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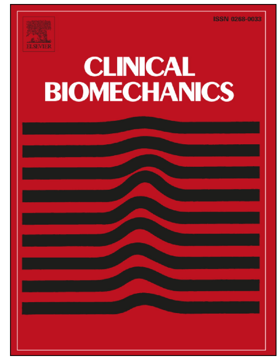

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Supplementary Medial Locking Plate Fixation Of Ludloff Osteotomy versus Sole Lag Screw Fixation: A Biomechanical evaluation

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ABSTRACT

Background: The Ludloff oblique osteotomy is inherently unstable, which might lead to delayed union and loss of correction. Supplementary fixation to two lag screw fixation has been proposed. The hypothesis is that the osteotomy fixation constructs supplemented by a mini locking plate provide greater resistance to osteotomy gaping and loss of angular correction in response to cyclic loading.

Methods: Twenty fourth generation composite 1st metatarsals were used and underwent a Ludloff osteotomy. They were divided in two fixation groups: two lag screws (Group A), and with a supplementary mini locking plate (Group B). Specimens were subjected to either monotonic loading up to failure or to fatigue (cyclic) tests and tracked using an optical system for 3D Digital Image Correlation.

Findings: The osteotomy gap increased in size under maximum loading and was significantly greater in Group A throughout the test. This increase was observed very early in the loading process (within the first 1,000 cycles). The most important finding though, was that with the specimens completely unloaded the residual gap increase was significantly greater in Group A after only 5,000 cycles of loading up to the completion of the test. The lateral angle change under maximum loading was also significantly greater in Group A throughout the test, with that increase observed early in the loading process (5,000 cycles). With the specimens completely unloaded the residual lateral angle change was also significantly greater in Group A at the completion of the test.

Interpretation: Supplementary fixation with a mini locking plate of the Ludloff osteotomy provided greater resistance to osteotomy gaping and loss of angular correction compared to sole lag screws, in response to cyclic loading.

1. Introduction

A number of proximal (Chow et al., 2008; Easley et al., 1996; Gallentine et al., 2007; Trnka et al., 1999) and diaphyseal (Chiodo et al., 2004; Robinson et al., 2009; Trnka et al., 2008) osteotomies have been utilized for the correction of moderate and severe hallux valgus deformities, but there are several issues regarding their mechanical instability, inadequate fixation and reduced healing potential which might lead to delayed union, dorsal malunion, or fixation failure with subsequent loss of correction (Chiang et al., 2012; Easley et al., 1996; Robinson et al., 2009; Trnka et al., 1999). The Ludloff diaphyseal oblique osteotomy (Chiodo et al., 2004; Robinson et al., 2009; Saxena, McCammon., 1997; Trnka et al., 2008) seems to be the most commonly used osteotomy (Pinney et al., 2006) (among foot and ankle surgeons in USA) for the correction of severe hallux valgus deformity. The procedure achieves deformity correction, pain reduction and functional improvement (Chiodo et al., 2004; Robinson et al., 2009; Saxena, McCammon., 1997; Trnka et al., 2008).

Several biomechanical studies have provided controversial data, with the Ludloff osteotomy fixed with two screws demonstrating superior (Lian et al., 1992; Hofstaetter et al., 2008; Scott et al., 2010; Trnka et al., 2000), equal (Acevedo et al., 2002) , or even inferior (Trnka et al., 2000; Unal et al., 2010) biomechanics comparing to other commonly performed osteotomies. Like other proximal osteotomies, the Ludloff osteotomy is inherently unstable due to its geometry thus the entire load is transferred from the distal fragment to the proximal through the fixation device (Sammarco, 2008). This instability inevitably leads to irritation callus formation at the osteotomy site with a reported incidence of 16% to 26,7% (Chiang et al., 2012; Trnka et al., 2008). Delayed union is a well described complication with an incidence of 2%-6,7% (Chiang et al., 2012; Chiodo et al.,2004; Robinson et al., 2009; Trnka et al., 2008). Significant loss of correction of the intermetatarsal angle early in the postoperative period has been reported (Robinson et al., 2009), and it is interesting that in one study led to a recurrence in 26,7% of the patients (Chiang et al., 2012). Malunion requiring revision has also been observed with a reported incidence of 1.5 % to 5%. (Chiodo et al.,2004; Trnka et al., 2008).

Our clinical observation in cases with inadequate fixation and mechanical instability of the Ludloff osteotomy, is that there is a tendency for the first metatarsal to rebound back in varus. The result is loss of the correction of the intermetatarsal angle (IMA). This observation along with the previously reported data have led us to modify the fixation of the Ludloff osteotomy by adding a small locking plate on the medial side of the metatarsal as a “medial buttress” (Stamatis et al., 2010). The theoretical advantages of such an application are: **a.** Neutralization of the forces across the compressed osteotomy site with the lag screws thus improving the mechanical stability and **b.** “Buttressing” of the dorsal fragment preventing from rebounding in varus in the setting of lag screw loosening.

The purpose of this study was to quantify the mechanical stability of supplementary fixation of the Ludloff oblique diaphyseal osteotomy utilizing a mini locking plate paying attention to loading under fatigue conditions.

2. Methods

2.1 Surgical procedure

Twenty fourth generation synthetic 1st metatarsals (Sawbone, Pacific Research Laboratories, Vashon, WA) were used for the completion of the present experimental study. The synthetic metatarsals underwent Ludloff oblique osteotomy starting dorsally 2 mm distal to the level of the metatarsocuneiform joint, aiming distally at a 30° angle with respect to the axis of the metatarsal shaft. After completion of the dorsal two thirds of the osteotomy, a 2.7 mm titanium interfragmental screw (Synthes, Synthes GmbH, Switzerland) was inserted in a lag mode 6 mm distal to the dorsal osteotomy, but it was not fully tightened to allow the completion of the plantar one third of the osteotomy. After completion of the osteotomy, the distal (dorsal) fragment was rotated 5° laterally (lateral distal-fragment angle) around an axis formed by the 2.7 mm screw. Finally, a second stainless steel interfragmental compression screw (double threaded cannulated headless Barouk screw DePuy International, Leeds, UK), was inserted from plantar to dorsal, and the overhanging bone of the proximal (plantar) fragment was removed, leaving a flat medial surface on the metatarsal shaft. At this point the specimens were randomly divided into two groups with ten specimens each.

The specimens of group A were tested as they were while the specimens of group B underwent supplementary fixation with a 4-hole, 2.4 mm titanium mini locking plate (Synthes, Synthes GmbH, Switzerland) which was applied on the medial surface, with two screws (the most proximal and distal) inserted in the plantar and dorsal fragments, respectively (Figure 1).

2.2 Mechanical testing

2.2.1 Monotonic loading up to failure tests

The mechanical tests were performed with the use of a servo-hydraulic load frame (Mini-Bionix 858, MTS Systems, Eden Prairie, MN) capable for applying quasi-static monotonic as well as cyclic (fatigue) loads. The applied load was measured with the use of a 500 N force transducer (MTS 661.11,Eden Prairie,MN). The specimens were fixed to the base of the load frame using a tilting vice to simulate the anatomical position of the 1st metatarsal during standing. Considering that the axis of loading corresponds to the direction of ground reaction forces and that a plane perpendicular to the axis of loading corresponds to the simulated ground, the samples were positioned in such way that their axis was forming a 15° angle with respect to a plane perpendicular to the loading axis (Acevedo et al., 2002). The load was applied at the distal-plantar side of the synthetic bones through a sphere (Figure 2B).

The specimens' response to loading was studied with the use of an optical system (LIMESS Messtechnik und Software GmbH, Q-400-3D) for 3D Digital Image Correlation (DIC). 3D DIC is a contactless video-based technique for performing full field measurements of the displacements and strains developed during loading of a specimen. The specimen is covered with a stochastic/speckle pattern and viewed by two cameras that are positioned in a relative angle to one another (≈40°) (Figure 2A, 2B). The 3D DIC system utilizes the stochastic/speckle pattern to define a set of “markers” on the surface of the specimen and map their 3D displacement field during testing. The measurement of out-of-plane displacements and strains is performed based on the principles of stereoscopic vision.

The loading conditions of the cyclic tests were defined with the help of a series of preliminary measurements. Three specimens of each group were tested until failure under monotonic quasi-static loading and their strength was assessed. The load-to-failure of the weakest construct was used as reference to define the maximum applied load during cyclic testing. More specifically the preliminary monotonic tests were performed under displacement control with a loading rate of 1 mm/min (Tsilikas et al., 2011). The displacement of the load frame piston, namely the grip-to-grip displacement and the resulted reaction force were recorded with a frequency of 1 Hz. At the same time the specimen was also photographed by the two cameras of the 3D-DIC system with the same frequency, (i.e.1 Hz) (3A, 3B). The 3D DIC was used to calculate the opening of the osteotomy gap and the change of the lateral distal-fragment angle between the distal and the proximal part of the specimen. These calculations were performed based on measurements of the displacements (Ux,Uy,Uz) of four predefined points. All calculations were performed using specialised software Istra4D (LIMESS Messtechnik und Software GmbH). As it can be seen in Figure 3C the osteotomy gap was calculated as a change in the distance between two points (a and b) at the plantar side of the specimen (one at each side of the osteotomy), while the lateral angle change was calculated using two points at the distal - medial side (c and d). The criterion for failure was either a drop of the force or excessive osteotomy opening, namely higher than 2 mm (Acevedo et al., 2002).

2.2.2 Fatigue (cyclic) tests

The experimental set-up used for the displacement-controlled monotonic tests was also utilized to perform load-controlled cyclic ones. The remaining fourteen specimens (seven specimens per group) were subjected to load-unload cycles at a frequency of 3Hz. The minimum force that was applied to the specimens during a load cycle was equal to 0.5 N while the maximum one was determined based on the results of the monotonic tests. More specifically, the load level of the cyclic testing was equal to the 70% of the monotonic load-to-failure of the "weakest" construct, namely the specimen with the lowest load to failure. Based on the above the load level of the cyclic testing was set to 87.5 N.

The tests were terminated when the displacement of the load frame piston or the load cycle number reached a critical value. The critical value for the displacement was 7 mm while the respective value for the load cycle number was 300,000 (Acevedo et al., 2002). For each load cycle the maximum grip-to-grip displacement was recorded. The specimens were also photographed by the two cameras of the DIC system. Before the initiation of the loading procedure each specimen was photographed unloaded. These photographs were used as reference for the DIC calculations. During testing the specimens were photographed once every 100 cycles for the first 5,000 cycles and then once every 5,000 cycles for the rest of the test while being under maximum load. These photographs were used to measure the progression of the osteotomy gap opening and the change of the lateral angle between the distal and the proximal part of the specimen. Moreover the specimens were also photographed unloaded after the first 5,000 and 300,000 cycles to assess permanent changes in terms of osteotomy gap opening and lateral angle change.

The results for the two specimen groups were compared to each other and the statistical significance of the differences that were observed was evaluated using two-sample t-test. The level of statistical significance was considered to be equal to 0.05. Preliminary analyses were performed to ensure the assumptions of normality, linearity and homoscedasticity were not violated. During cyclic testing, the osteotomy gap opening and lateral angle change were calculated following the same methodology used for the monotonic loading tests (Figure 3C).

3. Results

3.1 Baseline measurements

The average (±STDEV) load-to-failure for the three samples of group A (two lag screws) and B (supplementary nini locking plate) was 187N (±72N) and 150N (±15N) respectively. Out of the six specimens that were tested in total the specimen with the lowest quasi-static load-to-failure (i.e. the "weakest" construct) sustained a load of 125 N. Based on the above the maximum load level of the cyclic testing was set to 87.5 N. For this applied force the measured opening of the osteotomy was equal to 0.87 mm and the change of the lateral angle between the distal and the proximal part of the specimen was equal to 0.18 deg.

Based on these preliminary tests it was indicated that the applied loading generates relatively low but measurable osteotomy gap and relative rotation between the distal and the proximal parts of the specimens.

3.2 Cyclic testing

In the case of group A, four out of the seven specimens in total completed 300,000 load cycles without failing. For the other three specimens failure occurred after 3,200, 16,700 and 70,000 cycles respectively. In the case of Group B two specimens failed before completing 300,000 load cycles. One failed after 46,600 and the second after 45,000 load cycles. Examination of the aforementioned specimens after testing indicated that failure was caused by synthetic bone breakage in the vicinity of the screws and/or screw pullout. Unfortunately, the relatively low sampling rate for osteotomy gap and correction angle after the first 5,000 cycles doesn't allow for detailed analysis of the phenomena leading to failure. However in the case of the only sample that failed before the first 5,000 cycles, where osteotomy gap and correction angle were sampled every 100 cycles, it was found that the complete failure of the construct was preceded by significant change in its mechanical behaviour. More specifically initial failure appears to be followed by gradual increase in osteotomy gap and correction angle leading to the complete failure of the construct after a few hundred cycles.

Average results in terms of grip-to-grip displacement, osteotomy gap and the change of the osteotomy's lateral angle are presented in Figure 4 for all samples that completed 300,000 load cycles. As it can be seen average grip-to-grip displacement is very similar for both groups but clear differences exist in terms of gap and lateral angle change with Group A yielding higher values. Moreover most of the variation in terms of displacement, gap and lateral angle change occurs within the first few thousand load cycles while after the first 5,000 cycles the change rate is considerably lower (Figure 4). For example the average (±STDEV) increase of gap was 11.3% (±1.7%) for Group A and 5.7 (±0.89) % for Group B for the first 5,000 cycles but less than 1% (STDEV<1%) for both groups for the next 5000 cycles (i.e. between 5,000 and 10,000).

Detailed comparative results for the two groups can be seen in Tables 1 and 2. The measurements presented in Table 1 were taken during the 1,000th, 5,000th and 300,000th load cycle with the specimens under maximum load. As it can be seen no statistically significant difference was found between the two groups for the grip-to-grip displacement (p-value > 0.05). On the contrary statistically significant differences were found in terms of gap opening. More specifically, the average osteotomy gap measured during the 1,000th, 5,000th and 300,000th load cycle for the specimens of group B was smaller compared to those of group A by 30%, 33% and 27% respectively. Statistically significant differences between the two specimen groups were also observed in the case of the lateral angle change. The specimens of group B had 57% and 58% less lateral angle change during the 5,000 and 300,000 cycle than the specimens of group A.

The measurements presented in Table 2 were taken during the 5,000th and 300,000th load cycle with the specimens completely unloaded. As it can be seen the specimens of group B had 51% and 57% less residual gap than group A after 5,000 and 300,000 load cycles respectively. Moreover group B exhibited 75% less lateral angle change than group A after 300,000 load cycles. No statistical significant differences were observed for the grip-to-grip displacement (Table 2).

4. Discussion

There are several factors-both intrinsic and extrinsic- that might influence the mechanical behaviour of the Ludloff osteotomy. The latter osteotomy is inherently unstable due to its geometry thus the entire load is transferred from the distal fragment to the proximal through the fixation device (Sammarco, 2008). Additionally, the need for increased lateral rotation of the distal (dorsal) fragment for the correction of severe deformities with large intermetatarsal angles leaves less contact area between the two fragments thus reducing the area for implant placement and adequate fixation as well as the healing potential. Furthermore, since the entire load is transferred from the distal (dorsal) fragment to the proximal (plantar) through the fixation device there is a substantial force concentration at the small cortical bridge between the proximal drill hole and the osteotomy exit site at the dorsal aspect of the metatarsal which could potentially lead to a stress fracture and late displacement of the osteotomy. Finally, decreased bone mineral density compromises the strength of any given fixation as it is the case in all orthopaedic procedures (Hofstaetter et al, 2016). The lack of adequate fixation –which is of paramount importance for expeditious bone healing (Lienau et al., 2005)- results in increased motion at the osteotomy site which could lead to delayed union or nonunion with potential late loss of correction.

The most indicative radiographic sign of instability is the presence of abnormal callus formation at the osteotomy site. Several authors have reported the presence of callus in 4% -26.7% of the patients in their series (Chiang et al., 2012; Chiodo et al., 2004; Trnka et al.,2008) and correlated it with delayed union (4%-6.7%), loss of first intermetatarsal angle correction (16%), and recurrence (4.5%-26.7%). Choi et al. (2009) reported 5.7 % recurrence rate in the Ludloff group of their patients with two thirds of the cases occurring in the setting of osteopenia, thus with compromised fixation. Finally, Robinson et al. (2009) reported early loss of correction of hallux valgus and first intermetatarsal angle (six month follow up), while the reported delayed union rate was 5% resulting in 3.5 % of dorsiflexion malunion.

Schon et al. (2005) having noticed that clinical problem proposed supplementary fixation of the Ludloff osteotomy with two K-wires. Despite the fact that the proposed supplementary fixation did not provide significant difference in fixation strength in a biomechanical study (Jung et al., 2005), in a clinical study Choi et al. (2013) demonstrated that this kind of fixation significantly reduced the late loss of the postoperative correction of the first intermetatarsal angle. K-wire fixation has the advantage of ease of application and removal but very often causes traction and pain in the surrounding skin. Loosening of the K-wires necessitates premature removal and if buried a second surgical intervention is mandatory.

Our clinical observations and the reported issue-namely inadequate postoperative stability is strongly associated with loss of correction of first intermetatarsal angle- led us to modify the fixation of the Ludloff osteotomy by adding a small locking plate on the medial side of the first metatarsal (Stamatis et al., 2010). The issue arising from the use of locking plates is that they create rather stiff constructs which might lead to nonunion or implant failure (Smith et al., 2007). Careful use of the locking plates according to the neutralization principle to protect the lag screws in the osteoporotic bone is the answer. A previous study from our institution (Tsilikas et al., 2011) proved that the mini locking plate-screw constructs did not demonstrate a significant difference in stiffness compared to the sole screw constructs.

The results of the current study demonstrate that the osteotomy gap increased in size under maximum loading and was significantly greater in Group A (two lag screws) throughout the test. This increase was observed very early in the loading process (i.e. within the first 1,000 cycles). The most important finding though, was that with the specimens completely unloaded the residual gap increase was significantly greater in Group A after only 5,000 cycles of loading up to the completion of the test. The lateral angle change under maximum loading was also significantly greater in Group A throughout the test, with that increase observed early in the loading process (5,000 cycles). With the specimens completely unloaded the residual lateral angle change was also significantly greater in Group A at the completion of the test, and despite the fact there was no statistically significant difference after the first 5,000 cycles, there was a trend.

Extreme caution must be exercised in extrapolating the findings of biomechanical studies to the clinical setting. It needs to be highlighted that even though the differences between the two groups were statistically significant, they were also relatively small. Further clinical studies are needed to assess the clinical relevance of the observed differences. However, it is very interesting to correlate our results with the reported clinical observations in patients where the Ludloff osteotomy had been fixed with two lag screws. Our findings that the lateral angle change was significantly greater in the two lag screw fixation group throughout the test, even in the unloaded specimes, can be correlated with the reported early loss of first intermetatarsal correction (Chiang et al., 2012; Robinson et al., 2009). Another finding in our study is that supplementary fixation with a locking plate leads to a significantly greater resistance to the lateral angle change. This can be correlated with the clinical observation that supplementary fixation -by means of K-wires- significantly reduced the loss of the postoperative correction of the first intermetatarsal angle (Choi et al., 2013). We are currently performing a prospective clinical study investigating the effect of supplementary fixation on any potential change of postoperative first intermetatarsal angle correction in patients with severe hallux valgus deformities.

The current study has several limitations and strengths. As with all studies performed in a lab, we could not involve the natural response of bone healing and remodelling and its effect on stability during the postoperative period. Moreover the loads that are able to produce significant changes in the stability of any given constructs in the lab tests are lower than those a construct may endure during in vivo loading. This is mainly because lab measurements do not take into account the stabilizing effect of the plantar fascia, the peroneus longus, and the plantar musculature. All these soft tissues contribute to an intrinsic mechanism whereby part of the force of weight bearing is transferred to axial load rather than shearing or bending (Stokes et al. 1979). Another limitation of the current study is the use of fourth generation composite metatarsals, instead of paired, fresh-frozen specimens (which are considered the modern standard for biomechanical studies). Thus, we were not able to check the effects of biological variability in bone qualities, and we did not take into account the lubrication effects of moisture and fat present at the implant-bone interfaces in real human bone. The use of a contactless video-based technique (3D-DIC) in order to study several aspects of the samples' mechanical behaviour, is limited in the case of multi-cyclic loading. This limitation is due to the volume of the information that needs to be recorded and the size of the generated files of raw data. Indeed, each measurement is based on the post-processing of a pair of high quality images (approximately 3 Mb each) which makes recording at high sampling rates very challenging.

Composite analogue Sawbone® fourth generation bone models provide consistent geometric and structural properties, and their variability is significantly lower than that of cadaveric specimens for all loading regimens (Gardner et al., 2010; Heiner, 2008), that represent a valuable asset in a range of biomechanical analyses and testing procedures, which is paramount for demonstrating relative differences between different types of internal fixation (Hungerer et al., 2014; Jones et al., 2014; Lasanianos et al., 2013). We were able to use plates and screws of the same size, insuring bicortical purchase with each installation, similar levels of osteotomy position and rotation, and similar position of the plates and lag screws, while following standard operative technique. Finally the use of a contactless video-based technique (3D-DIC) enabled studying aspects of the samples' mechanical behaviour, such as angular correction loss, that could not be studied using conventional sensors.

5. Conclusion

The results of the current study demonstrate that the supplementary fixation with a mini locking plate of the Ludloff osteotomy creates a construct with greater resistance to deformation than the sole screws one. This supplementary fixation might be extremely useful in cases with osteopenia or when there is a need for increased rotation of the dorsal (distal) fragment (encountering a wide 1-2 intermetatarsal angle).

Legends

Figure 1: Typical samples of Group A (top) and Group B (bottom). The specimens are painted with a stochastic/speckle pattern to enable the use of DIC.

Figure 2: (A) A general view of the experimental set up with the sample mounted on the load frame, the light sources, and the DIC cameras. (B) A closer view of the sample on the tilting vice. The plantar side and the loading direction are indicated with arrows.

Figure 3: A specimen viewed from the left (A) and the right camera (B) of the DIC system and the 3D contour of the specimen where its full displacement field was measured (C). The measured displacements for points a and b were used to calculate the opening of the osteotomy while the respective ones of points c and d for calculating changes in the lateral angle between the distal and the proximal parts of the specimen.

Figure 4: The average values (±STDEV) of grip-to-grip displacement (A), osteotomy gap opening (B) and lateral angle change (C) under maximum load for the duration of the cyclic tests.

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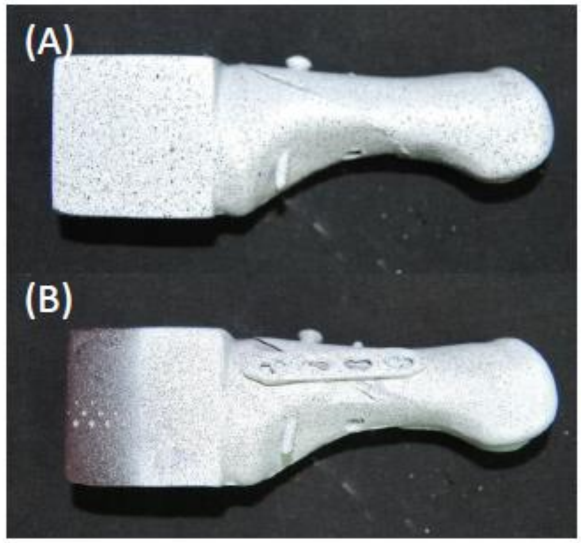


Fig. 1

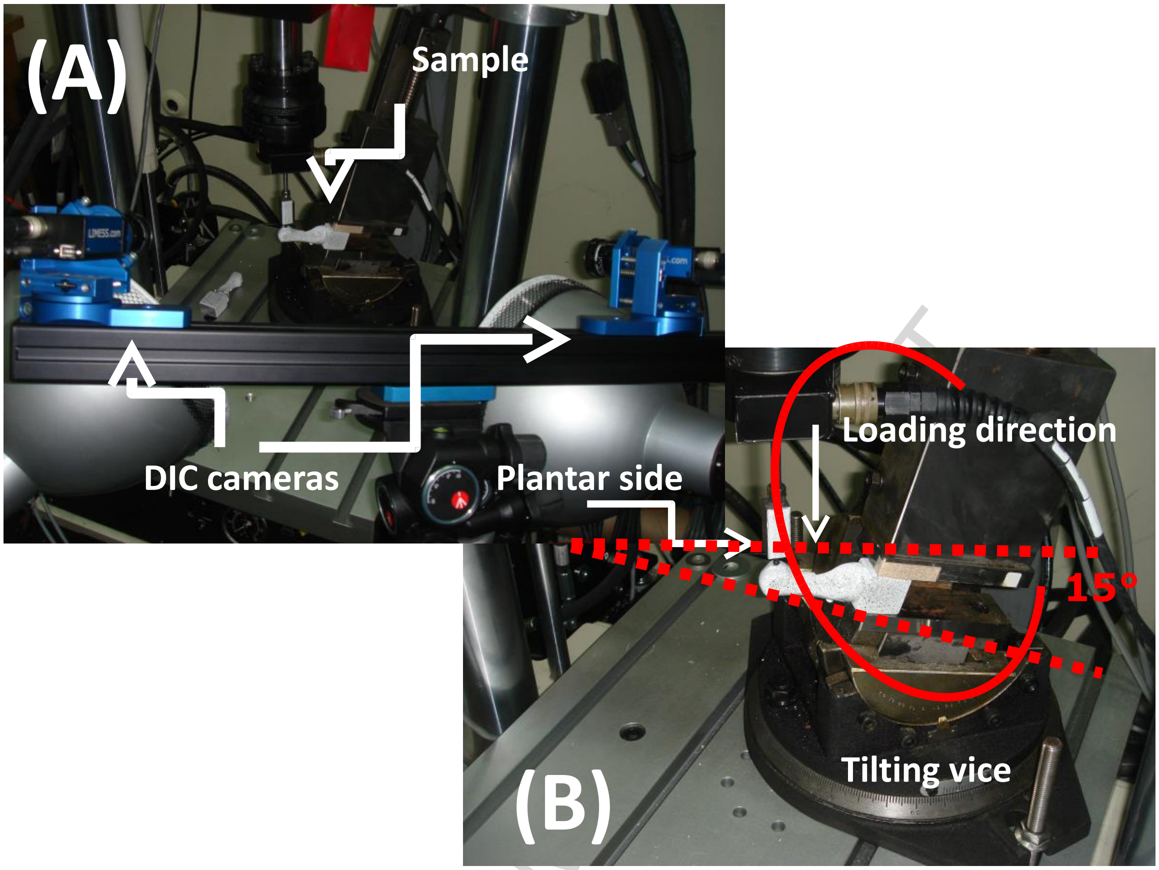

(A)
Sample
DIC cameras
Plantar side
Loading direction
15°
Tilting vice
(B)

Fig. 2

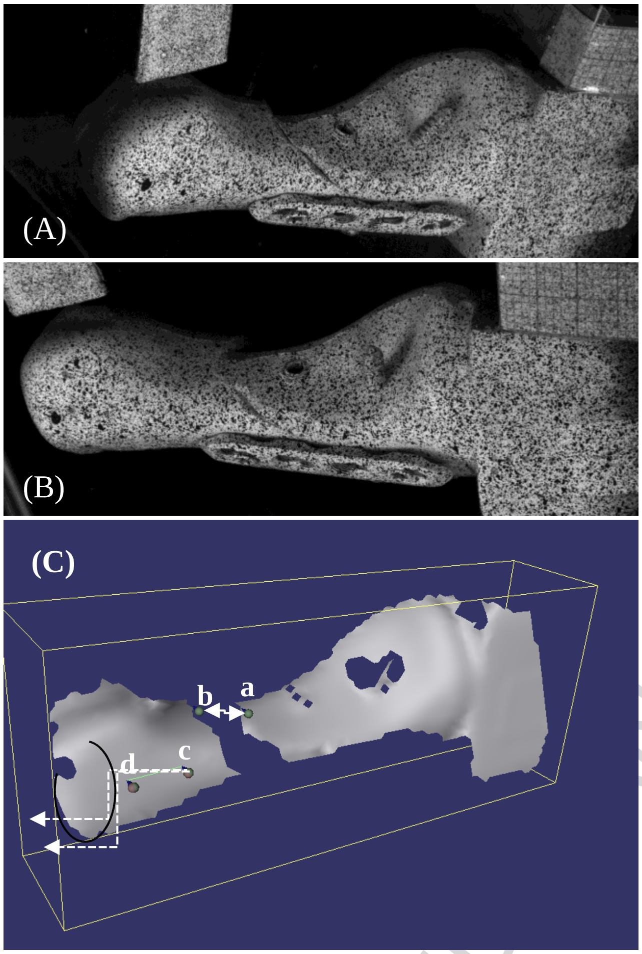
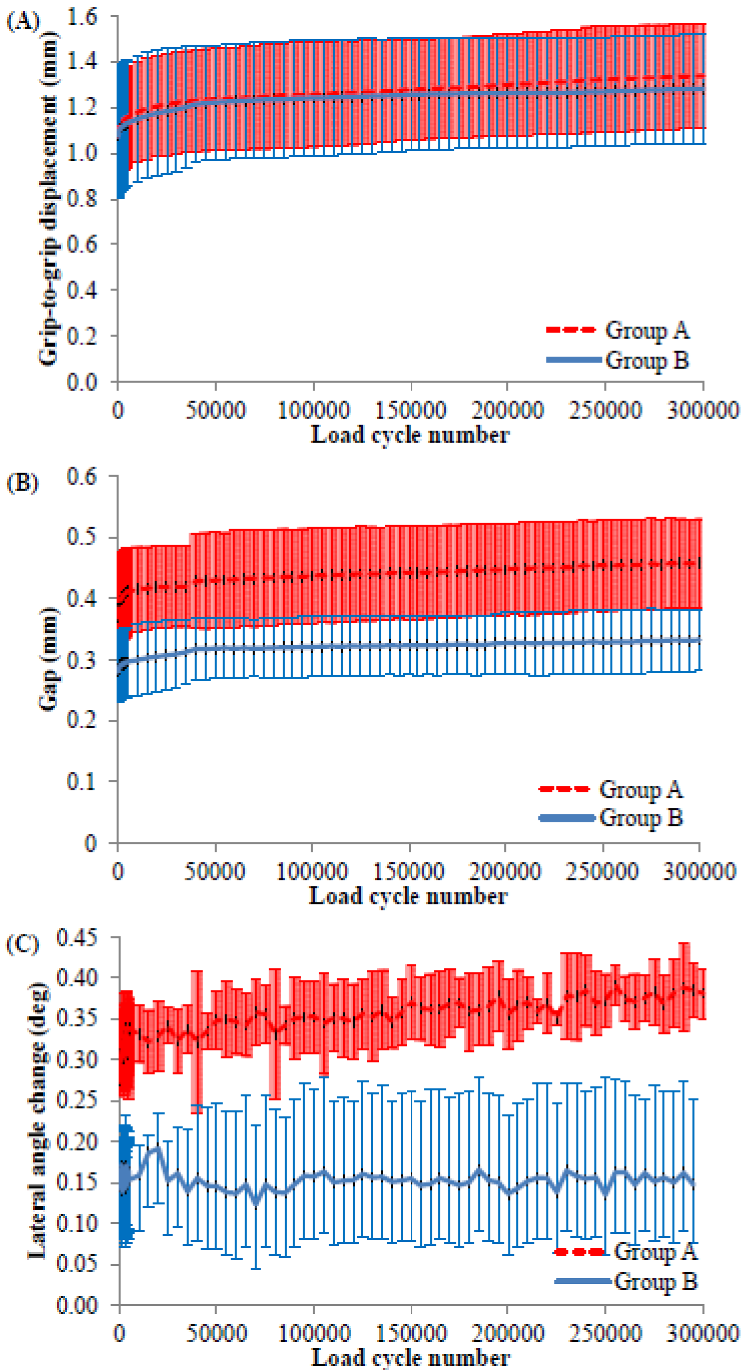


Fig. 3


(A)
Grip-to-grip displacement (mm)
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0
Group A
Group B
0
50000
100000
150000
200000
250000
300000
Load cycle number
(B)
Gap (mm)
0.6
0.5
0.4
0.3
0.2
0.1
0
Group A
Group B
0
50000
100000
150000
200000
250000
300000
Load cycle number
(C)
Lateral angle change (deg)
0.45
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
Group A
Group B
0
50000
100000
150000
200000
250000
300000
Load cycle number

Fig, 4

Table 1: The mean values and standard deviations of the maximum grip-to-grip displacement, osteotomy gap and lateral angle change for the two specimen groups at different load cycles. The sample size (N) for each of the measurements is also shown. The measurements correspond to the case where the specimens are under maximum load, namely 87.5 N. The % difference between the mean values is calculated only when the difference between the two groups is statistically significant (p-value < 0.05). For these cases the value of Cohen's d is also presented as a measure of effect size.

Load cycle number	**Measurement**	**Group A**			**Group B**			**Difference (%)**	**P value**	**Cohen's d**
		N	**Mean**	**StDev**	**N**	**Mean**	**StDev**			
1000	**Displacement (mm)**	7	1.24	0.17	7	1.18	0.28	-	0.68	-
	Gap (mm)	7	0.38	0.07	7	0.26	0.02	30	0.01	2.8
	Lateral angle change (deg)	7	0.19	0.15	7	0.15	0.05	-	0.53	-
5,000	**Displacement (mm)**	6	1.51	0.62	7	1.22	0.28	-	0.32	-
	Gap (mm)	6	0.40	0.08	7	0.27	0.02	33	0.01	2.6
	Lateral angle change (deg)	6	0.35	0.03	7	0.15	0.06	57	0.00	3.9
300,000	**Displacement (mm)**	4	1.35	0.16	5	1.24	0.15	-	0.41	-
	Gap (mm)	4	0.46	0.07	5	0.33	0.05	27	0.04	2.4
	Lateral angle change (deg)	4	0.38	0.03	5	0.16	0.10	58	0.02	3.2

Table 2: The mean values and standard deviations of the residual grip-to-grip displacement, osteotomy gap and lateral angle change for the two specimen groups after 5000 and 300000 load cycles. The sample size (N) for each of the measurements is also shown. The measurements were taken with the specimens completely unloaded. The % difference between the mean values is calculated only when the difference between the two groups is statistically significant (p-value < 0.05). For these cases the value of Cohen's d is also presented as a measure of effect size.

Load cycle number	Measurement	Group A			Group B			Difference (%)	P value	Cohen's d
		N	Mean	StDev	N	Mean	StDev			
5,000	Displacement (mm)	6	0.63	0.34	7	0.66	0.32	-	0.88	
	Gap (mm)	6	0.12	0.05	7	0.06	0.03	51	0.03	1.7
	Lateral angle change (deg)	6	0.18	0.11	7	0.08	0.11	-	0.08	
300,000	Displacement (mm)	4	0.66	0.17	5	0.67	0.22	-	0.93	
	Gap (mm)	4	0.18	0.04	5	0.08	0.02	57	0.01	3.7
	Lateral angle change (deg)	4	0.30	0.09	5	0.07	0.03	75	0.00	4.4

Highlights

- A modified fixation for Ludloff osteotomy is proposed utilizing a mini locking plate
- Fourth generation composite 1^{st} metatarsals underwent quasi-static monotonic load up to failure or fatigue (cyclic) tests
- The specimens were tracked using an optical system for 3D Digital Image Correlation
- The developed osteotomy gap was significantly lower in the modified fixation group
- The lateral angle change was significantly lower in the modified fixation group