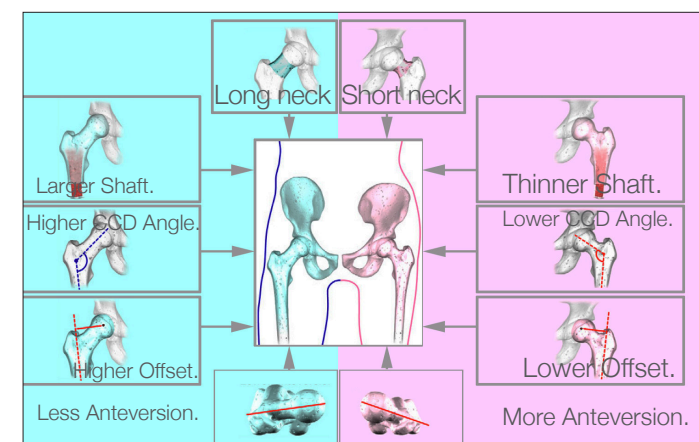


The ideal implant should be able to reproduce the human anatomy as faithfully as possible



- Larger Shaft.
- Higher CCD Angle.
- Longer Neck.
- Higher Offset.
- Less Anteversion.

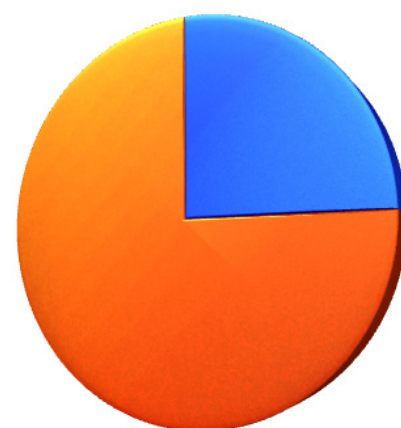


- Thinner Shaft.
- Lower CCD Angle.
- Shorter Neck.
- Lower Offset.
- More Anteversion.

Within the already large human variability, there are significant variations which are gender related (4,5,6)

The luxation problem

Luxations are the most common causes for revisions with an overall incidence between 1.5% and 3% (11)



• Luxations • Other causes

The use of modular stems reduced the overall incidence of luxations to 0.7%, and it also halved the recurrence of this complication in women (women/men ratio 2:1) (5)

Luxations cause in average 25% of all revisions (12;13;14). Research shows that the women/men ratio for this complication is 4:1 (12). Luxations have a higher incidence in women due to their higher physiological degree of anteversion:

- Impossible to reconstruct with monobloc stems.
- Difficult to compensate with non-linear modular systems.



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Ottobre 2013

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Modula® neck is protected by the following patents:
European Patent EP 1 635 742 B1
US Patent 7,588,602 B2
European Patent EP 1 663 077 B

Manufactured by Adler Ortho CE 0426

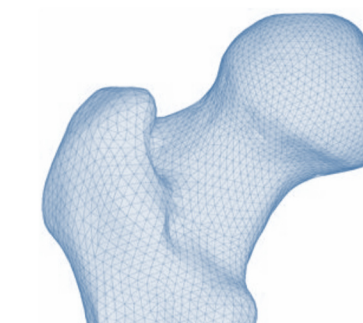
MODULA® is the true Universal Modular System.

MODULA® Modular Neck System



Universal Modular System

The importance of MODULARITY

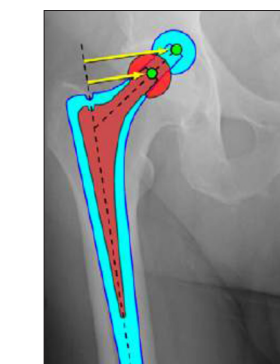


The main parameters of the human femur are:

- Neck Length
- Size of the diaphysis
- CCD Angle
- Offset
- Anteversion

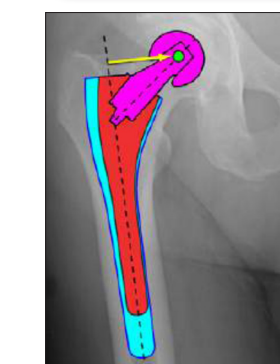
The proximal femoral anatomy has a great deal of variability. (1;2;3; 20)

There's no correlation between the diaphyseal size and the proximal femoral anatomy (1)



Monobloc stems

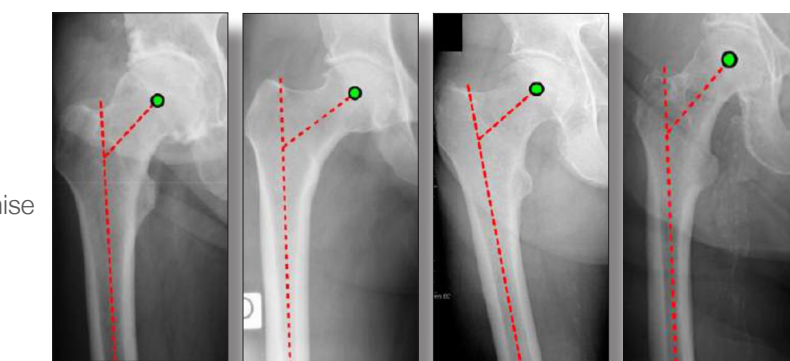
These stems are a compromise between dimensions which often vary in opposite ways.



Modular stems.

The stem is chosen according to the femoral shaft dimension. The necks are then selected based on the other parameters.

Anatomies which are difficult to reconstruct with monobloc stems.



Short Neck Large Shaft Low Offset
Long Neck Thin Shaft High Offset
Short Neck Large Shaft High Offset
Long Neck Thin Shaft Low Offset

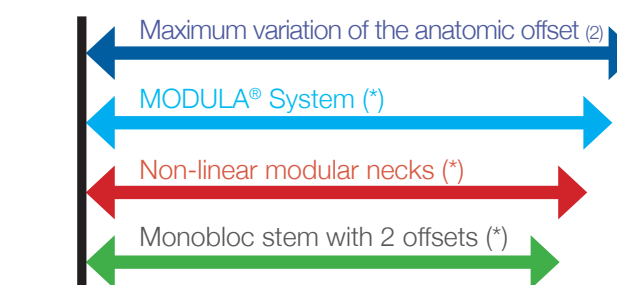
Monobloc stems, even with 2 offset options, cannot precisely reconstruct anatomic variables characterized by "non-standard" ratios between geometric parameters. (5;7)

The importance of the offset.

The human offset can vary between 27mm and 57mm. (2)

An incorrect offset reconstruction can cause:

- An increase of the risk of luxations (8)
- An increase of the mechanical stress on the implant (9)
- An increase of the Polyethylene wear (10)



The MODULA® system features an offset range between a minimum of 28mm and a maximum of 54mm.

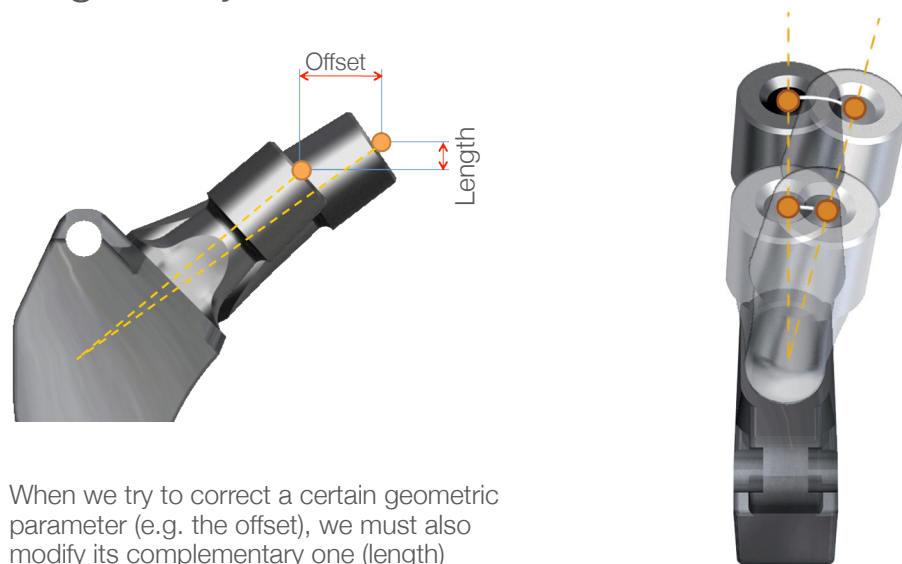
MODULA® reproduces the anatomy more precisely.

(*) Data available from Adler Ortho.

The MODULA® System is linear.

Modular systems aren't all the same. There are angular systems, that rely on pre-set angular variations. The MODULA® system is linear, because it's based on pre-set spatial positions.

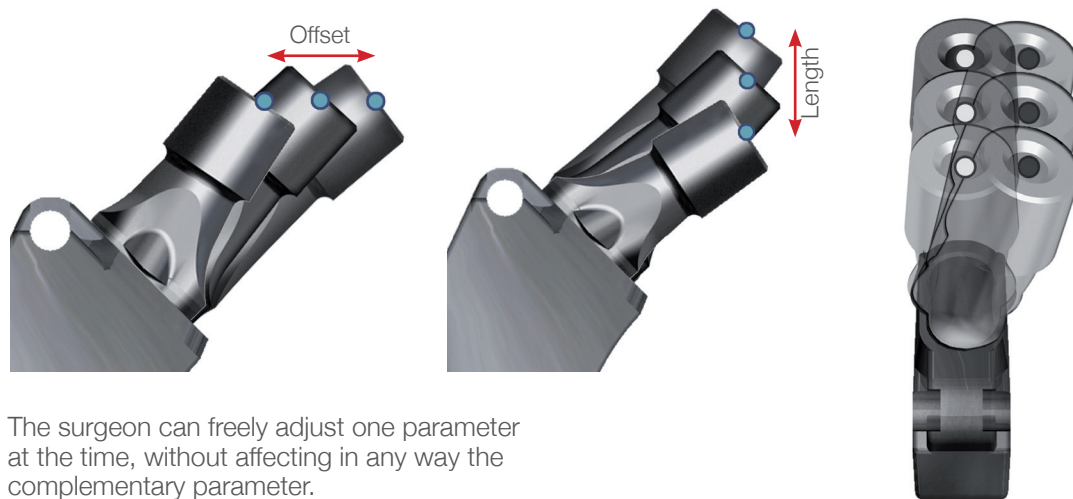
Angular Systems



When we try to correct a certain geometric parameter (e.g. the offset), we must also modify its complementary one (length)

In angular systems the modification of one parameter affects the others.

The MODULA® System



The surgeon can freely adjust one parameter at the time, without affecting in any way the complementary parameter.

The MODULA® system allows for the independent adjustment of the 3 main parameters: Length, Offset, Version. Changing one of these parameters does not affect the others.

Version correction is also non-linear. Shorter necks have lower version than longer ones.

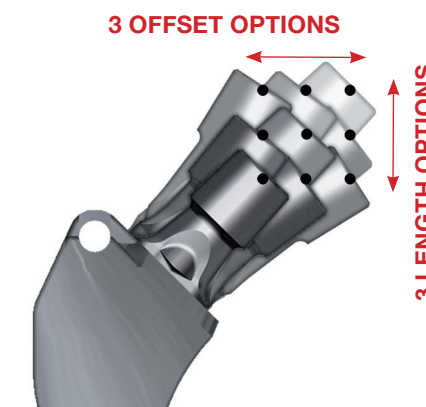
Anatomies with shorter necks and higher version degrees (mainly female patients) are not reconstructed correctly.

The version is the same for every neck length.

Patients with shorter necks can also achieve a sufficient version correction.

LOGICAL, SIMPLE, COMPLETE.

Logical



MODULA® Matrix frontal view the surgeon can select between 3 offset and 3 length options.

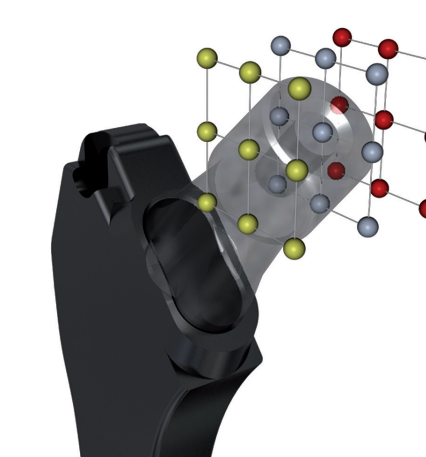
- **Vertical** to adjust the length.
- **Horizontal** to adjust the offset.

Simple



To help the surgeon in selecting the most suitable neck, the trial necks are positioned on a white plate which faithfully reproduces the square matrix on the frontal plane. Two more plates are used to accommodate the anteverted and retroverted necks.

Complete

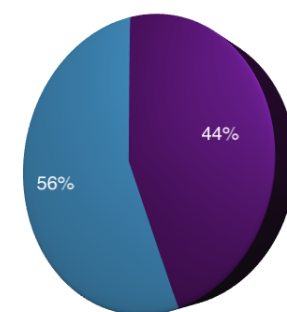


The 27 points of the tridimensional matrix are covered with the 15 different necks. By combining the matrix positions with the three head options available, the surgeon has **81 different options** at his disposal to accurately reconstruct the hip joint geometry.

The advantages of the modular system

The system includes 3 "straight" necks with the longitudinal axis aligned to the CCD angle and 12 "tilted" necks that are angled on one or two planes. The type of necks implanted are divided as follows (*):
The "tilted" necks (covering 24 points of the matrix) make up more than half of the implants (56%).
The 3 "straight" necks (covering 3 points of the Matrix) were used in 44% of cases.

- Tilted necks
- Straight necks

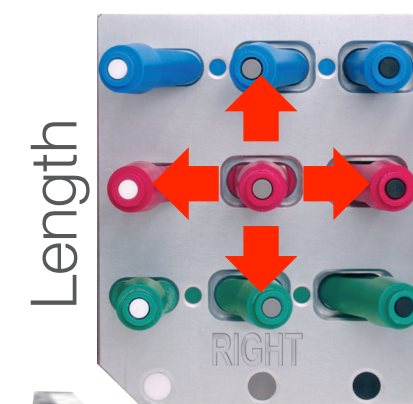


In most cases a "tilted" neck had to be implanted in order to reconstruct the patient anatomy.

(*): Data related to 40,000 implanted modular necks available from Adler Ortho.

Surgical Technique

Offset



The movement options available to the surgeon, starting from the central neck of the matrix.

The ideal neck can be found in 3 steps:

- **Starting neck.** The surgeon can identify the starting neck to perform the trial reduction from the pre-operative planning. Alternatively the surgeon can decide to start from the central neck of the matrix.
- **Identification of the ideal Offset/Length combination.** During the trial reduction, the surgeon can change the initially chosen trial neck (e.g. the central one) and modify the offset (and nothing else) by moving on the horizontal plane of the matrix, or the length (and nothing else) by moving on the vertical plane, to achieve the best combination between those two parameters.
- **Optimization.** The surgeon can optimize the result further by using the 3 head options available.

If, during the trial reduction, a risk of neck impingement is found, the surgeon can select the anteverted or retroverted neck for the neutral one that has already been defined, without changing the selected offset/length combination in any way.

Colour Code

The trial necks are coloured on the frontal plane according to their length:

Blue: Long Neck;

Red: Medium neck;

Green: Short neck;

The same colours are displayed on the trial necks lodging plate. The tip of the necks use a colour code identifying the offset:

White: Minus Offset;

Grey: Medium Offset;

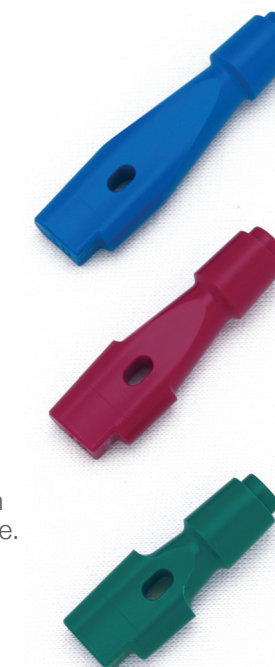
Black: Plus Offset.

These colours are also shown on the trial necks lodging plate. Two further colours:

Yellow

Red

Yellow and Red, are used to identify the anteverted and retroverted options.



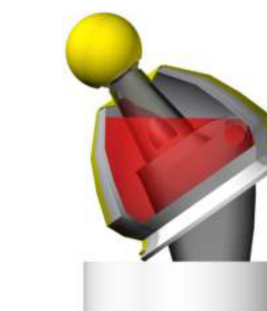
Why Titanium?

Titanium Alloy is the most suitable material for cementless stems. Modular necks can be made of titanium alloy or of Co-Cr-Mo alloy.

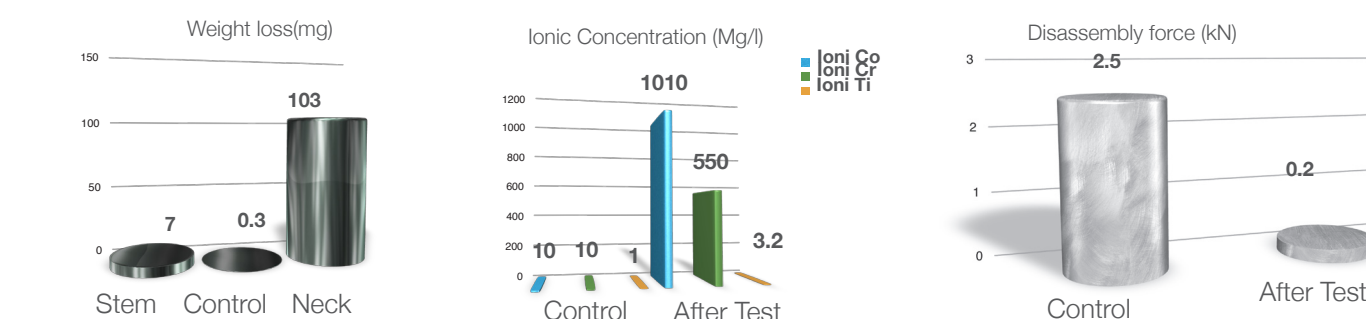
The coupling of two different metal alloys (Ti-6Al-4V and Co-Cr-Mo) has been associated with corrosion issues and the release of big quantities of metal ions. (15;16;17;18;19)

Laboratory Tests

A number of Co-Cr-Mo necks were assembled on titanium stems and submitted to 5 million load cycles according to ISO 7206/4. The neck area was maintained in a ferric chloride solution (FeCl3) according to ASTM G48-03. As a reference one of the samples was kept in the solution without load.



Results



After the test the CoCr neck lost 103 mg. There was practically no variation in the control neck weight.

After the test we found a significant increase in the concentration of Co and Cr ions in the Ferric Chlorine solution.

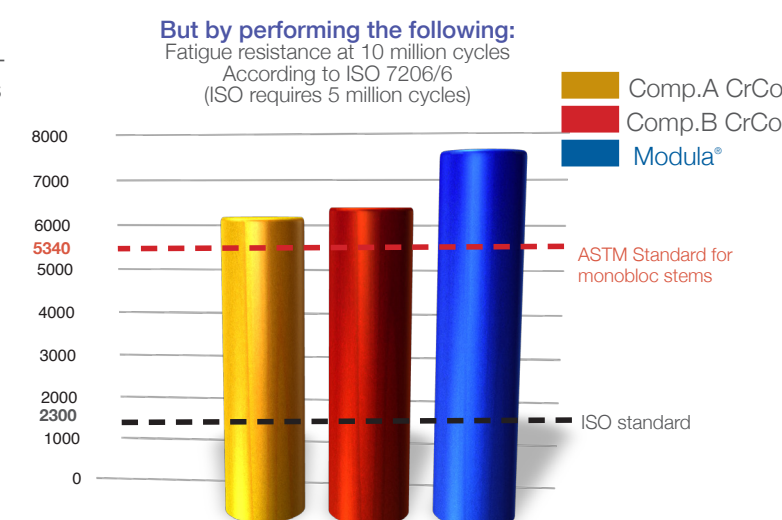
After the test the force needed to disassemble the neck decreased 10 times.

The titanium alloy/titanium alloy coupling does not present corrosion issues, but it can be sensitive to fretting issues that could undermine its mechanical performance. (21)

However by:

- Optimizing the coupling length.
- Submitting the male taper surface to an exclusive surface finish.
- Optimizing the shape and surface finish of the female taper.
- Optimizing the coupling clearance.

We achieved a very high mechanical strength for the MODULA® necks.



Titanium alloy MODULA® necks are more reliable and guarantee long lasting coupling.

Surgeon should carefully evaluate the use of modular necks with high frontal offset and/or anteversion or retroversion in heavy patients and/or performing high impact sporting and/or physical demanding working activities, because the risk of early complications could be higher than normal.