Views on "Report on Scope G-206"

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1. Endoscope Reprocessing and Decontamination

First we mention reprocessing and decontamination of TJF-Q180V referenced in "Report on Scope G-206". Olympus instructs users in reprocessing procedure of the endoscope with the instruction manual. Also, Olympus provides to them reprocessing equipment such as the dedicated brushes, the dedicated tubes and etc. Fig 1 shows the outline of the reprocessing instruction manual.

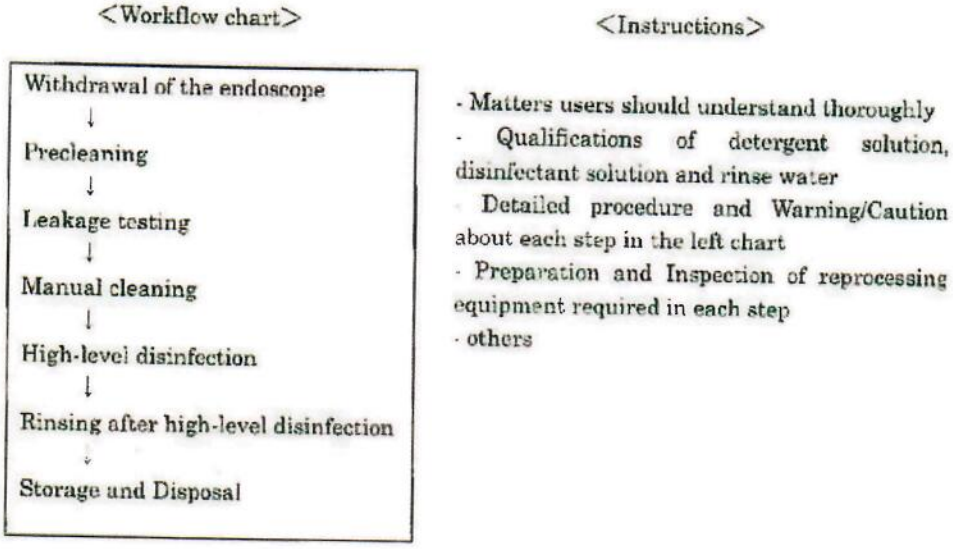

Fig. 1 The outline of the reprocessing instruction manual

Olympus confirmed the intended efficacy of disinfectant solution (glutaraldehyde) recommended in the instruction manual with microbiological tests. when the endoscope was properly reprocessed in accordance with the instruction manual. Fig. 2 shows the microbiological test result of TJF-Q180V. Test microorganism was Mycobacterium terrae which is one of the most resistant bacterium to disinfection. The test protocol is standard for testing cleaning and disinfection, and follows ASTM (American Society for Testing and Materials) E1837-96 (Reapproved2007) Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test) .

< Summary Protocol >

Sterilize the test device so that the device is in sterile condition

-> Contaminate the device with a specific kind of microorganism to evaluate the efficacy of cleaning and disinfection

> Clean the device in accordance with the instruction manual

-> Disinfect the device in accordance with the instruction manual

-> Collect the microorganism left

-> Incubate and count the microorganism collected

Test date (dd/mm/yyyy): 09/06/2008 [CFU/Site]

Scope / Site	Control		Test samples after cleaning and disinfecting				
	C1	C2	3	4	5	6	7
Distal end	3.11×10^6	3.89×10^6	0	ND*	0	0	0
Reduction (RF)			6.54	ND*	6.54	6.54	6.54

*) No.4 was judged "No Data", for miss operating. Therefore the following additional samples were tested.

Test date (dd/mm/yyyy): 07/07/2008 [CFU/Site]

Scope / Site	Control		Test samples after cleaning and disinfecting	
	C1	C2	3	4
Distal end	3.16×10^6	3.36×10^6	0	0
Reduction (RF)			6.51	6.51

Fig. 2 The microbiological test result of TJF-Q180V

The European standard of disinfection effectiveness of disinfectant: EN 14563:2008 "Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)" requires disinfection effectiveness of disinfectant to be 10^{-4} reduction at least. The test result demonstrated that all SAMPLEs showed cleaning and disinfection effect exceeding 10^{-6} reduction for all SITEs, which is well above the 10^{-4} reduction.
However, if just one instruction isn't followed, the device is improperly reprocessed and microorganism can remain on it. The instruction manual introduces that the medical literature reports incidents of cross-contamination resulting from improper cleaning, disinfection, or sterilization and warns that insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.

Users are required to pay full attention to all procedures in order that they achieve proper work described and instructed in the instruction manual. But if they are trained in advance, they will be able to achieve proper work without any trouble. Also, guidelines of endoscopy doctor/nurse society in various regions worldwide state that it is important to follow proper cleaning and disinfection procedures like instructed in the instruction manual for cross-infection prevention, and enlightens users for it. For example, in Europe, ESGE(European Society of Gastrointestinal Endoscopy) – ESGENA(European Society of Gastroenterology and Endoscopy Nurses and Associates) has published "Guidelines on Cleaning and Disinfection in GI Endoscope". Fig. 3 shows an extract from its introduction, as the point.

> The appropriate reprocessing of flexible endoscopes and endoscopic accessories is an essential part of safety and quality assurance in gastrointestinal endoscopy. -An omission- This guideline focuses only on flexible endoscopes and the accessories used in gastrointestinal endoscopy. It addresses a number of important aspects of safety in gastrointestinal endoscopy with special emphasis on avoiding infection that may result from inadequate reprocessing of endoscopes or endoscopic accessories. In addition to the general statements, it provides detailed technical protocols for the daily work of nurses and associates, as we are aware of multiple local variations in the use of general guidelines. This ESGE – ESGENA guideline is a consensus prepared by endoscopists, microbiologists, hygienists, endoscopy nurses, and representatives of the biomedical industry. -An omission- The ESGE – ESGENA guidelines are strong recommendations, but within each country, endoscopists, nurses, and hospital administrators have to comply with local regulations and national law, and at all times, it is important to follow manufacturers' instructions.

(Reference: Beilenhoff U et al. ESGE-ESGENA guideline: Cleaning and disinfection in gastrointestinal endoscopy... Endoscopy 2008; 40: 939-957)

Fig. 3 An extract from the introduction of ESGE – ESGENA guideline

When reprocessing an endoscope, it is valuable to use properly an Endoscope Reprocessor which has been validated for its reprocessability of the endoscope. However, if an Endoscope Reprocessor improperly reprocesses without following the instruction manual, it cannot obtain sufficient cleaning and disinfection efficacy.

An endoscope may be contaminated again, if it is improperly treated after reprocessed. For example, if a reprocessed endoscope comes in contact with contaminated devices or hands or is stored in a dirty container, it could be contaminated. Olympus warns user to pay attention to treatments and storage after reprocessing an endoscope with the instruction manual.

A reprocessed endoscope cannot remain clean for a long time. Some countries legally require users to reprocess an endoscope just before using it on the day.

Hospital infections aren't attributed only to endoscopes. If a hospital infection is attributed to an endoscope procedure, a vehicle for microorganism is considered to be not only endoscope, but also endoscope accessories, other various devices, hands of doctor/nurse and etc. which are used around the procedure. Even if microorganism is detected on an endoscope when a hospital infection breaks out, it doesn't necessarily prove that the endoscope is a vehicle which causes the hospital infection.

As explained above, Olympus validates sufficiently that Olympus endoscopes are reprocessable, provides users with necessary instructions and caution with the instruction manual, and enlightens them as necessary. As before, Olympus will continue to provide information and training to users so that they can understand proper cleaning and disinfection are important.

2. Our view on the process of making "Report on Scope G-206"

From viewpoint of 1, we have some doubts and problems on the process of making "Report on Scope G-206" (called Report S from now on) and describe below.

- Report S studied cause of contamination of TJF Q-180V on which microorganism was detected after user facility had reprocessed it, with sampling and culturing every parts of the endoscope. But the author didn't confirm whether user facility performed proper cleaning and disinfection procedures to the endoscope in accordance with the instruction manuals of the endoscope and the endoscope reprocessor used at the same time, despite the medical literature reports that improper cleaning and disinfection possibly cause hospital infection in general, as explained at 1. He didn't confirm also whether user facility treated the endoscope properly after reprocessing it. And, despite he didn't study validation for the microbiological test protocol, he is obsessed just as if the endoscope structure caused contamination of pseudomonas aeruginosa or residue after reprocessing, and develops imagination. Additionally, the author noticed a possibility that the user facility had reprocessed the endoscope improperly, it may have caused contamination of microorganism or residue, but he didn't examine and study it thoroughly. Therefore, Report S doesn't scientifically report on endoscope reprocessing and contamination, and includes much prejudiced and limited imagination.

- Report S often objects that endoscope reprocessing become difficult due to some small spaces in the distal end of the endoscope, and recommends Olympus to modify the design and the instruction of the endoscope. But, we suppose from all over Report S that the author, an engineer, doesn't have sufficient knowledge for endoscope reprocessing. We cannot trust such a person, even if he evaluates endoscope reprocessing and objects against the endoscope design.
- Report S often objects, from some results of evaluating exterior parts of the endoscope, that it is highly possible that some of the parts could cause leaks, and recommends Olympus to check on seals, to modify the sealing design, and to improve the maintenance system. But, the author, engineer, doesn't attempt to analyze scientifically the superficial discolored of the endoscope, and to perform a leakage test to check whether the endoscope leaks out actually, and he developed a leakage hypothesis only by his imagination. Report S includes many unscientific views, and isn't valuable to be trusted.

3. Our view on Observations and Recommendations in "Report on Scope G-206"

The below describes our view on observations and recommendations in Report S 6. View of an independent expert (P.23-24).

(1) Accessibility for brushes

(1)-1 Observations from Report S:

During the sampling, it became clear a number of times that there were various cracks, corners and cavities in the tip of Scope G-206 which could not be reached, or only with great difficulty, using the cytology brush with a 3 mm diameter. The following areas in particular proved difficult to reach for this brush:

- the crack under the hinge point of the elevator
- the crack caused by the axial play of the elevator
- the space below/behind the curve of the elevator

Our view:

The endoscopes have to have some small spaces around the forceps elevator due to the condition of structure and diameter, but each medical device including endoscope has similar space to a greater or less extent. Reprocessing a medical device, brushing is performed in possible extent. The instruction manual for the endoscope instructs users in reprocessing procedures including brushing around the forceps elevator. The endoscope has been confirmed to be sufficiently reprocessable following the instruction manual. (see Fig.2)

(1)-2 Recommendations from Report S:

In the scope design, increase the space around the said points so that these are accessible for brushes and/or make sure that the cleaning instructions are such that these points in the current scope can be cleaned thoroughly in one way of another. Verify that the modified designs and/or instructions do actually result in good cleaning.

Our view:

As explained at 1(Fig.2), the endoscope has been confirmed to be sufficiently reprocessable following the instruction manual.

(2) Quality seal

(2)-1 Observations from Report S:

The seals in and around the tip were shown to display abnormalities which could potentially create the danger of leakage. Specific observations:

- air bubbles, some of which open, in the sealant between the hard plastic cap of the tip and the flexible housing over the steerable part of the scope,
- cracks in the seals around the camera casing,
- worn-out looking O-ring, the purpose of which is to create a seal around the lever spindle.

The air bubbles in the sealant and the crack in the seal could form an open door to moisture and micro-organisms. Visualisation of the O-ring using a scanning electron microscope. On the basis of the images of the O-ring, particularly the rough/powdery structure of the surface and the crack that can be seen in the electron microscope photo, this O-ring does not seem to guarantee a reliable seal.

Our view:

The author objects, from some results of evaluating exterior parts of the endoscope, that it is highly possible that parts of the endoscope leak. And, he supposes that microorganisms infiltrate into the endoscope or remain on it. But, he doesn't attempt to perform a leakage test to check whether the endoscope leaks out actually, and all is only his imagination.

(2)-2 Recommendations from Report S:

Ensure that there are regular, strict checks on seals between use. Ensure that the O-ring is replaced regularly (this might have functioned well for a time, but it is still a moving seal and therefore requires maintenance). In future designs, improve the seal by creating several barriers or (and this should be the preferred option) avoid such seals completely and design an elevator without moving parts which enter a 'sterile' area of the instrument from the patient.

Our view:

We confirmed that the sealing has enough durability based upon the test simulating repetitive proper usage. And, as Fig. 1 Workflow chart indicates, the instruction manual instructs users in leakage testing in reprocessing between procedures. If they detect any leakages of the endoscope, they stop using it and send it to the manufacturer for repair in accordance with the instruction manual, and the manufacturer reseals a leakage of the endoscope. This maintenance system has already been established.

(3) Deposits of parts

(3)-1 Observations from Report S:

Deposits were found at a number of places in the tip of Scope.

The deposit behind the glass lens cover of the camera suggests that this space is not well sealed, as a result of which the growth of micro-organisms, deposits of liquids left behind or damage to a possible coating has occurred.

Our view:
An endoscope is sealed, but inside contains a certain degree of moisture since the connector part to a videoprocessor has the structure that the inside and the outside led to. The brownish area seems to be corroded metal surface, moisture possibly corroded metal surface in either inside or outside of sealing. Glue is considered to be discolored a little at the junction of lens and glue. In either case, discoloration on an endoscope isn't necessarily caused due to leakage. If leakage is suspected, the leakage test should be performed.

(3)-2 Observations from Report S:
The deposits on the edge of the space around the elevator must be examined in more detail before any conclusions can be drawn. It could be oxidation, but if some kind of contamination is involved, this could point to inadequate/incorrect cleaning by the Erasmus MC, as there is good, easy access to this location.

Our view:
At this point, the author just noticed insufficient and improper reprocessing by the user facility possibly cause contamination of microorganisms or residue. As explained at 2., he should have been sufficiently inspected this point for a start.

(3)-3 Observations from Report S:
The brownish deposits on the surfaces in the propulsion cavity, the propulsion cavity side of the lever and the O-ring are so consistent and equally distributed that it is highly unlikely that these are the result of oxidation caused by, for example, skin contact during assembly. It is more likely that moisture and/or biological material from the shaft or the tip of the endoscope entered the propulsion cavity and has remained and/or grown there.
The fact that the brownish deposits on the O-ring are visible on both sides of the O ring (propulsion cavity side and patient side) suggests that these deposits have migrated around and over the O-ring from one side to the other. It is considered highly plausible that this O-ring failed to function properly.

Our view:
As explained at (3)-1 Our view, moisture is contained in inside of sealing, moisture possibly corrode metal surface. The arm shaft consists of metal both in front and behind of the O-ring, is considered to have been uniformly corroded by moisture in either inside or outside of sealing. It seems to be unnatural imagination that the deposits might move into the inside through the O-ring.

(3)-4 Observations from Report S:
Also, the slit between the elevator and the housing and between the lever spindle and the housing seems too small to allow for brushing (and perhaps also for rinsing) and too big to prevent liquids and/or biological material from getting in.

Our view:
As explained at 1(Fig.2), the endoscope is sufficiently reprocessable following the instruction manual.

(3)-5 Observations from Report S:

Experience with O-ring seals on this scale teaches us that a deviation of less than 0.01 mm from the ideal play can already result in leakage. Deposit growth can therefore encourage leakage, or be caused by leakage. During the backward and forward axial movement of the lever spindle, it should be possible for the O-ring to make rolling movements axially, as a result of which moisture and/or biological material could possibly get between the O-ring and the lever spindle and, with every movement of the lever spindle, migrate further from the propulsion cavity side to the patient side or vice versa.

Our view:

Again at this point, the author didn't perform leakage test, but he mentioned an invasion of the deposits due to leakage only from his imagination. Also, he explained that during the backward and forward axial movement of the lever spindle (the arm shaft), it should be possible for the O-ring to make rolling movements axially, but the arm shaft cannot move the backward and forward axially and it rotates on the axis, thus he is probably misunderstanding the structure around the arm shaft.

(3)-6 Recommendations from Report S:

Check on the nature of the deposit behind the glass lens cover of the camera, measure the quality of this seal and improve if necessary. Take a critical look at the cleaning procedure to determine how deposits could have been left behind in the elevator channel at an easily accessible location and how these remained undetected.

Improve the seal of the propulsion cavity or prevent the use of such seals in future designs.

Check the existing seals in all existing scopes and make sure that the sealing quality is measured objectively, critically and quantitatively.

Our view:

We confirmed that the sealing has enough durability based upon the test simulating repetitive proper usage. (about other Olympus endoscopes the same can be said). And, as explained at 1(Fig.2). the endoscope is sufficiently reprocessable following the instruction manual. If residue remains in accessible space of the endoscope, it possibly is caused due to improper reprocessing by the user facility as the author also explained above.

(4) Cultures

(4)-1 Observations from Report S:

Only the cultures (both specific and general) from the hard plastic cap of the tip produced positive results. As the outside of the cap has been cleaned several times, is easily accessible and has already been dry for some time (and the bacteria found do not usually flourish on dry surfaces), it is highly likely that the bacteria were on the inside of the cap. These findings are very much in line with the observations regarding the quality of the seals.

The fact that no positive culture results were found at other places does not mean that nothing was present there. The inaccessibility of many places on the tip, the limitations of the sampling with swabs and the fact that biofilms grow more easily on plastics and rubbers than on metals mean that little can be concluded from the negative test results.

Our view:
The author suspected that microorganisms remained on the inside of the cap about detecting microorganisms on the cap. The inside of the cap faces back of the forceps elevator. Despite he suspected that the user facility improperly reprocessed around the forceps elevator due to the deposits at (3), he here doubted only the sealing quality of the distal end of the endoscope. It means he has prejudiced imagination.

(4)-2 Recommendations from Report S:
Also grow a culture from the reserve sample from the O-ring {5651}. If possible, carry out more detailed investigation to exclude the presence of undesirable biomaterials in the propulsion cavity. As Pseudomonas Aeruginosa was seemingly found within the tip, it would be sensible to subject all scopes of the same type, worldwide, to further investigation immediately. See also the recommendations under 'Quality of the seals' and 'Conclusion'.

Our view:
Repeatedly, as explained at 1(Fig.2), the endoscope is sufficiently reprocessable in accordance with the instruction manual.

(5) Conclusion
(5)-1 Observations from Report S:
All in all, this scope seems to have suffered badly as a result of use, the possible inadequate quality of seals, inadequate maintenance and insufficient critical mechanical checks. The very small slits and spaces in the elevator channel together form a series of locations where it seems by no means unlikely that moisture and/or biological material could remain or grow there. There seems to be no doubt that the seals, propulsion cavity and O-ring of all existing and planned scopes similar to Scope G-206 require serious attention, immediately.

(5)-2 Recommendations from Report S:
Immediately tighten up checks and maintenance on similar scopes worldwide, in particular overhauling the scopes with damaged seals and subjecting these to exhaustive sampling. Update the cleaning instructions and make stringent checks on compliance and adequate results. If further tests reveal that Pseudomonas Aeruginosa or other bacteria/viruses/substances are present in the propulsion cavity too, which do not belong there, it is recommended that all similar scopes be recalled immediately and/or, parallel with this, the possibility of there (also) being a leakage route that does not run via the O-ring or other seals be investigated.

Our view:

We confirmed that the sealing has enough durability based upon the test simulating repetitive proper usage. (about other Olympus endoscopes the same can be said). And, as Fig. 1 Workflow chart indicates, the instruction manual instructs users in leakage testing in reprocessing between procedures. If they detect any leakages of the endoscope, they stop using it and send it to the manufacturer for repair in accordance with the instruction manual, and the manufacturer reseals a leakage of the endoscope. This maintenance system has already been established. And, as explained at 1(Fig.2), the endoscope is sufficiently reprocessable in accordance with the instruction manual.