

Biomechanical Strength of Distal Femur Plates determined with a new Test Method: First Results

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Summary

Introduction: Stryker has developed a new periarticular locking plate system for the distal femur. The aim of the present biomechanical study was to develop a valid test method to compare this new Stryker plate biomechanically to clinically proven implants. **Materials & Methods:** A simplified anatomic test configuration was developed and validated by clinical cases. Stryker's AxSOS Distal Lateral Femur Plate was compared to the 4.5mm LCP™ Condylar Plate (Synthes®), the LISS™ Distal Femur Plate (Synthes®) and the DCP™ Condylar Buttress Plate (Synthes®) with a static and a dynamic test configuration. **Results:** The failure mode of the in vitro test was similar to clinically reported cases. The DCP™ showed the lowest stiffness followed by the LCP™, the LISS™ and the AxSOS™ system. The AxSOS™ system reached the highest fatigue strength followed by the LISS™, the LCP™ and the DCP™ system. **Discussion:** Since the clinically reported failure mode corresponds to the one found in this new test configuration, the model might be suggested as a valid set-up to compare different femur plates. Further, it gives a relative comparison of the tested systems regarding stiffness and fatigue strength. Within the field of the tested systems, the AxSOS™ plate configuration showed the highest fatigue strength.

1. Introduction

Stryker has developed a new Distal Lateral Femur Plate (AxSOS™) which provides a locked screw/plate interface comparable to systems such as the LCP™ from Synthes® (see Figure 1).



Figure 1: AxSOS™ Distal Lateral Femur Plate.

Further the new plate allows sub muscular insertion, which is supported by a tissue elevator, an attachable handle and a tapered design. An exemplary indication is shown in Figure 2.

To assess the safety and efficacy of the new system, it was compared to clinically proven products used for the same indications. Hence, Stryker's AxSOS Distal Lateral Femur Plate was compared to the following implants: The 4.5mm LCP™ Condylar Plate (Synthes®), the LISS™ Distal Femur Plate (Synthes®) and the DCP™ Condylar Buttress Plate (Synthes®). A static as well as a dynamic test configuration was used to evaluate the biomechanical characteristics of the different implants.



Figure 2: Distal Femur Fracture after Stabilization with AxSOS™ Distal Lateral Femur Plate, Scott & White Memorial Hospital, Temple, Texas, USA.

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2. Materials & Method

Test Set-up

Different test set-ups are suggested in the literature [1], [2] [3]. There is no consensus about a standard test configuration for biomechanical testing of such implants. The test design was adapted from L.L. Latta et al [3], which originally was designed for the biomechanical testing of intramedullary nails. This design was modified for plate testing by using the force vector suggested by L.L. Latta [4] (see Figure 3).

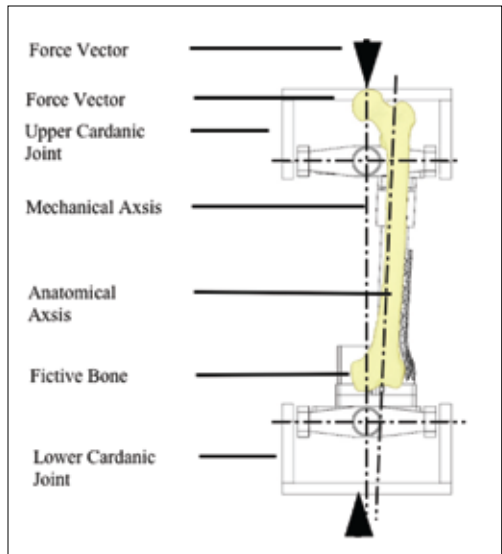


Figure 3: Schematic set-up acc. L.L. Latta et al, modified for Plate Testing.

The force was applied by two cardanic joints, to allow free rotation in all three degrees of freedom. Translation in the transversal plane was constrained.

The distal Femur was substituted by PU foam with a density of 15pcf (ASTM F-1839, Sawbones® [5]) (see Figure 4). The lateral side of the foam block was designed to match the anatomy of a distal lateral femur (cat# 1106, Sawbones® [5]). The diaphysis was substituted by an E-glass filled epoxy tube (cat# 3003-4, Sawbones® [5]) (see Figure 4).

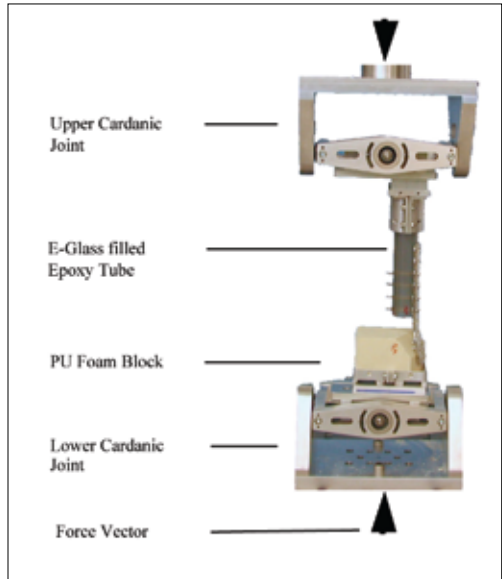


Figure 4: Set-up acc. L.L. Latta et al modified, for Plate Testing.

The plates were implanted according to the manufacturer’s surgical technique and an assembly device was utilized for accurate reproducibility. For the DCP™ Condylar Buttress Plate pre-operative bending was necessary. The fracture pattern was imitating a 33 A3 fracture (AO Classification), without any fragment contact to simulate a worst case configuration. In a room temperature testing environment (≈ 20°C), a servo hydraulic test machine (Instron 8874) was used for the load application.

Implants

Description	Cat#	QTY
DCP™ Condylar Buttress Plate 4.5mm (Synthes®)	240.930	3 (d) 1 (s)
LISS™ Distal Femur (Synthes®)	422.345	3 (d) 1 (s)
4.5mm LCP™ Condylar Plate (Synthes®)	222.659	4 (d) 1 (s)
AxSOS™ Distal Lateral Femur Plate (Stryker)	436506	4 (d) 1 (s)

d = dynamic Test, s = static Test

Table 1: Test Material

Screw Selection

Schatzker et al recommended three screws in each main fragment. In the case of osteoporotic bone, more screws might be necessary [6]. For sufficient stability and for comparison reasons four screws were used in the diaphysis. For the meta/epiphyseal area the fol-lowing screw configurations were selected:

The AxSOS™ surgical technique recommends to fill all locking holes to ensure maximum stability. Hence, all five locking holes were filled with locking screws. At minimum, four locking screws are recommended for the LISS™ plate. In the case of osteoporotic bone an appropriate number of additional screws is suggested. Because an osteoporotic model was simulated (PU foam with low density), all seven locking holes were filled. Due to no specific recommendation for the LCP™ and the DCP™ Condylar Buttress Plate, five screws were used for sufficient stability and due to comparison reason.

Static Tests

One plate of each system was tested statically. The specimens were loaded at a velocity of 5 N/s up to 300N. The applied force and the corresponding displacement were recorded. From the force/displacement plot the stiffness was determined as shown in Figure 5.

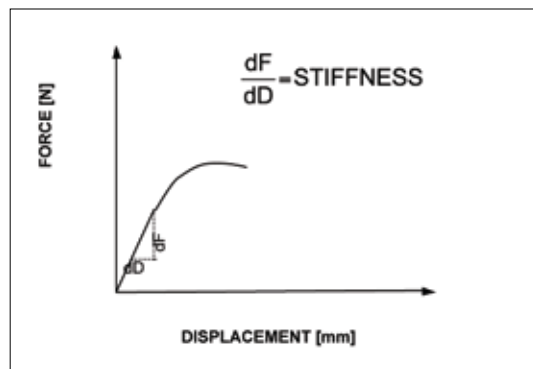


Figure 5: Stiffness

Dynamic Test

Four AxSOS™, four LCP™, three LISS™ and three DCP™ Condylar Buttress plates were tested. The specimens were loaded with a cyclic compression force (Sinus), at a frequency of maximum five Hertz and a load ratio of 0.1 (Fmin/Fmax). The dynamic strength was determined using a staircase method [1], [2]. Starting with a peak force of 175N, the load was increased by 20% of the static yield strength, of the weakest plating system, after each 100,000 cycles (see Diagram 1).

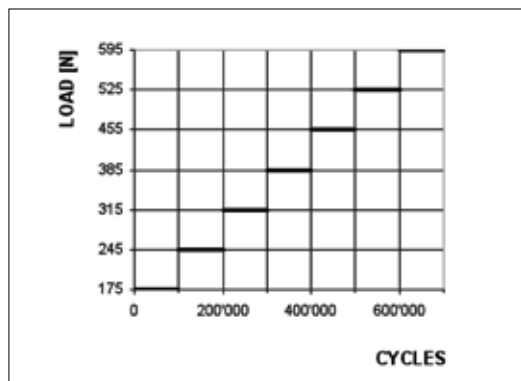


Diagram 1: Staircase Test Method

The test was stopped after gross failure such as screw cut-out, plate breakage, screw breakage or after a total subsidence of more than 2mm per load level. The load level, the number of cycles, the displacement (peaks) and the failure mode were documented.

3. Results

Static Test

The DCP™ Condylar Buttress Plate showed the lowest stiffness followed by the LCP™, the LISS™ and the AxSOS™ system [7].

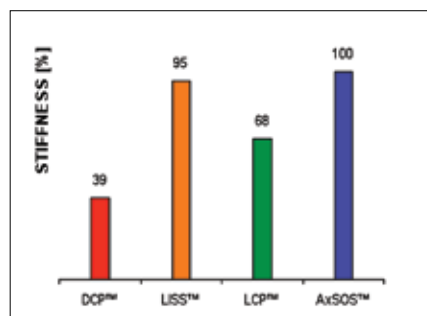


Diagram 2: Results Static Test

Dynamic Test

The following diagram shows the load level of failure for each tested specimen. The different systems failed within a range of 315 to 595 N [8].

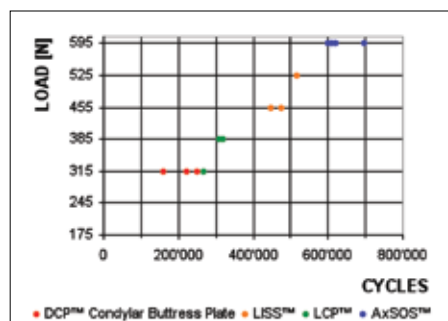


Diagram 3: Results Dynamic Test.

DCP™ Condylar Buttress Plate: For all specimens, plate breakage occurred in the distal fragment with a load level of 315 N. Figure 6 shows a typical location of failure of each system. LISS™. For all specimens the most proximal screw of the distal fragment broke. For two specimens the breakage occurred at 455 N and for one at 525 N. LCP™. All specimens failed due to plate breakage through the most proximal screw holes of the distal fragment. For two specimens the breakage occurred at 385 N and for one at 315 N. AxSOS™. All samples failed due to plate breakage on a load level of 595 N.



Figure 6: Failed Specimens from l. to r. DCP™ Condylar Buttress Plate, LISS™, LCP™ and AxSOS™.

4. Discussion

Vallier et al [9] reported three cases of plate fatigue failure after the treatment of distal femur fractures with a 4.5mm LCP™ Condylar Plate from Synthes®. The breakage pattern from the tests and those reported by Vallier were similar (see Figure 6 and Figure 7). The clinical cases and the in vitro tests had both the same screw configuration at the distal fragment.

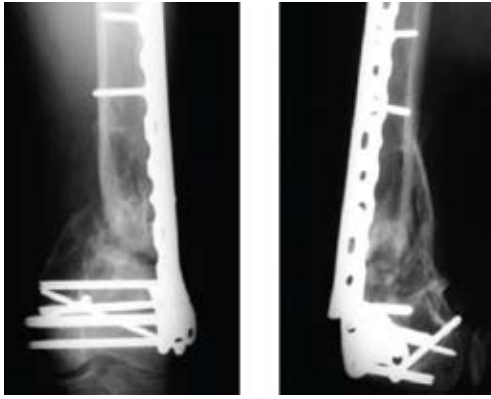


Figure 7: Broken LCP™ Condylar Plate [9], Reprinted with the permission from The Journal of Bone and Joint Surgery®, Inc.

Following these commonalities it might be concluded that the utilized test model generates clinically relevant failure modes of such implants. Hence, this test model might be suggested as a valid set-up to compare different osteosynthesis plates indicated for the distal femur.

However, the test model was limited by the simplified load case, in which the complex anatomic load situation was reduced to one single force. Especially torsional moments around the femur axis were not considered. Furthermore, biological processes such as bone remodelling were neglected.

Keeping the limitations of the utilized test model, the locking plates (AxSOS™, LISS™ and LCP™) showed superior fatigue strength if compared to the conventional DCP™ Condylar Buttress Plate. The AxSOS™ system reached the highest fatigue strength followed by the LISS™, the LCP™ and the DCP™ Condylar Buttress Plate system. The “stronger” design of the locking plates had the effect of a higher stiffness if compared to the conventional DCP™ plate. The AxSOS™ and the LISS™ plates were about twice as stiff as the DCP™ plate.

Taylor et al determined in vivo knee joint reaction forces during walking and stair climbing [10]. They found forces ranging from 3.0-3.3 times body weight (BW) during walking. Assuming an average BW of 87 kilograms [11], this might result in a peak force of 2.800 Newton. This is about 5 times the peak failure force of the strongest (AxSOS™) and about 9 times for the weakest plate (DCP™) tested. Hence, directly post-operative weight bearing should not exceed 0.2 BW in the case of a highly communitated distal femur fracture treated with an AxSOS™ plate.

5. References

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