NEW CUSTOM DEVICE FOR RPH - THE RPH TOUGH NAIL

Proximal femoral nailing has become a standard treatment method for femoral fractures with increasing usage since the late 1990’s. With broadening clinical use in high risk patients, (i.e. tumour patients, high social risk patients, elderly, obese, cases of potential non-union and remote patients) the catastrophic failure of nails has increased. Rates for failure have been reported to be between 5-15% depending on patient demand and requirement for long-term fixation.

The retrieval laboratory has analysed failures of the PFN, PFNA, IMHS, Gamma 3 and recently the new Zimmer Natural nail. All failures have occurred at the proximal lag screw hole with times in situ from 6 weeks to over 24 months. Whilst catastrophic failure is not the norm, it became apparent that there is a need for a custom designed nail for high demand patients where high fatigue strength is required. In this regard RPH Bioengineering set out to design a custom nail with high strength, and a 5 year fatigue life.

Since 2007 RPH Bioengineering has:

• Investigated and reported on nail failures (PFN, IMHS, PFNA, Natural Nail, Gamma 3)
• Evaluated 4 commercial nails for clinical use:
  • Fatigue strength
  • Cut out resistance
  • Rotational stability
• Designed the custom RPH Tough Nail
• Conducted Finite Element Analysis
• Conducted fatigue testing.

At present we can offer the nail as a patient specific custom device for:

• Prophylaxis - treatment of tumours
• High demand or non compliant patients
• Elderly patients - with a high propensity to fall
• Obese patients – where nail loads are above the general population
• Remote and rural patients - with a lack of orthopaedic follow up care
• Fracture patterns with missing medial cortical support.
• High risk of non-union.

Fig. 1. Mock up of custom nail with Stryker lag screw.

Fig. 2. A. Failed PFNA, B. Failed Gamma 3, C. X-ray of PFNA failure. D. Fracture pattern. E. Typical fatigue striations.
Finite element analysis showed that it was possible to increase the proximal diameter and gain a substantial advantage in strength. In addition small changes to the lag screw geometry on the lateral side of the nail, resulted in a significant lowering of the localised strain. This was especially important, in that most failures of the nail were initiated at least half way up the lateral aspect of the lag screw hole.

![Finite Element Analysis of tough nail.](image1)

Fig 3. Finite Element Analysis of tough nail.

Initial fatigue testing of the proximal nails revealed marked differences in fatigue strength with the stainless steel nails outperforming the titanium nails in all cases, hence the use of high nitrogen stainless steel.

![Fatigue testing of proximal femoral nails.](image2)

Fig 4. Fatigue testing of proximal femoral nails.

Manufacturing will be done in our specialist manufacturing facility (part of the Technical Services Division), under the guidance of our technical development engineers.

The nail will be manufactured from high nitrogen stainless steel which is ideally suited to applications where high strength and fatigue resistance is required.

![Fatigue Testing set up.](image3)

Fig 5. Fatigue Testing set up.

As the nails will be produced as custom devices, they are available in any length, as required. Work is proposed to further develop the design and prove its efficacy.

Please contact us for further information or referrals.

**REFERENCES**


Royal Perth Hospital Bioengineering Retrieval Database 2011


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