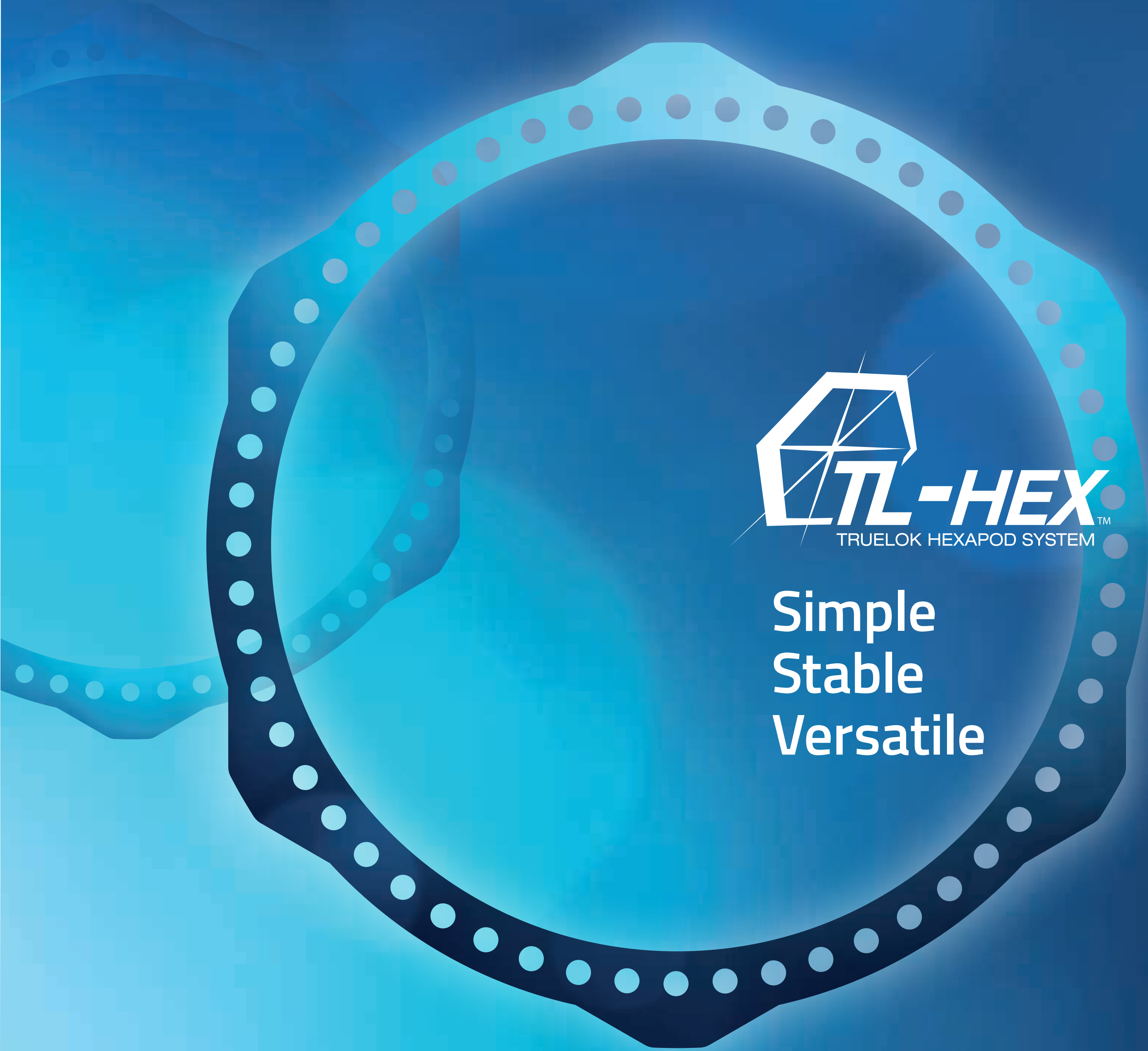

TL-HEX™

TRUELOK HEXAPOD SYSTEM

Simple
Stable
Versatile

ORTHOFIX®

Orthofix International

Who are we?

- Orthofix International N.V. is a diversified, global medical device company focused on improving patients' lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, TX, the company has four strategic business units that include BioStim, Biologics, Extremity Fixation and Spine Fixation.
- Orthofix products are widely distributed via the company's sales representatives, distributors and its subsidiaries.
- In addition, Orthofix is collaborating on research and development activities with leading clinical organizations such as the Musculoskeletal Transplant Foundations, the Orthopedic Research and Education Foundation and the Texas Scottish Rite Hospital for Children.

TL-HEX

What is it?

- TL-HEX TrueLok Hexapod System is a hexapod external circular fixation system developed at Texas Scottish Rite Hospital for Children (TSRHC) in Dallas, Texas, US.
- It consists of hardware and associated software for simplified deformity correction and trauma management. TL-HEX is fully compatible with the TrueLok System and will support fracture fixation, limb lengthening, treatment of non-union and deformity corrections in long bones in both adult and paediatric patients.

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Introduction

Complex deformities of the upper and lower extremities remain one of the most challenging surgical problems.

Due to versatility in segmental bone fixation and ability for gradual stretching of the soft tissues, application of circular external fixation devices for correction of those deformities show a growing popularity in the last two decades.

Two major types of circular external fixators are 1) Ilizarov-type modular fixators with hinges and various types of distractors and 2) hexapod-type frames with six variable-length struts. The hexapod-type frames utilize computer-assisted sequential or simultaneous manipulation of bone segments in three-dimensional space using a single deformity correction module consisting of two rings and six struts . Examples of well-known hexapod-type external fixators are the Taylor Spatial Frame or TSF (Smith & Nephew Orthopedics, Memphis, TN), PoliHex (Litos, Hamburg, Germany), Ortho-SUV (S.H. PITKAR, India), Smart Correction (Response Ortho, Edgewater, USA) and, more recently, TL-HEX Ring Fixation System (Orthofix, Verona, Italy).

TL-HEX Ring Fixation System

The Orthofix TL-HEX Ring Fixation System (TL-HEX) is a hexapod-based system designed in collaboration with the Texas Scottish Rite Hospital for Children (TSRHC) as a three-dimensional bone segment reposition module to augment the previously developed TrueLok Ring Fixation System (TrueLok). The system consists of circular and semi-circular external supports secured to the bones by wires and half pins and interconnected by six struts, to allow adjustment of the external supports in all 3 planes. All components of the TL-HEX are compatible with the TrueLok frame, therefore external supports from both systems can be connected to each other when building fixation blocks. All the basic components from the TrueLok Ring Fixation System (wire and half pin fixation bolts, posts, threaded rods, plates as well as other assembly components and instrumentation) can be used with the TL-HEX.

Key Design Features of TL-HEX:

- Ease of strut-to-ring attachment due to external supports (full ring, modular 5/8 + 3/8 ring and foot plate) with the angulated tabs
- Simplicity of compression and distraction due to one-turn strut adjustment
- Greater frame stability due to unique end joints design and metal-plastic interface

Other main hexapod systems on the market

Taylor Spatial Frame (TSF) (Smith & Nephew, USA)

The Taylor Spatial Frame™ (TSF) is a hexapod ring fixator with six cardan-joint struts connected on the outside of the ring.

PoliHex (LITOS, Germany)

The PoliHex frame is a hexapod system based on combination of a standard Ilizarov frame with ball-and-sockets-joint struts. The system does not provide rings, therefore can be used only with the original Ilizarov ring fixation system.

Ortho-SUV (S.H. PIKAR Orthotools, India)

Ortho-SUV Frame consists of two external supports, one basic and one mobile connected to six cardan-joint struts. The system does not provide rings but can be used with other ring fixation systems.

Aim of the study

Frame stability is mandatory in supplying a healing environment of a bony disruption treated with external fixation.[1] A stable frame might result in less delayed-unions, less non-unions, less pain and it lowers the risk of pin-site infections. The hexapod frame TL-HEX with ball-and-socket universal joints struts seems to provide more stability than the hexapod frames with cardan universal joints struts and recently it has been pointed out as a safe and effective treatment for gradual correction of tibial vara.[2] To demonstrate its superiority and that the magnitude of this stability is reversely proportional to the angle between the rings and the struts, biomechanical analyses were performed at TSRHC and here presented.

Materials and Methods

To test the stability of the four previously mentioned systems, the mechanical tests were performed by using a universal testing machine (MTS 858, Minneapolis, MN), applying a 5-N load to allow the free play evaluation and avoid frames deformation. The mechanical testing was divided into three phases:

1. Maximal axial free play measurement of the individual struts (Fig. 1).

For this analysis, one strut from each frame was orthogonally attached between two parallel external supports (section of the rings) followed by the measurement of the individual maximal axial free play that each strut may produce being attached to the ring. The measurements were repeated three times and statistical analysis performed using one-way ANOVA (analysis of variance) test. A p-value <0.001 was considered extremely significant.

2. Comparative free play of hexapod frame assembly in axial compression, torsion, AP translation and ML translation.

For this second mechanical testing, the complete frame configuration was used. All frame configurations for the following mechanical testing were constructed using rings and six struts according to the manufacture specifications. TSF and TL-HEX utilized their standard rings (155mm and 160mm, respectively) and long struts; while, for OrthoSUV and PoliHex systems, matching in size 160mm standard TrueLok rings (Orthofix, Verona, Italy) were used with their own length matching struts.

All frames were constructed to produce a ring separation of 180mm resulting in ring-to-strut angle (angle between the longitudinal axis of the strut and the plane of the ring) of approximately 70° (Fig. 2).

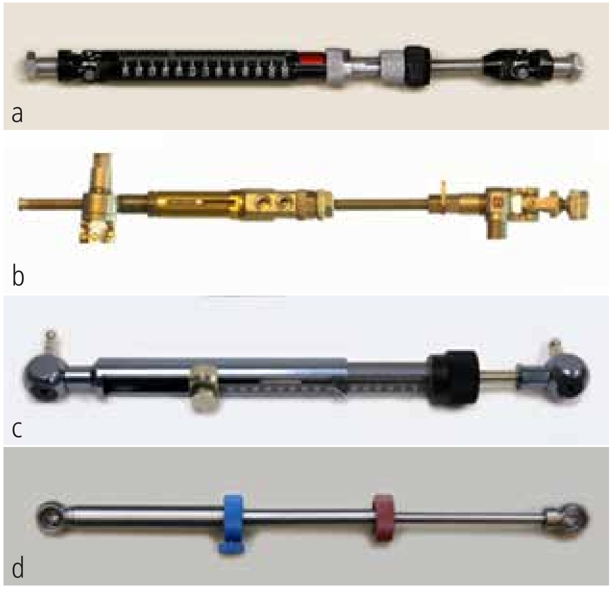

Fig 1. Hexapod struts:
a. TSF, b. Ortho-SUV, c. TL-HEX, and d. PoliHex

Fig. 2. Standard frame assembly with ring separation 180mm and ring-to-strut angle 70°

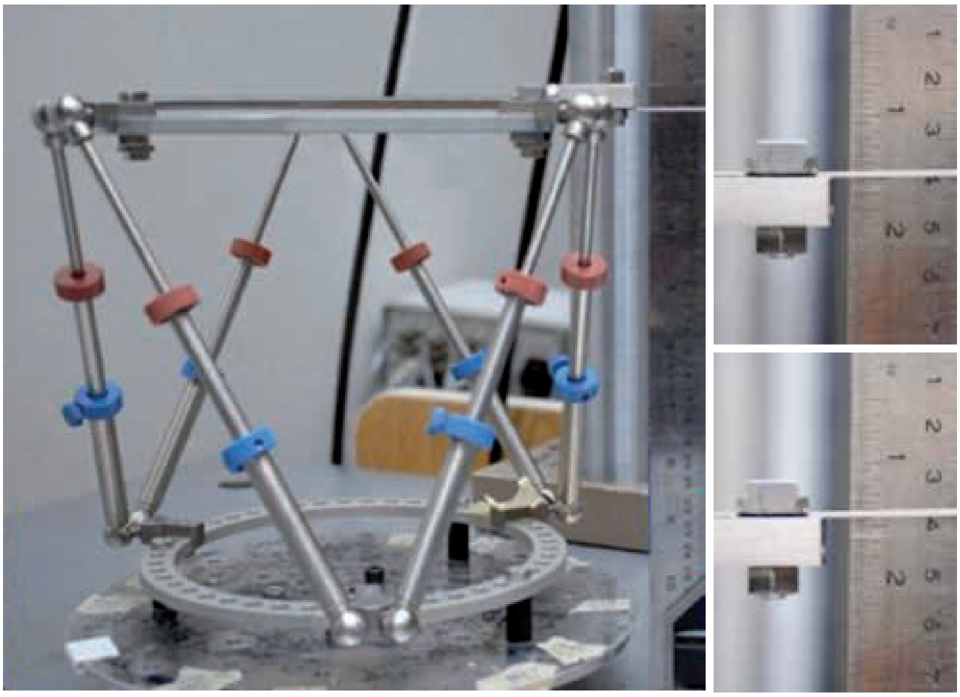

Fig. 3. Mechanical testing setup and frame positioning in the MTS machine to measure axial compression displacement.

In each construct, an aluminum base plate was rigidly attached to one of the rings (static ring) and fixed in the testing machine. Special 6mm diameter rigid stainless steel rod (loading rod), with the registry needle at the end, was rigidly attached to the center of the opposite ring (dynamic ring) to allow reproducible loading (Fig. 3).

Mechanical laxity was analyzed after applying a 5-N load in compression, AP translation and ML translation and in torsion, in two opposite directions by measuring the changes in distance (axial compression, AP translation, ML translation) or angle (torsion). The measurements for each frame were repeated three times and statistical analysis performed using one-way ANOVA test. A p-value <0.001 was considered extremely significant.

3. Influence of ring-to-strut angle (hexapod ring separation) on the axial free play of the hexapod frames.

Last phase of mechanical testing involved only two frames providing their own rings and the two different type of struts: TSF with cardan universal joint and TL-HEX with the ball-and-socket universal joints. Maximal axial free play was determined at the ring-to-strut angle (70°, 45°, 15° and 10°) resulting in reduction of ring separation from 180mm to 30mm.

Each configuration was tested three times per loading mode and the average values were evaluated to compare linear or angular dynamic ring displacements. The groups were compared using one-way ANOVA test. A p-value <0.001 was considered extremely significant.

Results

The results of the maximal axial free play of the four frame struts show that ball-and-socket struts of Poli-Hex and of TL-HEX, have a lower axial laxity compared to cardan struts of TSF and Ortho-SUV (Table 1).

The statistical analysis performed revealed a p-value <0.001 and it was considered extremely significant.

Hexapod	Universal Join	Axial Laxity (mm)
TSF	Cardan	0.70
Ortho-SUV	Cardan	1.60
TL-HEX	Ball-and-Socket	0.25
Poli-Hex	Ball-and-Socket	0.50

Table 1. Maximal axial free play of the individual hexapod struts

In the free play analyses of the complete system, the TL-HEX is the only frame among the four tested that shows the lowest displacement for all the loading mode considered (Table 2). While TSF shows the worst values in each condition tested: compared to TL-HEX, its free play is approximately three times higher. The statistical analysis performed revealed a p-value <0.001, considered extremely significant.

Loading Mode	TSF	Ortho-SUV	TL-HEX	PoliHex
Axial Compression (mm)	2.10 ± 0.20	1.63 ± 0.10	0.42 ± 0.14	1.06 ± 0.09
Torsion (degrees)	1.73 ± 0.04	1.14 ± 0.05	0.93 ± 0.01	0.67 ± 0.02
AP Translation (mm)	3.15 ± 0.03	2.81 ± 0.15	0.60 ± 0.02	1.07 ± 0.05
ML Translation (mm)	4.15 ± 0.31	2.99 ± 0.08	0.73 ± 0.15	0.86 ± 0.17

Table 2. Free play of the standard hexapod frame assembly
(ring size 160mm, ring separation 180mm, ring-to-strut angle 70°)

In the final test, ring-to-strut angle test, TSF confirmed this high displacement as seen in the previous two analyses. While TLHex records very low values independently from the ring-to-strut angle applied (Table 3). The statistical analysis performed revealed a p-value <0.001 and it was considered extremely significant.

Ring-to-Strut Angle	TSF	TL-HEX
70° (ring size 155/160mm)	2.10 ± 0.20	0.42 ± 0.14
45° (ring size 155/160mm)	2.73 ± 0.21	0.43 ± 0.05
15° (ring size 205/200mm)	3.83 ± 0.29	0.49 ± 0.01
10° (ring size 205/200mm)	7.87 ± 0.15	0.52 ± 0.02

Table 3. Maximal axial free play of the hexapod frame at the different ring-to-strut angle

Discussion

Due to its universal joint with ball and socket struts, the frame of TL-HEX appears considerably stable in every loading condition with a very low displacement, whereas the direct competitor TSF shows the worst performance. The results of the TSF confirm its relative instability, caused by its cardan struts, and chosen way of attaching the struts to the rings. This instability increases significantly as the ring-to strut angle decreases as other authors previously showed.[3,4] A severe collapse of the system below an angle of 30° in a clinical case was also reported[3]. Furthermore, the lower stability of the frame might be linked to weak clinical results as reported by some authors[5,6] and complications such as superficial and deep pin-track infections reported by others.[7,8]

From a clinical point of view, the high stability of the TL-HEX system might lead to a faster fracture healing, a reduced occurrence of complications (delayed- or non-union, tissue damage and related infections), that also may translate in reduced healthcare costs and an increased comfort for the patients, in respect to its competitors.

Conclusions

The mechanical tests performed contribute to highlight the superiority of TL-Hex to the other frame in the key features tested.

TL-HEX with its high frame stability, represents a time- and cost-saving solution for circular fixation.

References

1. Goodship et al., 1993.
2. Maré and Thompson, 2014.
3. Henderson et al., 2008.
4. Barker et al., 2013.
5. Kristiansen et al., 2006
6. Iobst et al., 2010.
7. Eidelman and Katzman, 2008a.
8. Blondel et al., 2009.

Web links

TL-HEX Strut Adjustment
www.youtube.com/watch?v=XeuTWjfCvYc

Orthofix Pin Site Care
www.youtube.com/watch?v=ZBBF81nwdtE

CE Marking indication:
TL-HEX

CE 0123

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CE 0123

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

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.

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