibia Lateral anatomical angles are shown).</p> <p>The Axis tools may be positioned either by <u>moving the solid central line</u> or by <u>adjusting the dashed lines</u> to correspond with the relevant outer cortex.</p> <div><p>NOTE: by pressing the CTRL key or dragging the deformity apex, it is possible to translate or rotate simultaneously both the Axes tools</p></div>	<div></div> <div></div>
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Dashed line behaviour	<p>If anatomical angles are unlocked, any of the six handles along the dashed lines can be selected and dragged in all directions.</p> <p>If anatomical angles are locked (🔒 is present on the labels), the handles at the ends of the dashed lines will extend or reduce the length of the related dashed segment keeping the anatomical angles as they are. The second dashed segment where no angles are identified by labels will be kept orthogonal to the main solid axis line.</p> <p>If anatomical angles are unlocked, handles at the ends of the dashed lines extend or reduce the length of the related dashed segment, allowing the anatomical angles to be modified.</p> <p><u>The axis line automatically moves to always be in the center of the related dashed segments for 1/2 option. In Lateral views, for applicable bone types, also the option 1/3 and 1/5 are available and, when selected, divide the dashed line respectively to 1/3 and 1/5 of the total length.</u></p> <p>Central Handle in the dashed line translates the dashed line along the main solid axis line.</p>	
APEX of the Deformity	<p>The intersection point of the bone segments axis is highlighted with a RED hexagon and the APEX label.</p> <p>The APEX represents the point from which translations are calculated and corrections (angular and translational) applied.</p>	

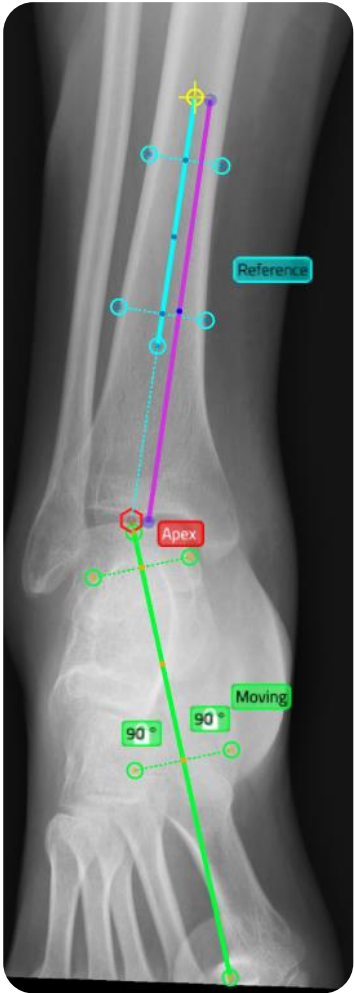
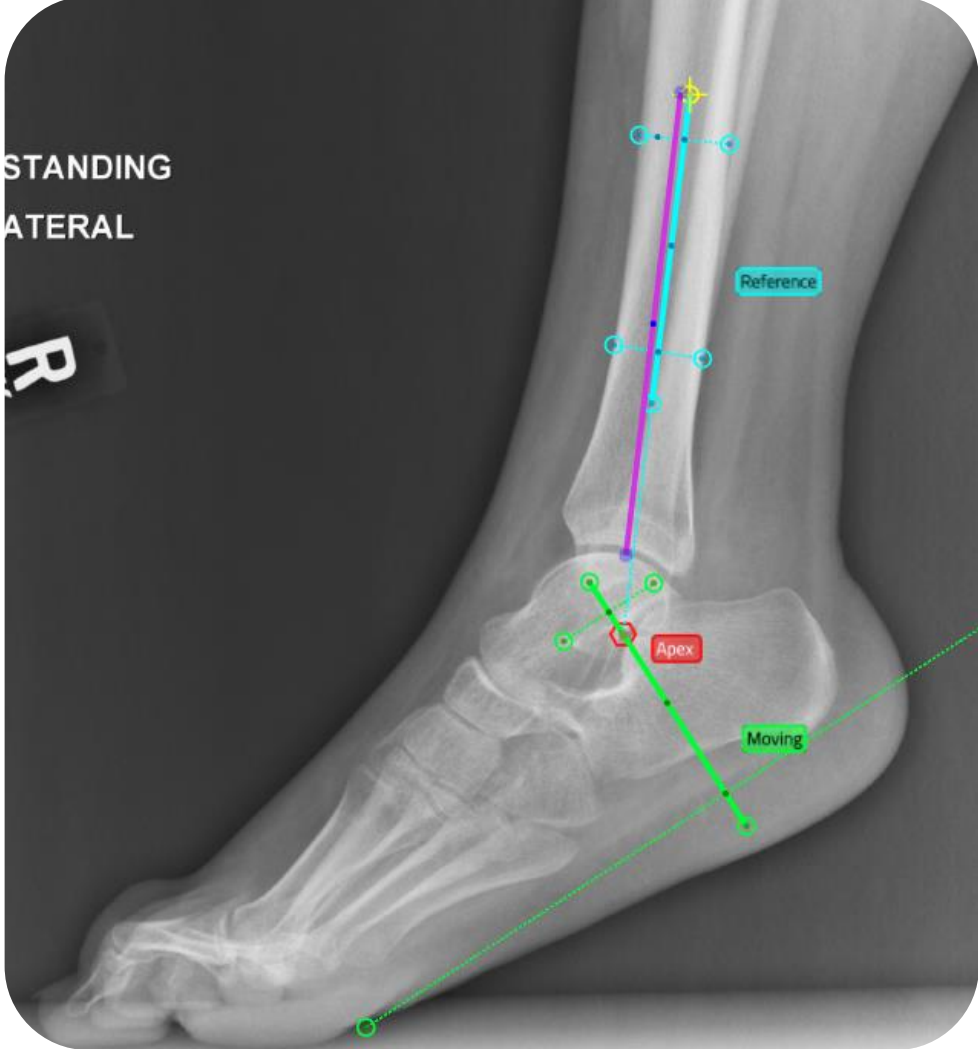
Axis tool interaction

Long Bone – Femur - Tibia

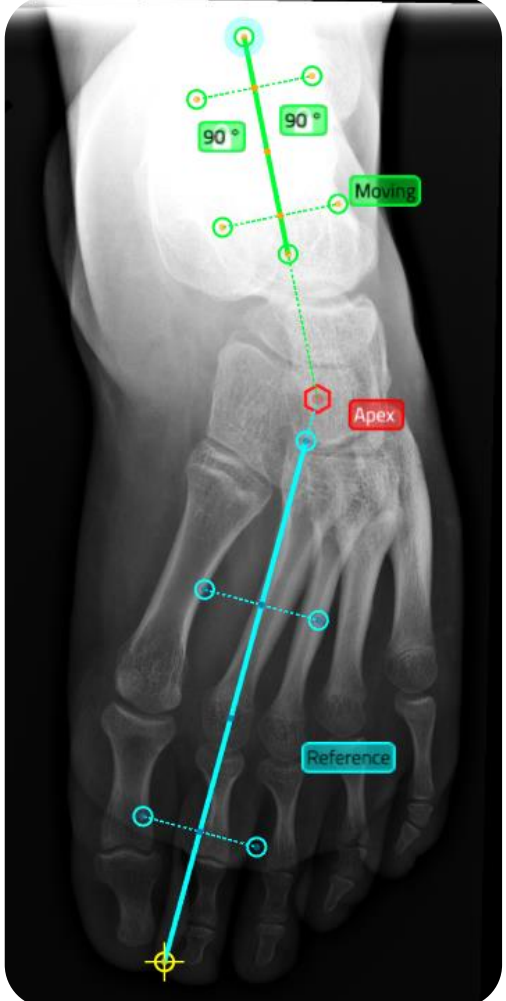
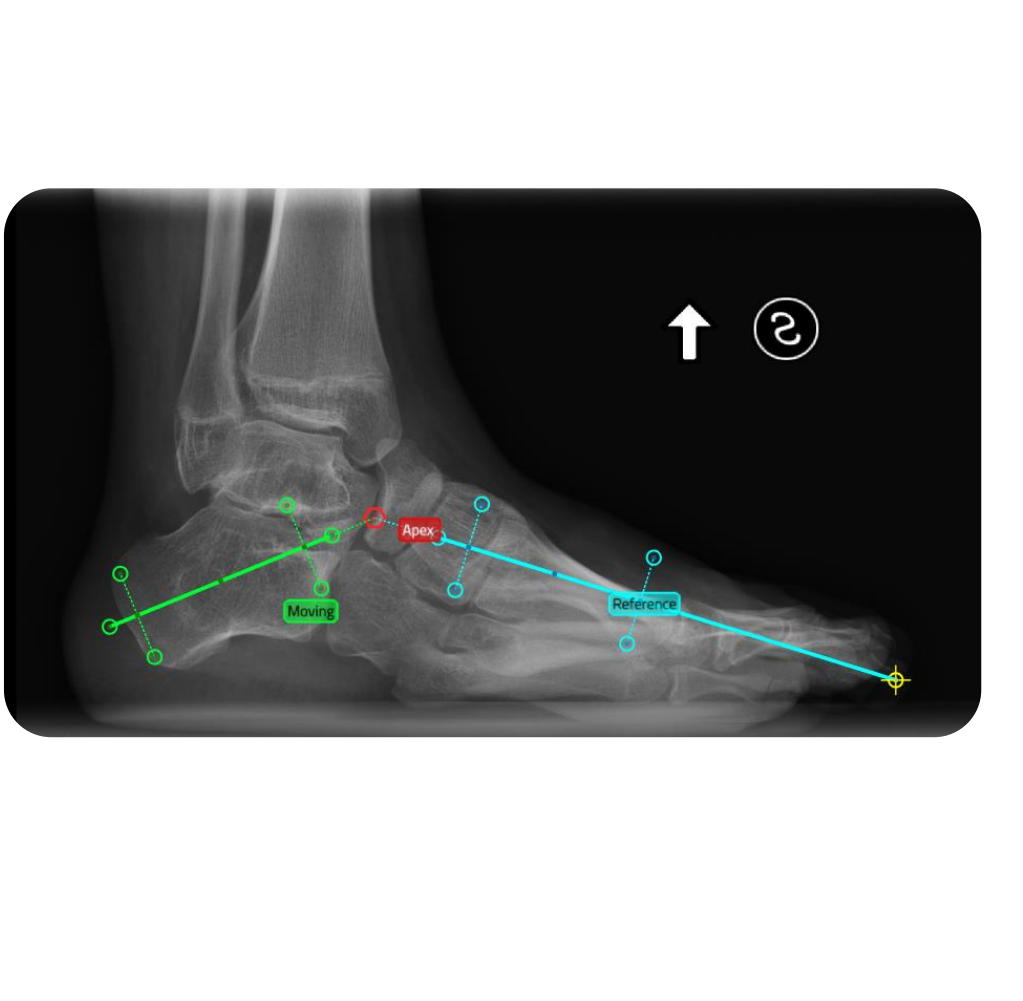
	AP View	Lateral View
<p data-bbox="181 660 215 1070">Long Bone – Metaphyseal deformity</p> <p data-bbox="241 379 969 443">In metaphyseal deformities the Axis tool will assess the relevant joint orientation angles for the:</p> <ul data-bbox="241 453 835 555" style="list-style-type: none"> ▪ Knee joint ▪ Ankle joint ▪ Proximal femur – mechanic and anatomic axis. <p data-bbox="241 600 969 775">In cases of metaphyseal and juxta-articular deformities, a mid-diaphyseal line can be drawn on the diaphyseal side of the APEX but not always on the articular side. Joint line referencing may be helpful in this case. The dashed line should be placed across the relevant joint line.</p> <p data-bbox="241 820 969 959">For Femur and Tibia bone types, the Axis tool is set with the typical Anatomical angles of the Anatomical axis with the corresponding joint line to support Axis tool positioning (e.g. in the images Right Tibia Anatomical angles are shown).</p> <p data-bbox="241 1003 383 1035">See images:</p> <p data-bbox="241 1038 969 1177">The corresponding AP and Lateral views demonstrate how the proximal dashed line of the proximal Axis tool is placed across the tibial plateau. In this case, the axis line of the juxta-articular segment is referenced from the tibial plateau.</p> <p data-bbox="241 1185 969 1249">The distal Axis tool (green) has been positioned with the extremities of the dashed lines aligned with the bone cortices.</p>		

	AP View	Lateral View
<p>Long Bone - Diaphyseal deformity</p> <p>The Diaphyseal deformity is identified by the anatomic axes intersection.</p> <p>In cases of diaphyseal deformity, the anatomic axes are defined by drawing mid-diaphyseal lines with the Axis tools as shown in HEX-ray views.</p> <p>Please observe in the images the positioning of matched reference points on the tibial plateau in orthogonal views.</p>		

Ankle

	AP View	Lateral View
<p>For Ankle cases, the suggested Axis tools are described in the image.</p> <p>A suggested method for proximal referencing is the use of a fixed AP and lateral marker of a set length in both views from the midpoint of the articular surface of the talus proximally.</p> <p>It should be in line with the reference Axis tool and is represented in the adjacent diagrams in purple.</p>		

Foot

	DORSAL View	Lateral View
<p>For Foot cases, the suggested Axis tools are described in the image.</p> <p>Please observe in the images the positioning of matched reference points in orthogonal views.</p>		

Fracture case

Within Deformity Analysis the HEX-ray module will enable the user to:

- **Position the axes tools** according to the bone fragments on both views
 - The HEX-ray provides numerical Angular Deformity and Translation values in the side table
- **Insert clinical evaluation** result of the **Axial Rotation**
- **Declare completion of the fracture analysis** and data entry secondary to clinical evaluation.

Deformity Analysis tools and value areas for Fracture cases:



BONE SEGMENT AXES SHOW / HIDE

User can hide or show the axes tools anytime

AXES DOWELS SHOW / HIDE

User can show or hide representation of the TL-HEX sticks overlapping on the bone segment axes



LINE

The Line tool allows the user to evaluate lengths of interest. It is possible to use up to 7 tools at the same time



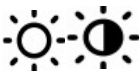
GONIOMETER

The Goniometer tool allows the user to evaluate angles and lengths of interest. It is possible to use up to 7 tools at the same time



DELETE SELECTED OBJECT

When a Line or Goniometer is selected, a Delete icon appears permitting the user to remove the object from the active view



BRIGHTNESS/ CONTRAST

User can fine tune the brightness/contrast of the image in the active view

Angular Deformity

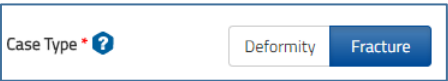
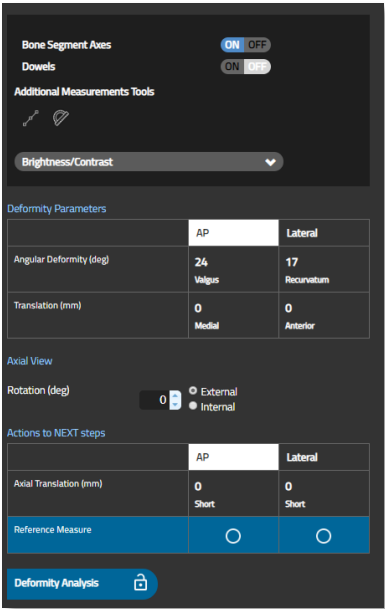
ANGULAR DEFORMITY

AP/Dorsal and Lateral Angular Deformity (degrees) are automatically provided by HEX-ray when the axis tools have been set in the views

Translation

AP/DORSAL AND LATERAL TRANSLATION

AP/Dorsal and Lateral Translation (mm) are automatically provided by HEX-ray when the axis tools have been set in the views



Axial Translation

AXIAL TRANSLATION

AP/Dorsal and Lateral Translation (mm) are automatically provided by HEX-ray when the axis tools have been set in the views.

Rotation

AXIAL ROTATION

Axial Rotation (degree) is manually inserted by the user to complete the set of TL-HEX Deformity parameters required to describe the deformity. The rotation value is obtained by the surgeon secondary to clinical evaluation.

Reference Measure

REFERENCE MEASURE FOR AXIAL TRANSLATION

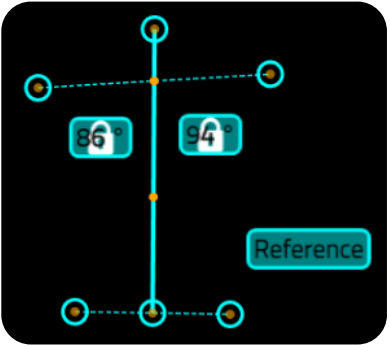
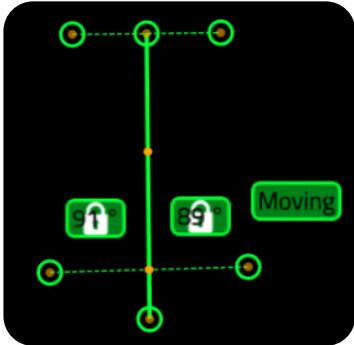
User must select the reference measure/view for Axial Translation value to be considered



DEFORMITY ANALYSIS LOCKED / UNLOCKED

Locking the Deformity Analysis declares completion of the fracture analysis and data entry secondary to clinical evaluation. When Reference Measure is selected and locked the user can access the Correction tab

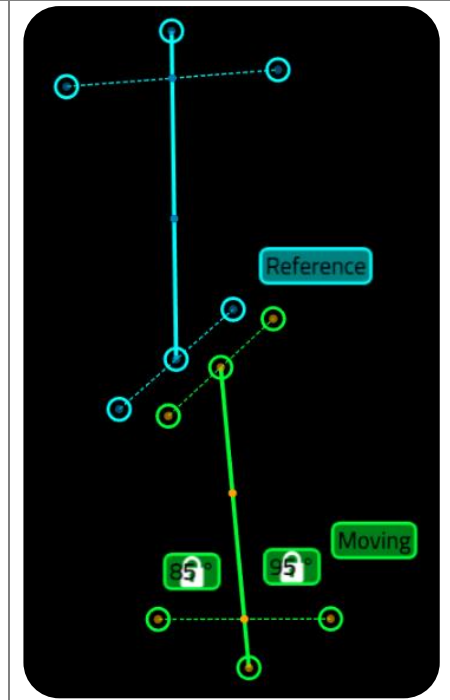
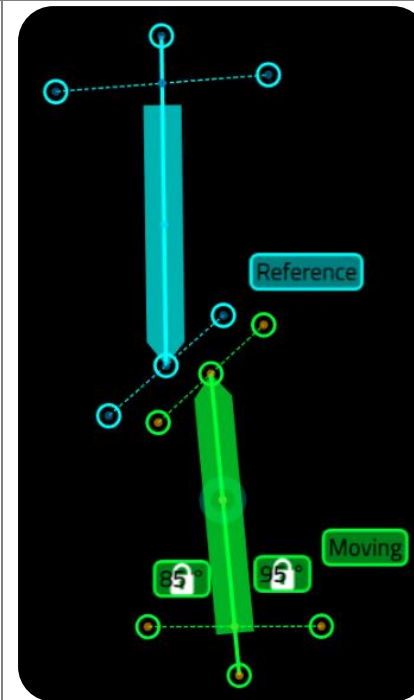
Axis tool description

<p>Fracture Axis tool</p>	<p>For a Fracture case the axis tools have been modified in order to permit using the bottom (for proximal) and top (for distal) by the use of dashed lines to mimic the ends of the bone segments.</p> <p>The Fracture Axis tool has 8 handle points to manage.</p> <p>Tools interaction.</p>		
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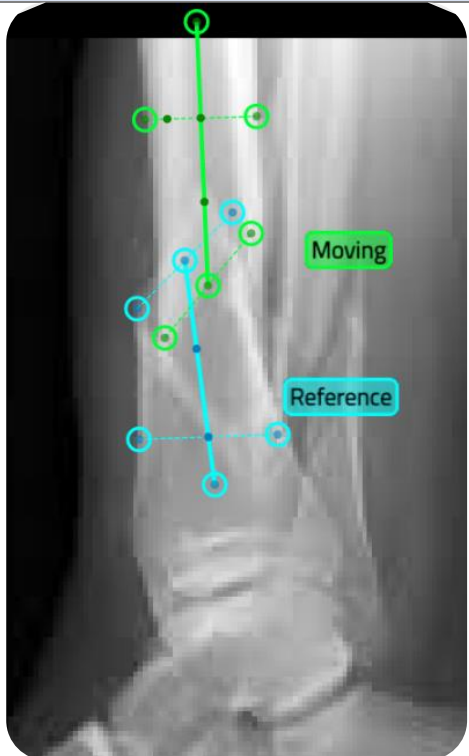
Axis tool Dowels

The Dowels Control depicts dowels representing bone fragments on each axis, as in the TL-HEX software.

The ending point of the Dowel on the Reference axis is the point from which translations are measured and corrections (angular and translational) applied.



Axis tool interaction

		AP View	Lateral View
Fracture	<p>By positioning a dashed line across corresponding fracture ends, the axis line will automatically centralize the Axis tool. With the positioning of the second dashed line at either end of the cortex as described above, HEX-ray will then calculate all the angulation and translation parameter values.</p> <p>The anatomic axis is defined by drawing mid-diaphyseal lines.</p> <p>In reference to the supplied screen grab, the top dashed line of the Reference axis tool mimics the distal part of the fracture, where the bottom dashed line of the Moving axis tool mimics the proximal part of the fracture.</p>		

Line and Goniometer tools

Line and Goniometer Tools are available in the Deformity Analysis, Correction and Mounting Tabs.

The **Line** provides the length (mm) measurement while the **Goniometer** provides both angle (degrees) and length (mm) measurements.

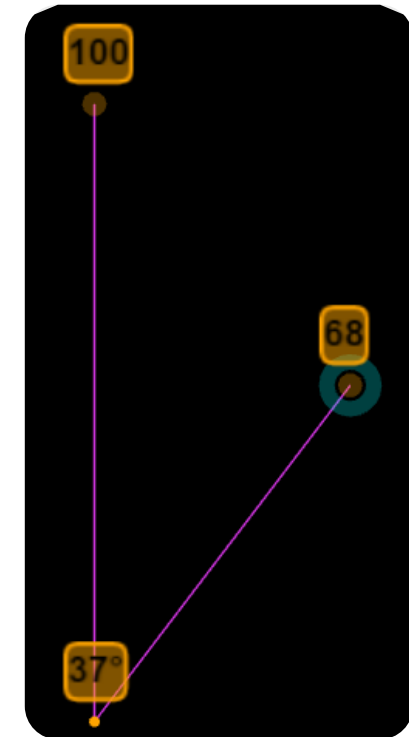
These tools can be used freely and as required in each view.

NOTE: Use of the tools will not affect the definitive case analyses performed on HEX-ray.

The Line and Goniometer tools have three handles to translate, rotate and shrink/enlarge the tool.

It is possible to insert multiple (up to a maximum of seven) lines and goniometers.

To **delete a line or goniometer** select the tool and press on the Delete icon or use the "Del" key.



CORRECTION

Deformity Case

Within Correction analysis the HEX-ray module will enable the user to:

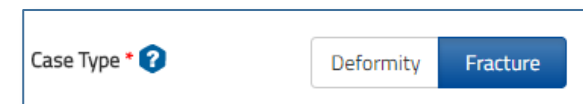
- **Review and fine tune** the proposed Correction to **the desired End Of Correction**
- **Insert the Axial Rotation** after clinical evaluation
- **Apply the Suggested Bone Length** calculated to avoid bone fragment impingements
- **Fine tune the Bone Length** to the desired value
- **Declare completion** of the correction analysis and data entry secondary to clinical evaluation.



Fracture Case

Within Correction analysis the HEX-ray module will enable the user to:

- **Review and fine tune** the proposed Correction to **the desired End Of Correction**
- **Insert the Axial Rotation** after clinical evaluation
- **Fine tune the Bone Length** to the desired value
- **Declare completion** of the correction analysis and data entry secondary to clinical evaluation.



Correction Analysis tools and values areas:



AXES DOWELS SHOW / HIDE

User can show or hide representation of the TL-HEX sticks overlapping on the bone segment axes

OSTEOTOMY LINE SHOW / HIDE

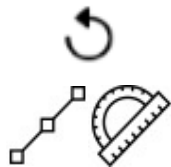
User can hide or show the osteotomy line anytime. Available only for Deformity cases.

CORRECTION ANALYSIS ON / OFF

User can assess and fine-tune the desired End of Correction.

RESET CORRECTION

User can reset the moving area position to the last saved values



LINE/ GONIOMETER

A Line or Goniometer tool the user may use to evaluate lengths and angles of interest. It is possible to use up to 7 tools at the same time.

DELETE SELECTED OBJECT

When a Line or Goniometer is selected, Delete icon appears allowing the user to cancel the object from the active view



BRIGHTNESS/CONTRAST

User can fine tune the brightness and the contrast of the image in the active view

OVER ANGULATION

AP/Dorsal and Lateral Over Angular (degrees) are 0 by default (Lateral is 37° for Foot cases) and are automatically provided by HEX-ray when the desired End of Correction has been fine-tuned graphically or, vice versa, user can enter the EOC values and see the effects on the image of the related view

Over Angulation

OVER TRANSLATION

AP/Dorsal and Lateral Over Translation (mm) are 0 by default and are automatically provided by HEX-ray when the desired End of Correction has been fine-tuned graphically or, vice versa, user can enter the EOC values and see the effects on the image of the related view

Over Translation

AXIAL ROTATION

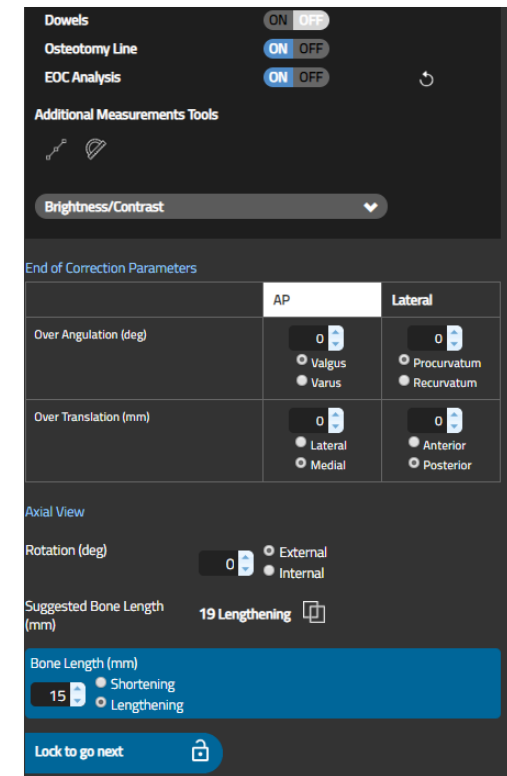
Axial Rotation (degree) is manually inserted by the user to complete the set of TL-HEX Deformity parameters required to describe the deformity. The rotation value is obtained by the surgeon secondary to clinical evaluation

Rotation

SUGGESTED BONE LENGTH (Deformity Cases only)

After the Osteotomy line has been positioned, the suggested Bone Length is automatically provided by HEX-ray to avoid bone segment impingement during treatment.

Suggested Bone Length



SUGGESTED BONE LENGTH COPY (Deformity Cases only)

The automatically provided Suggested Bone Length value may be copied by the user into the Bone Length field

Bone Length

BONE LENGTH

Bone Length to be used in the TL-HEX treatment calculation



BONE LENGTH LOCKED / UNLOCKED

Locking the Bone Length declares completion of the correction analysis. After locking, the user will gain access to the Mounting tab.

Angular Deformity	<p>AP/DORSAL AND LATERAL ANGULAR DEFORMITY</p> <p>AP/Dorsal and Lateral Angular Deformity (degrees) are provided by HEX-ray in the Deformity Analysis and reported here for reference.</p> <p>AP/DORSAL AND LATERAL TRANSLATION</p> <p><u>Deformity Case:</u> AP/Dorsal and Lateral Translation (mm) are automatically provided by HEX-ray when the Osteotomy tool has been positioned in the views.</p>
Translation	<p><u>Fracture Case:</u> AP/Dorsal and Lateral Translation (mm) are provided by HEX-ray in the Deformity Analysis and reported here for reference.</p>
Rotation	<p>AXIAL ROTATION</p> <p>Axial Rotation (degree) is defined in the Deformity Analysis and reported here for reference.</p>
Translation	<p>AXIAL TRANSLATION</p> <p>Axial Translation (mm) is defined in the Deformity Analysis and reported here for reference.</p>

Deformity Parameters		
	AP	Lateral
Angular Deformity (deg)	39 Valgus	32 Recurvatum
Translation (mm)	0 Medial	0 Posterior
Axial View		
Rotation (deg)	0 External	
Translation (mm)	0 Short	

Deformity case interaction

Suggested Bone Length in Deformity Analysis tab is a result of the placement of Osteotomy line in:

- Preoperative: Deformity Analysis tab
- Postoperative: Image Tools tab



In both cases, the Osteotomy line should be positioned in the desired position or on the real one on the images, paying attention to match the bone cortices, permitting HEX-ray to suggest the axial bone length to avoid segment impingement during treatment.

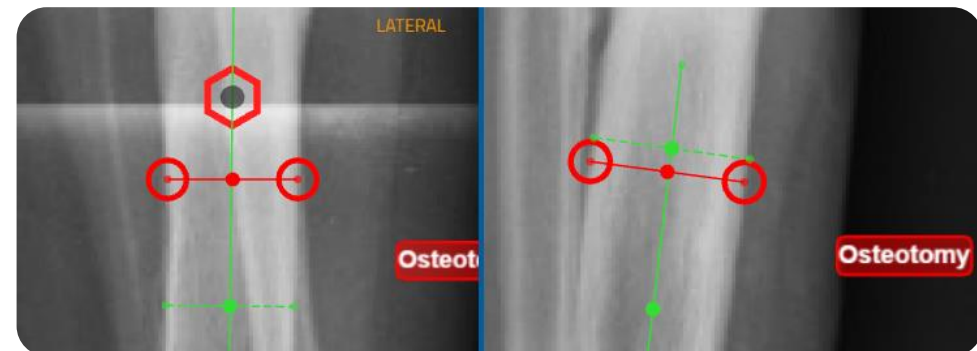
In Preoperative cases, any alteration of the Osteotomy position in one view will result in a coordinated move in the orthogonal plane in accordance with the Reference Points set in the Image Tools tab.

The **axial bone length suggested by HEX-ray** to avoid segment impingements during treatment considers the following:

- Angular Deformity
- Osteotomy length, inclination angle, distance from the APEX
- Default EoC position


The suggested bone length value is calculated based on both AP/Dorsal and Lateral views and the highest value is shown.


If the Osteotomy is not perfectly perpendicular to the bone axis, this value might be overestimated.



NOTE: It is recommended to review the value with the End of Correction analysis before continuing.



It is possible to *copy the Suggested Bone Length* value found inside the Bone Length field any time by clicking on the  icon. The Bone Length may be manually fine-tuned.

It is possible to review the Osteotomy Line placement by going back to the Image Tools or Deformity Analysis tab. The Suggested Bone Length will be recalculated according to the chosen stage of correction. Unlocking this tab and changing these parameters may result in a reset of the Correction analysis already done on HEX-ray. If the Correction Analysis has been completed (see Correction Analysis) and Axial Rotation has been clinically evaluated and entered, clicking on the  icon will declare activity completion and permit HEX-ray to move forward in the flow (blue arrow).

Fracture case interaction


Case Type * ?

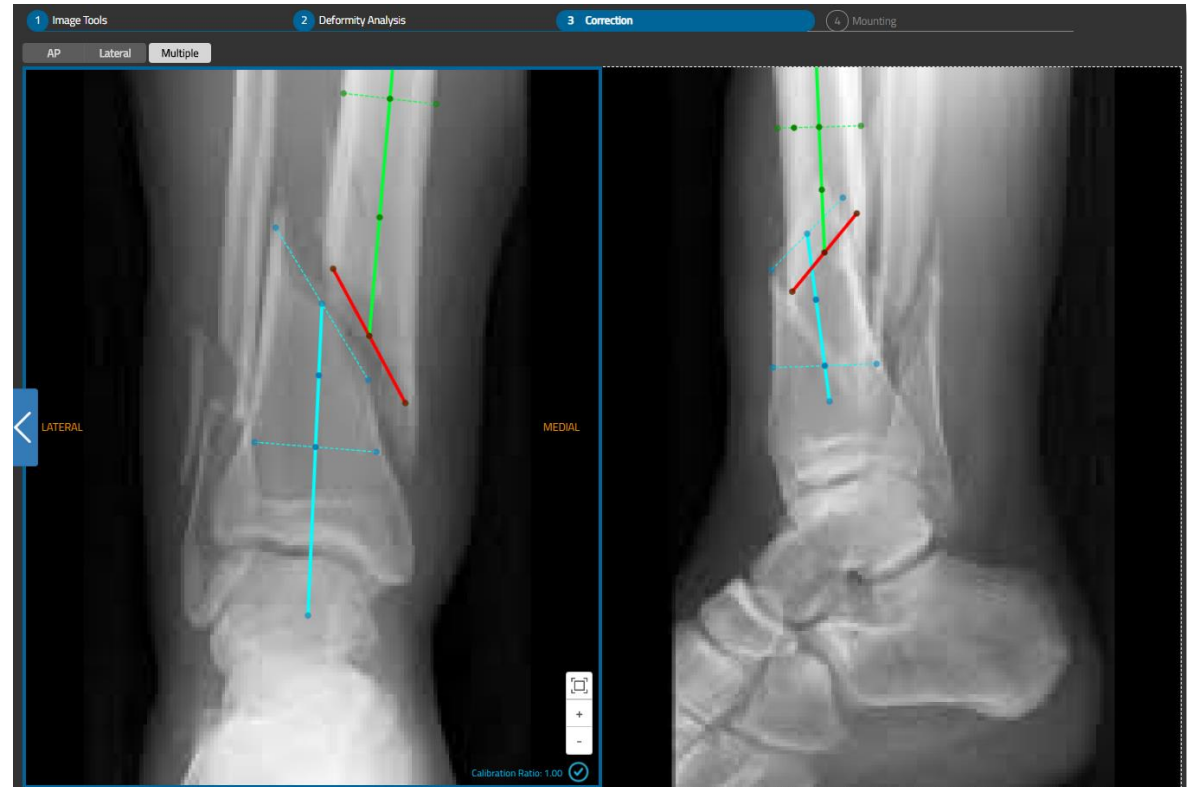
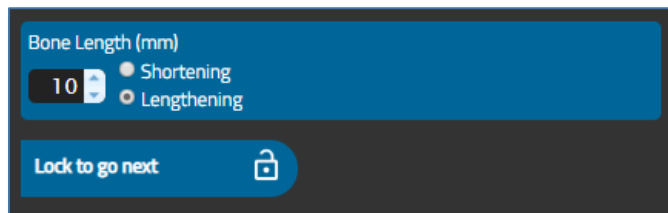
Deformity

Fracture

The **Fracture Level line (red)** is positioned on the **Moving Axis** tool as shown in the screen grab.

If the Correction Analysis has been completed (see Correction Analysis) and Axial Rotation has been clinically evaluated and

entered, clicking on the  icon will declare activity completion and permit HEX-ray to move forward in the flow (blue arrow).



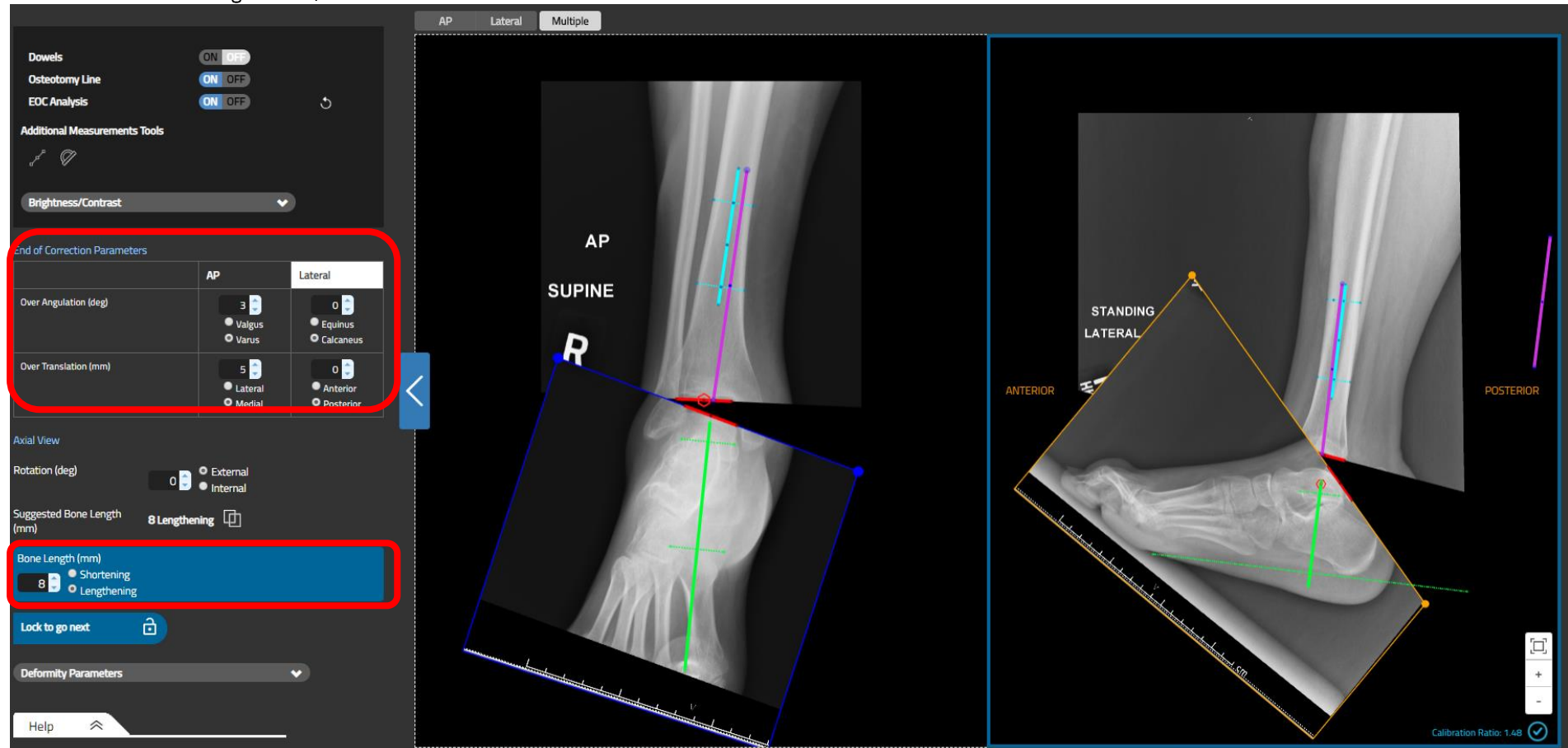
Correction Analysis

Hex-ray enables (by default) the option to visualize and review the End Of Correction on both views simultaneously.



EOC Analysis

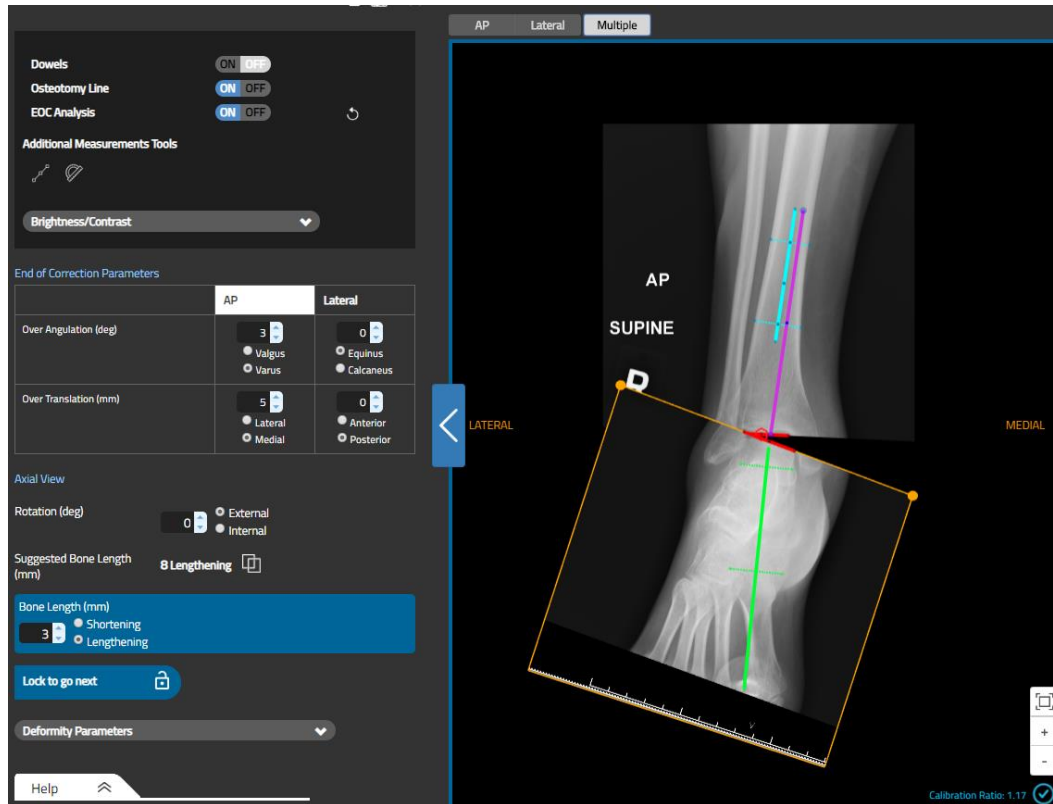
ON OFF


The moving area of the x-ray image is automatically defined by HEX-ray as the portion of the image where the moving segment lies. HEX-ray will automatically apply, on both views, the translation and angulation required to achieve the End of Correction and Bone Length (parameters in the red boxes in the image below).

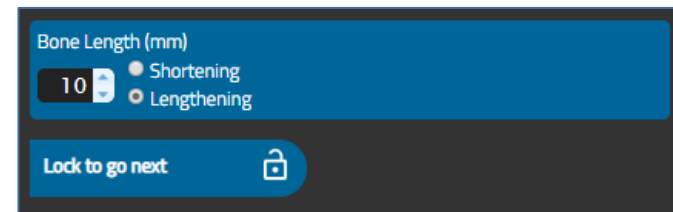



End of Correction parameters can be edited in two ways:

- 1) Using whole moving area to translate (mouse pointer becomes ) or the yellow handles on the corner to rotate (mouse pointer becomes ) , it is possible to manually adjust the End Of Correction. The **corresponding angulation and translation values are updated accordingly** in the related fields (red highlighted fields).
- 2) Editing the values in the End of Correction parameters table fields will update the moving area position accordingly.



When the desired End of Correction has been set in both views, click on the  icon to declare activity completion and permit HEX-ray to move forward in the flow (blue arrow).



NOTE: The End Of Correction analysis is active only when the lock icon is unlocked ().

Correction review reset

Pressing the  icon at any time during the End of Correction review, will **reset the moving area position to the last saved values**.

MOUNTING

Preoperative Planning

The Mounting in Preoperative Planning HEX-ray module will enable the user to:

- **Select Proximal and Distal supports**
- **Position the Proximal and Distal supports** along the relative axis
 - The HEX-ray provides the appropriate support position relative to the Osteotomy / Fracture Level
- **Angulate and / or Translate the Reference Ring** (blue) at the desired value
 - The HEX-ray provides the support Angle and/or Translation values relative to the Reference axis.

Mounting tools and value areas for Preoperative Planning:

Proximal and
Distal Support



PROXIMAL AND DISTAL SUPPORT

User can select the TL-HEX proximal and distal supports as required

RINGS SHOW / HIDE

User can hide or show the supports 3D model at anytime



DEFORMITY ONLY

ORIENTATION LINE SHOW / HIDE (AP/Dorsal – Lateral)

User can show or hide orientation line with measurements on each view

DEFORMITY ONLY

PRINT PREOPERATIVE PLANNING DOCUMENT WITH X-RAYS

User can print a pdf with Reference Ring Mounting parameters, orientation line with measurements, x-rays and other custom lines

Print your Plan



LINE

A Line tool the user may use to evaluate lengths of interest. It is possible to use up to 7 tools at the same time



GONIOMETER

A Goniometer tool the user may use to evaluate angles and lengths of interest. It is possible to use up to 7 tools at the same time

Angle

Print your Plan

Proximal Support
Full Ring - 140mm

Distal Support
5/8 Open Anteriorly Ring - 120mm

Rings ☒ ON ☐ OFF

Orientation Line ☒ ON ☐ OFF AP ☒ ON ☐ OFF Lateral

Additional Measurements Tools
Brightness/Contrast

Reference Ring Parameters

	AP	Lateral
Translation (mm)	0 Lateral	0 Posterior
Angle (deg)	0 Medial Side Up	0 Anterior Side Up

Axial View

Rotation (deg) 0 Internal

Rings Position Relative To Osteotomy / Fracture Level

Reference Ring Position (mm) 50 Distal

Second Ring Position (mm) 50

REFERENCE RING ANGLE

Reference Ring Angle (deg) is automatically provided by HEX-ray relative to the Reference axis



DELETE SELECTED OBJECT

When a Line or Goniometer is selected, Delete icon appears permitting the user to delete the object from the active view



BRIGHTNESS/ CONTRAST

User can fine tune the brightness/contrast of the image in the active view

Translation

REFERENCE RING TRANSLATION

Reference Ring Translation (mm) is automatically provided by HEX-ray relative to the Reference axis



PLAN YOUR FRAME

User enters mandatory schedule parameters and the tool calculates and shows the number of strut adjustments and exchanges and (if present) potential impingements or out of range struts.

Rotation

REFERENCE RING ROTATION

Reference Ring Rotation (deg) is automatically provided by HEX-ray relative to the selected supports

Reference
Ring Position

REFERENCE RING POSITION

Reference Ring position is automatically provided by HEX-ray relative to the Osteotomy / Fracture Level

Second Ring
Position

SECOND RING POSITION

Second Ring position is automatically provided by HEX-ray relative to the Osteotomy / Fracture Level

Postoperative Assessment

The Mounting Postoperative Assessment HEX-ray module will enable the user to:

- **Select Proximal and Distal supports**
- **Position the Reference Ring (blue)** along the relative axis
 - The HEX-ray identifies the appropriate support position relative to the Osteotomy / Fracture Level
- **Angulate and / or translate the Reference Ring (blue)** at the desired value
 - The HEX-ray identifies the support Angle and/or Translation values relative to the Reference axis
- **Rotate the Reference Ring (blue)** at the desired value
- **Manipulate Position and Rotation of the Reference Ring with uncoordinated views** (in situations where there is a mismatch between the ring model and acquired x-rays secondary that do not match the x-ray requirements)
 - The HEX-ray uses the value from the selected view.

Mounting tools and value areas for Postoperative Assessment:

Proximal Support [PROXIMAL SUPPORT](#)
User can select the TL-HEX proximal support

Distal Support [DISTAL SUPPORT](#)
User can select the TL-HEX distal support



[RINGS SHOW / HIDE](#)

User can hide or show the 3D model supports at anytime

[SYNC RINGS ON / OFF](#)

User can un-sync or re-sync the Reference Ring and its coordinated values at any time



[BRIGHTNESS/ CONTRAST](#)

User can fine tune the brightness/contrast of the image in the active view

Translation

[REFERENCE RING TRANSLATION](#)

Reference Ring Translation (mm) is automatically provided by HEX-ray relative to the Reference axis

POSTOPERATIVE

PREOPERATIVE

Proximal Support

Full Ring - 140mm

Distal Support

Full Ring - 140mm

Rings

ON OFF

Sync Rings

ON OFF

Additional Measurements Tools

Brightness/Contrast

Reference Ring Parameters

	AP	Lateral
Translation (mm)	2 Lateral	14 Anterior
Angle (deg)	15 Medial Side Down	0 Anterior Side Down

Axial View

Rotation (deg)

0

External

Internal

Rings Position Relative To Osteotomy / Fracture Level

Reference Ring Position (mm)

19 Distal

Angle

[REFERENCE RING ANGLE](#)

Reference Ring Angle (deg) is automatically provided by HEX-ray relative to the Reference axis

[REFERENCE RING ROTATION](#)

Rotation

Reference Ring Rotation (deg) is automatically provided by HEX-ray relative to the selected supports and the user may manually fine-tune

Reference
Ring
Position

[REFERENCE RING POSITION](#)

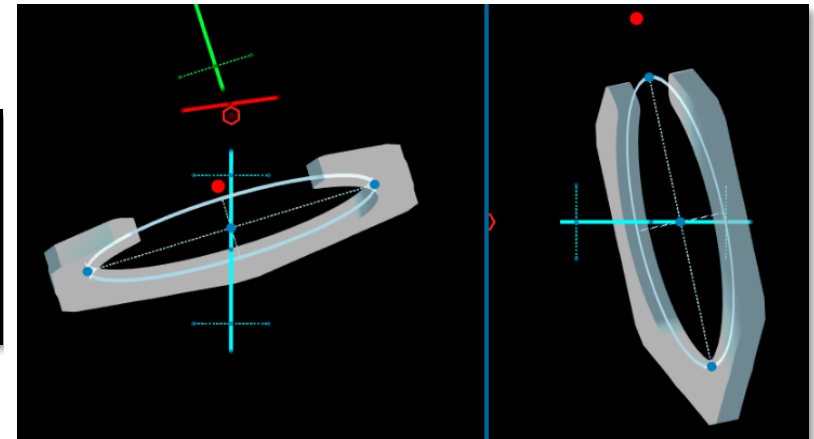
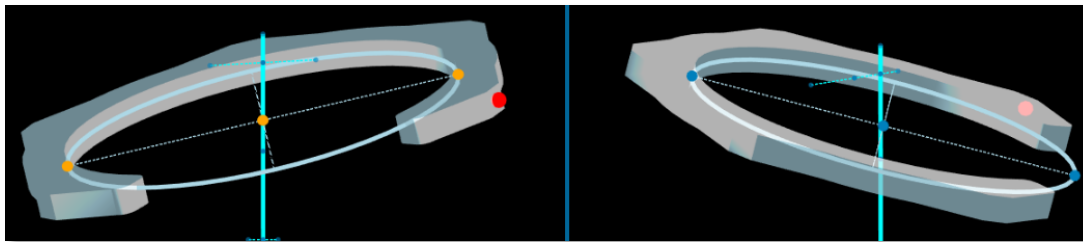
Reference Ring position is automatically provided by HEX-ray relative to the Osteotomy / Fracture Level

General interaction

Any movement of the Reference Ring is coordinated across all views. For example, fine-tuning the position or angulation of a support is automatically represented with a coordinated change in other view.

HEX-ray provides a consistent frame mounting representation with TL-HEX. In particular:

1. For **Long Bone / Femur / Tibia and Ankle bone types** the Reference Segments are placed parallel to each other in both the views
2. For **Forefoot and Hindfoot** the Reference Segment is placed orthogonal to each other.

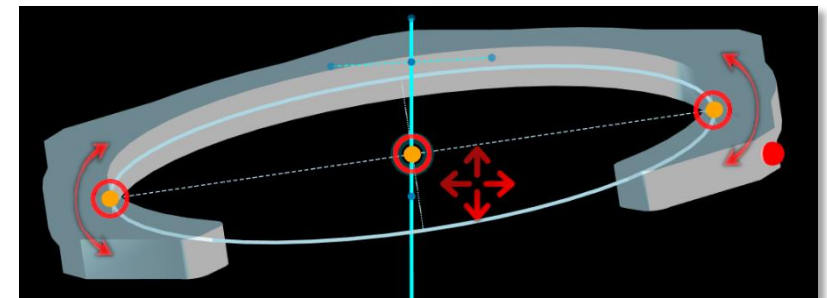


The support 3D model handles are identified by orange dots.

The image shows the handle location (red circles) and the Ring Orientation Tab (red dot). A support angulation, translation and position may be changed by interacting with the support model handles on the selected view.

The Ring Orientation Tab position depends on the support configuration selected.

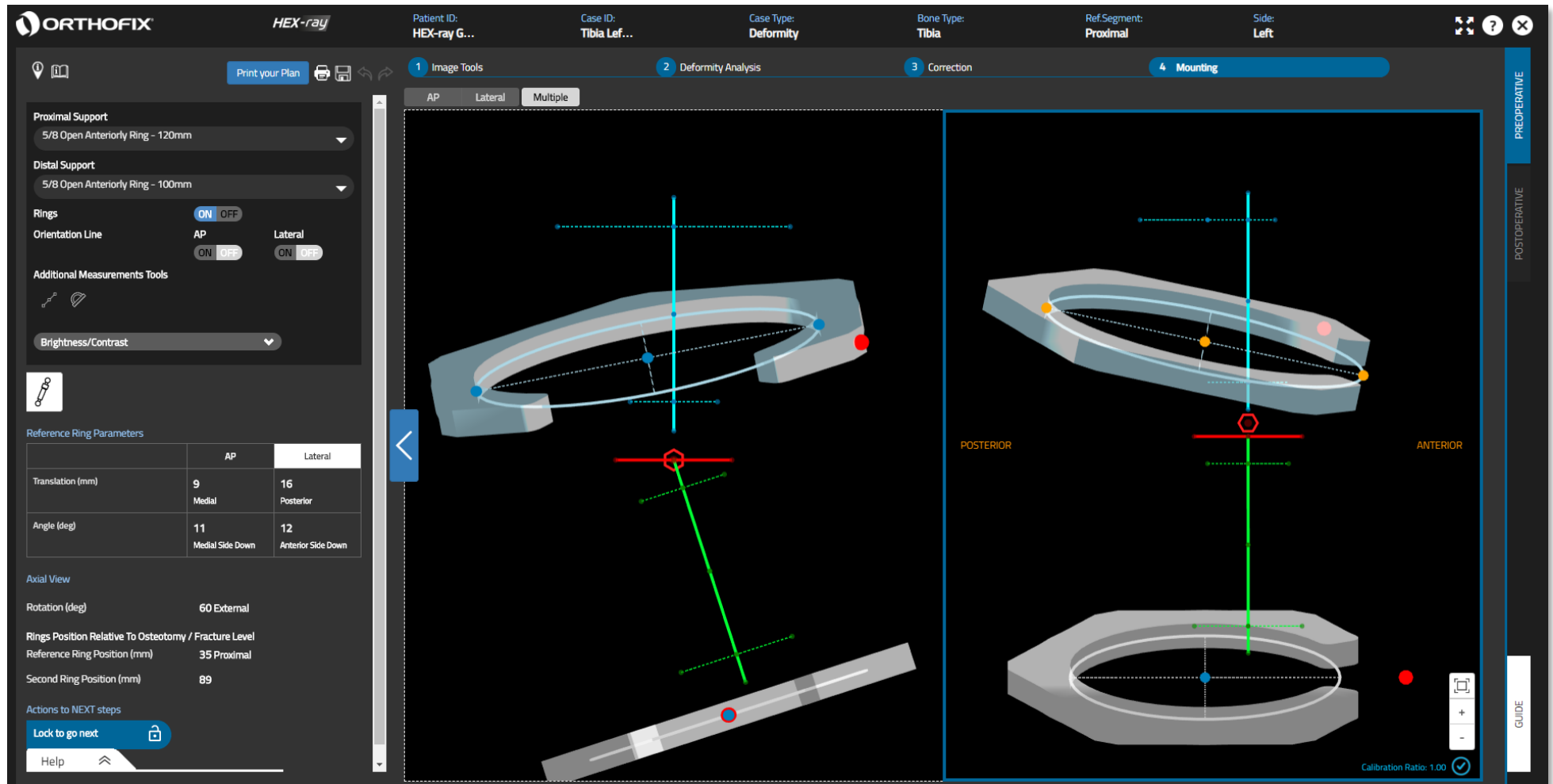
NOTE: It is possible to translate the support by clicking anywhere on its 3D model.



Preoperative Planning

HEX-ray provides a consistent frame mounting representation and rules with TL-HEX.

In addition to the General Interaction information, during the Preplanning stage both selected supports are visible, however, only the Reference Ring may be angulated and translated. In considering any modifications to the Second Ring, only its position relative to the Osteotomy / Fracture level may be fine tuned.



Orientation Line

For each view, user can choose to show an orientation line (in yellow) which appears on the reference segment and can be adapted and superimposed on the x-ray on a level chosen from the user and easily identifiable in the operating room.

The tool shows the measurements from the point of the line crossing the reference segment to:

- 1) The point of the osteotomy crossing the reference segment
- 2) The point of the reference ring crossing the reference segment

These measures are also shown on the preop plan document along with the x-rays and mounting parameters in order to give an overview of the planning done on the software before surgery.

Plan your Frame

This powerful tool gives the possibility to see, having entered the needed mandatory schedule parameters, the number of strut adjustments/exchanges the treatment will have and allows the user to plan the mounting of the frame directly on x-rays.

Hit Calculate or directly drag and move rings on the scenes to preplan the building of the frame and to see a simulation of the struts adjustments and/or exchanges. Try to minimize the number of adjustments/exchanges.

This feature will warn about the presence of potential strut impingements or out of range errors at this stage.

	1	2	3	4	5	6
Struts						
Exchanges	-	1	-	1	-	-
Adjustments	-	1	-	-	-	-

Print your Plan (Apply the frame)

An accurate preplanning is the key to reducing surprises in surgery. The “Print your Plan” functionality allows the user to print the preoperative x-rays with the following calculated parameters in one single page .pdf:

- 1) Details about the patient and case
- 2) (if shown on the view) Orientation Line measurements to osteotomy and reference ring
- 3) Reference Ring Mounting Parameters
- 4) AP/Dorsal and Lateral X-ray screenshots with the built frame on, (if shown) orientation line and (if added) custom lines with measurements

This document can be completed by printing a second one-page pdf (Print your Plan – Build the frame) printable from TL-HEX schedule screen where information about patient and case, calculated preoperative struts for the current frame and TL-HEX graphics are shown.

ORTHOFIX TL-HEX

Patient ID: HEX-ray Guide

Case ID: Ankle
Case Description:

Bone Type: Ankle
Side: Right

Frame ID: N/A

Apply the Frame

Reference Ring: Proximal

Distances from REFERENCE ORIENTATION LINE

	AP	Lateral
Reference Ring (mm)	82	77
Osteotomy (mm)	3	8

Reference Ring	AP	Lateral
Translation (mm)	0 Lateral	0 Anterior
Angulation (deg)	8 Medial Side Up	5 Anterior Side Down
Axial Rotation (deg)	0 External	

Preop Plan

Print date: 13/1/2020, 15:48:09

ORTHOFIX TL-HEX

Patient ID: HEX-ray Guide
Date of Surgery: 01/13/2020, 3:52:05 PM

Case ID: Ankle
Case Description:

Bone Type: Ankle
Side: Right

Frame ID: N/A

Build the Frame

Reference: Proximal

Proximal Support:
Full Ring - 140mm

Distal Support:
Foot Plate - 200mm

1 : Red	2 : Orange
Size A G	Size A G
Long 35 1	Long 1 1

3 : Yellow	4 : Green
Size A G	Size A G
Long 39 80	Medium 23 35

5 : Blue	6 : Purple
Size A G	Size A G
Medium 30 35	Long 0 10

AP view

Lateral View

Preop Plan

Print date: 01/13/2020, 3:52:05 PM

Postoperative Assessment

HEX-ray provides a consistent frame mounting representation and rules as TL-HEX.

In addition to the General Interaction information, during the Postoperative stage only the selected Reference Ring is visible in the views and may be angulated, translated and rotated. The Rotation is fine tuned using the spinner on the side table (or manually inserting a value in the input field).

Since the Reference Ring movements are coordinated between the views, the user must match the ring model to the Reference Ring on the x-ray images simultaneously in both the views.

HEX-ray provides the angulation and translation values in relation to the Reference Segment to be used for the TL-HEX treatment calculation.

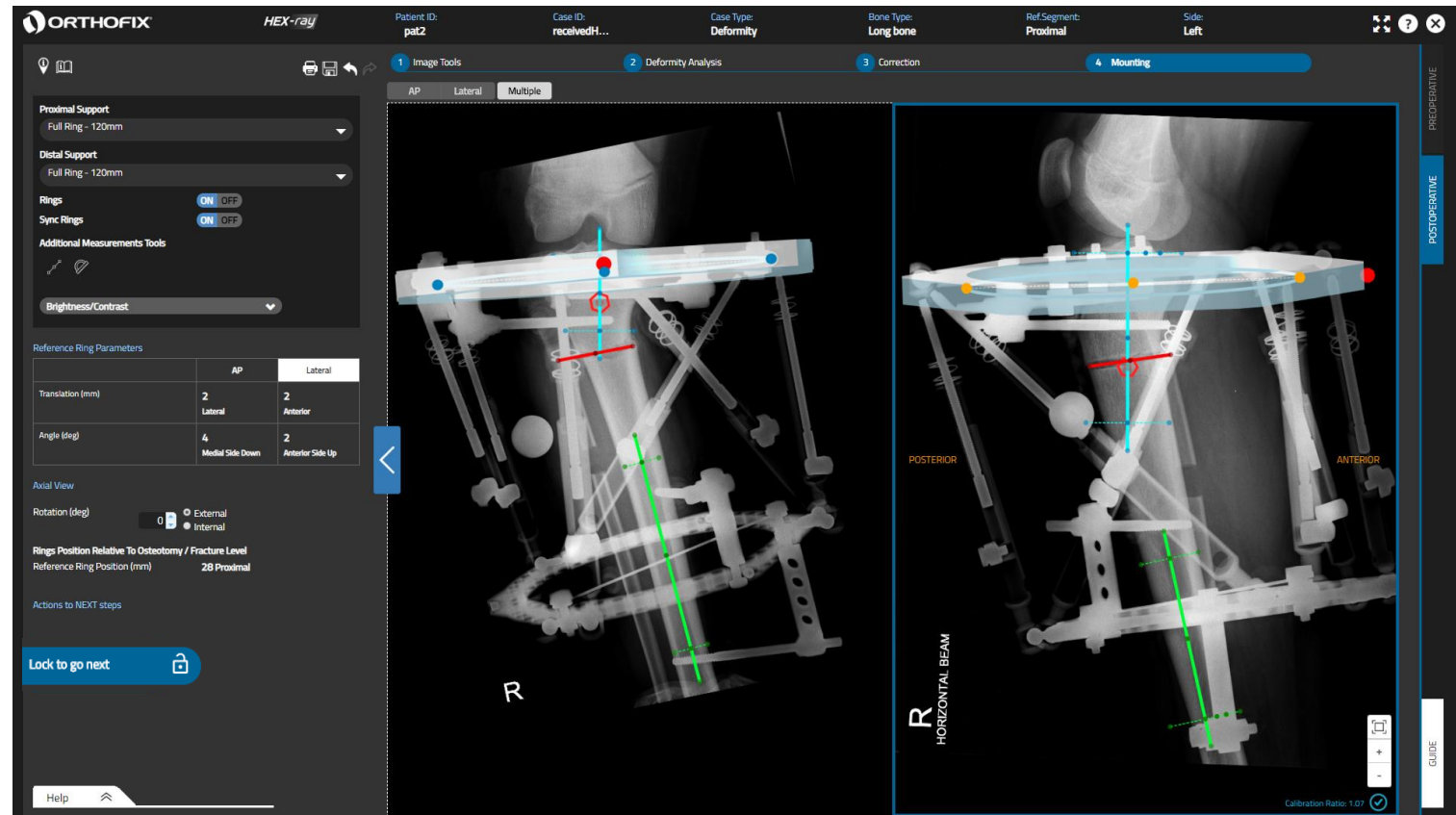
When Postoperative assessment has been completed, click on the



icon to declare activity completed and permit HEX-ray to save and move back to TL-HEX (blue arrow) or simply click the



icon to exit HEX-ray, and save and import the data in the TL-HEX software.




Reference Ring model not matching the actual x-ray images perfectly


X-ray images should be taken in accordance with the following instructions:

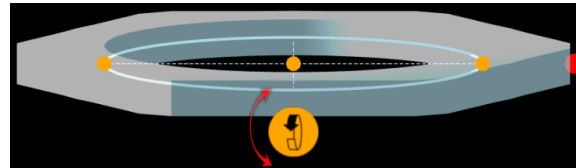
- The Reference Segment in the x-ray image must be perpendicular to the beam, in both views
- Orthogonal (90°) x-ray images are required

In case these instructions are not followed, the HEX-ray Reference Ring model will not match the actual x-ray image perfectly on both views.


To overcome this situation HEX-ray allows for independent movement of the Reference Ring models between both views.


To activate this feature, **switch OFF the Sync Rings** option  permitting the user to alter the desired Reference Ring position to match the actual x-ray image in either view independently.

With the  icon present on the 3D ring model, it is possible to tilt the Reference Ring on the Coronal (Frontal) and Sagittal planes independently to better match the x-ray images.



When Reference Ring matching is completed, select from which view the Rotation and Reference Ring Position has to be taken and imported by the TL-HEX software for completion of the treatment calculation.

When Postoperative assessment has been completed, , click on the  icon to declare activity completed and

permit HEX-ray to save and move back to TL-HEX (blue arrow) or simply click the  icon to exit HEX-ray, and save and import the data in the TL-HEX software.

Rings ☒ ON ☐ OFF
 Sync Rings ☒ ON ☐ OFF

Additional Measurements Tools

Brightness/Contrast

Reference Ring Parameters

	AP	Lateral
Translation (mm)	0 Medial	0 Anterior
Angle (deg)	0 Medial Side Down	0 Anterior Side Down

Actions to NEXT steps

Rotation (deg)

0

External
Internal

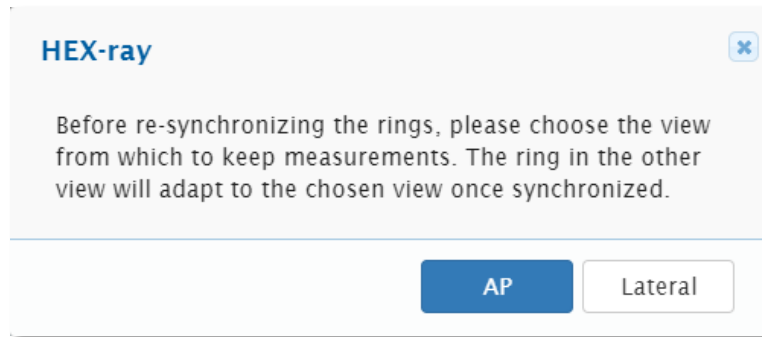
0

External
Internal

Reference measure relative to Osteotomy / Fracture Level

Reference Ring Position (mm)	50 Proximal	50 Proximal
------------------------------	-------------	-------------

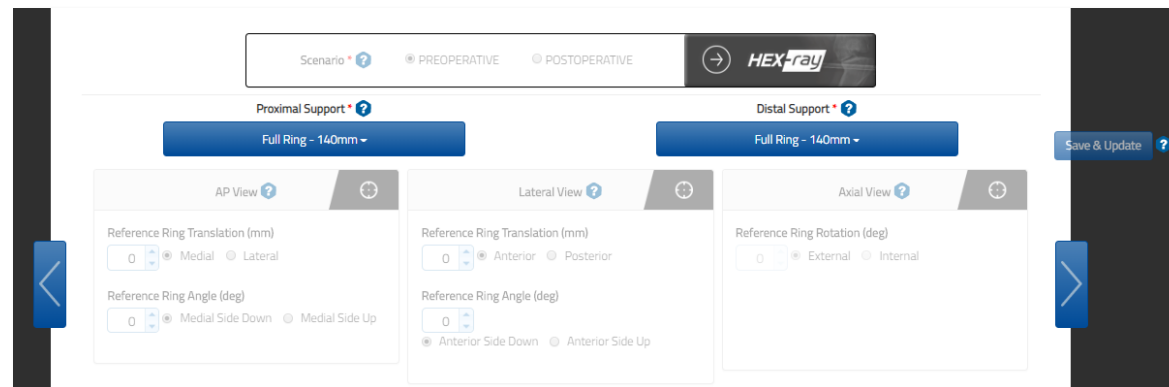
Press X to save and go back to TL-HEX struts calculation postop



Re-Sync the Reference Ring models

In case of uncoordinated Reference rings models, it is possible to **coordinate them again by moving the Sync Rings control to ON**. The user is asked to choose the reference view to refresh the side table accordingly. After the reference view selection, HEX-ray works as described before.

Now complete the TL-HEX Mounting Parameters by inserting the strut values and press  button. After data saving, HEX-ray becomes available in the TL-HEX Mounting tab.



Annex A - HARDWARE ACCELERATION ON BROWSERS

SUMMARY

Hardware acceleration is a feature that lets the Browser move all graphics and text renderings from the CPU to the Graphics Processing Unit (GPU).

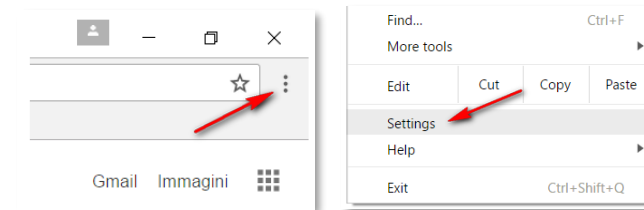
Enabling the hardware acceleration will allow some HEX-ray functions to perform more efficiently.

CHROME® VERSION 79 - HOW TO TURN ON / OFF GPU HARDWARE ACCELERATION

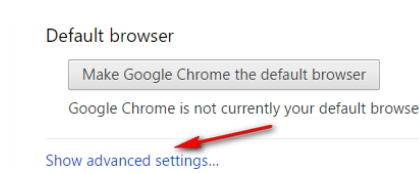
STEP 1. OPEN GOOGLE CHROME

Click the three horizontal lines icon to the far right of the address bar.

Now choose settings.

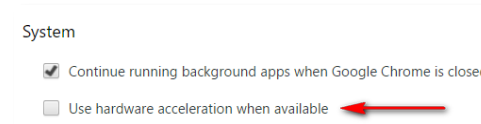


STEP 2. AT THE BOTTOM OF THE PAGE CLICK ON 'SHOW ADVANCED SETTINGS...'

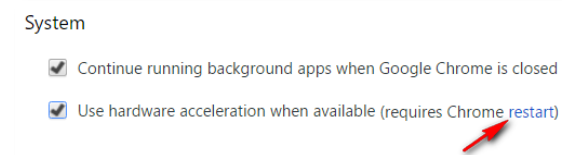


STEP 3. SCROLL DOWN THE PAGE UNTIL YOU FIND THE SYSTEM HEADING, BELOW WHICH IS AN OPTION TO 'USE HARDWARE ACCELERATION WHEN AVAILABLE'

Tick the box to turn on hardware acceleration (or remove the tick to turn it off).



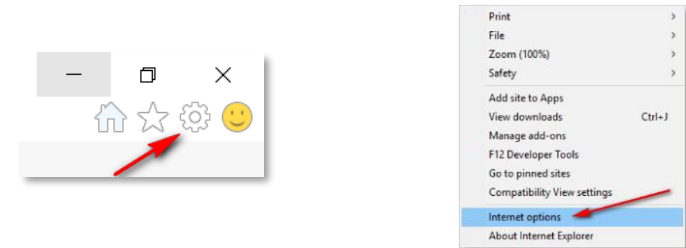
STEP 4. TAP 'RESTART' ON THE LINK TO RESTART CHROME WITH OR WITHOUT HARDWARE ACCELERATION



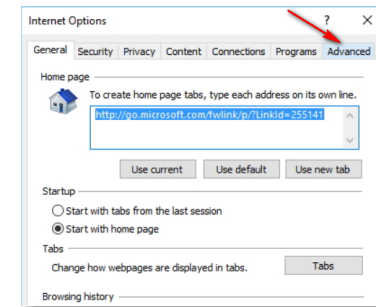
INTERNET EXPLORER® VERSION 11 - HOW TO TURN ON / OFF GPU HARDWARE ACCELERATION

STEP 1. OPEN INTERNET EXPLORER

Click on the gear icon at the top right corner of the window. Then select Internet options.

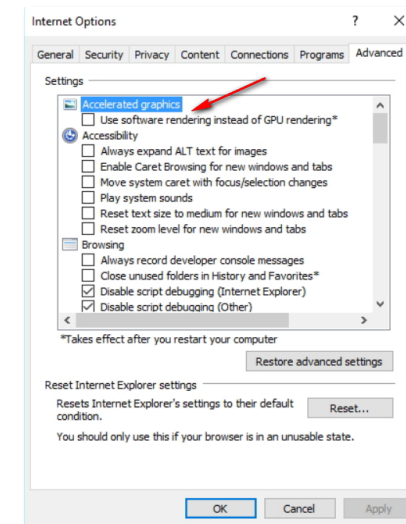


STEP 2. ON THE INTERNET OPTIONS WINDOW CLICK THE 'ADVANCED' TAB



STEP 3. SCROLL DOWN THE SETTINGS MENU UNTIL THE 'ACCELERATED GRAPHICS' HEADING, WHICH IS AN OPTION TO 'USE SOFTWARE RENDERING INSTEAD OF GPU'

Tick the box to turn off hardware acceleration (or remove the tick to turn it on).

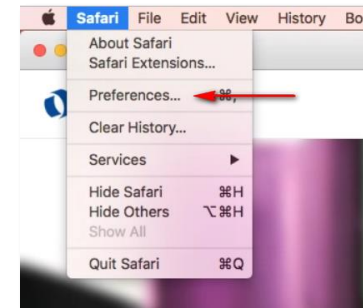


STEP 4. CLICK OK AND RESTART YOUR COMPUTER TO HAVE INTERNET EXPLORER WITH OR WITHOUT HARDWARE ACCELERATION ACCORDING TO YOUR CHOICE

SAFARI® VERSION 13 - HOW TO TURN ON / OFF GPU HARDWARE ACCELERATION

STEP 1. OPEN SAFARI

Bring up Safari's Preferences window.

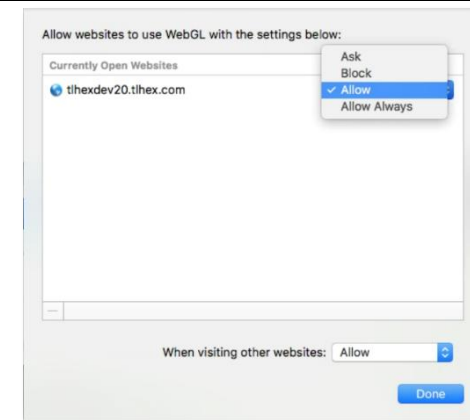


STEP 2. SELECT THE 'SECURITY' TAB AND ENABLE THE 'ALLOW WebGL' SETTINGS



STEP 3. CLICK 'WEBGL SETTINGS...' TO SEE WHICH WEBSITES IN YOUR HISTORY USE WebGL AND SET POLICIES FOR WebGL

- *Ask*: When you visit the website, Safari displays a dialog asking whether you want to trust the website's use of WebGL. See ["If a website has WebGL graphics" on support Apple site](#).
- *Block*: When you visit the website, Safari tells the website WebGL is not supported.
- *Allow*: Safari lets the website use WebGL, unless WebGL presents a security risk on your computer.
- *Allow Always*: Safari lets the website use WebGL, even if WebGL presents a critical security risk on your computer. Choosing Allow Always may present a security risk, so only select this option for websites you trust.



Select the *Allow* option for the HEX-Ray website, if not already done.

MORE INFORMATION

If your current video card or video driver does not support GPU hardware acceleration, download the latest video driver that supports hardware acceleration.

To do this, you can look for a driver on the manufacturer's website. You can usually find driver updates in the support section of the website.

If you find an updated driver, follow the installation instructions on the website; most drivers are self-installing.

Annex B – LANDSCAPE PRINTING CONFIGURATION


Different printers may yield different results, and the printing dialog box may contain different options, depending upon the specific printer and browser you are using, but generally, you should follow these steps:

PC Users

Internet Explorer 11

1. Click the **Gear** icon in the upper right-hand corner of the browser.
2. Click **Print > Page Setup**.
3. Under Paper Options, select "Landscape".
4. Place a check next to the "Enable Shrink-to-Fit" option.
5. Click **OK**.
6. Print your case summary

Chrome 79+ for Windows


1. Open the page, image, or file you want to print.
2. At the top right, click **More**  **> Print...** or use a keyboard shortcut: **Ctrl + P**.
3. In the window that appears, select the destination printer and change **Layout** print settings: "Horizontal".
4. When ready, click **Print**.

MAC Users

Safari 13

1. Click **File > Print**.
2. Click **Show Details**.
3. Next to Orientation, click on the second icon of a man standing sideways.
4. Click on **Print**.

Chrome 79+ for MAC

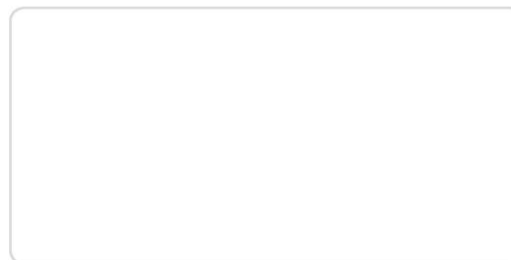
1. Open the page, image, or file you want to print.
2. At the top right, click **More**  **> Print...** or use a keyboard shortcut: **⌘ + P**
3. In the window that appears, select the destination printer and change **Layout** print settings: "Horizontal".
4. When ready, click **Print**.



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Distributed by:



Instructions for Use: See actual package insert for Instructions for Use.

www.thhex.com
www.orthofix.com

TH-1902-PL-E0 B.02/20

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.