Modular short stem endoprosthesis

Investigation of the loading stability of the modular conical connection

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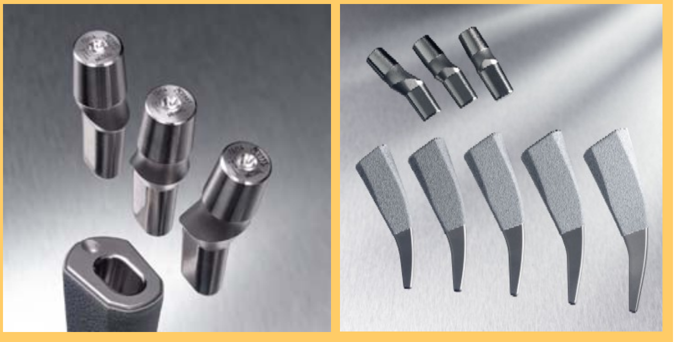
A new short stem implant (Metha®, Aesculap Tuttlingen) has been developed for a cementless primary hip replacement with metaphyseal stem anchoring and preservation of the femoral neck and greater trochanter. Due to a triple wedge-shaped design, a proximal metaphyseal fixation with optimal bone integration is achieved.

The modular connection between stem and neck offers the possibility of an intraoperative adaptation of the CCD angle, offset, and antetorsion by means of different neck adapters. Thus the reconstruction of the anatomical joint functions with respect to the rotation center and the soft tissue condition can be achieved regardless of stem positioning. The variability of the neck and head implants also enable a more precise adjustment of the range of motion and leg length [8,9,10,11].

The different neck adapters of the short stem are available in CCD angles of 130°, 135° and 140° with the corresponding offset variances of - 5 mm, 0 mm, + 5 mm as well as antetorsions of 7,5°Retro, 0°, 7,5°Ante. A cone with an oval cross section and small taper angle is used as a connection element (Fig. 1). Thus any rotational movement within the connection is prevented.

In spite of the advantages of modularity, each additional implant interface contains potential clinical risks. Risks include friction generated wear particles (so called fretting) of the boundary surfaces of the interface [2,3,7,10,11], fatigue fracture under dynamic load [1,4,6] as well as the possibility of a postoperative separation of the neck - stem connection.

Therefore the aim of the current biomechanical investigation is a preclinical evaluation of possible



▲ ***Fig. 1:***
Modular designed implant components for the intraoperative optimization of the joint function

mechanism of failure such as fatigue fracture, fretting corrosion, and dislocation stability of the selected modular neck connection.

Examination of the fatigue strength

The modular neck connection of the prosthesis stem was examined in a dynamic fatigue tests for determination of the fatigue strength according to ISO 7206-4:2002 on a servo-hydraulic test equipment (MTS 858 MiniBionix II) in 0,9 % NaCl solution. The test was conducted by embedding the stem in bone cement (Palacos® R) whereby its position (α = 10° frontal und β = 9° sagittal) and the embedding height (D=44.8 mm) was adapted to the anatomical situation and the specific design of this short stem prosthesis (Fig. 2).

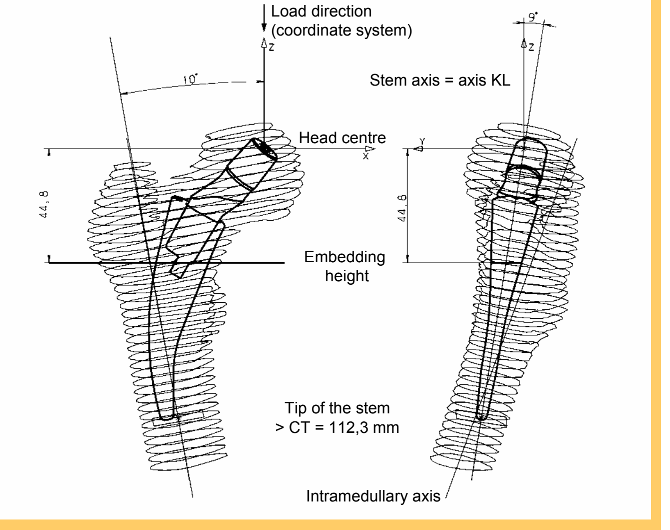
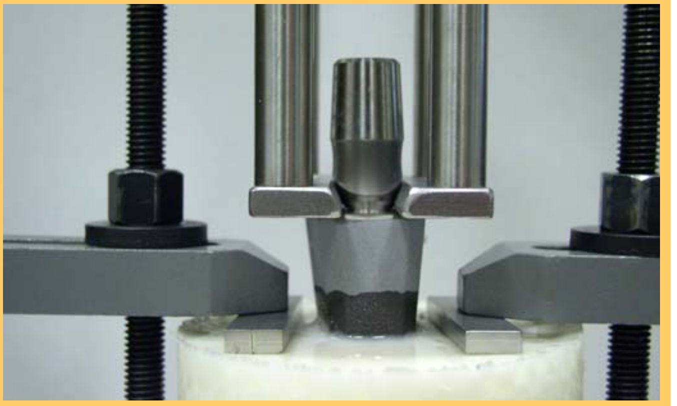


Fig. 2: ▶
Adjustment of the implant components relative to the resulting hip contact force and definition of the embedding height for the examination of the fatigue strength ISO 7206-4: 2002 (E) (frontal and lateral view)



▲ *Fig. 4:*
Test set-up for the examination of extraction force of the modular neck connection

◀ *Fig. 3:*
Test set-up on the servo-hydraulic universal test equipment with transverse force-free load application, contacting of the implant, reference electrode for the measurement of the free redox potential and container for the admission of the physiological NaCl solution (0,9%)

Examination of fretting corrosion

Modular neck connection wear within the interface (fretting corrosion) was evaluated (see fig. 3) by dynamic tests under constant peak load of F = 3300 N (R = 0.1) and 10 million load cycles.

For the gravimetric determination of the wear debris quantity resulting from fretting corrosion, the mass change of the modular neck was measured. Before assembling of the components and after the completion of the test, the modular necks were cleaned for15 minutes in an ultrasonic bath with ethyl alcohol and acetone (after the test) and weighed on an analytical balance (Mettler Toledo type AG 204) with a resolution of 0,1 mg.

Examination of the pull-off force of the neck/stem connection

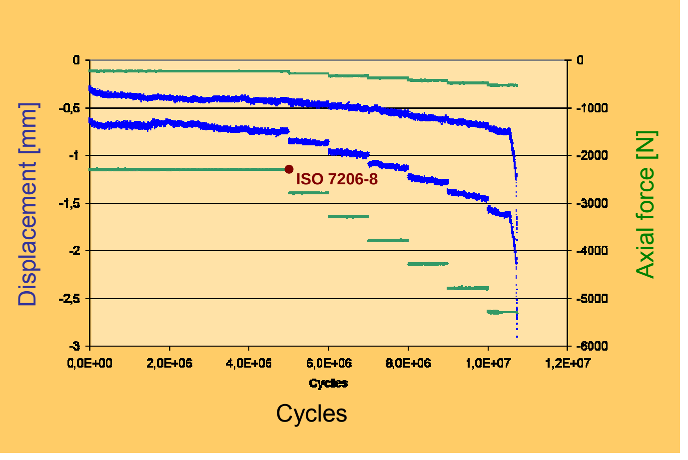
The dislocation stability was determined by the examination of the pull-off force of the modular neck / stem connection in quasi-static tests following ISO 7206-10: 2003 on universal test equipment (Zwick/Roell type Z020 Zwick, Ulm) as seen in Fig. 4.

Fatigue strength results

In the fatigue strength test according to ISO 7206-4: 2002 (E) the conical connection of the short stem prosthesis showed very good endurance properties with a high degree at reproducibility. After the fulfillment of the demands as specified in ISO standard (5 million load cycles with F = 2300N) only

Tab. 1: Results of the dynamic test with progressive stepwise loading (Locati-method)

Level	Min. Load [N]	Max. Load [N]	Cycles	Result
ISO	230	2300	5,000,000	no failure
1	280	2800	1,000,000	no failure
2	330	3300	1,000,000	no failure
3	380	3800	1,000,000	no failure
4	430	4300	1,000,000	no failure
5	480	4800	1,000,000	no failure
6	530	5300	750,629	fracture of the oval cone



▲ ***Fig. 5:***
Axial displacement depending on the load level and cycles - Locati test (ISO/CD 7206-8:2004)

stepwise load increase according to ISO/CD 7206-8: 2004 with a hip contact force of F = 5300 N leads to the mechanical implant failure by a fatigue fracture in the neck connection (Tab.1).

The crack formation, which finally led to the fatigue fracture of the oval cone connection, took place in load level 6 at F=5300 N after over 10 million cycles (Fig. 5).

The results of the fatigue tests over 10 million load cycles with constantly high load (F=3800 N) exceed the requirements of the ISO 7206-8 regarding the hip contact force by a safety factor of σ_F = 1,65 and by the numbers of cycles without failure about σ_{cyles} = 2,0.

Fretting corrosion results

The short stem prosthesis also shows in case with constantly high hip contact force of F=3300 N and load cycle numbers between 10 million and over 20 million a high resistance in the modular neck connection against fretting corrosion. The weight changes of the modular neck are minimal with values under -0.1 mg and show a high grade of reproducibility (Tab. 2) [5].

The recording of the free redox potential (corrosion potential) dependant upon the hip contact forces and load cycle numbers shows a clear repassivation characteristic of the modular neck connection up to the load level F=3800 N. A beginning fretting corrosion starts only from a force level of F = 4300 N. The examined implant size was not significantly dependant when measured upon the generation of particles.

Results of the pull-off force of the neck / stem connection

On basis of the quasi-static examinations for the pull-off force of the modular neck connection in accordance with ISO 7206-10: 2003 the short stem prosthesis demonstrates a high resistance against postoperative separation of the components. A contamination of the oval cone connection with calf serum immediately prior to the assembling procedure did not have any significant influence on the pull-off force. The good reproducibility of the pull-off force under standardized assembling conditions with a defined compression force F = 2000 N show the high manufacturing quality in the adjustment of the modular oval cone connection.

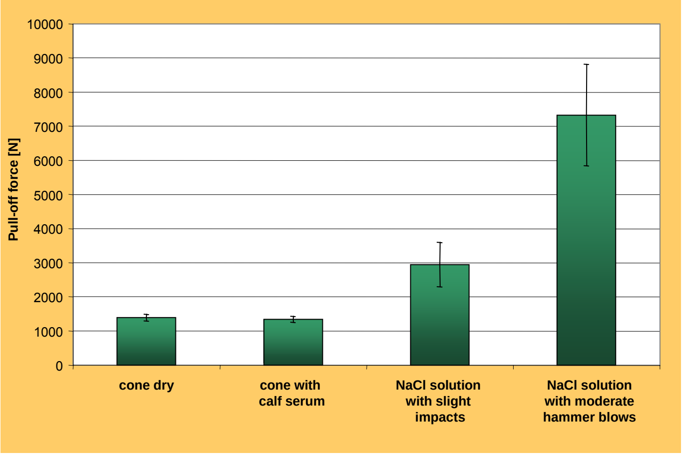
The current cone design with a small taper angle is slightly impacted after cleaning with NaCl solution and leads to a high pull-off force of F = 2.949 N +/- 652 N. Moderate hammer blows already during a soft prosthesis storage (hold in the left hand) generate extreme extraction forces F = 7.325 N +/- 1.491 N.

Independent of this, the available results show clearly that the modular oval cone design ensures a high fixation quality of the components, even if the contaminated cone is inserted intraoperatively without force and the corrective assembling is done postoperatively by hip contact force of the patient (Fig. 8).

Summary

The new Metha® short stem prosthesis far exceeded the requirements of ISO 7206-8 fatigue strength and showed high resistance against fretting corrosion in the additional interface. Its clinical use ensures a high resistance against mechanical failure and generation of wear particles. In addition, the theoretical clinical failure mechanism, “separation of the neck components,” has been overcome by the high clamping stability of the oval cone design with a small taper angle.

Tab. 2: Dynamic test with constant load level	
Level	2
Minimal load (N)	330
Maximal load (N)	3.300
Load cycles	10 Million
Result	no failure
Weight reduction of the modular neck after 10 million load cycles ≤ 0,1 mg	



▲ ***Fig. 6:***
Pull-off force with defined assembly force F=2.000 N (cone dry and cone with calf serum) as soon as clinical assembly methods with contamination by NaCl solution

Neck modularity that optimizes implant design by offering a wide intraoperative range of variations has significant clinical advantages. This modularity also optimizes the correct reconstruction of the anatomical joint function with respect to of the rotation center and soft tissue management. Furthermore, neck modularity maximizes the range of motion and allows adaptation of the joint stability in order to decrease the tendency of dislocation and impingement without adding risks for the patient.

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