Shaving Down Obstacles for Verification in Testing and Inspection of Shaver Handpieces: Case Study (2023-2024)

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Cleaning verification and testing of shaver handpieces remains a patient safety concern despite technological advancements in testing, verification and inspection methods. The purpose of this study was to identify issues related to debris and damage (internal and external) in shaver handpieces as well as the contributing factors linked to inadequate tools for cleaning, inspection, verification and education. The results were based on a 12-month study that consisted of 28 facilities in 10 states from May 2023 to May 2024 where 28 handpieces were inspected.

Of the 28 healthcare facilities visited, 22 shaver handpieces were tested for the integrity of the internal seals with a shaver leak tester; the failure rate was 23%. Of the 27 shaver handpieces examined with an interchangeable borescope with a 60 cm catheter for debris and damage in both internal lumens, the failure rate was 92%. Additionally, when 13 shaver handpieces were examined externally for debris or damage with the use of an enhanced inspection microscope, the failure rate was 77%. Finally, of the 10 shaver handpieces verified for protein externally with the use of a protein test, the failure rate was 80%.

During the study period, the U.S. Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database was reviewed for recorded adverse events related to failures with shaver handpieces. Three such examples were found related to handpiece malfunction and were included in this case study.

The integrity failures and retained debris underscore the importance of a proactive approach with a) testing tools in conjunction with protein and inspection or verification tools; b) using adequate cleaning brushes designed for designated key areas of the complex device; and c) providing targeted education to identify failures and debris, internally and externally, in arthroscopic shaver handpieces. Such a proactive approach is essential for reducing the risk of negative patient outcomes.

Key words: *arthroscopic shaver handpieces, retained debris, seal leakage pressure test, borescope inspection, protein residue test, verification inspection tools.*

Introduction

Arthroscopic shaver handpieces are complex devices that Sterile Processing (SP) professionals are challenged with processing daily. Variations of design, multiple lumens, an internal lever, and different manufacturers' instructions for use (IFU) are just a few contributing factors that may lead to overlooked debris and damage.

Shaver handpieces have been used in arthroscopic procedures for many years; however, the devices came under scrutiny when they were linked to a 2009 outbreak in Texas that involved seven cases of infection following arthroscopic procedures. In response to reports received about retained debris, the FDA released a safety communication letter in 2014 acknowledging that pieces of tissue can remain inside arthroscopic shavers. It also encouraged facilities using arthroscopic shaver handpieces to comply with the device manufacturers' IFU and provided considerations for inspecting the inside of the complex devices.

Background

Outbreaks and arthroscopic procedures

In April 2009, an outbreak involving arthroscopic procedures at a Texas facility affected seven patients. During the investigation, borescope examinations were performed on arthroscopic shavers, and it was determined that "retained tissue in inflow/outflow cannulae and shaver handpieces could have allowed bacteria to survive sterilization procedures."[4]

The FDA issued a safety alert about arthroscopic shavers, warning of the possibility of retained tissue that cannot be seen with the naked eye alone (only a borescope used to penetrate the lumens allowed it to be visualized). The FDA also stated, "If you discover retained tissue in arthroscopic shavers at your facility after following the manufacturer-recommended cleaning procedures, you may file a voluntary report with MedWatch."[5]

Recommendations for inspection

ANSI/AAMI ST79:2017/(R)2022 *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities*, section 8.2.1, states "Each time a medical device is processed, it should be visually inspected for cleanliness and integrity. Enhanced inspection with magnification, borescopes, or other inspection methods to verify cleanliness and integrity may be used."[6] The standard also states that damaged instruments or incomplete instrument sets/trays may cause a procedural delay or cancellation and increase risk of patient harm related to instrument malfunction.[6] Lastly, it states that borescopes or other methods may be used to inspect internal channels of instrumentation for cleanliness and integrity unless otherwise recommended in the IFU.[6]

The Association of periOperative Registered Nurses' (AORN's) *Guidelines for Perioperative Practice, Guideline for instrument cleaning* also address the issues and concerns surrounding orthopedic shavers. Section 10.3.3 states to "inspect the internal channels of reusable arthroscopic shavers using an endoscopic camera or borescope."[7] The guidance also notes that it is "not possible to visually inspect arthroscopic shaver channels without a device that can penetrate the channel. Retained organic material or debris in lumens can harbor pathogens and lead to patient injury."[7]

FDA MAUDE database reports

Despite the release of the FDA's 2014 safety communication, there continue to be documented reports within the MAUDE database regarding adverse events associated with arthroscopic shaver handpieces. Concurrently to the study, there was a multitude of adverse events reported in the database.

Three of the recorded adverse events were selected based on the event types under the categorization of malfunction:

- On August 20, 2023, it was reported that upon evaluation of the device, moisture was found in the unit from seal failure.[1]
- On January 25, 2024, a shaver handpiece was reported because part of the shaver broke off during patient use.[2]
- On February 5, 2024, it was reported that a shaver was becoming hot in the doctor's hand while it was used during a procedure.[3]

Although adverse events for retained debris were not identified during the database research, it would be plausible (based on the location of the debris within the shaver handpiece) that debris cannot be seen during the surgical procedure.

Methods

Twenty-eight shaver handpieces were examined, representing various makes and models, to capture the differences in complexity such as whether the shaver lever was fixed or removable in some models. The study included facilities ranging from a 50-patient-bed capacity to those with over 3,500 patient beds, spanning 10 states. Randomized arthroscopic shavers were selected based on availability on the clean side of the Sterile Processing department (SPD) (those already cleaned and awaiting assembly) and those that were sterilized and patient ready. Any abnormality identified, whether internally or externally, were addressed according to the findings; they were either sent back for reprocessing in the decontamination area or sent out for repair.

Tools used to conduct the study in order of use consisted of a(n):

- Shaver leakage pressure integrity tester to identify seal leaks caused by degraded seals within the shaver
- Interchangeable borescope with the use of a 60 cm catheter to penetrate the lumens within the orthopedic shavers
- Enhanced magnification microscope to identify abnormalities externally
- Residue protein test (used externally on the surface of the shaver) to detect residual protein

Results

The 12-month study was conducted from May 2023 to May 2024 at 28 healthcare facilities across 10 states, with a total of 28 shaver handpieces inspected. For the orthopedic shaver seal pressure leakage test, 22 were tested and five exhibited seal integrity failures (a 23% failure rate; see **Figure 1**). The study revealed that internal

abnormalities within the lumens of the shaver had the highest failure rate (92% of the 26 examined), and 24 demonstrated integrity failures (see **Figure 2**). For the external surface inspection of 13 shavers, 10 (77%) were identified with an integrity failure (see **Figure 3**). Lastly, of the 10 shavers tested for residual protein, eight had traces of protein, representing a failure rate of 80% (see **Figure 4**).

Discussion

The results (illustrated in **Figures 1–4**) revealed a high degree of damage to the handpieces examined. It is hypothesized that there were numerous contributing factors to undetectable integrity failures internally and externally. The identified contributing factors included:

- Absence of leakage verification tools that would proactively identify seal integrity failures to avoid possible overheating or stalling of the shaver during the surgical procedure (see **Figures 1** and **5**).
- Lack of appropriate magnification for internal lumen inspection (e.g., borescope) and external inspection (e.g., enhanced microscope). (See **Figures 2** and **3** and **5** through **9**.)
- Absence of a chemical verification tool when an abnormality is identified externally to detect residue protein for recleaning (See **Figures 4** and **10**).
- Lack of education to identify abnormalities and areas of concern (e.g., debris or damage) internally and externally (see **Figures 5** through **10**).

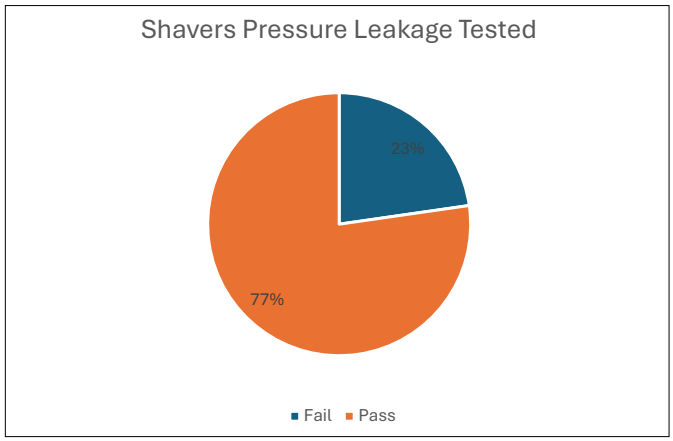


Figure 1: Leakage pressure Integrity failures

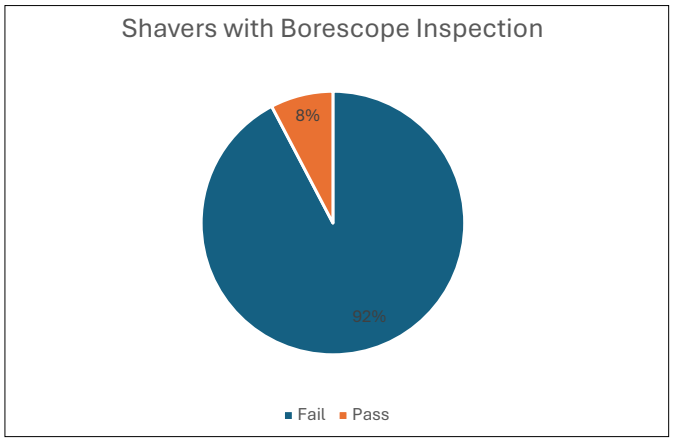


Figure 2: Borescope internal inspection of both lumens within the shaver

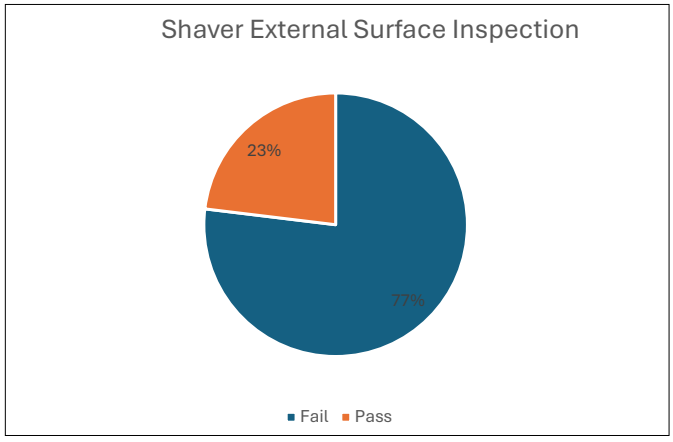


Figure 3: Shaver external surface inspection

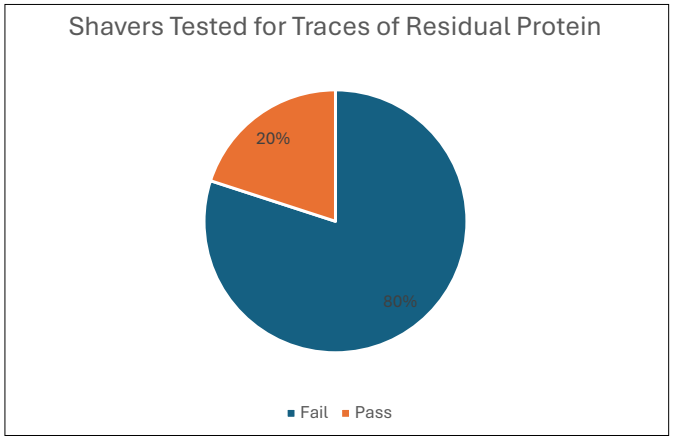
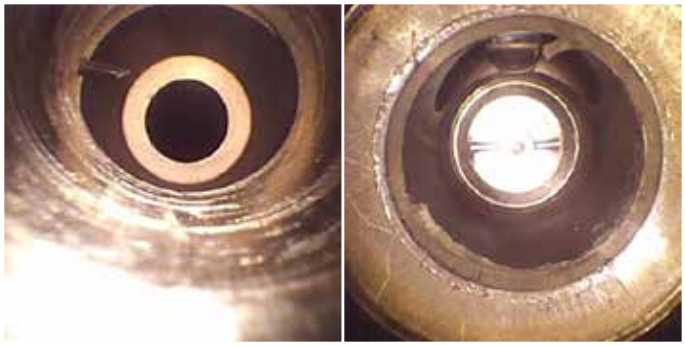
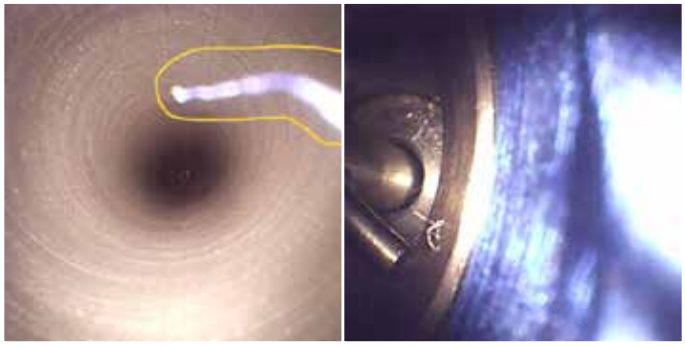


Figure 4: External testing for residual protein



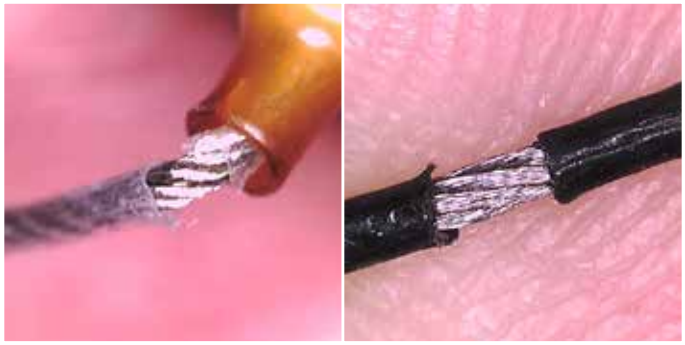
Figures 5A and B: Identified internal damage with the use of a borescope (exposed seals); additionally, shavers were identified with failures when performing leakage pressure testing.

Figures 6A and B: Identified internal debris with the use of a borescope



Figures 7A and B: Identified internal foreign object (lint) with the use of a borescope

Figures 8A and B: Identified external debris (around the buttons) with the use of an enhanced microscope



Figures 9A and B: Identified external damage with the use of an enhanced microscope (connecting cable to solution protection cap)

Figure 10A & B Identified external debris that tested positive for residual protein (damaged silicone insert)

- Lack of tools to effectively clean internally (e.g., multiple lumens of different lengths and diameters, and the drive fork area). (See **Figures 6A** and **B**.)
- Lack of cleaning tools externally (e.g., around the buttons, lever, serrations dependent on the model, and silicone inserts). (See **Figure 8.**)

Root causes for Figures 5 through 10: Compromised seal integrity identified

The compromised seal integrity in both cases was due to an absence of ongoing maintenance, no borescope for internal inspection, and no leakage pressure verification tool. (See **Figures 5A** and **5B**).

Identified debris

Two facilities were identified with insufficient cleaning brushes for both the internal channels and fork area, and there was no internal borescope inspection. (See **Figures 6A** and **6B**.) Lastly (regarding the debris behind the internal lever rotating ball), the facility was not aware of the IFU for the specific shaver handpiece stating the lever was to be removed during the cleaning process.

Identified lint

When lint was identified in two different facilities, it came from two different sources and steps in the process.

- The root cause of the blue lint identified within the irrigating channel came from the assembly process when wrapping the shaver inside a reusable blue surgical huck towel (see **Figure 7A**).
- The root cause of the white lint identified within the fork drive lumen came from inappropriately using an X-ray detectable lap sponge (used during surgical procedures) as a cleaning tool during the decontamination process. (see **Figure 7B**).

Additionally, there were no internal borescope inspections for both sites and insufficient internal cleaning brushes.

Identified external debris

In both facilities (see **Figures 8A** and **8B**), the technicians were using a sponge to clean the handpiece and cable as a whole and not using a block-style brush to clean around the buttons, lever and handle serrations. Moreover, an enhanced microscope or desktop lighting tool was not being used to identify debris.

Identified external damage

External damage was identified specifically on the cable that holds the water-resistant safety cap (See **Figures 9A** and **9B**). The coating laminate had exposed pieces of metal cables that cannot be cleaned, and fraying cables posed an employee safety concern with the potential to puncture a technician during cleaning.

Numerous facilities had similar findings and worse, with exposed metal completely unraveled and outwardly protruding. For most of the external damage identified, the silicone inserts used to cover screws in the handpiece were chipped, gouged or missing.

Identified external protein residue

An external silicone insert, used to cover the screw to hold the lever in place, had protein detected and significant integrity damage (e.g., gouges and recessed areas to expose the hole). (See **Figures 10A** and **10B**.) There were no enhanced inspection microscopes to identify damage and also no residue protein tests.

Limitations

Inconsistencies between facilities for the number of arthroscopic shaver handpieces available to be evaluated for the study could affect the sample size and skew the failure percentages. The variations of makes and models at each facility also hinder the ability to effectively answer the question of which handpieces are harder to clean than others. Overall, there was a limited sample size, which could be expanded for future studies.

Conclusion

The occurrence of integrity failures and the presence of retained debris underscore the importance of taking a proactive approach in testing shaver handpieces. It is imperative to use the correct tools (in conjunction with protein and inspection verification tools) as well as employ appropriate cleaning brushes designed for designated areas of the complex device. By collaborating with key stakeholders to establish early detection methods for damage and debris (internally and externally), providing tailored education on arthroscopy shaver handpieces, and implementing continuous monitoring of process results, the potential for adverse patient events can be significantly reduced.

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