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Biomechanical evaluation of the femoral neck fracture fixation technique with the new implant FNS in comparison to DHS Blade, DHS Screw with antirotation screw and Three Cannulated Screws

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“Man muss nicht alles glauben, was man hört“

nach Cicero

106-43 v. Chr.

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AO	Arbeitsgemeinschaft Osteosynthesefragen
ap	anterio-posterior
BMD	Bone Mass Density
CCD	Caput Collum Diaphysis
CI	Confidential Interval
deg.	degree
DHS	Dynamic Hip Screw
et al.	et alii
excl.	excluding
ff.	the following
fig.	figure
Fh	force femoral head
FNS	Femoral Neck System
Ft	Force tractus iliotibialis
HR	High Resolution
Hz	Hertz
incl.	including
keV	kiloelectron Volt
kN	kiloNewton
kVp	peak kilo voltage
µA	microAmpere

mgHA/ cm3	milligramm hydroxylapatite per cubic centimeter
mm	millimeter
µm	micrometer
ms	millisecond
N	Newton
nr.	number
n	sample size
ORIF	Open Reduction Internal Fixation
p	significance
PMMA	Polymethylmethacrylate
pQCT	periphere quantitative computertomography
S	second
SD	standard deviation
SEM	Standard Error of the Mean
TAN	Titanium/Aluminium/Niobium
US/USA	United States (America)
v.	version
X-ray	Röntgen radiation
3CS	3 Cannulated Screws

1 Introduction

The rate of femoral neck fractures, a common injury in the elderly, increases constantly (Cooper et al. 1992; Cummings et al. 1990; Johnell & Kanis 2004). Therefore, two ways of addressing have been established, consisting of the use of the 3CS (3 Cannulated Screws) on the one and the DHS (Dynamic Hip Screw) systems (blade and screw) on the other hand. (Gjertsen et al. 2010; Gurusamy et al.2005; Husby et al. 1989; Ly & Swiontkowski 2008). The most challenging aspects in managing femoral neck fractures result from achieving satisfying reduction on the one and facing poor bone quality in osteoporotic bone on the other hand (Chua et al. 1998; Duckworth et al. 2011; Husby et al. 1989; Rehnberg & Olerud 1989; Smith et al. 1992; Swiontkowski 1994; Thein et al. 2014). While the old styled 3CS technique works as a minimally invasive procedure, the use of the DHS systems affords open surgery. The role of an ideal minimal invasive implant would assure the required stability of fixation providing compression force to the fracture site and preventing rotation of the femoral head as well, found in both, the 3CS and the DHS systems. Furthermore, such a system would introduce the opportunity of working minimally invasive found in the 3CS method.

Whereas the DHS Blade has been established as a European gold standard for the treatment of femoral neck fractures concerning cases of osteoporotic bones in special, the conventional DHS Screw with antirotation screw continues to be an international gold standard for the purpose of comparison (Bhandari et al. 2009; Müller et al. 1991, Russell & Crenshaw 1992). The conventional fixation with the 3CS can be used for treatment of femoral neck fractures type AO (Arbeitsgemeinschaft Osteosynthesefragen) 31-B (Ruedi & Murphy 2001). The new minimal invasive implant FNS (Femoral Neck System) was developed for the treatment of the mentioned types of femoral neck fractures and was thought to become a replacement for the aged 3CS.

The aim of this project was to evaluate the biomechanical performance of the newly designed FNS under cyclic loading in comparison to the existing clinical implant solutions on the market, DHS Blade, DHS Screw and the 3CS. There for, an elderly human cadaveric model was set up. In its course a 70°Pauwels III/AO 31–B2.3 fracture was performed in 21 human cadaveric frozen femora after augmentation through one of the 4 mentioned implants. Additional 30° distal and 15° posterior wedges were applied to the fracture, to create the worst case scenario as far as terms of stability are concerned.

FNS and its ancestors

The 3 introduced implants are mainly used in the case of cervical femur fractures concerning the entities AO 31-B.1-3. Their use can be expanded to fractures occurring in the pertrochanteric region concerning the entities AO 31-A.1-3 (Fig.1) except the 3 CS, their use is limited to fractures concerning the transcervical region due to a missing medial buttress needed for single use of screws in the proximal femur.

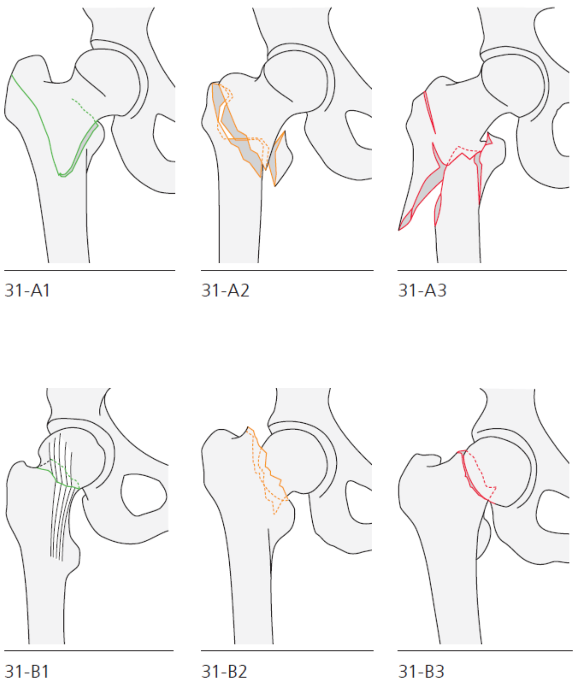

Fig.1: Fracture indications suitable for fixation via DHS (AO type A1-2&B), 3CS (AO type B) and FNS (AO type B). The colored lines (green, orange, red) show the location of the fracture. The fracture is categorized by its severity and classified with A-C concerning pattern and location of the fracture. With kind permission of DePuySynthes. AO=Arbeitsgemeinschaft Osteosynthesefragen, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3 Cannulated Screws.

3CS

The 3CS represent the basic method of fixating a fracture in the proximal femur region. Consisting of 3 single screws the principle of lag screwing is used for bringing compression to the fracture site and achieving absolute stability.

Concerning mainly the entities AO 31-B.1-3 the 3 CS have become a standard procedure in fracture fixations for decades.

By using a 3-point-lagging-model the screws work in terms of lagging and buttressing as well and provide rotational and axial stability to the cervical region of the proximal femur.

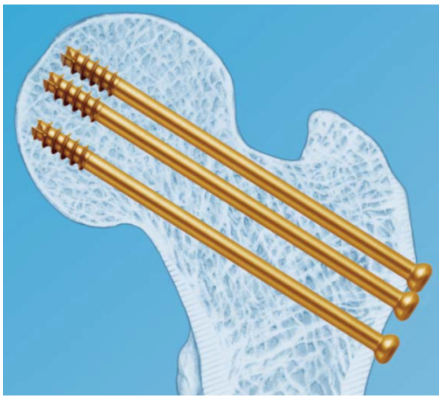

Fig.2: 3 Cannulated screws (gold) applied to the proximal femur. With kind permission of DePuySynthes.

The Cannulated screws provide the described features by being designed as a true lag screw with naked screw collar and threaded screw tip (Fig.3).

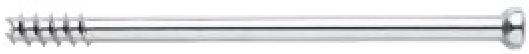

Fig.3: The Cannulated Screws is a true lag screw by offering a naked collar and a threaded tip. With kind permission of DePuySynthes.

Due to the fact the screws are used in single use only, a buttress connection to the femoral shaft cannot be achieved. In consequence the technique isn't suitable for the entities AO 31-A.1-3. The missing stabilizing connection to the femoral shaft wouldn't deliver the demanded aim of stability needed for fixing the harmed pertrochanteric region.

DHS Screw

The next step as far as the width of its use is concerned was the DHS screw. The use of the implant enables the operator to fix fractures concerning the transcervical and the pertrochanteric region due to its design.

The aim of the implant is to combine the element of lagging found in the 3 CS with the element of buttressing provided by a conventional used plate. As a result you can find an implant which enables you to address both, fractures in the pertrochanteric and the transcervical region. An additional antirotational screw was added optionally to achieve the prevention of rotation provided by the 3-point-idea of the 3 CS.

Fig.4: Shown is the DHS Screw system. By combining a lag screw element with a buttress plate element, the range of indication could be widened to the pertrochanteric region. With kind permission of DePuySynthes. DHS=Dynamic Hip Screw.

After introducing the DHS screw, first cases of implant failure showed loosen screws that slipped out along the way of entrance they were brought into the femoral head. This complication called “cut out” occurs as a result of axial load that is applied to the fixed fracture leading to pressing and shearing forces. The repetitive cycles of weight, applied to the implant, led to loosening of the threaded part of the screw in its bony anchor. This typical complication is reported to appear in 1.7 – 6.8% of the invastigated cases of fractures that were fixed with DHS screw (Luo Q et al. 2013).

Considering the design of the screw, it has to be mentioned, that a threaded screw design leads to a “cutting in” of the screw into the bony mass by driving forward over the thread. In consequence the screw head is blocked into the bone mass by being threaded in.

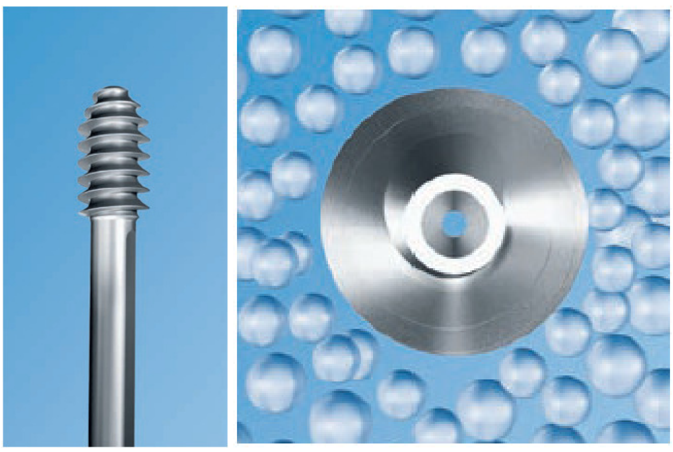

Fig.5: The threaded tip-design of DHS Screw does not compress the surrounding bone mass (shown as bubbles) due to the cutting character of a thread. With kind permission of DePuySynthes. DHS=Dynamic Hip Screw.

DHS Blade

After recognizing the tendencies of cutting out, a way of more stable locking into the bony surroundings was investigated. By changing the threaded design of the screw tip, a more stable locking could have been achieved. The idea of changing from a “cutting in” mechanism to a “squealing in” mechanism led to the solution. There for, the design of the screw tip had to be changed.

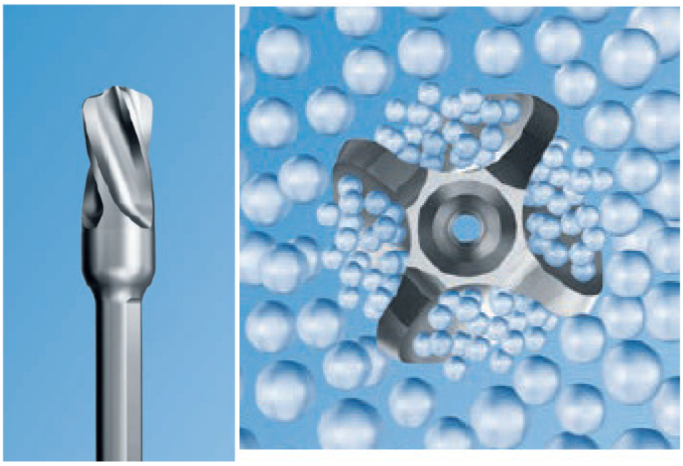

Fig.6: The design of the screw tip was changed from a threaded and cutting to a winded and volumetric impacting geometry, allowing volumetric impact of the surrounding bone mass (shown as bubbles). With kind permission of DePuySynthes.

By changing the geometry of the screw tip to a winded design, suppressing forces were achieved by bringing in the screw. In consequence the density of the surrounding bone was increased, which led to a reduced risk of cutting out. The screw turned into a blade and was able to produce a volumetric impaction of the cancellous bone it was brought into.
By introducing the new design cutting out rates were reduced significantly compared to the screw design, as far as linear cutting out and rotational loosing is concerned, as well (Luo Q et al. 2013).

FNS

By improving the DHS to a more balanced implant the width of indications concerning the 3 CS becomes smaller. By presenting an implant that makes use of the stability advantages found in the DHS systems and the minimal invasiveness of the 3 CS as well, a replacement for the 3 CS could be introduced. Previous works show that an intramedullar solution is superior to an extramedullar solution like DHS, as far as time of intervention, blood loss and dimension of the wound are concerned (Yeganeh et al. 2016). The goals for a new implant to replace the 3 CS as the minimally invasive standard for fixing femoral neck fractures should be the following:

- The possibility of shaft fixation provided by a screw-into-plate design.
- Improved stability behavior in terms of axial, rotational and varus/valgus stability.
- Feasibility as a minimally invasive implant to reduce blood loss, floor damage and size of the wound.

As a result, FNS is introduced. Its design was brought on the way by making use of the advantages that were found in its preceding implants (DHS, 3 CS).

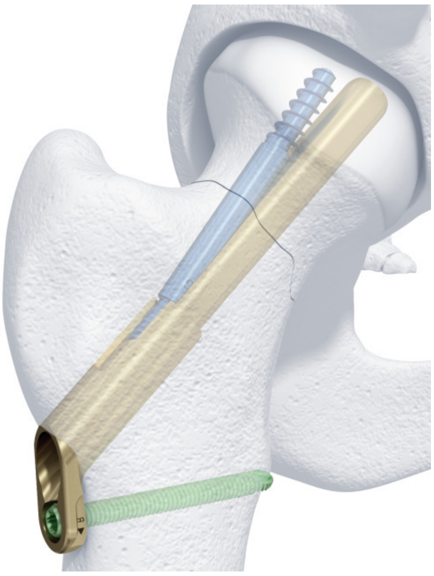

Fig.7: FNS consisting of a hollow main component (gold) which features a bridge on the outer aspect as a point of fixation via an angle stable screw (green). An additional diverging lag screw (blue) provides compressing forces to the fracture and rotational stability as well. With kind permission of DePuySynthes. FNS=Femoral Neck System.

The main part of the implant is represented by a hollow shaft construction which ends up in a little plate-like bridge on its outer end. The bridge offers a threaded hole-design to enable angle stable screw fixation to the femoral shaft.
The shaft construction is brought in by sticking into the femoral head through a drilling channel set before. A side hole is placed along the hollow shaft, where an anti-rotational screw is placed in diverging direction to the main axis of the shaft. The screw also achieves a lagging effect by being designed partly threaded. The double characterization of the implant, working with buttressing and lagging force, combines the advantages of both, the DHS and the 3 CS as well. The small size of the implant offers the ability of minimal

invasiveness, furthermore, the implants diverging geometry promises to end up in a reduced risk of being exposed to pull out and rotational dislocating forces as well. By offering the features mentioned above, the implant could be introduced as a qualitative fully and improved replacement for the 3 CS, used for many years.

It was hypothesized, that there would be a significant difference between FNS and the 3CS regarding the most important outcome parameters of interest such as 1) initial construct stiffness, 2) cycles to failure and 3) load to failure.

The biomechanical validation of the hypothesis would confirm FNS being a stable solution for fixing AO type 31-B fractures in the proximal femur. As a consequence, the system would be a suitable alternative for the treatment of femoral neck fractures, providing the advantages found in both, the DHS systems and the 3CS as well.

2 Materials & Methods

2.1 Specimens

The specimens were ordered and obtained from Science Care, an US-American Association dealing with human tissue. The company fulfills the guidelines set by the American Association of Tissue Banks and stands as an approved and authorized institution. Furthermore, the study was performed in compliance with the local ethical regulations of the AO Research Institute.

Twenty-one pairs of fresh frozen (–20°C) human cadaveric femora from donors aged between 60 and 75 years were used in this project. The specimens were thawed at room temperature for 24 hours and separated from surrounding tissue afterwards as well.

The following excluding criteria were chosen to obtain a homogeneous distribution regarding donor's morphology, to achieve comparable initial conditions for every single specimen.

1) Severe osteoporosis. The assessment was based on literature data and BMD, surveyed with HR pQCT.
2) Grade 3 and 4 arthrosis, surveyed with conventional X-ray.
3) CCD angle smaller than 125° and bigger than 135°, surveyed with conventional X-ray.
4) Previous hip fracture treated conservative or post hardware removal after ORIF, surveyed with conventional X-ray.
5) Cancer, surveyed by patient history.

Record of the femoral Head Diameter (mm.) (Fig.8a), CCD Angle (deg.) (Fig.8b) and Lever Arm (mm) (Fig.1c) was performed for all specimens and BMD was defined using HR pQCT as follows. First, each specimen was scanned along the shaft axis with XtremeCT (SCANCO Medical AG, Brüttisellen, Switzerland). The X-ray tube was set at 60 kVp with an effective energy of 40 keV, 900 µA, nominal isotropic resolution of 82 µm and integration time 200 ms. Next, the scans were downscaled after reconstruction to a resolution of 123 µm and rotated in space to achieve the new scan axis along the femoral neck axis. Finally, the slice with the largest diameter of the femoral head was determined and further 80 proximal slices from this slice onwards were selected for evaluation. BMD of the selected bone volume was calculated after contouring the bone area in each of the 80 slices.

2.2 Implants

The following implant systems were used:

1) Two–hole 130° DHS with short threaded Ø 6.5 mm Cancellous Bone Screw and two Ø 4.5 mm cortical distal screws, 10 sets, Stainless Steel

2) Two–hole 130° DHS Blade and two Ø 4.5 mm cortical distal screw, 10 sets, TAN

3) One–hole FNS with one Ø 5.0 mm locking–head distal screw, 11 sets, TAN

4) Three Ø 7.3 mm Cannulated Screws, short threaded, 11 sets, TAN

All mentioned implants are crafted by Manufacturer DePuySynthes.

2.3 Study groups

The specimens were randomized in the following four groups based on their BMD:

Group 1: DHS Screw

Group 2: DHS Blade

Group 3: FNS

Group 4: 3CS

Accordingly the randomization was performed pair wise, either groups 1 and 2, or groups 3 and 4.

The group code was consistent with the respective implant type used for instrumentation. One pair - F09-2060L/R (Group DHS Blade) - had to be excluded from the mechanical testing due to failure during instrumentation which led to a total amount of 21 specimen pairs that were assessed.

Each of the groups 1 and 2 consisted of nine paired specimens for the main series plus one paired pilot (n = 9+1), whereas each of the groups 3 and 4 included 10 paired specimens for the main series plus 1 paired pilot (n = 10+1), deciding that a 33% lower performance of group 3CS compared to FNS in view of cycles at failure occurrence would be enough for achieving statistically significance. Presuming that group 3CS would reach a mean of 5’000 cycles and FNS a mean of 7’500 cycles, both featuring a standard deviation of 2’000 cycles, a number of 10 samples was claimed to be sufficient to detect significant differences between the groups at a level of significance $\alpha = 0.05$, with a statistical power of 97.7%.

Table 1: Group assignment, pair number and name of each specimen. DHS=Dynamic Hip Screw, 3CS=3 Cannulated Screws, FNS=Fermoral Neck System.

pair	**DHS Screw**	**DHS Blade**
8	M13-1009R (pilot)	M13-1009L (pilot)
11	F12-1104R	F12-1104L
18	M13-1307L	M13-1307R
4	F10-1092R	F10-1092L
1	F09-2061R	F09-2061L
3	F10-1041R	F10-1041L
14	M13-1303L	M13-1303R
10	F11-4004L	F11-4004R
21	F13-1310R	F13-1310L
20	M13-1309L	M13-1309R
	FNS	**3CS**
5	F10-1094L (pilot)	F10-1094R (pilot)
19	F13-1308L	F13-1308R
6	F13-8004_FemR	F13-8004_FemL
17	M13-1306R	M13-1306L
12	F13-1301L	F13-1301R
7	M10-1091L	M10-1091R
15	F13-1304R	F13-1304L
13	M13-1302R	M13-1302L
2	F09-2062L	F09-2062R
16	F13-1305R	F13-1305L
9	M09-2056L	M09-2056R

2.4 Specimen preparation

First, the specimens were instrumented according to the manufacturer's guidelines. The DHS Screw and FNS were instrumented 10% inferiorly (4.8±0.4 mm, mean±SD) than the center–center position in the coronar plane and in center–center position in the sagittal plane, referring to the position of the implant in correspondence to the femoral neck. DHS Blade was instrumented with center–center positioning in both, coronar and sagittal plane as well. Deviations from a central implant positioning in sagittal plane were measured using digital image processing software (AxioVision, V4.6, Carl Zeiss AG, Göttingen, Germany). Thereby, the shortest distance from the femoral head centre to the implant axis was registered in two different manners to create two outcomes named “Implant Axis Off Center Relative” (mm) and “Implant Axis Off Center Absolute” (mm) (Fig.8f). In case of the former mentioned, investigation contained, whether the implant was brought in anteriorly or posteriorly compared to its referring center. This is indicated by positive (anterior position) and negative (posterior position) values. In case of the latter mentioned, positive values are recognizable only, representing the undefined distance to the referring center. The described outcomes were evaluated for the groups DHS Screw, DHS Blade and FNS only. The FNS locking screw and the antirotation screw were tightened with force of 4 Nm. The 3CS were inserted parallel to each other into the femoral head according to the AO technique. By performing so, exceeding of the threads as far as the fracture line is concerned, was ensured. Washers were additionally used in any of the 3CS to raise intraosseous deadlock. The intraosseous construct length “x” was measured and defined as “Implant Length” (mm) (Fig.8d), according to the distance between the implant insertion point at the lateral cortex side of the trochanteric region and the implant tip. In the group 3CS, the averaged construct length of all three screws was taken as an arithmetically averaged Implant Length. The combined implant distance to subchondral bone on the AP and the lateral view at the medial aspect of the femoral head was performed less than 20 mm and registered as “Tip-Apex Distance” (mm) (Fig.8e). A custom c-shaped measuring tool was used to define the length between the implant insertion point at the lateral cortex side and the possible exit point of the implant at the femoral head tip. The Tip-Apex Distance was evaluated by subtracting the Implant Length from the measured distance between the lateral cortex and the tip of the femoral head. In case of group 3CS the Tip-Apex Distance was based on the arithmetically averaged Implant Length of all three screws.

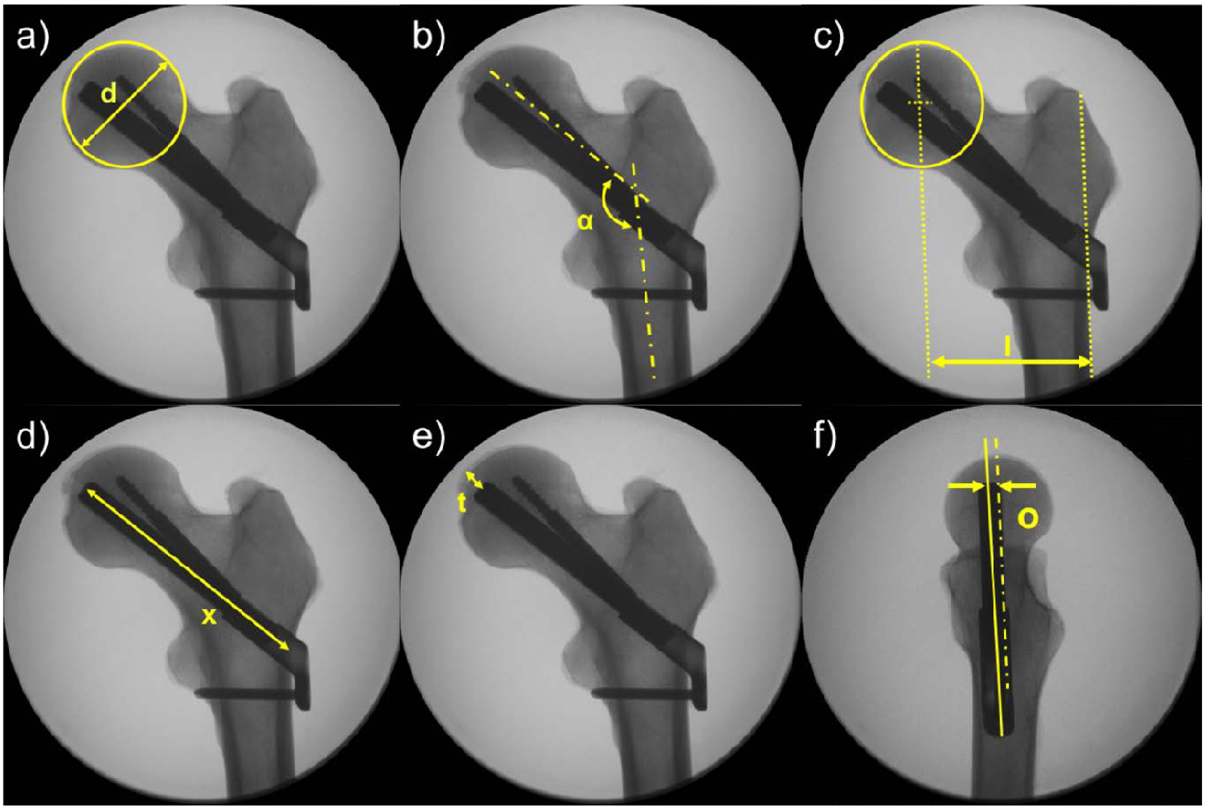

Fig.8a-f: Outcomes based on specimen's morphology, shown on an FNS implant using yellow symbols: a) d = Head Diameter (mm), defined as the diameter of the femoral head; b) α = CCD Angle (deg), defined as the angle between the axis of the femoral neck and the femoral shaft; c) l = Lever Arm (mm), defined as the distance between the center of the femoral head and the lateral cortex of the femur in the coronal plane; d) x = Implant Length (mm), defined as the intraosseous working length of the femoral neck component of the particular implant; e) t = Tip-Apex Distance (mm), defined as the distance between the tip of the implant and the surface of the femoral head; f) o = Implant Axis off Center (mm), defined as the axial deviation of the particular implant to the axis of the femoral neck in the coronal plane. With kind permission of the AO Research Institute Davos. CCD=Caput Collum Diaphysis, deg=Degree, FNS=Femoral Neck System, mm=millimeter.

Secondly, a formerly reduced (DHS Screw, DHS Blade, FNS or 3CS) femoral neck fracture with a 70°Pauwels III/AO 31–B2.3 with 30° distal and 15° posterior wedges in respect to the fracture plane, representing an extreme case for the tested implants, was set to the femora. The kind and dimension of the wedge was set to produce the mechanic worst case concerning stability of the fracture. A special device (Fig.9) was used to perform consistent osteotomies in each of the specimens (Windolf et al.2009).

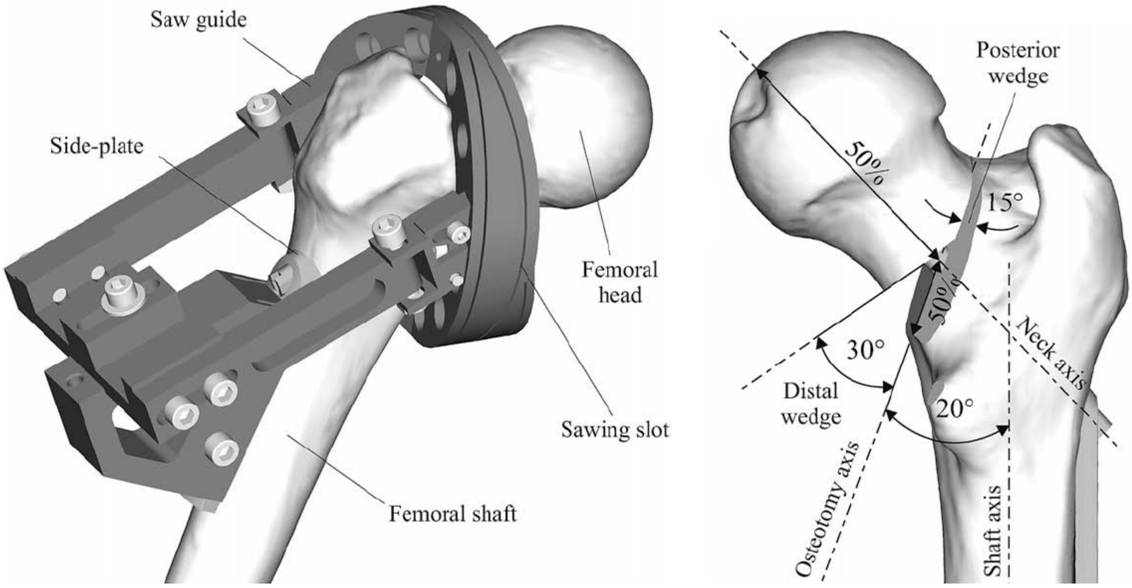

Fig.9: Proximal femur with a special custom made device to set consistent osteotomies. Shown are the device in situ (left) and the osteotomies set by using the device (right). With kind permission of the AO Research Institute Davos.

Finally, all femora were cut to a total specimen length of 400 mm each and embedded in PMMA prior to biomechanical testing angled in 16° adduction. Retro–reflective marker sets were attached to the shaft and the femoral head fragment to enable optical motion tracking as shown in Fig.10. Two collinear markers were additionally attached to each implant to determine the orientation of the implant axis. In the case of 3CS the markers were attached to the most caudal screw.

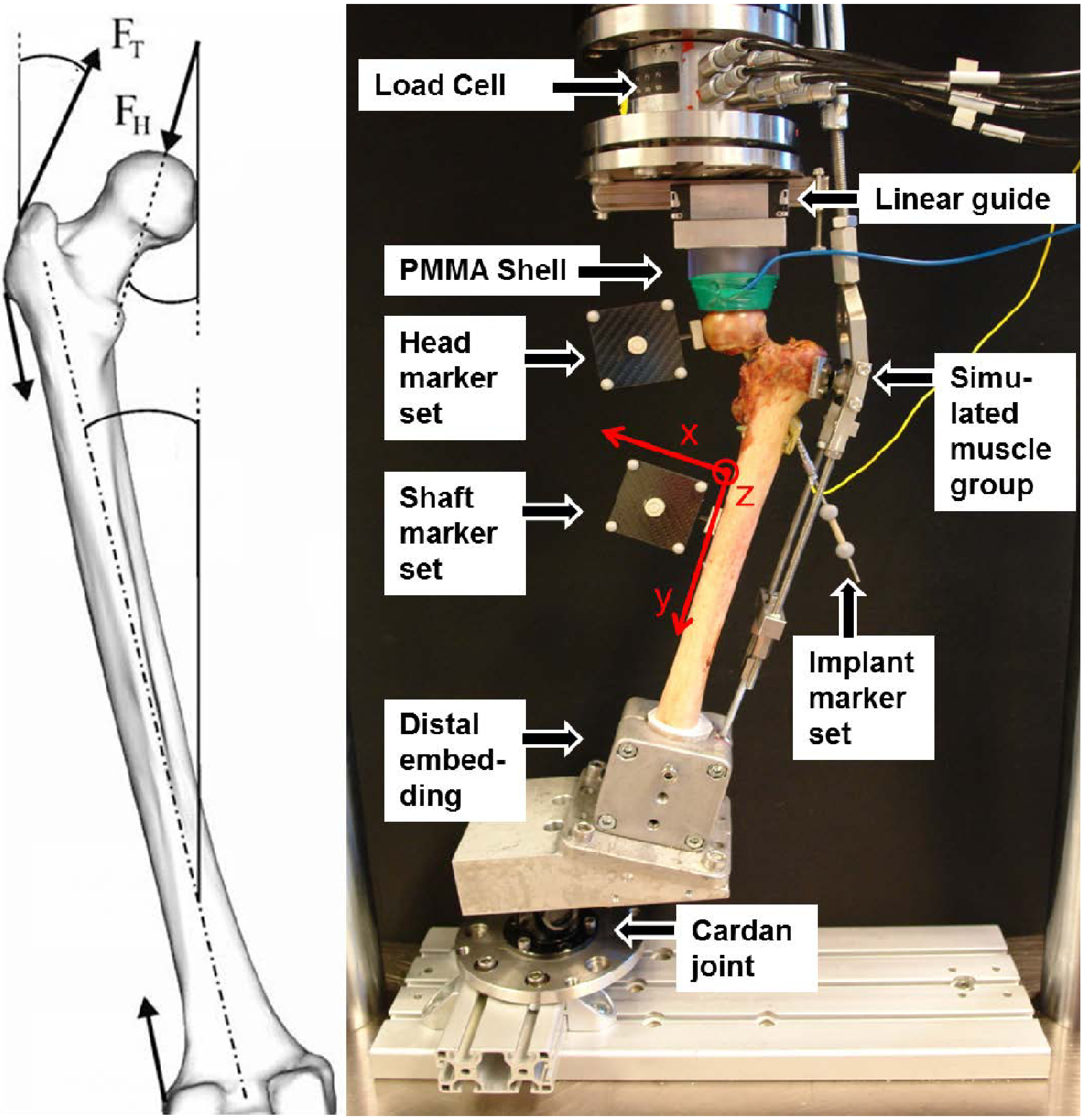

Fig.10: Test setup. Left: free body diagram of the femur with the main applied forces, mainly represented by the abductive and valgizing force of the tractus iliotibilis and the axial force applied to the femur. Right: Test setup with a left femur specimen, mounted for biomechanical testing, instrumented with FNS and equipped with retro-reflective markers for optical motion tracking analysis in a coordinate system (red) with y-axis parallel to the long bone axis and x-axis in the frontal plane. The specimens were placed in 16°adduction to simulate the physiological situation (Stoffel K et al. 2017). With kind permission of the AO Research Institute Davos. Fh=Force femoral head, FNS=Femoral Neck System, Ft=Force tractus iliotibialis, PMMA=Polymethylmethacrylate.

2.5 Biomechanical testing

Biomechanical testing was performed on a servo hydraulic test system (Bionix 858; MTS Systems, Eden Prairie, MN) with a 4 kN load cell at room temperature (20°C) in a dry environment.

The biomechanical test setup and the loading protocol were adopted from previous performed studies (Bergmann et al. 2001; Bonnaire et al. 2007; Windolf et al. 2009) (Fig. 10).

All specimens were tested in 16° adduction (Bergmann et al. 2001). The femoral head was axially loaded in compression along the machine axis. A PMMA shell cup, attached to the machine actuator via a linear horizontal guide, was used for this purpose. A special custom made foil from electro– conducting material was implanted at the distal surface part of the cup to achieve immediate detection of the cut–out and interruption during the mechanical tests. The feasibility of appropriate X–ray images at region of interest was provided by the semi–transparency cup.

Fig.11: X-ray of implanted femur with electro-conductive semi-transparent metal cup shown on a DHS Screw implant. With kind permission of the AO Research Institute Davos. DHS=Dynamic Hip Screw.

The cranial contact area was defined in terms of the physiological joint situation to the acetabulum. The distal specimen end was attached to the machine floor-frame via a cardan joint. By installation of a lateral bracing enclosing the whole cranio-caudal distance of the specimen, the abductive forces of the iliotibial ligament were simulated (Windolf et al. 2009). Finally, the zero point for vertical displacement was set at 50 N compression.

The biomechanical test of each specimen was performed according to the following loading protocol:

1) Initial quasi–static loading in a linear protocol of increasing axial compression of 50–200 N at a rate of 15 N/s.
2) Cyclic compression loading at a rate of 2 Hz and 0.1N/cycle.

An increasing cyclic ramp loading (Windolf et al. 2009) with a physiological profile of each cycle (Bergmann et al. 2001) was performed. Every cycle started at a valley load of 200 N heading to a constantly increased maximum load, until failure of the bone–implant construct occured. The initial maximum load was set to 500 N. The model of an increasing load ramp used to achieve implant failure within a predefined number of cycles has been found useful in studies performed before (Gueorguiev et al. 2011; Windolf et al. 2009). The test protocol was tuned with pilot tests and adjusted if necessary, the aim of the tuning was to achieve failure of the bone–implant construct between 10’000 and 30'000 cycles.

The following test stop criteria were defined:

1) Detection of cut-out with foil in PMMA shell cup.
2) 30 mm axial displacement of the machine actuator.
3) 4’000 N axial compression load.

2.6 Data acquisition and evaluation

Radiographic images were taken at the beginning (50 N) and the end (200 N) of the quasi–static test, as well as every 250 cycles during the cyclic test at valley load of 200 N using a triggered C–arm. Machine data in terms of time (s), axial displacement (mm) and axial load (N) were acquired from the machine actuator and the load cell. Based on these,

- "Axial Stiffness" (N/mm), (Fig.12) was calculated from the slope of the axial load–displacement curve in the third loading cycle between 300 N and 400 N axial compression and considered as an outcome.

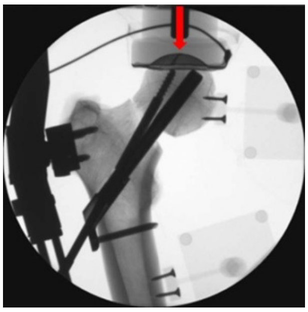

Fig.12: Axial Stiffness (N/mm, red arrow), shown here on an FNS implant, defined as the force needed per mm of axial displacement of the implant bone construction. With kind permission of the AO Research Institute Davos. FNS=Femoral Neck System, mm=millimeter, N=Newton.

Radiographic images were used to especially focus on the behaviour of the distal screws, the plate (of the DHS and FNS implants) and the lateral cortex in proximity to the mentioned screws and the particular plate. The following outcomes were calculated:

- "Deformation Plate to Screw after 10'000 cycles" (deg.) (Fig.13), defined as the angular offset of the distal screw relative to the plate after 10'000 cycles at valley load of 200 N relative to the angle between the distal screw and the plate at the end of the initial quasi-static test.

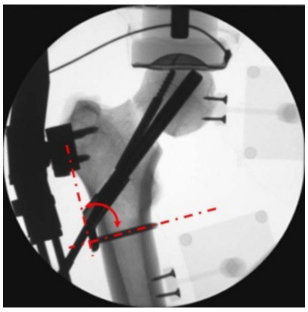

Fig.13: Deformation Plate to Screw (deg., red lines and arrows), shown here on an FNS implant, indicating the deformation of the plate compared to the fixation screw. With kind permission of the AO Research Institute Davos. Deg.=Degree, FNS=Femoral Neck System.

- “Plate Lift-off after 10’000 cycles” (deg.) (Fig.14), defined as the angular offset of the plate relative to the lateral cortex after 10’000 cycles at valley load of 200 N relative to the angle between the distal screw and the plate at the end of the initial quasi-static test.

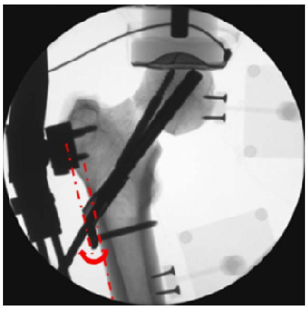

Fig.14: Plate Lift-off (deg., red lines and arrows), shown here on an FNS implant, indicating the deviation of the plate to the femoral shaft. With kind permission of the AO Research Institute Davos. deg.=Degree, FNS=Femoral Neck System.

- “Deformation Screw to Shaft after 10’000 cycles” (deg.) (Fig.15), defined as the angular offset of the distal screw relative to the lateral cortex after 10’000 cycles at valley load of 200 N relative to the angle between the distal screw and the plate at the end of the initial quasi-static test.

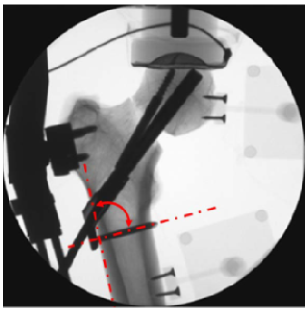

Fig.15: Deformation Screw to Shaft (deg., red lines and arrows), shown here on an FNS implant, indicating the deformation of the fixation screw to the femoral shaft. With kind permission of the AO Research Institute Davos. deg.=Degree, FNS=Femoral Neck System.

The performance of the bone–implant construct in terms of femoral head movements with respect to the shaft in all six degrees of freedom as well, as precise implant migration/telescoping were investigated by means of optical motion tracking analysis as described in Windolf et al. 2009.

Out of motion tracking data, the following variables, representing the relative interfragmentary movements were evaluated:

- “Leg Shortening” (mm), defined as movement of the head centre along the shaft axis (Fig.16).

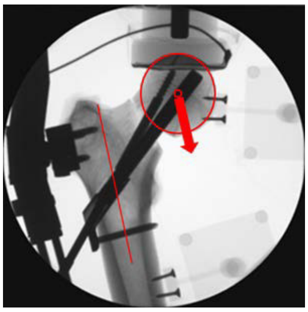

Fig.16: Leg Shortening (mm, red lines, arrows and circles), shown here on an FNS implant indicating the shortening of the specimen under axial load. With kind permission of the AO Research Institute Davos. FNS=Femoral Neck System, mm=Millimeter.

- “Neck Shortening” (mm), defined as displacement of the osteotomy aspect point along the neck axis. This specific point was located in the middle of the line connecting the most superior and most inferior osteotomy points (Fig.17).

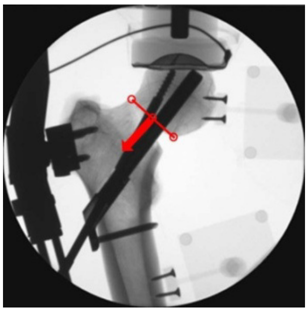

Fig.17: Neck Shortening (mm, red lines, circles and arrow), shown here on an FNS implant, indicating the shortening of the specimens neck under axial load. With kind permission of the AO Research Institute Davos. FNS=Femoral Neck System, mm=millimeter.

- “Implant Tip Migration parallel to Implant Axis” (mm), defined as movement of the femoral head aspect point, initially located at the implant tip, along the implant axis (Fig.18).

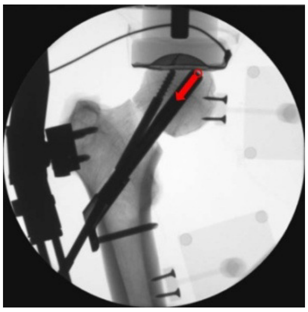

Fig.18: Implant Tip Migration parallel to Implant Axis (mm, red arrow and circle), shown here on an FNS implant, indicating the movement of the femoral head along the axis of the implant. With kind permission of the AO Research Institute Davos. FNS=Femoral Neck System, mm=millimeters.

- “Implant Tip Migration perpendicular to Implant Axis” (mm), defined as the vector, representing the transverse movement of the femoral head aspect point, initially located at the implant tip (same as above), in the coronal plane perpendicular to the implant axis (Fig.19).

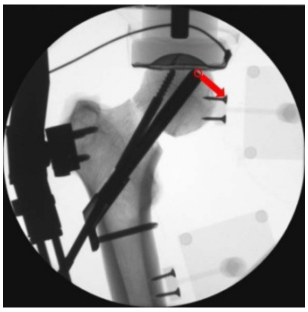

Fig.19: Implant Tip Migration perpendicular to Implant Axis (mm, red arrow and circle), shown here on an FNS implant, indicating the dislocation of the implant tip in the coronal plane perpendicular to the implant axis. With kind permission of the AO Research Institute Davos. FNS=Femoral Neck System, mm=millimeter.

- “Total Implant Tip Migration” (mm), defined as the vector, representing the three-dimensional movement of the femoral head aspect point, which was initially located at the implant tip (Fig.20).

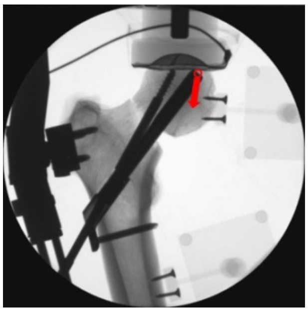

Fig.20: Total Implant Tip Migration (mm, red arrow and circle), shown here on an FNS implant, indicating the movement of the point in the femoral head, that was located at the implant tip initially. With kind permission of the AO Research Institute Davos. FNS=Femoral Neck System, mm=millimeter.

- “Varus Deformation” (deg.), defined as rotation of the femoral head in the coronal plane around the sagittal z-axis (Fig.21).

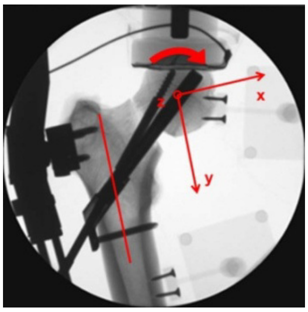

Fig.21: Varus Deformation (deg., red lines, arrows and circle), shown here on an FNS implant, indicating the rotation of the femoral head at the fracture site in the coronal plane. With kind permission of the AO Research Institute Davos. FNS=Femoral Neck System, mm=millimeter, x/y/z=axes of the room.

- “Rotation around Implant Axis” (deg.), defined as rotation of the femoral head around the implant axis (Fig.22). Note: Implant axis for 3CS was defined by the most caudal screw.

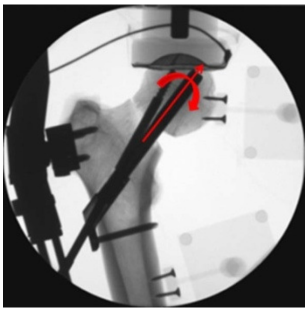

Fig.22: Rotation around Implant Axis (deg., red arrows), shown here on an FNS implant, indicating the rotation of the femoral to the axis of the implant. With kind permission of the AO Research Institute Davos. FNS=Femoral Neck System, deg.=Degree.

- “Rotation Implant to Shaft” (deg.), defined as rotation of the implant axis in the coronal plane (Fig.23).

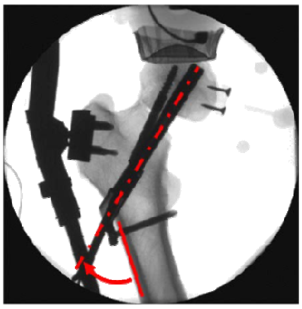

Fig.23: Rotation Implant to Shaft (deg., red lines, dots and arrow), shown here on an FNS implant, indicating the rotation of the implant in the coronal plane. With kind permission of the AO Research Institute Davos. FNS=Femoral Neck System, deg.=Degree.

Based on diverse specimen's failure criteria, the following outcomes were calculated from the motion tracking variables above and the machine data:

- “Cycles to 15mm Leg Shortening”, defined as the number of cycles until 15 mm relative Leg Shortening occured with respect to an initial reference time point under 200 N valley loading (see Fig.24).
- “Cycles to Nonlinear Leg Shortening”, defined as the number of cycles until a sudden change in the Leg Shortening over time occured with respect to the initial reference time point under 200 N valley loading.

- "Cycles to 15mm Neck Shortening", defined as the number of cycles until 15 mm relative Neck Shortening occured with respect to the initial reference time point under 200 N valley loading.
- "Cycles to Nonlinear Neck Shortening", defined as the number of cycles until a sudden change in the Neck Shortening over time occured with respect to the initial reference time point under 200 N valley loading.
- "Cycles to Machine Stop", defined as the number of cycles until fulfillment of the stop criterion (30 mm axial displacement of the machine actuator) with respect to the initial reference time point.

The initial reference time point was defined for each specimen separately at the beginning of the cyclic test after specimen's settling, which occurred after 3 to 5 cycles.

Taking into account all failure criteria described above, an outcome, named "Cycles to Earliest Failure", was defined and calculated as the lowest number of cycles, when any of these criteria was fulfilled. Further, an outcome "Cycles to Failure without Nonlinear Influence" was defined and calculated as the lowest number of cycles, when any of the failure criteria for evaluation of the outcomes "Cycles to 15mm Leg Shortening", "Cycles to 15mm Neck Shortening" or "Cycles to Machine Stop" was fulfilled. This outcome was introduced in order to investigate the influence of both outcomes "Cycles to Nonlinear Leg Shortening" and "Cycles to Nonlinear Neck Shortening" on "Cycles to Earliest Failure".

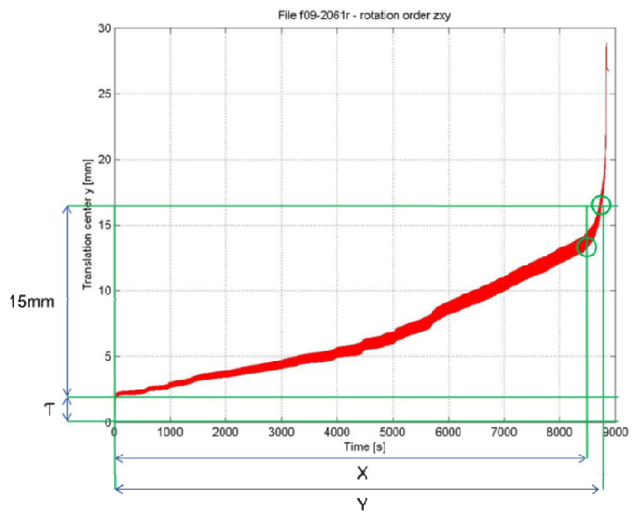

Fig.24: Schematic drawing explaining the evaluation principle for the failure criteria by setting cycles needed to reach nonlinear deviation and cycles needed to reach 15mm relative Leg Shortening into relation. T indicates the offset after the initial 3 to 5 cycles when specimen's setting occurs. X represents the number of cycles needed to reach nonlinear deviation of the specimens loading curve. Y is the number of cycles needed to reach 15mm relative Leg Shortening (here labeled as Translation Center y) after specimens settling. Green circles indicate evaluation in condition under 200 N valley loading. With kind permission of the AO Research Institute Davos.

The summative values of all variables represent the relative interfragmentary movements, excluding the variable “Rotation around Implant Axis”. The mentioned values were calculated after 2000 cycles and 5000 cycles at valley load of 200 N, considering the respective level of specimen's settling at the initial reference time point after 3 to 5 cycles as zero level.

Based on this, the following outcomes were created:

- “Leg Shortening after 2’000 cycles”, “Leg Shortening after 5’000 cycles”, “Neck Shortening after 2000 cycles”, “Neck Shortening after 5’000 cycles”, “Implant Tip Migration parallel to Implant Axis after 2’000 cycles”, “Implant Tip Migration parallel to Implant Axis after 5’000 cycles”, “Implant Tip Migration perpendicular to Implant Axis after 2’000 cycles”, “Implant Tip Migration perpendicular to Implant Axis after 5’000 cycles”, “Total Implant Tip Migration after 2’000 cycles”, Total Implant Tip Migration after 5’000 cycles”, “Varus Deformation after 2’000 cycles”, “Varus Deformation after 5’000 cycles”, “Axial Displacement after 2’000 cycles”, “Axial Displacement after 5’000 cycles”.

The variable Rotation around Implant Axis was used to calculate the following outcomes:

- “Cycles at 2deg. Rotation around Implant Axis”, defined as the number of cycles until a femoral head rotation of 2 deg. around the implant axis occurred at the valley load of 200 N relative to the initial reference time point of specimen's settling.
- “Rotation around Implant Axis after 10’000 cycles”, defined as the rotation of the femoral head around the implant axis after 10’000 cycles at valley load of 200 N relative to the rotation at initial reference time point of specimen's settling.

The variables Varus Deformation and Rotation Implant to Shaft were used to evaluate the following outcomes:

- “Varus Deformation after 10’000 cycles”, defined as the rotation of the femoral head in the frontal plane around the sagittal z-axis after 10’000 cycles at valley load of 200 N relative to the rotation at initial reference time point of specimen's settling.

- "Rotation Implant to Shaft after 10'000 cycles" (deg.), defined as the rotation of the implant axis in the frontal plane around the sagittal z-axis after 10'000 cycles at valley load of 200 N relative to the rotation at initial reference time point of specimen's settling.

The variables "Implant Tip Migration parallel to Implant Axis", "Implant Tip Migration perpendicular to Implant Axis" and "Total Implant Tip Migration" were used to evaluate the following outcomes:

- "Implant Tip Migration parallel to Implant Axis at Earliest Failure without Nonlinear Influence", defined as the movement of the femoral head aspect point, initially located at the implant tip, along the implant axis at the time point when the corresponding event Cycles to Earliest Failure without Nonlinear Influence occurred, at valley load of 200 N relative to the initial reference time point of specimen's settling.
- "Implant Tip Migration perpendicular to Implant Axis at Earliest Failure without Nonlinear Influence", defined the vector, representing the transverse movement of the femoral head aspect point, initially located at the implant tip (same as above), in a plane perpendicular to the implant axis, at the time point when the corresponding event Cycles to Earliest Failure without Nonlinear Influence occurred, at valley load of 200 N relative to the initial reference time point of specimen's settling.
- "Total Implant Tip Migration at Earliest Failure without Nonlinear Influence", defined as the vector, representing the three-dimensional movement of the femoral head aspect point, which was initially located at the implant tip at the time point when the corresponding event Cycles to Earliest Failure without Nonlinear Influence occurred, at valley load of 200 N relative to the initial reference time point of specimen's settling.

Thereby the latter six outcomes, together with the six outcomes based on radiographic evaluation were evaluated for the groups DHS Screw, DHS Blade and FNS only, because most of the specimens of group 3CS failed before reaching 10000 cycles in view of Earliest Failure without Nonlinear Influence. Furthermore, the evaluation of the latter three outcomes was additionally introduced to compare the respective three groups only.

Finally, all outcomes described above, together with the BMD, CCD Angle, Lever Arm, Head Diameter, Implant Axis off Center Relative, Implant Axis off Center Absolute, Implant Length and Tip-Apex Distance were considered as parameters of interest and selected further for statistical evaluation.

2.7 Statistical power

Concerning the group FNS/3CS the sample size n=10 was chosen with the assumption that FNS would fail under fourfold body weight of a statistically average person, equaling 2'800 N. Furthermore, we assumed that a 25% lower performance of 2'100 N in group 3CS compared to FNS would appear as a clinically meaningful difference, and that a standard deviation of ¾ from the mean value, namely 2'100 N for FNS and 1'575 N for 3CS, could be an expected range of deviation. Based on these assumptions, a sample size of n=9 specimens would be necessary to reach significant differences between the two groups under a level of significance 0.05 and a power of 0.8. In order to be more concrete, a sample size of n=10 was chosen. Facing the sample size of n=8 in the group DHS Screw/DHS Blade an overall power of 94.2% was achieved for the testing.

Statistical evaluation was performed with SPSS v.21 (IBM, USA). Normal distribution and homogeneity of variance were investigated with Shapiro-Wilk and Levenre tests, the differences between the paired groups were assessed with Haired-Samples T-test. For the comparison of the other independent groups the General Linear Model Univariate Analysis of Variance test including Bonferroni post-hoc correction was performed.

3 Results

Four pairs of specimens (F10-1092, F10-1094, M10-1091, M13-1303) were included in the study despite the donors' cause of death specified as non-specific cancer in the patient history, which has been defined as an excluding criteria in its general form. However, the BMD values of the four pairs did not differ significantly compared to those considering all specimens (201.8±37.4 mgHA/cm^3 versus 207.6±48.7 mgHA/cm^3), p>0.1. Further specifications are depicted in Table 2.

Table 2: Complementary specifications of specimens with general cancer history. BMD=Bone Mineral Density, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3Cannulted Screws.

Specimen	Group	Cause of Death	BMD, Head
F10-1092L	DHS Blade	Cancer	191.4
F10-1092R	DHS-Screw	Cancer	145.3
F10-1094L	FNS	Cancer, Heart failure	167.1
F10-1094R	3CS	Cancer, Heart failure	181.4
M10-1091L	FNS	Cancer	205.5
M10-1091R	3CS	Cancer	229.8
M13-1303L	DHS Blade	Cancer	244.5
M13-1303R	DHS-Screw	Cancer	249.1

In 37 cases the tests stopped due to fulfillment of the stop criterion of 30 mm machine transducer's axial displacement. Three tests stopped due to cut-out detection sensoring (specimens/axial displacement: F10-1041L / 29.35 mm; F13-1310L / 27.38 mm; F13-1308L / 27.64 mm). In one case the test stopped reaching 4000 N load limit (specimen/axial displacement: M13-1009R / 28mm). Extraordinary fractures were observed in two cases: F12-1104L (DHS Blade) and F13-1301L (FNS). Both specimens failed by femoral shaft fracturing in the subtrochanteric region around the distal screws. After Pilot testing, the shape of the PMMA shell cup was adapted to allow proper load transfer to the femoral head. The machine had to be restarted twice while specimen M13-1009L (pilot) was tested, respectively once during specimen's F09-2062L testing, due to technical error. Furthermore, the first tested pilot (F10-1094R) was statically loaded under 200 N compression during the motion tracking measurements for definition of the points of interest for translational degrees of freedom, whereas for the rest of specimens these measurements were performed under 50 N compression. Initial quasi-static ramp was not recorded from the Motion Tracking cameras for the following Specimens due to technical error, which practically has not led to any limitations during the data evaluation:

1) DHS-Screw: M13-1009R(Pilot)
2) DHS Blade: M13-1009L (Pilot),F10-1041L
3) FNS: F10-1094L (Pilot), F13-1308L, M13-1306R, F13-1304R, M13-1302R, F09-2062L, F13-1305R
4) 3CS: F10-1094R (Pilot), F13-1308R, M13-1306L,F13-1304L, M13-1302L, F13-1305L

3.1 Outlier

Two pairs of specimens were additionally removed from evaluation due to machine stop before construct failure occurred, as a result of distal fixation failure, leading to high shaft distal movements, causing stress concentrations around the distal screws during the tests:

- Group 1: Specimen F13-1310R/L (18 mm shaft distal migration)
- Group 3: Specimen F13-1301L/R (>7 mm shaft distal migration)

As a consequence from the exclusion of 1 pair of specimens after the instrumentation (pair F09-2060L/R) and 3 pairs of specimens (pairs F09-2061R/L, F13-1301L/R and F13-1310R/L) after the biomechanical testing a total sample size of n=18 (8 pairs group DHS, 10 pairs group FNS/3CS) paired femora was included in the statistical evaluation whereas the pilot pairs were respected in the statistical findings (Table 3).

Table 3: Group assignment used for the statistical analysis after subtraction of the outliers. DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3Cannulted Screws.

pair	**DHS Screw**	**DHS Blade**
8	M13-1009R (pilot)	M13-1009L (pilot)
11	F12-1104R	F12-1104L
18	M13-1307L	M13-1307R
4	F10-1092R	F10-1092L
3	F10-1041R	F10-1041L
14	M13-1303L	M13-1303R
10	F11-4004L	F11-4004R
20	M13-1309L	M13-1309R
	FNS	**3CS**
5	F10-1094L (pilot)	F10-1094R (pilot)
19	F13-1308L	F13-1308R
6	F13-8004_FemR	F13-8004_FemL
17	M13-1306R	M13-1306L
7	M10-1091L	M10-1091R
15	F13-1304R	F13-1304L
13	M13-1302R	M13-1302L
2	F09-2062L	F09-2062R
16	F13-1305R	F13-1305L
9	M09-2056L	M09-2056R

3.2 Evaluation of accuracy

Based on fluoroscopic image resolution of 0.2 mm/Pixel, the outcomes “Implant Axis off Center Relative” and “Implant Axis off Center Absolute” were evaluated at a systematic error of 0.4 mm (0.2 mm for defining the implant axis and 0.2 mm for defining the femoral head center). Further, the systematic error for the outcomes “Deformation Plate to Screw after 10’000 cycles”, “Plate Lift-off after 10’000 cycles” and “Deformation Screw to Shaft after 10’000 cycles” was calculated to be 2.5 deg., under the presumption of calculating the angle between lines of 30 mm (one-hole FNS side plate) and 50 mm length (FNS locking–head distal screw).

Accuracy of optical motion tracking using a similar system, applied in a relatively large volume of 400x400x300 mm^3 has been found to be capable of recording displacements of 20 µm at an accuracy being at the lowest 3.7 µm (Yang et al. 2012).

3.3 Figural results

In chapter 3 the results of each parameter of interest are depicted in figures, composed of overlaid blue bars and green lines, representing the median, respectively the mean values for each group separately. The respective blue and green error bars show the 95% confidence intervals, respectively the standard errors of each group. The overlaying principle is schematically shown in Fig.25.

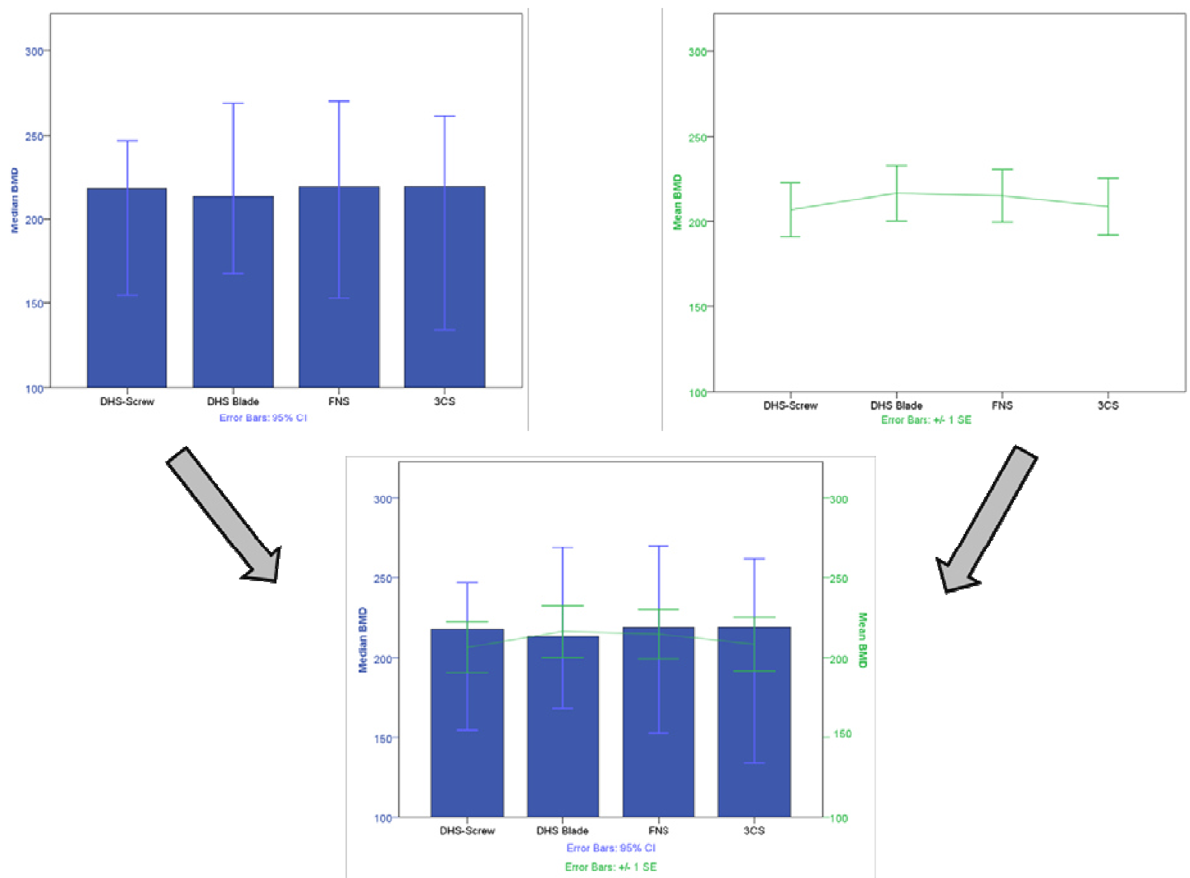

Fig.25: Results example showing the overlaying principle of median bars and mean line. With kind permission of the AO Research Institute Davos. BMD=Bone Mineral Density, CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.1 BMD

Highest average BMD values were obtained in group DHS Blade (216.3±16.0 mgHA/cm^3 (mean± SEM)), followed by FNS (214.8±15.3 mgHA/cm^3), 3CS (208.6±16.5 mgHA/cm^3) and DHS Screw (206.7±15.7 mgHA/cm^3, Fig.26). No significant differences were observed between any of the groups (p≥0.52).

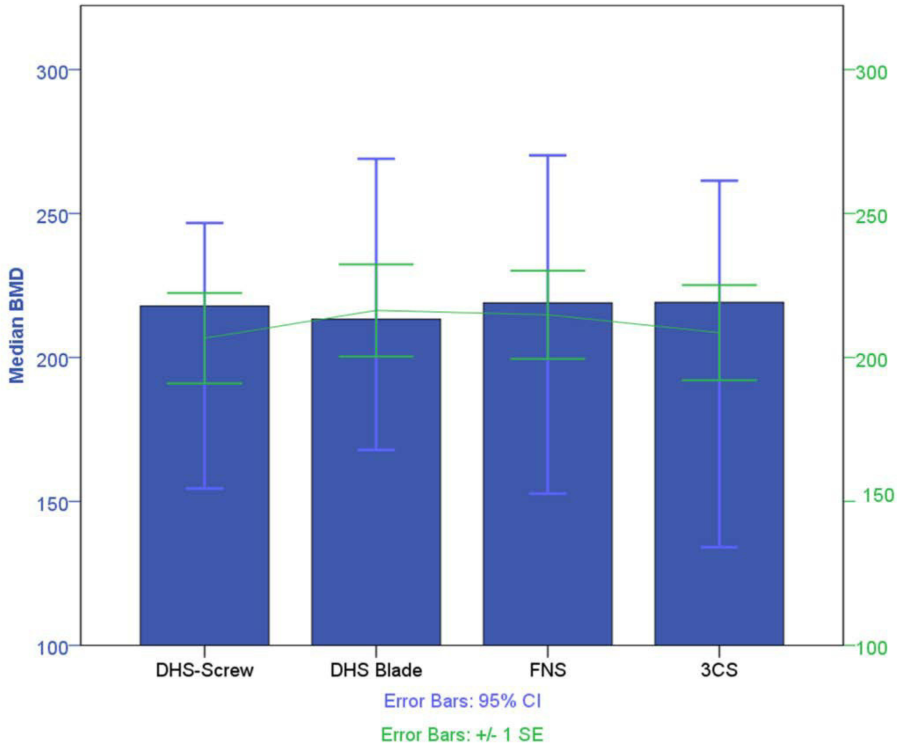

Fig.26: BMD (mgHA/cm^3) median and mean values in the study groups. With kind permission of the AO Research Institute Davos. BMD=Bone Mineral Density, CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mgHA/cm^3 =milligramm hydroxylapatite per cubic centimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.2 CCD Angle

Average CCD Angle in the groups was 129.6±1.3 deg. (DHS Screw), 130.5±1.0 deg. (DHS Blade), 130.8±1.2 deg. (FNS) and 130.8±0.9 deg. (3CS) with no significant differences between them (p≥0.861, Fig.27).

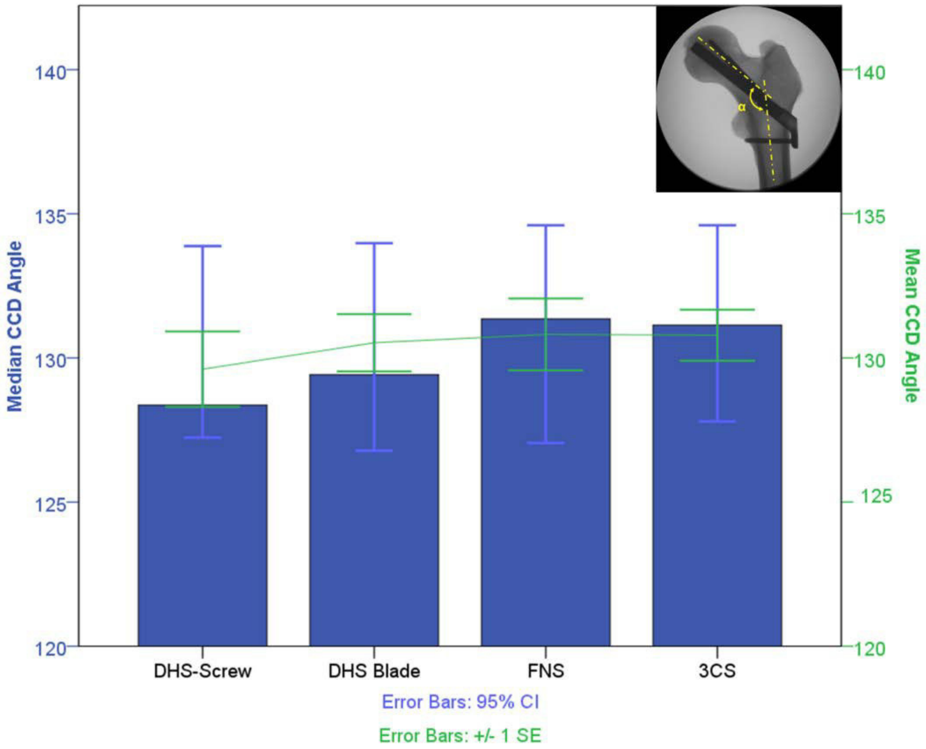

Fig.27: CCD Angle (deg., yellow lines, dots and arrows) median and mean values in the study groups, defined as the angle between the axis of the femoral neck and the femoral shaft. With kind permission of the AO Research Institute Davos. CCD Caput Collum Diaphysis, CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3Cannulated Screws, SE=Standard Error of the mean.

3.3.3 Lever Arm

The Lever Arm average values measured in each group were 59.4±2.1 mm (DHS Screw), 59.2±2.5 mm (DHS Blade), 57.5±1.9 mm (FNS), and 57.0±1.6 mm (3CS, Fig.28). No significant differences were observed between the groups (p≥0.540).

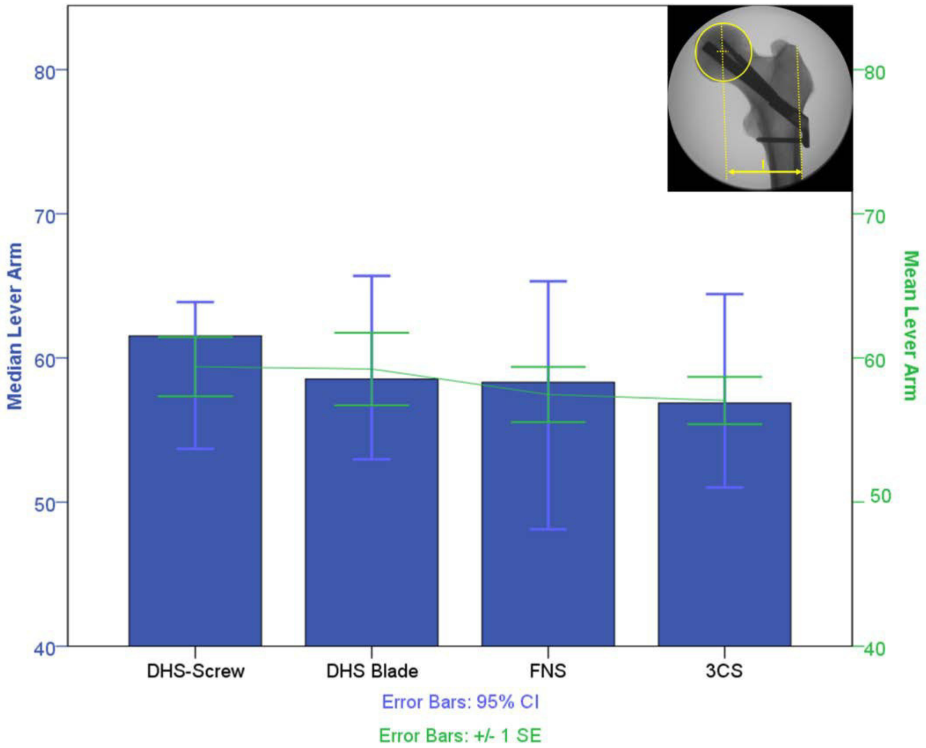

Fig.28: Lever Arm (mm, yellow dots, circle and arrow) median and mean values in the study groups, defined as the distance between the center of the femoral head and the lateral cortex of the femur in the coronal plane. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.4 Head Diameter

Similar relations were observed for Head Diameter with average values of 48.7±1.6 mm for DHS Screw, 48.5±1.7 mm for DHS Blade, 48.4±1.1 mm for FNS and48.2±1.1 mm for 3CS (Fig.29). No statistical differences were observed between any of the groups ($p \geq 0.575$).

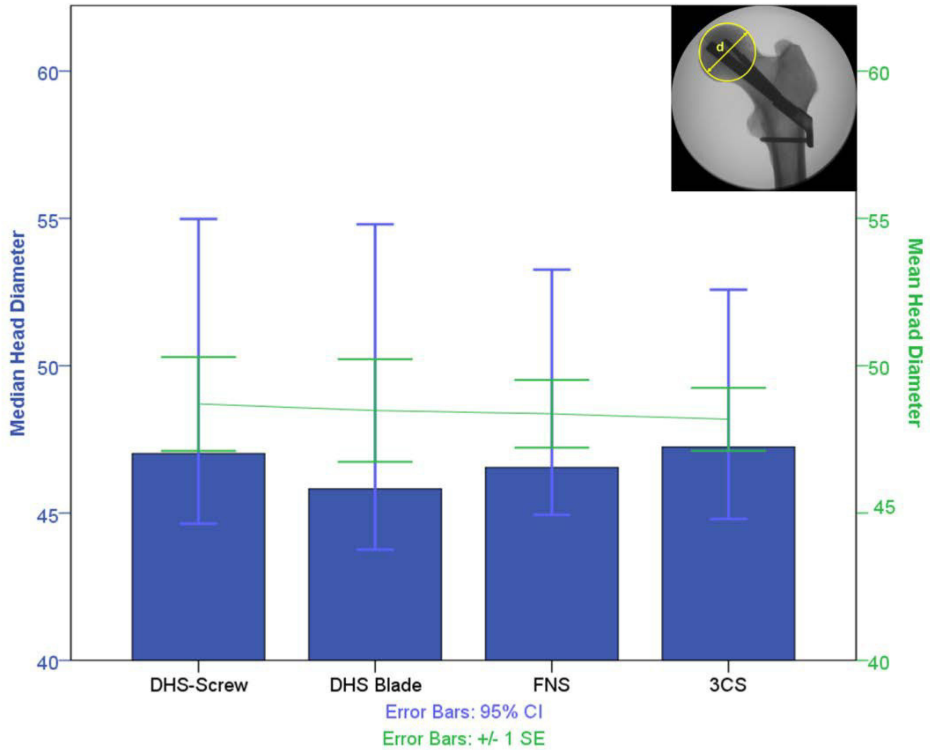

Fig.29: Head Diameter (mm, yellow circle and arrow) median and mean values in the study groups, defined as the diameter of the femoral head. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.5 Implant Length

Evaluation of the mean Implant Length (description: see chapter 3.4) in the groups revealed average values of 95.0±3.5 mm for DHS Screw (tolerance: ± 0.5 mm), 92.8±3.5 mm for DHS Blade (tolerance: +0.4/-0.2 mm), 97.0±2.8 mm for FNS (tolerance: ±0.5 mm), and 96.4±2.9 mm for 3CS (tolerance: ±0.5 mm) (Fig.30). Significantly different values were detected between DHS Screw and DHS Blade ($p=0.046$). No further statistical significances were observed ($p \geq 0.529$).

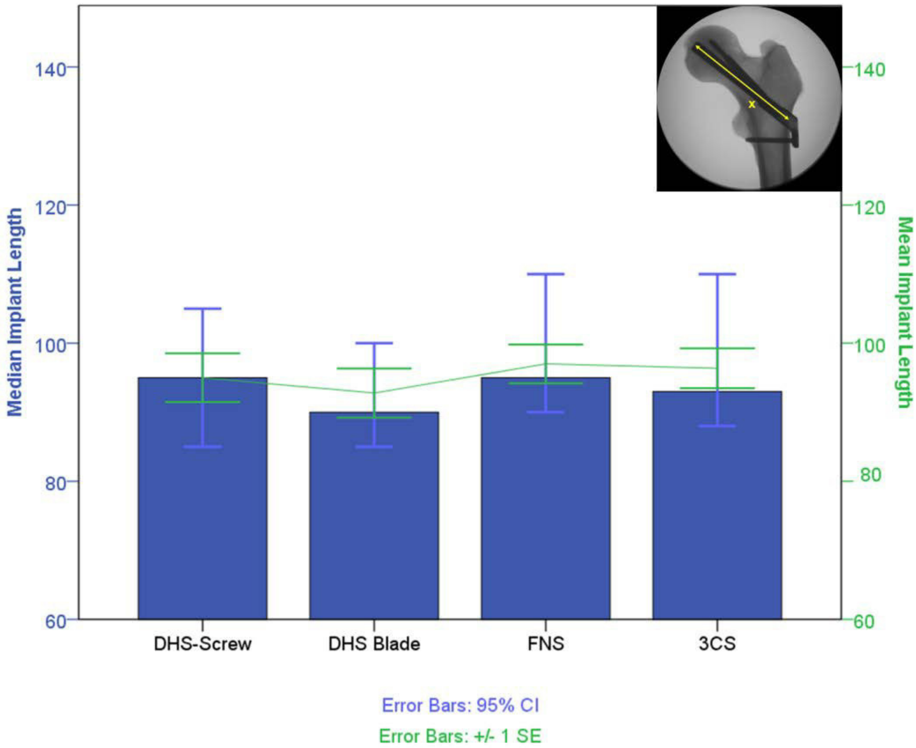

Fig.30: Implant Length (mm, yellow arrow) median and mean values in the study groups, defined as the intraosseous working length of the femoral neck component of the particular implant. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.6 Tip-Apex Distance

The Tip-Apex Distance average values measured in each group were 12.2±0.6 mm (DHS Screw), 11.3±0.9 mm (DHS Blade), 9.8±0.6 mm (FNS), and 8.0±1.1 mm (3CS, Fig.31). Significantly different values were detected between DHS-Screw and 3CS ($p=0.008$). No further statistical significances were observed ($p\geq0.055$).

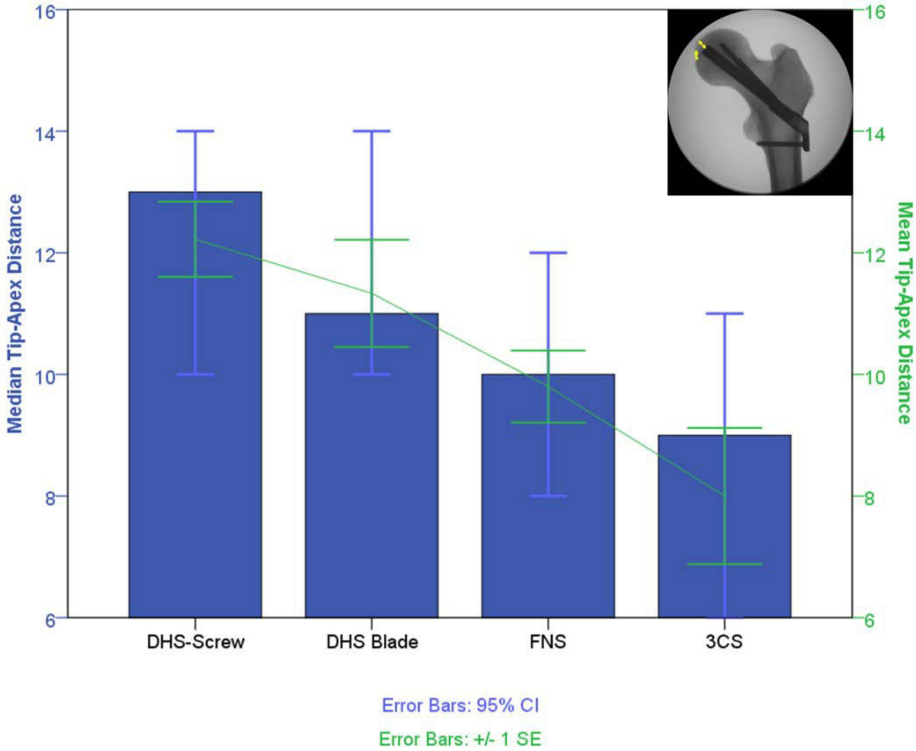

Fig.31: Tip-Apex Distance (mm, yellow arrow) median and mean values in the study groups, defined as the distance between the tip of the implant and the surface of the femoral head. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.7 Implant Axis off Center Relative

Highest average value was obtained in group FNS (1.09±0.99 mm), followed by DHS Blade (-0.26±0.50 mm) and DHS Screw (-0.45±0.95 mm, Fig.32). No significant differences were observed between the three groups (p=0.387).

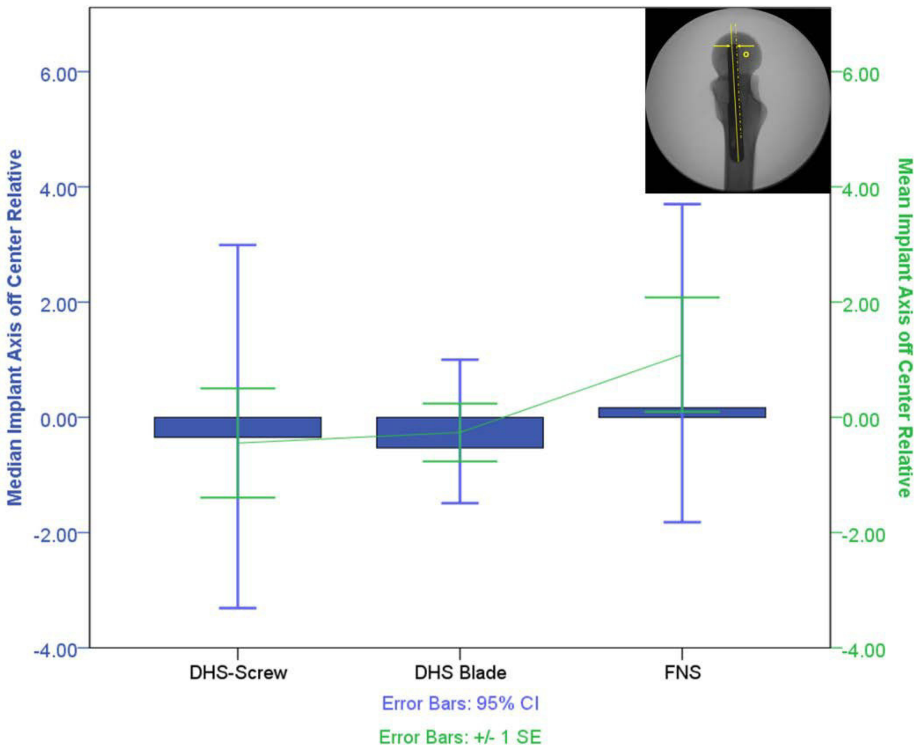

Fig.32: Implant Axis off Center Relative (mm, yellow dots, lines, arrow and circle) median and mean values in the study groups, defined as the axial deviation of the particular implant to the axis of the femoral neck in the coronal plane, respecting posterior (negative values) and anterior (positive values) position of the implant to the axis. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, SE=Standard Error of the mean.

3.3.8 Implant Axis off Center Absolute

Group DHS Screw revealed the highest average value for Implant Axis off Center Absolute (2.43±0.43 mm), followed by FNS (2.35±0.71 mm) and DHS Blade (1.11±0.33 mm, Fig.33). Significant difference was observed between DHS Screw and DHS Blade (p=0.036).

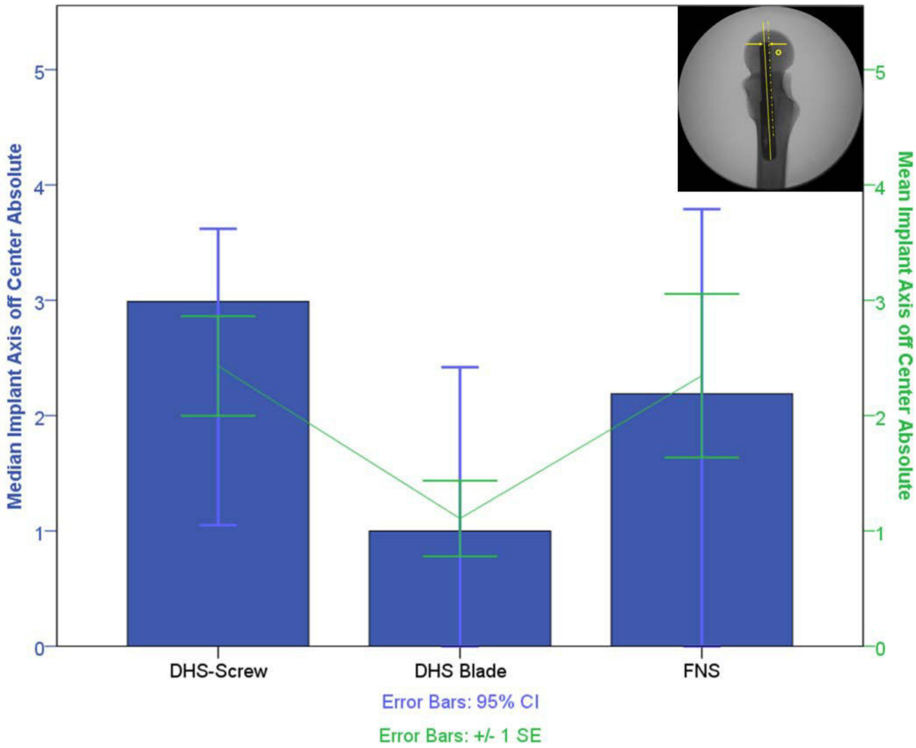

Fig.33: Implant Axis off Center Absolute (mm, yellow dots, lines, circle and arrows) median and mean values in the study groups, defined as the axial deviation of the particular implant to the axis of the femoral neck in the coronal plane. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, SE=Standard Error of the mean.

3.3.9 Axial Stiffness

Group FNS revealed the highest average axial stiffness (748.9±66.8 N/mm), followed by DHS Screw (688.8±44.2 N/mm), DHS Blade (629.1±31.4 N/mm) and 3CS (584.1±47.2 N/mm, Fig.34) with no significant differences between the groups ($p \geq 0.067$). However, a significant influence of BMD as a covariate on Axial Stiffness was detected ($p=0.017$).

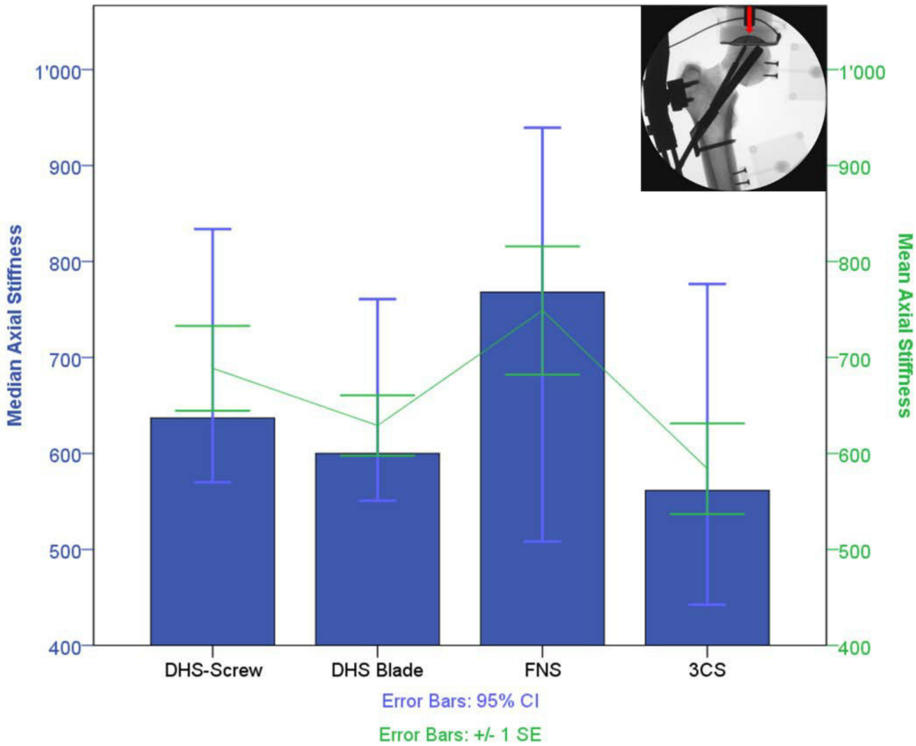

Fig.34: Axial Stiffness (N/mm, red arrow) median and mean values in the study groups, defined as the force needed per mm of axial displacement of the implant bone construction. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, N=Newton, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.10 Cycles to 15mm Leg shortening

Average number of cycles to 15mm Leg Shortening was highest in group DHS Screw with 20’542±2’488 cycles, followed by DHS Blade (19’161±1’264), FNS (17’372±947) and 3CS (7’293±850, Fig.35). DHS Screw, DHS Blade and FNS revealed significant higher values than 3CS ($p<0.001$). On the other hand, no significant differences were detected between these three groups ($p \geq 0.487$). In addition, BMD was found to have a significant influence as a covariate ($p=0.013$). Note: The criterion 15 mm was chosen because no specimen reached the initially defined 25 mm at test stop.

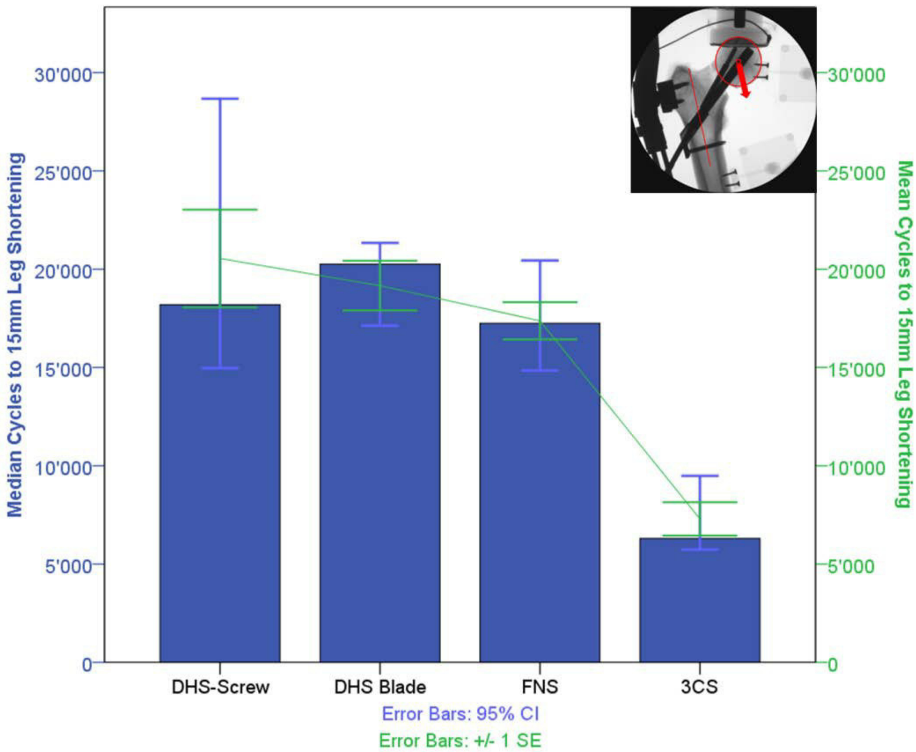

Fig.35: Cycles to 15mm Leg Shortening (red lines, circle and arrow) median and mean values in the study groups, defined as cycles needed, to reach 15 mm leg shortening. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.11 Leg shortening after 2’000 cycles

Highest average values for Leg Shortening after 2’000 cycles were obtained for 3CS (3.21±0.37 mm), followed by FNS (2.51±0.45 mm), DHS Blade (1.20±0.19 mm) and DHS Screw (1.04±0.22 mm, Fig.36). DHS Screw, DHS Blade and FNS revealed significant lower values than 3CS ($p \leq 0.014$). Moreover, DHS Screw was with significantly lower values than FNS ($p=0.025$). No further significant differences were detected between the groups ($p \geq 0.067$). BMD showed no significant influence as covariate ($p=0.267$).

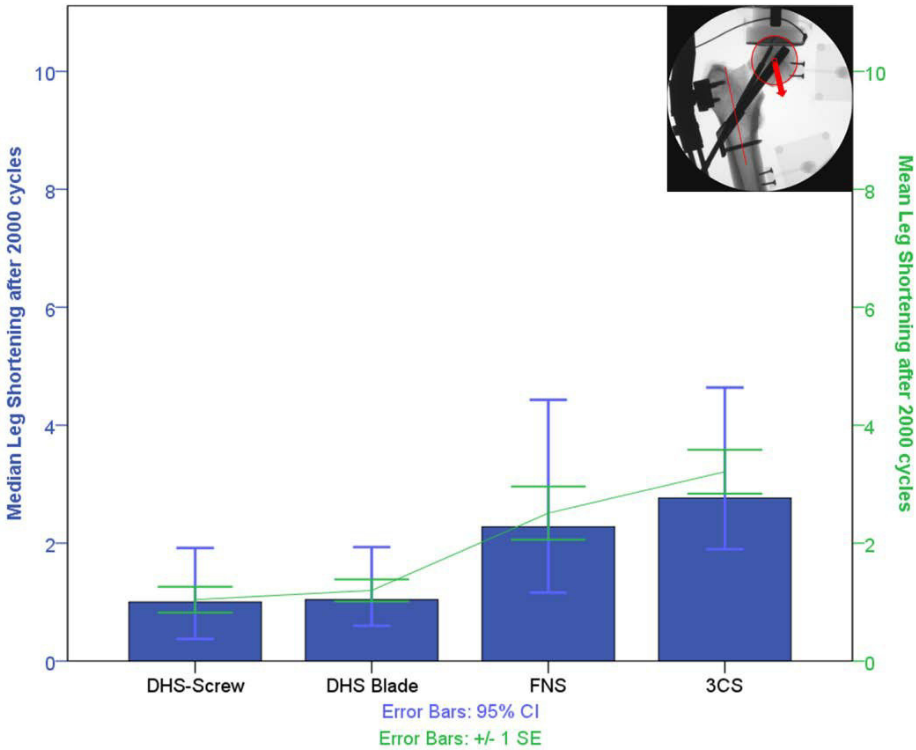

Fig.36: Leg shortening after 2’000 cycles (mm, red lines, circle and arrow) median and mean values in the study groups, defined as leg shortening after 2’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.12 Leg shortening after 5’000 cycles

Group 3CS revealed the highest average value for Leg Shortening after 5’000 cycles (6.79±0.77 mm), followed by FNS (4.77±0.53 mm), DHS Blade (4.26±0.40 mm) and DHS Screw (2.44±0.42 mm, Fig.37). DHS Screw, DHS Blade and FNS revealed significant lower values than 3CS (p≤0.024). In addition, DHS Screw resulted in significant lower values in comparison to DHS Blade and FNS (p≤0.034). No significant difference was detected between DHS Blade and FNS (p=0.99). No significant influence of BMD as covariate was observed (p=0.392).

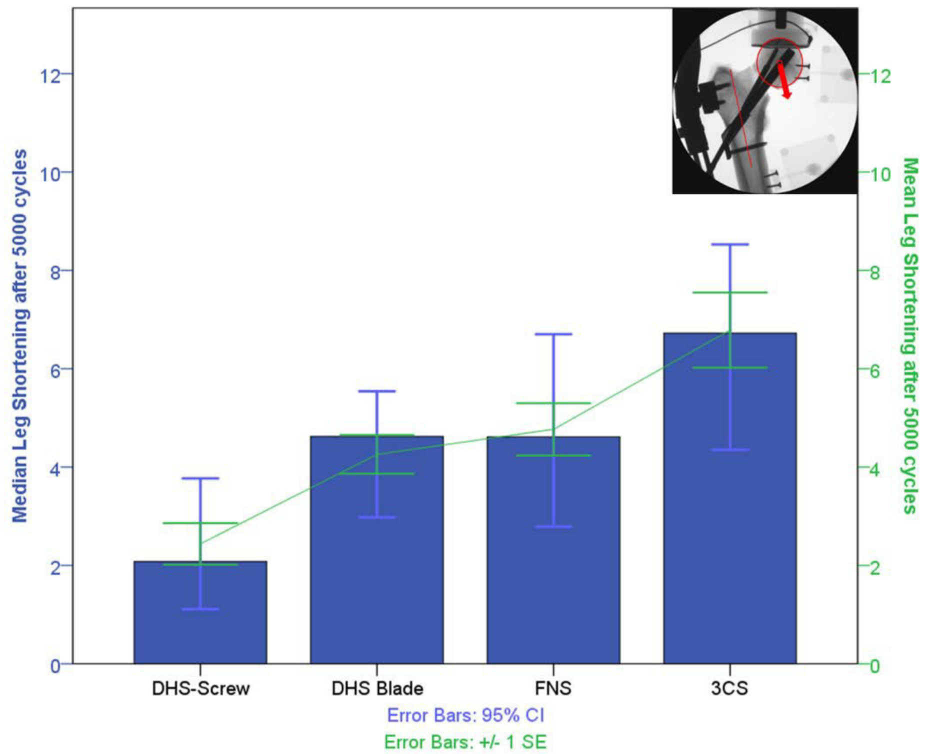

Fig.37: Leg shortening after 5’000 cycles (mm, red lines, circle and arrow) median and mean values in the study groups, defined as leg shortening after 5’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.13 Cycles to Nonlinear Leg Shortening

The highest average value for Cycles to Nonlinear Leg Shortening were observed in group DHS Blade (18’845±1’468), followed by DHS Screw (18’128±2’530), FNS (15’250±971) and 3CS (6’896±811, Fig. 38). DHS Screw, DHS Blade and FNS achieved significant higher values than 3CS ($p<0.001$). On the other hand, no significant differences were detected between these three groups ($p\geq0.462$). In addition, BMD was found to have a significant influence as a covariate ($p=0.004$).

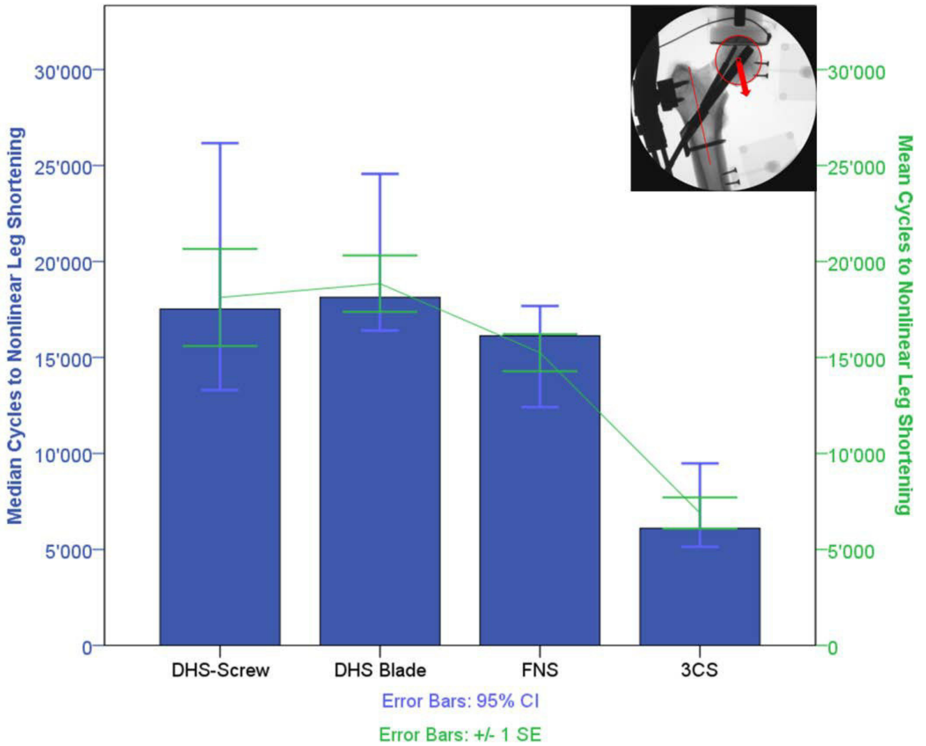

Fig.38: Cycles to Nonlinear Leg Shortening (red lines, circle and arrow) median and mean values in the study groups, defined as the number of cycles, until sudden leg shortening occurs. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.14 Cycles to Machine Stop

Average Cycles to Machine Stop was highest in group DHS Screw (21’936±2’525), followed by DHS Blade (21’745±1’646), FNS (18’381±838) and 3CS (8’043±838, Fig.39). DHS Screw, DHS Blade and FNS revealed significant higher values than 3CS ($p<0.001$). On the other hand, no significant differences were detected between these three groups ($p\geq0.339$). In addition, BMD was found to have a significant influence as a covariate ($p=0.005$).

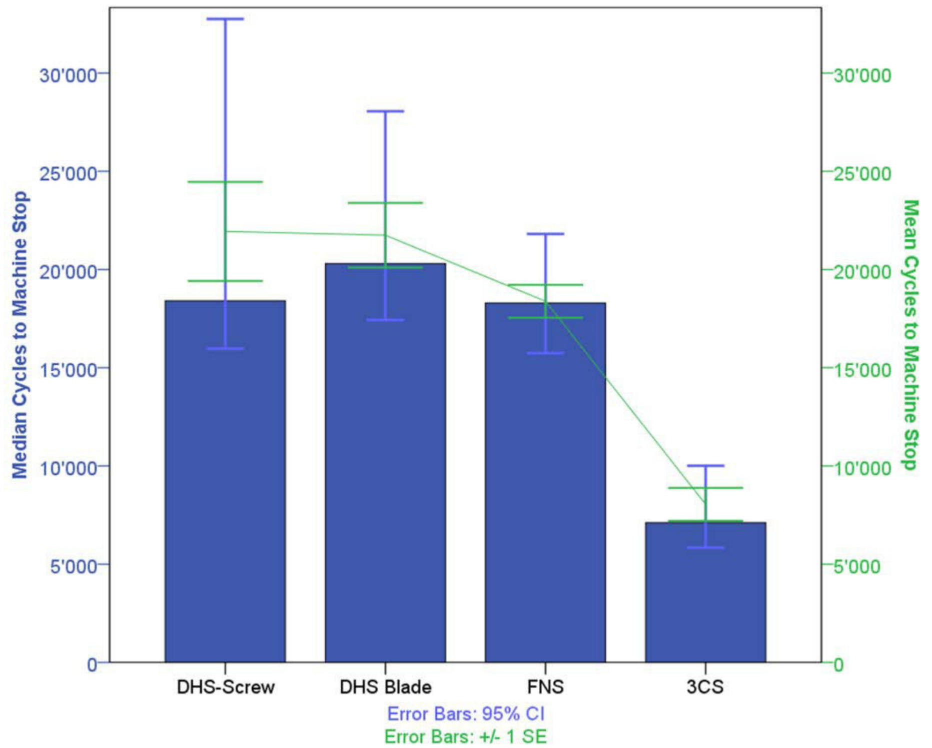

Fig.39: Cycles to Machine Stop median and mean values in the study groups, defined as cycles, until machine stop criteria (contact between bone implant construction and machine actuator, 30 mm axial displacement of the bone implant construction, 4’000 N axial load reached) are fullfilled. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, N=Newton, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.15 Cycles to 15mm Neck Shortening

Group DHS Screw revealed the highest average value for Cycles to 15mm Neck Shortening (20’846±2’446), followed by DHS Blade (18’974±1’344), FNS (18’171±818) and 3CS (8’039±838, Fig.40). DHS Screw, DHS Blade and FNS revealed significant higher values than 3CS ($p<0.001$). On the other hand, no significant differences were detected between these three groups ($p\geq0.6$). In addition, BMD was found to have a significant influence as a covariate ($p=0.005$). Note: The criterion 15mm was chosen because no specimen reached the previously defined 25mm at test stop.

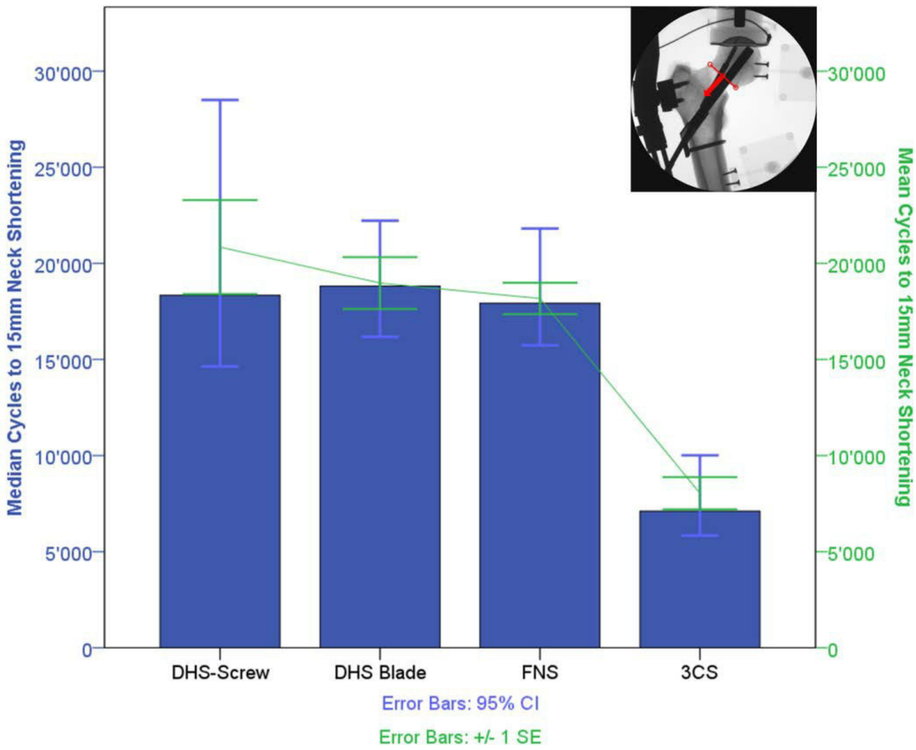

Fig.40: Cycles to 15mm Neck Shortening (red line, circles and arrow) median and mean values in the study groups, defined as cycles needed, to reach 15 mm neck shortening. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.16 Neck shortening after 2’000 cycles

Highest average values for Neck Shortening after 2’000 cycles were observed in FNS (1.920±0.48 mm), followed by 3CS (1.72±0.24 mm), DHS Blade (0.99±0.20 mm) and DHS Screw (0.79±0.21 mm, Fig.41). No significances were observed between the Groups (p≥0.055). The covariate BMD was not influencing the results significantly (p=0.241).

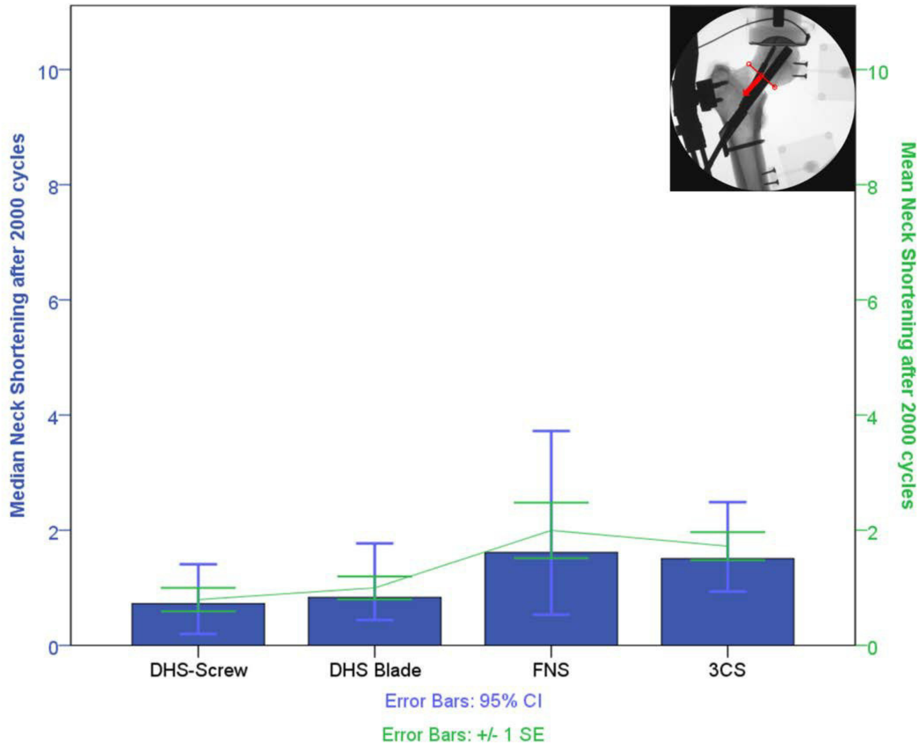

Fig.41: Neck shortening after 2’000 cycles (mm, red line, circles and arrow) median and mean values in the study groups, defined as neck shortening after 2’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.17 Neck shortening after 5’000 cycles

Highest average values for Neck Shortening after 5’000 cycles were observed in DHS Blade (4.27±0.58 mm), followed by 3CS (4.08±0.41 mm), FNS (3.64±0.53 mm) and DHS Screw (2.09±0.45 mm, Fig.42). DHS Screw revealed significant lower values than DHS Blade, FNS and 3CS ($p \leq 0.046$). No further significances were observed between the groups ($p \geq 0.180$). BMD showed no significant influence as covariate ($p=0.259$).

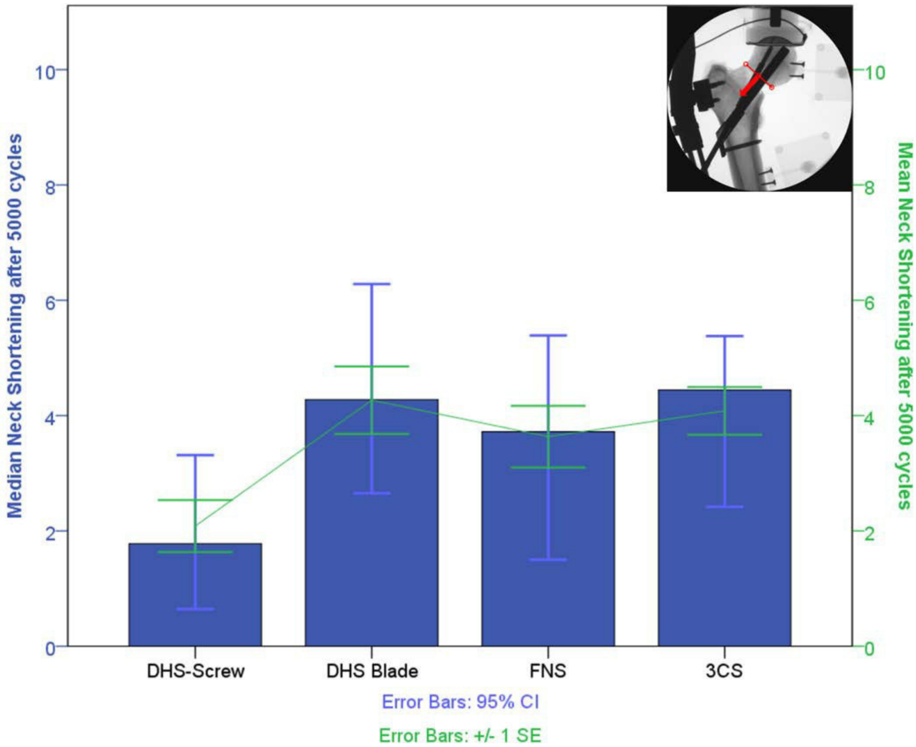

Fig.42: Neck shortening after 5’000 cycles (mm, red line, circles and arrow) median and mean values in the study groups, defined as neck shortening after 5’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.18 Cycles to Nonlinear Neck Shortening

Group DHS Blade revealed the highest average value for Cycles to Nonlinear Neck Shortening (18'616±1'379), followed by DHS Screw (17'212±1'837), FNS (15'685±921) and 3CS (6'962±798, Fig.43). DHS Screw, DHS Blade and FNS revealed significant higher values than 3CS ($p<0.001$). On the other hand, no significant differences were detected between these three groups ($p\geq0.268$). In addition, BMD was found to have a significant influence as a covariate ($p=0.004$).

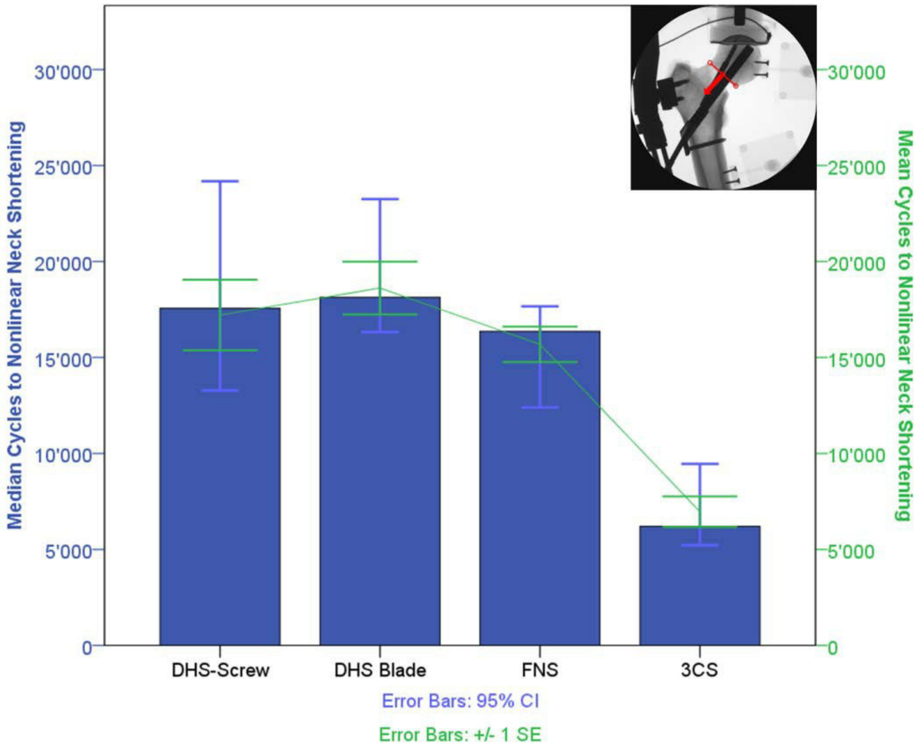

Fig.43: Cycles to Nonlinear Neck Shortening (red line, circles and arrow) median and mean values in the study groups, defined as the number of cycles, until sudden neck shortening occurs. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.19 Cycles to Earliest Failure

Group DHS Blade revealed the highest average value for Cycles to Earliest Failure (18’252±1’311), followed by DHS Screw (16’712±1’869), FNS (14’899±926) and 3CS (6’717±800, Fig.44). DHS Screw, DHS Blade and FNS revealed significant higher values than 3CS ($p<0.001$). On the other hand, no significant differences were detected between these three groups ($p\geq0.216$). In addition, BMD was found to have a significant influence as a covariate ($p=0.004$).

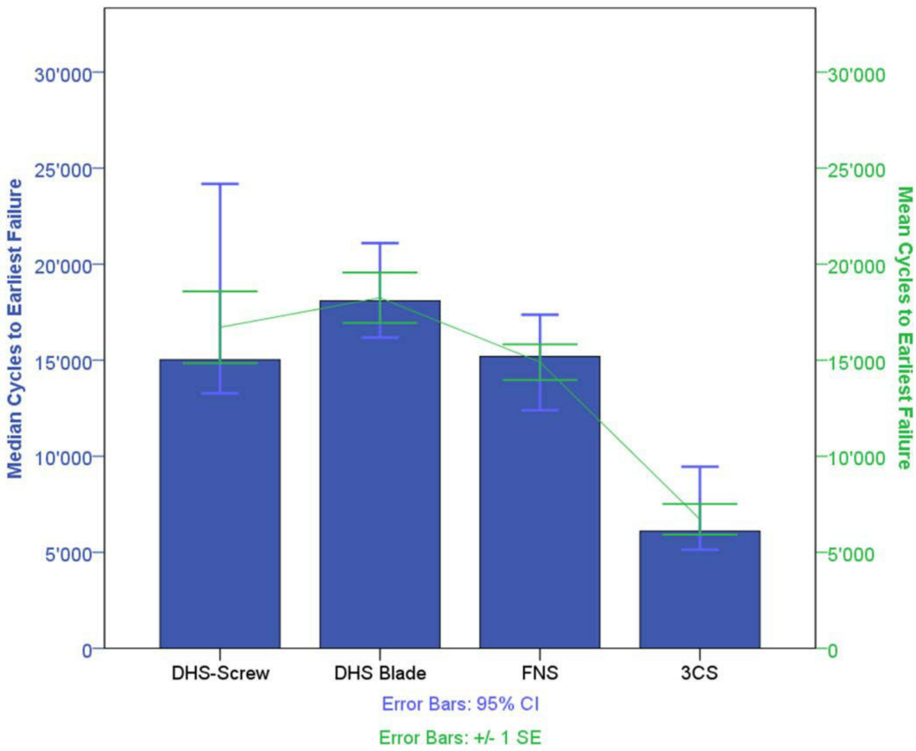

Fig.44: Cycles to Earliest Failure median and mean values in the study groups, defined as the number of cycles, until one of the following failures occurs: Cycles to 15mm Leg Shortening, Cycles to Nonlinear Leg Shortening, Cycles to 15mm Neck Shortening, Cycles to Nonlinear Neck Shortening, Cycles to Machine Stop. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.20 Cycles to Earliest Failure without Nonlinear Influence

Group DHS Screw revealed the highest average value for this parameter of interest (20’485±2’491), followed by DHS Blade (18’731±1’295), FNS (17’353±945) and 3CS (7’293±850, Fig.45). DHS Screw, DHS Blade and FNS revealed significant higher values than 3CS ($p<0.001$). On the other hand, no significant differences were detected between these three groups ($p\geq0.379$). Further, BMD was found to have a significant influence as a covariate ($p=0.008$). In addition, Implant Axis off Center Absolute was a significant covariate for this very important outcome ($p=0.019$), whereas no significant influence was observed considering Implant Axis off Center Relative as a covariate ($p=0.678$).

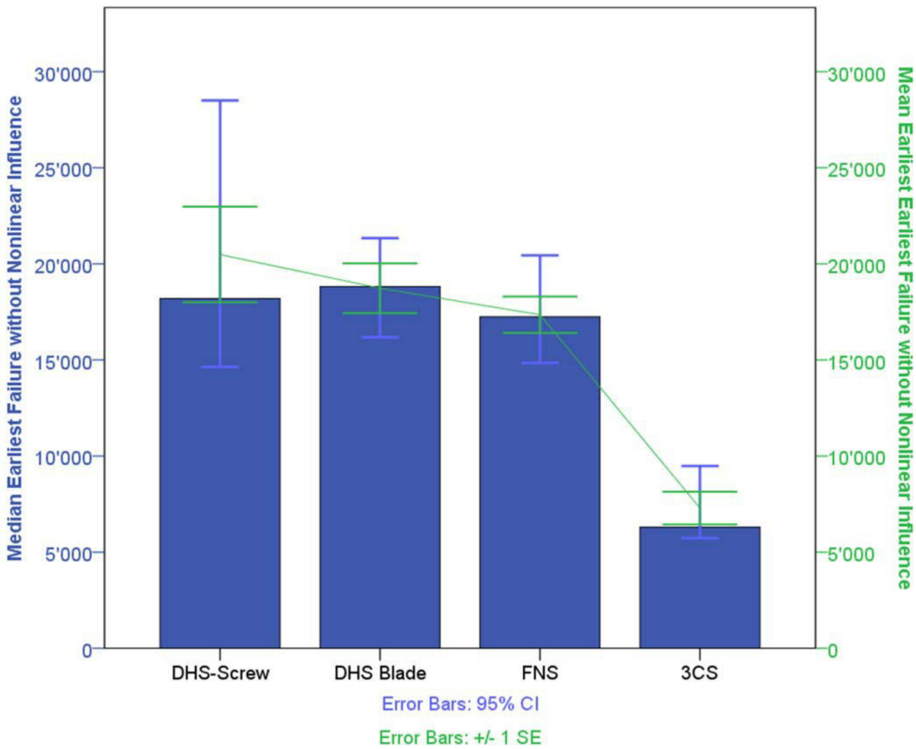

Fig.45: Cycles to Earliest Failure without Nonlinear Influence median and mean values in the study groups, defined as the number of cycles, until one of the following failures occurs: Cycles to 15mm Leg Shortening, Cycles to 15mm Neck Shortening, Cycles to Machine Stop. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.21 Total Implant Tip Migration after 2’000 cycles

Highest average Total Implant Tip Migration after 2’000 cycles was observed in 3CS (1.07±0.19 mm), followed by FNS (0.48±0.11 mm), DHS Blade (0.25±0.05 mm) and DHS Screw (0.12±0.04 mm, Fig.46). DHS Screw, DHS Blade and FNS revealed significant lower values than 3CS ($p \leq 0.037$). No further significances were observed between the groups ($p \geq 0.105$). BMD showed no significant influence as covariate ($p=0.271$).

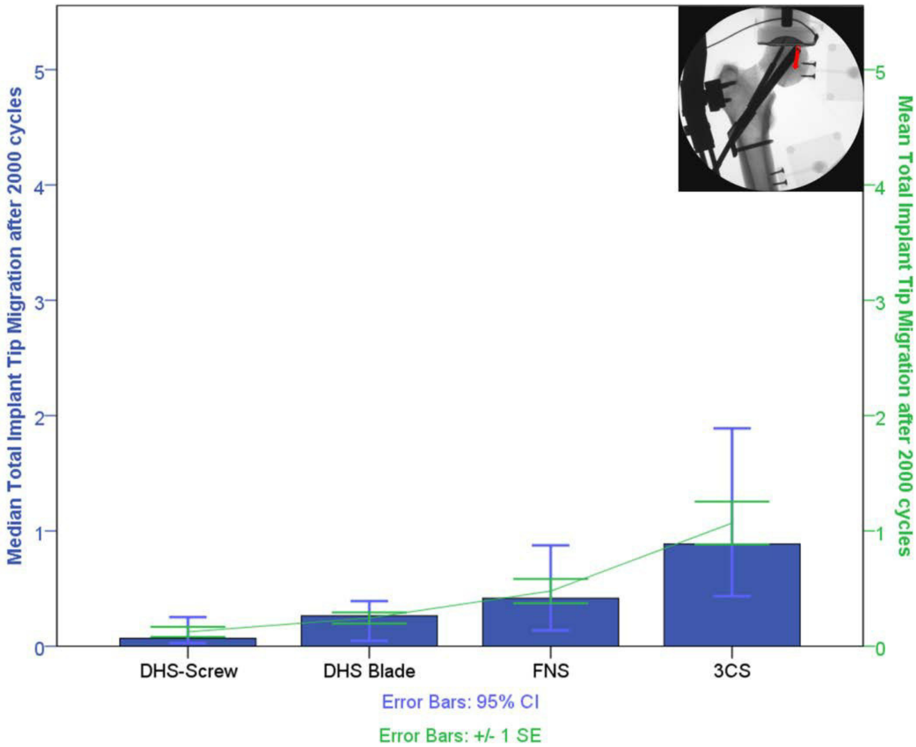

Fig.46: Total Implant Tip Migration after 2’000 cycles (mm, red arrow) median and mean values in the study groups, defined as movement of the point in the femoral head that was located at the implant tip initially after 2’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.22 Total Implant Tip Migration after 5'000 cycles

Highest average Total Implant Tip Migration after 5'000 cycles was observed in group 3CS (3.98±1.60 mm), followed by FNS (0.67±0.17 mm), DHS Blade (0.64±0.18 mm) and DHS Screw (0.30±0.09 mm, Fig.47). Group 3CS revealed significant higher values than DHS Screw (p=0.036). No further significances were observed between the groups (p≥0.073). BMD showed no significant influence as covariate (p=0.932).

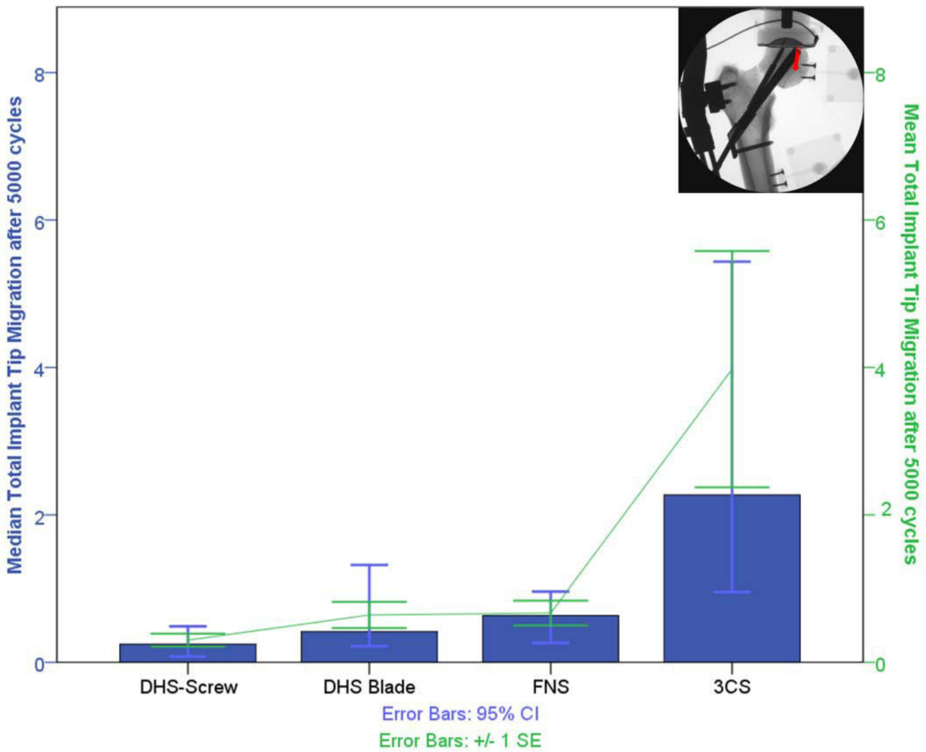

Fig.47: Total Implant Tip Migration after 5'000 cycles (mm, red arrow) median and mean values in the study groups, defined as movement of the point in the femoral head that was located at the implant tip initially after 5'000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.23 Total Implant Tip Migration at Earliest Failure without Nonlinear Influence

Highest average value was observed in group FNS (3.03±1.05 deg.), followed by DHS Screw (2.33±0.54 deg.) and DHS Blade (1.45±0.47 deg., Fig.48). No significances were observed between the groups (p=0.58).

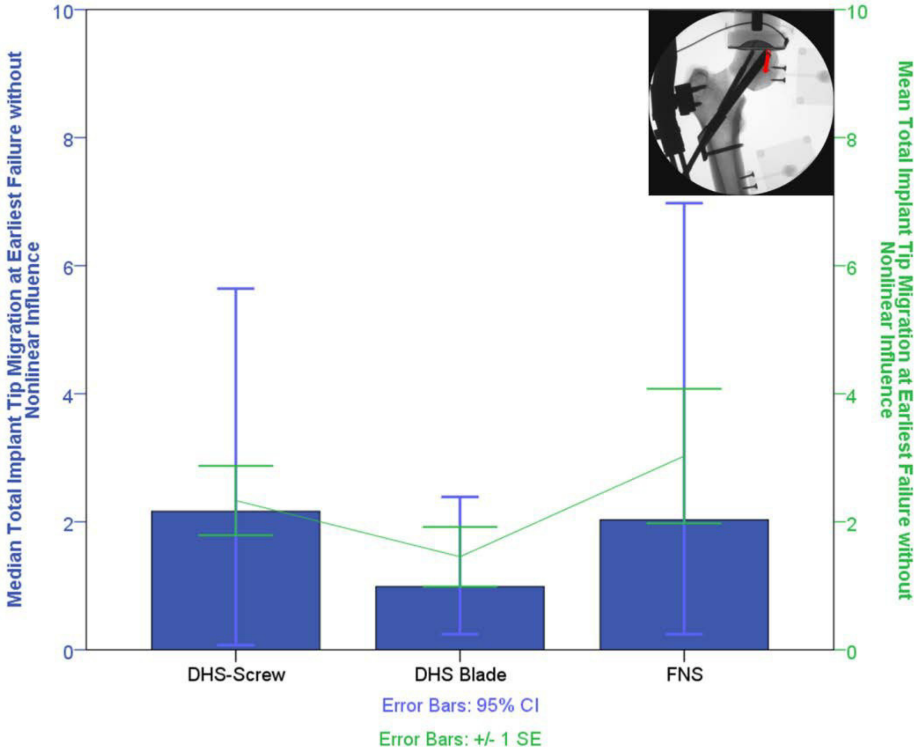

Fig.48: Total Implant Tip Migration at Earliest Failure without Nonlinear Influence (mm, red arrow) median and mean values in the study groups, defined as movement of the point in the femoral head that was located at the implant tip initially when one of the following failures occurs: 15mm Leg Shortening, 15mm Neck Shortening, Machine Stop. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, SE=Standard Error of the mean.

3.3.24 Implant Tip Migration parallel to Implant Axis after 2’000 cycles

Highest average Implant Tip Migration parallel to Implant Axis after 2’000 cycles was observed in group 3CS (0.34±0.16 mm), followed by group FNS (0.07±0.03 mm), DHS Blade (0.02±0.01 mm) and DHS Screw (0.01±0.002 mm, Fig.49). Group 3CS revealed significant higher values than DHS Screw, DHS Blade and FNS (p≤0.028). No further significances were observed between the groups (p≥0.063). BMD showed no significant influence as covariate (p=0.064).

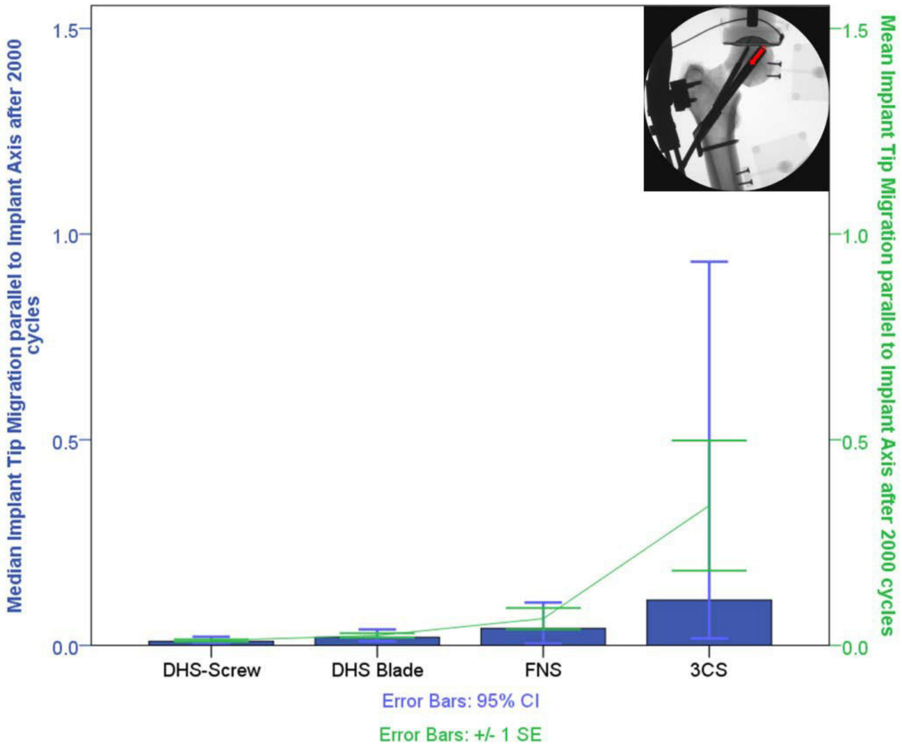

Fig.49: Implant Tip Migration parallel to Implant Axis after 2’000 cycles (mm, red arrow) median and mean values in the study groups, defined as movement of the femoral head along the axis of the implant after 2’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.25 Implant Tip Migration parallel to Implant Axis after 5’000 cycles

Highest average Implant Tip Migration parallel to Implant Axis after 5’000 cycles was observed in group 3CS (1.03±0.47 mm), followed by group FNS (0.10±0.03 mm), DHS Blade (0.05±0.02 mm) and DHS Screw (0.03±0.01 mm, Fig.50). Group 3CS revealed significant higher values than DHS Screw, DHS Blade and FNS (p≤0.028). No further significances were observed between the groups (p≥0.067). BMD showed no significant influence as covariate (p=0.146).

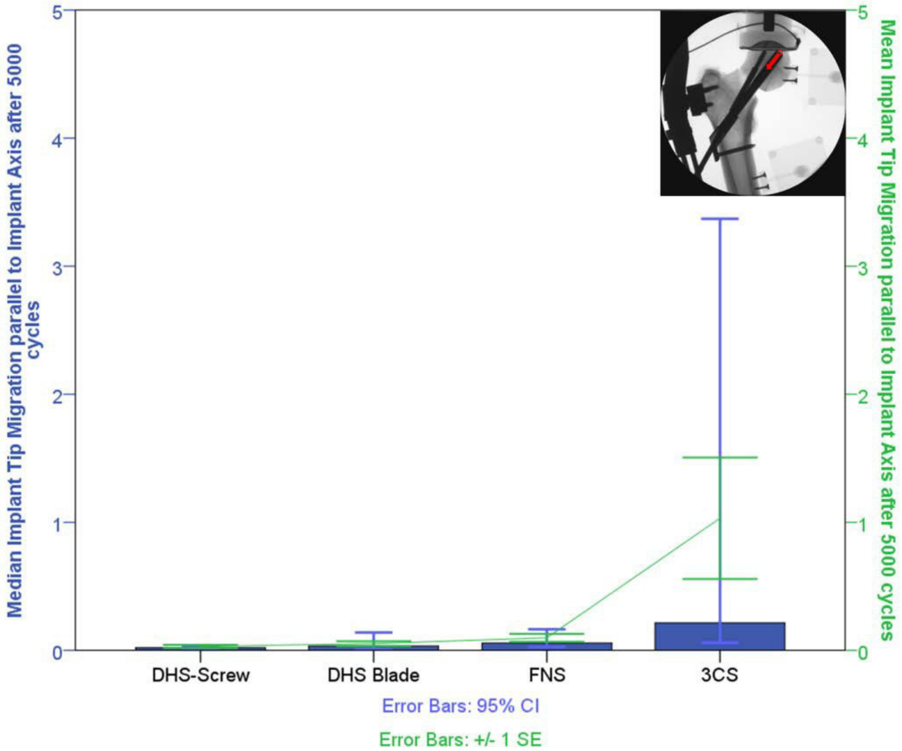

Fig.50: Implant Tip Migration parallel to Implant Axis after 5’000 cycles (mm, red arrow) median and mean values in the study groups, defined as movement of the femoral head along the axis of the implant after 5’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean

3.3.26 Implant Tip Migration parallel to Implant Axis at Earliest Failure without Nonlinear Influence

Highest average value was observed in group DHS Blade (0.73±0.45 deg.), followed by DHS Screw (0.60±0.19 deg.) and FNS (0.60±0.27 deg., Fig.51). No significances were observed between the groups (p=0.80).

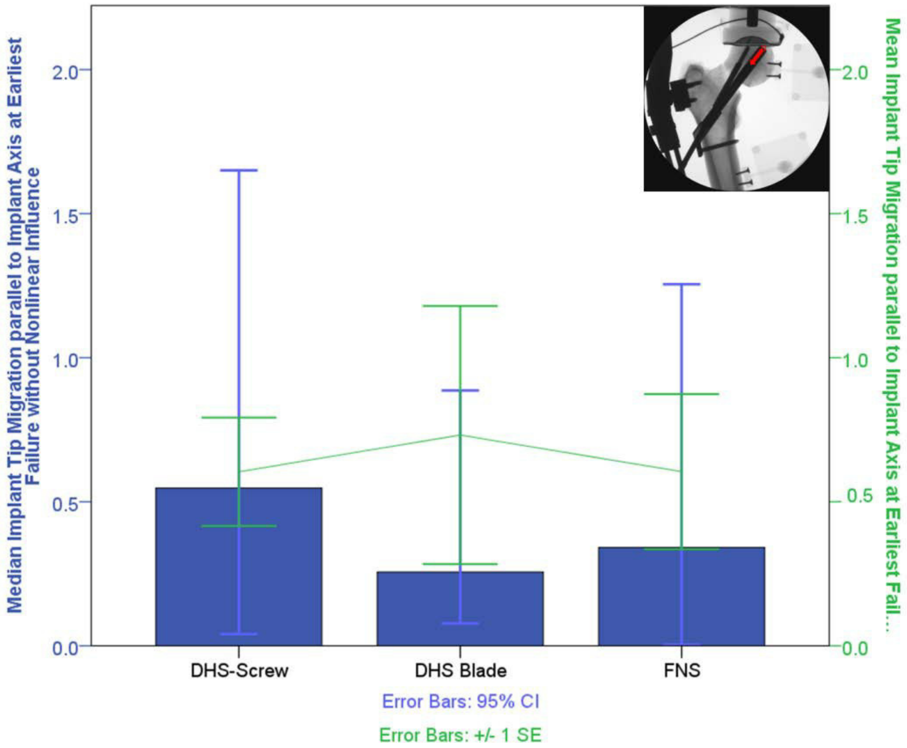

Fig.51: Implant Tip Migration parallel to Implant Axis at Earliest Failure without Nonlinear Influence (mm, red arrow) median and mean values in the study groups, defined as movement of the point in the femoral head that was located at the implant tip initially, parallel to the implant axis when one of the following failures occurs: 15mm Leg Shortening, 15mm Neck Shortening, Machine Stop. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, SE=Standard Error of the mean.

3.3.27 Implant Tip Migration perpendicular to Implant Axis after 2’000 Cycles

Group 3CS revealed highest average value for Implant Tip Migration perpendicular to Implant Axis after 2’000 cycles (1.05±0.17 mm), followed by FNS (0.49±0.10) mm, DHS Blade (0.24±0.05 mm) and DHS Screw (0.13±0.04 mm, Fig.52). DHS Screw, DHS Blade and FNS revealed significant lower values than 3CS (p≤0.027). No further significances were observed between the groups (p≥0.109). BMD showed no significant influence as covariate (p=0.445).

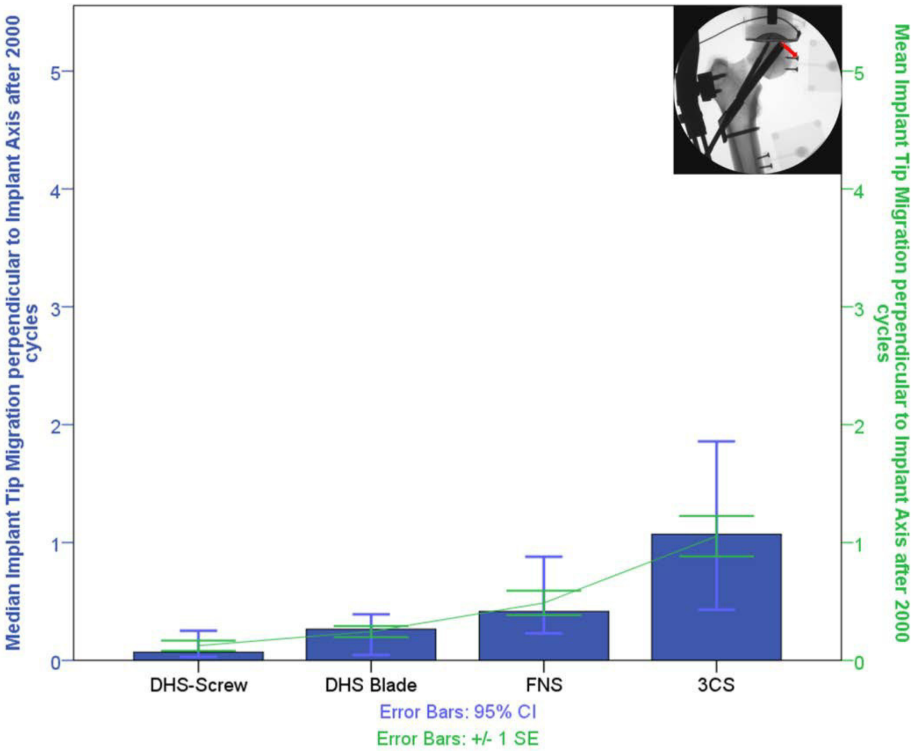

Fig.52: Implant Tip Migration perpendicular to Implant Axis after 2’000 cycles (mm, red arrow) median and mean values in the study groups, defined as movement of the point in the femoral head that was located at the implant tip initially, perpendicular to the implant axis after 2’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.28 Implant Tip Migration perpendicular to Implant Axis after 5’000 Cycles

Group 3CS revealed the highest average value for Implant Tip Migration perpendicular to Implant Axis after 5’000 cycles (3.78±1.60 mm), followed by FNS (0.78±0.18 mm), DHS Blade (0.64±0.18 mm) and DHS Screw (0.30±0.09, Fig.53).

Group 3CS revealed significant higher values than DHS Screw (p=0.047). No further significances were observed between the groups (p≥0.052). BMD showed no significant influence as covariate (p=0.986).

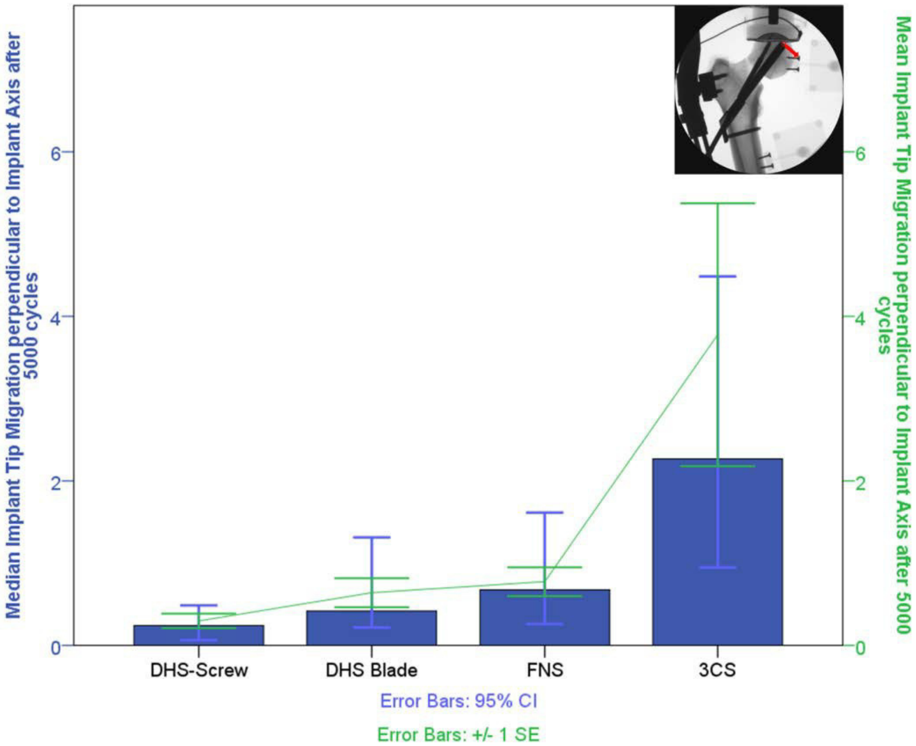

Fig.53: Implant Tip Migration perpendicular to Implant Axis after 5’000 cycles (mm, red arrow) median and mean values in the study groups, defined as movement of the point in the femoral head that was located at the implant tip initially, perpendicular to the implant axis after 5’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.29 Implant Tip Migration perpendicular to Implant Axis at Earliest Failure without Nonlinear Influence

Highest average value was observed in group FNS (2.91±1.07 deg.), followed by DHS Screw (2.16±0.57 deg.) and DHS Blade (1.30±0.36 deg., Fig.54). No significances were observed between the groups (p=0.62).

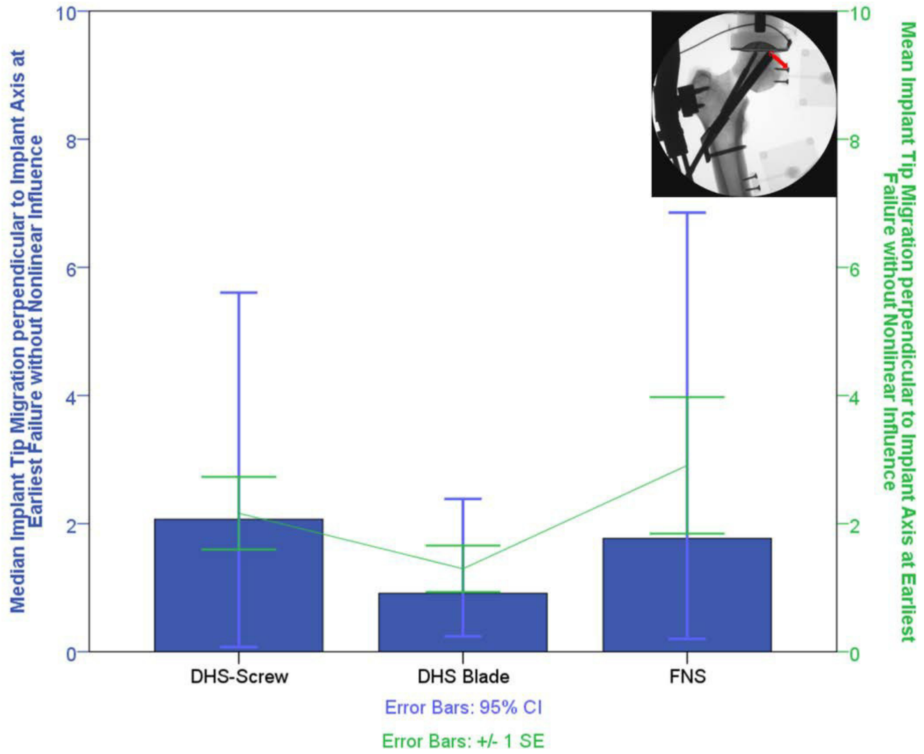

Fig.54: Implant Tip Migration perpendicular to Implant Axis at Earliest Failure without Nonlinear Influence (mm, red arrow) median and mean values in the study groups, defined as movement of the point in the femoral head that was located at the implant tip initially, perpendicular to the implant axis when one of the following failures occurs: 15mm Leg Shortening, 15mm Neck Shortening, Machine Stop. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, SE=Standard Error of the mean.

3.3.30 Varus Deformation after 2’000 cycles

Highest average value for Varus Deformation after 2’000 cycles was observed in group 3CS (2.58±0.33 deg.), followed by group FNS (1.41±0.15 deg.), DHS Blade (0.61±0.10 deg.) and DHS Screw (0.50±0.10 deg., Fig.55). DHS Screw, DHS Blade and FNS revealed significant lower values than 3CS ($p \leq 0.002$). In addition, the values for DHS Screw were significantly lower than for FNS ($p=0.031$). No further significances were observed between the groups ($p \geq 0.484$). BMD showed no significant influence as covariate ($p=0.479$).

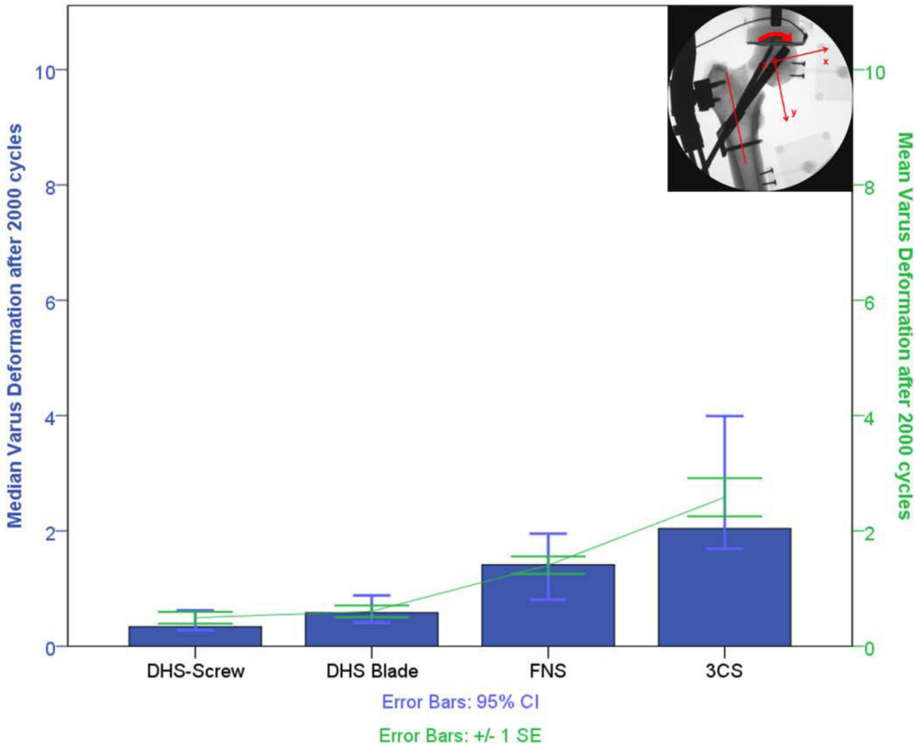

Fig.55: Varus Deformation after 2’000 cycles (deg., red lines, arrows, letters) median and mean values in the study groups, indicating the rotation of the femoral head at the fracture site in the coronal plane after 2’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.31 Varus Deformation after 5'000 cycles

Highest average value for Varus Deformation after 5'000 cycles was observed in group 3CS (5.28±0.69 deg.), followed by FNS (2.89±0.31 deg.), DHS Blade (1.46±0.07 deg.) and DHS Screw (0.91±0.18 deg., Fig.56). DHS Screw, DHS Blade and FNS revealed significant lower values than 3CS ($p \leq 0.004$). In addition, the values for DHS Screw were significantly lower than for DHS Blade and FNS, as well as significantly lower for DHS Blade in comparison to FNS ($p \leq 0.032$). BMD showed no significant influence as covariate ($p=0.797$).

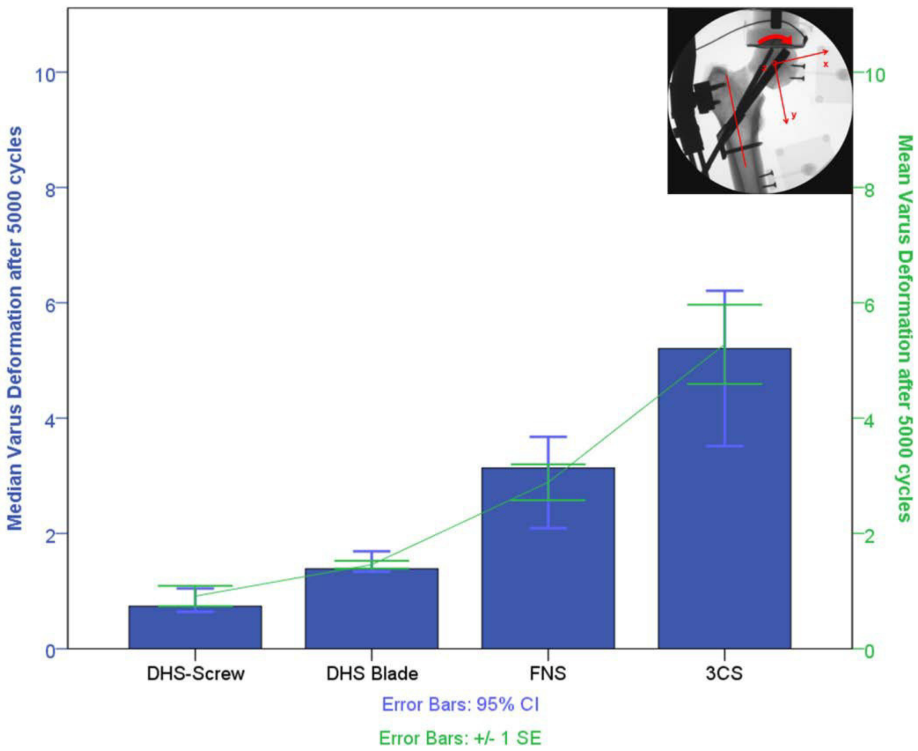

Fig.56: Varus Deformation after 5'000 cycles (deg., red lines, arrows, letters) median and mean values in the study groups, indicating the rotation of the femoral head at the fracture site in the coronal plane after 5'000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.32 Varus Deformation after 10’000 cycles

Highest average value for Varus Deformation after 10’000 cycles was observed in group FNS (4.41±0.45 deg.), followed by DHS Screw (2.29±0.67 deg.) and DHS Blade (2.18±0.27 deg., Fig.57). DHS Screw and DHS Blade revealed significant lower values than FNS (p≤0.015). No further significances were observed between the groups (p=0.99). No significant influence was observed for BMD as covariate (p≥0.537).

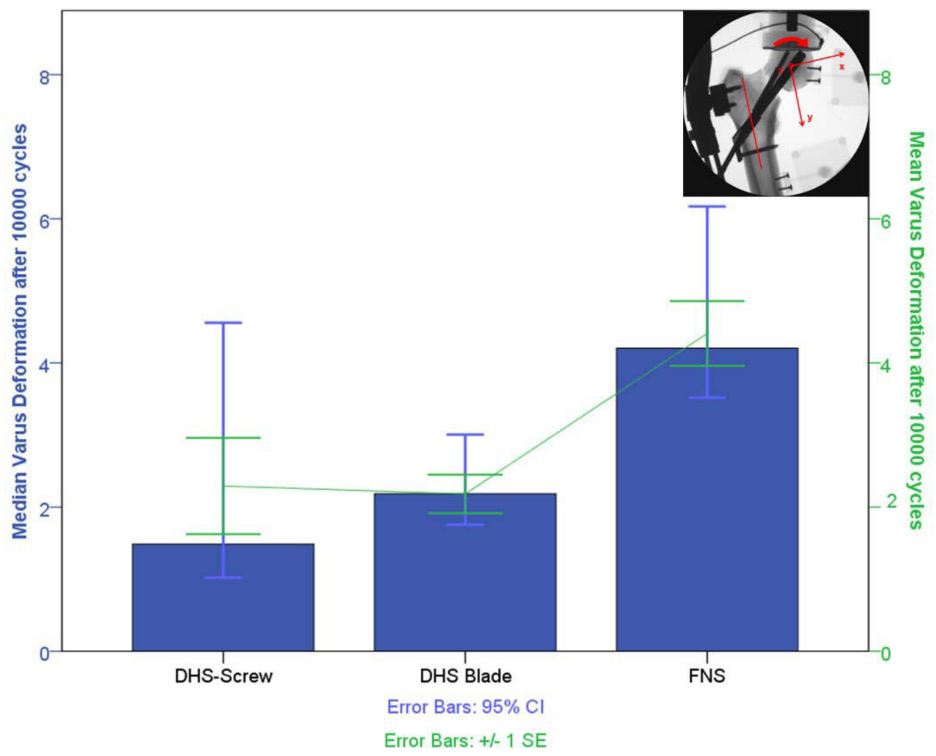

Fig.57: Varus Deformation after 10’000 cycles (deg., red lines, arrows, letters) median and mean values in the study groups, indicating the rotation of the femoral head at the fracture site in the coronal plane after 10’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, SE=Standard Error of the mean.

3.3.33 Axial Displacement after 2'000 cycles

3CS revealed the highest average value for Axial Displacement at 2'000 cycles (3.29±0.40 mm), followed by FNS (3.01±0.52 mm), DHS Blade (1.57±0.27 mm) and DHS Screw (1.35±0.24, Fig.58). DHS Screw and DHS Blade revealed significant lower values than 3CS ($p \leq 0.02$). In addition, the values for DHS Screw were significantly lower compared to FNS ($p=0.019$). No further significances were observed between the groups ($p \geq 0.073$). BMD showed no significant influence as covariate ($p=0.086$).

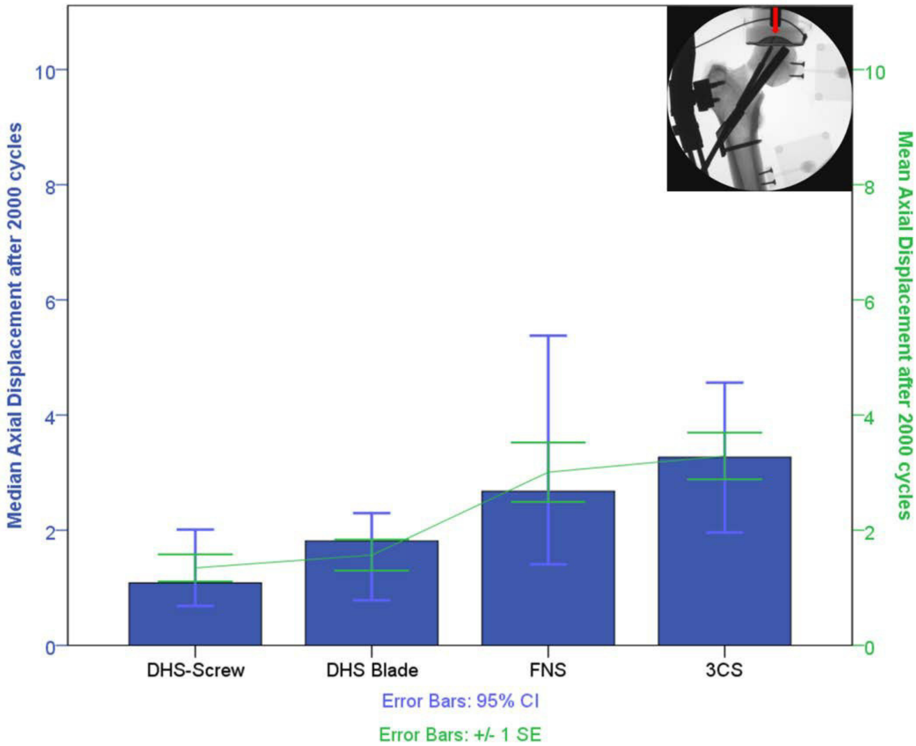

Fig.58: Axial Displacement after 2'000 cycles (mm, red arrow) median and mean values in the study groups, defined as total axial displacement of the bone implant construction after 2'000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.34 Axial Displacement after 5'000 cycles

Highest average value for Axial Displacement at 5'000 cycles were observed in group 3CS (6.78±0.59 mm), followed by FNS (5.47±0.62 mm), DHS Blade (4.93±0.46 mm) and DHS Screw (3.38±0.51 mm, Fig.59). DHS Screw, DHS Blade and FNS revealed significant lower values than 3CS ($p \leq 0.01$). In addition, the values for DHS Screw were significantly lower compared to DHS Blade ($p=0.034$). No further significances were observed between the groups ($p \geq 0.179$). BMD showed no significant influence as covariate ($p=0.141$).

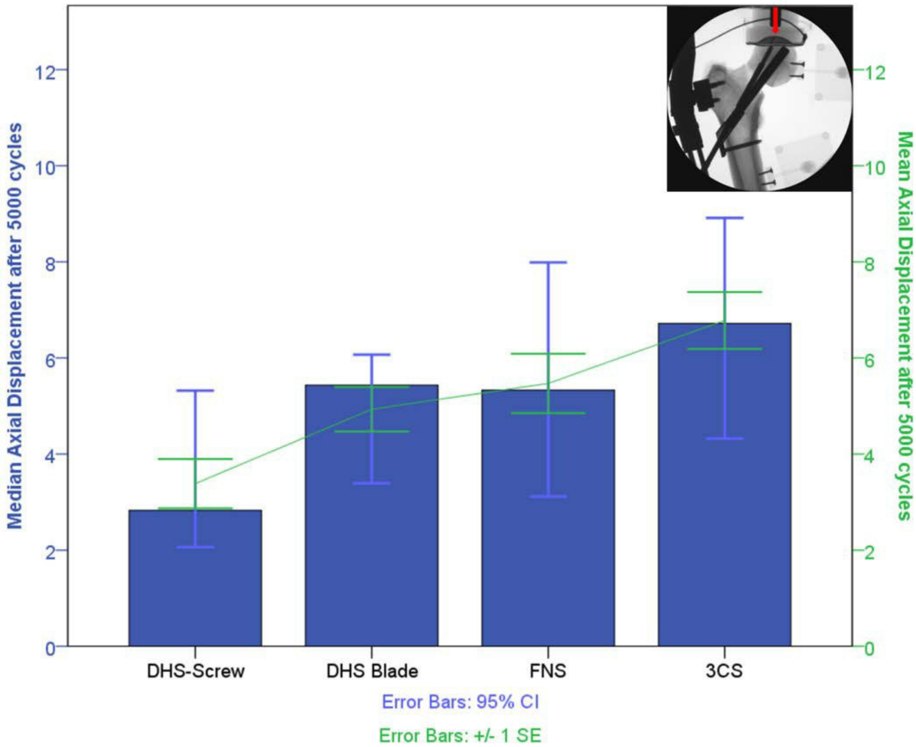

Fig.59: Axial Displacement after 5'000 cycles (mm, red arrow) median and mean values in the study groups, defined as total axial displacement of the bone implant construction after 5'000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, mm=millimeter, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.35 Cycles at 2 deg. Rotation around Implant Axis

Groups DHS-Screw showed highest average value for Cycles at 2deg Rotation around Implant Axis (16’463±4’361), followed by DHS Blade (12’252±1’917), FNS (5’184±1’447) and 3CS (4’568±870, Fig.60). DHS Screw revealed significant higher values than FNS and 3CS (p≤0.045). No further significances were observed between the groups (p≥0.38). Axis off Center Absolute showed significant influence as covariate (p=0.008), whereas no significant influence was observed for BMD and Implant Axis off Center Relative as covariates (p≥0.544).

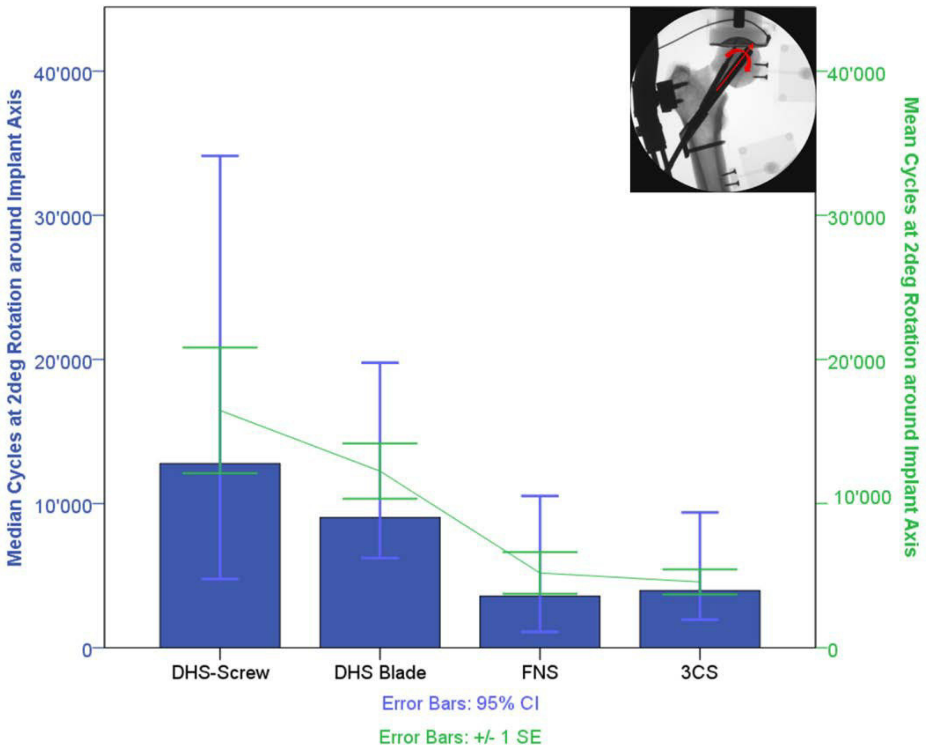

Fig.60: Cycles at 2 deg. Rotation around Implant Axis (deg., red arrows) median and mean values in the study groups, indicating the number of cycles needed, until 2 deg. of femoral head rotation around the implant axis occur. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, 3CS=3 Cannulated Screws, SE=Standard Error of the mean.

3.3.36 Rotation around Implant Axis after 10'000 cycles

Highest average value for Rotation around Implant Axis after 10'000 cycles was observed in group DHS Screw (6.37±3.98 deg.), followed by FNS (4.51±0.86 deg.) and DHS Blade (1.60±0.42 deg., Fig.61). No significant differences were observed between the three groups (p≥0.054). Implant Axis off Center Absolute was with significant influence as covariate (p=0.039).

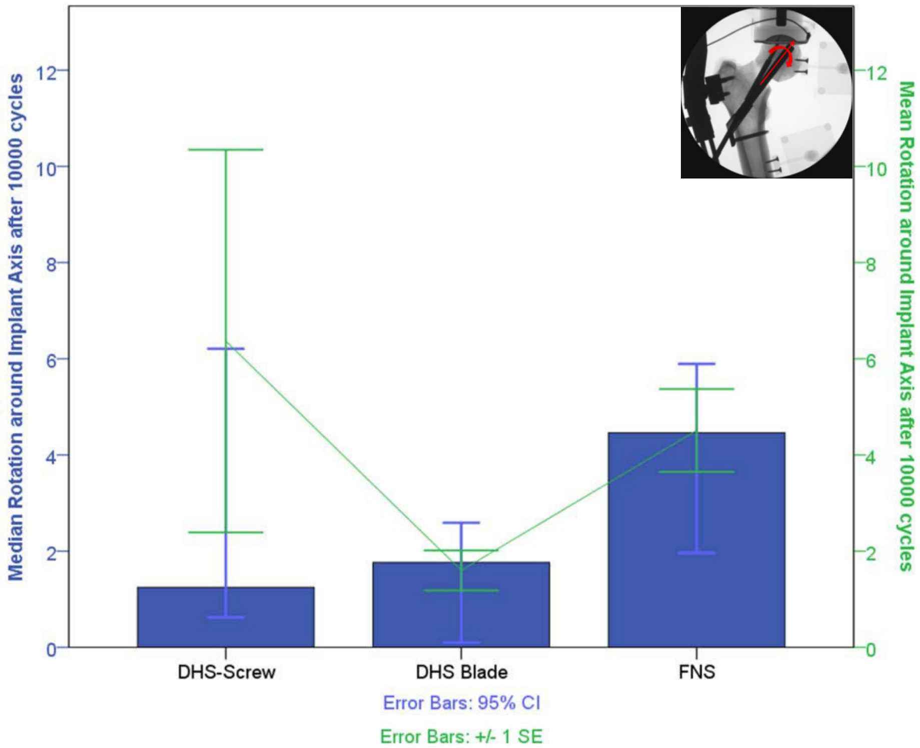

Fig.61: Rotation around Implant Axis after 10'000 cycles (deg., red arrows) median and mean values in the study groups, indicating the rotation of the femoral head around the implant axis after 10'000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, SE=Standard Error of the mean.

3.3.37 Deformation Plate to Screw after 10’000 cycles

Highest average value were observed in group FNS (3.59±0.48 deg.), followed by DHS Screw (2.11±0.36 deg.) and DHS Blade (1.93±0.37 deg., Fig.62). DHS Blade revealed significant lower values than FNS (p=0.027). No further significances were observed between the groups (p≥0.054).

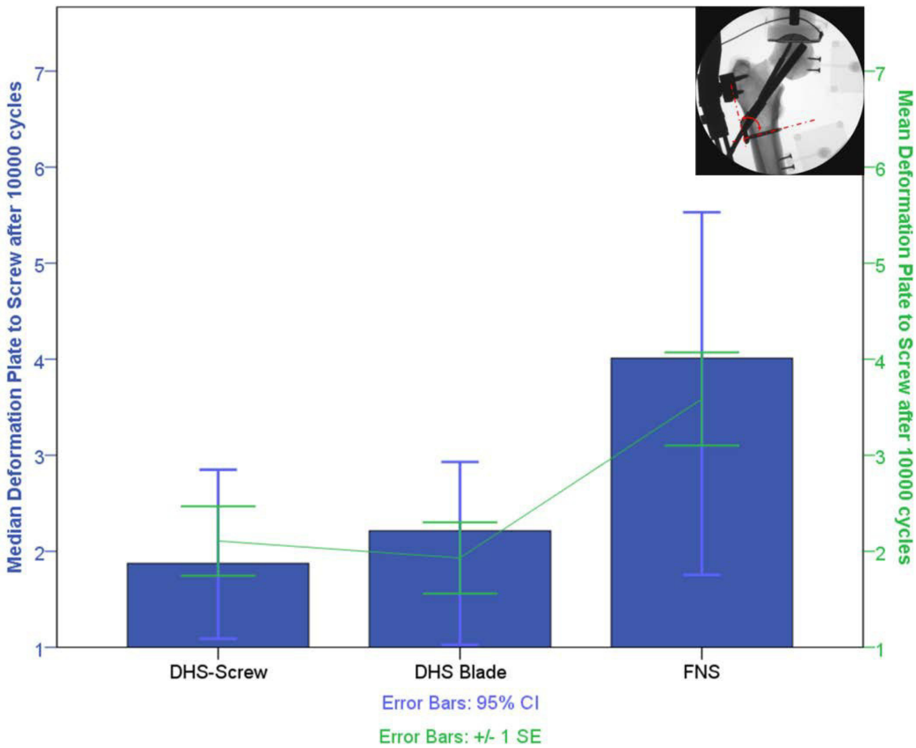

Fig.62: Deformation Plate to Screw after 10’000 cycles (deg., red lines and arrow) median and mean values in the study groups, indicating the deformation of the plate compared to the fixation screw after 10’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, SE=Standard Error of the mean.

3.3.38 Plate Lift-off after 10’000 cycles

Group FNS showed highest average value for Plate Lift-off after 10’000 cycles (1.80±0.56 deg.), followed by DHS Screw (0.56±0.12 deg.) and DHS Blade (0.49±0.10 deg., Fig.63). No significant differences were observed between the groups (p≤0.101).

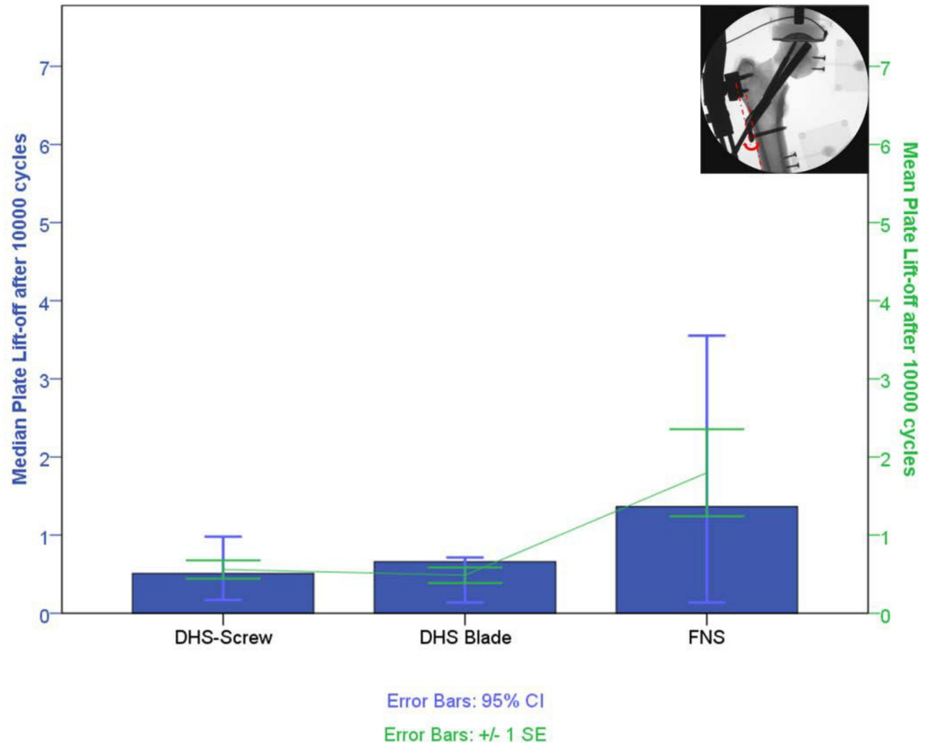

Fig.63: Plate Lift-off after 10’000 cycles (deg., red lines and arrow) median and mean values in the study groups, indicating the deviation of the plate to the femoral shaft after 10’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, SE=Standard Error of the mean.

3.3.39 Deformation Screw to Shaft after 10’000 cycles

Highest average value were observed in group DHS Screw (1.22±0.31 deg.), followed by DHS Blade (0.97±0.25 deg.) and FNS (0.85±0.14 deg., Fig.64). No significances were observed between the groups (p≥0.538).

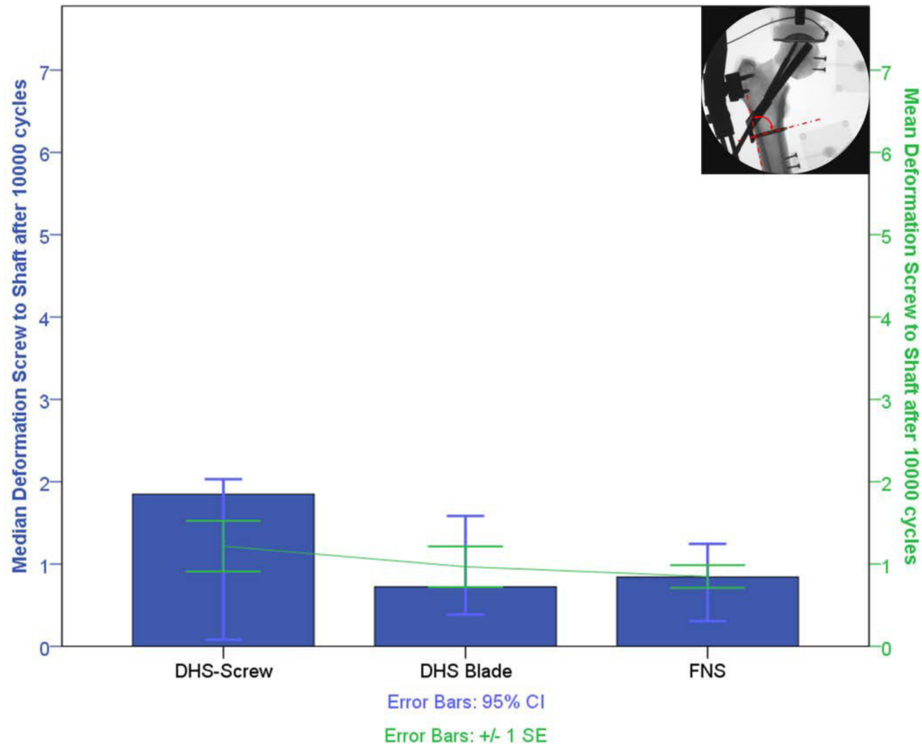

Fig.64: Deformation Screw to Shaft after 10’000 cycles (deg., red lines and arrow) median and mean values in the study groups, indicating the deformation of the fixation screw compared to the shaft after 10’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System SE=Standard Error of the mean.

3.3.40 Rotation Implant to Shaft after 10’000 cycles

Highest average value for Rotation Implant to Shaft after 10’000 cycles was observed in group FNS (2.82±0.31 deg.), followed by DHS Blade (1.76±0.16 deg.) and DHS Screw (0.94±0.18 deg., Fig.65). DHS Screw and DHS Blade revealed significant lower values than FNS (p≤0.012). No further significances were observed between the groups (p=0.69). No significant influence was observed for BMD as covariate (p≥0.597).

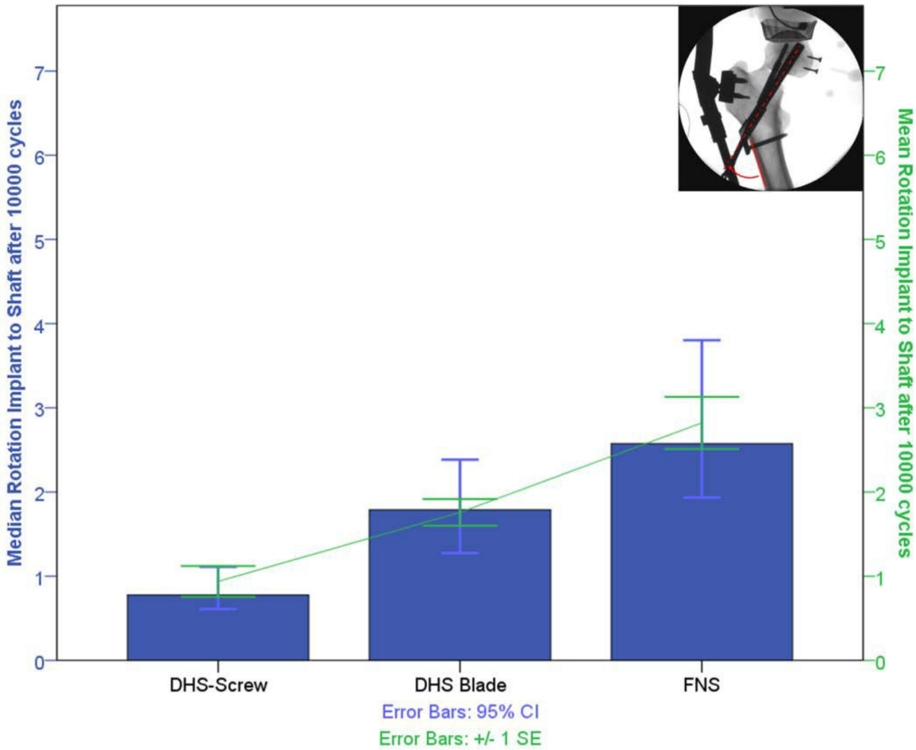

Fig.65: Rotation Implant to Shaft after 10’000 cycles (deg., red lines and arrow) median and mean values in the study groups, indicating the rotation of the implant to the shaft after 10’000 cycles. With kind permission of the AO Research Institute Davos. CI=Confindential Interval, deg.=Degree, DHS=Dynamic Hip Screw, FNS=Femoral Neck System, SE=Standard Error of the mean.

4 Discussion

The goal of the biomechanical investigations was to evaluate the performance of the newly designed implant FNS compared to the existing solutions DHS Screw, DHS Blade and 3CS under identical initial conditions. The presumed outcome would find FNS in third position concerning its biomechanical performance right before 3CS. Homogenization of the study groups was assured by selecting the femora using predefined exclusion criteria. Cancer was the only exclusion criterion which was only partially complied with, depending on the influence of the basic disease on the BMD found in the proximal femur. Four pairs of tested specimens, whose donors' cause of death was specified as non-specific cancer, were included in the evaluation. The following consideration was taken into count as far as their inclusion is concerned: Firstly, the BMD values of the four pairs didn't show a significant difference compared to the other specimens. Secondly, the four pairs were assigned homogeneously to all four groups. Thirdly, the definition of cancer was not related to bone in general or the femur in special, it was noticed as a non-specific diagnosis.
Finally, the fractures were generated as reproducible as possible using the same custom made device for every single of the tested specimens.

Axial Stiffness was highest in the FNS group, although no significant differences were observed between the four groups.
Regarding the parameters of interest, considered as diverse Cycles to Failure and based on a variety of failure criteria, the FNS group failed after a significantly higher number of cycles than the 3CS group, being in the same range as for the DHS Screw and DHS Blade groups with no significant difference to them.
The average values of various movements at the implant tip after 2'000 and 5'000 cycles, such as Implant Tip Migration parallel to Implant Axis, Implant Tip Migration perpendicular to Implant Axis and Total Implant Tip Migration, were highest in the 3CS group and mostly significantly higher to those in the DHS Screw, DHS Blade and FNS groups. Similarly, the highest values for Varus Deformation after 2'000 and 5'000 cycles were observed in group 3CS, differing significantly from the DHS Screw, DHS Blade and FNS groups. These parameters, indicating the moments at the implant tip and the tendency of varization at the fracture site, were defined as the clinically most relevant findings according to the needs of stability requested most in vivo.

In consequence their influence on the estimation of the biomechanical performance of the tested implants was prioritized.

Beside the above mentioned, clinically most relevant parameters, more data has been analyzed. Eight outcomes concerning DHS Screw (Axial Displacement at 2'000 cycles, Leg Shortening after 2'000 cycles, Leg Shortening after 5'000 cycles, Neck Shortening after 5'000 cycles, Varus Deformation after 2'000 cycles, Varus Deformation after 5'000 cycles, Varus Deformation after 10'000 cycles and Cycles at 2deg Rotation around Implant Axis), and another three outcomes concerning DHS Blade (Varus Deformation after 5'000 cycles, Varus Deformation after 10'000 cycles and Deformation Plate to Screw after 10'000 cycles) evidenced the superiority of the DHS systems regarding the investigated parameters.

During the cyclic test, the criterion for machine stop was fulfilled, before any of the specimens was able to reach neither of the originally set failure criteria for Leg Shortening nor Neck Shortening. This mismatch between the stop criterion on the one hand, and the criteria for Leg Shortening and Neck Shortening on the other, was amended by corrections of both criteria for Leg Shortening and Neck Shortening, whose values were decreased by 10 mm to be 15 mm instead of 25 mm. The definition of the new clinically relevant failure criteria was based on the fact, that the migration of the femoral head along the neck axis (Neck Shortening) revealed a stable interdigitation of the femoral head after a distance of 15 mm. This would be a clinically acceptable situation concerning the fracture position, except the mismatch of the greater trochanter position relatively to the femoral head and except the implants sticking out at the lateral femur. This configuration is well known from former DHS applications. At this position, no further shortening would be possible without destruction of the femoral neck or head, so that failure criterion had to be set at 15 mm, where bones were still intact. Due to the bone contact, catastrophic failure occurred during further testing at a displacement >15mm.

Specimens F13-1310R (Group DHS-Screw) and F13-1301L (Group FNS) revealed relatively big distal femoral shaft movements, which were caused by distal embedding errors. These movements induced relatively high pulling forces on the bracing, leading to stress concentrations in the femoral shafts and causing in the case of the latter specimen a shaft fracture below the lateral plate. This was the only reported shaft fracture in this group. For that reason these specimens were considered as outliers and discarded from evaluation. In addition, the failure area of the latter specimen appeared cystic after fluoroscopic re-assessment. The donor of this specimen died of renal disease, which could explain the pathological changes in the bone.

After setting the osteotomies, the femoral head of one specimen (F12-1104L, DHS Blade) lost its anatomical reduction and displaced cranially. In consequence the reduction was restored by placing four flat washers in between the plate and the shaft around the distal screw.

Another shaft fracture was observed in specimen F12-1104L (Group DHS Blade). The instrumentation of this specimen was readjusted after setting the osteotomy, in order to restore the anatomical reduction. The cause for loss of reduction was inner tensions in the bone and implant, which appeared, when the Blade was inserted into the femoral head with a slight angular deviation. Pulling the fixed angle plate to the bone with the cortex screws, which is standard procedure for this implant, was then leading to the inner tension within the bone/implant construct. After performing the osteotomy, these tensions were set free and resulted in head migration. However, to achieve a good reduction, parallel alignment between the plate and the shaft axis was compromised, leading to a change in biomechanical forces acting on the whole construct. It can be assumed that the shaft fracture in this specimen originated from the washer placing. However, this specimen was not considered as an outlier, as the biomechanical performance was in the range with the other specimens of the same group, and the distal fixation did not show any shaft migrations.

5 Summary

The Femoral Neck System shows significantly higher overall construct stability compared to 3 Cannulated Screws in a biomechanical femoral neck fracture model. The superiority was proofed in the main parameters concerning the axial and rotational stability of the implant.

Following the trend of reduced linear cutting out and rotational loosing as well observed in the improvement from Dynamic Hip Screw Screw to Dynamic Hip Screw Blade, the newly introduced implant Femoral Neck System can continue this progress by utilizing the mentioned advantages compared to the 3 Cannulated Screws. This biomechanical superiority may be beneficial in clinical use, especially in combination with the small side plate, potentially allowing a minimally invasive treatment. The side plate offers the additional opportunity of angle stable screw locking as well, which might lead to a tighter plate-to-shaft-connection, as the investigations demonstrated. Furthermore, no significant differences between the Femoral Neck System and the Dynamic Hip Screw systems could be shown in the clinically most relevant parameters concerning the axial and rotational stability of the implant. The potential role of the Femoral Neck System being a fully trustable addition to the existing implants Dynamic Hip Screw Screw, Dynamic Hip Screw Blade and the 3 Cannulated Screws in a manner of fixing transcervical fractures of the proximal femur can be considered as valid from a biomechanical point of view. The Femoral Neck System can be considered as a replace of the 3Cannulated Screws due to its proven biomechanical superiority.

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8 Curriculum vitae

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Nov 2013: Approbation nach deutscher Weitebildungsordnung.

Lehre

Okt. 08- Juli 12: Anstellung als Demonstrator am Anatomischen Institut der Medizinischen Universität Wien für alle im Rahmen des humanmedizinischen Curriculums abgehaltenen anatomischen Präparierkurse und somit den gesamten anatomischen Inhalt des Studiums. Zusätzliche Abhaltung von Präparierkursen für Zahnmediziner/Physiotherpeuten sowie Kursen im orthopädischen und traumatologischen postgraduate-Bereich.

März 13-Jan.14: Universitätslektor am Anatomischen Institut der Medizinischen Universität Wien für alle im Rahmen des Curriculums abgehaltenen Präparierkurse des Studiums der Humanmedizin.

Beruflicher Werdegang

Okt. 12-Jan.14: Assistenzarzt am *Kantonsspital Graubünden* (Chur/Schweiz). Zentrumsklinik mit A-Status für Traumatologie.

seit Feb. 2014: Assistenzarzt am *Universitätsklinikum Ulm, Klinik für Unfall-, Hand-, Plastische und Wiederherstellungschirurgie*.

Seit Apr. 2016: Koordinator Traumanetzwek Ulm.