On Argon-plasma cleaning – some comments from regulatory and scientific perspectives

In his editorial (Eur J Oral Implantol 2015;8:111) Matthias Kern discussed the validity of a conclusion from a study using "unapproved cleaning and disinfecting methods". This statement deserves its own discussion. In addition, the editorial underlines the importance of understanding some basic notions on cleaning and sterilisation methods of devices used in clinical work. In the cited study, a 'new' method of cleaning and sterilisation has been used in an attempt to answer the question "can [plasma treatment of the abutment] affect peri-implant marginal bone levels?"

There are actually at least two important topics raised by this discussion: 1) what is the 'gold standard' for abutment cleaning and sterilisation? and 2) what is the influence of the cleaning and sterilisation method on the clinical outcome?

While, according to the authors of the study, it appears that there is a lack of clarity in the literature on the standard cleaning and sterilisation process for customised dental abutments, all implant and abutment manufacturers are required by law to give such instructions in their *Instructions For Use*[1]. It is accepted that the common praxis is standard cleaning using disinfection agents in ultrasonic baths (as for any surgical instrument) followed by normal steam sterilisation at 135°C for 5 minutes. Nobel Biocare's IFU reads: "Note: Use of non-sterile abutments may lead to infection of tissues or infectious diseases"[2]. Of course there is no difference in the risks involved in using a non-sterile standard manufactured or customised abutment. So my conclusion in regards to the 'gold standard' procedure is: read the manufacturer's IFU.

Now, the discussion around the use or not of plasma cleaning and sterilisation requires some understanding of the process. In the scientific literature, several good general reviews on the subject exist, which are well worth reading for those who consider using this type of device[3]. Furthermore, it is worth noting that the two issues 'cleaning' and 'sterilisation' are really two separate issues and should be discussed and studied separately[4].

Let us start with the sterilisation issue. It appears that plasma sterilisation cannot be regarded as a 'general (cleaning and) sterilisation method' for any and all types of devices. On the contrary, the mode of action of the plasma sterilisation implies a careful consideration and validation of its use for each device.

There are several approved processes and apparatus for effective plasma sterilisation of medical devices. The different competent authorities have given directives for the requirements and validation processes to be followed, such as in the ISO 14937 standard together with a series of other standards, which implant manufacturers have to comply with to be able to declare a product as 'sterile' (see e.g. 'EC Declaration of Conformity' by Megagen, 12 March 2012[5]).

The main working principle of the plasma sterilisation method is through the generation of certain reactive species such as photons in ultraviolet (UV) wavelengths and chemically reactive radicals. These reactive species will degrade the bacterial DNA and destroy the capability of the microorganism's reproduction. In addition, the chemical radicals will have an oxidative, etching or abrasive effect on the device. It is therefore important to verify and understand on the one hand if the device's geometry allows the photons and the radicals to attain all volumes and areas where microorganisms can hide, and on the other hand to know if the device material will be affected by the chemically reactive UV light and radicals.

The use of plasma treatments to clean implants and abutments has recently been launched commercially. It should be kept in mind that plasma treatment

processes were first developed for flat surfaces in the microelectronics industry for etching or for the deposition of materials. Furthermore, the plasma generates free ions and electrons, in addition to the chemically reactive radicals and photons. In the early 1990s a development programme aimed at understanding plasma cleaning for intricately-shaped three-dimensional implants, was undertaken by the author and his colleagues resulting in several publications and a patent[6]. It was shown that several physical parameters will influence the plasma and hence its treatment effectiveness. Those parameters include the type of gas (the most commmonly used is hydrogen peroxide vapour), the pressure, flow and temperature of the gas, the power of the plasma source, the geometry of the plasma chamber and the plasma generating electrodes in relation to the device geometry and materials. One of the main difficulties with plasma cleaning is to obtain homogeneous treatment on the implant surface. While some areas will be correctly cleaned, others, more hidden areas might not be cleaned at all and it is possible the plasma may deposit new unwanted materials on the implant surface. It was concluded that it is of utmost importance that the correct plasma treatment set-up and parameters are used for each type of treatment and adapted to the specific implant or abutment device.

Other important questions to consider are: What kind of 'dirt' should the plasma treatment clean (what is left behind by or even added by the pre-cleaning methods)? What is the bio-burden? What happens to the supposedly dead or inactivated microorganisms? What is the biological influence of remaining pyrogenes? Which is the adequate verification of sterility (as requested by the ISO 14937 standard)? Plasma treatments are mostly used in industry to deposit materials onto devices and the ratio of deposition from plasma chamber walls and electrodes should also be considered.

Coming back to the main question about peri-implant marginal bone levels, in my view it is evident that if the above questions on the method and its influence on the device are not correctly clarified there is no possibility to draw any sufficient conclusion with regard to the causality of an observed phenomenon. Secondly, the relationship between the abutments cleanliness and peri-implant marginal bone levels has, to my knowledge, not been shown. A study focusing on this question should have a 'standardised' negative control (where the contamination of the surface is defined and always the same), a positive test surface, and most importantly, well characterised surfaces using Electron Spectroscopy for Chemical Analysis ('ESCA', also named 'XPS') and Scanning Electron Microscopy (SEM). The use of such methods have become custom praxis for implant manufacturers, who take surface quality seriously.[7, 8]. Finally, while the study authors' conclusion that "Clinicians should clean and sterilise customised abutments before placing them in a patient's mouth" is obvious and stated in all IFUs, until the response of the above-mentioned and other questions are known, the use of argon plasma treatment as a 'chair-side' method is still not a validated method and its use can therefore not be recommended.

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