I. Subcontractors:

- none -

II. Specimens:

Date of receipt: 21-Jul-02
Test period: 03-Sep-02 to 05-Sep-02

1 Pc. Platon nail; 11mm, L190, 125, Stainless Steel; Ref: 100-400; LOT K501100
1 Pc. Platon lag screw; 12mm, L100; Stainless Steel; Ref: 100-223; LOT K501323
1 Pc. Platon fixation bolt 125; Stainless Steel; Ref: 100-308; LOT K502608
1 Pc. Platon connection screw; M7; Stainless Steel; Ref: 100-304; LOT K501504
1 Ps. Platon AR-clip; M; Stainless Steel; Ref: 100-305; LOT K503505
2 Pcs. Bone Substitution Material, Cellular riged polyurethane foam, Ref: 1522-10, Sawbones - Sweden
2 Pcs. Bone Substitution Material, Cellular riged polyurethane foam, Ref: 1522-11, Sawbones - Sweden

Fig.1: Specimen tested.

III. Test procedure:

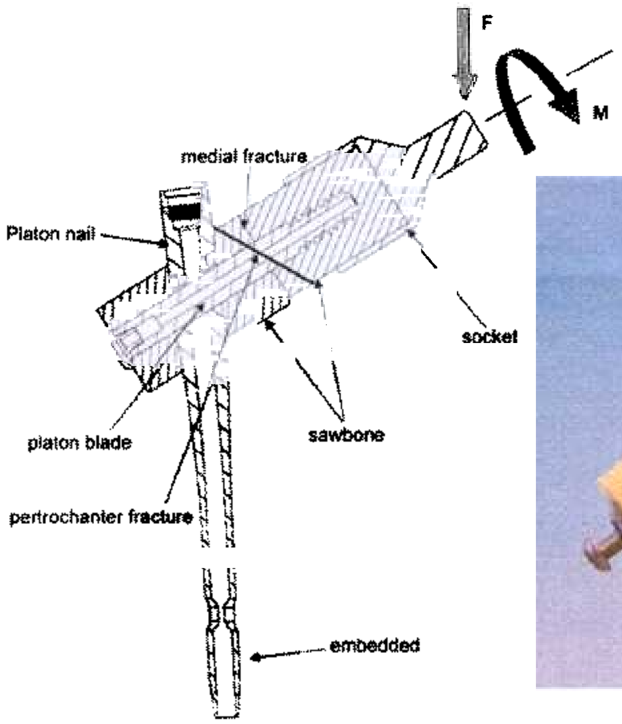
The tests have been performed according to data given by the customer.

The aim of the test is to compare the torsional stability of three Platon Nail configurations (Fig 2).
The rotation of the platon nail blade can be prevented either by the AR-Clip or a fixation bolt (Fig. 3). The effectiveness of these two types compared to the configuration without any rotational fixation (Fig. 2) shall be compared for medial and. pertrochanter fracture at two diffrenet bone qualities (Tab. 1). For the tests two bone substitution materials with a compressive strength of 2.3 MPa and 3.9 MPa (sawbone, Ref. 1522-10 and Ref. 1522-11) have been used.

The Platon nail has been embedded in filled epoxy resin with a frontal inclination angle of 10° corresponding to the distal axis.

The lever arm has been set to 81.6 mm. The preload F has been set to 98.1 N (10 kg) for the tests with a high degree of osteoporosis and 196.2 N (20 kg) for the tests with a low degree of osteoporosis resulting in a bending moment of 8 Nm for high and 16 Nm for low degree of osteoporosis.

To compare the data achieved, the torsional deflection has been measured at 1.0 Nm external load (high degree of osteoporosis) and 2.0 Nm external load (low degree of osteoporosis).



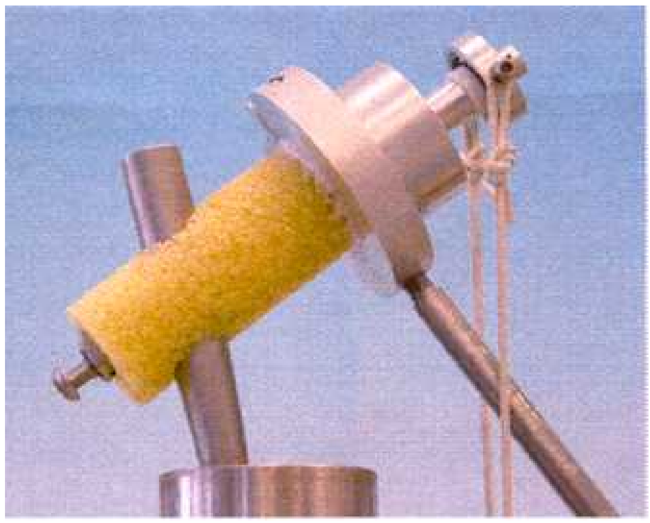


Fig. 2: Experimental set-up.

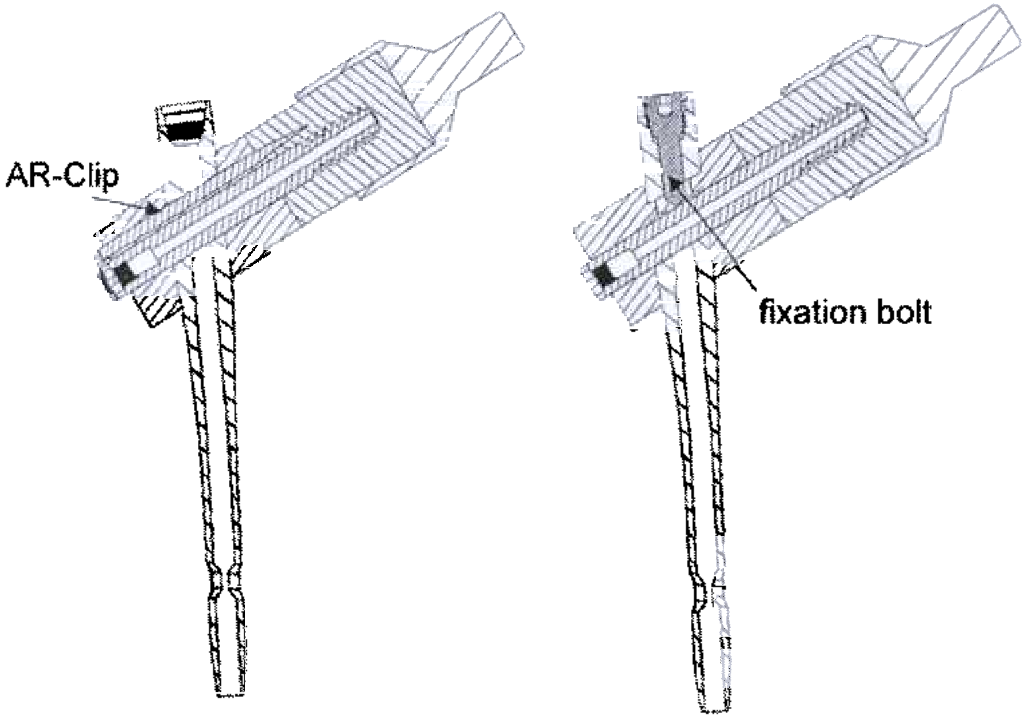


Fig. 3: Two types of blade fixation. Left the AR-Clip and right the fixation bolt.

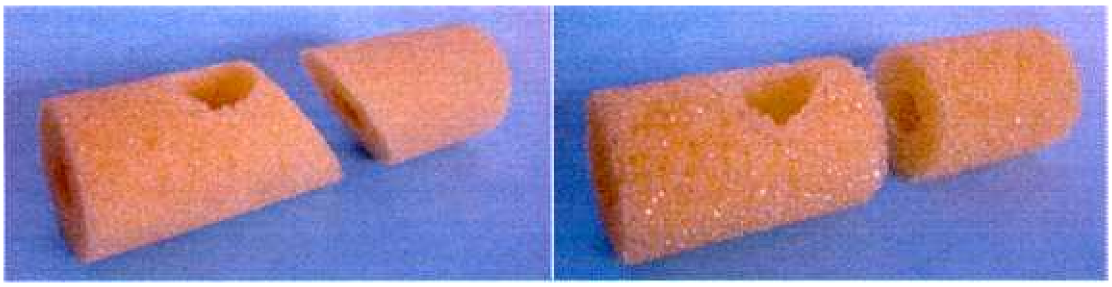


Fig. 4: Sawbone bone substitution material.
Left low degree of osteoporosis (Ref. 1522-10) and pertrochanter fracture.
Right high degree of osteoporosis (Ref. 1522-11) and medial fracture.

Tab. 1: Test parameter.

Test	Modification	Degree of osteoporosis	Fracture	Preload [Nm]
1	blade	high	medial	8
2	blade	high	pertrochanter	8
3	blade	low	medial	16
4	blade	low	pertrochanter	16
5	AR-Clip	high	medial	8
6	AR-Clip	high	pertrochanter	8
7	AR-Clip	low	medial	16
8	AR-Clip	low	pertrochanter	16
9	Fixation bolt	high	medial	8
10	Fixation bolt	high	pertrochanter	8
11	Fixation bolt	low	medial	16
12	Fixation bolt	low	pertrochanter	16

IV. Results:

Results – High degree of osteoporosis.

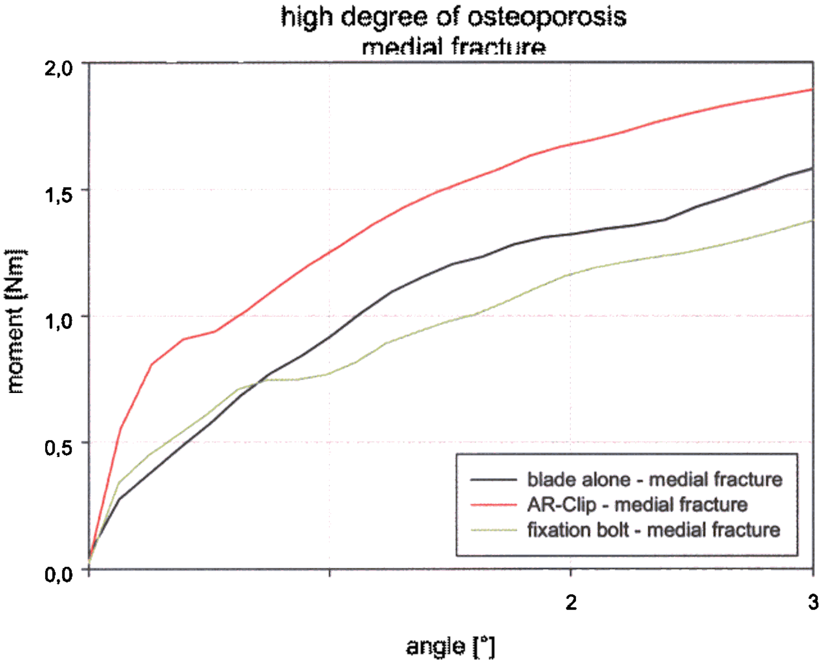


Fig. 5: High degree of osteoporosis and medial fracture.

Tab. 2: Results – High degree of osteoporosis and medial fracture.

high degree of osteoporosis
medial fracture

modification	moment [Nm]	angle [°]
Blade	1.0	1.13
Blade + AR-Clip	1.0	0.65
Blade + fixation bolt	1.0	1.60

57%

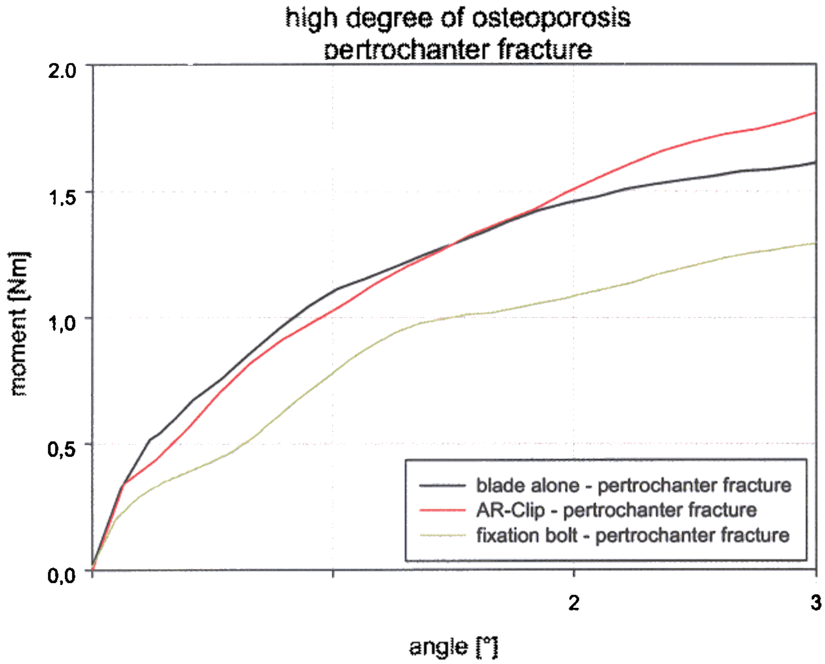


Fig. 6: High degree of osteoporosis and pertrochanter fracture.

Tab. 3: Results – High degree of osteoporosis and pertrochanter fracture.

high degree of osteoporosis pertrochanter fracture		
modification	moment [Nm]	angle [°]
Blade	1.0	0.89
Blade + AR-Clip	1.0	0.95
Blade + fixation bolt	1.0	1.51

Results – Low degree of osteoporosis.

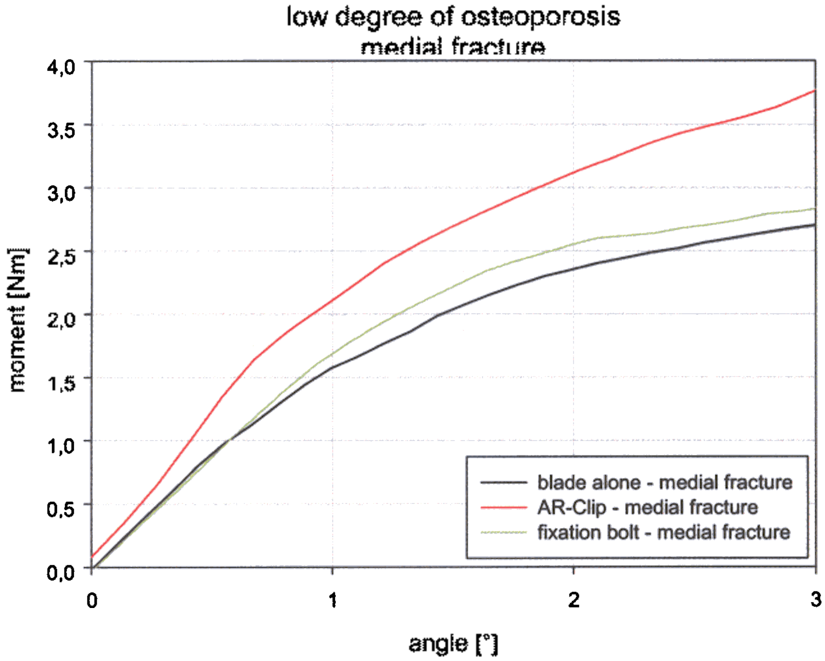


Fig.7: Low degree of osteoporosis and medial fracture.

Tab.4: Results – Low degree of osteoporosis and medial fracture.

low degree of osteoporosis
medial fracture

modification	moment [Nm]	angle [°]
Blade	2.0	1.47
Blade + AR-Clip	2.0	0.94
Blade + fixation bolt	2.0	1.28

50%

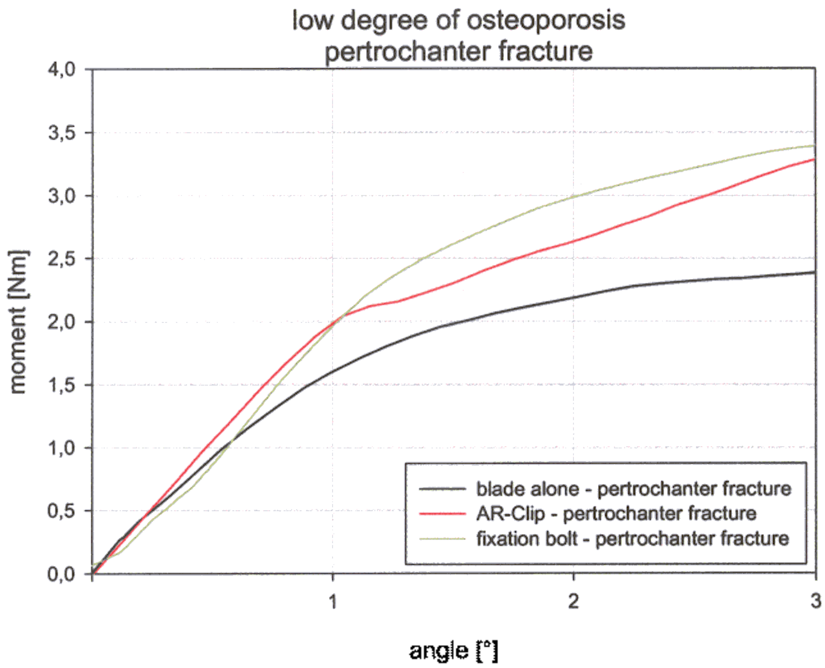


Fig.8: Low degree of osteoporosis and pertrochanter fracture.

Tab.4: Results – Low degree of osteoporosis and pertrochanter fracture.

low degree of osteoporosis pertrochanter fracture		
modification	moment [Nm]	angle [°]
Blade	2.0	1.56
Blade + AR-Clip	2.0	1.02
Blade + fixation bolt	2.0	1.01

> 50%

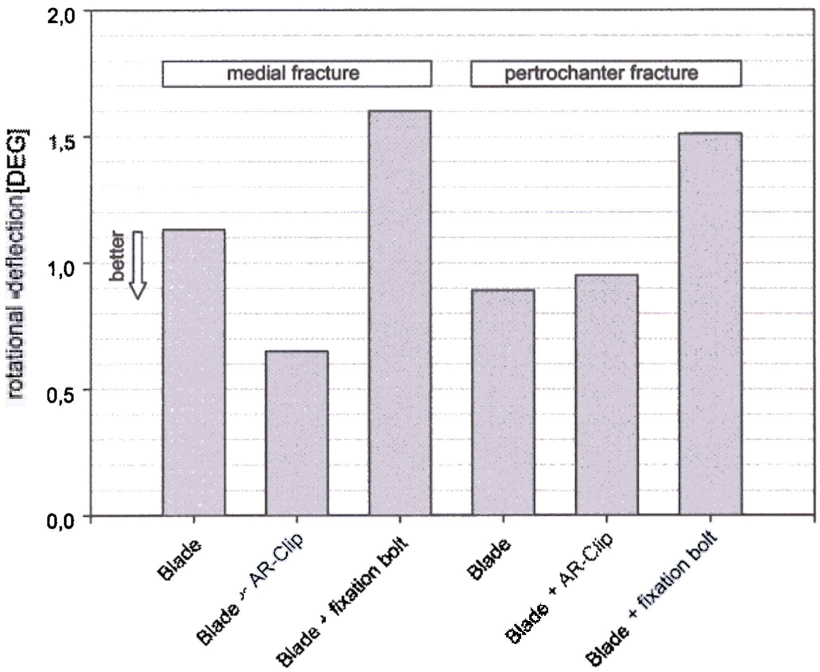


Fig. 9: Comparison of the primary stability achieved for high degrees of osteoporosis.

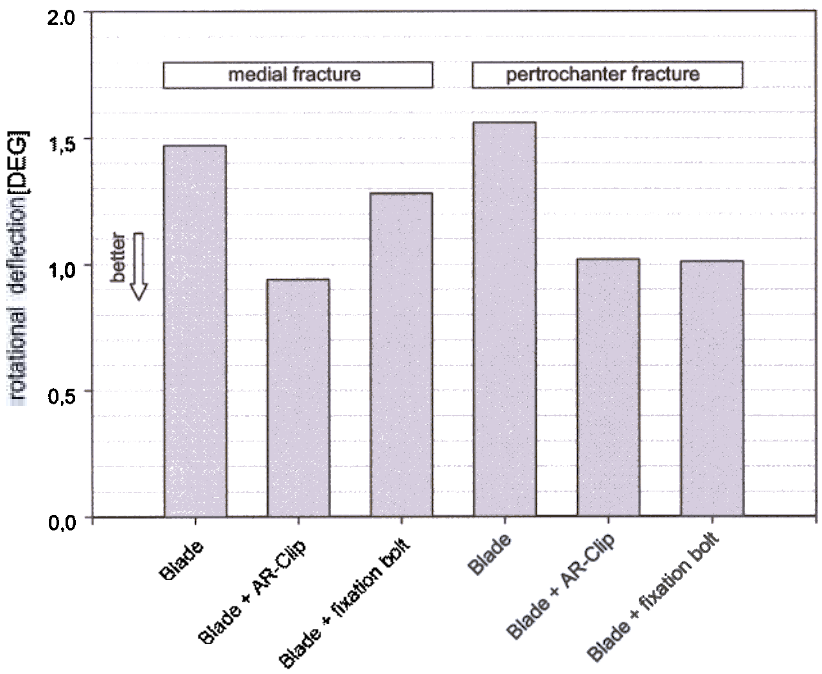


Fig. 10: Comparison of the primary stability achieved for low degrees of osteoporosis.

V. Discussion:

Two different types of fractures as well as two different types of bone quality have been investigated for the tests described herein. Due to severe deformation of the high osteoporosis material, the external load F has been reduced to 50% of the low osteoporosis material.
The rotation measured at a predefined level of the torsional moment applied has been selected to represent the quality of the primary stability achieved. Again, the rotation at 1 Nm torsional load of the high osteoporosis specimens did correspond to the rotation at 2 Nm torsional load of the low osteoporosis material. Due to the different mechanical loading conditions, direct comparison between the two bone qualities should be avoided.

At the **high osteoporosis material group**, lowest rotational deflections (best primary stability) have been measured when using the AR-clip. Preventing the rotation of the blade by using the fixation bolt did increase the rotational deflection. It is assumed that this effect is caused by a reduction of the axial compressive load.
No effect of the AR-clip could be measured when simulating a pertrochanter fracture. It is assumed that unloading of the proximal aspect of the simulated bone material causes destabilization of the AR-clip.

At the **low osteoporosis material group**, again lowest rotational deflections (best primary stability) have been measured when using the AR-clip. In contrast to the high osteoporosis group, improvement of the primary stability has also been achieved by using the fixation bolt. It is assumed that the differences between the two bone qualities groups tested with pertrochanter fractures are caused by the lower stiffness of the high osteoporosis material.

Best primary stability has been achieved for all groups when using the AR-clip. The effect of the fixation bolt depends on the bone quality and has been found to be helpful for all low osteoporosis tests performed herein.