Failure Analysis of the Autoclave Sterilizer Fracture

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Abstract The fracture reason of the autoclave sterilizer was analyzed by metallographic examination, fracture analysis and chemical composition analysis. The results showed that failure of the autoclave sterilizer was due to stress concentration at the closed angle of poor fusion area by cyclic stress via vacuumizing and filling water vapor.

1 Introduction
The failed autoclave sterilizer is one of the horizontal pulsating vacuum sterilizers with the type of SVW-103 used by a medical instrument company in Shanghai, and obvious cracks were found in the inner layer near the weld heat affected zone in March 2020. The working principle of this sterilizer is to expose the medical instruments to the environment of high temperature and humidity and so destroy the bacterial spores tissue using the physical characteristics that a large amount of latent heat was released by saturated steam during condensation[1].

The basic parameters of the autoclave sterilizer in the nameplate are that the working pressure is 0.22MPa, the working temperature is 135℃, the volume is 1.5m³, and the working medium is saturated steam. The pressure vessel is vacuumized and filled with water vapor circularly. The inner layer of the sterilizer is made of stainless steel, the specific material brand is unknown (The pressure vessel manufacturing documents were missing). The sterilizer has been in use for nearly 11 years. The autoclave sterilizer was designed and manufactured according to GB150-1998 "Steel Pressure Vessel", which conforms to "Supervision Regulation on Safety Technology for Pressure Vessel". The autoclave sterilizer and its fractured sampling site are shown in Fig.1.

![Fig.1. sample site of the broken-down autoclave sterilizer.](image-url)
2 Fracture test analysis
The autoclave sterilizer has been scrapped by the user. In order to ensure normal operation of other sterilizers with the same type, a large piece region (Fig. 2 (a)) was cut from the inner layer of the autoclave sterilizer where the fracture was found for analysis and comparison. And a sample (sample 1) containing the crack defects (the white rectangular box position on Fig. 2 (a)) was taken, as shown in Fig. 2 (b).

![Fig.2. the fracture sample of the autoclave sterilizer.](image)

2.1 Physical and chemical inspection
The chemical composition and mechanical property of the base material of the inner layer were tested, and the test data were shown in Tab. 1 and Tab. 2.

| Elements | C     | S     | P     | Si    | Mn    | Ni    | Cr    |
|----------|-------|-------|-------|-------|-------|-------|-------|
| Measured values | 0.05  | 0.008 | 0.012 | 0.46  | 0.81  | 8.16  | 18.12 |
| Specified values of S30400 | ≤0.07 | ≤0.030 | ≤0.045 | ≤0.75 | ≤2.00 | 8.0  | 10.5  |
| Specified values of S30408 | ≤0.08 | ≤0.015 | ≤0.035 | ≤0.75 | ≤2.00 | 8.0  | 10.5  |

By analyzing the chemical composition of the inner base material and comparing with the specified values of S30400 (type: 304) chemical composition in ASME SA240 standard, it can be concluded that the inner shell material of the autoclave sterilizer meets the requirements of S30400 stainless steel[2]. The corresponding Chinese material type is S30408 in GB 24511 and the brand is 06Cr19Ni10[3].

| Items                  | Yield strength $R_{p0.2}$ (Mpa) | Tensile strength $R_m$ (Mpa) | Elongation after fracture $A$ (%) |
|-----------------------|----------------------------------|------------------------------|----------------------------------|
| Measured values       | 325                              | 755                          | 55.0                             |
| Specified values of S30400 | ≥205                            | ≥515                          | ≥40                              |
| Specified values of S30408 | ≥220                          | ≥520                          | ≥40                              |

The mechanical properties of the inner layer material can satisfy the material S30400 in ASME SA240 or S30408 in GB 24511 standard through tensile test.

2.2 Metallographic examination
When the sample in Fig. 2 (b) is macroscopically examined, cracks were found at the end point of the
weld (including weld zone and heat affected zone) on the large piece region. The measured plate thickness of the sample was about 4mm, and the longest crack length was about 4.5mm.

Two observed metallographic surfaces were made from the sample at the inner crack-free weld and the section of the block at large piece region without cracks. The microstructure of the sample at the corroded crack-free weld was austenite plus a large amount of intermittent banded ferrite, as shown in Fig.3 (a). The upper part of the figure was the base material zone and the lower part was the weld zone in Fig.3 (a). The microstructures of the block at large piece region without cracks were austenite and a small amount of ferrite, as shown in Fig.3 (b) \(^4\).

![Fig.3. metallographic structures of the sample at the inner crack-free weld and the section of the block at large piece region without cracks.](image)

The metallographic fracture section of the sample 1 was observed by scanning electron microscope, and the fracture section was shown in Fig.4 (a). Compared with Fig.2 (b), it could be found that the fracture fatigue source was located at the unfused zone, and its low and high magnification morphologies were shown in Fig.4 (b) ~ Fig. 4(f). In metallographic structures with high magnification of Fig.4 (e) and Fig.4 (f), the typical characteristics of fatigue striations could be observed clearly \(^4\).

![Fig.4. Fracture morphologies of the sample 1.](image)
Fig.4. metallographic analysis of the fracture sample 1.

2.3 Analysis of fracture corrosion products

The metallographic picture of the corrosion products on the fracture of sample 1 was taken and shown in Fig.5, which shows that there are many dimples indicating the good toughness of S30400 stainless steel. The energy spectrum diagram and quantitative calculation of the corrosion products were shown in Fig.6. Compared with the base materials, the chemical composition of the corrosion products contained a large amount of element O and a certain amount of elements Al, Ca and Ti, which indicates that these elements contained in the working medium of the sterilizer were related to the medical equipment materials heated by steam of the sterilizer. By judging the appearance of excess oxygen and the color of corrosion products, the fracture section must have a large amount of rust (Fe₂O₃), and no CL ions are found in the energy spectrum diagram.

Fig.5. metallographic picture of the corrosion products.

Fig.6. Energy spectrum diagram of the corrosion products.

3. Conclusion of fracture analysis

Based on the above tests, the elements by chemical analysis and mechanical properties of the inner shell satisfied the requirements of the material S30400 in ASME SA240 or S30408 in GB 24511, and
the chemical composition of the base material was confirmed also by the energy spectrum analysis of the corrosion products. A large number of strip ferrite was observed in metallographic structure of sample 1, which belongs to abnormal structure. The fatigue striations appeared on the fracture, and the fatigue crack expanded from the unfused part of the weld, and the corrosion products did not contain chlorine.

Therefore, the analysis conclusion is that the crack is a fatigue crack, and the fatigue source is located at the sharp angle of the unfused zone. When the inner layer of the sterilizer shell is subjected to cyclic vacuum-filled water vapor periodic stress, the stress concentration occurs and expands gradually as the fatigue source at the sharp angle of the unfused zone, and the strip ferrite structure also aggravates the generation of fatigue cracks [5].

In order to avoid the same problem happened in the company's other horizontal pulsating vacuum sterilizers with the type of SVW-103, the following measures could be taken according to the regulations and standards:

1) Welding shall be made in strict accordance with the welding procedure specification, and the welding seam shall be fully welded. Visual inspection and nondestructive testing shall be taken at the welded joints and the welding quality shall be guaranteed and traced. When cracks are found in operating, timely welding repair and post-weld NDT are important and essential.

2) The manufacturing documents, installation documents, inspection documents and other documents of the autoclave sterilizers with this type shall be kept properly, and daily operation, maintenance and periodic inspection shall be conducted and recorded in detail according to the regulation.

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