

## 1. Introduction

Steel instruments are indispensable for any surgery and reused for multiple sterilization. They need to be strong and functional for a safe surgery. Japanese Industrial Standard (JIS) has established a quantitative evaluation method for the standard of biological material and metal material of the product. However, the standard of quantitative evaluations for the surgical instruments has not yet been established in Japan<sup>1,2)</sup>. Most of forceps are to use for ten years and more, but some of them may be damaged in a year or less. I have wondered about the difference of forceps on my clinical experience. The purpose of this study is to evaluate the several characteristics of the forceps available in Japan.

## 2. Methods

Seven types of hemostatic forceps available in Japan. Each was named as A to G. The fatigue test was carried out by repeated loading, the grasp state of jaw serration, the distribution of pressure, observation of the fracture surface after fatigue test with the electron microscope.

## 3. Results

### The fatigue test due to repeated loading (Table.1)

In the results for the number of the fatigue test, the minimum number was 199 times for Forceps A, and the maximum number was 4721 times for Forceps F. In comparison with the average load times, the difference between Forceps A and F was 10 times or more. On the result of the fatigue test, the Forceps G showed the most variations in the loading number.

### The occlusion state of jaw serration gripper.

The projection photographs of the grip portion showed that all forceps tips in jaw serrations occluded without a gap. There needs to be a gap in jaw serrations center. However, for Forceps A, B and G, there was not obvious gap third ratchet teeth ( Figure.2).

### The observation of the fracture surface with the electron microscope

The damage on the hemostatic forceps surface in case of a fracture was examined in the fatigue test with an electron microscope. And it revealed the characteristic of the damage( Figures.3-4).

Table.1 The fatigue test due to repeated loading : Comparison of the loading times.

n=5

Forceps	Average load times	Maximum value	Minimum value	Standard deviation	Coefficient of variation
A	278.8	403	199	91.47	0.33
B	660.2	791	470	129.39	0.20
C	992.6	1404	599	366.64	0.34
D	979.4	1585	626	445.54	0.45
E	652.0	1001	351	256.57	0.39
F	3226.0	4721	2321	943.28	0.29
G	1760.6	3206	960	865.99	0.49

## 4. Discussion

This study showed a significant in the loading difference for more than 10 times on the hemostatic forceps. The result proved that, it is difficult to maintain the good condition of hemostatic forceps from possible damage and to plan the purchase at a hospital. Even today, the mechanization in the production is making a steady progress, the large difference in the fatigue test with a repeated loading showed the difficulty in homogenization of the product in the manufacturing process. For the presence and pressure distribution of the gap of forceps tips in jaw serrations, it is easy to evaluate performance in the inspection that was using a pressure measurement film in addition to the visual inspection. The observation of fracture forceps surface with an electron microscope revealed difference in features of the fracture by fatigue test due to the repetitive loading. This study revealed the current problem of hemostatic forceps used in Japan.

## 5. Conclusion

The current study examined the strength of hemostatic forceps widely used in the clinical field multi directionally for the medical safety. The results suggest that, in the future, the methods of quantitative and qualitative evaluations should be standardized because they are crucial information in clinical settings.

### Conflict of interest statement

HK is consultant for Yoshida Pharmaceutical Co., Saraya Co. and Sakura Seiki.

### Funding sources

None.

## References

1. Cobalt based alloys for surgical implant applications-Part2:Wrought cobalt-chromium-molybdenum alloy JIS T 7402-2, Japanese Industrial Standard 2005;1-6. (in Japanese).
2. General Rules for Fatigue Testing of Metals JIS Z 2273: Japanese Industrial Standard 2010 ; 1-13. (in Japanese).

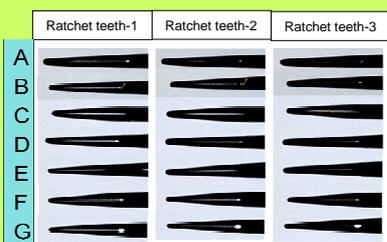


Figure 1. The occlusion state of jaw serration gripper by the projection photographs (n=3)

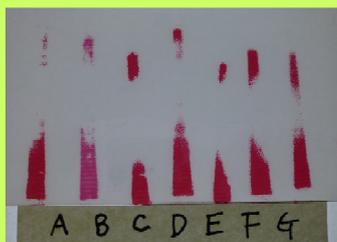


Figure 2. The occlusion state of jaw serration gripper by the pressure measurement film. (n=3)

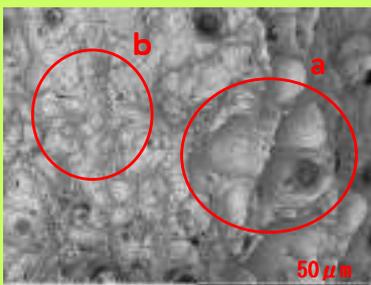


Figure 3. Forceps A : The observation of fracture forceps surface with an electron microscope (×1500)  
a : In the dimple admitted sphere.  
b : The dimple was small compared to "a".

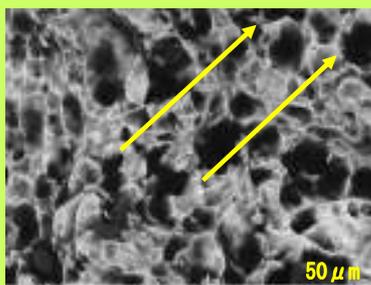


Figure 3. Forceps F : The observation of fracture forceps surface with an electron microscope (×1500)  
There were extended dimples. The force was applied toward to upside from lower side on the image.