High Impact and Improved Corrosion Resistance for Bone Cutting Tools

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High Impact and Improved Corrosion Resistance 17-4PH Stainless Steel for Rasps, Broaches and Other Bone Cutting Tools

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Executive Summary

Orchid Orthopedic Solutions has developed a form of 17-4ph stainless steel which, following initial testing, increases the impact strength by up to 5 times and vastly improves its corrosion resistance, whilst maintaining all other properties, such as tensile strength and hardness. This is anticipated to make broaches and rasps safer for the patient, more reliable for the surgeon and reduce overall costs for the provider by maintaining the cutting edge for longer and thus increasing its serviceable life.

Abstract

The performance of surgical rasps and broaches is critical for the preparation of the bone cavity to ensure stability and longevity of the implant in service. However, a failure of such an instrument can be extremely traumatic, particularly if parts of the broken tool are left inside the bone cavity.

Surgical instrumentation used for the preparation of the bone cavity i.e. hip broach and impactor/extractor instruments are subjected to high stresses, and there are recorded incidences of product failures in service.

Secondly, maintaining the sharpness of the tool is also vitally important in enabling a swift procedure, which is less likely to split the femoral bone itself, owing to a lack of cutting action. The overall cost could also be greatly improved through the extended life of the instrument this would offer.

These high impact instruments are typically manufactured from 17-4PH Precipitation Hardened Stainless Steel material. This study was based on the feasibility of optimising the material properties to enhance to performance of these critical instruments in service.

1.0 Introduction

The hip broach (Figure 1), or rasp, is used during implant surgery to form the cavity in the bone into which the hip stem will be implanted. It is manufactured to the same shape as the hip stem with serrated edges to allow removal of the soft tissue and spongy bone from the center of the femoral bone.

Figure 1 – Example of a Hip Broach showing serrated cutting edges.

The broach/rasp is inserted into the bone cavity by the use of a detachable handle (Figure 2,) which is attached to a spigot at the end of the rasp stem. The rasp is then repeatedly driven into the cavity by impact force to form the cavity.

The rasps are cleaned and reused after each procedure, and it is important that the edge definition of the tooth remains sharp, so as not to cause the need for additional pressure to create the cavity.

Figure 2 – Image showing insertion of the Hip Broach into the Acetabular canal with the use a detachable handle.

Typically, there will be a range of different size rasps available to gradually increase the size of the cavity until it achieves the required size of the implant.

The rasp instruments are subjected to a high level of repetitive stress and there are recorded incidences where the broach or broach handle has failed during service (1). In the worst case, the consequence of a broken broach/rasp is that it may be difficult to remove if left inside the bone cavity, causing an increase in surgery time and a potential risk to patient health.

2.0 Material

The 17-4PH material is characterised as a Martensitic Precipitation Hardened Stainless Steel. It is one of the most common materials used for the manufacture of surgical instruments.

Precipitation Hardened Stainless Steel materials can be heat-treated to form a wide range of mechanical properties. This exercise is based in the optimisation of the material properties, fracture toughness and corrosion resistance by incorporating the Orchid proprietary thermal processing and heat-treatments.

3.0 Manufacturing Process

The experiment was a direct comparison between the Standard machined wrought hip broach instrument and Orchid Proprietary thermal treated product (Orchid)

The starting point for both product types was wrought material in the solution annealed condition, otherwise known as -Condition A.

The standard products were fully machined from wrought slab.

The Orchid products were manufactured by utilising a combination of mechanical work and heat-treatment processes. The products were then machined to the same dimensions as the fully machined product.

On completion of the machining operations, all products were subjected to the final Heat-treatment of 482 °C (900 °F) for 1 hour then – air cooled (to Age Hardened -H900 Condition).

All product were subjected to an electro-polishing process for 2 minutes cycle at a setting of 7 volts.

4.0 Test Method

4.1 Microstructure Analysis

Sections were taken in the transverse direction of the broach for microstructure by radiac saw. The microstructure samples were mounted, ground, polished and etched to reveal the microstructure.
The analysis of the microstructure was completed using a Zeiss microscope and photographs with the Pro plus imaging software – Vision 7.0

4.2 Mechanical Properties (Tensile Test)

Tensile testing (also known as torsion testing) is where the material is subjected to uniaxial tension until it reaches failure. From this test, 0.2% proof stress, ultimate tensile strength, elongation and reduction of area measurements are recorded. From this, the results are typically compared to material specifications to ensure material quality.

Test samples were machined from the stem section of the products. Mechanical testing was completed in accordance with BS EN ISO6892-1[12] & ASTM E8[13].

4.3 Charpy Impact Strength

The Charpy impact test (also known as V-Notch) is a method of testing where the material is subjected to a sudden high rate of loading I.E striking force from a known height of a known mass. It is classed as the amount of energy absorbed during fracture.

Test samples were machined from the neck section of the broach instrument. Testing was completed in accordance with BS EN ISO 148-1[14].

4.4 Hardness Testing (Rockwell C, 150KG)

Rockwell C hardness testing is an empirical indentation hardness test that provides information about the resistance of a metal to plastic deformation, or hardness of a material. The machine applies a load to the material in question and then measures the depth of penetration, where typically, the smaller the indentation the harder the material.
Rockwell Hardness checks were completed using an Avery Type 6402 Rockwell machine testing utilising the C scale (150KG) HRC.

Hardness testing was completed in 5mm intervals across the micro sections of the product.

4.5 Corrosion Testing - Salt Spray and Autoclave testing

4.5.1 Salt Spray Testing

This is completed in order to analyse a material's corrosion resistance by placing components into an enclosed cabinet and subjecting them to a continuous indirect spray of salt water solution, typically 5%NaCl. Any indications of corrosion will show as iron oxide, which is typically red and commonly known as rust.

Salt Spray Testing was completed in accordance with ASTM B117[10] at +35°C, using 5%NaCl for 2 hours - ASTM A967[11] Practice C.

4.5.2 Autoclave testing

Medical autoclaving is a unit that subjects components to steam in order to clean sterilise them from bacteria, viruses, fungi and spores that may be present.

– The product were subjected to 40 off cycles of steam Autoclave at 134 °C for 40 minutes,

5.0 Results

5.1 Microstructure

The Standard wrought products in the H900 Condition displayed a matrix of lath martensite and the precipitation of of ε-Cu phase[5] (figure 3). Grainsize was deemed acceptable in accordance ISO 643 and gave an overall measurement of 5[9].

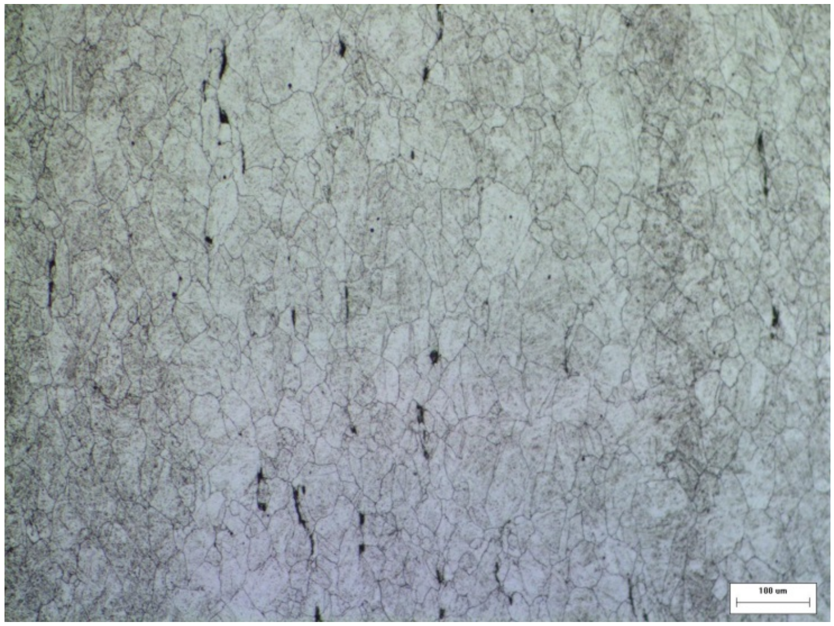

Figure 3- Microstructure of the Standard wrought 17/4PH Stainless Steel in H900 Condition

The Orchid product in the H900 condition displayed a microstructure of small lathed martensite and retained austenite ɣ. There is no visible evidence of Cu phase precipitation. Grainsize was deemed acceptable in accordance ISO 643 and gave an overal measurement of 9[9].

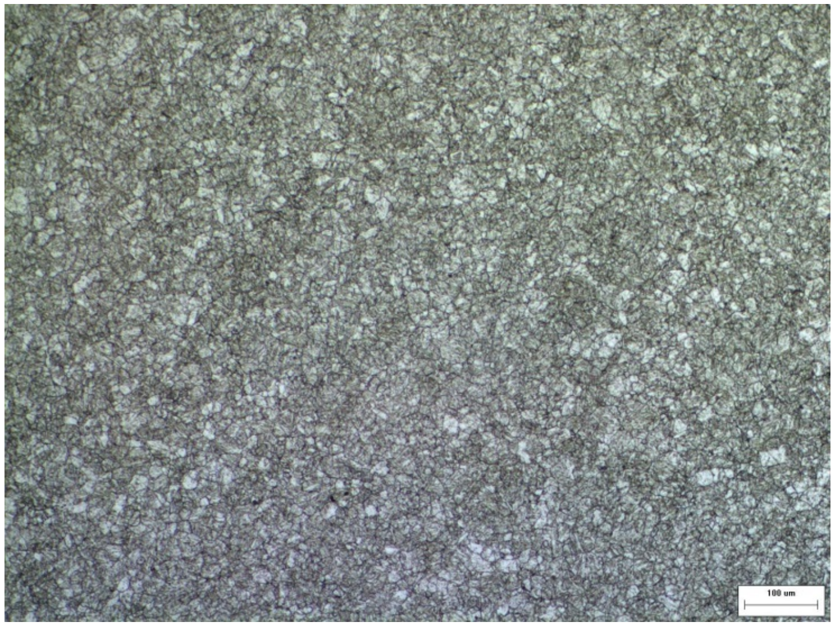

Figure 4 – Microstructure of Optimised Thermal treated 17/4PH Stainless Steel in H900 condition

The introduction of retained austensite (Ɣ) into martensitic steel is known to be one of the most effective means of improvements in toughness and ductility[16,3].

5.2 Mechanical testing

The Tensile strength and 0.2% proof stress is higher in the Standard wrought materials (Figure 5) However, the mechanical properties of both products met the requirements of A564/A564M-13[15] This is combined with a higher ductility in the Orchid material which is product of the heat-treatment process [5,6,7]

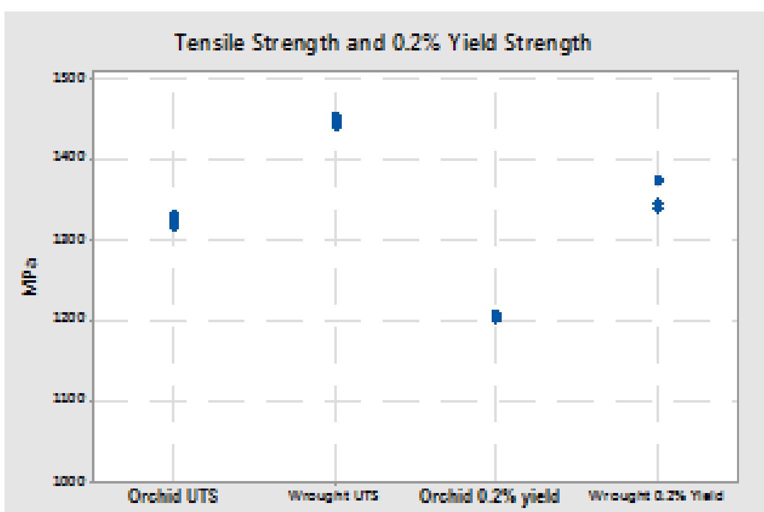

Figure 5 – Comparative Tensile Strength and 0.2% proof stress

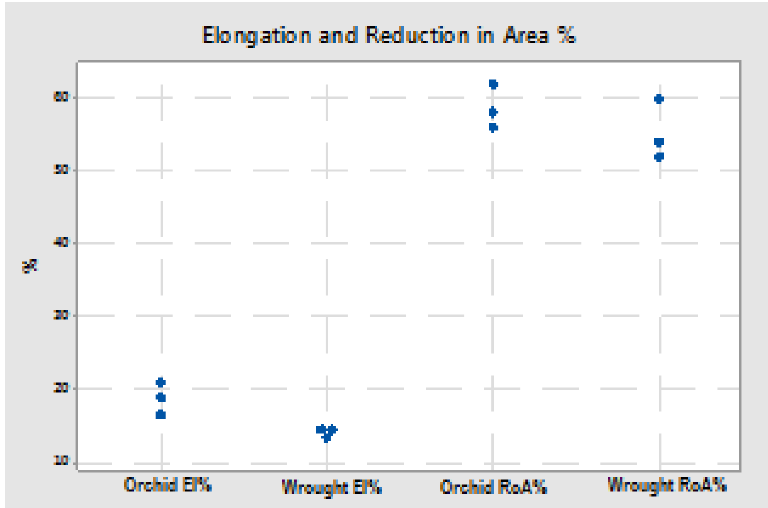

Figure 6 – Compartive Elongation and Reduction of Area Results

5.3 Charpy Impact Strength

The impact strength of the optimum products was significantly higher in impact strength **"up to 5 times"** when compared to that of **Standard** wrought product (Figure 7). There is evidence to support that there is relationship between the conditions of Heat-treatment and the facture toughness of the material [(2).]

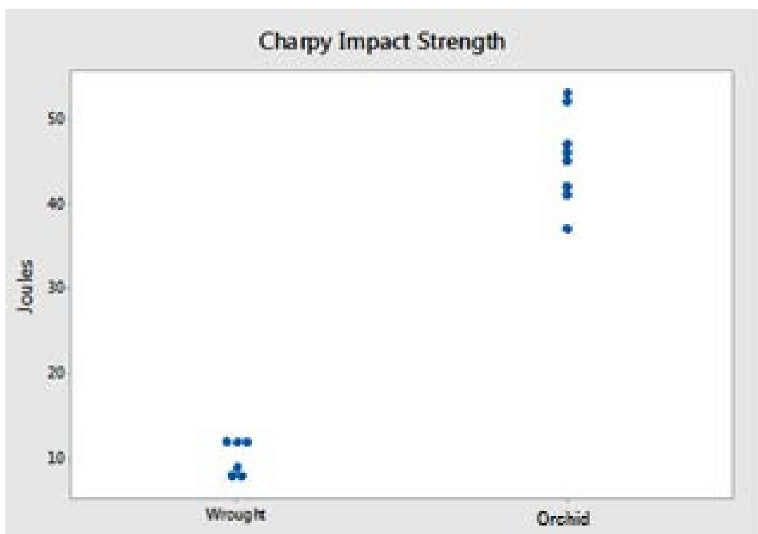

Figure 7 – Comparative Charpy Impact Strength

This result has the potential to significantly reduce the risk to the patient by producing a material which has up to 5 times the impact strength of the conventional machined and Heat-treated 17/4PH in the H900 condition

5.4 Hardness Testing

The hardness properties of the Orchid material in the H900 condition were slightly higher than the wrought material, specifically;

- Wrought 35 HRC to 38HRC
- Orchid 40HRC to 44HRC

It is reported in the literature that the changes to the copper phase and the formation of reversed austenite precipitation may cause a hardening effect in the material [(15),]

5.5 Corrosion Testing

The potential effects of corrosion on the broach instrumentation are twofold:

- **Deterioration in the performance of the product**
  Corrosion will initiate on the machined cutting edges of the product ,and over time will result a blunting effect, reducing the effectivity of the product to remove the bone cavity.

- Pitting Corrosion on the surface of the material can reduce the fatigue strength of the material [(4)], potentially resulting in an initiation of fracture of the product under repetitive stresses.

5.6 Salt Spray

On completion of the test, the Standard wrought product showed evidence of pitting corrosion which initiates from the cutting edges of rasp instruments (Figure 8).

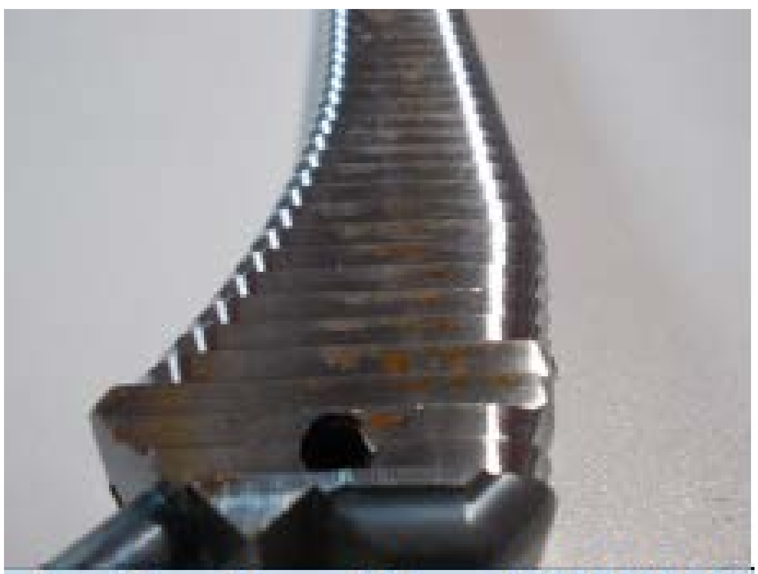

Figure 8- Standard wrought broach showing evidence of Pitting corrosion

In comparison the Orchid Broach remained in polished condition with no evidence of the corrosion putting on the machined surface (Figure 9)

Figure 9 – Orchid Broach product after Salt Test

5.7 Autoclave testing

On completion of the autoclave testing, there was no evidence of pitting corrosion. However, after 11 cycles the Standard wrought material displayed a discolouration which was maintained throughout the process (Figure 10). The Orchid product maintained and polished surface after 40 off autoclave cycles.

Figure 10 – Photograph showing discolouration of wrought product at 11 autoclave cycles and Orchid product maintained polished surface after 40 autoclave cycles

In both the salt spray and autoclave testing, the Orchid product showed a significant improvement in the corrosion resistance of the material.

6.0 Summary

The high impact and improved corrosion resistant 17/4PH precipitation hardened stainless material was developed to enhance the performance of instrumentation in service, specifically the hip broach and associated products.

The exercise was based on the manufacture of a hip broach utilising the Orchid propriety thermal process and heat-treatment.

The microstructure of the Orchid product produces a combination of lathed martensite and retained austenite.

The results of the experiment showed a significant improvement in Charpy impact test results which were up to 5 times that of the Standard wrought material. The literature documents that this microstructure will produce improved fracture toughness.

The mechanical results for both the Orchid and Wrought product met the specification requirements of A564/A564M-13.

The Wrought material hardness is slightly higher in the Orchid material, which is believed that this is a product of the saturation of the Copper in the material matrix.

The comparitive corrosion properties of the showed that there was a significant improvement in the in corrosion resistance of the Orchid products.

To learn more about how **Orchid** can help you strategically consolidate your supply chain, reduce risk, improve quality, and strengthen your competitive advantage in the new medical device economy, call us at **(517) 694-2300** or visit us online at www.orchid-ortho.com.

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7.0 Literature References

(1) ConsumersUnion. A Summary of Hip Impant Recalls, Safe Patient Project- September 9,2013

(2) M. Abdelshehid,K Mahmodieh,K Mori,L Chen,P Stoyanov. On the correlation between Fracture toughness and Precipitation hardened heat treatments in 15-5ph Stainless Steel. Engineering Failure Analysis 14 (2007) 626-631

(3) Laurent Couturier, Frederic De Geuser, Alexis Deschamps. Evolution of the microstructure of 15-5ph martenisitice stainless steel during precipitation hardening treatment. Materials and Design 107 (2016) 416-425

(4) Bernd M Schonbauer. The influence of various types of small defects on the fatigue limit of precipitation – hardened 17-4ph stainless Steel. Theoretical and Applied Fracture Mechanics 87 (2017) 35-49

(5) H.R Habibi Bajguirani. The effect of ageing upon the microstructure and Mechanical properties of type 15-5ph stainless steel. Material Science and Engineering A338 (2002) 142-159

(6) Xin-yuan PENG, Xian- Liang ZHOU. Effect of Aging on Hardening Behaviour of 15-5 PH Stainless Steel. Jornal of iron and steel research Int. 2015 22(7): 607-614

(7) Jong- Ho Shin. Microstructural Evolution and the variation of tensile behavior after aging heat-treatment of precipitation hradened martensitic steel. Material Characterisation 99 (2015)230-237

(8) E.S. Park, D.K. Yoo, J.H. Sung, C.Y. Kang, J.H. Lee, J.H. Sung. Formation of reversed austenite during tempering of 14Cr–7Ni–0.3Nb–0.7Mo–0.03C super martensitic stainless steel. Metals and Materials International, 10 (6) (2004), pp. 521–525

(9) ISO 643 :2003 – Steel- Micrographic determination of the apparent grain size.

(10)ASTM B117:2016 – Standard Practise for operating salt Spray (Fog) Apparatus.

(11)ASTM A967 / A967M – 13 Standard Specification for Chemical Passivation Treatments for Stainless Steel Part

(12)BS EN ISO6892-1:2016- Metallic materials. Tensile testing. Method of test at room temperature

(13)ASTM E8/E8M:2013 Standard Test Methods for Tension Testing of Metallic Materials

(14) BS EN ISO 148-1:2016 Metallic materials. Charpy pendulum impact test. Test method

(15)A564/A564M-13 Standard Specification Hot-Rolled and Cold-Finished Age- Hardening Stainless Steel

(16)H Nakagawa, T Miyazaki. Effect of retained austenite on the microstructure and Mechanical properties of Martensitic precipitation hardening stainless steel. Journal of materials Science 34 (1999) 3901-3908

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