Template

PROJECT FINAL REPORT

Grant Agreement number: 286888

Project acronym: CLEANTOOLS

Project title: *Crevice-free, high reliability bi-metallic surgical instruments manufactured from shape memory alloys*

Funding Scheme: FP7

Period covered: from 1 to 27

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Project website Error! Bookmark not defined. **address:** http://www.cleantools.de/

[1] Usually the contact person of the coordinator as specified in Art. 8.1. of the Grant Agreement.

4.1 Final publishable summary report

This section must be of suitable quality to enable direct publication by the Commission and should preferably not exceed 40 pages. This report should address a wide audience, including the general public.

The publishable summary has to include **5 distinct parts** described below:

- An executive summary (not exceeding 1 page).
- A summary description of project context and objectives (not exceeding 4 pages).
- A description of the main S&T results/foregrounds (not exceeding 25 pages),
- The potential impact (including the socio-economic impact and the wider societal implications of the project so far) and the main dissemination activities and exploitation of results (not exceeding 10 pages).
- The address of the project public website, if applicable as well as relevant contact details.

Executive Summary

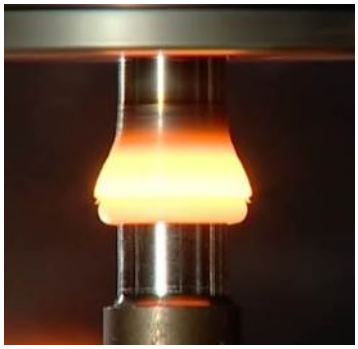
CleanTools (286888): Crevice-free, high reliability bi-metallic surgical instruments manufactured from shape memory alloys

The members of the European funded FP7 project consortium for CleanTools are delighted to announce the development of a novel **rotary friction welding** methodology to join Nitinol, a metal alloy of nickel and titanium, to stainless steel using a **biocompatible interlayer**. This pioneering technology will dramatically improve the manufacture and usability of **medical devices** that have previously needed mechanical joints or coupling.

This innovative project has enabled the development of rotary friction welding parameters that provide tripartite joints, ideally suited for use in medical instruments such as **intramedullary reamers**. Traditional methods have used double wound shafts and mechanical joints which have been difficult and expensive to clean and sterilise. However, the use of shape-memory alloy Nitinol for the shaft provides sufficient elasticity to allow the rotating tool to be used in curved bone. It produces crevice free, highly reliable, bi-metallic surgical instruments, instantly removing the need for mechanical joints in this type of medical device. This means cleaning, disinfecting and sterilising is easier, more efficient and more reliable, which in turn reduces the risk of cross infection between patients. Approximately 7000 cases of MRSA infections were reported in UK hospitals during 2007 and similar issues are prevalent across Europe. Such infections are of particular concern in post-surgery patients.

Rotary friction welding is a solid phase process, where no melting takes place. The simplest mechanical arrangement for continuous-drive rotary friction welding involves two cylindrical bars held in axial alignment. One of the bars is rotated while the other is advanced into contact under a pre-selected axial pressure (see illustration). Rotation continues for a specific time, sufficient for achieving the temperature at which metal in the joint zone is in the plastic state. Having achieved this condition, the rotating bar is stopped while the pressure is either maintained or increased to consolidate the joint.

The project consortium is confident that this novel welding methodology will be brought to market quickly and successfully, and is currently assessing potential partners for the commercialisation of the technology. For more information please visit the project website www.cleantools.de



Project Context and Objectives

Flexible medical instruments such as bone reamers are currently constructed from reusable component parts. These component parts are commonly manufactured from dissimilar metallic materials with very different compositions and properties through the use mechanical couplings and fasteners. The materials involved such as Shape Memory Alloys (SMAs) and stainless steels are challenging to fusion weld and their properties are severely degraded when they are melted during conventional welding.

Effective decontamination of medical instruments is critical to avoid cross infection between patients. The current approach to instrument assembly (particularly bone reamers and similar tools used in preparation of bone for joint replacement implants) produces a crevice in the region between the stainless steel cutting head and the SMA flexible shaft. This crevice makes decontamination very challenging, time consuming and chemically intensive. The crevice area is also of concern with respect to tool fatigue performance and there have been instances of cutting heads becoming detached from the flexible drive shaft during use, (causing serious implications in theatre and potential long term impacts on patient quality of life).

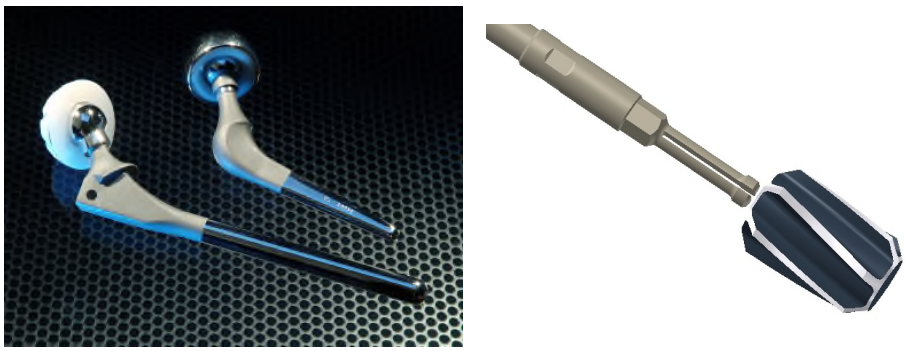


Figure 1 Replacement hip joints and a typical click-fit bone reamer instrument.

In 2007 there were 399,000 total primary hip replacements in the US and 385,550 in Europe (1). In the same year there were 79,800 revision operations (corrective procedure following initial surgery) in the US and 50,410 in Europe. In 2007, 70% of all hip replacements in Europe were primary total hip replacements, while 13% were revision procedures, (the remainder being partial replacements). Growth in partial and revision procedures undertaken is expected in the future as patient demand for these procedures increases, due primarily to our ageing population.

Approximately 7000 cases of MRSA infections of the blood were reported in UK hospitals during 2007 (2) and similar issues are prevalent across Europe. MRSA infections are of particular concern in post surgery patients. The CleanTools project aims to develop technology which will reduce this issue by making surgical instruments easier to fully clean and disinfect.

In addition to infection issues 209 ‘Foreign objects’ were left behind in patients after surgery during 2009 (3). The technology to be developed by the CleanTools project will reduce the likelihood of instrument cutting heads disengaging during use inside the body.

The CleanTools project has developed and proven a methodology and procedure for the manufacture of innovative, easy to clean and reliable, bi-metallic flexible surgical instruments containing SMA materials though the use of rotary friction welding (RFW) as an enabling technology. The outcomes of the CleanTools project will improve the function of flexible surgical instruments, reduce the required cleaning and disinfection effort, improve reliability and reduce cost of manufacture.

Rotary Friction Welding (RFW) is the only joining method available which has shown promise for effectively joining advanced SMA materials to one another and to stainless steels. There are however challenging technical barriers which must be overcome before the process can be used by industry. RFW is a low heat input process which minimises modification to the SMA microstructure and hence ensures that the advanced material’s properties are maintained. As RFW is a solid phase technology it minimises the formation of brittle

microstructural phases at the joint line (which are formed by most other welding techniques and can lead to premature failure during service).

Benefits, in terms of surgical tooling assembly, which will come about through delivery of the CleanTools project include:

- Reduced instances of cross infection as instruments will be crevice free.
- Reduced instrument cleaning and disinfection time giving an associated increase in medical staff availability for patient care.
- Reduction in chemical usage and cleaning costs.
- Removal of crevices in surgical tooling associated with mechanical couplings and fasteners.
- Reduced cost and improved quality of manufacture for flexible medical instruments containing bi-metallic joints including SMAs through the use of RFW.

Development of RFW parameters and dynamics to provide high quality joints which maintain near original material properties will be required to enable European companies to compete with current manufacturing methods dominated by large providers predominantly based in the USA. While RFW has shown great promise for these applications there are significant welding, material science and medical validation activities required to deliver the CleanTools methodology and procedures.

In order to develop the CleanTools approach to surgical instrument manufacture the following technical barriers must first be addressed:

- There are a wide range of potential materials which could be used as the RFW enabling interlayer material. The most appropriate for use as a bio-compatible interlayer are not currently known. A number of bio-compatible and RFW enabling interlayer alloy materials will be identified.
- RFW procedures and parameters do not currently exist for creating high performance joints between SMAs and stainless steel. Using the above range of potential interlayer materials, extensive welding trials based on scientific understanding of materials weldability will be undertaken.
- The static and dynamic mechanical and metallurgical performance of the RFW joints is not fully characterised at this time. Laboratory testing must be carried out to overcome this barrier.
- The viability of surgical use must be proven prior to commercialisation through evaluation of instrument durability and pre-clinical trials.

As a result of addressing these technical barriers the key outputs of the project will be:

- Identify, characterise and rank potential RFW interlayer materials in terms of bio-compatibility, cost (which should be equal to or less than current Nitiniol SMA value - currently 330 Euro per kilogram) and availability.
- Develop RFW welding procedures and parameters for joining round bar SMA to stainless steel each having a round cross section in the range 13mm2 to 200mm2 using the optimum identified interlayer material, as required, and achieving a joint strength and ductility equal to at least 95% of the weaker parent material.
- Develop support procedures for immediate post processing of the RFW joints to remove weld flash and forge upset.
- Characterise the joints produced in terms of static (tensile, bend and torsion) and dynamic (fatigue) performance to ensure that they are equal to at least 95% of the lower performance parent material in all cases.
- Characterise the SMA performance and metallographic appearance following welding to establish any reduction in percentage terms from the parent SMA performance (response to temperature change and super elastic properties). At most a reduction of 5% is targeted.
- To manufacture a series of 3 prototype surgical instruments based on bone reaming operations for pre-clinical validation testing (see below). It is anticipated that the ultimate selling price of this product will be between 800-1200 Euro/instrument.
- To establish the viability of the CleanTools manufacturing procedure for use in surgical instruments, the prototypes will be subjected to ASTM specification pre-clinical testing.

Main Results

The CleanTools projects developed a novel method to join Nitinol to stainless steel using a biocompatible interlayer. This report describes the work and main results achieved by the consortium partners. The description of the main results follows the progress of the project.

Service Requirement Definition

The initial work of the CleanTools project focused on the definition of the service requirements for the targeted surgical instruments to guide the selection of suitable materials and define the requirements for the weld properties. The consortium reviewed the technical requirements as well as the legislative requirements governing the selection and use of materials for surgical instruments. Key to this analysis was a review of The Medical Device Directive (93/42/EEC) highlighting key requirements such as:

- Classification of instruments
- Supplier registration or registration of products via a Notified Body (CE Marking)
- Safety requirements
- Administrative requirements
- Conformity assessment
- Vigilance procedures
- Enforcement

Additionally, the requirements related to Cleaning and Sterilisation Regulations, as located in Annex D of the European Harmonised Standard 17665-1 were reviewed in detail to understand the requirements placed on Medical Devices.

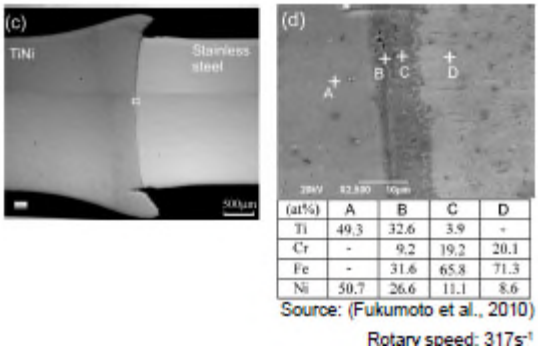
The results of the definition of the service requirements for the targeted surgical instrument resulted in defining that the target instrument as a Class 1 or Class 2b instrument requiring particular attention to the safety of the design, minimisation of the risks from contamination, the minimisation of infection and microbial contamination, adequate product marking and user instructions.

The review of the Cleaning and Sterilisation Regulations defined the requirement for sterilisation which were for steam sterilisation. That is the exposure of the instrument to saturated steam at 134°C for a period of at least 3 minutes, in the total absence of air.

These results were used to define the testing parameters of the prototype instruments to be made as part of the CleanTools project.

Material Selection

The key technical difficulty to overcome by the CleanTools project was the formation of brittle intermetallic phases during the rotary friction welding of Nitinol directly to stainless steel. The formation of brittle intermetallic phases during the welding process degrades joining strength as described by Fukumoto et al. 2010



(at%)	A	B	C	D
Ti	49.3	32.6	3.9	-
Cr	-	9.2	19.2	20.1
Fe	-	31.6	65.8	71.3
Ni	50.7	26.6	11.1	8.6

Source: (Fukumoto et al., 2010)

Rotary speed: 317s^{-1}

Figure 1: Brittle Intermetallic Phases between Nitinol and stainless steels

To overcome this issue, the CleanTools project suggested using an interlayer between the Nitinol and stainless steel to overcome the formation of the brittle intermetallics. The selection of the interlayer material was driven by the following demands on the interlayer material:

- Prevention of intermetallic phases
- Similar mechanical properties to Nitinol and stainless steel
- Related thermal properties
- Biocompatibility
- Weld ability with rotary friction welding
- Availability and price

A number of suitable materials were identified, categorised and assessed for suitability for use within rotary friction welding of Nitinol and stainless steel. The initial long list of suitable materials was quickly reduced to a small number primarily because of the biocompatibility requirement for the material.

The results of the assessment of interlayer material characterisation resulted in the selection of an interlayer for rotary friction welding trials.

Welding Trials

Having selected the appropriate materials, welding trials were undertaken at TWI, Cambridge, UK to establish the preliminary rotary friction welding parameters required to achieve joint strength and ductility equal to at least 95% of the weakest parent material.

The welding procedure and parameter trials assessed a number of different parameters including, but not limited to, different surface preparation, touch-down, friction, forge stage pressures, rotational speed and halt rate, carriage advance rate, etc.

The trial welds were subjected to a number of tests to ascertain whether the welding parameters achieved the required weld strength. The testing undertaken included tensile testing, bend testing, fatigue testing, hardness testing and metallographic examination. These tests were carried out within TWI's lab in Cambridge. Additional metallurgical evaluation was carried out by Fraunhofer IWm in Freiburg, Germany.

Over 150 rotary friction welds were undertaken to produce the samples used throughout the CleanTools project. The initial milestone was to achieve ten consecutive welds of required strength. The process to make the Nitinol to Stainless steel weld using an interlayer material followed the same basic procedure. Firstly, all items were prepared for the welding trial. Secondly, the Nitinol was welded to the interlayer material. Thirdly, this weld was then prepared for further welding by removing flash and preparing the interlayer material for welding. Fourthly, the stainless steel was welded to the interlayer material. The final step in the process was to remove any flash material and prepare the sample welds for testing.

Flash removal was undertaken using industry standard tools and procedures.

Figure 2: Typical interlayer to Nitinol welds prior to preparation for further welding

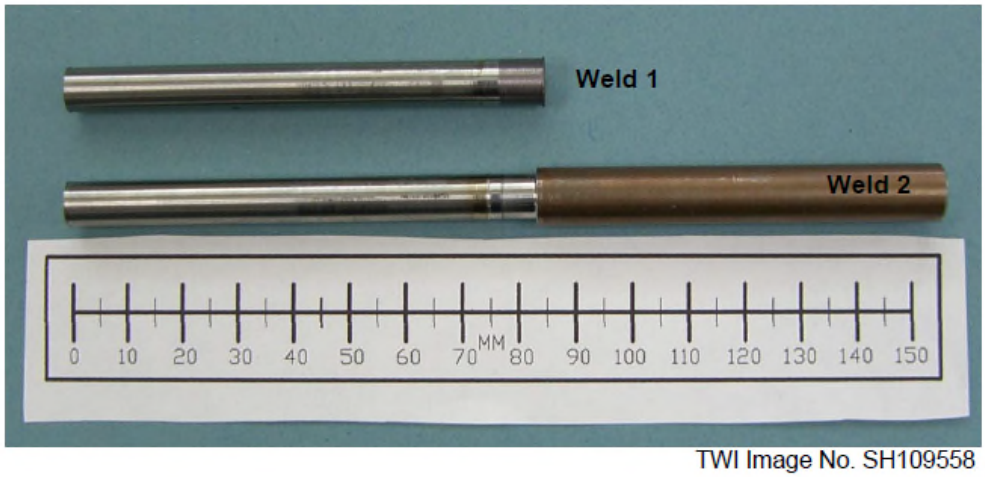


Figure 3: Details of welds following flash removal.
Weld 1 Nitinol to Interlayer Material. Weld 2 Nitinol/Interlayer/Stainless Steel

Figure 4: Fully machined TWI Test House tensile test sample (TWI Image)

During the development of the welding procedures and parameters it was noted that a reduction in weld area of the material may improve the quality of the joint by providing a more even thickness of interlayer. This theory was tested in a number of welds and was found to increase weld strength significantly. The difference between the interlayer thickness is shown in Figures 5 and 6 below. All subsequent welds were undertaken with tapered weld surfaces to improve the quality of the welds.

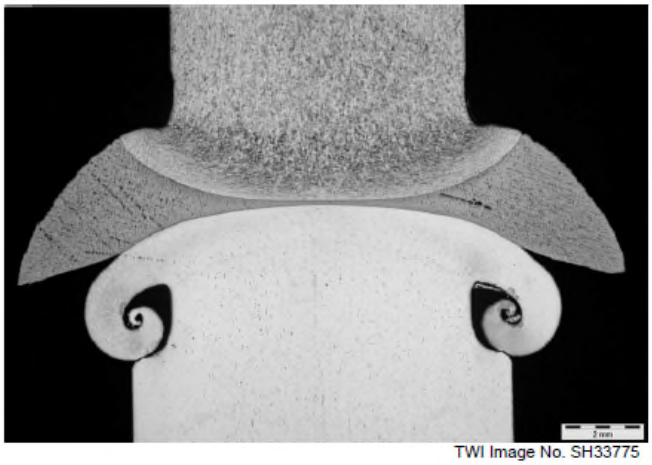


Figure 5: Typical cross section of a Nitinol to 17-4PH stainless steel weld utilising an interlayer. Note the limited interlayer thickness at the centre of the joint

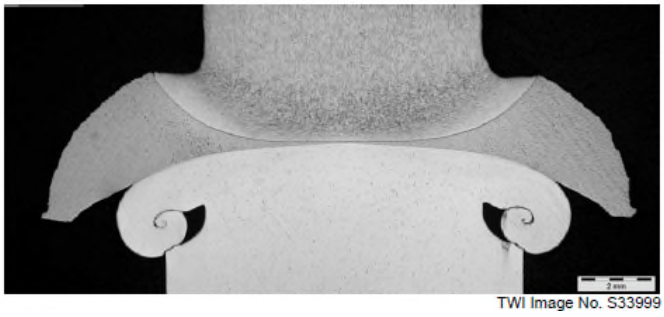


Figure 6: Macrograph of a Nitinol to Stainless Steel weld using an interlayer. This weld was produced with a taper on the stainless steel which produces a larger area for the interlayer, and increased reproducibility

During the welding parameter and procedure trials it was also noted that the quality and source of the interlayer material was critical to the reproducibility and strength of the achieved welds. A number of experiments on the metallurgical properties of the interlayer material were undertaken. The experiments and the experience of using a number of suppliers of interlayer material suggests that the source of the interlayer material is highly relevant to the success of the welds and that the interlayer material must undergo validation testing prior to use to ensure the material properties meet the requirements of the rotary friction welding procedure.

As a result of welding the mechanical as well as the functional SMA properties might change due to the heat and stress applied during RFW process. Therefore, samples of the welded specimens and also the base material were investigated by Fraunhofer IWM in order to determine the mechanical and functional properties of the welding zone and evaluate the possible impacts of any change in the material behaviour on the functionality and design of the medical instrument in application.

Microstructural Properties:
In order to rule out the existence of any brittle intermetallic Fe2Ti phase in the weld region, x-ray diffraction analysis has been performed at nine positions across the weld. The XRD measurements have shown that brittle Fe2Ti phase does not exist at any of the measured positions in the weld region. Using the low heat impact rotary friction welding process in combination with an interlayer, the formation of any brittle intermetallic phase could successfully be prevented.

Mechanical Properties:
In order to determine the mechanical properties of the joint, tensile tests have been carried out on the parent materials Nitinol and stainless steel (cf. 7) and on the welded joints.

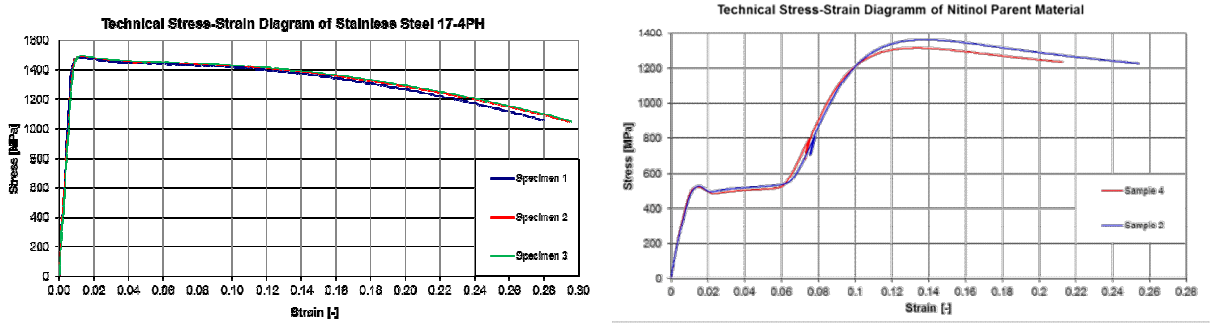


Figure 7: Technical Stress vs. Strain Diagram obtained by Tensile Tests on Stainless Steel 17-4PH (left) and Superelastic Shape Memory Alloy Nitinol (right)

In Nitinol, the pseudo-elastic transformation from austenite to martensite occurs at plateau stress between 480MPa to 530MPa. Beyond 530MPa, after an elastic/pseudo-elastic strain of approx. 6%, plastic deformation of the martensite takes place (cf. Figure). In order to ensure long term stability of the weld, any plastic deformation in any of the three materials should be avoided.

Since the stress distribution in the compound of three materials with the given weld geometry is complex, the local strain distribution has been measured during tensile test, using the optical surface displacement tracking system Aramis®. (cf. 9) From the tensile tests it was observed, that the adjacent Nitinol and steel materials support the narrow interlayer. But large deformations such as the pseudo-elastic deformation in Nitinol induce plastic flow in the interlayer. Due to this supporting effect, the ultimate tensile strength of the weld is more than 700MPa, which is about triple the interlayer material's strength.

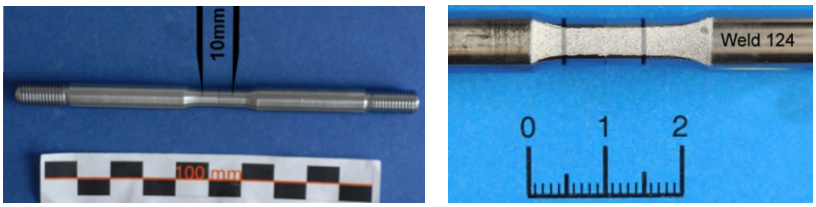


Figure 8: Tensile Test Specimen from Welds for Determination of the Local and Global Mechanical Material Behaviour of the Welded Area

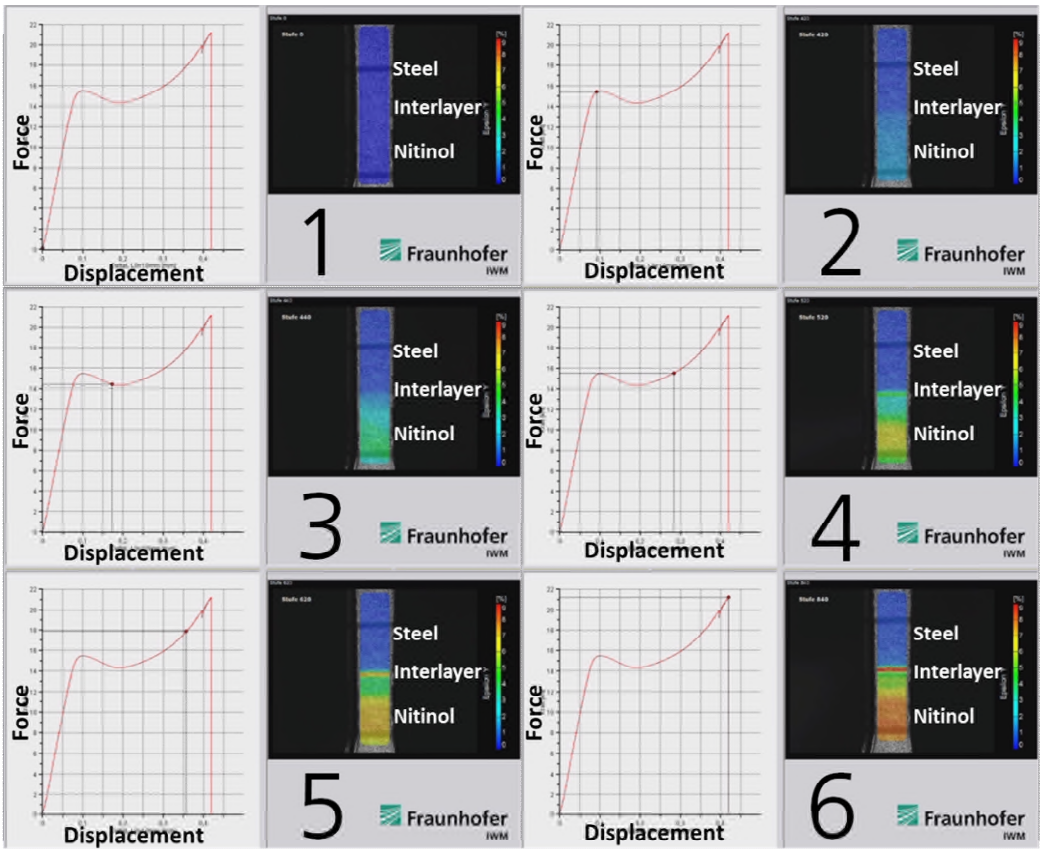


Figure 9: Tensile Test on a Weld Specimen Using the Optical Strain Measurement Technique „Aramis“

Since a surgical reamer has to withstand torsion as well as tension and compression loads in application, torsion tests have been carried out in order to determine the mechanical behaviour for the rotary friction welded joints.

The performed torsion tests have shown that the ø7.8mm specimen deform purely elastically up to an average maximum torque of approx. 30Nm. For torsional load as well as for tensile load, plastic deformation of the interlayer is induced by pseudo-elastic deformation of the adjacent Nitinol. Below the pseudo-elastic plateau stress, no plastic deformation is observed on the weld.

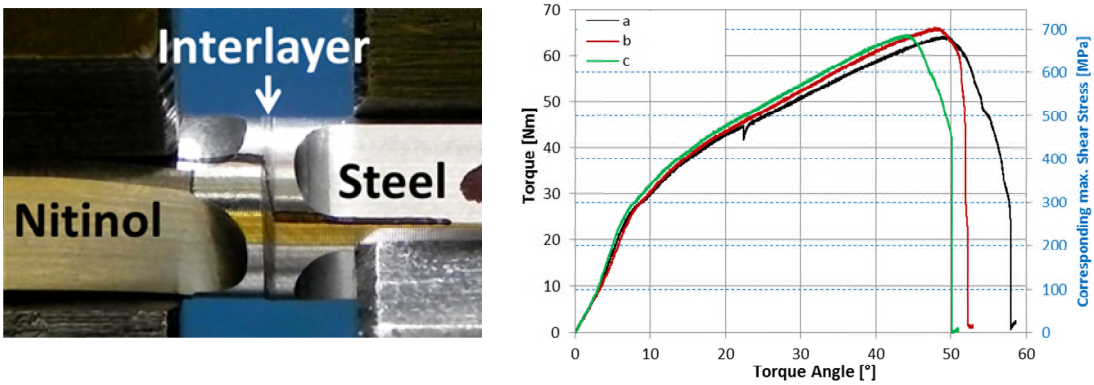


Figure 10: Experimental Setup of a Torsion Test on a Weld Specimen (left) and Torque Diagrams of 3 Torsion Tests (right)

Target strength for the friction welded joint is quoted as 95% of the weakest parent material in the description of work. As the Nitinol and stainless steel parent material ultimate tensile strength (UTS) was in the region of 1100MPa to 1250MPa then the interlayer material (218MPa UTS) was obviously the weakest parent material used within the friction welded tri-partite joint. Indeed, weld tensile results realised UTS values from 635MPa to 835MPa which equates to 290% - 383% stronger than that of the parent interlayer material strength, at room temperature.

Summarizing the results from the experiments carried out at Fraunhofer IWM, very high weld strength in tension, as well as in torsional loads have been achieved. Having aimed for 95% of the weakest material's strength, the rotary friction welding technique produced welds with strengths of around triple the weakest material's strength. Microstructural analyses have found that no brittle intermetallic phases exist in the weld zone or in the heat affected zone.

Design and Production of the CleanTools Intramedullary Reamer Prototype

Having achieved repeatable and robust welds between Nitinol and stainless steel the consortium produced 8 prototype intramedullary reamers for testing. From two candidates, the intramedullary reamer and the acetabular reamer, the intramedullary reamer was selected after an extensive market survey (as described in the PUDF). The intramedullary reamer was also chosen for the prototype as the designs currently in the market use flexible double wound wire spiral which has all the problems with cleanability and cross contamination that lead to the CleanTools project.

The design of the prototype was split into 3 parts:

1. Design of the drive end – this was a standard part machined from welded blanks provided by TWI (Figure 11).

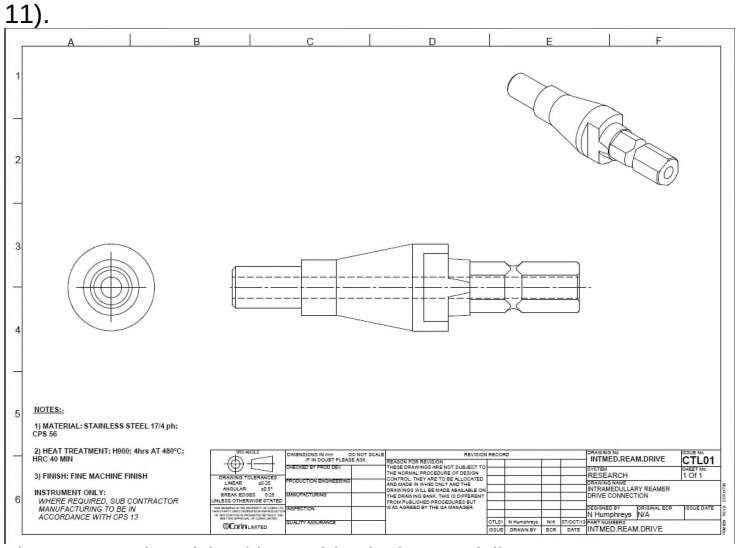


Figure 11: Design of the drive end for the intramedullary reamer

2. Design of the cutting tool – This was a novel 3 flute design, with a helix angle of 15 degrees. This part was machined from friction welded blanks (Figure 12).

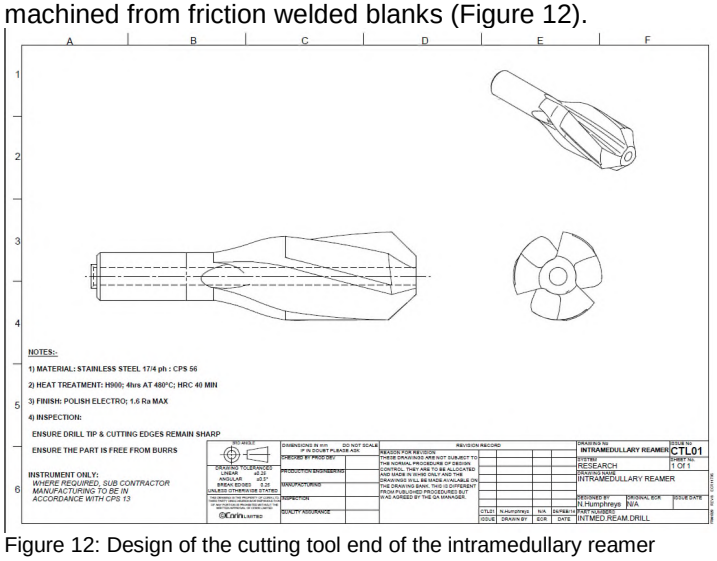


Figure 12: Design of the cutting tool end of the intramedullary reamer

3. Design of the shaft of the tool – this was a decision on the length and thickness of the tubing

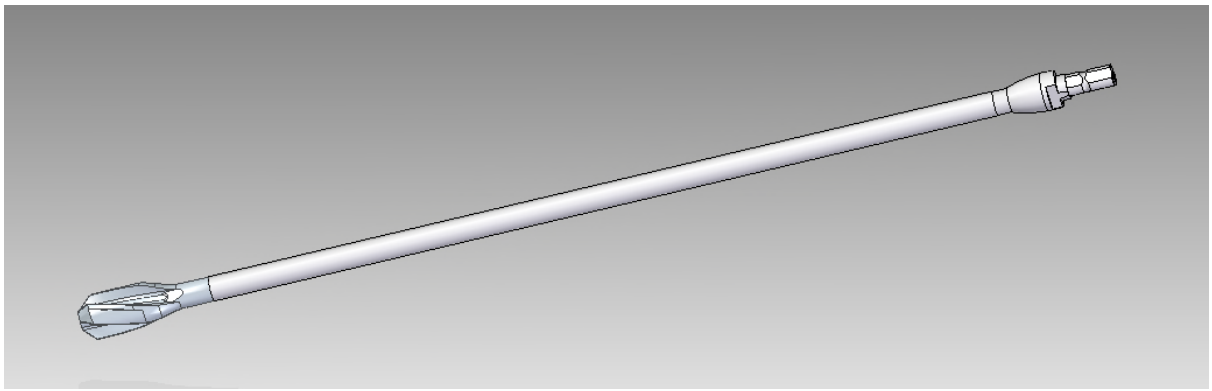


Figure 13: Image of the finished prototype

Manufacture of the prototype, Figure 13 and 14, took place in 5 distinct stages:

1. Friction welding of Stainless Steel to Nitinol bar using an interlayer (D2.3 CleanTools (2866888) TWI Welding Procedure and Properties Definition.pdf)
2. Machining of drive end from friction welded bar stock
3. Machining of cutting tip from friction welded bar stock
4. Deep hole drilling of finished machined parts
5. Laser welding of Nitinol tubing to complete flexible instrument

An image of the completed prototype reamer is shown below.

Figure 14: CleanTools Intramedullary Reamer Prototype

Several production issues were identified during the manufacturing of the prototype. These related to areas of the production process not related to the CleanTools rotary friction welding of Nitinol to stainless steel using an interlayer. The issues encountered related to the strength of the laser beam welds joining the Nitinol tube to the Nitinol in the reamer/drive ends. These issues were related to the quality of the sub-contractor undertaking the laser beam welding. After initial failures an alternative sub-contractor was found with the help of TWI. This subcontractor provided reliable welds resolving the issues encountered.

Prototype Testing

Once complete the prototypes were sent to Universiteit Twente to undergo the defined testing regime related to corrosion testing and simulated surgical use.

The Universiteit Twente reviewed testing requirements and industry standards to devise a set of corrosion and use tests to assess the suitability of the CleanTools Intramedullary Reamer and in particular the performance of the rotary friction welds in simulated use. The testing regime involved corrosion tests (boil, thermal exposure and copper sulphate test) followed by simulated surgical use and sterilisation cycles. Further corrosion testing was undertaken once the simulated use cycles had been completed. Corrosion testing followed the requirements of the relevant standards. The summary of the tests is shown in figure 15 below.

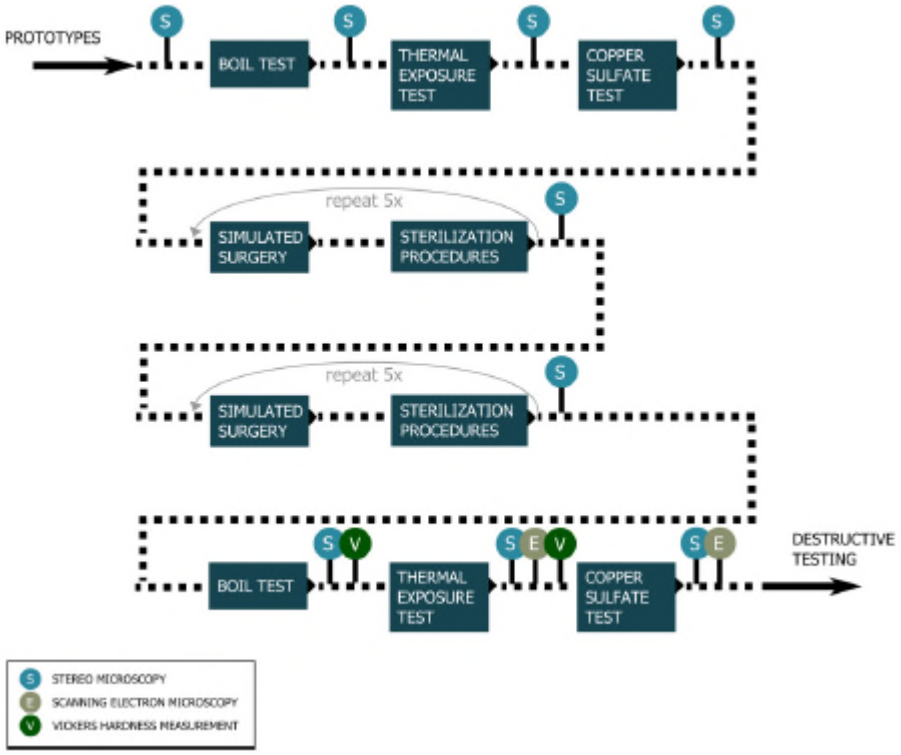


Figure 15: Simulated test regime for CleanTools Intramedullary Reamer Prototype

Simulated Use Testing

In order to simulate surgical use, the Universiteit Twente team, developed a laboratory based test rig that measured the torque achieved whilst reaming a hole through a comparison material. The rig consisted of a lathe mounted instrumented chuck adapter to hold the intramedullary reamer with the sample clamped to a lathe sled. The sled allows the sample to be advanced towards the reamer at a set rate. The rig was set up to allow both straight and curved samples to be assessed. The schematic of the test rig is shown below. Figure 16 shows the rig set up for straight samples. Figure 17 shows the schematic of the rig for curved sample. In both cases the rig was set up to allow the reamer to follow a guide wire as would be the normal situation in surgery.

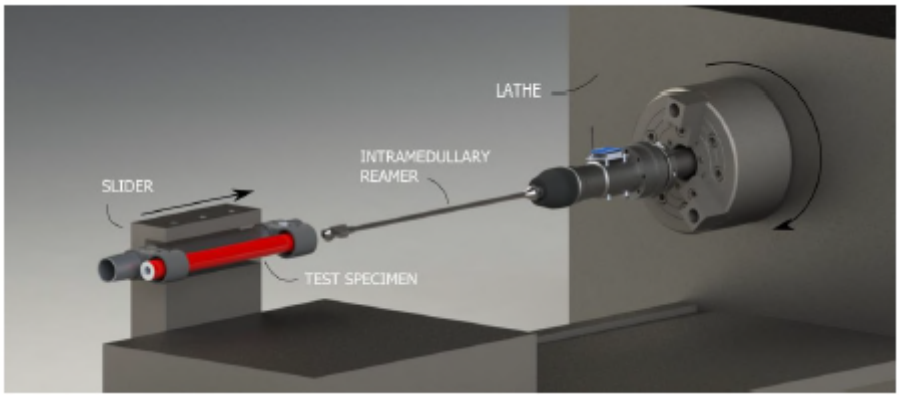


Figure 16: Lathe set up with framework for straight test pieces

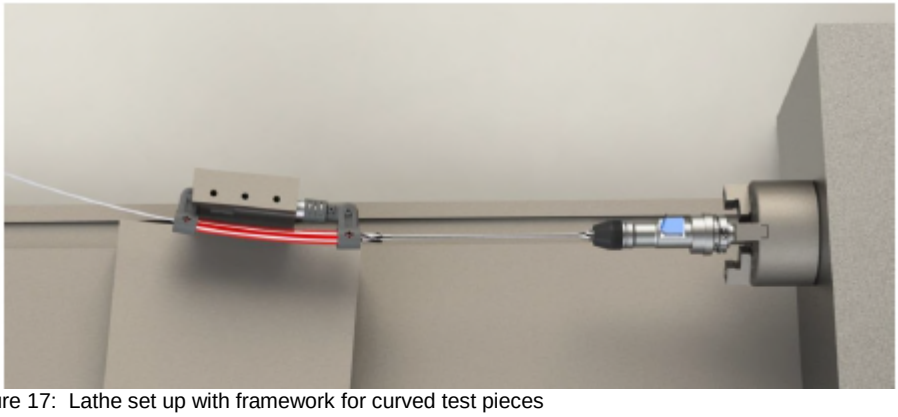


Figure 17: Lathe set up with framework for curved test pieces

Because of the laboratory conditions the test pieces could not be human cadaveric or animal material. Therefore an alternative substitute material not requiring specialist containment or decontamination procedures was used. The material selected as a standard test specimen was oak. This was because of its material properties, cost and availability. Materials short listed and their comparison to human bone materials are given below in Figure 18.

	Advantages	*Disadvantages*
E-Glass Epoxies	- Cheap - Comes in right shape and diameter - Easily cut into test specimens - Low variance in material properties - Availability - Uncontaminated and clean test environment	- May react unexpectedly to cutting, drilling and tapping - Prone to crack formation and failure in fatigue or repeated quasi-static loading of the model (greatly improved in fourth generation compared to third generation) - Hole has to be drilled to simulate medullary canal - Not suitable for temperature experiments
Viable bovine, porcine	- Best analogs - Widely available	- Expensive to prepare - Variable in nature - Difficult to fixture - Not very reproducible
Cadaveric specimens	- "Gold standard"	- High variability caused by death, aging, freezing, thawing, embalming, lifestyle, general health, area of interest, etc.
Oak wood	- Cheap - Comes in right shape and diameter - Easily cut into test specimens	- Variance in material properties - Lower density, strength than human cortical bone

Figure 18: Overview of advantages and disadvantages of different material options

A video of testing activities can be viewed at: www.cleantools.de

During the initial testing two prototypes failed at the Nitinol to Nitinol laser beam welding junctions. These prototypes failed early in the corrosion testing and were excluded from the full tests. The failures were related to the issue related to the sub-contracting of laser beam welding discussed in the prototype production section.

The results from the corrosion testing prior and post simulated use testing showed that none of the rotary friction welds showed any signs of corrosion. All welds passed the corrosion testing.

The simulated use testing showed that the CleanTool intramedullary reamers prototypes withstood the torque subjected to them during the testing in straight (Figure 19) and in curved (Figure 20) oak test specimens.

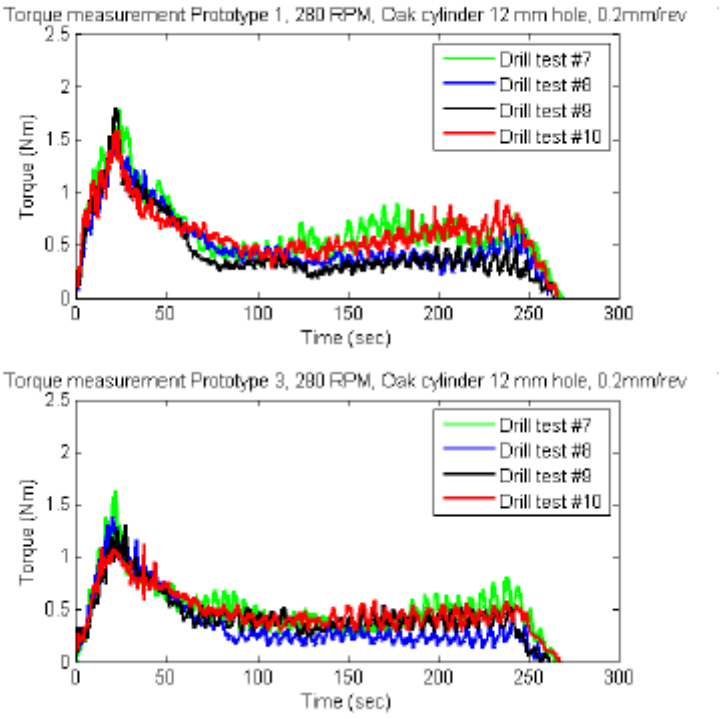


Figure 19: Cutting Torque measured during drill tests in oak wood for prototype 1 (top) and prototype 3 (bottom)

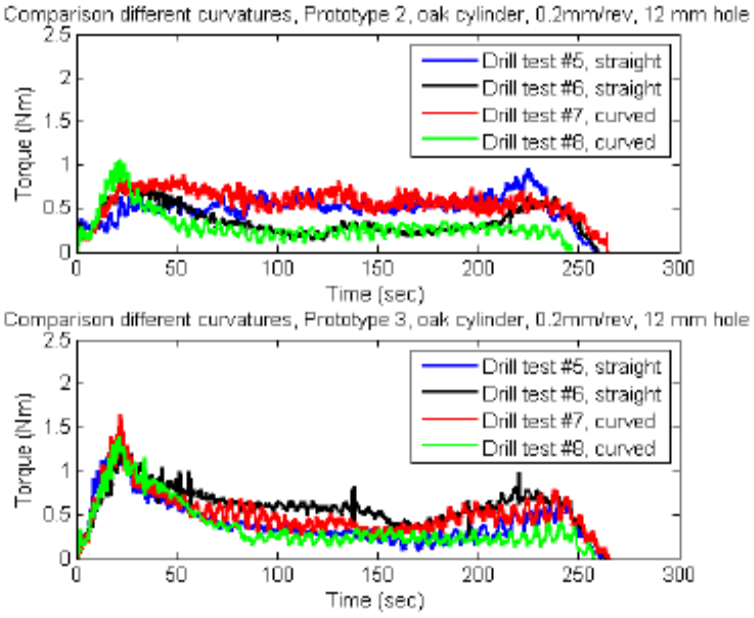


Figure 20: Cutting Torque measured during drill tests in curved oak wood for prototype 1 (top) and prototype 3 (bottom)

Further testing comparing the CleanTools Intramedullary Reamer prototype to a competitive product showed that the performance of the CleanTools matched, and in some cases, bettered the performance of the competitive product. The results for comparison tests in straight oak samples are shown in figure 21. The results for comparison tests in curved oak samples are shown in figure 22.

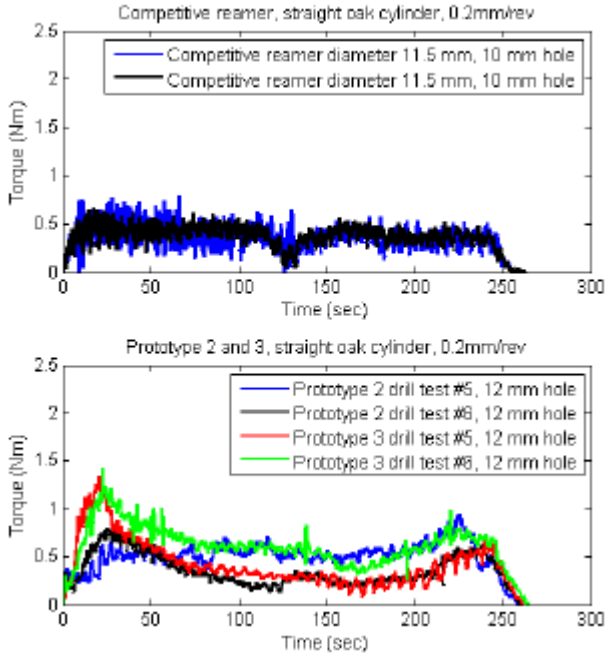


Figure 21: Cutting Torque comparison between CleanTools and Competitor Intramedullary in straight oak samples

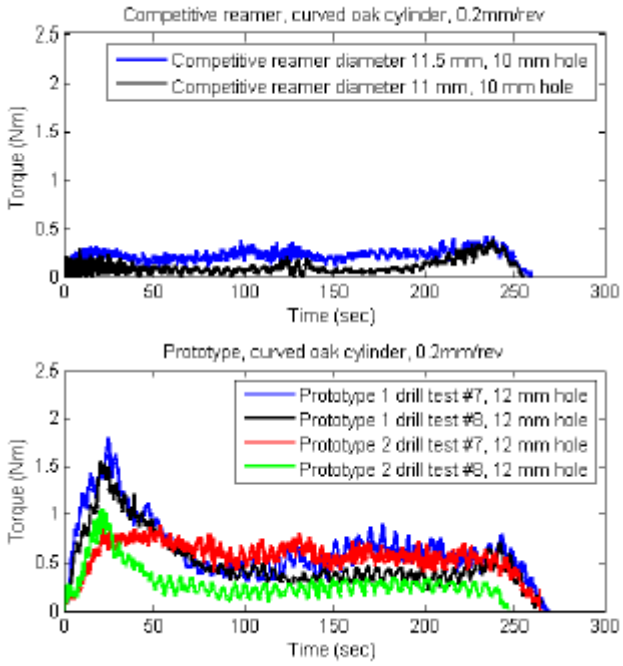


Figure 22: Cutting Torque comparison between CleanTools and Competitor Intramedullary in curved oak samples

Prototype Testing Conclusion

All completed tests for the CleanTools (286888) Intramedullary Reamer prototypes showed that the rotary friction welds developed by the CleanTools project meet the requirements for surgical instruments.

The CleanTools developed rotary friction welds joining Nitinol to stainless steel using an interlayer showed no issues related to their use. The function of the welds tested exceeded expectations. Analysis of the welds before, during or after testing showed no issues. Instead, issues identified during the testing of the prototypes related to the design of the reamer, in terms of clearing angle, bend stiffness of the Nitinol tube and laser beam welds. These issues have or can all be resolved through future design changes to further prototypes and production units.

The limitations placed on the testing due to lack of facilities to use biological material, whether human cadaveric or bovine specimens, have resulted in the need to undertake further testing to fully prove the CleanTools intramedullary reamer prototypes. Further testing should focus on testing the reamer, and therefore the rotary friction welds in human of bovine material to assess the performance in higher strength and density material.

Additional testing should also focus on the design changes proposed to overcome issues identified during prototype testing. Suggested areas for further investigation are; the use of smaller outer diameter Nitinol tube to improve bend stiffness without compromising the strength of the reamer, optimisation of the reamer design itself to improve reaming performance, and review of reaming performance to establish whether the CleanTools prototype intramedullary reamer performs better than established reamers.

On finalisation of the CleanTools intramedullary reamer design, testing relevant to the device as a whole would be required. This testing must reflect the regulatory requirements for type 2a medical devices in the target markets, and any sales and marketing claims made.

Finally, the welding of Nitinol tube directly to stainless steel would represent a significant step forward in reducing the production costs of the CleanTools prototype intramedullary reamer as it would reduce the number of manufacturing steps.

Dissemination and Commercial Aspects

The CleanTools consortium has applied for a European Patent to protect the intellectual property (foreground) developed during the CleanTools project. The consortium is currently awaiting the review of the application by the European Patent Office. Until the patent is granted/pending the consortium will not be publishing or disseminating information related to this project or the interlayer used.

A number of articles have been drafted by consortium members, particularly the RTD partners, but these will not be released for publication until the patent application has been approved.

Press releases have been issued by the consortium partners to local and national newspapers and case studies developed for websites and self publication purposes.

The Consortium partners have reviewed the business case for the further development of the CleanTools Intramedullary Reamer and will pursue this opportunity if the patent is granted.