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Innovative Decontamination Solutions

The story behind the development of new Process Challenge Devices for evaluation of cleaning efficacy

Part 2 - Looking deep inside

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Picking up the pieces

In the first part of the article we described our approach to development of new Process Challenge Devices (PCDs) with the underlining goal of making the cleaning challenge as realistic as possible.

Within this premise we identified the variability of results when it came to the Edinburgh test soil and recognised that stainless steel samples surface roughness played a significant role in cleaning efficiency due to adhesion properties of the test soil to the surfaces. The problem proved to be far more complex and required further research.

Guidance mentions the need for development of new methods for residual protein detection and highlights the possibility of using process challenge devices to simulate contamination on surgical instruments to perform daily and weekly testing. That seemed like a reasonable idea – develop a range of process challenge devices. Here we will attempt to explain the reasoning as well as the experiments we have performed, and lessons we have learned during the process.

Effects on surface roughness on different materials

As presented in Part 1, the preliminary results showed that Edinburgh test soil adhered stronger to finer surfaces on tags made of 316L stainless steel. When the same approach was tried on polymer tags the results were different and test soil would not adhere to untreated glossy surfaces.

Polymers like PTFE, Acetal or Peek, commonly used in medical devices have low surface free energy and lack polar functional groups on their surface, resulting in inherently poor adhesion properties (Awaya et al. 2009). However, these adhesion properties can be altered by manipulating the surface. This can be done through a range of methods, from simple mechanical abrasion through chemical and heat treatments to more sophisticated methods like gas plasma (Dayss et al. 1999) or plasma enhanced ion beam treatments (Dong and Bell 1999).

Our study started with application of heparinised sheep blood onto untreated surfaces of natural Acetal C. Inoculation itself became a problem because during application of blood on the surface with a 1ml syringe equipped with a 90o blunt end needle the effect of poor adhesion could be observed by naked eye as droplet would easily follow the needle tip and not adhere to the surface. Increasing the surface temperature to 30oC, 50oC and 70oC improved initial adhesion, however could not be used – as blood dried it also gradually peeled off from the surface. At elevated temperatures peeling was similar in nature to material warping, often observed in fused deposition modelling (3d printing technology) where the effect is caused by poor adhesion to the printer bed and internal stress in the material caused by different thermal expansion rates of different layers of the material. In our case the higher the temperature was the more severe and rapid the effect of blood peeling off the surface. The same effect was not observed on 316L stainless steel where blood dried on to the surface very well even at elevated temperatures.

For this study we chose the simplest method of mechanically sanding the surface with different grit size sand papers. Unlike 316L stainless steel where it was not possible to visually distinguish between adhesion to different roughness surfaces with this polymer it was only possible to precisely deposit sheep blood on surfaces treated with sand paper between 450 and 800 grit.

To visualise the problem we prepared a sample where one half was left untreated and the other was wet sanded with 600 grit sand paper. To best demonstrate the effect we attempted to deposit narrow lines on both sides of the sample (Photo 1). After 1.5h of drying in room temperature (22°C) blood that dried on untreated surface partially peeled of and could be easily removed from the surface with tweezers. On the right hand side where surface was sanded blood remained firmly attached, and it was not possible to remove it with tweezers (Photo 2).

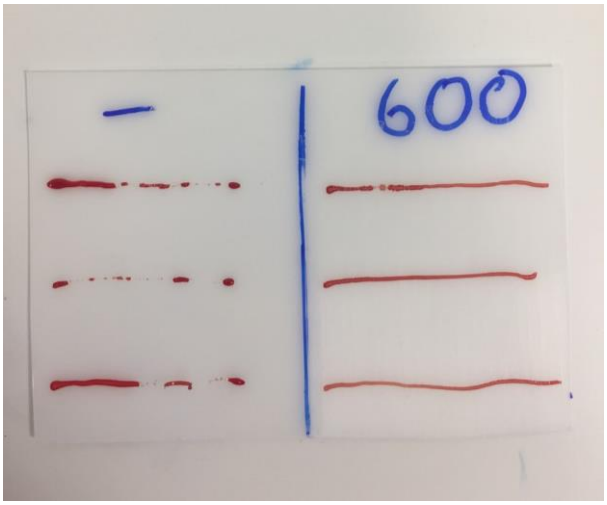


Photo 1. Freshly inoculated surfaces.

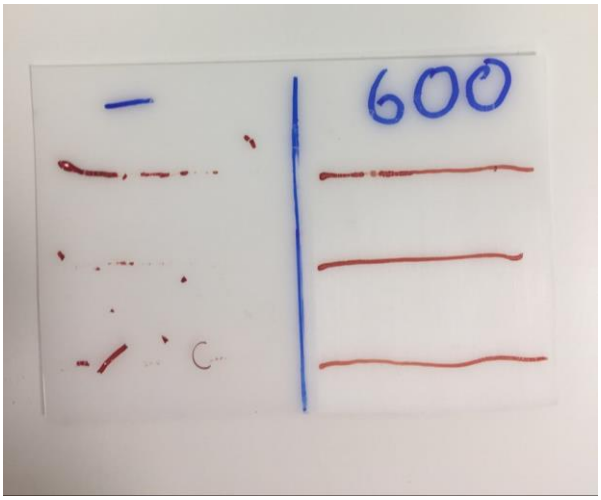


Photo 2. Surfaces after 1.5h drying.

Looking for more realistic test soils

We identified the surface condition to have a significant impact on the performance of PCDs. The test soil itself is also critical. In the UK washers and washer disinfectors are typically validated with Edinburgh test soil as per ISO 15883-5:2005.

This study we identified Edinburgh test soil to be too inconsistent to be used as a base for an entire product range. We have obtained the soil from several manufacturers and the differences in physical properties between them were visible by naked eye – colour, consistency and viscosity differed so much that we had to modify pipette tips to maintain consistency in droplet size on the samples.

The lack of fibrin in the horse blood Edinburgh test soil is made with is an additional problem. Fibrin, being an insoluble and hydrophobic protein (van Oss 1990), increases adhesion to surfaces – and therefore its removal certainly does not make the cleaning challenge more realistic.

Even though the initial studies use manual techniques for inoculating samples the intention is to have a fully automated process of tags production. Therefore the test soil has to be more consistent with regards to physical properties than Edinburgh test soil. Because the composition needs to be as realistic as possible we aim to use proteins of mammalian origin that can be obtained at reasonable cost. The early experiments with sheep blood and sheep brain tissue offered a much more consistent alternative to Edinburgh test soil from the manufacturing point of

view, and most importantly comparable cleaning efficiency results when run in equivalent conditions.

Flat tags vs. real instruments

Whenever we aim to develop new surrogate devices we attempt to somehow replicate real surgical instruments such that they imitate particular cleaning challenge as closely as possible. In our case we simulate the process of a surgical instrument cleaning with a sample inoculated with a test soil. In principle we are reducing a three dimensional object to a single flat surface – therefore it is critical to understand the limitations of this transition. It is a little bit like comparing driving a car to driving a car in a computer game or comparing diving to watching Blue Planet – it is almost the same but not quite.

Surrogate devices need to be used with not only full understanding of their limitations but also with in depth understanding of the environment they are used in – in this case knowledge of particular washer or washer disinfector. Because we are simulating three dimensional objects we have to evaluate cleaning of horizontal and vertical surfaces – ideally at the same time.

Furthermore, surgical instruments come with many difficult to clean features like crevices and narrow gaps in box-joints and like internal hollow channels in minimally invasive instruments. PCDs have got to be able to replicate these conditions to give us reasonable confidence in the process. Assuming, that if a flat piece of stainless steel lying flat in the basket with the inoculated surface pointing upwards was cleaned properly the inside of a narrow lumen was adequately cleaned in the same cycle is highly misleading and potentially catastrophic.

Evaluation of internal surfaces – PCDs for hollow instruments

Now that we have established that PCDs need to be used in relation to the challenge they evaluate, it is essential to look into the evaluation of narrow channel cleaning in more detail. The first major roadblock in effective evaluation of narrow lumen cleaning is the lack of accurate in-situ methods for detection of contamination on internal surfaces.

The only available direct method that allows looking through the entire instrument is the Radionuclide (RNM) championed by SMP GmbH. However, this method is used for evaluation and validation of particular processes or technologies and because of associated costs is certainly not suitable for day-to-day monitoring.

Because cleaning of internal surfaces is an entirely different physical process to spray cleaning performed by spray arms or jet nozzles it needs to be evaluated independently. In the absence of direct methods we have to resort to indirect methods and that is where surrogate devices provide quick answers but only if they simulate realistic conditions inside the lumens.

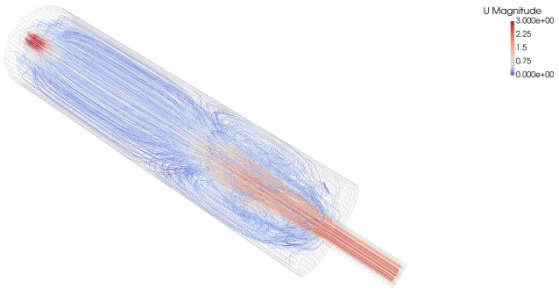
Hollow instruments are typically cleaned by the stream of water flowing through them. The internal walls of the lumen are therefore washed over with fluid that gradually erodes contamination from the walls. This process has two main elements: mechanical force and chemical process of dissolution. Mechanical force (drag) results from the velocity of the fluid that mechanically

detaches particles of soil from surfaces and carries them in the stream – in principle the higher the source pressure the higher the fluid velocity in the lumen and the stronger the drag force. The other process is based on water dissolving contamination and carrying in in the stream. This process is greatly aided by addition of chemistry that helps to break down contamination thus increasing dissolution rate. It is worth mentioning that both these processes can be further aided by ultrasonication that helps to mechanically break down and detach contamination from internal walls of the hollow channels – the caveat is that some materials conduct ultrasonic waves well and some do not, therefore the effect may vary from one instrument to another.

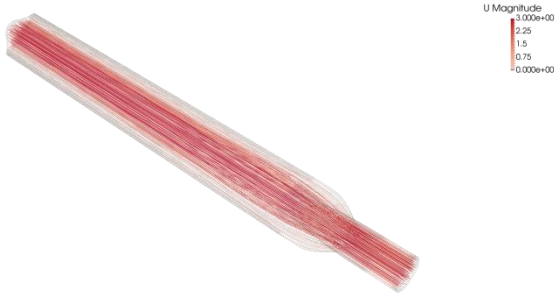
So, as we established that fluid velocity is the critical factor in lumen cleaning it is important to consider the velocity behaviour inside the lumens. If we assume a hollow channel of a defined constant diameter the fluid flowing through will have a constant average velocity – that in fluid mechanics is described by the law of continuity. According to this rule, if a section of the same hollow channel was to increase in diameter the average velocity in this section would decrease. Therefore if we are to construct a process challenge device to simulate the flow of, for example a 2mm inner diameter channel, we have to ensure the velocity profile in the PCD will be equivalent to the 2mm inner diameter channel.

In practice we inoculate tubes of particular diameters, put them through a washing cycle and evaluate for the presence of contamination. This process is laborious as there is no easy method of accessing contamination – typically the tube is cut open and contamination is desorbed from the inside or eluted. None of these processes is fast and requires skilled personnel and a laboratory – not really suitable for on-site use. The alternative to this are PCDs with removable samples that are placed in small capsules that simulate the inside of the lumens – these however come with their own problem – what are they actually evaluating? These capsules are typically of much larger diameters (or cross section equivalents) than the actual lumens they meant to simulate. It creates different cleaning conditions – sometimes the flow velocity in the capsule is several times slower than in the lumen it evaluates!

We designed a PCD based on the concept of a capsule that holds a removable sample, and made them in several sizes. The principle was to optimise capsule's internal cavity shape to maintain fluid velocity and position the sample such that it simulates one of the walls of the cavity. The approach was to create 3d models of the internal cavities of the capsules and use Computational Fluid Dynamics (CFD) to virtually simulate the flow. To demonstrate the problem with the tubular capsules we also simulated conventional capsules. Picture 3 shows velocity traces in a non-optimised capsule with the fluid velocity change clearly demonstrated by the change of traces colour when they enter the cavity. Picture 4 shows velocity traces inside an optimised capsule cavity where fluid flows over an inoculated sample. In this case the capsule replicates cleaning conditions more realistically.



Picture 3: Non optimised capsules cavity.



Picture 4: CFD Optimised internal capsules cavity.

Optimised capsules in combination with stainless and polymer tags (Photo 5) provides an easy solution for on-site monitoring of internal cleaning performance in washers and washer disinfectors of different types of hollow instruments.

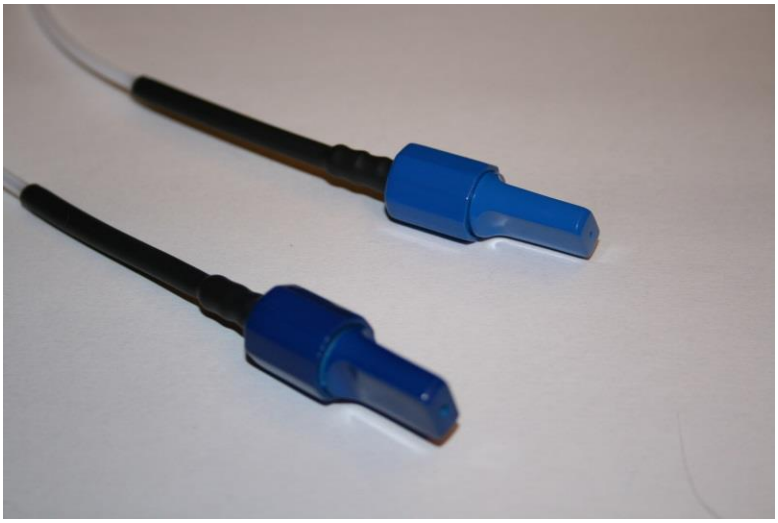


Photo 5: Complete PCD assembly.

Conclusions

When we attempt to develop new process challenge devices it is essential to first consider what the challenge is and how can we simplify it without compromising the relevance. Like in the case of non-optimised capsule cavities it is relatively easy to create a surrogate device that evaluates different cleaning conditions to ones intended. PCDs will always simplify the reality to some extent so we have to understand those limitations to use them effectively – when we do, they can be a great help in optimising washer performance and monitoring process quality on a daily basis.

We demonstrated that sheep blood behaves differently on different materials. Surface finish, especially in case of polymer materials, is a critical factor that needs further consideration. Our task was to find a surface treatment that will improve adhesion of blood to surfaces so we can test for the worst case scenario and we have noticed that the same surface finish does not produce same results in different materials – especially when 316L stainless and Acetal C were

compared. The understanding of those differences will be critical in further research on Process Challenge Devices and new test soils. At the same time surface finish can be looked at from another perspective – it gets altered by wear and tear from use and reprocessing, as well as exposure to chemicals and high temperatures – especially in case of polymers. More research is required to evaluate the rate of surface change and its impact on cleanability.

Internal and external surfaces of surgical instruments are cleaned with processes that are fundamentally different and require individual verification. Design of the PCDs for internal cleaning must consider the critical parameters of flow inside of the instruments to simulate the processes accurately. If capsules with removable samples are used the capsules need to be designed such that their internal cavities with samples fully inserted replicate cleaning conditions of the internals of equivalent size lumens as closely as possible to.

Overall, Process Challenge Devices come in a variety of shapes and forms and are a simple and effective way to quickly evaluate cleaning processes, provided they are used with full knowledge of their limitations. However, PCDs themselves need to be designed such that they get us as close to real instruments as possible – that is what we are putting our attention to.

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