

Project Description

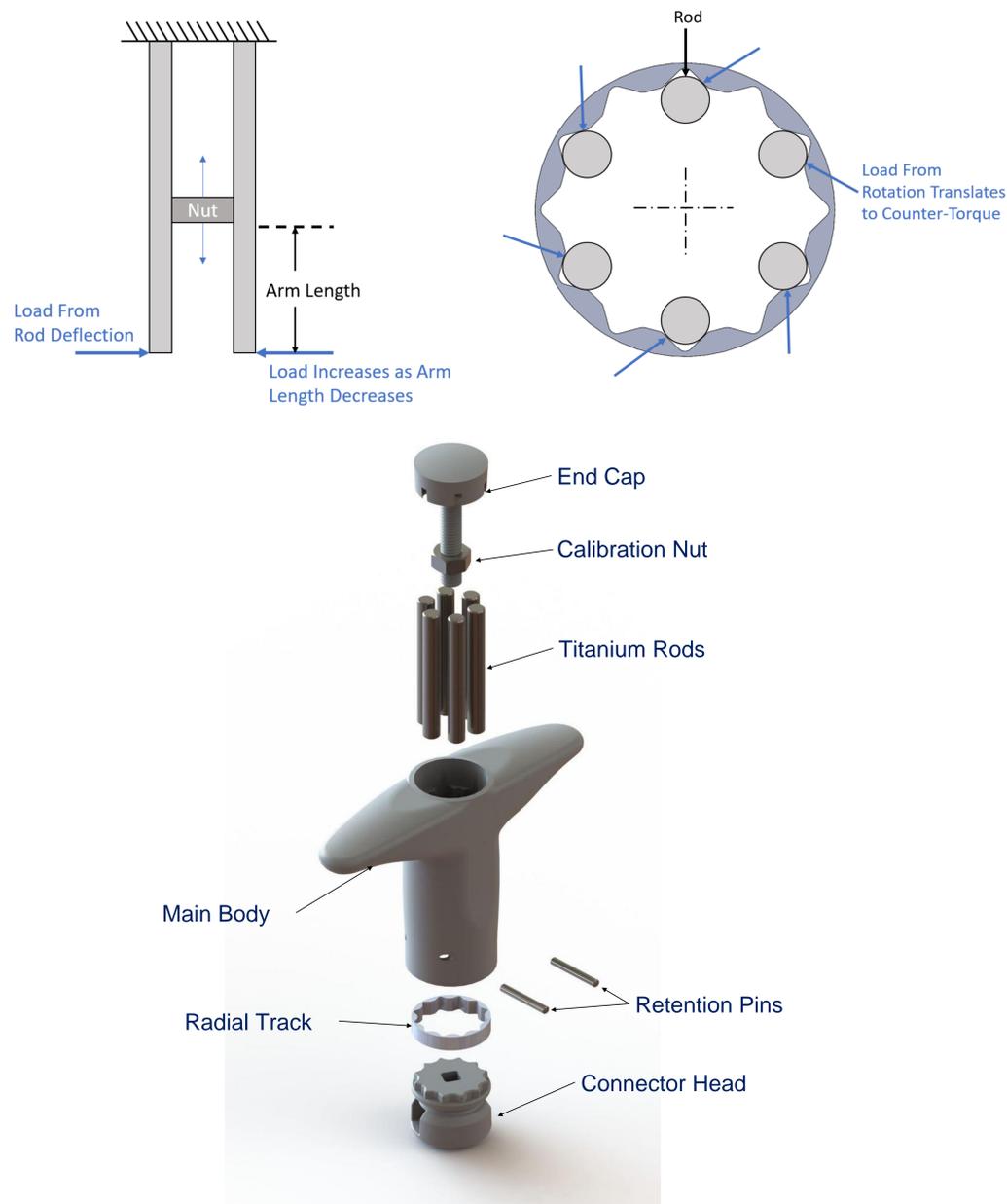
Single-use, surgical tooling is becoming increasingly popular. Some surgical procedures require the use of a torque limiting driver for consistent, and reliable installation of fasteners. There are only a handful of companies currently producing single-use drivers and they are relatively expensive.

Problem: Design and develop a disposable single procedure, torque limiting driver of equal or greater quality and reliability than competitors.

Constraints: 20-40 repeatable torque applications, easy to manufacture, 0.5 - 14 N-m torque range.

Design Description

- Generates torque by deflecting titanium rods inside a rotary track.
- Drivers are calibrated to customer specified torque using a standard nut.
- By decreasing the Arm length, the force of deflection increases thus increasing the torque output.
- All designs can use a 2, 3, or 6 rod configuration. More rods equals more torque.
- Handles are designed to support shafts using the AO quick connect or the 1/4" square quick connect ends.
- Three different body styles allow for comfortable use at different torque ranges.
- Injection Molded body lowers cost per unit.
- Use of common parts limits molds needed.
- Body can be customized to customer requests.
- Uses off shelf components to reduce cost.



Performance Review

- Several rounds of prototyping and testing were performed to prove the repeatability of torque applications for up to 40 clicks, torque range of the drivers, and calibration nut placement.

Requirement	Target	Thresholds	Actual Performance
Torque Variance (%)	10	15	8
Repeatable Results of Torque Application (Clicks)	40	20	40+
Assembly Steps (Steps)	4	12	10
Part Count (# of Parts)	5	15	11
Device Cost (\$)	20	50	31.27
Weight of Device (kg)	0.5	1.5	0.2
Material Sterilization Effects (%)	1	5	*
Material Aging Effects (%)	1	5	*
Axial Force Effects (%)	1	5	**
Torque Range (N-m)	0.5-14	1-12	0.5-14
Moldability (Pull Count)	1	5	4
Mold Cost (\$)	80000	150000	~297000***
Handle Diameter (mm)	20	40	34****

*Materials were selected that are historically resilient against sterilization and aging effects. No testing has currently been performed on these devices. Further validation testing is required.

**During torque variability testing, axial forces were changed and seemed to have no effect on the result. Further testing is required that isolates the effects of axial forces.

***Initial threshold was set with only once configuration (the Axial Handle) and a basic quote from one vendor. Adding two more configurations increased mold cost drastically. To reduce mold cost, handle configurations can be optimized and work with multiple vendors for quotes.

****Diameter is only applicable to the Axial Handle configuration; T-Handle and D-Handle are exempt.



Conclusion

- The concept is proven to be able to reach the torque range of 0.5-14 N-m and perform repeatable torques up to 40 clicks.
- Lessons Learned:
 - 14 N-m is unachievable for a human with an axial handle; therefore, T and D-Handle configurations are required.
 - The plastic in the connector head is not strong enough to last for 30 "clicks" at the 14 N-m range. Further development and testing is required for the D-Handle.
- Next Steps:
 - Continue qualification testing of all torque ranges.
 - Develop calibration table for calibration nut placement.
 - Purchase molds and test production parts.
 - Perform all testing required for 510K submission to FDA (verification, validation, aging, biocompatibility, etc).
 - Submit for FDA clearance.