A comparison of the efficacy of lumen-cleaning devices for flexible gastrointestinal endoscopes

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Abstract
The cleaning efficacy of a new lumen cleaning device for endoscopes, a ‘Pull Thru’, was compared to cleaning devices that use brushes. Efficacy was tested by applying a simulated blood soil to lumens of two different diameters (to match those of biopsy and suction lumens, which require manual cleaning) and comparing the weight difference before and after cleaning. The Pull Thru device was found to offer a consistently significant improvement in soil removal and was equally effective across both lumen sizes and for both new and used lumens.

Introduction
Current international and Australian standards for the reprocessing of endoscopes can be summarised as a manual pre-clean, followed by a manual or automated wash and a terminal high level disinfection or sterilisation cycle. Quality control at the manual pre-cleaning stage is of paramount importance. If the lumen has not been thoroughly cleaned and all gross soil removed, there is a risk that the disinfection or sterilisation process will not be effective. Disinfection or sterilisation without pre-cleaning has in some cases resulted in cross-infection rates of 90% and in a number of studies around the world, the insufficiently cleaned lumens were found to range from 12% to >50%.

Current manual pre-cleaning procedures generally involve the repeated passage of a lumen brush up and down the suction and biopsy lumens of flexible gastrointestinal endoscopes. While GENSA recommends brushing until visible soil is removed, in the USA brushing cycles vary from centre to centre, with one to five brushing cycles being performed. Furthermore, each endoscope manufacturer supplies their own cleaning recommendations for each model of endoscope. Pre-cleaning tests have focused on whether or not pre-cleaning is effective in reducing soil loads and the link between effective pre-cleaning and sterilisation/disinfection.

There are a number of challenges with current manual pre-cleaning procedures in terms of the time involved, cleaning efficacy and occupational health and safety (OH&S). In particular, multiple passages of a brush lumen cleaning device can be a relatively time-consuming task in a clinical environment where there is often a need for rapid turnaround of endoscopes. Additionally, as the tip of a conventional cleaning brush emerges from the lumen, the bristles have the potential to flick soil into the environment, onto other endoscope parts, or onto other instruments, increasing the risk of cross contamination and presenting an added OH&S risk for staff reprocessing the equipment.

Furthermore, re-usable lumen brushes require reprocessing time to clean and disinfect or sterilise after each use and may abrade the inside surface of the lumen via the stainless steel shaft.

The Pull Thru (Novapharm Research Australia Pty Ltd) was designed to significantly reduce the time required to manually pre-clean the lumens and to improve the overall efficiency of the pre-cleaning process. The cleaning efficiency of the Pull Thru was compared to a range of commercially available lumen-cleaning brushes via a simple test, removing a simulated medical soil from both the biopsy and suction lumens for a gastrointestinal endoscope.

Materials and Methods
Three lumens were used for testing. One lumen was unused (supplied by Pentax) and had dimensions of 2.8 mm internal diameter (id) x 170 cm (length). The other lumens were removed from used endoscopes during servicing and had dimensions of 2.8 mm x 101 cm and 5.0 mm x 156 cm. The used lumens had been cleaned and disinfected prior to use in this study. The internal diameters of the lumens represent typical biopsy and suction lumen dimensions for a gastrointestinal endoscope.

The cleaning devices compared were:
A) A Pull Thru (Novapharm Research Australia Pty Ltd)
B) A triple-headed brush (Pentax Corp, supplied by CR Kennedy Pty Ltd).
C) A single use brush (Flolite Industries, Australia).
D) A re-usable brush (Pentax Corp, supplied by CR Kennedy Pty Ltd).
A new Pull Thru device was used for each test, while the other devices were cleaned and dried before re-use. The soil consisted of a red dye (FD & C Red #40, HCA Colours Aust Pty Ltd.) dissolved in defibrinated horse blood (Oxoid Aust Pty Ltd) to give a 1% (w/v) solution.

For the soil test, the simulated blood solution was injected into the lumen until it dripped from the other end. After excess was drained from the lumen, it was coiled and held in place with tape and weighed. After weighing the lumen was uncoiled and the cleaning device was inserted into the lumen. The Pull Thru device was passed once through the lumen whereas the cleaning action for all of the brushes involved pushing the brush down and then pulling it back up the lumen three times (a total of six passes of the brush). The lumen was again coiled, taped and weighed. The weight of soil before and after cleaning was calculated by difference, after accounting for the weight of the tape and unsoiled lumen. This process was repeated twice to give a total of three soil challenges for each combination of lumen and cleaning device. The exception was application of the re-usable brush with the 5.0 mm lumen, which was not performed as the diameter of the brush was too small for the bristles to make complete contact with the lumen. The lumens were photographed before and after application of the cleaning device.

\[
\%SR = 100 - \left( \frac{Sac \times 100}{Sbc} \right)
\]

*Equation 1. Percent soil removed (%SR) after application of the cleaning device*

Sac; Weight of soil - after cleaning  
Sbc; Weight of soil – before cleaning

The efficacy of each cleaning device was quantified by recording the weight difference from the weight of soil before cleaning and the weight of soil after cleaning and then calculating % Soil Removed (Equation 1). Significant differences between treatments were determined using ANOVA (analysis of variance).

**Results**

Visual inspection of the lumens after cleaning showed a clear difference between the Pull Thru device and the conventional brushes (Figure 2). For all three lumens, very little residual soil could be observed after passage of the Pull Thru (Figures 2.2 A–C). In comparison, substantial quantities of soil could be observed in the lumens after cleaning for all three brushes (Figures 2.3 A–C; 2.4 A–C and 2.5 A–B).

The average weight of residual soil before and after cleaning with the four types of cleaning devices was also compared (Table 1). The loading of soil in the lumens before cleaning was dependent to some extent upon the dimensions of the lumen, with the new and old 2.8 mm lumens retaining the least soil (0.31 g – 0.87 g) and the 5.0 mm lumen retaining the most (1.13 g – 1.15 g). There was also a greater level of soil in the new 2.8 mm lumen, for the most part, compared to the old 2.8 mm lumen, which was likely due to the greater length of the new lumen. The relatively

<table>
<thead>
<tr>
<th>Lumen Types</th>
<th>2.8 New</th>
<th>2.8 Old</th>
<th>5.0 Old</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residual Soil (g)</td>
<td>Before Cleaning</td>
<td>After Cleaning</td>
<td>Before Cleaning</td>
</tr>
<tr>
<td>Pull Thru</td>
<td>0.64±0.22</td>
<td>0.02±0.01</td>
<td>0.41±0.07</td>
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<td>Re-usable brush</td>
<td>0.44±0.03</td>
<td>0.15±0.04</td>
<td>0.31±0.01</td>
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<tr>
<td>Single-use</td>
<td>0.87±0.21</td>
<td>0.37±0.07</td>
<td>0.47±0.05</td>
</tr>
<tr>
<td>Triple-head</td>
<td>0.67±0.19</td>
<td>0.32±0.10</td>
<td>0.46±0.11</td>
</tr>
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</table>

*Table 1. Average residual soil (Mean ± SD) before and after cleaning with the four cleaning devices and three lumens.*
1. Soiled control

2. “Pull-thru”

3. Triple

4. Single

5. Re-usable

A. “2.8 new”  B. “2.8 old”  C. “5.0 old”

Figure 2. Lumens (A – C) before application of the cleaning devices (1. Soiled control) and after application of the 4 types of cleaning devices (2-5). INSERTS: A close-up of a section of each lumen.

Notes: 1. The re-usable brush was too narrow for the 5.0 mm lumen. 2. Lumens were only coiled for the photo and weighing.
high variation in soil loading for the new 2.8 mm lumen (0.44g – 0.87g) may have been due to variation in the amount of time taken to drain the dyed blood from the lumen before weighing and applying the cleaning device.

After cleaning, the least amount of soil recorded across all three lumens was observed for the Pull Thru (0.00g – 0.02g). The re-usable and triple-headed brushes achieved the next lowest amount of residual soil with 0.07 g and 0.06 g respectively for the old 2.8 mm lumen. A similar pattern followed for the new 2.8 mm lumen.

The highest levels of residual soil occurred on the 5.0 mm lumen after cleaning with the single-use and triple-headed brushes (0.75g and 0.81g respectively). The higher level of residual soil was possibly due to lesser contact between the bristles and the inner wall of the large diameter lumen. The low level of residual soil in the 5.0 mm lumen, after cleaning with the Pull Thru, is likely to be due to the sustained contact between the rubber discs and the walls of the lumen along its length. The reusable brush could not be tested on the 5.0 mm lumen as its diameter was too small to be effective.

To enable the direct comparison of soil remaining after cleaning, the results were standardised using percentage of soil removed and analysed using ANOVA (Figure 3).

For the new 2.8 mm lumen cleaned with the Pull Thru, the amount of soil removed was 96% of the original loading. The Pull Thru also removed significantly more soil (P<0.000) when compared to any of the brush devices. There were significant differences between the brushes (P=0.044) and the percentage of soil removed from all three ranged between 52% and 65% of the original loading.

Results for the old 2.8 mm lumen were similar with the Pull Thru device having no detectable soil residual, and removing significantly more soil (P<0.000) after cleaning with the single and reusable brushes. There was no significant difference in percent of soil removed for the three brushes (73% – 85%). A similar pattern was found for the 5.0 mm lumen with percent of soil removed for Pull Thru (99%) being significantly higher (P<0.000) than for either the single or triple-headed brushes (35% and 29% respectively).

**Discussion**

The brushes and Pull Thru use two fundamentally different mechanisms to remove gross soil from the lumen. Brushes rely on associated water and detergent while the Pull Thru cleaner uses complete surface contact between the circular rubber discs of the Pull Thru and the lumen wall to physically remove the soil. We compared the basic soil removal properties of the two different techniques. As standard practice in endoscope clinics is to use three brush cycles in a backwards and forwards motion to clean the endoscope lumens, this was applied to test the different brush types. The Pull Thru requires a different action and was pulled through the lumen only once.

The brushes were not as effective in the larger lumen as in the smaller lumen. The cleaning consistency of the brushes relies in part on a match between the diameter of the brush and the size of the lumen. Some manufacturers recommend the use of a range of brush sizes to clean the different sized lumens in a single endoscope. As the Pull Thru works on a flexible full contact system, it is likely to be equally effective on lumens across a range of sizes. As a gastrointestinal endoscope contains different sized lumens, having a single device that can accommodate the range of lumen sizes without reducing cleaning efficacy would allow rationalisation of cleaning devices.

The greatest factor in reduction of soil was the type of cleaning device. The Pull Thru was more consistent within different
types of lumen. More consistent results were obtained across the different types of lumens and the Pull Thru outperformed the brushes in general cleaning ability. The flexible full contact system of cleaning is not only more effective than a brushing system of cleaning, but given that only one pass is required, is more time efficient. Furthermore the need for only one passage of the Pull Thru device is likely to reduce the OH&S risk associated with the potential for soil to flick from brushes as they emerge from the endoscope. While the potential remains for soil to be flicked from the circular rubber discs as they emerge from the lumen the requirement for only a once-through passage results in a lower potential for ‘soil-flick’ when compared to the cleaning process required for brushes.

A further reduction in OH&S risk may be possible as a consequence of the single pull-through motion required for the Pull Thru device compared to the backwards and forwards motion and multiple passes required for brushes. After passage of the Pull Thru down the lumen there is less exposure of the contaminated shaft and cleaning head of the Pull Thru to the clinical staff because it emerges only once from the contaminated lumen whereas the cleaning motion required for brushes results in the brush and shaft emerging six times from the lumen. The shaft of the Pull Thru can then be wound up as it emerges from the lumen and discarded.

While the link between cleaning efficacy and reduction of soil-associated microorganisms has been clearly demonstrated, it is also important to recognise that the build-up of inorganic and organic soil on the lumen can also lead to conditions that favour the establishment of microbial biofilms on medical devices. As biofilms provide an additional protective environment for pathogens against disinfection agents maintenance of an effective cleaning regimen is a necessary precaution against a long-term build-up of residual soil over repeated cleaning-disinfection cycles. As cleaning devices may compound the accretion of residual soil and the development of microbial biofilm by causing surface abrasion or grooving of the lumen wall an additional study to compare brushes and the Pull Thru to address this issue would be worthwhile.

The most commonly used pre-cleaning devices rely on brushes to dislodge soil in the presence of water and cleaning formulation, while the Pull Thru device maintains a complete physical contact with the wall of the lumen. This alternative approach to lumen cleaning is worth considering in the light of a recent report that indicates that current recommended manual pre-cleaning practices are at best comparable to automatic washer disinfectors, but under normal clinical conditions are likely to fall short of optimal cleaning.

The test used for this study demonstrates the efficacy of this system in removing artificial soil from the lumen, without the presence of a water-detergent solution. The results demonstrate that the cleaning mechanism of the Pull Thru is more effective and consistent in removing soil from the lumen than the traditional brush configuration even in the absence of water and detergent. Therefore, use of the Pull Thru device is more likely to lead to consistent performance in the clinical setting.

No one test is able to replicate the range of soil challenges that occur in clinical settings. The test applied in this study highlights the different cleaning action of the Pull Thru compared to brushes on the biopsy and air/water lumens used for gastrointestinal endoscopes. It should be noted that the Pull Thru has not been designed to clean endoscopes with smaller or larger diameter lumens such as those in paediatric bronchoscopes or a large double channel gastroscopes. Other tests that could provide additional information on the efficacy of this approach include disinfection efficacy, cleaning in the presence of a water-detergent solution, the use of a thickened surrogate soil such as Hucker’s soil or ‘Edinburgh’ soil.

**Conclusion**

In a simple measure of cleaning, the Pull Thru lumen cleaning device significantly increases cleaning efficiency, removing between 96% and 100% of residual soil on a single pass compared to traditional brushes, which removed between 29% and 90% after three brushing cycles. As the Pull Thru is disposable, additional time and cross-infection potential is reduced through eliminating the need to clean and sterilise the brushes. Additionally, the Pull Thru can be used with a variety of channel sizes without any reduction in cleaning efficacy, eliminating the need for multiple sized cleaning devices. When compared to conventional lumen brushes, the Pull Thru offers a significant increase in cleaning efficacy while reducing the potential for cross-infection and time spent reprocessing endoscopes.

The reprocessing of endoscope lumens is now considered a critical standard operating procedure. Therefore, there is a need to ensure that the reprocessed lumens are correctly cleaned and sterilised to avoid cross infection. Pathways to improved cleaning include improving the efficacy of cleaning devices and the reduction of variability and human error. The Pull Thru lumen cleaning device achieves both these aims.

**Acknowledgements**

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**References**


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