Rigidity of unilateral external fixators - A biomechanical study

Rigidity of unilateral external fixators

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Keywords: biomechanics, Dynafix, external fixation, Orthofix, rigidity

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Abstract

Introduction: External fixation is the primary choice of temporary fracture stabilisation for specific polytrauma patients. Adequate initial fracture healing requires sufficient stability at the fracture site. The purpose of this study was to compare the rigidity of the Dynafix DFS® Standard Fixator (4 joints) with the Orthofix ProCallus Fixator® (2 joints), which differ in possibilities for adapting the configuration for clinical needs.

Materials and Methods: Both devices were tested 10 times in a standardised model. In steps of 10N, loading was increased to a maximum of 160N in parallel, transversal and axial direction (distraction and compression). Translation resultant and rotation resultant were calculated.

Results: With a force of 100N in parallel direction the mean translation resultant (Tr_{mean}) of the Dynafix DFS® Standard Fixator (6.65±1.43mm) was significantly higher than the ProCallus Fixator® (3.29±0.83mm, $p<0.001$; Student's T-test). With a maximum load of 60N in transverse direction the Tr_{mean} of the Dynafix DFS® Standard Fixator was significantly lower (8.14±1.20mm versus 9.83±0.63mm, $p<0.005$). Translation was significantly higher with the Dynafix DFS® Standard Fixator, for both distraction (2.13 ± 0.32mm versus 1.69 ± 0.44mm, $p<0.05$) and compression (1.55 ± 1.08mm versus 0.15 ± 0.33mm, $p<0.005$). The mean rotation resultant (Rr_{mean}) at 160N distraction was lower for the Dynafix DFS® Standard Fixator (0.70±0.17 versus 0.97±0.21°, $p<0.005$).

Conclusions: Both fixators were most sensitive to transverse forces. The Dynafix DFS® Standard Fixator was less rigid with parallel and axial forces, whereas transverse forces and rotation at distraction forces favored the Dynafix DFS® Standard Fixator. Repeated heavy loading did not influence the rigidity of both devices.

Introduction

External fixation is a simple and effective method of initial fracture stabilisation for polytraumatised patients who are at high risk for systemic complications [13, 15]. If placed correctly the risks associated with these devices are low and therefore this method is also frequently applied for combat and disaster related casualties [5, 9, 12, 16, 18, 20].

Furthermore, compared with two decades ago the wearing comfort has been improved by the unilateral and lightweight design. Other advantages are the possibility for wound observation and care for surrounding injured soft tissue.

The rigidity of the unilateral body is important since the amount of motion of the device does not only influence fracture alignment and healing, but also affects pin- and screw loosening. There may be a substantial risk of treatment failure if either one of these factors is inadequate [1, 11, 19].

From previous research it was concluded that a relatively simple unilateral frame can be as rigid as a three-dimensional apparatus [3, 8, 17]. Based upon the stability of the frame and the simple application some authors propagated the use of the ProCallus Fixator®, a simple 2-joint device in clinical practice. Another modern unilateral device which is currently frequently applied is a 4-joint device, the Dynafix DFS® Standard Fixator. This device has more possibilities for adapting the configuration to the clinical need, but was not yet available during earlier laboratory testing [3].

To our best knowledge data comparing the rigidity of these two devices in a model with equal and standardised pin-diameter is not available. Therefore, the aim of the current study was to compare the rigidity of these two commonly used external fixators, which differ in the possibilities to adapt the configuration to the clinical needs, in a standardised *in vitro* model.

Materials and Methods

External fixation devices

The anodised aluminum central body (B) of the ProCallus Fixator® (Orthofix®, Verona, Italy) (Figure 1) is constructed in two parts. Both components slide against each other in a groove (range 0 to 4 cm). The central body locking nut secures this movement. The micromovement nut can be loosened in order to allow a 2 mm of controlled cyclic movement in the fixator body. In this study the nut was tightened. Either side of the central body is connected to the pin clamp by one ball-joint. Each unlocked joint allows a movement of 20 degrees in all directions. The stainless steel ball is fixed in a grooved aluminum cam (C). Final locking of the cam was performed by a supplied and calibrated torque wrench (A) (torque = 21N) which turns an asymmetric bush (D) against the cam. For every set of measurements a new set of cams and bushes was used, according to the manufacturer's instructions. Since pins do not deform or break the same pins have been used throughout the measurements. Two bolts in each pin clamp secured three standard predrilled, tapered, self-tapping 200/50 stainless steel pins. The fixator itself weighs 645 grams. A variety of accessories is available for this device.

The central body component of the Dynafix DFS® Standard Fixator (EbiFix®, Iowa City, Iowa, USA) (Figure 2) is also made of anodised aluminum alloy. It is composed of two parts which allow a 360-degree rotation around the axis. When the locking set screw (D) is tightened, rotation can be set and blocked. On either side of the central body dual locking connectors with serrated discs are assembled to provide a maximum angle of 120 degrees in each parallel direction. The locking connector bolts (C) locks these four joints. Telescoping arms are secured by one bolt to the serrated discs of both connectors. Two lengths of the telescopic fixator arms are available, one that ranges 0-5 cm excursion and another 0-8 cm. The 0-5 cm-type arm was used to fit in the current model. The telescopic component is secured by two locking set screws. Two locking bolts secure the stainless steel pins (ø 5mm) within the clamps. Before each set of measurements the device was disconnected and assembled again, following the supplier's guidelines. Similar as for the ProCallus Fixator®, the same pins were used during all recordings. This device weighs 736 grams. Several accessories are available for different clinical applications.

Test setup

Measurements were performed using a non-neutral, standardised setup as described before [3]. This model was chosen since it allows for measurement of rigidity of the fixator devices alone, without any influence of variability in anchorage of the pins into the surrogate bony elements. Moreover, a larger series of fixator devices has previously been tested using this model, and thus allows for better comparison of our data. Technical details of this setup are shown in Figure 3. Two rectangular vertically positioned perspex rods (upper: 50x50x180 mm and lower: 50x50x100 mm) represent the fracture parts. The lower rod was fixed to a rigid metal block (50x50x100 mm) by four stainless steel bolts (6x50 mm). The external fixator devices were fixed into the two perspex rods by six tapered, 5-mm, stainless steel cortical bone pins (Figure 3A). The fracture gap (Figure 3B) was standardised for the ProCallus Fixator® and Dynafix DFS® Standard Fixator needing retraction of the telescopic component of 31mm and 42mm, respectively.

The pulling forces in axial, transverse and parallel direction were exerted stepwise with increments of 10N from 0 N to 160N. In axial direction also compression forces were exerted. The points of application of the different forces at the upper perspex rod are given in figure 3B. The forces were exerted by means of calibrated weights which were attached to the construction via a nylon rope, which ran over two pulleys. Using five clock gauges (Mitutoyo; NO.: 2046-08; accuracy 0.01 mm) the displacement of the upper rod in relation to the fixed lower rod was measured after each separate weight was applied. The position of the clock gauges differed for each direction in which the forces were applied (Figure 3C, a-h).

For both devices, measurements in all directions were repeated ten times in order to enhance reliability. After each measurement series, in which 0N was increased to a maximum of 160N, the entire device was removed from the six pins, completely loosened and reassembled as described above. All measurements were done by the principal investigator [PTPWB] in order to minimise any variation.

Data analysis

Before start of the study a sample size calculation was performed. Previous data showed that the variation coefficient of measuring the translation and rotation resultant ranged from 5 to 22%, indicating that the standard deviation (SD) would not exceed 22% of the mean value [3]. Ten measurements were therefore sufficient for detecting a 25% change in mean value (SD 16.5) with at least 80% statistical power, using a two-sided test with an alpha level of 0.05.

Translation was defined as the displacement of all points of the fracture surface in the same direction and over the same distance [3]. From the measurements of the displacements at the several points defined in Figure 3C the translations along the three axes were calculated using the formulas given in Table 1. The resulting displacement was defined as the translation resultant T(r).

Rotation was defined as the angle of displacement of the fracture surface from the chief axis to the starting position [3]. The resulting rotation (Rr) followed from the rotation around the three axes (Ra, Rp, Rt) in which the force was applied (Table 1).

The Student's t-test was used to test the differences in translation and rotation resultants between two fixators. A p-value <0.05 was considered statistically significant. All the measurements were performed by one researcher [PTPWB].

Results

Figures 4 -7 show the translation and rotation resultants as a result of the exerted forces in the several directions. Forces applied in parallel direction at a maximum of 100N resulted in significantly less rigidity for the Dynafix DFS® Standard Fixator (6.65±1.43mm (SD) compared with the ProCallus Fixator® (3.29±0.83mm; $p < 0.001$) (Figure 4A). The rotation resultant was similar for both devices: the Dynafix DFS® Standard Fixator 2.28±0.62˚ and for the ProCallus Fixator® 2.23±1.01˚ (Figure 4B).

For both devices the maximum recordable displacement with loading in transverse direction was reached with 60 N. The mean translation resultant with the Dynafix DFS® Standard Fixator was statistically significantly lower than found with the ProCallus Fixator® (8.14±1.20mm versus 9.83±0.63mm; $p<0.005$) (Figure 5A). The rotation resultants were similar for both devices (Figure 5B).

Force applied in the axial plane (distraction, maximum 160N) showed a mean translation resultant of 2.13±0.32mm for the Dynafix DFS® Standard Fixator versus 1.69±0.44 mm ($p<0.05$) for the 2-joint device (Figure 6A). The mean rotation resultant was 0.70±0.17° for the Dynafix DFS® Standard Fixator compared with 0.97±0.21° for the ProCallus Fixator® ($p < 0.005$) (Figure 6B).

The translation resultant after maximum compression was 1.55±1.08mm for the Dynafix DFS® Standard Fixator versus 0.15±0.33mm for the 2-joint device ($p < 0.005$) (Figure 7A). The rotation resultant with a maximum force of 160N distraction was similar for the Dynafix DFS® Standard Fixator (1.68±0.53°) and the ProCallus Fixator® (1.07±0.13°) (Figure 7B).

Discussion and Conclusions

The present *in vitro* study was performed in order to compare the rigidity of two commonly used unilateral external fixators, which differ in possibilities for adapting the configuration for clinical needs. The results indicate that both fixators were most sensitive to forces in transverse direction. Superiority of the rigidity of the devices depended upon the direction of the loading forces. Also, repeated use of both external fixators had no significant influence on the rigidity of the devices.

All measurements were performed with the external fixators in a standardised, non-neutral configuration. The maximum load of 160N was chosen as it represents the total weight of an adult leg, which is about 20% of an average total body weight of 80kg [14]. Therefore the measurements mimic the clinical situation of an adult long bone fracture as much as possible.

In a previous study Jaskulka et al. showed more rigidity of the ProCallus Fixator® upon loading in parallel, transverse, and axial (i.e., compression) direction; however, they could not confirm that this was due to differences in rigidity of the devices or due to the difference in diameter of the screws [6]. Since the pin numbers, pin diameter, pin material and pin offset distance are considered as important determinants of fixation stiffness [2, 7], these factors were kept constant in the present study.

Moreover, the pins were firmly fixed into Perspex rods in order to exclude any variability in bone density. In this way a model was constructed to determine the rigidity of the device - Perspex combination.

The ProCallus Fixator® proved to be least prone to parallel forces as well as to compression and distraction; with maximum applied forces, the mean displacement was only 50% (parallel), 10% (compression) and 80% (distraction) compared with the Dynafix DFS®

Standard Fixator. The opposite was true for rigidity towards forces in transverse direction; the mean displacement of the Dynafix DFS® Standard Fixator was approximately 80% of that found with the ProCallus Fixator®. Rotational stability was similar for both devices in parallel and transverse direction. With maximum applied compression the rotation of the ProCallus Fixator® was only 60% compared with the 2-joint device. With maximum distraction the rotation with the Dynafix DFS® Standard Fixator was 70% compared with the ProCallus Fixator®.

At 60N in transverse direction the limited range of the clock gauges was reached for translation of the fracture surface. The maximum range of the clock gauges was reached at 60N for rotation. So, both devices proved to be most sensitive to forces in transverse direction. This finding was consistent with previous results from comparable *in vitro* studies [3, 6]. Except for translation upon compression, reproducibility of the measurements was high as can be concluded from the small standard deviations.

Several factors may have influenced the different values between the devices. Especially the sliding mechanisms and the joints can be considered as weak points of external fixation systems [6]. The ProCallus Fixator® is designed with two ball joints, each allowing a 20 degrees movement in all directions. The Dynafix DFS® Standard Fixator, on the other hand, has four perpendicular to each other arranged joints, individually allowing for 60 degrees of movement. From the current data it cannot be concluded to what extent the higher number and differences in design of the joints might have affected the response to loading.

External fixators are sometimes re-used in clinical practice. Therefore, all measurements were performed with the same two devices. Given the small standard deviations in our measurements it is clear that repeated heavy loading had no adverse effect on the rigidity of the devices. This is in line with previous data [10],[4].

The present study has a couple of limitations. Fixators are expected to be most rigid when no extension is applied. Both devices were extended at a slightly different level, which was necessary for obtaining a fracture gap with a fixed size. It is not possible to exclude that this had had some effect on the results. Since the Dynafix DFS® Standard Fixator was extended most, some overestimation of the differences could have occurred.

More sophisticated motion capture systems are available. Nevertheless the current practical approach had proved to provide sufficiently precise data to compare the different fixation systems.

Especially for loading in transverse direction the maximum range of displacement detection was reached after only 60 N. For future research with the same setup clock gauges with a greater displacement detecting capacity would be recommended for this direction.

Ideally, a randomised clinical trial should be performed in order to confirm the clinical relevance of the results of the current study. However, a randomised trial among a population of patients that are known to be heterogeneous with respect to patient characteristics (*e.g.*, comorbidities) and injury patterns is unlikely to provide a reliable and definitive answer. The current *in vitro* approach is a suitable alternative for testing and comparing rigidity of external fixator devices.

In conclusion, the results of the current *in vitro* study showed that both external fixator devices tested were most sensitive to forces applied in transverse direction. The Dynafix DFS® Standard Fixator showed to be more prone to displacement following forces in parallel and axial direction compared with the ProCallus Fixator®. Rigidity with transversal forces and rotation at distraction were in favor of the Dynafix DFS® Standard Fixator. Repeated heavy loading had no significant influence on the rigidity of both devices. For clinical use, the most rigid fixator is preferable; flexibility of the construct is already present due to anchorage of pins into the bone. The four-joint Dynafix DFS® Standard Fixator device is better adaptable in clinical situation than the two-joint ProCallus Fixator®, which makes specific corrections of alignment of the fracture parts more easy.

Acknowledgements

The authors wish to thank Orthofix® (Verona, Italy) and EbiFix® (Iowa City, Iowa) for kindly providing the ProCallus Fixator® and the Dynafix DFS® Standard Fixator, respectively.

Conflict of interest

No funding was received for the preparation of this manuscript. There have been no conflicts of interest in the preparation of this manuscript.

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Table 1. Formulas of translation and rotation

	Translation (mm)	Rotation (degrees)
Axial direction	Ta= 0.5* (g+h)	Ra= arctan ((e - f)/ M)
Parallel direction	Tp= b	Rp= arctan ((c-d)/ N)
Transverse direction	Tt= 0.5* (e+f)	Rt= arctan ((a-b)/ N)
Resultant	Tr= $\sqrt{(Tp^2 + Tt^2 + Ta^2)}$	R_r= $\sqrt{(Rp^2 + Rt^2 + Ra^2)}$

The points a to h represent the standardised measuring points as shown in Figure 3C. M represents the distance between the points e and f (40mm). N represents the distance between the points c and d and between the points a and b (160mm)

Figure legends

Figure 1. Separate major parts of the 2-joint fixator

The fixator consists of a central body (B) with sliding mechanism to set the length of the device and with on either side a pin clamp connected with a ball-joint. For fastening the ball-joint a calibrated torque wrench (A) is used. The aluminum cam (C) and bush (D).

Figure 2. Separate major parts of the Dynafix DFS® Standard Fixator

The fixator consists of a body (A), central rotary joint and set screw (B), locking connector bolt (C), pin clamp unit with sliding mechanism to set the length of the device (D).

Figure 3. Overview of the measurement setup

A: Overview of the laboratory test model, set up with the 2-joint device. Contact between "fracture ends" was not possible. The displacement of the free upper fragment is measured by placing the clock gauges at each of the measuring points.

B: Two rectangular perspex rods were used to represent a fracture of an adult long bone. The lower part is fixed and represents the proximal portion. The fracture surface had been shaded. The positions of the pins and rods are standardised. Arrows indicate the direction of the forces. Lengths are given in mm.

C: Standardised measuring points a to h of the clock gauges on the upper fragment of the test model. Formulas used to calculate translation and rotation are stated in Table 1.

Figure 4. Translation resultant (**A**) and rotation resultant (**B**) of the displacement of the centre of the fracture surface following forces applied in parallel direction.

Measurements were performed by one researcher [PTPWB]. Data are given as mean with standard deviation of 10 measurements per device. Student t-test was performed to assess statistical significance of differences between the devices: $^{a}p<0.05$, $^{b}p<0.01$, $^{c}p<0.005$, and $^{d}p<0.001$.

Figure 5. Translation resultant (**A**) and rotation resultant (**B**) of the displacement of the centre of the fracture surface following forces applied in transverse direction.

Measurements were performed by one researcher [PTPWB]. Data are given as mean with standard deviation of 10 measurements per device. Student t-test was performed to assess statistical significance of differences between the devices: $^{a}p<0.05$, $^{b}p<0.01$, $^{c}p<0.005$, and $^{d}p<0.001$.

Figure 6. Translation resultant (**A**) and rotation resultant (**B**) of the displacement of the centre of the fracture surface following distractional forces.

Measurements were performed by one researcher [PTPWB]. Data are given as mean with standard deviation of 10 measurements per device. Student t-test was performed to assess statistical significance of differences between the devices: $^{a}p<0.05$, $^{b}p<0.01$, $^{c}p<0.005$, and $^{d}p<0.001$.

Figure 7. Translation resultant (**A**) and rotation resultant (**B**) of the displacement of the centre of the fracture surface following compressional forces.

Measurements were performed by one researcher [PTPWB]. Data are given as mean with standard deviation of 10 measurements per device. Student t-test was performed to assess statistical significance of differences between the devices: $^{a}p<0.05$, $^{b}p<0.01$, $^{c}p<0.005$, and $^{d}p<0.001$.

Figure 1

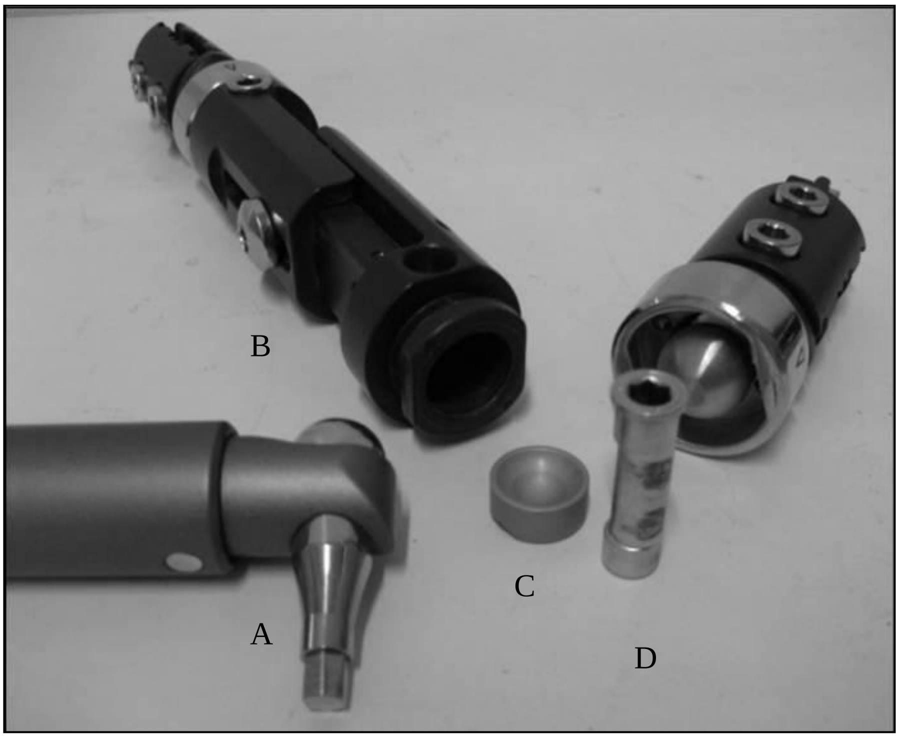

Figure 2

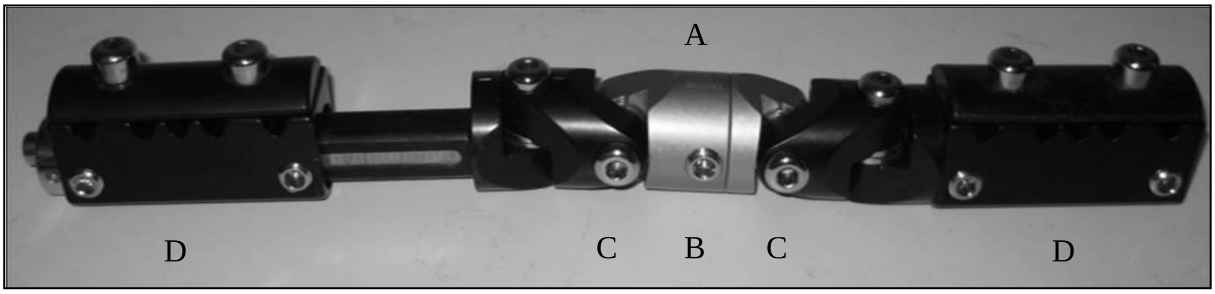

Figure 3

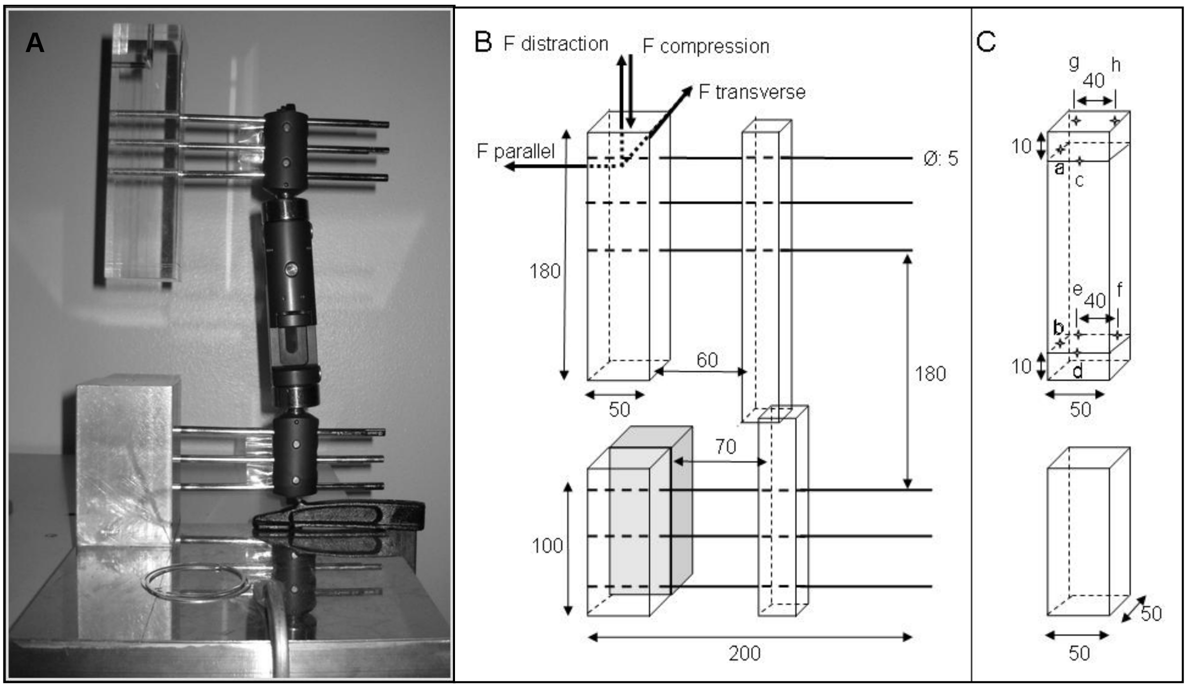
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Figure 4

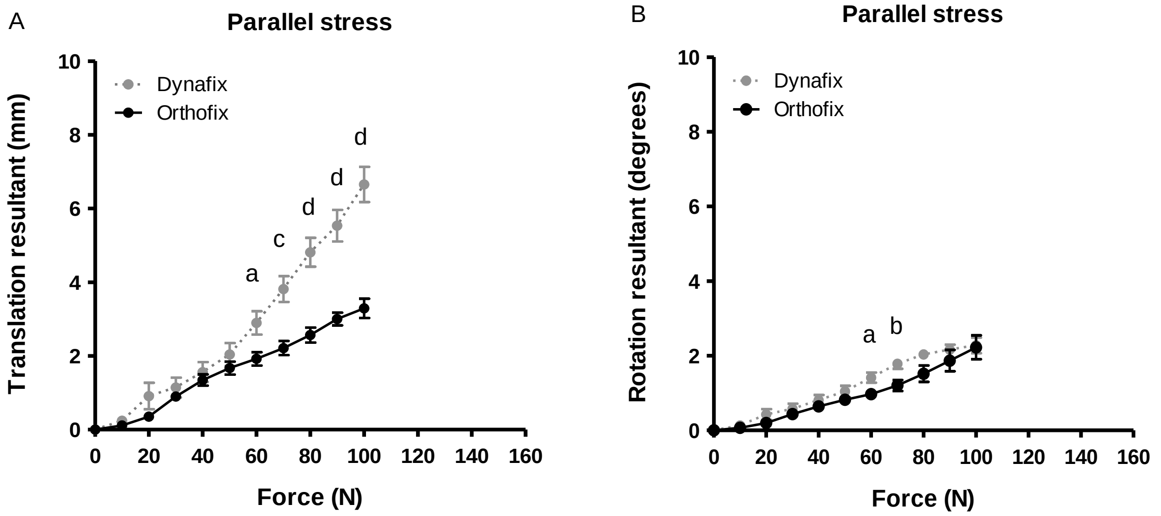

Figure 5

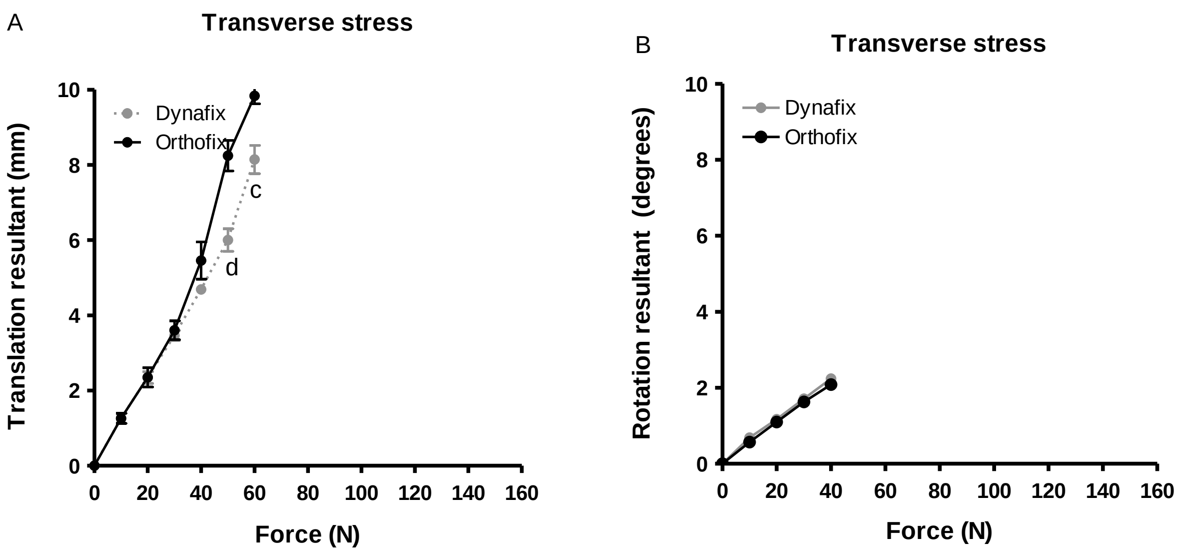

Figure 6

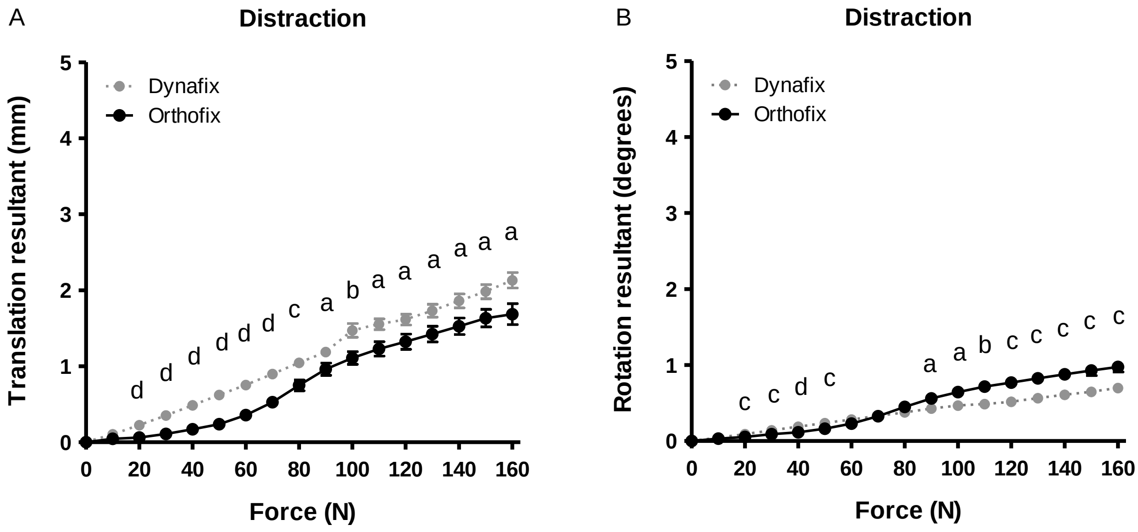

Figure 7