Efficacy, accuracy, stability, versatility, ease-of-use and cost-effectiveness

6 evidence-based advantages of the TrueLok Hexapod System™

ORTHOFIX®

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The Challenges

Nonunion, deformity, and complex fractures of femur and tibia, represent a spectrum of conditions which are challenging to treat.[1,2,3,4]

Nonunion

Nonunion remains a significant and demanding clinical problem. The pathophysiology of nonunion is multifactorial, most commonly inadequate fracture stabilization and poor blood supply. Other causes fall into broad categories such as infection, location, and pattern of injury.

Authors investigating the efficacy and functional outcomes of external fixation have focussed on dividing the implant-related variables into those involving faulty biologic processes, biomechanics, or both.[1]

In keeping with the spectrum of pathophysiology, types of nonunion include septic nonunion; pseudoarthrosis; hypertrophic nonunion that characteristically heals once mechanical stability is improved (secondary to inadequate stability with adequate blood supply and biology that results in callous formation without bridging bone); atrophic nonunion (instigated by inadequate immobilization and an inadequate blood supply); oligotrophic nonunion (following inadequate reduction with fracture fragment displacement).

A multitude of these nonunion types have been reported, with or without deformity, segmental bone defects, or limb length discrepancy.[4,2,3]

Accordingly, either on their own or together with additional complications of injury, long bone diaphyseal nonunion profoundly influences quality of life.[7]

Deformity Correction

Multiplanar limb deformities are not an infrequent cause of presentation to a paediatric orthopaedic surgeon. Although, for example leg length discrepancy, may not be symptomatic, such deformities are associated with progressive conditions such as back pain, functional scoliosis, inefficient gait, equinous contractures of the ankle, and osteoarthritis.

Osteoarthritis may result from decreased coverage of the femoral head on the longer limb. With progressive osteoarthritic symptoms into adulthood, there is an understandable impetus to restore normal alignment in childhood whenever possible.[4]

Complex Fractures

Complex fractures represent severe limb-threatening injuries that can lead to high levels of patient mortality and protracted hospital care. Complications include nonunion, infection, and soft tissue loss needing bone restoration and soft tissue reconstruction with tissue flaps. These complications are especially pronounced in the tibia owing to its anatomical location and minimal soft-tissue coverage.[1]

Furthermore, and frequently associated with attempts to manage patients with an intra-medullary nail, complications surrounding complex long bone diaphyseal fractures include deformity secondary to malunion and rotational malalignment, heterotopic ossification, and intra-operative complications such as neurovascular injury, iatrogenic fracture, and inadvertent mechanical axis deviation.

Surgical management

The options for the surgical management of such conditions is almost as varied as the breadth of conditions served. Even within treatment groups, management is affected by host factors, the state of the surrounding soft tissue, and the morphology of the condition itself.[4]

With such a broad spectrum of possibilities, orthopaedic surgeons will naturally be mindful when matching a device and its associated risk-benefit profile for a given patient. Furthermore, and perhaps regardless of the healthcare system in consideration, hospital administrators, their procurement teams, and indeed surgeons themselves, need to evaluate the characteristics and cost of the appropriate devices on the market.

Many surgical techniques have been developed to correct the aforementioned clinical conditions, from internal fixation including conventional compression plating, locked plating, reamed intramedullary nailing, to external fixators.[4]

Hexapod circular external fixators, such as the Orthofix TL-HEX TrueLok Hexapod System™ (TL-HEX), have been shown to be a reliable and successful treatment option for both fractures and nonunions, and for treating adult[2] and paediatric deformities.[8]

Hexapod systems are paired with computer software. The software, through its ability to simulate virtual hinges of movement, directs surgeons with simple instructions to correct complex multi-planar deformity. These corrections may be simultaneous or sequentially over an extended time period, and without the need to change the frame construct, or take the patient back to the operating room.[1] In short, complex three-dimension correction may be achieved with ease and efficacy.

TL-HEX TrueLok Hexapod System™ (TL-HEX)

The TrueLok Hexapod System™ (TL-HEX) is a hexapod circular external circular fixation system designed as a computer-assisted three-dimensional bone segment repositioning module. The system consists of circular and semi-circular external supports secured to bones by wires and half pins and interconnected by six telescopic struts, to allow simultaneous or sequential adjustment of the external supports in all three planes. It is intended for adult and paediatric limb lengthening by metaphyseal or epiphyseal distraction, fixation of open and closed fractures, treatment of nonunion or pseudo arthrosis for long bones and correction of bony or soft tissue defects or deformities.

The following is a review of recently published studies cumulatively highlighting the key benefits that characterise the TL-HEX system:

- Efficacy
- Accuracy
- Stability
- Versatility
- Ease-of-use and
- Cost-effectiveness

Efficacy and Accuracy

Several studies[1,2,4,5,6,7] amongst the recent literature have mentioned the efficacy and accuracy of hexapod external fixators when applied across various indications.

These fixators were developed to improve the accuracy of fragment positioning as compared to the original Ilizarov frame. In the past, the Ilizarov treatment strategy was perceived as complex. With a steep learning curve and complementarily high complication profile in under-experienced hands (fixation instability, pin-site infection and joint contracture), the Ilizarov technique evidentially has a limit to its implementation. This is reflected in the paucity of surgeons adopting the Ilizarov in the contemporaneous practice.

With a standard circular fixation device the accuracy of fracture reduction and bone fragment re-positioning can be challenging, subsequent mal-alignments may occur. However, in hexapods, frame construction includes six variable length struts as acting as a specialised three-dimensional hinge. In combination with software assistance, the resulting octahedral hexapod frame creates a parallel kinematic platform permitting very accurate fragment positioning and manipulation. This technology dramatically and simplistically minimises corrective errors.

> Surgeons are therefore able to achieve union having corrected any complexity of mechanical misalignment through the hexapod fixator more efficiently than with any other modality of external fixation.[5]

Adult tibial nonunions

The efficacy of hexapod external fixators in the treatment of tibial nonunions has been extensively demonstrated. Mahomed et al.[5] reported on the treatment of 33 consecutive adult patients with tibial nonunions treated with various hexapod systems, including the TL-HEX. The study results further confirm the efficacy of the hexapods in the treatment of tibial nonunions as union was achieved in 29/33 (88%) cases. The authors concluded that the technique of mono-focal closed distraction treatment of hypertrophic nonunions with hexapod fixators produced 'excellent' outcomes in their hands.

In another study, Ferreira et al.[4] analysed 122 uninfected tibial nonunions treated with different circular and hexapod fixators, including the TL-HEX. Post-operative bone union was recorded in 113 out of 122 tibias (92.6%). Of the nine that had treatment failure, seven persistent nonunions were successfully retreated and resulted in final bone union of 120 out of 122 tibias (98.3%). Thus, the proposed treatment algorithm appears to produce high union rates across a broad group of prior nonunions patients.

In addition to generating either the required stability, with or without distraction (in the context of hypertrophic nonunion with the aim of distraction being to stimulate osteogenesis), to achieve union, hexapod external fixators can accurately correct concurrent deformities and limb length discrepancies. A study published by Ferreira et al.[6] reported on 46 adult stiff tibial nonunions treated with TL-HEX and Taylor Spatial Frame (TSF). Patients' mean age was 35 years (18 to 68) and mean follow-up was 12 months (6 to 40). The bone union was achieved after initial surgery in 41 tibias (89.1%). Four persistent nonunions united after secondary treatment with closed monofocal distraction, increasing the total number of bony unions to 45 (97.8%) patients. The mean time to union was 23 weeks (11 to 49). Leg length was restored to within 1cm of the contralateral side. Mechanical alignment was restored to within 5° of normal parameters in 42 individuals (91.3%).[6]

Adult tibial/fibular angular deformities

With regard to deformity correction, Rodríguez-Collazo et al.[2] studied 17 patients with angular tibial/fibular deformities treated with TL-HEX. The external fixator was applied for an average of 17 weeks, and the initial surgical intervention was supplemented with bone marrow 9X concentrate drawn from the tibia and injected into the osteotomy region. There was no nonunion, malunion or infection observed. The authors declared improved outcomes from gradual deformity correction and lengthening for distal tibial and fibular osteotomy with a combined orthoplastic approach to avoid further damage in patients with a poor soft tissue envelope.

> Rodríguez-Collazo et al. defined the TL-HEX application as a useful alternative with simultaneous correction of a multiplane deformity in an easily applied prescription principle format.[2]

Paediatric tibial deformities

Amongst a paediatric cohort, the literature supports the TL-HEX external fixator as an efficacious modality.

> TL-HEX accurately corrects tibial deformities with a significant improvement in mechanical axis deviation (MAD), and is effective in limb lengthening.

Reflective of this are the results reported by Pesenti et al.[8] In considering data from 31 paediatric tibial deformities, the authors describe having successfully treated all patients in the series by gradual correction with the TL-HEX system. At last follow-up, significant decreases were found in mean MAD (32.1mm to 10.2mm, $p<0.001$) and mean leg length discrepancy (LLD) (36.8mm to 9.1mm, $p<0.001$). In the patients managed with proximal osteotomy, the medial proximal tibia angle improved significantly, from 80.6° pre-operatively to 88.5° at last follow-up ($p=0.006$). The posterior proximal tibial angle showed no significant change in this group (81.6° vs. 80.3°, $p=0.56$). For all 31 patients, the MAD and LLD goals set pre-operatively were achieved.[8]

Trauma

O'Farrell et al.[1], illustrate the novel use of TL-HEX in a case study describing a salvage technique described as 'bayonet apposition'. The bayonet procedure was first established at the Ilizarov Institute to treat an open lower limb fracture with significant soft tissue defects. This technique involves overlapping the viable bone edges in a bayonet-like manner in order to appose the wound edges. The limb length is then restored by gradually distracting the bone segments once the soft tissues have healed. In effect, the 'bayonet' method is alleged to allow primary closure of a wound and rapid restoration of the native length of the limb.

At the time of discharge, O'Farrell et al. report that the patient had indeed achieved symmetrical leg lengths. At 2-year follow-up, radiographs confirmed fracture union and bone alignment. It is documented that the patient gained a satisfactory clinical and functional outcome, however, although the exact outcome measures are not reported in detail, it is suggested that the patient achieved independent full weight bearing.

> The authors claimed that the TL-HEX is effective in this salvage technique, because it allows the skin defects to be closed primarily, without any complication.[1]

In relatively resource poor settings, or hospitals that simply do not benefit from a specialist orthoplastic department (the 'flap and fix' strategy is accordingly being unavailable), the implementation of hexapod-assisted deformity correction provides orthopaedic surgeons with another tool to facilitate patients returning safely and promptly to their premorbid function.

Stability

Hexapod external fixators allow surgeons to simultaneously correct complex multi-planar deformities without the need to alter the frame construct. This results in much higher precision in deformity correction in comparison to traditional external fixation techniques.[3]

To take advantage of this accuracy for deformity correction and fracture reduction, it is paramount that the construct is stable and therefore able to translate all movement from the rings directly to the respective bone segments.

The literature reports that one of the key design features of any hexapod frame is the desired balance between strut range of motion capabilities and strut stability.[1]

> In general, cardan type universal joints often utilised in hexapod struts, tend to have a greater range of motion than ball and socket joints. Ball and socket joints as found in TL-HEX, tend to have more stability than cardan type universal joints.

Adult tibial nonunions

In a study published by Ferreira et al.[6], 44 consecutive adult patients with 46 stiff tibial nonunions were treated with a variety of hexapod external fixators, including the TL-HEX. The authors concluded that the advantages of a hexapod system include not only mechanical stability, but also the ability to provide functional rehabilitation. The downstream effects of which are reported as being both improved bone stock, and the prevention and improvement of contractures at adjacent joints.[6]

In stiff nonunions, the hexapod external fixator has the ability to provide controlled correction of existing deformities[7]. Through tension-stress effect, this process stimulates new bone formation. This 'tension-stress effect during gradual distraction', initially described by Ilizarov, is the biological basis of distraction osteogenesis technique. Ferreira and Marais[7] proposed a mechano-biological hypothesis of the efficacy of closed distraction to achieve union. They suggest that hexapod distraction of a stiff nonunion has a dual effect on interfragmentary strain. First, the tension caused by distracting an inherently stiff environment with stable fixation of bone segments diminishes interfragmentary movement. Second, incremental axial distraction of bone segments gradually increases the intersegmentary gap. As a result, there is an overall reduction of strain to a range within which bone formation is facilitated. The clinical evidence for this theory appears to be supported not only by Ferreira and Marais, but also by another study.[5] The authors concluded that hexapod fixators have a unique ability to eliminate bending and translation shear while maintaining a degree of axial micromovement. This translates into a biomechanical environment that is conducive to bone healing and regeneration.[6]

Adult stiff hypertrophic femoral nonunions after failed locking plate fixation

The stability of TL-HEX system has been reported in a study describing the successful treatment of two cases of adult stiff hypertrophic femoral nonunions after failed locking plate fixation[7].

> TL-HEX was reported to provide stable fixation that allowed immediate functional rehabilitation and the gradual correction of deformities to restore the normal mechanical alignment of the respective limbs.[7]

Trauma

Notwithstanding the benefits described in deformity fixation, stability is a prerequisite for a successful surgery in trauma.

The aforementioned study by O'Farrell et al.[1] may have described a novel use-case, however, broadly speaking it involved an adult open lower limb fracture with soft tissue defects treated with a TL-HEX frame.

O'Farrell et al. concluded that although repairing this condition can be a technically challenging,

> hexapod-assisted deformity correction with 'bayonet apposition' allows for both soft tissue management and a stable biomechanical fixation.[1]

Versatility

Depending on the type of universal joints utilized in the strut structure, hexapod external fixators can be divided into two basic categories or design groups:

1) frames using ball and socket joint universal joints usually attached to the outer surface of the rings, like TL-HEX;

2) frames using the cardan universal joints attached to the upper or lower surface of the rings, like the TSF.

Iobst et al.[9] compared the deformity correction capabilities of these two different types of hexapod frames in an in-silico study. Different frame configurations were tested by using different struts and ring sizes. For each configurations, the software inherent to each system was used to initially create the maximum deformity limit of each particular strut. This was repeated for each of the frame constructs in all six planes of deformity correction: angulation, translation, and rotation in the coronal and sagittal planes. The deformities were pure in each plane without any induced secondary deformity. The frames were then built using the software's prescription for each of the strut lengths. Clinical scenarios were compared (equinus contracture, moderate and severe Blount disease) and the number of strut changes necessary to correct the deformity were recorded. This model then provided the authors with three test situations: firstly, as described, the maximal deformity possible with each frame; secondly, the amount of deformity correction possible before soft tissue impingement inside the rings would occur; and thirdly, to evaluate the number of strut changes necessary to achieve full correction of several different clinical deformities.

While both systems are comparable with mild to moderate deformity correction, the ball and socket joint design allowed for more correction with less strut changes in patients with severe deformity. For the small and medium-sized struts, each frame was equivalent in its capability of correcting angular deformity, but

> the amount of lengthening possible was greater for the ball and socket joints. For the largest size of strut, the ball and socket joints had a greater range in every category, except for rotation.[9]

In patients requiring significant rotational correction, the struts with the cardan type universal joints were found to impinge on the soft tissues 13° earlier than the ball and socket joint struts (39° vs. 52°). This is more likely related to the attachment points for the struts on the rings. The cardan-type universal joints are attached inside the rings compared to the ball and socket strut attachment on the outer surface of the ring. As the amount of rotation increases, the cardan-type universal struts begin to encroach far earlier due to their proximity. This finding is perhaps most relevant to clinical scenarios in the femur or humerus whereby a frame is built using two 5/8 rings instead of a full ring. The openings of the rings are usually arranged to be 90° offset from one another to make the frames fit the limb. Iobst et al. concluded that in such configurations,

> the ball-and-socket joints are better in avoiding soft tissue impingement.

Ease-of-use

Ease-of-use of a medical device is a factor affecting that devices wider adoption in medical practice. With regards to fracture fixation, stability and efficacy are not necessarily enough to clearly extol one system over another. Although related, but not exclusively so, the learning curve associated with adoption of a new device, would logically have an impact upon experts either when considering its adoption, or when considering the training of others to use it.

By way of example, the traditional Ilizarov method using transosseous osteosynthesis has established successful outcomes in the management of fractures and nonunion[5]. However, barriers to the wider implementation of this treatment strategy have been perceptions of complexity, the steep learning curve, and complications (pin-site infection and joint contracture – though these complications admittedly occur with any external fixation method)[5]. In direct contrast and given their popularity, hexapod fixation systems are considered less demanding than first generation Ilizarov constructs.

Part of the ease-of-use is due to the web-based TL-HEX software and the support it provides surgeons throughout all phases of treatment: pre-operative, intra-operative, and post-operative. The HEX-ray integrated module is an application designed to facilitate pre-operative planning and post-operative adjustment of deformity correction through uploaded x-ray images, allowing the user to:

- Calculate measurements;
- Pre-plan frame templates;
- Automatically add data input into the TL-HEX software.

The literature reports that the

> TL-HEX hardware and associated software simplify both deformity correction and trauma management: frame pre-assembly allows easier mounting on a limb with complex deformity, the software allows for non-orthogonal mounting which simplifies frame-mounting assessment, and double telescoping struts allow greater excursion while the outside mounting on the ring increases mounting options for fixation elements.[1-9]

For example, Ferreira et al.[3] created a sawbone lab model to illustrate the different approaches used for data acquisition with the TSF and the TL-HEX systems and to highlight the different measurements that would result from the different approaches. The fundamental

> difference between the TSF and TL-HEX stems from the ability of the TL-HEX software to account for non-orthogonal mounting of the reference ring.

This is a function of slightly different algorithmic assumptions built into the software. The TSF software uses a CORA-centric approach to radiographic analysis (placing the fixator virtual hinge directly over the CORA) and always assumes perfect orthogonal mounting of the reference ring on the reference segment. The user triangulates an arbitrary location on the bone – the origin – to the reference rings' centre ignoring the rest of the reference segment's relationship to the reference ring. In contrast, the TL-HEX software 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.[3]

In trauma cases and in foot and ankle applications, orthogonal mounting of the reference ring is often not possible due to physical anatomical constraints. With TSF, the surgeon must take account of this by working around the assumptions in the software. This is a further step that the surgeon must do and, as it is not intuitive, it could also lead to errors.

With TL-HEX software this additional step is not necessary as the surgeon is able to indicate in TL-HEX software the degrees of inclination of the reference ring in respect to the reference bone segment. Furthermore, with the HEX-ray module, this is done automatically.

Cost-effectiveness

In considering the management of any healthcare centre or provision, systems that reduce overall expense in comparison to others that achieve the same outcome have inherent added value. While it is important that surgeons and physicians alike undertake clinical decisions and prescriptions on the basis of what is in the best interests of their patient, there is a duty to consider the cost of the device itself, and to make a cost-benefit analysis of any treatment considered. Ultimately, the cost-burden may be paid by the patient in some form: either indirectly through nationalised health provision, or directly in a self-funded private healthcare setting.

The literature referenced by this White Paper supports that the economic benefits of hexapods systems, including TL-HEX are that they have the ability to allow for multiple corrections of bone deformity and leg length discrepancy with a single admission and single surgical procedure.

Studies on the treatment of nonunions[6-7] showed the use of hexapods, including TL-HEX, did not cause additional morbidity from harvesting an autograft or any additional cost of allograft or biological agents.

With particular reference to differentiating TL-HEX from other hexapods specifically on cost, Iobst et al.[9] found that in order to achieve the same correction and with the same size rings and the same distance between the rings for a Blount disease case,

> the TSF required six total strut changes, whereas the TL-HEX required only one strut change and two strut adjustments.

These results indicate that TL-HEX requiring fewer strut changes, harbours reduced hardware costs.

> Furthermore, if fewer struts changes are required, the patient will experience fewer outpatient clinic visits, leading to potential cost savings for the hospital.

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