TL-HEX

TrueLok Hexapod System®

Evidence-based Advantages of TL-HEX Software

ORTHOFIX® ORTHOPEDICS

Evidence-based Advantages of TL-HEX Software

The Challenges

Traditionally, orthopedic planning has been performed by paper tracing and cutting along with rotation about a pin or thumbtack. This cumbersome process began with preparing a sketch or trace of the affected bones followed by measurements using rulers, protractors, and goniometers. While these tools certainly worked well with hard copy X-rays, the current digital era has required an evolution towards more efficient software programs enabling both pre-operative planning of surgery and post-operative planning of treatment.

The TL-HEX Software is a web-based application which supports orthopedic surgeons in applying the TL-HEX TrueLok Hexapod System® (TL-HEX hereinafter). The software, starting from the initial fracture or deformity, is able to calculate a prescription for the surgeon review and approval, indicating the direction and daily amount of adjustment in length for each strut in order to achieve the treatment goals.

To properly assist surgeons, such a medical device software should be:

- Accurate in estimating the deformity and achieving the desired correction.
- Efficient.
- Cost-effective by reducing the surgery time and the amount of hardware needed to be purchased.

There are more pubblications on TL-HEX Software use in combination with TL-HEX. In this review we have identified some preclinical or clinical studies highlighting key benefits that characterize the software.

Accuracy of Deformity Estimation

When aiming to successfully correct deformities, the first requirement for a medical device software is the ability to accurately estimate the deformity.

Basha et al. [1] evaluated the accuracy of deformity estimation comparing different hexapod software platforms, namely TL-HEX Software (Orthofix), TraumaCAD (BrainLab), and Orthex (OrthoPediatrics) used in combination with Taylor Spatial Frame (TSF; Smith & Nephew), Truelok Hexapod System (Orthofix), and Orthex (OrthoPediatrics) frames, respectively.

To this aim, sawbones models of femur with 30° of valgus deformity of the lower end and tibia with 30° of varus deformity in the middle of the shaft were used. As shown in Figure 1, the estimated means of the 30-degree bone deformities (n = 8 repeated measures) were 29.87°, 25.6° and 25.35°, by the Orthex, TSF (Trauma CAD), and TL-HEX Software, respectively.

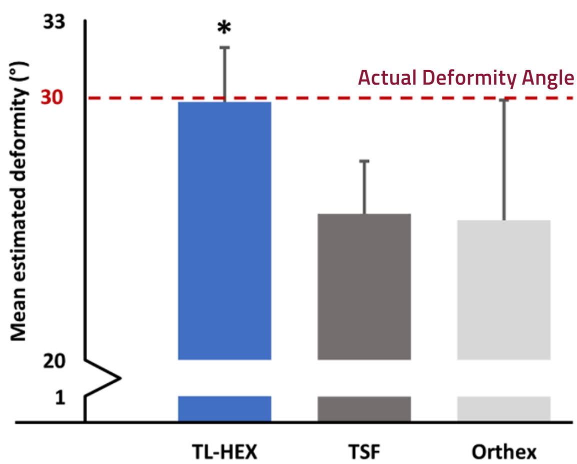

Fig. 1 Evaluation of deformity using different frames' software.

One-way ANOVA showed a significant difference in the findings (P-value = 0.014). Post-hoc analyses using three different statistical tests (Tukey, Least Significant difference, and Bonferroni) showed that the TL-HEX was significantly different from the TSF (Trauma CAD) and Orthex software in estimating the deformity magnitude with TL-HEX being closer to the true value (30°).

> "Our study showed that the TL-HEX Software was statistically more accurate than the other frames in estimating 30-degree deformity" [1]

Accuracy in Correcting the Deformity

The second key feature that a medical device software should possess to efficiently assist surgeons in correcting deformities is the capability of planning a correction as close as possible to the one that will be achieved post-operatively.

Roy et al. [2] evaluated the accuracy of TL-HEX Software by comparing the correction planned to the actual correction achieved post-operatively in children with lower bone deformities (20 girls and 24 boys; mean age of 11.4 years [range 2.7-18]).

In the patients in whom the lengthening program did not need to be modified (n = 38 limbs), there was no significant difference between the correction planned and the one achieved for the mLDFA (87.2° vs. 87.3°, p = 0.9; difference from planned of 0.4°), the mMPTA (86.2° vs. 87.9°, p = 0.07; difference from planned 3.2°), and the amount of femur lengthening (54.4mm vs. 62.1mm, p = 0.1; difference from planned of 7.6mm) (Figure 2).

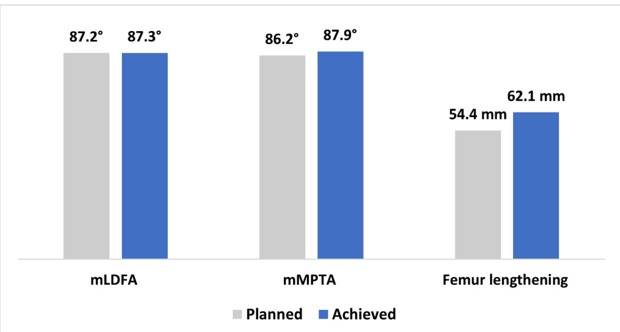

Fig. 2 Difference between the correction planned and the one achieved for the mLDFA,mmPTA and the amount of femur lengthening when using the TL-HEX Software.

> "In the patient group who did not have the lengthening program modified, no significant difference was shown between the correction planned and the one achieved." [2]

Studies highlight that the accuracy, between the planned correction and the actual correction, decrease as the necessary correction increases. In children with large lower limb deformities more than 30% of lengthening programs were modified during the treatment. When the program had to be modified, the software for the TL-HEX still allowed the surgeon to edit the lengthening plan without having to modify the external fixator's assembly[2].

Efficiency

A further advantage of the TL-HEX Software is represented by the efficient approach it uses for data acquisition and the subsequent measurements.

Ferreira et al. [4] points out that the TL-HEX software differs from other software by offering the surgeon the ability to correct for non-orthogonal mounting in the axial, coronal and sagittal planes. Indeed, it uses an AXO-centric approach whereby the reference ring is mounted in relation to the anatomical axis of the reference segment and the orientation of the reference ring can be angled in relation to this segment.

In trauma and foot and ankle applications, orthogonal mounting of the reference ring is often not possible due to physical anatomical constraints. With TSF Software (based on a CORA-centric approach), the surgeon must take into account this by working around the assumptions in the software. This is an extra step that the surgeon must do and, often leads to errors, given the steps are not intuitive. With the TL-HEX Software, this additional step is not necessary as the surgeon is able to indicate in the software the degrees of inclination of the reference ring in respect to the reference bone segment.

> "TL-HEX Software offers the surgeon the ability to correct for non-orthogonal mounting in the axial, coronal and sagittal planes" [4]

In addition *Iobst et al.* [3] highlighted efficiency during the treatment by comparing the number of strut changes necessary to complete a deformity correction when using either the TL-HEX or the TSF system. Indeed, they found that, in cases of severe multiplanar Blount's disease, fewer strut changes were associated with the use of TL-HEX.

> "The ball and socket joint design allows more correction with fewer strut changes for patients with severe deformity" [3]

Cost-effectiveness

In addition to the aforementioned performance characteristics, a medical device software can offer value to the surgeon and hospital by reducing clinic time and thus, lowering overall healthcare costs.

Basha et al., [1] compared different frames' software (namely, TSF, TL-HEX, and Orthex), highlighting the software features that are useful and have an impact on patients' journeys. Specifically, the ability of TL-HEX Software in predicting the best hardware to correct a specific deformity (pre-operative planning) is regarded as valuable for:

- Reducing the amount of hardware that needs to be purchased;
- Reducing the number of struts adjustment and/or exchange.

Accordingly, the pre-operative planning option in software of TL-HEX is considered an advantage.

Iobst et al. [3] showed that during the treatment phase fewer strut changes were associated with the use of TL-HEX. According to the authors, such an achievement is important for two main reasons:

- Less clinic time is consumed managing the strut changes which allows for an optimization of health care personnel time and resources;
- Using fewer struts translates into cost savings for the hospital.

> "Pre-planning option of TL-HEX Software reduces the purchased hardware, struts adjustment, and/or exchange" [1]

Conclusions

Multiple peer-reviewed clinical publications demonstrate that the key benefits of the TL-HEX software are accuracy, efficiency and cost effectiveness.

The TL-HEX Software is shown to be highly accurate in performing the deformity analysis during pre-operative planning as well as with achieving the desired correction during the post-operative treatment planning.

TL-HEX Software has an efficient approach mainly for two reasons: firstly, for data acquisition and the subsequent measurements. Comparing TL-HEX Software with other software it requires less steps and is more intuitive in the preplanning. Secondly, it is efficient during the treatment phase by reducing the number of strut adjustments and/or exchanges.

Finally, TL-HEX is a cost-effective solution by reducing the amount of clinic and surgery time and reducing the amount of hardware needing to be purchased.

References

1. Basha K, Alawadhi A, Alyammahi M, Sukeik M, Abdulhadi HS, Dsouza AP, Majid I, Alshryda S. Comparison of Three Circular Frames in Lower Limb Deformity Correction: A Biomechanical Study. Cureus. 2022 May 24;14(5):e25271. doi: 10.7759/cureus.25271.
2. Roy A, Pesenti S, Chalopin A, Peltier E, Jouve JL, Launay F. Can the TrueLok Hexapod System™ be used to accurately correct lower limb deformity in children? Orthop Traumatol Surg Res. 2020 Nov;106(7):1361-1366. doi: 10.1016/j.otsr.2020.06.013.
3. Iobst, Christopher & Samchukov, Mikhail & Cherkashin, Alexander. (2016). A comparison of deformity correction capabilities in hexapod frame systems. Journal of Limb Lengthening and Reconstruction. 2. 29. 10.4103/2455-3719.182573.
4. Ferreira N, Birkholtz F. Radiographic analysis of hexapod external fixators: fundamental differences between the Taylor Spatial Frame and TrueLok-Hex. J Med Eng Technol. 2015 Apr;39(3):173-6. doi: 10.3109/03091902.2015.1025993.

To know more...
www.tlhex.com
www.limbhealing.com

orthofix.com

ORTHOFIX® ORTHOPEDICS

TH-1903-PL-E0 B 06/23