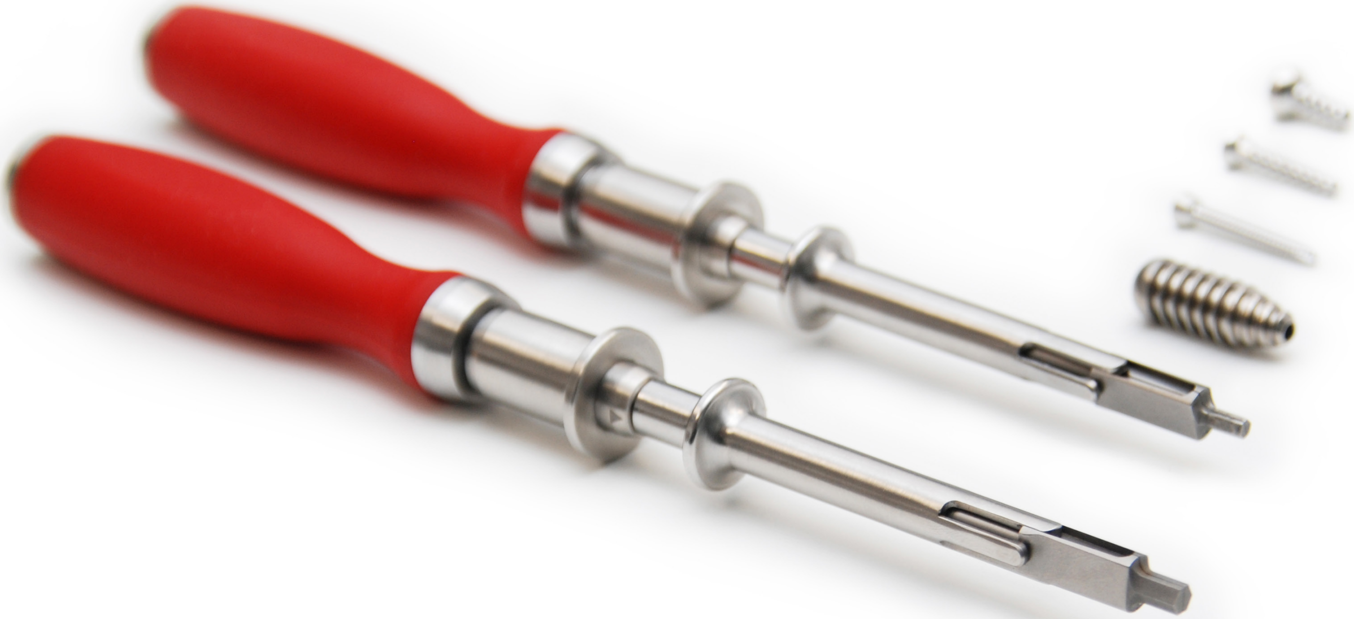
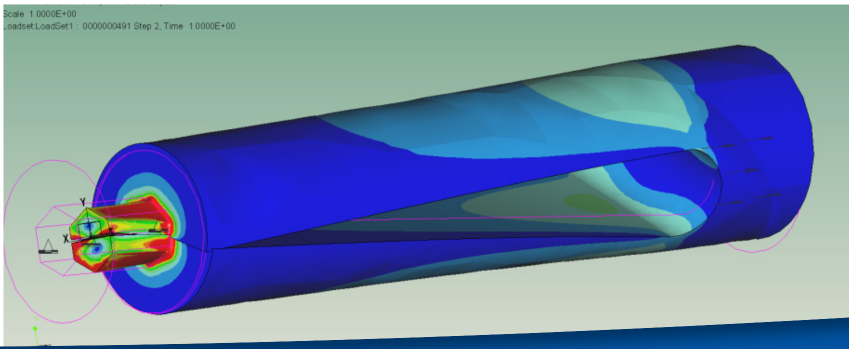
MEDICAL AMRC

The University Of Sheffield.
Advanced Manufacturing Research Centre
BOEING

Case Study
Harvard Healthcare

Orthopaedic Surgical Screwdrivers





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The Product

The Medical AMRC has successfully completed a commission from sports injury, trauma and orthopaedic products specialist Harvard Healthcare to design and develop a range of innovative orthopaedic screwdrivers for use in operating theatres.

The screwdrivers had to retain screws securely until they were anchored in place, offering an easy to use alternative for surgeons who currently employ a variety of devices to retain screws, which tend to be overly complex, difficult to use and hard to manufacture.

The initial brief was to develop a range with interchangeable shafts for fixing 1.5, 2.5 and 3.5 mm screws with hexagonal heads. Practical and theoretical studies resulted in a decision to develop a separate design to enhance the capabilities of the 1.5mm device in order to achieve the torque specified in the British BS 3531-5.1-1997 standard covering devices used to tighten orthopaedic screws.

The pre-production prototype consists of three parts – a sleeve, shaft and handle - manufactured from different grades of stainless steel to ensure resistance to corrosion and ease of disassembly to allow sterilisation.

The sleeve and shaft are made from a 17-4 ph and 440c stainless steel respectively, while the handle was purchased from a third party. The shaft is attached to the handle using an AO coupling – a universal coupling used for a range of orthopaedic instruments. Because users have been known to accidentally release the coupling when trying to lock it, the coupling on the prototype was adapted by a third party to reverse the unlock function.

Disassembled screwdriver.

The screwdriver design makes use of frictional principles. The tip of the shaft has a slot, created by Electrical Discharge Machining (EDM) using a 250 micron filament - an extremely accurate process with a tolerance of 10 microns for a given slot. The size and accuracy of the slot geometry was determined through significant research and practical examination and the results were then fed back into the tolerances assigned to other features.

Sleeve working in conjunction with driver.

EDM machined slot down proportion of driver part.

The slot is a fundamental part of the screwdriver's functionality. When it is closed, the dimension across the flats conforms to values specified in BS 3531-5.1-1997. For example on a 3.5mm product the flats will fall within a tolerance band of 3.485 ± 0.015 when the slot is closed.

When the sleeve is moved down the shaft towards the tip of the screwdriver, the two halves of the slot are pushed apart to create the required mechanical fixation between the shaft and the screw. The spring-like characteristics of the tip geometry creates static friction (stiction) between the head of the shaft and screw. Stiction also occurs where the tapered end of the sleeve meets the shaft and, following the principles of a Morse taper, the device will never release under its own loading conditions due to this stiction.

Testing

Testing was extremely important to determine the strength of the screwdriver because the presence of the slot significantly increases stress concentration at a given load.

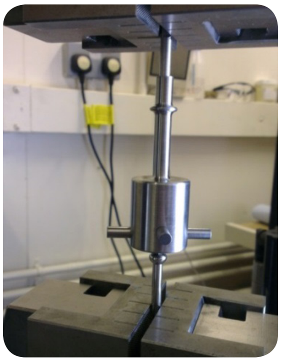
Testing samples to determine achievable torque for each size.

A range of samples was tested to determine the best combination of geometry and material. Following these extensive tests, we decided a different design should be used for the 1.5mm version. A series of theoretical and practical tests was carried out to help understand the issues and optimise the solution.

FEA simulations on simplified geometry revealed the stress distribution around the most vulnerable areas of the device. These results were combined with practical examination to create a holistic overview of performance and demonstrate whether the screwdrivers could achieve the required standards.

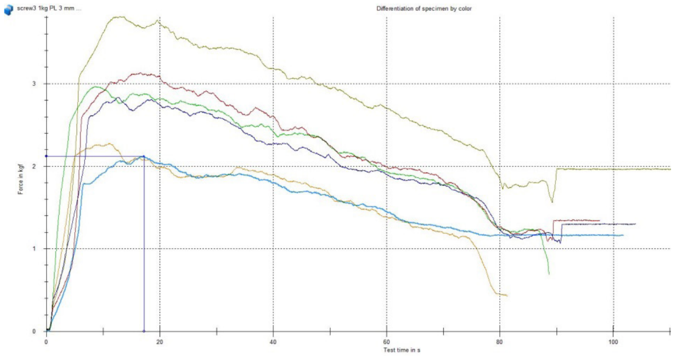
Three samples of each size were tested to their corresponding maximum torque specified in BS 3531-5.1-1997. Four batches were tested using different materials with varying Ultimate Tensile Strength (UTS) characteristics, to determine the optimum material for the component.

Once the torque testing was complete, researchers were able to understand the relationship between the actuation force exerted by the user pushing the sleeve towards the tip of the screwdriver and the resulting pull-off load – the load at which the retaining mechanism ceases to hold the screw. Thanks to the Morse taper-like mechanism, the pull-off load increases with further sleeve actuation. Discussions with Harvard Healthcare and their clinical contacts revealed that a 2Kg minimum pull-off force would be sufficient in use.

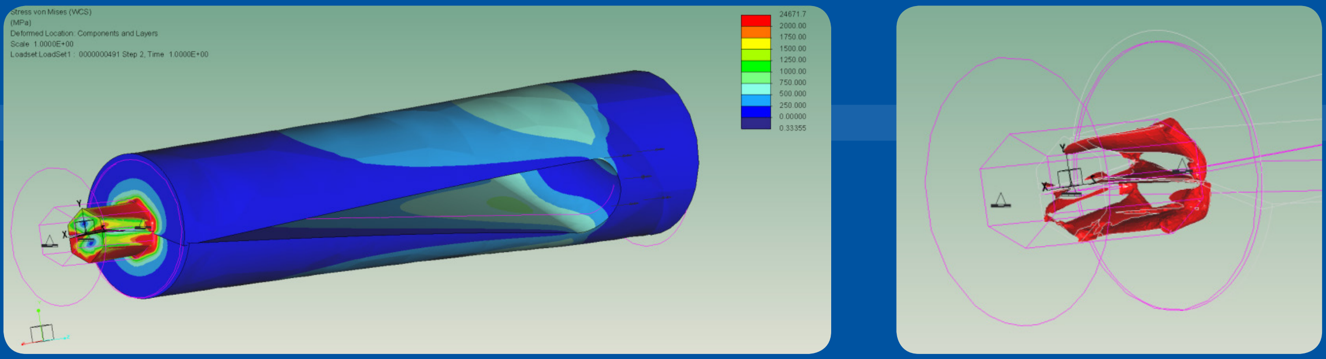


Sample being tested.

Test rig.



Graph showing pull off force vs actuation.



FEA (Finite Element Analysis) carried out to determine stress concentrations across the range at different torque values.

Geometry

Creating the driver and sleeve geometry was extremely challenging, especially as some manufacturing processed were being pushed to the limit when it came to meeting the specified tolerances.

The incorporation of the slot caused internal stress, strength and geometric stability issues. The tolerance specified by the British Standard is relatively tight at 48 microns across the hexagonal flats but is achievable using existing machining technology. The integration of the slot resulted in an even tighter tolerance across the hexagonal flats due to the associated tolerance applied to the gap. This part of the project was extremely challenging as the Medical AMRC needed to work at the limits of machine capabilities whilst understanding the correct processes and the relationship between part geometries. The Medical AMRC worked in collaboration with Sheffield Precision Medical to determine the correct operating procedures to optimise the manufacturing process.

Conclusion

Harvard Healthcare was extremely pleased with the outcome of the project and the novelty, functionality and simplicity of the product developed by the Medical AMRC. The product works better than any competitor product, yet costs less to manufacture because it requires fewer parts and is far less complex. A patent application has been filed for the device and confidence is high that it will be extremely popular and find applications beyond the medical sector, in other industries.

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