PO 3043: New methods for reprocessing of medical devices based on plasma treatment

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Introduction

The rapid progress in the development of new devices for minimal invasive surgery leads to more complex and fragile instruments including a mixture of different materials most of them thermo labile. In consequence these instruments become more and more expensive which increases the demand for reuse. By now, the manufacturer are obligated to specify the reprocessing procedure which may be a restriction in the development of new products. Therefore, there is a real need for new reprocessing procedures.
Especially, plasma processes are commonly discussed as a promising alternative although only few plasma based techniques are currently commercial available.

Three examples for plasma based reprocessing are discussed in detail:

1. Classical gas sterilization device: Based on commercial steam sterilizers of low temperature and formaldehyde (LTSF). The formaldehyde unit is replaced by plasma gas generator based on the PLexc® technology developed at INP. This plasma based decontamination technique was tested on long tubes similar to biopsy channels of endoscopes.
2. Atmospheric pressure plasma coating with nanoparticles in order to generate antimicrobial acting surfaces. With a special treatment unit based on the principle of a dielectric barrier discharge the inner surfaces of tubes are coated with nanoparticles.
3. "Plasmoscope": using special plastic tubes, which include a helical electrode structure it is possible to manufacture endoscopes which allow plasma operation in their biopsy channel. This plasma can either used for decontamination, a reprocessing or under modified operation condition also for therapeutically applications. To simulate the complete reprocessing procedure the "plasmoscope" can be integrated in a reprocessing demonstrator allowing the combination of cleaning and decontamination steps.

Classical gas sterilization device

The prime father of all plasma gas decontamination devices was the ozone tube invented in 1857 from Werner von Siemens. In 1898 the company Siemens&Halske delivers first industrial scale water plants to the waterworks of Wiesbaden-Schierstein and Paderborn in Germany [1, 2] based on this technology and up to now the main application of ozone is drinking water purification. But the generation of ozone is only one example to use the process gases of plasma for decontamination applications. According to the gas temperature the composition of the plasma changes and with increasing temperature the dominant decontaminating species changes from reactive oxygen (ROS) to reactive nitrogen species (RNS). As DBD and Corona discharges are good choices for generating ROS, microwave discharges become interesting for the generation of RNS.

For the generation of ROS and RNS the atmospheric pressure region is preferred due to higher species densities and lower equipment costs. Unfortunately, microwave plasma sources at atmospheric pressure suffer from two kinds of difficulties:

1. Stable ignition is a problem because of the low electrical field strengths generated by the applied microwave field [3, 4]
2. Wall burning: the microwave plasma has the tendency to move towards the source of radiation which usually destroys the device within short time [5]

To a certain extend these problems are solved by the special plasma source PLexc® developed by INP, s. Figure 1. This plasma source is described in details elsewhere, e.g.[6].

In order to apply this technique to a complex reprocessing problem endoscopic biopsy channels are chosen as a critical object. These channels are made of thermo labile materials as e.g. PTFE, and their typical dimensions are length of 1m and an inner diameter of 2 mm. Therefore the specimen are chosen in the same dimensions.

Figure 1: microwave excited plasmasource PLexc® developed by INP

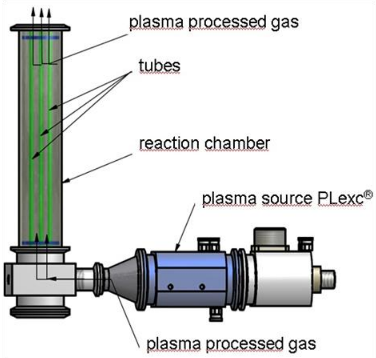

Figure 2: PLexc® gas treatment device for plastic tubes

The treatment of the specimen is performed in a tube which has a length of 1.1 m and an inner diameter of 50 mm and serves as process chamber. The size of the chamber allows the simultaneously treatment of up to 3 specimen. The plasma treated gas is supplied from the bottom as depicted in Figure 2. The plasma device was operated for 10 s to ensure a complete gas exchange in the process chamber. The overall incubation time was set to 30 min in order to allow the gas to diffuse into the lumina of the specimen. The results are shown in Figure 3. This technique is now integrated into a commercial available formaldehyde sterilizer by removing the formaldehyde system and implementing the PLexc® source instead, see Figure 4. For more details see [7].

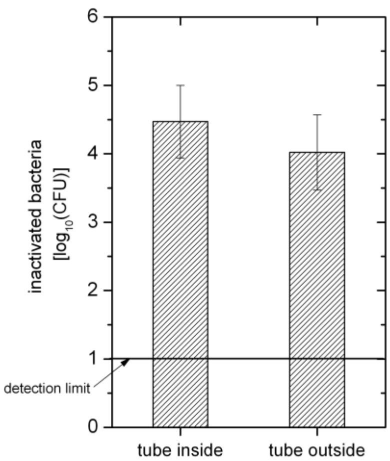

Figure 3: results of plasma gas treatment of PTFE tubes as specimen for biopsy channels of flexible endoscopes

Figure 4: commercial sterilizer with integrated PLexc® plasma source

Atmospheric pressure plasma coating with nanoparticles

Antimicrobial surface, as can be achieved by e. g. coatings, can act as an alternative or addition to classical inactivation processes. These coatings are especially helpful in cases where reprocessing is known to be critical, such as biopsy channels of flexible endoscopes. The coating is based on nanoparticles, see [8], which have to be fixated by a plasma process in order to withstand the shear forces in a biopsy channel.

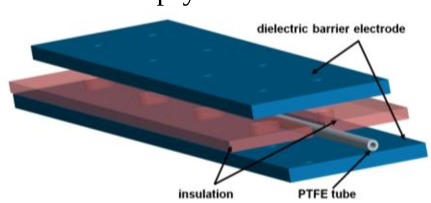

Figure 5: Scheme of DBD setup

Figure 6: Photograph of realized setup

"Plasmoscope": using special plastic tubes, which include a helical electrode structure

The reprocessing of flexible endoscopes is mandatory due to the high costs of these devices. Unfortunately the reprocessing is difficult because of two reasons:

1. The devices are made of a complex mixture of sensitive materials. e. g. plastic tubes several kinds of glue, optics etc.. In most cases they a thermo labile and scratch sensitive due to the necessary high bending properties.
2. The flexible endoscopes have a complex geometry, especially the long fine lumen of the biopsy channels which is highly contaminated after the usage.

All gas sterilization processes, as e. g. ethylene-oxide- (EtO), low-temperature-steam-and-formaldehyde- (LTSF) or hydrogen-peroxide-sterilizers suffer from the transportation problem which is without any special equipment limited by diffusion. The new idea is to implement the plasma directly into the endoscope so that the antimicrobial effect is generated directly where it is needed and without a change in the essential bending properties.
This can be achieved by a modification of the tube used for the endoscope channel, as shown in [9].

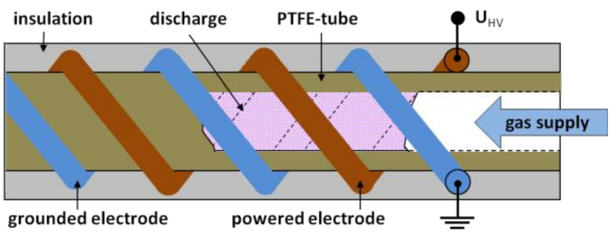

Figure 7: Scheme of the bifilar setup

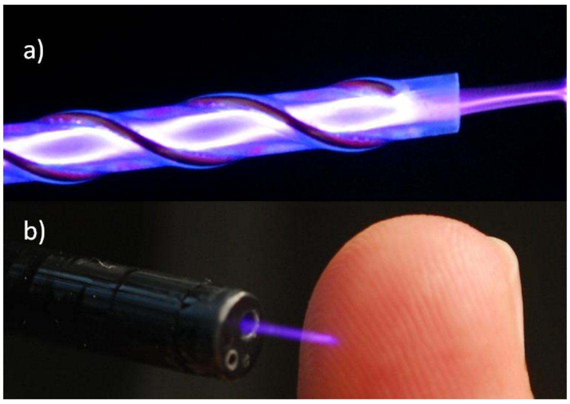

Figure 8: Photographs of a tube with the bifilar electrode structure a) and the realization of this technique in an endoscope b)

For the complete reprocessing of endoscopes equipped with this technique special reprocessing equipment is needed. In order to simulate the reprocessing process a demonstrator is build up which is capable of different cleaning and plasma inactivation steps, see Figure 9.

Figure 9: Demonstrator for a reprocessing unit for endoscopes equipped with bifilar plasma generator

Acknowledgement

The work is partly supported by the BMBF under the contract acronyms and numbers: Endoplas 13N9320 and Nanogiene 13N11358.

Key words (5 words)
non-thermal plasma; atmospheric pressure plasma; plasma coating plasma decontamination; nanoparticles

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