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Minimally invasive screw plates for surgery of unstable intertrochanteric femoral fractures: A biomechanical comparative study

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Abstract

Background. This study presents the first biomechanical comparison of two minimal invasive screw plates used in the treatment of intertrochanteric fractures of the femur.

Methods. Six fresh cadaveric pairs of human femur were included, following dual energy X-ray absorbsiometry analysis to obtain two cohorts of homogenous femurs. In each pair, unstable four-part trochanteric fractures were created and reduced. In each cohort, one femur was randomly selected to undergo instrumentation using one of the two minimal invasive devices, and the other femur was instrumented using the other device (minimally invasive screw system (MISS) or per cutaneous compression plate (PCCP)). Femurs were positioned at 25° of adduction in order to simulate the anatomical loading during one-legged stance. Biomechanical tests were performed using a single vertical compressive load applied on the femoral head. Cycling loading was applied with three-dimensional fracture motions with stereophotogrammetric analysis and global displacement analysis throughout the cyclic test. Intact femurs after cyclic loading were tested to failure. Failure mode was diagnosed with macroscopic or radiographic analysis.

Findings. Significant difference were detected between PCCP and MISS in sliding of the lag screw. Global vertical displacement of the femoral head during cyclic loading was higher for the PCCP. No statistically significant difference was noted in three-dimensional inter fragmentary displacement and load to failure between these two devices. Failure mode in both devices mainly consisted in fracture impaction, but no cut-out was noted.

Interpretation. PCCP and MISS appear to be mechanical devices that may improve clinical outcomes and reduce the risk of co-morbidities associated with unstable trochanteric fractures without increased risk of mechanical failure.

Keywords: Intertrochanteric fracture; Minimally invasive surgery; Sliding hip screw; Biomechanical study

1. Introduction

Proximal femoral fracture (PFF) remains a subject of great interest. This is because there have been recent developments in regards to optimising treatment and design of new prosthesis. Minimally invasive (MI) surgery has been shown to reduce operative blood loss, surgical time, pain and hospital stay (Bellabarba et al., 2000; Dipaola et al., 2004; Gotfried et al., 2000). These factors are particulary important for elderly patients, in whom surgical treatment that allows early weight-bearing can reduce complications (Langlais et al., 2005).

At present, sliding hip screws (SHS) are still widely regarded as the most conventional devices for fixation of intertrochanteric femoral fractures and are associated with failure rates between 5% and 20% (Ahrengart et al., 2002; Baumgaertner et al., 1998). Surgical fixation of femoral intertrochanteric fractures can be undertaken with standard devices (SHS or trochanteric nails) using a MI approach (Alobaid et al., 2004), specifically designed MI implants (Gotfried et al., 2000) or MI surgical techniques

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(Moroni et al., 2005). Recently, Gotfried et al. (2000) published the first clinical and biomechanical results of the PCCP (percutaneous compression plate), a MI sliding screw plate implant, used for pertrochanteric fractures, with favourable clinical complications rates and biomechanical results (Gotfried et al., 2002). In contrast to the PCCP, no other MI screw plate devices have been previously tested or implanted. A new MI screw plate implant, the MISS (Lépine, Lyon, France), has been developed that has several differences as compared with PCCP in terms of implant characteristics (double small diameter screw fixation into the femoral head for PCCP, on larger for MISS) and required surgical approach. The goal of this study was to analyse the biomechanical behaviour of these two minimally invasive screw plate implants before any prospective clinical comparison.

2. Methods

Two minimally invasive screw plate devices were tested in this study. The percutaneous compression plate (PCCP) (Fig. 1) is composed of a plate fixed using three femoral shaft screws 4 mm in diameter. Femoral head fixation using the PCCP is achieved with two dynamic neck screws that are fixed with a double barreled screw on a plate at 135° neck–shaft angle. Two separated percutaneous portals permit assembly of the device. The second implant, the MISS (Fig. 2), is also composed of three independent parts, consisting in a five hole titanium plate fixed using 5 mm diameter shaft screws and a single femoral head screw measuring 14 mm in diameter with a 25 mm screw head length and a total length between 60 mm and 110 mm. The screw is fixed with an eccentric screw barrel measuring 40 mm long at a 130° femoral neck–shaft angle. Assembly within the patient uses a single minimally sized incision for the shaft screws. Fracture compression is realised with the screw-driver of the neck screws for the PCCP and a compression screw that can be removed for the MISS. Compared to conventional sliding hip screws, those two devices use a surgical approach with smaller incisions and a sparing muscle approach, without detachment of the vastus lateralis.

Twenty femurs (10 pairs) were harvested from fresh cadavers of un-embalmed donor patients. Ages ranged from 65 to 85 years (mean 74 years) and consisted in eight males and two females. Femurs were stripped of all soft tissues, stored in moistened towels, and kept frozen at −20 °C. They were thawed at room temperature before device implantation and mechanical tests. Radiographs in two planes were taken in order to exclude pairs of femurs presenting with evidence of bone defects. Femoral neck–shaft angles and femoral neck lengths were measured and compared with X-ray length measures. Dual energy X-ray absorbsiometry (DXA) was performed and measured on usual data and especially on the femoral head that was measured with a 4 cm^2 surface. In order to obtain two homogenous cohortes of femurs, two pairs were excluded because of bone density mismatch. Seven pairs were included and randomly assigned in two groups to be treated using either the MISS or the PCCP. Unstable four-part intertrochanteric fractures, as described by Kaufer et al. (1974), were created in each specimen using an oscillating saw. The reproducibility of this fracture method was tested prior to use on two excluded pairs of femurs. All femurs were instrumented following the recommendations of the respective implant manufacturers under radiological image intensifier control. Six pairs were finally included for

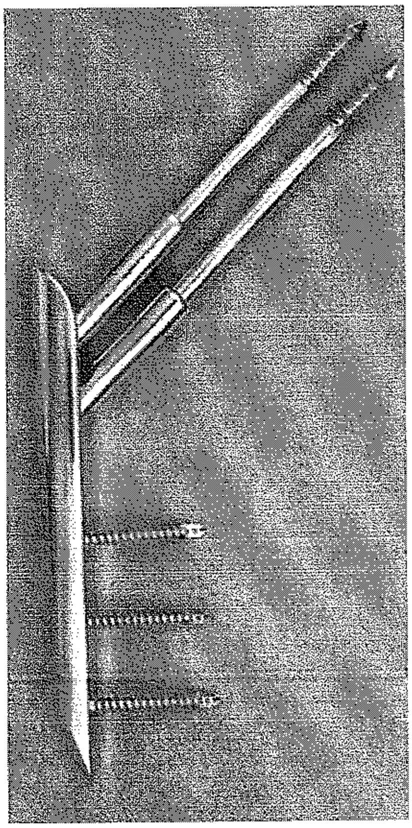

Fig. 1. The PCCP implant.

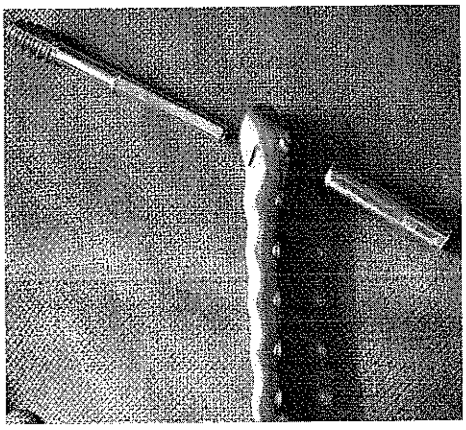

Fig. 2. The MISS implant.

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the tests, as a shaft screw breakage occurred during one implantation. All fractures were anatomically reduced.

Optimal implant positioning was achieved using two radiographic analyses by measuring tip–apex length (Baumgaertner et al., 1995) and central head position on the antero-posterior and lateral views. To ensure equivalent lengths of tested femurs for the tests, the distal femoral condyles were removed, retaining 7 cm from the distal apex of the MISS and 8.5 cm for PCCP (the MISS plate is 1.5 cm longer than the PCCP plate). Femoral shafts were so potted with low fusion metal (Cerobond©) in a 6 centimeter depth box. All the femurs were align in neutral rotation in every case with reference to the small trochanter. Implanted specimens were mounted on a servohydraulic mechanical testing machine (Instron 8500) at 25° of adduction in order to simulate the anatomical loading during one-legged stance (Chang et al., 1987; Duda et al., 1997; Pedersen et al., 1997) (Fig. 3). Femurs were regularly moistened during all tests to avoid desiccation.

Femurs of each pair were first fitted symmetrically with distribution with small black markers mimicking femoral shaft and neck axis (three markers for the diaphysis and three markers for the femoral neck), placed on each side of the fracture so that they could be detected by two analytic cameras (PULNIX Model PE2015 (Mk2) ENEO Lens, F 1.38 mm, Resolution: 768 × 576, frame rate 2 images/s) permitting analysis of displacements between fragments and measurement of angular movements of neck and shaft axis during the tests (Fig. 3). All the femurs were cyclically loaded with the same single vertical load applied vertically through a cup moulded on each femoral head (no muscle loads were simulated in this experiment). A cross roller bearing was used onto the cup to avoid transmission of horizontal force component. One hundred cycles at 20 N were undertaken as an initial cycle to ensure fracture reduction. Following this, cycling loading was applied with a sinusoidal mode from 20 N to 500 N for 2000 cycles at 1 Hz. Inferior displacement data of the femoral head was collected during all tests. On the other part, three-dimensional fracture motion was collected at the level of the trochanteric fracture using a stereophotogrammetric analysis with the two cameras. Analysis was realised every 100 cycles (with a sinusoidal mode at 0.01 Hz, permitting inducible motion analysis in the single cycle) using different point: neck, head and on both part of the trochanteric fracture. Then, remaining femurs after cyclic loading were loaded to failure at 12.7 mm/min. Failure was diagnosed with macroscopic or radiographic analysis. Maximal load to failure was defined as a marked discontinuity in the slope of the load/displacement graph.

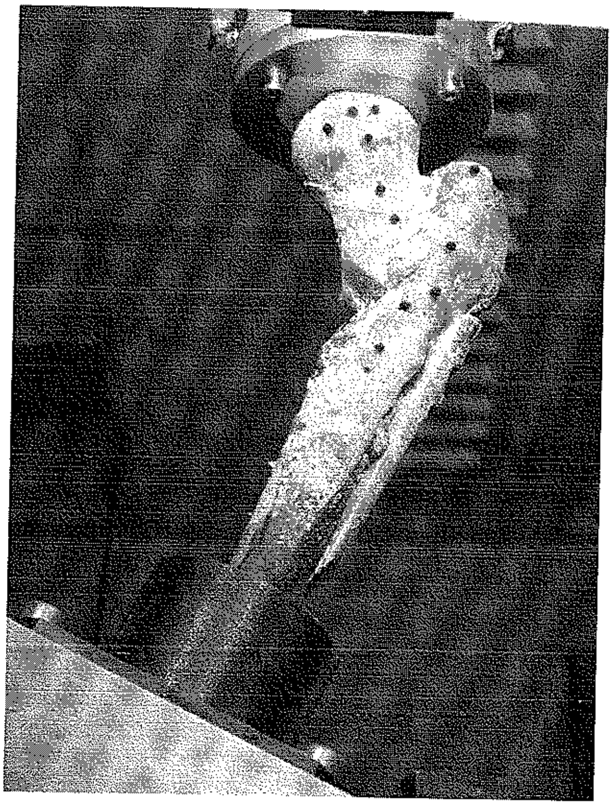

Fig. 3. Implanted femur with stereophotogrammetric marker implanted.

Statistical analysis was undertaken using a JMP IN 5.1 software (SAS institute, Cary, NC, USA). Data was presented as mean ± standard deviation. T tests (paired, two-tailed), or if necessary, Wilcoxon tests were used to compare distribution of all the variables in each group (MISS or PCCP). Statistical significance was defined as $p \leqslant 0.05$.

3. Results

The average tip–apex measured on X-ray analysis was 18 mm (range 13–22 mm) for MISS and 20 mm (range 16–24 mm) for the lower screw of the PCCP ($p > 0.3$). The neck–shaft angle ($p = 1$), neck length ($p = 0.91$) and mean bone density for each MISS and PCCP group showed no differences in either density zone tested: femoral head ($p = 0.96$), trochanteric ($p = 0.76$) and global ($p = 0.81$) Table. 1.

All specimens completed 2000 cycles of cyclic testing and all tests were included in the statistical analysis. 3D displacements of the fractures and shaft-angle changes were not statistically different. Mean inferior femoral head displacement during cyclic loading was superior for the PCCP ($p = 0.07$) (Table 2).

None of the specimens failed during the cyclic loading. Peak failure load of the PCCP was 3697 N (771 SD) and slightly greater for the MISS 4021 (771 SD) ($p = 0.77$). Failure occured due to impaction of the fracture (Fig. 4), hardware failure or bone fracture beneath the plate (Table 3). Fracture impaction during failure was significantly superior for the MISS ($p \leqslant 0.03$) with a mean of 11.9 mm (1.23 SD) and 7.4 mm (1.23 SD) for the PCCP.

4. Discussion

Mini invasive techniques for intertrochanteric fracture fixation is of great interest in elderly patients with regards

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Table 1
Anatomical and densitometric description of femurs

Specimen	Implant	Side	Age	Sex	Neck length (mm)	Neck–shaft angle (degrees)	Head bone density (g/cm^2)	Global bone density (g/cm2)
1	PCCP	Right	78	MAL	115	135	0.939	0.634
	MISS	Left	78	MAL	110	130	0.986	0.629
2	MISS	Right	82	MAL	105	130	1.43	1.018
	PCCP	Left	82	MAL	110	130	1.035	1.035
3	MISS	Right	85	MAL	100	130	1.001	0.86
	PCCP	Left	85	MAL	100	135	0.942	0.827
4	MISS	Right	83	MAL	105	140	0.85	0.696
	PCCP	Left	83	MAL	105	135	0.995	0.768
5	MISS	Right	83	FEM	100	135	0.563	0.472
	PCCP	Left	83	FEM	100	135	0.524	0.422
6	PCCP	Right	74	MAL	120	140	1.256	0.915
	MISS	Left	74	MAL	120	145	0.81	0.721

Table 2
Inferior head, 3D and angle displacement after 2000 cycles

	MISS	PCCP	P values
3D displacement after 2000 cycles (mm)	0.08 (0.02 SD)	0.1 (0.02 SD)	0.52
Angle displacement after 2000 cycles (degrees)	0.2 (0.06 SD)	0.3 (0.06 SD)	0.36
Inferior head displacement (mm)	0.4 (0.06 SD)	0.6 (0.06 SD)	0.07

to reducing blood loss and shortening hospital stay but is only of use if the procedure is simple, has few mechanical complications, and allows early weight-bearing (Langlais et al., 2005). According to recent clinical series conventional sliding screw plates still remain the gold standard for treating trochanteric fractures. They allow use of a large screw and if the screw is placed in the dense center of the head, induce low strains on the femoral head bone (Saudan et al., 2002; Schipper et al., 2004) which can reduce the risk of cut-out (Parker, 1992).

In an attempt to reduce co-morbidities associated with MI surgery, Gotfried et al. first developed the PCCP, a MI device with initially encouraging clinical results (Brandt et al., 2002) in terms of morbidity and hospital stay compared to conventional devices. This MI implant is a new alternative to implantation using conventional devices with a MI approach (Alobaid et al., 2004). Biomechanical studies prior to clinical testing is important for MI devices and necessary to understand fracture stabilisation and fixation failure to improve techniques of fixation. All results should be correlated to clinical outcomes. This principle is particularly important for MI devices which must be safe biomechanically before being clinically tested. Gotfried et al. tested the PCCP providing biomechanical behaviour data that can be compared to that derived from conventional devices (Gotfried et al., 2002). Torsional stability of the PCCP is similar to that of other multiple-axis fixations, providing high resistance against torsion (Blair et al.,

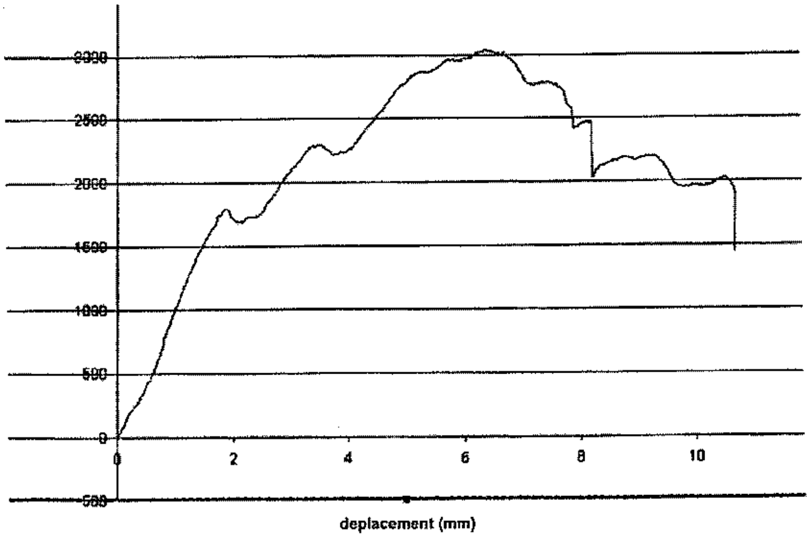

Fig. 4. Load/displacement curve at failure (specimen no. 3, PCCP implant).

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Table 3
Failure testing results

Failure mode	MISS	PCCP
Fracture impaction	4	4
Hardware failure (lag screw bending)	1	1
Fracture under the plate	1	1
Average displacement at failure (mm)	11.9 mm (1.23 SD)	7.4 mm (1.23 SD)
Average load to failure (Newtons)	4021 N (771 SD)	3697 N (771 SD)

Same failure mode occurred within the same pair in every cases.

1994; Deneka et al., 1997). Nevertheless, this configuration with multiple-axis fixation results in reduced screw sliding and fracture impaction as shown in our results during loading to failure. This reduced screw sliding may also be a result of low lag screw–plate angle (Meislin et al., 1990) or a short barrel (Loch et al., 1998). The association of a double axis fixation for the head combined with lower stiffness will decrease sliding but provides greater primary stability and better fracture healing (Olsson, 2000).

Bending stiffness was different for the two devices tested. A higher stiffness was obtained using the implant with a large lag screw (MISS), and prevented motion at the fracture healing site. Concerning three-dimensional displacement analysis, this study used a stereophotogrammetric approach that has not been used before (Chang et al., 1987; Flahiff et al., 1993; Jacobs et al., 1980; Mahomed et al., 1994). Such a technique can provide global three-dimensional displacement of different markers with a 0.1 mm sensitivity and theoretically allows rotational and fragment displacement analysis. Difficulties of this included problem in enabling the two cameras to detect all the markers during the tests. If two markers were not detected the technique did not permit a rotational analysis and only a shaft–neck angle analysis. After reviewing the results, small variation in this angle appeared to be a result of the 500 N bending load applied being insufficient to create differences between the two devices.

In this testing protocol configuration, load to failure for both device were comparable to those of conventional screw plates (with an average between 3000 N and 4000 N) (McLoughlin et al., 2000; Walch et al., 1990). No cut-out were noted in our series and implant failures were mainly seen in hard femoral head bone. In these particular cases, load to failure was higher, further testing the device stiffness. The literature indicates that failure mode seems to be highly dependant upon the biomechanical testing protocol. A good position in the centre of the head with an adapted tip–apex and a high bone density decreased the risk of cut-out during failure tests. Failure may occur more quickly during cyclic loading when not using fresh cadaver femurs. McLoughlin et al. (2000) used such non-fresh cadavers and the same testing protocol as in this study. His results showed a higher number of cut-out and failure occurred during cyclic testing. This may be related to decreased bone density that appears to be a major factor influencing cut-out. A high plate angle of 150° (Meislin et al., 1990) or a non-anatomical fracture reduction will also change the failure mode and will increase the cut-out risk (Jenny et al., 1999; Sommers et al., 2004). All these variations underline difficulties in comparing different implant behaviour within the literature in term of testing protocol and anatomical specimens. In such comparison studies, anatomical specimens should ideally be fresh to be as similar as possible to in vivo conditions (Wu et al., 1996) and DXA used rather than Singh index (Singh et al., 1970) to create two comparables groups with no mismatch in bone density as in this study. Body weight and sex should be also considered in the protocol and adapted to clinical incidence. For the same implant different positions of the femur during cyclic loading will give different results in resistance and mode of failure. This should be also conditioned by the fact that mechanical test are realised only after immediate post-operative conditions. For cyclic loading, only one load is generally applied, but frequency and magnitude are usually different in literature studies, usually approaching monopodal strain during gait (Duda et al., 1997; Pedersen et al., 1997). As many others, a potential limitation is that the proposed study did take into account any muscles load applied during gait. Using standard conditions for all tests in the future, comparisons between different studies and implants should be easier.

5. Conclusion

This study indicates that both MISS and PCCP have biomechanical properties which are as favourable as conventional hip screws. Loading and mode of failure of these two implants were found to be similar. Future clinical and biomechanical comparisons of these two implants with standard devices will provide further informations. MISS and PCCP may improve clinical outcomes and reduce the risk of co-morbidities associated with unstable trochanteric fractures without increased risk of mechanical failure.

Conflicts of interest

None.

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