Design of a Crevice-Free Bi-Metallic Intramedullary Reamer

C.J.W. Haarman, E.E.G. Hekman, E. Augenstein, D. Helm, P. Sketchley, H.F.J.M. Koopman

Laboratory of Biomechanical Engineering
University of Twente

1 Background

An intramedullary reamer is a tool used by orthopedic surgeons to prepare the medullary cavity for insertion of an intramedullary nail. Such nails are commonly used to treat fractures of the long bones (such as the thighbone (or “femur”) In order to follow the existing curvature of the femur, these instruments have to be flexible. A typical current intramedullary reamer (Fig.1a) therefore consists of a long, spring-like shaft (either coiled, Fig. 1A, wound, fig. 1B, or spiral-cut out of a tube) to provide flexibility, connected to a reamer head. Alternatively, the shaft may be a solid tube fabricated from superelastic material like Nickel-Titanium (NiTi) (Fig. 1C). The reamer head may be connected to the shaft by welding, press fitting or other means. Head may (Fig. 1D) or may not be interchangeable.

Due to the flexibility of the spring-like reamer shafts, they can not carry much torque. For this reason, reaming to the desired diameter is carried out in many small steps (0.5 - 1.0 mm). Using a tubular shaft with increased stiffness, it is possible to ream the medullary cavity in larger steps, possibly even in one pass.

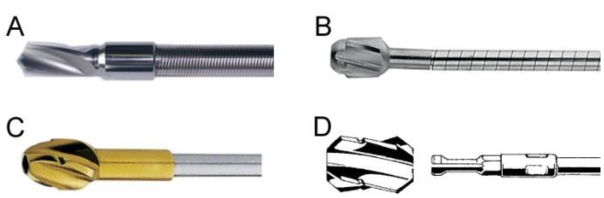

Figure 1: A. Coiled shaft (Biax flexible power); B. Wound shaft (OptiMedical); C. Press-fitted head on NiTi shaft (Sentinel, Zimmer); D. Modular head on NiTi shaft (SynReam, Synthes)

There are a number of problems associated with current intramedullary reamer designs.

The main problem of spring-like shafts is the challenge to properly clean and disinfect the reamer, due to the crevices. Sometimes repeated processes are necessary to completely remove all reaming debris. Typical cleaning steps include soaking in a enzymatic solution, ultrasonic cleaning, brushing of the cannulation and outer shaft, followed by a run in the automated washer-disinfector using a range of chemicals and detergents. The process is time-consuming and chemically intensive. Sterilization procedures are performed to inactivate all microorganisms present on the instrument. If the reamer cannot be cleaned effectively, complete sterilization might not be possible. The risk of cross infection is then relatively high. [1] On the other hand, fixed reamer systems with NiTi shafts are easier to clean and disinfect.

Reversing the spring-like shaft with power is not recommended. The reamer shaft may uncoil. [2] This means that reverse cutting is not possible if the head gets stuck.

Reaming increases the intramedullary pressure and can cause fat intravasation. [3, 4] This may lead to cardiorespiratory dysfunction and occlusion of pulmonary vessels. [5] Modular flexible reaming systems often use one shaft with multiple reaming heads. The ratio between head and shaft diameter therefore varies. Because large shaft diameters are associated with higher intramedullary pressures, reaming with a relative small head has a negative effect on the pressure peak. [6, 7]

In case the head becomes detached from the shaft the reamer head can be withdrawn by retracting the guide wire. Efforts have to be made to avoid detachment by ensuring an excellent joint performance. This may be a risk associated with NiTi-reamer shafts, since this material can not be welded to steel [8] and thus must be fixed by other means such as gluing or press-fitting.

Ideally, a medullary reamer should have a solid, flexible shaft, rigidly and solidly attached to a stainless steel reamer head. Advantages of such a design are manifold. Due to the absence of crevices, cleanability and sterilizability will be improved and cleaning costs reduced. Also larger steps in reamer size are possible since the torsional stiffness and strength of a solid reamer shaft are higher than of a spring-like reamer. The associated reduction of the required number of reaming steps reduces both surgery time and risk of infections. Larger reamer heads also mean more clearance between shaft and bone. Since this way reaming debris can be more easily drained, the pressure peak caused by reaming will be reduced;

We have constructed such a reamer using a steel reamer head and a NiTi reamer shaft. The two parts have been connected using Rotary Friction Welding. Rotary friction welding (RFW) has shown to be effective in joining NiTi to stainless steels. [8, 9] The reason is that during RFW no molten phase occurs, In this paper we present a means to produce a reliable, high quality joint between NiTi and stainless steel using RFW. The results are applied in the design of a crevice-free bi-metallic intramedullary reamer.

2 Methods

Rotary Friction Welding

RFW is a solid-state welding process that uses mechanical friction to generate enough heat to fuse materials when a compressive force is applied. Major parameters that are controlled during the rotary friction welding process include spindle speed, axial force and time duration. [10] An advantage of RFW is that the heat-affected zone is relatively small. This minimizes modification to the NiTi so that its properties are maintained.

Despite the small heat-affected zone, during welding of steel to titanium or to NiTi brittle intermetallic phases (Fe_2Ti) develop close to the weld and decrease the joint strength. [11] A way to prevent the formation of brittle intermetallic phases is to use a suitable interlayer material which keeps the base materials completely separated. By using this material the overall welding temperatures can be reduced and joint strength increased. [11]

Design considerations

Rotary friction welding of NiTi tube to stainless steel is not possible due to the inability of handling small diameter tubes by the friction welding machine. Therefore, for our prototype we used solid cylindrical bars through which an axial hole is drilled after the friction welding procedure is completed. For the friction welds the smallest diameter of material that can be handled by the friction welding machine is used. Using this method we first created two ends of the reamer, i.e. the reamer head and the power tool connector, each of stainless steel with a stub of NiTi friction-welded to it. These two ends were laser-welded to a NiTi tube with suitable diameter. This leads to two additional welds.

Figure 2 displays the final product. The weld regions are highlighted with the friction welds indicated in blue and the laser welds in red. The diameter of the stainless steel cutting head is 15 mm. It is attached to a 6 mm NiTi shaft (3mm ID) which is sufficiently strong to withstand torques up to 17.8 Nm before the material reaches its superelastic plateau of 450 MPa. The overall length of the surgical tool is 350 mm. The reamer is fully cannulated with a 3 mm hole. The shear stress increases for higher torques. To reduce these stresses, the outer diameter of the weld region is increased to 8 mm for the friction welds.

Controlled trials have provided the best parameter values for the friction welding of the NiTi bar to Stainless Steel.

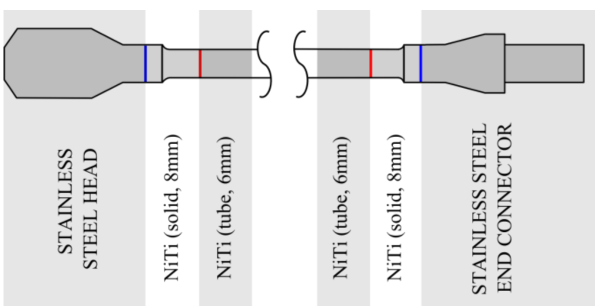

Figure 2: The design of the intramedullary reamer.

Advantages of the new design are as mentioned above. An additional advantage of a NiTi-shaft is vibration damping. In current reaming designs, the low stiffness of the shaft may lead to vibrations during reaming, which can damage the tool and can lead to multi-cornered or non-cylindrical holes. This may result in improper fixation of the nail. [12] In the new design damping occurs due to hysteresis in the flexible NiTi shaft.

Although NiTi tubing is relatively expensive compared to stainless steel, the overall costs of a complete reamer set will be low, because fewer reamers are needed to establish a full reaming procedure.

Experimental setup

A total of four prototypes was manufactured to investigate the ability to perform a reaming procedure with the new design. The testing material should closely reflect mechanical properties of compact bone. Two materials have been selected for this purpose, glass-fiber filled epoxy cylinders (Sawbones inc., OD 20 mm, 5.25 mm wall thickness, 250 mm length) and oak wood cylinders, OD 20 mm, pre-drilled to ID 12 mm. [12] Prior to reaming, the specimens were bent into a 1.2 m radius, which is similar to the radius of curvature of the human femur. [13]

Testing was carried out on a conventional lathe. The reamer was clamped in an instrumented clamp in a lathe chuck. The specimen to be reamed was clamped on the sled of the lathe and advanced towards the rotating tool. After each reaming pass, the tool was cleaned in a washer-disinfector (Miele Professional) and sterilized in an autoclave (Davenport), as would be the case in clinical practice. [14, 15] In total, 10 reaming passes were carried out, 3 on the Sawbones specimen and 7 on the oak wood specimen.

Each of the four prototypes passed the reaming and sterilization tests without failure of the friction welds. Upon visual inspection under a microscope, no damage to the welds or deterioration of the surface of the base materials was noted.

3 Discussion

In this design study a new rotary friction weld method for friction welding stainless steel to a nickel-titanium alloy was developed.

With this new knowledge intramedullary reamer prototypes were created. Weld performance was assessed by carrying out repeated reaming and sterilization procedures. Failure of the friction welds did not occur and no deterioration of base materials was noted.

References

1. Choice Framework for local Policy and Procedures, *Management and decontamination of surgical instruments used in acute care*, Department of Health, Editor 2013: England.
2. Meena, S., et al., *Uncoiling of reamer during intramedullary nailing for fracture shaft of femur.* Journal of Natural Science, Biology and Medicine, 2013. **4**(2): p. 481-484.
3. Frölke, J.P.M., et al., *Intramedullary Pressure in Reamed Femoral Nailing with Two Different Reamer Designs.* European Journal of Trauma, 2001. **27**(5): p. 235-240.
4. Kröpfl, A., et al., *Intramedullary pressure and bone marrow fat extravasation in reamed and unreamed femoral nailing.* Journal of Orthopaedic Research, 1999. **17**(2): p. 261-268.
5. Husebye, E.E., et al., *The influence of a one-step reamer-irrigator-aspirator technique on the intramedullary pressure in the pig femur.* Injury, 2006. **37**(10): p. 935-940.
6. Mousavi, M., et al., *Pressure changes during reaming with different parameters and reamer designs.* Clin Orthop Relat Res, 2000(373): p. 295-303.
7. Muller, C.A., R. Frigg, and U. Pfister, *Can modifications to reamer and flexible shaft design decrease intramedullary pressure during reaming? An experimental investigation.* Techniques in Orthopaedics, 1996. **11**(1): p. 18-27.
8. Schwartz, M., *New Materials, Processes, and Methods Technology*2005: CRC Press.
9. TWI. *Rotary friction welding for medical application*. 2013; Available from: http://www.twi-global.com/news-events/case-studies/rotary-friction-welding-for-medical-application-500/.
10. Gowri, S., *Manufacturing Technology-I*2007: Pearson Education.
11. Fukumoto, S., et al., *Friction welding of TiNi alloy to stainless steel using Ni interlayer.* Science and Technology of Welding and Joining, 2010. **15**(2): p. 124-130.
12. Peindl, R.D., *Assessment of reamer system mechanical loads as factors affecting intramedullary pressurization.* Proceeding of the 1997 ASME Bioengineering Conference, 1997. **35**: p. 247-248.
13. Egol, K.A., et al., *Mismatch of current intramedullary nails with the anterior bow of the femur.* Journal of Orthopaedic Trauma, 2004. **18**(7): p. 410-415.
14. Miele Professional. *G 7893 Washer-disinfector Key features*. Available from: http://www.miele-pro.com/us/prof/products/14071_16033.htm
15. Davenport Sterilisation Systems. *Turbi-ster 20*. 2006; Available from: http://www.davenport-sterilisatoren.nl/EN/turbister20.htm