

ANALYSIS OF THE CAUSES OF FAILURE OF SOME SURGICAL HARDWARE

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ABSTRACT

Analysis of the causes of failure of some surgical hardware viz. artery forceps and crocodile forceps was undertaken. These forceps imported from a particular country were found to get corroded and fractured after a few months, while normal service life of such items was reported to be several years. Failed samples were collected and the history of failure recorded. The failed samples were investigated by chemical analysis, metallography, scanning electron microscopy, energy dispersive x-ray microanalysis etc. Results show that the forceps material corresponds to AISI 420 martensitic stainless steel. Microstructural investigation reveals the presence of a large number of slag and non-metallic inclusions in the failed samples. Fractures are found to be intergranular in nature. Presence of chloride ion is detected in the rust spots on the forceps as well as in cracks. Tests reveal that water used to disinfect the forceps in the hospitals contains chloride ion. It is suggested that stress corrosion cracking caused by exposure of the hardware to chloride ion and stress is the dominant mode of failure. Poor quality steel having excessive slags and inclusions is thought to have led to the premature failure.

Keywords: Stress corrosion cracking, Surgical hardware, Martensitic stainless steel.

1. INTRODUCTION

Surgical tools or instruments used by medical practitioner are usually made from stainless steel to resist corrosion for chemical safety. Different grades of stainless steels like austenitic, martensitic, duplex etc. are used depending upon the applications in which the tools are used. Stainless steels used in medical fields should satisfy more stringent property, compositional and microstructural requirements than for non-medical applications in order to avoid infections and other related complications as far as possible.

In our country, surgical tools are imported from abroad. Earlier, such items were imported exclusively from industrialized countries. These tools are used to perform satisfactorily for several years as reported. However, in recent time, surgical tools are also being imported from neighbouring South Asian countries mainly because of their low cost. It has been reported that the tools imported from neighbouring countries sometimes do not perform well and fail prematurely, even in a few weeks.

Recently, it was reported by a local hospital that most of the forceps belonging to a lot imported from South Asian country failed within a couple of months. The present study is intended to investigate the cause(s) of premature failure of these surgical tools.

2. EXPERIMENTAL

A number of forceps were collected and investigated in the laboratory. The forceps material was investigated

chemically by standard techniques. Chromium, sulphur, phosphorous contents were determined by wet chemical analysis, while carbon contents were estimated by combustion method. Cross-sectional, transverse sectional samples were prepared from the fractured zones of the forceps for macro examination by standard metallographic technique. Samples were also prepared for microexamination and examined under optical microscope and scanning electron microscope. Energy dispersive x-ray microanalysis of the sample was recorded. Microhardness tests were conducted on the metallographic sample in the as-received condition and further heat-treated condition.

3. RESULTS AND DISCUSSION

A number of different types of forceps, which failed prematurely, were collected. The failed forceps were visually examined. The forceps mostly failed by cracking. Cracks were found to occur mainly near the rivet (fig 1a) and at area where there is a sharp change in cross section (fig 1b). A close-up view of a crack near the rivet of an artery forceps is shown in fig 1c. In addition to cracks, the failed forceps also contained rust spots, reddish brown in colour. The rust spot were few in number and mainly found in the lower portion of the forceps, which is used for gripping. Rust spots also occurred at the internal faces near the rivet the size of the rust spots was small, less than a millimeter across. Rust product adhering to a crocodile forceps is shown in fig 2. Investigation revealed that cracking took place near area where rust

spots are concentrated. The forceps appeared to be made from stainless steel. All the samples were found to be attracted by a hand magnet.

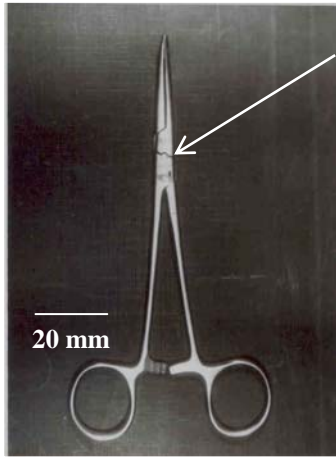


Fig 1(a). Crack in an artery forceps (indicated by an arrow).



Fig 1(b). Fractured artery forceps (indicated by an arrow).

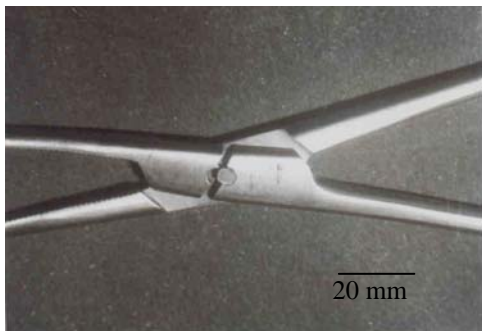


Fig 1(c). Crack in an artery forceps (indicated by an arrow).

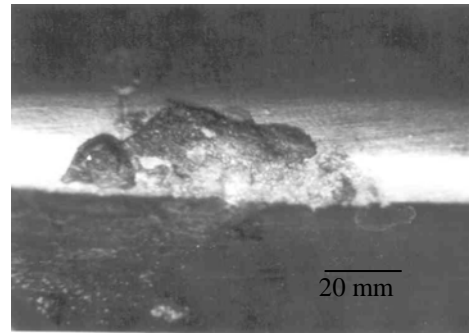


Fig 2. Rust products on the surface of a crocodile forceps.

A couple of failed forceps sample were randomly selected and chemically analysed. The results of the chemical analysis are shown in table 1. A couple of new samples reportedly made by the same manufacturer as the failed once were also chemically analysed and their composition are shown in table 1. The results reveal that the material used in the manufacture of the forceps is an alloy steel containing 0.23 – 0.24 % C and 12.22 – 12.83% chromium. The chemical composition of the materials falls within the specification AISI 420 martensitic stainless steel.[1]

Table 1: Results of chemical analysis of the failed and new forceps

Element in wt (%)	Failed forceps 1	Failed forceps 2	New forceps 1
C	0.23	0.24	0.25
Cr	12.22	12.83	12.31
S	0.016	0.02	0.02
P	0.015	0.012	0.017

The average microhardness of the failed as well as new forceps sample was found to be about VHN 464. This hardness value is normal for a heat treated martensitic stainless steel.[2]

Optical micrograph of a failed sample in the etched condition reveals that its microstructure contains tempered martensite and inclusions(fig 3).

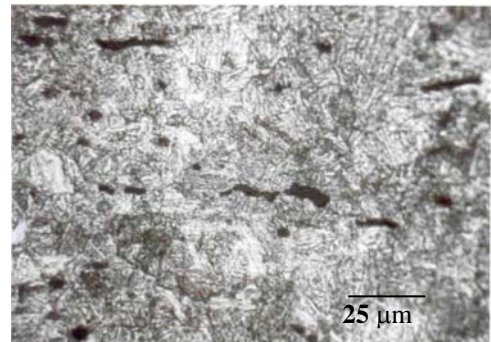
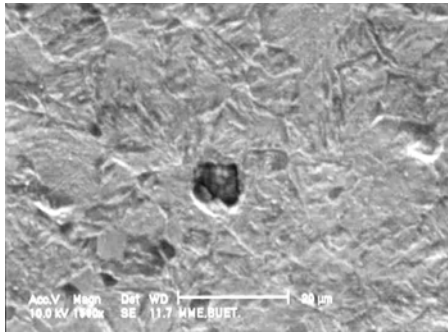


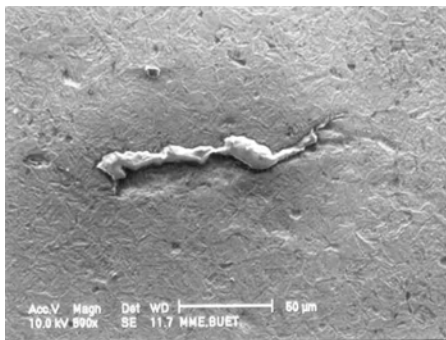
Fig 3. Optical microstructure of failed sample.

The above results thus confirm that AISI 420 grade martensitic stainless steel has been used in the manufacture of the forceps and the same have been supplied in a quenched and tempered state.

Fig 2 further reveals that the failed samples contain numerous round as well as elongated black features. Under SEM (fig 4a) these features are found to be inclusion/slag.



(a)



(b)

Fig 4. SEM microstructure of artery forceps (a) round inclusion (b) elongated inclusion on which EDX carried out.

Microanalysis by EDX reveals that the slag exhibited in fig 4b contains silicon, aluminium and oxygen (fig 5). Carbon is also found due to contamination. Thus the slag is basically identified as of alumino-silicate type.

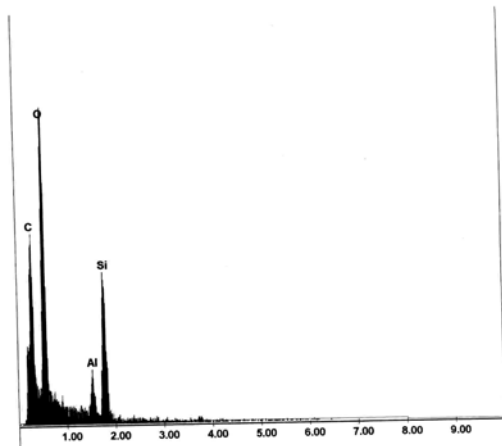


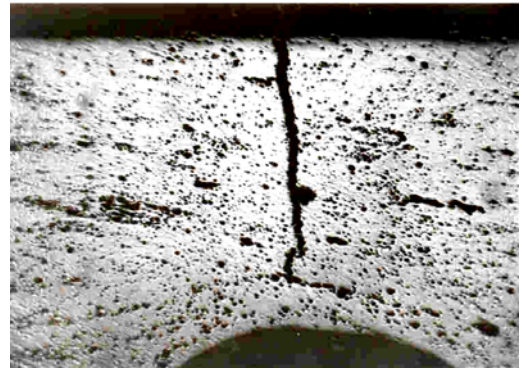
Fig 5. EDX analysis of inclusion in failed artery forceps.

Fig. 6 shows a cross-sectional micrograph of a failed forceps taken at a cracked region. The main crack is running horizontal at the top portion of the micrograph. Secondary cracks are seen running down. The crack morphology is intergranular in nature.



Fig 6. Optical microstructure showing intergranular cracks in failed forceps.

A polished section containing a crack was examined without etching at a lower magnification (fig 7a). The crack occurred near a riveted hole, which is seen at the lower portion of fig 7a. The crack started at such a location where stress is supposed to be high when the forceps is in use. On the contrary optical micrograph (Fig 7 b) of a good sample under unetched condition shows less amount of inclusions. It is seen in fig 7a that the unetched polished section contains numerous dark spots.



(a)

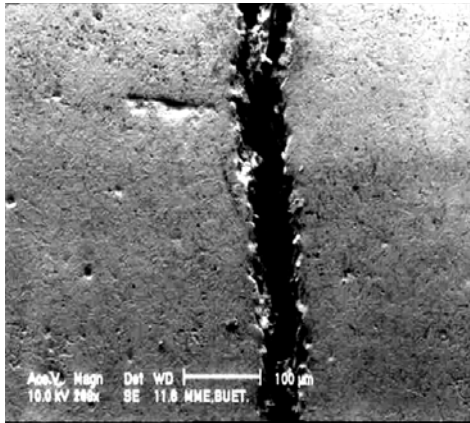


(b)

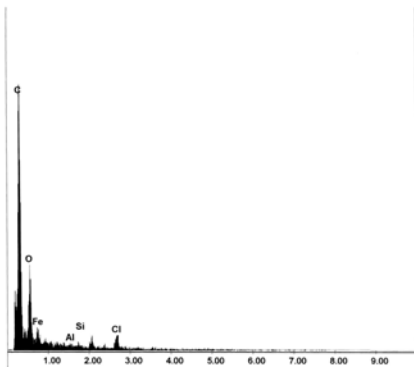
Fig 7. Optical microstructure (a) showing crack around inclusion population in failed crocodile forceps (b) of a good forceps.

As has been shown earlier, these spots are actually slag/inclusion. Presence of such large amount of inclusion is not expected in clean steel. The morphology of the crack shows that the propagation of the crack is assisted by the presence of inclusions.

The crevice inside the crack (fig 8a) was analysed by EDX and the spectrum is shown in fig 8b. The spectrum reveals the presence of chlorine inside the crevice. It may be noted that water used for cleaning the forceps is one of the hospitals where failure occurred was also tested for chlorine. A large amount of chloride ion was found to be present in water.



(a)



(b)

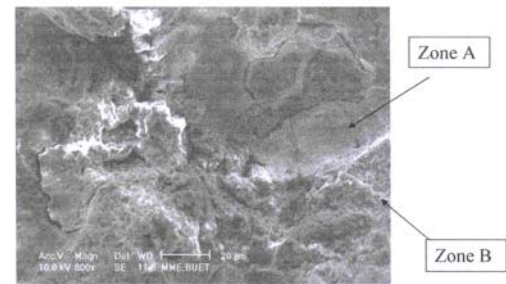
Fig 8 (a).SEM microstructure showing secondary crack on crocodile forceps and (b) EDX analysis on crevice of the crack of crocodile forceps

Scanning electron microscopy was carried on fracture surface of failed forceps and it clearly shows the intergranular mode (fig 9a) and mixed mode of intergranular and transgranular (fig 9b) fracture.

The material used for manufacturing the forceps is a martensitic stainless steel of grade AISI 420. The 400 series stainless steels are mostly used for surgical tools mainly because of their good mechanical properties viz. hardness and strength in the quenched-tempered state, durability and fairly good corrosion resistance in critical environment where repeated sterilization e.g. by autocleaning is required



(a)



(b)

Fig 9. SEM of fracture surface showing (a) intergranular and (b) mixed mode of intergranular (zone A) and transgranular (zone B) type.

Investigations described above reveals that the forceps failed by cracking or fracture. The presence of rust spots is also observed. Cracking took place in areas of high stress concentration e.g. near rivet and near areas of abrupt change of cross-section. Chloride is found to be present in the crevice of the crack. All these suggest that the forceps failed by stress corrosion cracking. Stress corrosion cracking of stainless steel occurs in the simultaneous presence of chloride ion in the environment and stress in the materials [3]. It has been suggested that cracking of martensitic stainless steel in chloride containing environment is mainly due to an actual path corrosion mechanism [4]. The source of chloride in the present case is the water used for cleaning. Obviously the cleaning water is not fully demineralised, as is recommended for such application. Repeated exposure to such chloride-contaminated water can cause chloride enrichment on the surface. The forceps undergoes cycles of stress when these are used in their normal function e.g. gripping. It is thought that the presence of unusually high amount of inclusion/slugs accelerated the cracking process. The presence of large amount of inclusion/slugs indicates that the steel used in the manufacture of the failed forceps is dirty steel which did not undergo adequate refining. Such steel should not have been used particularly for surgical tools. The role of inclusion and metallurgical quality on the performance of tools and devices used in medical field are increasing being recognized. [5,6]

4. CONCLUSIONS

Surgical tools with high inclusion content used under adverse environment can cause premature failures. Investigations show that failure in the form of crack originates at high highly stressed region. The following conclusions can be made from the investigations :

Stress corrosion cracking predominates the failure of surgical tools. Corrosion originates from the presence of chlorine usually associated with water used for routine wash. Corrosion products as well crevice of the crack reveals the presence of chlorine. Corrosion assisted by stress during service through application of pressure originates crack.

Crack branching in association with secondary cracks establishes the presence multi axial stress system at highly stressed region i.e. near rivet holes or abrupt change in section. Crack path primarily follows intragranular due to weak grain boundary resulted from precipitation of carbides at grain boundary. As the cracks grow stress concentration accelerated by the decohesion of matrix from inclusions and final fracture occurs in the form of intergranular and transgranular in nature as shown by scanning electron microscopy.

6. REFERENCES

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7. NOMENCLATURE

Symbol	Meaning
SEM	Scanning Electron Microscopy
EDX	Energy Dispersive X-ray
VHN	Vickers Hardness Number