SURGEON CONTROLLED FACTORES ELIMINATING TAPER CORROSION and TRUNNIONOSIS

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Taper Corrosion and Trunnionosis in Hip Arthroplasty has been recognized as a major complication presenting as a variety of clinical problems collectively referred to as adverse local tissue reactions (ALTR). These problems are created by metal debris that is produced at the taper interface through a process referred to as mechanically assisted crevice corrosion (MACC).

Factors involved in the causation of MACC include Mixed alloy components, Taper Design, Head Offset, Femoral Head size, and Taper Impaction Technique (Surgeon Controlled Factors).

There appears to be a universal problem with the process of head impaction unto the Trunnion and the engagement of the taper interface that dooms the trunnion to failure.

We asked the question whether *surgeon's technique* can stop micro motion, fretting, MACC and Trunnionosis?

Surgeon-controlled factors include Assembly force magnitude, alignment, and environmental factors.

Many studies have shown *assembly force* to be the most significant factor affecting fretting and corrosion.

Increased assembly load produces the strongest interlock, improves seal, produces the greatest resistance to micro motion, and prevents local fretting and corrosion.

Best practices recommend 4000N of assembly force in a clean environment to obtain 2000N of pull-off force. Typically, a surgeon may apply up to 1000N of force which may amount to 500N of force due to damping. A light tap is ≈ 1000N and a heavy tap ≈ 4000N. Can surgeons produce in the OR what engineers recommend in the Lab with servo hydraulic testing machines?

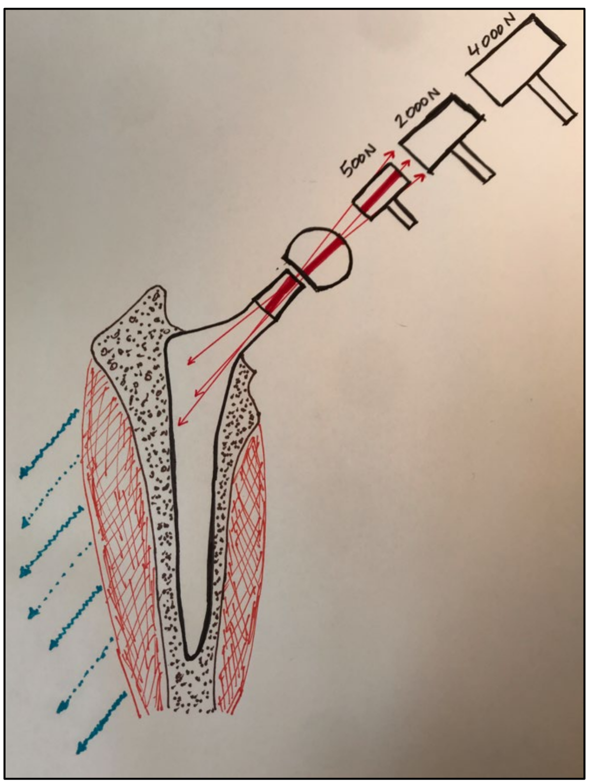
Generally, surgeons are unwilling to produce large assembly forces of 4000N for fear of fracture.

Currently there is no good method available to the surgeon to optimally assemble a Morse-taper.

We asked the question: how can we standardize the process of modular taper assembly to eliminate the scrouge of metal debris, trunnionosis and adverse local tissue reactions?

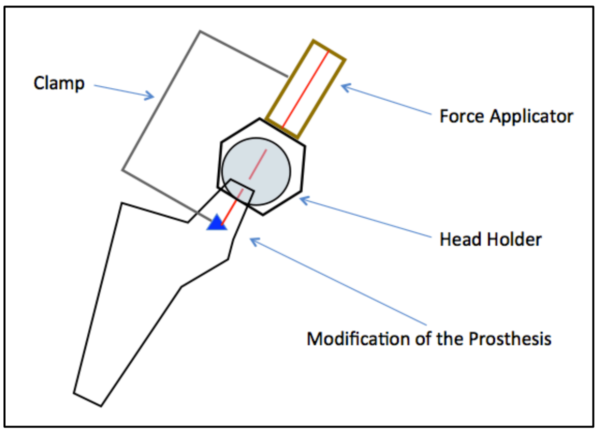
We have identified three deficiencies in the current taper assembly technique:

1. The magnitude of Force is uncontrolled (cannot quantify or modulate).
2. The direction of Force is uncontrolled (the axis of the mallet, head and trunnion are not aligned), which leads to canting and poor interlock.
3. The system is unconstrained, which produces significant damping and compliance (requiring 50% more force than otherwise required for proper interlock).



To solve these problems, we recommend four adaptations to address these deficiencies and to create Standardization of Taper Interlock Assembly:

1. A force applicator
2. Head Holder
3. Clamp
4. Modification of the Prosthesis (docking for clamp)

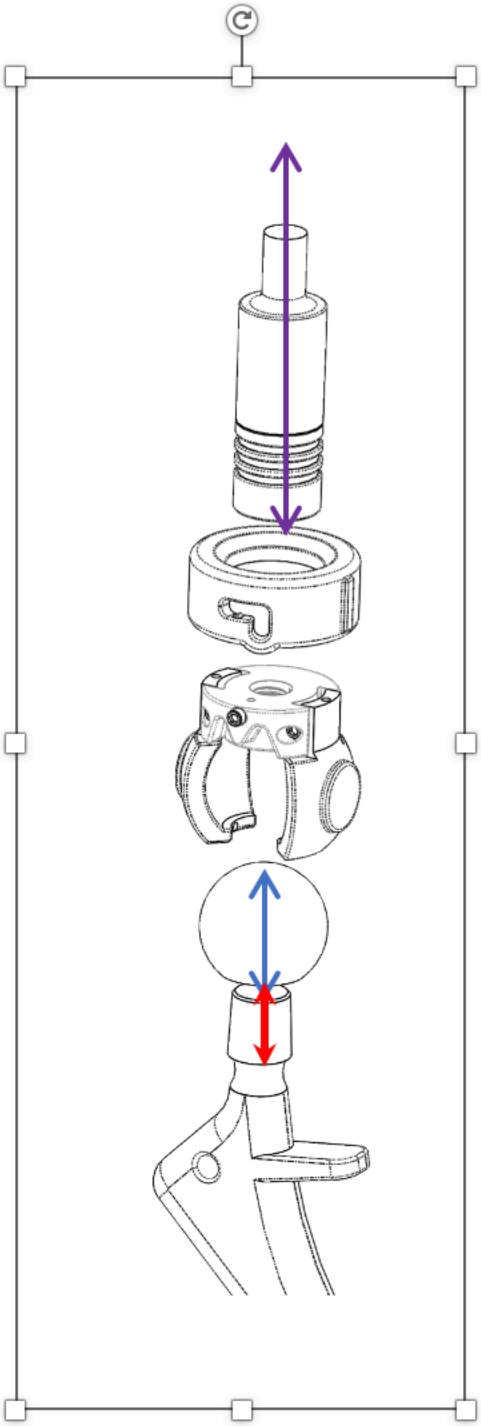


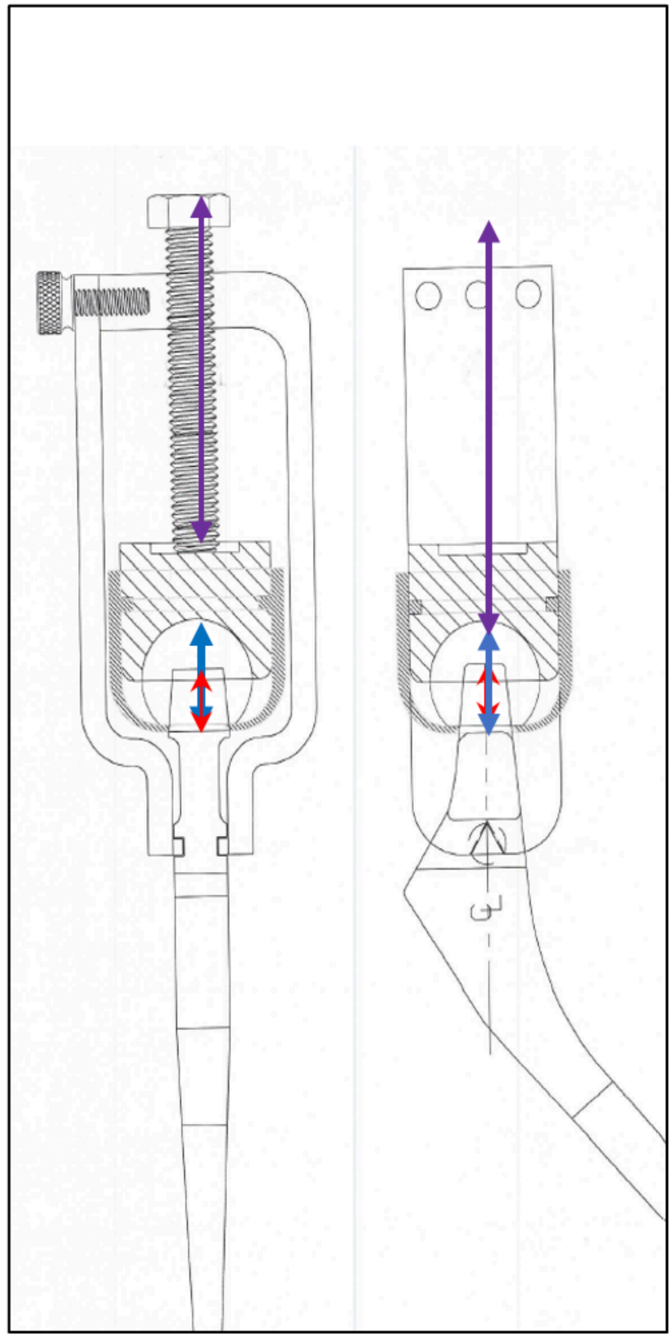
The force applicator applies force in a controlled and quantifiable fashion. The head holder grasps the head on its flat surface and defines the central axis of the head and attaches to the force applicator in normal alignment. The clamp attaches the force applicator to the prosthesis in normal alignment, *such that the axis of the force applicator, the head and the trunnion are perfectly co-linear.*

In summary this system corrects the three deficiencies.

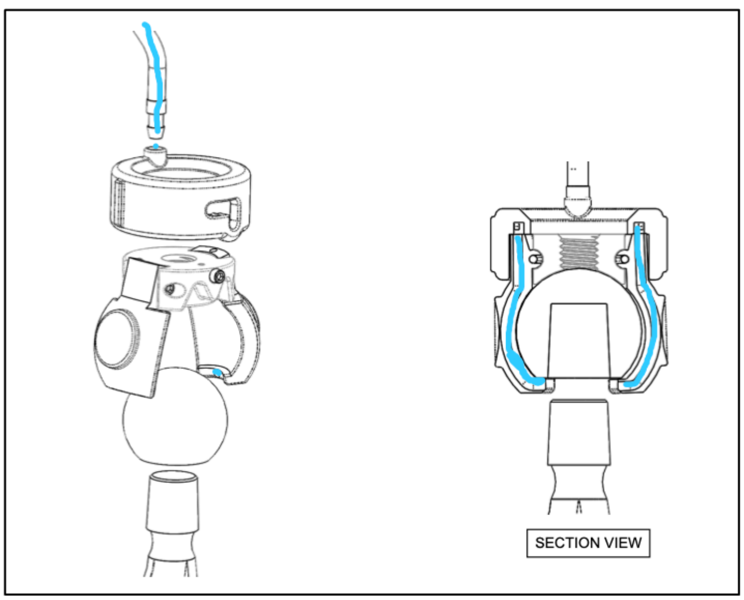
1. Application of force is constrained with no damping.
2. The axis of force, head and trunnion are ALL perfectly aligned.
3. And the magnitude of force is controlled and quantified.

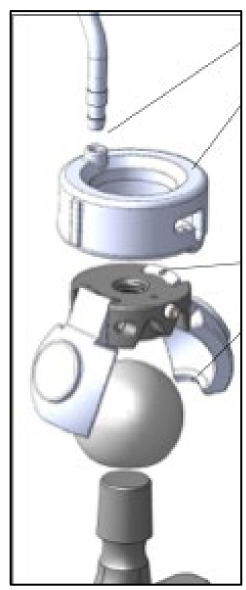
Define Axes → Align and Lock



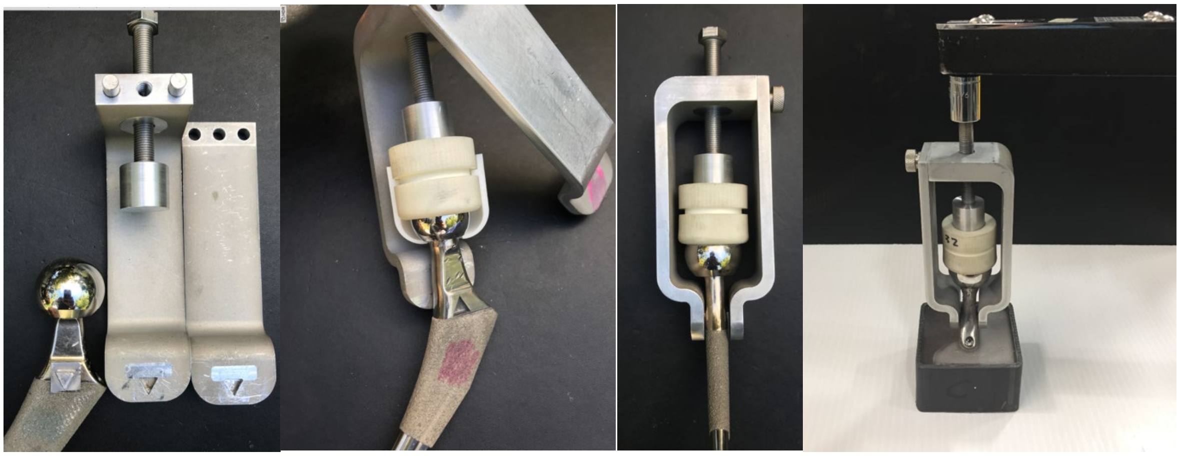


In addition, the environment is kept clean by addition of a ventilation system that allows dispersion of air at the head trunnion interface to keep the interface dry and contaminant free.

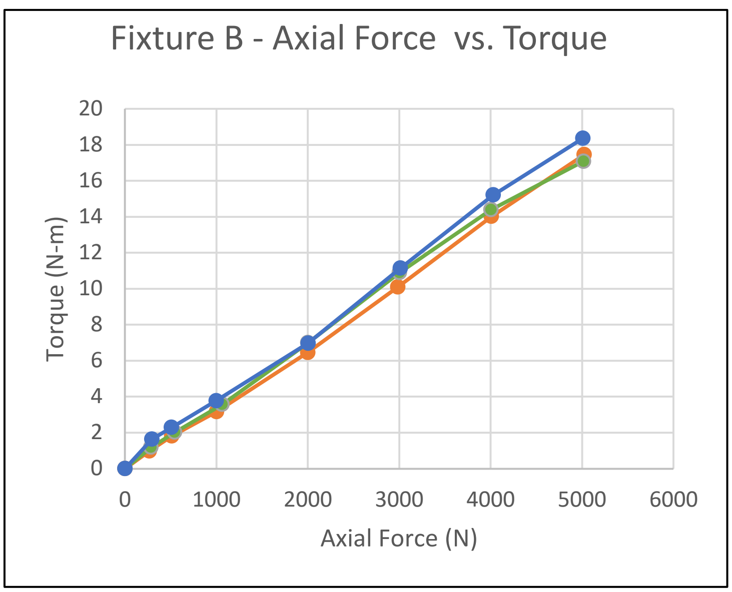




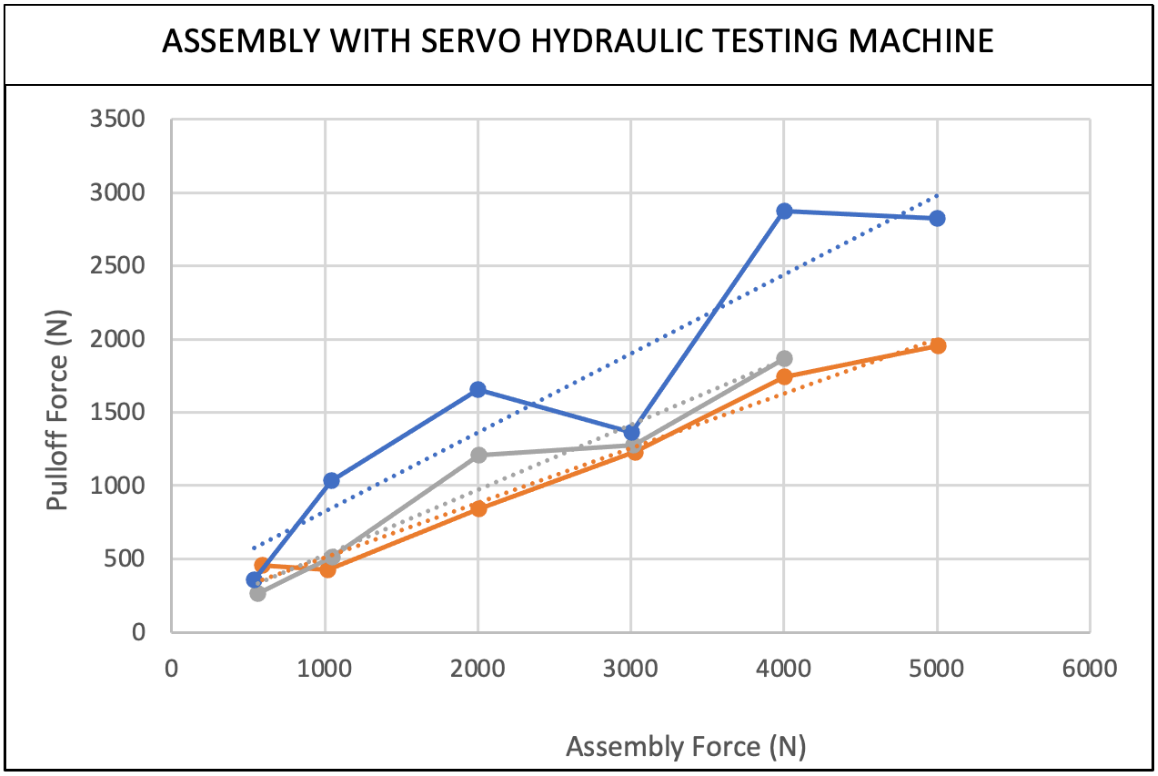
We developed several <u>Torsional Prototypes</u> which incorporate the four adaptations for proof of concept.

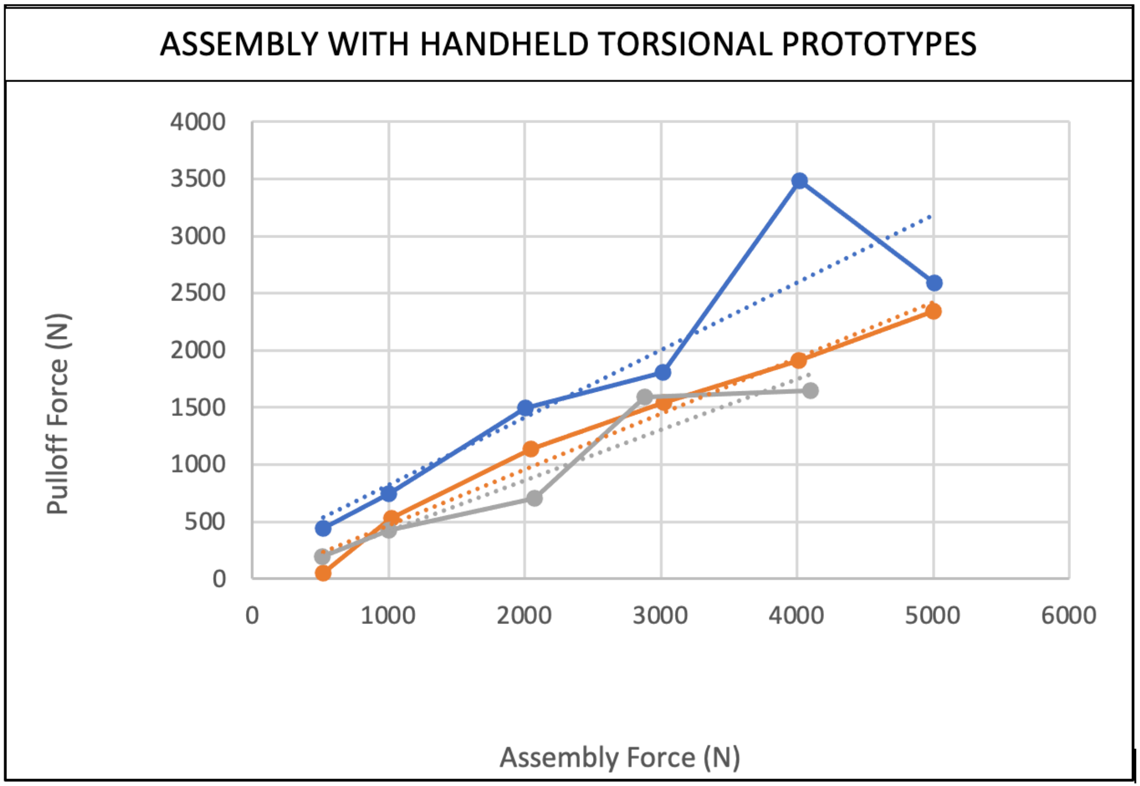


The relationship between Torque and axial loads is linear and easily calibrated.



Our results show that *Torsional prototypes* can produce high assembly forces of up to 5000N in reproducible fashion, like forces produced by *servo hydraulic testing machines*.


ASSEMBLY WITH SERVO HYDRAULIC TESTING MACHINE
3500
3000
2500
2000
1500
1000
500
0
Pulloff Force (N)
0
1000
2000
3000
4000
5000
6000
Assembly Force (N)



As there is a linear relationship between assembly load and pull off load, these tools can produce a *cold weld* and perfect interlock with pull-off forces of greater than 2000N for any combination of mixed alloy components, eliminating micro motion, taper corrosion and Trunnionosis in total hip arthroplasty.

Finally, our current research indicates that optimal taper assembly could be achieved with even less force by superimposition of ultrasonic vibrations on the force applicator. This technique could allow us to achieve 2000N pull off force with less than 300N of assembly force.

Once a such a system is developed, a **formulary** of *force vs. cold weld* can be created *for mixed alloy tapers and different designs.* So, a perfect taper interlock can be obtained regardless of design or materials.