Beyond Endoscopes: Pilot Study of Surgical Instrument Lumen Inspection

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Abstract

Objective: Borescope examinations of endoscope channels are commonly described in literature, but no studies on surgical instrument lumen inspection have been published recently. Inadequately processed surgical instruments have been implicated in patient infections. This study assessed the utility of borescopes for inspecting surgical instruments.

Methods: The study team inspected and photographed sterilized, patient-ready arthroscopic shaver handpieces and suction tips using a tablet camera and borescopes to characterize internal anatomy, defects found in lumens, and the impact of recleaning on debris or residues.

Results: Ten suctions and eight shavers were inspected. All suctions had internal ridges and suction holes that were perpendicular to the lumen. All shavers had visible ridges, elbows, and lever mechanisms inside lumens. Of the 18 instruments, 16 (88%) had internal features that appeared rough or jagged and 17 (94%) had visible debris or discoloration in the lumens. Recleaning efforts generally were effective for suctions, but multiple rounds of recleaning with enhanced steps were less effective for shavers, which were replaced. Researchers documented retained soil and brush bristles in several new shavers despite following manufacturer instructions for cleaning and found visible damage and discoloration within five uses.

Discussion: This study demonstrated the value of borescope examinations for surgical instrument lumens. Visual inspections identified anatomical features that could influence cleaning effectiveness and detected residual soil, discoloration, and debris in most instruments. The findings suggested that manufacturer cleaning instructions were insufficient and additional cleaning was not always effective. In response, the site's multidisciplinary team strengthened risk assessment protocols and enhanced their cleaning practices.

Numerous studies have demonstrated the utility of visual inspection with borescopes for identifying defects in endoscope channels. Upon initiating borescope examinations, investigators in diverse healthcare institutions and departments have detected defects in 100% of endoscopes, including residual fluid, damage, soil, and debris.[1–10] Recent standards and guidelines have incorporated new research on visual inspection into recommendations for endoscope processing.[11,12] In response to strengthened recommendations, one study evaluated a model for training sterile processing technicians on performing visual inspection.[5] After a group of certified sterile processing technicians received 10 hours of training on visual inspection using lighted magnification and borescopes, all of the trained technicians identified clinically relevant defects in some of the "patient-ready" endoscopes in their facility's inventories. The findings resulted in actions, such as device recleaning, repair, or replacement and trialing new technologies, to improve the effectiveness of cleaning and drying methods.

Borescopic inspection of interior lumens and surfaces of surgical instruments was first reported following a 2009 outbreak investigation. In this outbreak, seven patients were infected with *Pseudomonas aeruginosa* during knee or shoulder surgery, and arthroscopic shaver handpieces ("shavers") were implicated as the cause.[13] Investigators observed retained tissue and brush bristles in the lumens, despite processing performed per manufacturer instructions for use (IFUs). They concluded that the *P. aeruginosa* that caused the patient infections after arthroscopic surgery was the same strain found in the decontamination sink and likely had survived sterilization due to the retained debris in shaver lumens.

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As a result of this outbreak, the Food and Drug Administration (FDA) announced a safety review of shavers that encouraged facilities to inspect these devices using a borescope.[14] Following this, Azizi and colleagues[15,16] investigated surgical suctions and shavers using borescopes. They found that device design and manufacturing defects rendered them nearly impossible to effectively clean, with visible soil and debris detected in all of the 144 sterilized instruments evaluated.[15] To address the retained soil, researchers performed multiple rounds of additional processing steps, including repeat rinsing and brushing (after which 75% remained contaminated), a 20-minute enzymatic soak and automatic reprocessor cycle (49% remained contaminated), and up to three ultrasonic cycles that were still unable to remove all of the debris (11% remained contaminated).

Despite a published outbreak[13] and the research of Azizi and colleagues documenting that processing IFUs for lumened medical devices were insufficient,[15,16] no other evidence on the use of borescopes for real-world inspection of clinically used surgical instrument lumens has been published. To address this gap in the literature, researchers explored the methods used by sterile processing departments (SPDs) to inspect lumens by reaching out to several SPD leaders.

One SPD supervisor photographed a fully processed Poole suction using a borescope (FIS-007; Healthmark Industries, Fraser, MI). This instrument has an inner core encased in an exterior sleeve with numerous small holes that are perpendicular to the lumen and intended to prevent blockage by tissue or fat while allowing large quantities of blood, secretions, and other fluids to be rapidly removed from bodily cavities (Figure 1*A*; unpublished data on file). The perforated outer sleeve may be removed to facilitate pinpoint aspiration through the tip. Borescope examination found that the exterior was smooth, while the interior surfaces had substantial variation, with smooth edges around some of the holes and jagged edges ("claws") around others (Figure 1*B*–*E*). A small chunk of debris was visible on one of the metallic claws (Figure 1*C*, arrow).

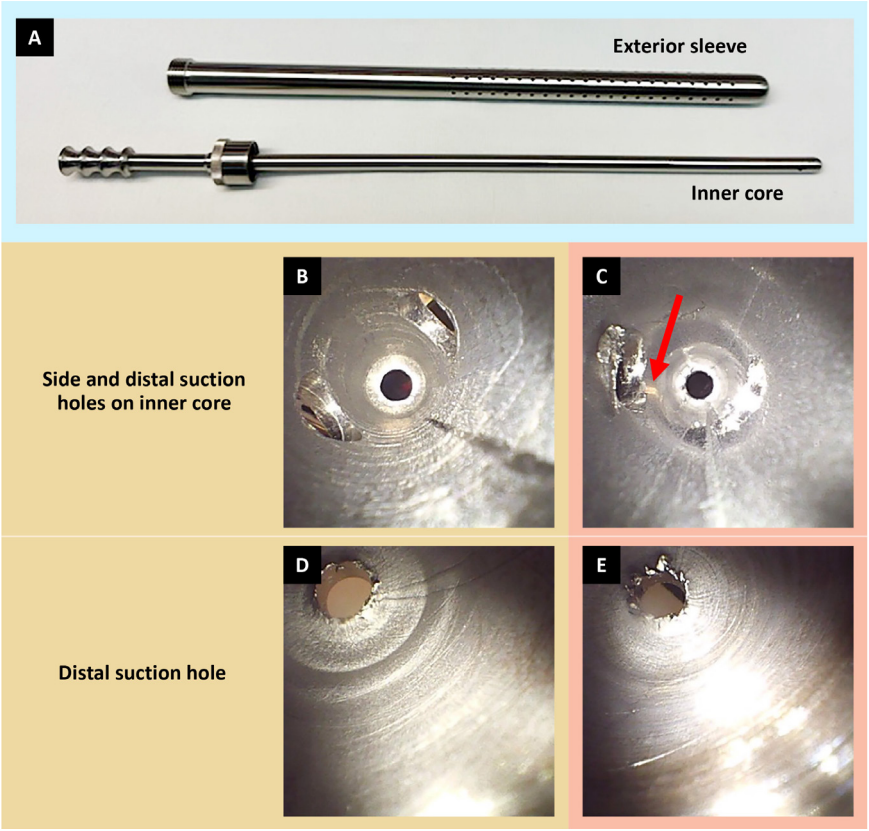

Figure 1. Anatomy and manufacturing features of a Poole suction. Images courtesy of Ofstead & Associates, Inc. Used with permission.

Visible debris inside the Poole suction echoed concerns raised by Azizi and colleagues about manufacturing quality and implications for cleaning effectiveness in surgical instruments. These initial observations served as a catalyst for designing this study, which aimed to assess the value of using borescopes to inspect surgical instrument lumens, characterize the internal anatomy and nature and frequency of defects, and evaluate the impact of recleaning on visible debris or residues found inside lumens of a subset of inspected instruments.

Methods

This study was conducted by an independent research team with extensive experience performing borescope exams of flexible endoscopes. The team worked in collaboration with SPD personnel in a large urban hospital. The facility had obtained several new borescopes but had not begun performing borescope exams. The project was approved by hospital leadership as a quality improvement initiative that did not involve

human subjects and therefore was exempt from review by the institutional review board.

Risk Assessment Protocol

Prior to commencing the study, the facility's SPD manager conducted a failure modes and effects analysis in collaboration with the infection prevention, risk, and quality departments to develop an internal process for reporting and responding to potential adverse findings. The SPD manager provided detailed information to multidisciplinary leadership staff to keep them informed during the course of the study.

Visual Inspection Tools and Protocols

Visual inspections were conducted on a stainless steel counter in a packaging station located on the clean side of the SPD. Exterior surfaces of instruments were photographed using a tablet camera (Tab M8HD, Lenovo, Quarry Bay, Hong Kong), while internal surfaces were photographed using a borescope (Endoinspect Videoscope EP5013 or EP5000; Advanced Inspection Technologies, Melbourne, FL).

Inspections were systematically conducted on arthroscopic shaver handpieces (Dyonics PowerMax Elite and Platinum models; Smith and Nephew, Watford, UK) and suctions (Frazier suction tubes [12Fr, 10Fr, and 8Fr]; V. Mueller, Vernon Hills, IL) that had been cleaned and sterilized following procedural use. Researchers used a log sheet for documentation of notable anatomical features and defects, including debris, staining, damage, or residual fluid. Inspections were conducted from the proximal end of the instrument through the lumen to the distal end, with additional inspections from the distal end as needed to thoroughly examine a defect or feature. Researchers used swabs and brushes to investigate visible discoloration and debris. In some cases, brushes were inserted in one end while a borescope was inserted in the other end to directly observe the impact of brushing on the visible defect. Forced air was used in one instance to determine if visible debris could be blown out.

In accordance with the study protocol, all instruments were recleaned and sterilized after inspection. If substantial visible debris or residue was observed, instruments were recleaned and reinspected with the study team to evaluate suitability for being returned to service.

Results

Suctions

Ten Frazier suctions were examined, including three 12Fr, three 10Fr, and four 8Fr tips pulled from cervical or lumbar laminectomy sets (Table 1). These suctions have very narrow lumens with an angled elbow between the grip and distal tip (Figure 2*A*). The grip has an opening called the suction hole that is covered or uncovered with the surgeon's thumb to control suction during procedures (Figure 2*B*). Researchers found that the 12Fr suction lumens were large enough for inspection with a 1.9-mm borescope, while

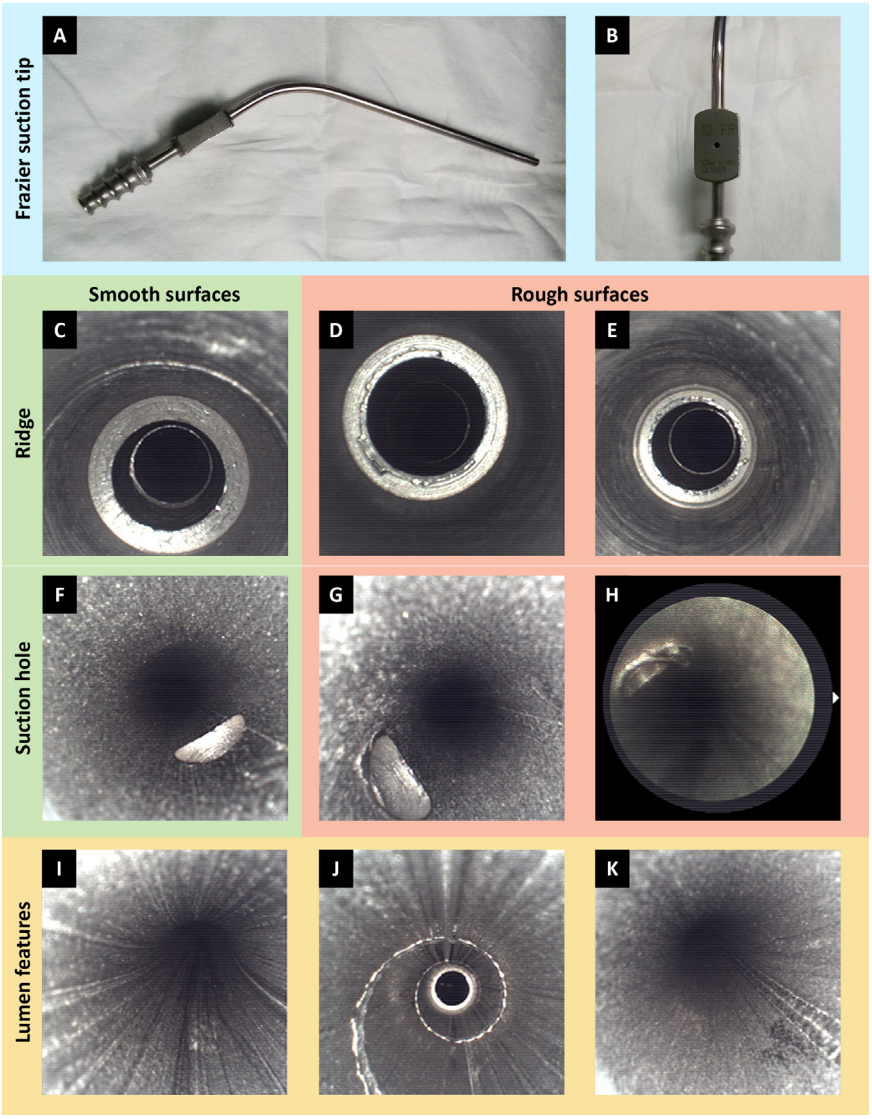

Figure 2. Suction anatomy and manufacturing features. Images courtesy of Ofstead & Associates, Inc. Used with permission.

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No.	Instrument	Manufacturing Features	Defects	Response to Findings
Suction tips				
1	Cervical Frazier 8Fr	Unremarkable	White speckles	NA
2	Cervical Frazier 10Fr	Rough suction hole	White speckles	NA
3	Cervical Frazier 12Fr	Etching/"tiger stripes"	Yellow and white debris, fibers/lint	Reinspected after recleaning
4	Cervical Frazier 12Fr	Rough ridge surface	Brush bristle, white debris and speckles	NA
5	Lumbar Frazier 8Fr	Rough suction hole	Red discoloration, white chunk	Reinspected after recleaning
6	Lumbar Frazier 8Fr	Rough suction hole, rifling	Potential debris	NA
7	Lumbar Frazier 10Fr	Unremarkable	None	NA
8	Lumbar Frazier 10Fr	Rough suction hole	Yellow chunks, possible brush bristle	NA
9	Lumbar Frazier 12Fr	Rough ridge, rifling, "tiger stripes"	Small bits of debris throughout	NA
10	Lumbar Frazier 12Fr	Rough ridge and distal end, rough suction hole	Brush bristle, discoloration	NA
Arthroscopic shaver handpieces				
11	Shaver 1*	Rough surfaces	Substantial thick reddish debris on ridge, small chunks of debris throughout, discoloration, fibrous debris	Multiple attempts to reclean, replaced
12	Shaver 2*	Rough surfaces	Discoloration, chunks of debris throughout, substantial debris at suction control lever	Multiple attempts to reclean, replaced
13	Shaver 3*†	Unknown	Debris on ridge, chunks of bone, soil	Multiple attempts to reclean, replaced
14	Shaver 4‡	Rough ridge	Fibrous debris	Recleaned
15	Shaver 5‡	Rough surfaces	Discoloration, pitting	Recleaned
16	Shaver 6‡	Rough ridge	Blue debris, white debris	Recleaned
17	Shaver 7‡	Rough ridge	Scratches with residue, fibrous debris, brush bristle, discoloration	Recleaned
18	Shaver 8‡	Rough edges on lever hood, rough ridge	Scratches, discoloration	Recleaned

Table 1. Summary of findings for visual inspection of suction tips and arthroscopic shavers. "NA" refers to "not applicable," in that instruments were recleaned and resterilized prior to use (without repeat visual inspection). *Shavers 1–3 were the Smith and Nephew Dyonics Powermax model, which is depicted in Figure 4. †Photo files corrupted while transferring from the laptop with the borescope software to research file. ‡Shavers 4–8 were acquired to replace the initial shaver fleet following visual inspection findings and recleaning attempts. They were the Smith and Nephew Platinum model, which is depicted in Figure 5.

10Fr and 8Fr suctions were inspected with a 0.8-mm borescope due to narrow lumens.

Borescope examination revealed a ridge where the suction port connected to the rest of the lumen. This ridge had a smooth surface in seven of 10 suctions, while the ridge surface was rough in three suctions (Figure 2*C*–*E*). When researchers inspected

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the interior of the suction hole (Figure 2*F*), five holes had raised or jagged edges (Figure 2*G* and *H*). Lumen surface features varied considerably among instruments, with some having striations along the length (Figure 2*I*), rifling (Figure 2*J*), and what appeared to be a metallic seam (Figure 2*K*).

Nine of 10 suctions harbored visible debris. Retained brush bristles were found in two instruments (Figure 3*A* and *B*), and linty, fibrous debris was observed just inside the distal tip of one instrument following recleaning (Figure 3*C*). The suction with the fibrous debris was reinspected following application of forced air, and no debris was observed. Lumens also contained unidentified substances, including yellow and white chunks and tiny white speckles (Figure 3*D*–*F*). The study team recleaned and reinspected two suctions with particularly significant debris. Recleaning appeared to successfully remove most observed debris, and instruments underwent another round of cleaning prior to being sterilized and returned to service. In some cases, it was unclear whether observed defects were truly debris or features of the lumen surface.

Arthroscopic Shaver Handpieces

Eight shavers were inspected using a 1.9-mm borescope. These shaver models (Figure 4*A*) have a lumen running from an outlet in the distal disposable attachment port (Figure 4*B*) through an elbow with a hooded mechanism controlled by a lever that controls suction by opening and closing the hood (Figure 4*C*). The lumen has a ridge (Figure 4*D*) between the lever and the suction connection port. The surface inside the suction connection port is highly textured, appearing rough and almost knurled (Figure 4*E*).

The first shaver inspected (shaver 1) had thick brownish-red debris coating the ridge (Figure 4*F*), and the second (shaver 2) had soil and debris that appeared to include tissue and bone fragments on the elbow underneath the suction control lever (Figure 4*G*). In addition, retained debris was observed throughout the lumens of both shaver handpieces, including chunks of yellow and white soil and fibers that appeared to be lint or brush bristles. Rusty-appearing discoloration was also noted in the lumens, particularly along rough surfaces in the suction port connection.

Visible soil persisted in both shavers through an initial round of recleaning, and

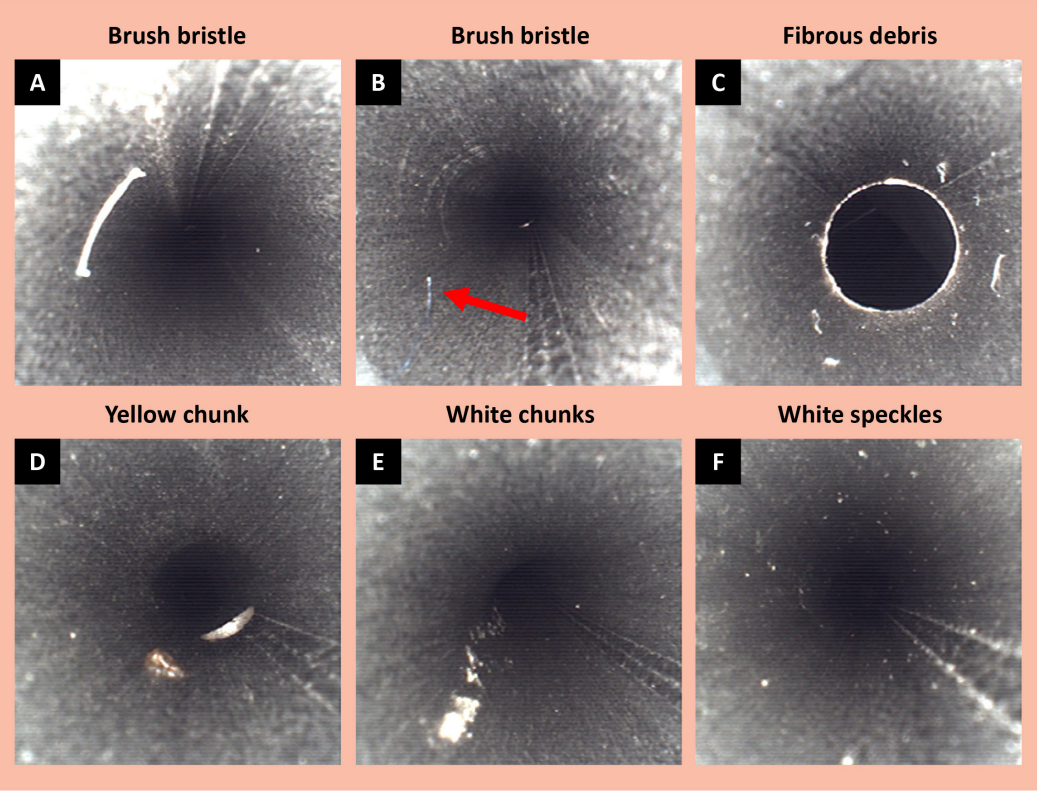

Figure 3. Debris observed in sterilized suctions. Images courtesy of Ofstead & Associates, Inc. Used with permission.

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site personnel reviewed the IFU to determine potential methods for addressing retained soil. The IFU allowed for automated washing and disinfecting, but only with a special rack and connectors that the facility did not have. Site personnel activated their risk assessment protocol and combined recommendations in the IFU, departmental guidance, and expert advice to develop a strategy for removing retained debris. The protocol was adjusted incrementally when visible debris remained through four more rounds of increasingly intense cleaning. These enhanced rounds of cleaning included:

- Round 1: 2-minute rinse, 5-minute enzymatic soak, brushing per IFU, and final 2-minute rinse
- Round 2: 2-minute rinse, 16-minute enzymatic soak, brushing per IFU, and final 2-minute rinse
- Round 3: 2-minute rinse, 16-minute enzymatic soak, brushing per IFU, two 90-second mechanical flushes, and final 2-minute rinse
- Round 4: 2-minute rinse, 16-minute enzymatic soak, brushing per IFU, two 2-minute bidirectional flushes, and final 2-minute rinse

After enhanced cleaning, debris was still observed on the suction connection ridge in shaver 1 (Figure 4*H*). The debris at the suction lever elbow in shaver 2 had been removed, but the surface underneath appeared to be compromised, with visible pitting and discoloration (Figure 4*I*). A third shaver (shaver 3) was inspected and had visible debris that appeared to include soil and bone fragments prior to multiple rounds of recleaning as described above. Enhanced recleaning seemed to be effective in removing soil and debris, but the surface underneath appeared pitted and rusty, similar to the conditions observed in shaver 2. A brush bristle, pitting, and rusting were detected by site personnel in a fourth shaver. However, the data collected were incomplete, and as a result, this instrument was not included in analysis or Table 1.

Due to these findings, the site retired all four shavers and acquired six new shavers (Figure 5*A*). They routinely inspected the new shavers with a borescope and found that

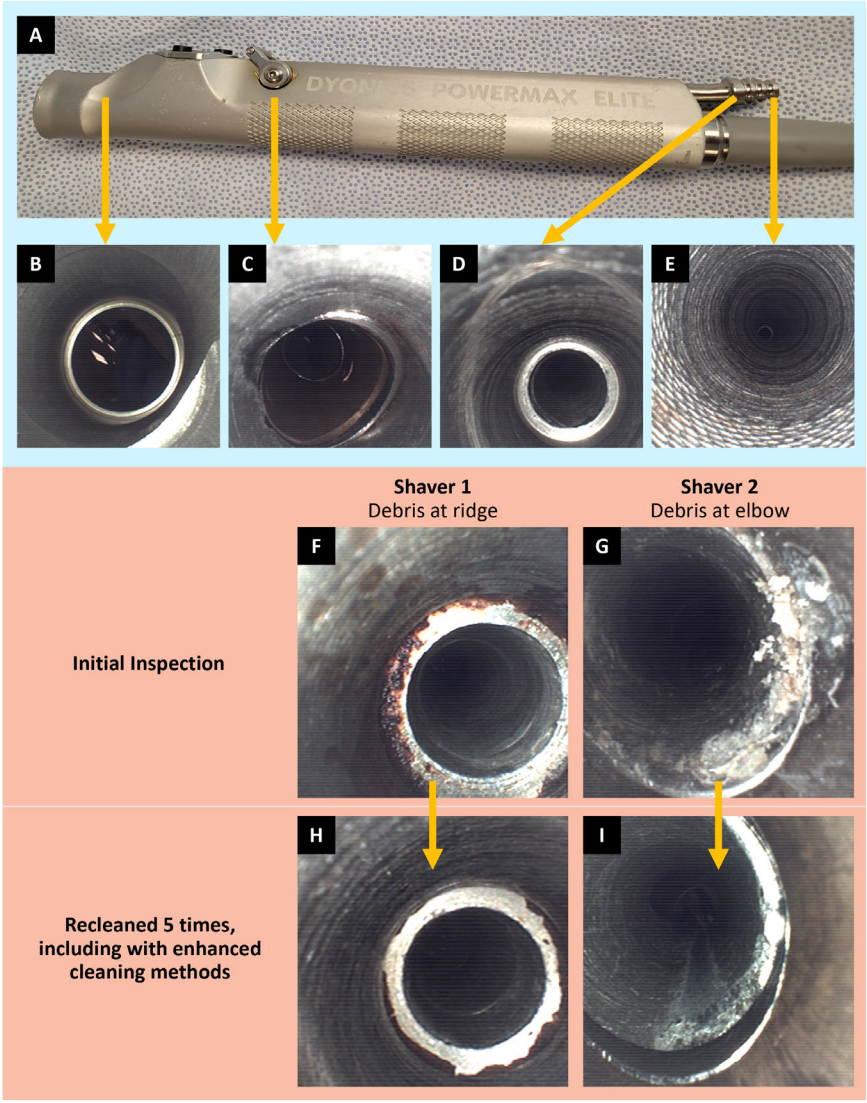

Figure 4. Arthroscopic shaver handpiece anatomy and residual soil. Images courtesy of Ofstead & Associates, Inc. Used with permission.

following the manufacturer IFU for cleaning did not consistently remove visible soil. After the first use, defects (e.g., fibers, scratches) were observed by site personnel in some processed shavers. The SPD amended the cleaning protocol to include an overall 4-minute bidirectional flush. The additional flushing appeared to remove visible debris but did not eliminate rusty discoloration. Approximately 1 month after acquisition, five of the six new shavers were systematically inspected by the research team. At that time, they had each been used for orthopedic surgery a total of three to five times. Researchers observed brown residue in scratches (Figure 5*B*) and what appeared to be bone fragments or other substances along ledges (Figure 5*C*). Rusty discoloration (Figure 5*D*),

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new divots and damage to the surface (Figure 5*E*), and fibrous debris (Figure 5*F* and *G*) were also observed in these new shavers.

Discussion

During this pilot study, researchers found that suction and shaver lumens were diverse and highly textured, with ridges, elbows, and suction holes that commonly had rough or jagged edges. Most instruments (90% of suctions and 100% of shavers) had brown or rusty discoloration or harbored visible debris, including blue and white fibers, brush bristles, and yellow and white chunks that sometimes appeared to be tissue or bone fragments. Soil was observed throughout lumens, most commonly on or near internal ridges and elbows. Brush bristles were observed in lumens several times after instruments were recleaned. Although site personnel followed manufacturer IFUs and actuated suction levers during manual cleaning to ensure internal surfaces of suction mechanisms were cleaned, debris was observed in the elbows of two shavers.

The clinical relevance of the retained debris is unknown, but tissue and brush bristles were observed in the lumens of shavers at another facility that had an outbreak involving seven arthroscopic surgery patients.[13] Investigators hypothesized that the debris "provided a sanctuary" that protected the outbreak pathogen from sterilization. More research is needed to determine whether internal characteristics that make a lumen difficult to clean (e.g., rough surfaces, jagged edges) are more likely to cause brush bristles to disconnect from the brush shaft, as well as to clarify the potential impact of retained debris on patient outcomes.

After fewer than five uses, surface changes, including scratches, were observed on ridges, elbows, and lumen walls in the new shavers. The impact of this early damage on processing effectiveness and device durability is unknown. Rusty, brown discoloration that site personnel thought might be rust appeared after one use in some new shavers. They were unable to remove the discoloration with additional cleaning and flushing. The scope of this pilot study did not include testing visible residue or debris to determine its nature and potential origins.

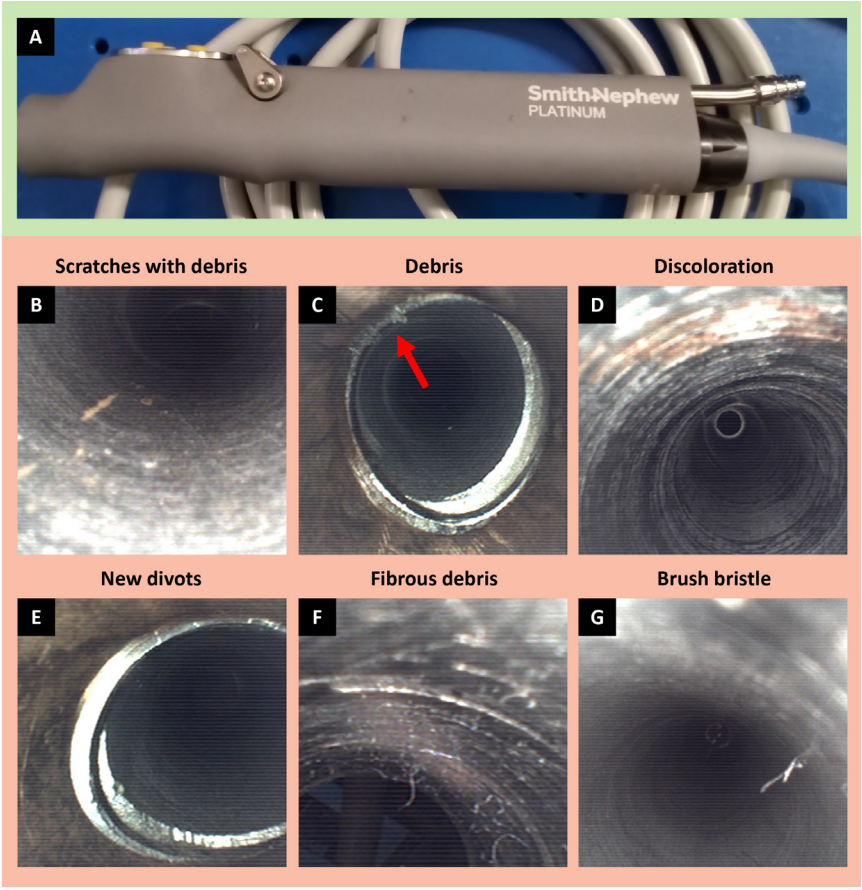

Figure 5. Defects in new arthroscopic shaver handpieces used five or fewer times. Images courtesy of Ofstead & Associates, Inc. Used with permission.

Studies are needed to determine the utility of tests for organic soil to verify cleanliness of surgical instrument lumens as recommended by current standards for flexible endoscopes[11] based on a substantial body of evidence.[2–4,7,17–21] However, these tests would not detect brush bristles, lint, or other nonbiological debris. The FDA's 2009 safety communication encouraged facilities to "evaluate the adequacy" of their manual cleaning practices and to consider inspecting shaver lumens after cleaning,[14] and two shaver manufacturers recommended borescope examination of lumens.[22,23] The IFUs for models inspected in this study only specified that shavers be inspected "under normal lighting,"[24,25] which was not sufficient to identify the debris found in the lumens with borescopes.

Further research should be performed to describe the internal anatomy of these and other instruments, identify features that could influence cleaning effectiveness, and establish the feasibility of routine visual

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inspections in instruments with very narrow lumens or extreme internal angles that could prevent the use of borescopes. More work is also necessary to characterize the nature and clinical relevance of observed defects. Finally, given the training and time necessary to effectively perform borescope examinations, the use of artificial intelligence (AI) to assist with inspection should be explored. Preliminary work by Barakat et al.[26] suggested that AI could play a role in flagging damage and debris in flexible endoscopes. The utility of AI systems for supporting inspection of surgical instruments is unexplored, and collaborations among manufacturers, programmers, and experts in sterile processing and device repair may be beneficial.[27]

Limitations

This pilot study was performed in a single site, and only two types of lumened instruments were inspected. Site personnel had received borescope training prior to study commencement and were coached by the research team during instrument inspection. Previous research has shown that SPD personnel who received extensive training gained the knowledge and skills necessary to successfully perform visual inspections of complex instruments.[5] This level of training and guidance may have enhanced the ability of site personnel to identify visible defects and may not be feasible in other settings.

Conclusion

Visual inspection can identify instruments with damage, residual soil, and retained debris that could otherwise harm patients, but it requires substantial time, training, and support from stakeholders. Currently, little guidance exists from manufacturers and regulatory bodies on visual inspection of surgical instrument lumens. Solutions should address device design issues, IFU adequacy for real-world circumstances, and the need for automation and training to facilitate optimal outcomes in the field. This undoubtedly will require collaboration by manufacturers, guideline-issuing bodies, and users to relieve the burden on workers and improve patient safety.

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Disclosures

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