

Custom 465® Offers Significant Advantages Over Other Precipitation-Hardened and Austenitic Stainless Steels for Cutting and Shaping Instruments

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Abstract

As surgical procedures have become more complex and non-invasive, the requirements for instruments have become more demanding. Proper material selection is critical in instrument development. The material properties that must be considered include bio-compatibility, physical and mechanical properties as well as fabricability.

Historically, UNS S30400 stainless steel has been used to make tubular components for surgical instruments. However, it has some significant drawbacks including poor edge retention and poor wear resistance. Precipitation-hardened alloys, such as UNS S17400 have been used for many years with limited success. While better than UNS S30400, the cutting characteristics and edge retention of UNS S17400 is marginal in the new, more demanding applications. UNS S42010 (TrimRite®) and UNS S46500 (Custom 465®) are newer precipitation-hardened alloys with improved cutting characteristics, edge retention and fabricability.

In this study, tests were performed to determine and compare the cutting characteristics and edge retention of these various alloys used for cutting and shaping instruments. Finally, the ability to fabricate these alloys into tubular components necessary to manufacture cutting and shaping instruments is discussed.

Introduction

Currently various stainless steels are used in medical instrument applications. The materials are selected depending on the properties required for a given application. Typical parameters that would be considered are hardness, edge retention, wear resistance, other mechanical properties, corrosion resistance, bio-compatibility, etc. In addition these materials may also be selected for their ease of fabrication, including welding, drawing, and machining.

Edge retention and wear resistance are paramount when designing cutting and shaping instruments. In order to evaluate these characteristics a series of experiments was conducted at CATRA (Cutlery and Allied Trades Research Association located in Sheffield, United Kingdom).

For the purpose of this study, this selection was narrowed down to five alloys: UNS S30400, UNS S17400, UNS S45500, UNS S46500, and UNS S42010. Table 1 states the conditions of these alloys as they were tested. Throughout the remainder of this paper, these materials will be referred to as 304, 17-4 pH®, Custom 455®, Custom 465®, and TrimRite®, respectively.

Table 1: Typical Conditions and Hardness Values for the Various Alloys.

Alloy	Condition	Hardness
304	Annealed and Cold worked	HRC 31
17-4 pH®	Aged at 900°F	HRC 43
Custom 455®	Aged at 900°F	HRC 50
Custom 465®	Aged at 900°F	HRC 54
TrimRite®	Hardened at 1900°F and Tempered at 350°F	HRC 51

Typically, technical data from the manufacturers of these stainless steels will show trends toward the following results for Edge Retention/ Wear Resistance. Table 2 displays typical results.

Table 2: Typical Ratings for Edge Retention/ Wear Resistance. [1]

Alloy	Edge Retention/ Wear Resistance
304	Poor/ Poor
17-4 pH®	Good/ Good
Custom 455®	Very Good/ Very Good
Custom 465®	Very Good/ Very Good
TrimRite®	Excellent/ Excellent

Experimental Conditions

In order to validate this data, a series of experiments was conducted on the CATRA automatic edge tester. The blades were machined to a chisel-style edge with an included angle of 32° and honed. The testing was completed in accordance with ISO 8442.5, “Materials and Articles in Contact with Foodstuffs- Cutlery and Table Holloware-Part 5: Specification for Sharpening and Edge retention Test of Cutlery”, and the following parameters were used:

- Test Load: 50N
- Test Stroke distance: 40mm forward and back
- Test Speed: 50mm/s
- Test Media 5% Silica paper
- Total of 60 Cutting cycles

During this test, the blade was mounted with the edge positioned vertically and the synthetic paper is automatically lowered onto the blade. The blade is then oscillated back and forth, allowing the blade to cut into the synthetic paper. The depth of the cut is then measured and the sum of the first three cuts is reported as the Initial Cutting Performance (ICP). The ICP is a representative value for the sharpness of the blade material.

The media is then loaded with 5% silica (allowing for a slight dulling effect on the blade) and effectively slightly lowering the edge retention. Wear curves are then constructed plotting the cut depth per subsequent stroke. This value (sum of all cuts for the 60 Cycles) is reported as the Total Card Cut (TCC). [2]

Results

The scope of this paper was limited to the blade geometry, however, preliminary data indicates that similar results would be obtained for biopsy punches and other tubular components as well. The resulting data is displayed in Fig. 1 and Table 3.

Figure 1 shows the TrimRite® material achieved the longest number of cycles while still maintaining its sharpness. This result was closely followed by the Custom 465® stainless steel.

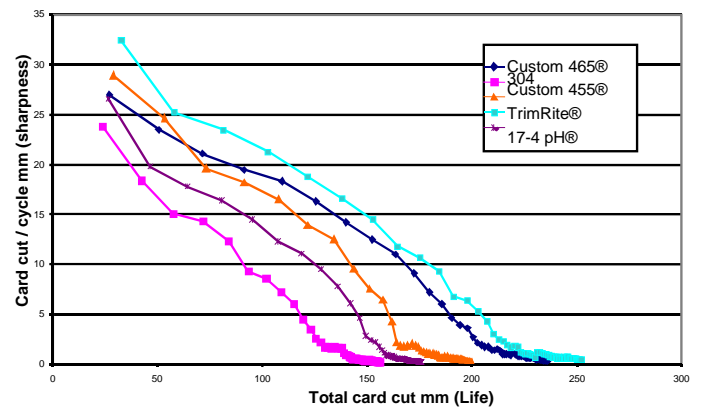


Figure 1: Average blade cutting performance data from Catra Cutting Test to ISO 8442.5. [3]

Using the results of this data, Table 3 was constructed ranking the five materials. They are shown below in order of increasing properties.

Table 3: Typical Ratings for Sharpness/ Edge Life (Wear Retention).

Alloy	Sharpness/ Edge Life
304	Poor/ Poor
17-4 pH®	Good/ Good
Custom 455®	Very Good/ Good
Custom 465®	Very Good/ Very Good
TrimRite®	Very Good/ Excellent

Conclusion

Based on these results, one is able to confidently rank the new pH stainless steels as having better edge retention and wear resistance than the commonly used austenitic stainless steels and older pH alloys. TrimRite® does show a slightly better edge retention over Custom 465®. On the other hand the more complex heat treatment required for hardening this alloy may offset this advantage. Furthermore, it is easier to fabricate tubing from Custom 465® because of improvements to the material’s welding and cold drawing characteristics. When all attributes are considered, edge retention, processing time, economics, etc. Custom 465® is an alloy that provides significant advantages.

References

1. Fender William, Brown Robert S Stainless Steel Options for Medical Instrument Tubing *Medical Device and Diagnostic Industry*, January 2005
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3. Cutlery and Allied Trades Research Association (CATRA) Report 962505 dated February 6, 2006. Conclusions for testing requested by Veridiam Inc. (Formerly Carpenter Special Products).

*17-4 pH® is a registered trademark of Armco Steel Corporation.
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