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Increased stability by a novel femoral neck interlocking plate compared to conventional fixation methods. A biomechanical study in synthetic bone



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<i>Keywords</i> : Femoral neck fracture Biomechanics Internal fixation Locking plate Composite bone	Background: Stable fixation promotes union in the common femoral neck fractures, but high non-union rates due to fixation failure remain with traditional fixations. To enhance stability, a plate interlocking pins, but without further fixation to femur has been developed. To our knowledge, no comparison to other conventional fixation methods has been performed. We tested the hypothesis that the novel implant biomechanically leads to a more stable femoral neck fixation. <i>Methods:</i> Fifty synthetic femurs with a cervical wedge osteotomy were allocated to intervention with three hookpins interlocked in a plate (Hansson Pinloc [®] System) or standard fixations with a two-hole Dynamic Hip Screw [®] plate with an anti-rotational screw, three cannulated screws (ASNIS [®] III) or two screws (Olmed [®] or Cannulated Hip Screws [®]). Quasi-static non-destructive torsion around the neck, anteroposterior bending and vertical compression were tested to detect stiffness. The specimen's deformation was evaluated after cyclic compression simulating weight-bearing. Local deformation of implant channels was measured. Fixation failure was defined by fissure formation. <i>Findings:</i> Compared to the conventional implants all together, the interlocked pins enhanced mean stiffness 130% in torsion and 33% in bending ($P < 0.001$), while compressive stability was increased by a reduced deformation of 62% in average of the global test specimen and 95% decreased local implant channel deformation after cycling ($P < 0.001$). In comparisons with each of the standard fixations the interlocking pins revealed no signs of adverse effects. <i>Interpretation:</i> The novel femoral neck interlocking plate allowed dynamic compression and improved multi-directional stability compared to the traditional fixations.

1. Introduction

The ever-present challenge of patients with intracapsular femoral neck fractures justifies an intensified development of treatment strategies (Thorngren et al., 2002). The main objection to internal fixation has been the key complication of failure of the fracture to heal. Insufficient fixation stability with increased implant rotation, posterior tilting of the femoral head and femoral shortening has been identified to predict fractures that subsequently do not heal (Palm et al., 2009; Ragnarsson and Kärrholm, 1991; Ragnarsson and Kärrholm, 1992). Following a paradigm shift arthroplasty is now indicated in elderly patients with a displaced fracture (Gjertsen et al., 2010; Rogmark and Johnell, 2006). In spite of a reduced reoperation rate and improved patient reported outcome with arthroplasty in middle-aged patients (Bartels et al., 2018), closed reduction and internal fixation are commonly recommended in these patients (Bhandari et al., 2005). While increased mobility and fewer major reoperations have been reported with primary arthroplasty in undisplaced fractures (Dolatowski et al., 2019), internal fixation by traditional multiple cannulated screws, pins or a sliding hip screw device remains the preferred method amongst surgeons in this setting (Gjertsen et al., 2008). However, no clear answer to which conventional fixation is superior with the common cervical or transcervical fractures was concluded by a recent international, multicentre, randomised controlled study (FAITH Investigators, 2017). This conclusion confirms the results from a previous meta-analysis (Parker and Gurusamy, 2001) and an international survey, which showed that surgeons disagree on the optimal implant for internal fixation in this setting (Bhandari et al., 2005).

Locking plates show a potential in reducing non-union and revision rates by internal fixation (Alshameeri et al., 2017; Yin et al., 2018).

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Fig. 1. The Hansson Pinloc® System.

A triangular configuration with three hook-pins and the femoral neck interlocking plate.

(The medium sized plate is coloured green in the online version) (Illustration from Swemac Innovation AB). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Improved stability is principally achieved by combining the favouring medial hold by multiple implants and lateral hold by a side plate anchored to the lateral cortex (Parker and Stedtfeld, 2010). However, preventing micromotion at the fracture site places the mechanical burden on the implant and may result in implant cut-out or failure in displaced fractures (Berkes et al., 2012). Allowing fracture settling by combining telescoping screws and locking plates may also more commonly cause implant cut-out with a displaced fracture (Biber et al., 2014).

Accordingly, the novel Hansson Pinloc® System (Pinloc) (Fig. 1) was introduced in 2013 to replace the conventional Hansson hook-pins used in pairs (Strömqvist et al., 1987). The plate locking the pins' threaded heads in a triangular pin configuration categorises the design as a locking plate. Without further fixation to the lateral femur, the plate is allowed to transport away from the lateral wall as fracture dynamizes. The three-pointed support of each interlocked pin is supposed to increase the important torsional, bending and compressive stability. Enhanced torsional stability by medial anchorage and lateral enforcement compared to its precursor pins has been reported (Brattgjerd et al., 2018), but no comparison to other osteosynthesis is available. In the context of more strict requirements to technical documentation of novel implants (EU regulations, 2017), systematic evaluation of new implants and their components in relevant tests and bone models is recommended (Basso et al., 2012; Hausmann, 2006; Hunt et al., 2012; Schemitsch et al., 2010).

The aim of the present study was to investigate biomechanically whether the new implant improves medial and lateral stabilisation without the expense of adverse effects when compared to other relevant femoral neck fixations in undisplaced or anatomically reduced fractures. Our hypothesis was that the new device would increase the stability of the bone-implant construct.

2. Methods

2.1. Model preparation

Fifty left synthetic femurs (model #3406, large, Fourth Generation Composite Bone, Sawbones, Pacific Research Laboratories, Vashon, WA, USA) were predrilled with drill bits corresponding with the implant's diameter with following anatomical reduction or undisplaced fixation.

To ensure a standardised positioning of implants in each group and between groups, a drilling jig was used. Parallel implant positioning corresponding with optimal clinical use was guaranteed by the jig, with identical angle, length and distances between screws/pins. With standardised dimensions according to the femoral neck, the drill jig was used to achieve the recommended top-down triangular implant configuration with multiple implants (Oakey et al., 2006).

Up to three channels were drilled with an isosceles triangular configuration of 14.5 mm centre-to-centre distance between the distal and proximal channels and 12.0 mm between the proximal ones. For configurations with two implant channels the anterior channel was omitted. With one main channel this was standardised at the centre of the triangle in the femoral head and drilled 110 mm ending subcortically. A supplementary minor channel of 105 mm length was drilled in parallel proximally. Similarly, the depth of the other channels was 105 mm proximally and 115 mm distally with corresponding implant length. The multiple channels were drilled 125° to the femoral shaft in parallel with the neck. The single major channel at 135° corresponded with the angle of the sliding hip screw device.

The mid-cervical neck was cut in an osteotomy jig with a hack-saw perpendicularly to the multiple channels, 53 mm from the head surface in their extensions. This created an osteotomy 55° to the horizontal, i.e. midway between a type 2 (30° - 50°) and a Pauwels type 3 fracture (Pauwels, 1935). This was done according to the increased complication rate by Pauwels type in locking plate technology (Biber et al., 2014). To simulate a displaced fracture associated with the specific healing disturbances with other locking plates (Berkes et al., 2012; Biber et al., 2014), a 18° subcapital wedge was removed inferiorly with a maximum width of 7.5 mm in the frontal plane to simulate unfavourable comminution of the calcar, which has been reported to predict healing disturbances in displaced fractures (Alho et al., 1992). Leaving a few millimetres of cortical bone in contact superiorly at the fracture site created a semi-stable fixation and allowed both compression and shearing forces to work along the osteotomy (Fig. 2).

2.2. Fixation methods

Five different fixation methods were applied with 10 specimens in each group (Fig. 3). In group A Pinloc was installed with three titanium (Ti6Al4V) hook-pins (diameter 6.5 mm) interlocked in a medium-sized aluminium plate in agreement with the drilled configuration (Swemac Innovations AB, Linköping, Sweden). Group B was fixed by a two-hole Dynamic Hip Screw Locking Compression Plate® (DHS-LCP) in steel fixed with two cortical screws and a 12.5 mm diameter lag screw (Synthes GmbH, Oberdorf, Switzerland). A 6.5 mm diameter anti-rotational screw (ARS) with 32 mm thread was supplemented. Group C was prepared by three ASNIS® III 6.5 mm diameter cannulated 20 mm threaded titanium screws (Stryker GmbH, Selzach, Switzerland). Group D consisted of two Olmed® cannulated 8.0 mm diameter screws with 22 mm thread in steel (Zimmer Biomet, by Elos Medtech AB, Timmersdala, Sweden). Group E was fixed by two Cannulated Hip Screws® (CHS) in steel with 8.0 mm diameter and 16 mm thread (Smith and Nephew, Tuttlingen, Germany). The osteosyntheses were inserted following technical instructions, the only difference between the groups was the implants.





The novel implant fixating a composite femur with a mid-cervical wedge osteotomy simulating a femoral neck fracture, 55° to the horizontal with simulated subcapital comminution by an 18° varus wedge removed in the frontal plane.

2.3. General test procedure

The proximal femurs of 15 cm length were press-fitted into a steel tube mounted in a testing machine (MiniBionix 858 MTS Systems, Eden Prairie, MN, USA). The load cell exhibited respective axial and torsional characteristics (capacity, 10 kN and 100 Nm; resolution, 1 N and 0.005 Nm; Displacement, 1 μ m and 0.1°; accuracy < 0.5%). The load and displacement by the piston were recorded by a computer.

2.3.1. Quasi-static testing

Introductory quasi-static testing was performed (Fig. 4). Non-destructive load levels were chosen to allow further testing without incriminating the latter tests (Zdero et al., 2010). In the torsional test, the femoral head was point-fixed in a cylindrical steel cup simulating the acetabulum (Zdero et al., 2010). The actuator transferred torque at a rate of 1°/s until 10° rotation around the longitudinal axis of the neck, a clinical interesting value concerning the risk of non-union (Ragnarsson and Kärrholm, 1992). Rotation was tested clockwise, then anticlockwise viewed from medially. In anteroposterior bending the model was oriented horizontally and the femoral head was loaded anteriorly. This simulated the orientation of the joint reaction force in sitting down or walking stairs (Bergmann et al., 2001). A support was placed beneath the minor trochanter to isolate displacement to the osteosynthesis (Kauffman et al., 1999) (Fig. 4). In compression, specimens were mounted vertically with 7° adduction to mimic the contact force vector during one-leg stand phase (Bergmann et al., 2001). A low friction piston avoided accumulation of shear forces in bending and compression and loaded 500 N at a rate of 200 N/s. All quasi-static tests were repeated three times with a minor axial preload of 30 N.

2.3.2. Dynamic testing

Cyclic compression followed with a number of cycles often considered to simulate the steps until fracture consolidation (Aminian et al., 2007). The dynamic load was applied at the femoral head with sinusoidal motion using load control (rate 1 Hz; cycles 10,000; maximum load 1900 N; preload 60 N). This load approximated the estimated joint reaction force in one-leg stance phase of a 92 kg Caucasian



Fig. 3. The implants.

From the top the implants A-E are pictured.

A: The novel Hansson Pinloc[®] System.

B: A two-hole Dynamic Hip Screw plate $^{\ensuremath{\circledast}}$ with cortical screws and a 6,5 mm cancellous screw.

C: Three ASNIS III® screws.

D: Two Olmed® screws.

E: Two Cannulated Hip Screws®.

male, the model of the applied synthetic bones (Basso et al., 2014a; Bergmann et al., 2001).

2.3.3. Outcomes

The mean slope of the linear load-deformation curves from the quasi-static loadings defined the initial torsional, bending and compressive fixation stiffness (Zdero et al., 2010). Deformation of the model in unloaded phase after cycling intended to reflect deformation by weight-bearing in the fracture healing period. To evaluate local deformation, the femoral head implant channels were measured by a calliper after dismantling. The mean difference between drilled and measured channel diameter was calculated in each group. In group B, only the lag screw channel was measured. The formation of fracture lines defined initial fixation failure.

2.4. Statistical analysis

Descriptive statistics were calculated, average values expressed as



Fig. 4. The test set-up.

To the upper left: The torsional test with main fracture line oriented horizontally by laser with torque around the central axis of the femoral neck implant. At the bottom left: The bending test with femur and implant horizontally and a bending moment by application of a vertical force on the anterior aspects of the femoral head

To the right; the compression test with femur oriented in 7° adduction, while neutral in the sagittal plane.

arithmetic means, and dispersion as standard deviations or confidence intervals. The presence of failure pattern was described as proportions, as well as the evaluation of unconventional versus the merged conventional methods, based on the fact that no clear difference exists between conventional implants clinically with the fracture pattern in our study (FAITH investigators, 2017). To compare continuous parameters, one-way analyses of variance with post hoc multiple comparisons with Bonferroni correction were performed using IBM SPSS Statistics (version 25 for Windows; SPSS Inc., Chicago, IL, USA). Level of significance was set to P < 0.05. For the categorical variables, crosstabs were computed and Fisher's exact test applied. A Pearson productmoment correlation analysis was performed to determine the relationship between outcomes. The coefficients were interpreted as low, moderate or high respective of their size in intervals between 0.00, 0.30, 0.50, and 1.00.

3. Results

3.1. Biomechanical parameters

Mean stiffness, deformations and proportions of initial failure for the implants and their comparisons are presented in Table 1. The mean stiffness of the fixations ranged from 355 to 1371 Nmm/° in torsion (E vs A), 180 to 258 N/mm in bending (B vs A) and 236 to 403 N/mm in compression (E vs A). Mean global deformation of the test model ranged from 3.4 to 11.1 mm (A vs E, Fig. 5) and from 0.1 to 2.5 mm (A vs E) locally in the femoral head (Fig. 6). Screw channels were deformed in the proximal-distal direction, while no deformation was evident within the pins' channels (A vs B–E). The only indication of an initial failure pattern was a cortical crack medially in the neck, which developed inferior to the distal screw along the femoral calcar during cyclic compression in group C, D and E (Fig. 6). The proportions of this initial failure pattern ranged from absent (A + B) to 7 out of 10 specimens (D). Also, all CHS entry holes revealed cortical erosions from insertion.

3.1.1. Novel versus conventional implants

The interlocking pin device enhanced mean torsional stiffness by 130% with a mean difference (95% CI) of 774 Nmm/° (575 Nmm/° to 973 Nmm/°) and 33% in bending with a mean difference 64 N/mm (27 N/mm to 101 N/mm) compared to the conventional methods altogether (P < 0.001). The mean global deformation of the test model was reduced 62% with a mean difference of 5.6 mm (2.8 mm to 8.5 mm) and 95% locally in the femoral head after cycling with a mean difference of 1.9 mm (1.1 mm to 2.7 mm) when compared to the conventional methods (P < 0.001). The initial failure pattern by a fissure was absent with interlocking in contrast to the proportions of 14/40 for the conventional methods (P = 0.045). These statistically significant findings after cyclic compression were preceded by only a positive trend of non-destructive compressive stiffness in favour of interlocking (P = 0.8).

In comparison between all fixation methods (Fig. 7), interlocking affiliated a higher mean torsional stiffness in pairwise comparison with each group (P < 0.001). Similarly, mean bending stiffness was significantly increased (P < 0.001), except from only a positive trend in comparison to Olmed (P = 0.4). Regarding mean compressive stiffness, only CHS performed significantly inferiorly (P = 0.001). After cycling, fixation with the Pinloc reduced mean deformation, both globally and locally against all other fixations (P = 0.004). Its zero-failure mode was reduced compared to Olmed and CHS (P = 0.033), a trend favoured the Pinloc over ASNIS (P = 0.2), while failure was absent also with DHS + ARS.

3.1.2. Conventional implants

In comparisons between the conventional implants, DHS + ARS and ASNIS showed a higher mean torsional stiffness (P < 0.001). Olmed had increased mean bending stiffness (P = 0.024). DHS + ARS and Olmed excelled CHS in mean compressive stiffness and model deformation (P = 0.017). DHS + ARS reduced mean local deformation compared to CHS and ASNIS (P = 0.048). The zero-failure mode with DHS + ARS was different from CHS and Olmed (P = 0.033). No

Table 1

Results from biomechanical testing of all fixation methods.

Fixation methods	Torsional stiffness (Nmm/°)	Bending stiffness (N/ mm)	Compressive stiffness (N/ mm)	Model deformation (mm)	Channel deformation (mm)	Initial failure (n/ N)
A: PINLOC	1371 (215) a	258 (17) a	403 (73) a	3.4 (0.9) a	0.1 (0.1) a	0/10 a
B: DHS + ARS	840 (122) b	180 (46) b	401 (99) a	7.4 (2.3) b	1.3 (0.5) b	0/10 a
C: ASNIS	743 (86) b	184 (12) b	342 (66) a,b	10.2 (1.7) b,c	2.2 (0.2) c	2/10 a,b
D: OLMED	450 (156) c	229 (47) a	364 (127) a	7.4 (2.3) b	1.9 (0.5) b,c	7/10 c
E: CHS	355 (48) c	183 (14) b	236 (36) b	11.1 (3.7) c	2.5 (1.2) c	5/10 b,c
B-E	597 (229)	194 (39)	336 (106)	9.0 (3.0)	2.0 (0.8)	14/40
A/(B–E)	2.30*	1.33*	1.20	0.38*	0.05*	0.00*

Mean values with standard deviation (SD) and proportions of failure mode from tests.

Different small letters indicate significant difference in the same column (p < 0.05).

Two letters in a cell indicate no significant difference to groups with any of these letters.

Proportion Y vs X = Y/X.

* Comparison of corresponding means with statistically significant difference (p < 0.05).

fixation methods provided statistically significant inferior parameters to CHS.

3.2. Correlations

The Pearson product-moment correlation analysis between the outcomes is presented in Table 2. The stiffnesses documented statistically significant correlations between the different load directions revealing low or moderate correlation coefficients (r = 0.29-0.49, n = 50, P < 0.05). The outcomes within compression exposed statistically significant moderate to high coefficients with absolute values from 0.39 to 0.80 (P < 0.01).

4. Discussion

4.1. Interpretation

Compared to the established methods altogether (A vs B–E), Pinloc improved torsional, bending and compressive stability. In compression the impact was most evident by enhanced dynamic stability without adverse effects in fatigue testing. This indicates the presence of an increased multidirectional stability with retained intermediate dynamic compression.

In pairwise comparisons to each of the other fixations, improvements are explained by Pinloc outperforming the advantageous lateral hold by fixed angle fixations and medial hold by multiple screws. Compared to cannulated screws (A vs C, D, E), multi-directional fixation stability was significantly increased in most parameters. The exceptions were only a trend towards Pinloc compared to Olmed in bending and compressive stiffness and to ASNIS in compressive stiffness and failure frequency. These findings agree well with increased medial fixation and lateral enforcement by interlocking compared to individual implants (Brattgjerd et al., 2018). Between the plate osteosyntheses (A vs B), the only exceptions to increased multi-directional stability by Pinloc was no difference in compressive stiffness and failure frequency. This is suggestive of no beneficial lateral hold by fixating the plate to the lateral cortex between these fixed angle devices. The additional strengthened medial fixation attributed the multiple femoral head fixation combined with fixed angle devices (Aminian et al., 2007; Brandt et al., 2011) is in correspondence with our findings.

In-between conventional implants, the torsional and compressive stability with the fixed angle device were increased in most comparisons to no-plate devices (B vs C, D, E). Cannulated screws were also unable to prevent fatigue failure of calcar which is indicative of a reduced lateral purchase. A less stable CHS fixation followed damage of the lateral entry holes by the screw with a prominent larger thread than shaft diameter. These findings reflected the insufficient lateral hold by cannulated screws (Parker and Stedtfeld, 2010), which showed somewhat similar characteristics in our study. The increased stability measurements by DHS + ARS over multiple screws correspond with the preference in more unstable basicervical fractures (FAITH Investigators, 2017). However, a most likely deficient medial fixation was manifested



Fig. 5. Model deformation.

From left to right global deformation of test models A–E. Depression of the femoral head was reduced by Pinloc* (A) compared to the conventional fixations (B–E) after cyclic testing.



Fig. 6. Local deformation.

From left top femoral heads with implant channels corresponding with implants A–E (for definitions see Fig. 3). No clear deformation of the implant channels was detected with the Pinloc[®] (A).

In conventional fixations the lag screw in group B or the distal screw with calcar support in group C–E increased load transmission between the femoral head and the relative strong fixation in the lateral fragment. This resulted in most deformation of the distal channels at the femoral head side.

To the right at bottom the initial sign of failure by calcar fatigue only evident within conventional fixations of multiple screws (C–E). New fracture lines of the neck formed medially underlaying the distal screw (arrows), but was prevented by offloading with the sliding hip screw device (B). No signs of these adverse effects with interlocking pins (A) is explained by a more equal distribution of load between pins not reaching visible destruction in these tests.

by channel erosions in all traditional screw fixations.

Acting as a fixed angle device with sufficient lateral hold, and with improved medial hold by interlocked multiple femoral head fixation, Pinloc preserved the benefits and reduced the drawbacks by the conventional fixations. This explains the increased fixation stability according to our hypothesis.

4.2. Review of the literature

Several treatment strategies have been developed to improve the results after internal fixation of femoral neck fractures. Comparisons to one or more traditional fixations have been made experimentally by mechanical testing with novel fixation strategies and further development of the traditional ones. Besides improved stability by locking plates preventing fracture site motion (Aminian et al., 2007; Chang et al., 2004), locking plates allowing dynamic compression with multiple telescoping or interlocked screws have also been reported in combined torsional and compressive testing (Basso et al., 2014b; Basso et al., 2014c; Brandt et al., 2011). Both the sliding hip with rotationally stable screw-anchor and the anti-rotator compression hip screw have been shown to increase torsional and compressive stability (Knobe et al., 2018; Sağlam et al., 2014). The expansive cannulated screw documented a higher compressive and pull-out strength (Zhang et al., 2011). While the dynamic locking blade plate has been documented to enhance torsional stability (Roerdink et al., 2009), no significant advance in compressive stability was detected with the self-locking cannulated compression anti-rotation blade (Yang et al., 2011). Different screw configurations have also revealed improved stability ex vivo. Biplane double-supported screw fixation increased compressive, but not bending stability (Filipov and Gueorguiev, 2015), while a triangular configuration including a trochanteric lag screw also showed improved compressive stability (Hawks et al., 2013). Opposing the extramedullary fixation methods, the intramedullary nailing with two cephalocervical screws has been reported to increase compressive stability (Rupprecht et al., 2011).

To our knowledge, the current investigation of interlocking pins is the first to demonstrate increased multidirectional stability without adverse effects by a modern treatment concept in multiple comparisons, identifying global biomechanical effects.

4.3. Clinical relevance

One should be careful not to draw too firm conclusions on clinical relevance about the behaviour ex vivo in general. However, supportive information from biomechanical studies plays an important role to provide the short-term patient safety requirements when introducing implants (Schemitsch et al., 2010). From a biomechanical point of view the impact of allowing intermediate dynamic compression without deformation of implant channels medially or other adverse effects should be less likely to cause implant fatigue and cut-out as with other locking plates (Berkes et al., 2012; Biber et al., 2014).

Regarding long-term safety declarations in need of bone healing, increased fixation stability may improve healing conditions, as suggested with other modern fixation strategies (Alshameeri et al., 2017; Filipov et al., 2017; Yin et al., 2018) and the safe introduction by interlocking triangular pin/screw configurations (Xiao et al., 2018; Yamamoto et al., 2019). The increased torsional stability demonstrated by the interlocked pins compared to its precursor was more profound with increased distance between pins in unstable fractures (Brattgjerd et al., 2018). The stabilising impact detected in the current study may be too low to reduce the main complication of non-union, as similar complication and reoperation rates between Pinloc and two Hansson pins have been reported. Hence, concerns were raised regarding the biomechanical performance of the novel device (Kalland et al., 2019). So far, the clinical results are preliminary without considerations on osteoporosis, and a bias of multi-centre trials including a learning curve may apply. More clinical studies are warranted to disclose the potential superiority of the Pinloc demonstrated in the current biomechanical study.

4.4. Limitations

Several limitations are noted. The numerous conventional implants in our study represent an advantage, but other modern fixations should be included in future research. However, the novel implant exceeded most positive features of multiple screws and the sliding hip screw



Compression (N)

Compressive cycles (No.)

Fig. 7. Load-deformation curves.

The mean load-deformation curves for each fixation from all tests with comparisons.

*Increased stability by Pinloc in comparison with each fixation. This applies to both static torsional and dynamic compressive stability.

**Increased stability by Pinloc in comparison with each fixation, with an exception of the comparison against Olmed (Quasi-static bending stability).

***No significant difference by Pinloc in comparison to other fixation methods, except a lower stability with CHS compared to each of the other fixation methods in quasi-static compression.

Only minor impaction occurred in quasi-static testing in bending and compression in the first 100 N, while testing was most destructive in initial dynamic testing.

device; the key concepts of locking plate technology.

In our study, the standardised composite bone models facilitated the findings of relative differences between multiple implants and are an acceptable test medium when comparing several implants (Knobe et al., 2018). Further biomechanical studies with human femurs are needed to exclude a possible negative impact by increased stability with osteoporosis. However, the increased relative stability is expected to be generalised to human femurs (Gardner et al., 2010) and consequently

also to bone with some degree of lower bone quality.

Unstable Pauwels type 3 fractures (Aminian et al., 2007; Knobe et al., 2018; Sağlam et al., 2014) or wedges (Brandt et al., 2011) are commonly evaluated ex vivo. The wedge osteotomy in our study avoided the unrealistically stable fixation in more brittle, synthetic bones (Basso et al., 2014a), even if such comminution may be more common in the posterior and superior neck. To avoid weakening of the femoral strut, only a minor wedge was removed. It may have

Table 2

The Pearson product-moment	t correlations	of inter- a	and intra-	-directional	outcomes
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Comparison		Correlation coefficient
Inter-directional	Torsional stiffness vs bending stiffness	0.49*
	Torsional stiffness vs compression stiffness	0.48*
	Bending stiffness vs compression stiffness	0.29**
Intra-directional	Compressive stiffness vs model deformation	-0.57*
	Compressive stiffness vs channel deformation	-0.50*
	Compressive stiffness vs medial failure	-0.39*
	Model deformation vs channel deformation	0.80*
	Model deformation vs medial failure	0.48*
	Channel deformation vs medial failure	0.53*

* Correlation significant at the 0.01 level.

** Correlation significant at the 0.05 level.

contributed to stress accumulation and inferior fissuring, which were prevented by interlocked pins. The wedge may have enabled the finding of intermediate dynamic compression with Pinloc. The osteotomy's reduced inherent stability allows expecting a biomechanical effect of the intervention also in mild dislocation with less successful implant positioning, but further investigation of more stable fracture patterns is necessary regarding undisplaced fractures.

Testing of intact specimens validated the use of the 4th generation synthetic femurs (Heiner, 2008), and an equivalent test may have given interesting parameters of relative stability between intact and fixed bone in our study. In correspondence with our aim, this procedure was not performed, as it is unclear to what extent this would reflect the stability requirements with fracture healing. Otherwise, the relative differences between implants detected in our study, also should apply when compared with an intact test specimen. When comparing a similar isosceles triangular screw configuration interlocked in a similar plate in fractured human bone with the intact specimens, a 22% reduction in lateral strain and 5% increased medial strain were detected (Basso et al., 2014b). A corresponding reduction in stability would be expected in our study if the fixed specimens had been compared with the intact ones.

With the standardised material and dimensions of test models in our study, the load-deformation curves by each implant correspond with global stress-strain curves, while local measurements are needed for assessments of local stress distribution. However, the load distribution has been reported as not being influenced by the corresponding inter-locking of three screws during compression and torque (Basso et al., 2014b).

Our study design was motivated by the recommended more systematic evaluations (Hunt et al., 2012; Schemitsch et al., 2010). Not even within compression the results are categorically supportive of locking plates, as improved initial static strength has not been reported to be followed by improved fatigue performance (Hunt et al., 2012). We report significant correlations between stability in different directions and between static and dynamic stability. These findings add to the argumentation of testing relevant load directions and modes to reveal implant's strength and weaknesses, where the variation in coefficients expresses different aspects of stability. However, only failure by fixation fatigue and not load to failure was evaluated in our study. To investigate the implications of implant modification on load distribution, the use of cadaver femurs has been recommended (Basso et al., 2014a; Hunt et al., 2012) with relevant overloading and analysis of three-dimensional motions and strain (Aminian et al., 2007; Basso et al., 2014b; Basso et al., 2014c), which are warranted in further studies. Our findings of high correlation (r = 0.80) between local and global deformation adds to the discussion on the necessity of use of such expensive equipment, as most deformation obviously takes place at the fracture site.

5. Conclusions

The plate with interlocking of pins demonstrated improved multidirectional stability in synthetic bone compared to frequently used femoral neck fixations. These experimental findings are considered safe and beneficial, but are not coincident with preliminary clinical results, and more clinical results are needed.

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Declaration of competing interest

All authors declare no conflict of interest.

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References

- Alho, A., Benterud, J.G., Rønningen, H., Høiseth, A., 1992. Prediction of disturbed healing in femoral neck fracture. Radiographic analysis of 149 cases. Acta Orthop. Scand. 63 (6), 639–644.
- Alshameeri, Z., Elbashir, M., Parker, M.J., 2017. The outcome of intracapsular hip fracture fixation using the Targon Femoral Neck (TFN) locking plate system or cannulated cancellous screws: a comparative study involving 2004 patients. Injury 48 (11), 2555–2562.
- Aminian, A., Gao, F., Fedoriw, W.W., Zhang, L.Q., Kalainov, D.M., Merk, B.R., 2007. Vertically oriented femoral neck fractures: mechanical analysis of four fixation techniques. J. Orthop. Trauma 21 (8), 544–548.
- Bartels, S., Gjertsen, J.E., Frihagen, F., Rogmark, C., Utvag, S.E., 2018. High failure rate after internal fixation and beneficial outcome after arthroplasty in treatment of displaced femoral neck fractures in patients between 55 and 70 years. Acta Orthop. 89 (1), 53–58.
- Basso, T., Klaksvik, J., Syversen, U., Foss, O.A., 2012. Biomechanical femoral neck fracture experiments - a narrative review. Injury 43 (10), 1633–1639.
- Basso, T., Klaksvik, J., Syversen, U., Foss, O.A., 2014a. A biomechanical comparison of composite femurs and cadaver femurs used in experiments on operated hip fractures. J. Biomech. 47 (16), 3898–3902.
- Basso, T., Klaksvik, J., Foss, O.A., 2014b. Locking plates and their effects on healing conditions and stress distribution: a femoral neck fracture study in cadavers. Clin. Biomech. 29 (5), 595–598.
- Basso, T., Klaksvik, J., Foss, O.A., 2014c. The effect of interlocking parallel screws in subcapital femoral-neck fracture fixation: a cadaver study. Clin. Biomech. 29 (2), 213–217.
- Bergmann, G., Deuretzbacher, G., Heller, M., Graichen, F., Rohlmann, A., Strauss, J., Duda, G.N., 2001. Hip contact forces and gait patterns from routine activities. J. Biomech. 34 (7), 859–871.
- Berkes, M.B., Little, M.T., Lazaro, L.E., Cymerman, R.M., Helfet, D.L., Lorich, D.G., 2012. Catastrophic failure after open reduction internal fixation of femoral neck fractures with a novel locking plate implant. J. Orthop. Trauma 26 (10), e170–e176.
- Bhandari, M., Devereaux, P.J., Tornetta 3rd, P., Swiontkowski, M.F., Berry, D.J., Haidukewych, G., Schemitsch, E.H., Hanson, B.P., Koval, K., Dirschl, D., Leece, P., Keel, M., Petrisor, B., Heetveld, M., Guyatt, G.H., 2005. Operative management of displaced femoral neck fractures in elderly patients: an international survey. J. Bone Joint Surg. Am. 87 (9), 2122–2130.
- Biber, R., Brem, M., Bail, H.J., 2014. Targon femoral neck for femoral-neck fracture fixation: lessons learnt from a series of one hundred and thirty-five consecutive cases. Int. Orthop. 38 (3), 595–599.
- Brandt, E., Verdonschot, N., van Vugt, A.B., van Kampen, A., 2011. Biomechanical analysis of the sliding hip screw, cannulated screws and Targon[®] FN in intracapsular hip fractures in cadaver femora. Injury 42 (2), 183–187.
- Brattgjerd, J.E., Loferer, M., Niratisairak, S., Steen, H., Strømsøe, K., 2018. Increased torsional stability by a novel femoral neck locking plate. The role of plate design and pin configuration in a synthetic bone block model. Clin. Biomech. 55, 28–35.
- Chang, Y.B., Yin, D., Li, P.Y., 2004. Design and biomechanical structure evaluation of selflocking screw plate system for femoral neck fracture. Chin. J. Clin. Rehab. 8 (35), 8126–8128.
- Dolatowski, F.C., Frihagen, F., Bartels, S., Opland, V., Šaltytė, Benth, J., Talsnes, O., Hoelsbrekken, S.E., Utvåg, S.E., 2019. Screw fixation versus hemiarthroplasty for nondisplaced femoral neck fractures in elderly patients: a multicenter randomized controlled trial. J. Bone Joint Surg. Am. 101 (2), 136–144.
- Filipov, O., Gueorguiev, B., 2015. Unique stability of femoral neck fractures treated with the novel biplane double-supported screw fixation method: a biomechanical cadaver study. Injury 46 (2), 218–226.
- Filipov, O., Stoffel, K., Gueorguiev, B., Sommer, C., 2017. Femoral neck fracture osteosynthesis by the biplane double-supported screw fixation method (BDSF) reduces the risk of fixation failure: clinical outcomes in 207 patients. Arch. Orthop. Trauma Surg. 137 (6), 779–788.
- Fixation using Alternative Implants for the Treatment of Hip fractures (FAITH) Investigators, 2017. Fracture fixation in the operative management of hip fractures (FAITH): an international, multicentre, randomised controlled trial. Lancet 389 (10078), 1519–1527.
- Gardner, M.P., Chong, A.C., Pollock, A.G., Wooley, P.H., 2010. Mechanical evaluation of large-size fourth-generation composite femur and tibia models. Ann. Biomed. Eng. 38 (3), 613–620.
- Gjertsen, J.E., Engesæter, L.B., Furnes, O., Havelin, L.I., Steindal, K., Vinje, T., Fevang, J.M., 2008. The Norwegian Hip Fracture Register: experiences after the first 2 years and 15,576 reported operations. Acta Orthop. 79 (5), 583–593.
- Gjertsen, J.E., Vinje, T., Engesaeter, L.B., Lie, S.A., Havelin, L.I., Furnes, O., Fevang, J.M., 2010. Internal screw fixation compared with bipolar hemiarthroplasty for treatment of displaced femoral neck fractures in elderly patients. J. Bone Joint Surg. Am. 92 (3), 619–628.

Hausmann, J.T., 2006. Sawbones in biomechanical settings - a review. Osteo Trauma Care 14 (4), 259–264.

- Hawks, M.A., Kim, H., Strauss, J.E., Oliphant, B.W., Golden, R.D., Hsieh, A.H., Nascone, J.W., O'Toole, R.V., 2013. Does a trochanteric lag screw improve fixation of vertically oriented femoral neck fractures? A biomechanical analysis in cadaveric bone. Clin. Biomech. 28 (8), 886–891.
- Heiner, A.D., 2008. Structural properties of fourth-generation composite femurs and tibias. J. Biomech. 41 (15), 3282–3284.
- Hunt, S., Martin, R., Woolridge, B., 2012. Fatigue testing of a new locking plate for hip fractures. J. Med. Biol. Eng. 32 (2), 117–122.
- Kalland, K., Åberg, H., Berggren, A., Ullman, M., Snellman, G., Jonsson, K.B., Johansson, T., 2019. Similar outcome of femoral neck fractures treated with Pinloc or Hansson Pins: 1-year data from a multicenter randomized clinical study on 439 patients. Acta Orthop. 27, 1–5.
- Kauffman, J.I., Simon, J.A., Kummer, F.J., Pearlman, C.J., Zuckerman, J.D., Koval, K.J., 1999. Internal fixation of femoral neck fractures with posterior comminution: a biomechanical study. J. Orthop. Trauma 13 (3), 155–159.
- Knobe, M., Altgassen, S., Maier, K.J., Gradl-Dietsch, G., Kaczmarek, C., Nebelung, S., Klos, K., Kim, B.S., Gueorguiev, B., Horst, K., Buecking, B., 2018. Screw-blade fixation systems in Pauwels three femoral neck fractures: a biomechanical evaluation. Int. Orthop. 42 (2), 409–418.
- Oakey, J.W., Stover, M.D., Summers, H.D., Sartori, M., Havey, R.M., Patwardhan, A.G., 2006. Does screw configuration affect subtrochanteric fracture after femoral neck fixation? Clin. Orthop. Relat. Res. 443, 302–306.
- Palm, H., Gosvig, K., Krasheninnikoff, M., Jacobsen, S., Gebuhr, P., 2009. A new measurement for posterior tilt predicts reoperation in undisplaced femoral neck fractures: 113 consecutive patients treated by internal fixation and followed for 1 year. Acta Orthop. 80 (3), 303–307.
- Parker, M.J., Gurusamy, K.S., 2001. Internal fixation implants for intracapsular hip fractures in adults. Cochrane Database Syst. Rev. 4, CD001467.
- Parker, M.J., Stedtfeld, H.W., 2010. Internal fixation of intracapsular hip fractures with a dynamic locking plate: initial experience and results for 83 patients treated with a new implant. Injury 41 (4), 348–351.
- Pauwels, F., 1935. Der schenkelhalsbruch, ein mechanisches problem: grundlagen des heilungsvorganges, prognose und kausale therapie. Ferdinand Enke Verlag, Stuttgart, Germany.
- Ragnarsson, J.I., Kärrholm, J., 1991. Stability of femoral neck fracture. Roentgen stereophotogrammetry of 29 hook-pinned fractures. Acta Orthop. Scand. 62 (3), 201–207.
- Ragnarsson, J.I., Kärrholm, J., 1992. Factors influencing postoperative movement in displaced femoral neck fractures: evaluation by conventional radiography and stereoradiography. J. Orthop. Trauma 6 (2), 152–158.

- Regulation (EU), 2017. 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Off. J. Eur. Union 117, 1–175 L.
- Roerdink, W.H., Aalsma, A.M., Nijenbanning, G., van Walsum, A.D., 2009. The dynamic locking blade plate, a new implant for intracapsular hip fractures: biomechanical comparison with the sliding hip screw and Twin Hook. Injury 40 (3), 283–287.
- Rogmark, C., Johnell, O., 2006. Primary arthroplasty is better than internal fixation of displaced femoral neck fractures: a meta-analysis of 14 randomized studies with 2,289 patients. Acta Orthop. 77 (3), 359–367.
- Rupprecht, M., Grossterlinden, L., Ruecker, A.H., de Oliveira, A.N., Sellenschloh, K., Nüchtern, J., Püschel, K., Morlock, M., Rueger, J.M., Lehmann, W., 2011. A comparative biomechanical analysis of fixation devices for unstable femoral neck fractures: the Intertan versus cannulated screws or a dynamic hip screw. J. Trauma 71 (3), 625–634.
- Sağlam, N., Küçükdurmaz, F., Kivilcim, H., Kurtulmuş, T., Sen, C., Akpinar, F., 2014. Biomechanical comparison of antirotator compression hip screw and cannulated screw fixations in the femoral neck fractures. Acta Orthop. Traumatol. Turc. 48 (2), 196–201.
- Schemitsch, E.H., Bhandari, M., Boden, S.D., Bourne, R.B., Bozic, K.J., Jacobs, J.J., Zdero, R., 2010. The evidence-based approach in bringing new orthopaedic devices to market. J. Bone Joint Surg. Am. 92 (4), 1030–1037.
- Strömqvist, B., Hansson, L.I., Nilsson, L.T., Thorngren, K.G., 1987. Hook-pin fixation in femoral neck fractures. A two-year follow-up study of 300 cases. Clin. Orthop. Rel. Res. 218, 58–62.
- Thorngren, K.G., Hommel, A., Norrman, P.O., Thorngren, J., Wingstrand, H., 2002. Epidemiology of femoral neck fractures. Injury 33 (Suppl. 3), c1–c7.
- Xiao, Y.P., Shu, D.P., Bei, M.J., Ji, T., Kan, W.S., Li, S.G., 2018. The clinical application of a novel method of internal fixation for femoral neck fractures-dynamic locking compression system. J. Orthop. Surg. Res. 13 (1), 131–138.
- Yamamoto, T., Kobayashi, Y., Nonomiya, H., 2019. Undisplaced femoral neck fractures need a closed reduction before internal fixation. Eur. J. Orthop. Surg. Traumatol. 29, 73–78.
- Yang, M., Chen, J., Zhang, D., Wang, J., Yu, K., Fu, Z., Zhang, H., Jiang, B., 2011. Biomechanical evaluation of a new device for internal fixation of femoral neck fractures. Artif. Cells Blood Substit. Immobil. Biotechnol. 39 (4), 252–258.
- Yin, H., Pan, Z., Jiang, H., 2018. Is dynamic locking plate (Targon FN) a better choice for treating of intracapsular hip fracture? A meta-analysis. Int. J. Surg. 52, 30–34.
- Zdero, R., Keast-Butler, O., Schemitsch, E.H., 2010. A biomechanical comparison of two triple-screw methods for femoral neck fracture fixation in a synthetic bone model. J. Trauma 69 (6), 1537–1544.
- Zhang, Y., Tian, L., Yan, Y., Sang, H., Ma, Z., Jie, Q., Lei, W., Wu, Z., 2011. Biomechanical evaluation of the expansive cannulated screw for fixation of femoral neck fractures. Injury 42 (11), 1372–1376.