



## On the scientific evidence that the sterilisation of customised implant abutments is required

In 2013 a small randomised controlled trial (Canullo et al. *Eur J Oral Implantol* 2013;6:251–260) was published that appeared to show that cleaning and sterilisation of customised abutments resulted in better maintenance of the marginal bone level, than when using customised abutments cleaned with commonly utilised methods.

In fact, 12 min argon plasma treatment of the abutments resulted in significantly less marginal bone loss around the implants over a 2 year period, in comparison to 5 s water steam cleaning. The following conclusion was made: “It is therefore important to use cleaned and sterilised customised abutments in patients”.

In fact, this conclusion created the impetus for many discussions in implant dentistry, as it promotes the use of a rather expensive instrument, despite the fact that standard procedures as controls had not been used in this study. However, this begs the question is this conclusion justified by the presented results?

In my opinion, this study did not comply with European health regulations, e.g. BS EN ISO 17664: 2004, that require the use of approved cleaning and disinfection procedures, when providing semi-critical medical devices such as customised implant abutments for patients. Steam cleaning with a laboratory steam cleaner is not an approved cleaning and disinfection procedure. In contrast, cleaning customised abutments in an ultrasonic bath and using approved disinfectants would be a standard procedure, which complies with European health regulations that might have been used in the study as a control instead.

In addition, 12 min argon plasma treatment might be considered an effective cleaning and disinfection procedure but according to the manufacturer, with the instrument used in the study, it is not a valid sterilisation method. In contrast, sterilisation in an accurately calibrated autoclave at 134°C would be a valid sterilisation method that should have been used as a control in that study.

Therefore, in my opinion, the conclusion that it is important to use cleaned and sterilised customised abutments cannot really be drawn from the results of this study as a valid sterilisation method was not used. Therefore, from the study results it must be concluded that customised abutments require adequate cleaning and disinfection procedures prior to their use in patients.

But, can it be considered ‘ethically correct’ to evaluate unapproved cleaning and disinfecting methods in a randomised controlled trial when patients are exposed to health risks, i.e. marginal bone loss, as shown by the results of this study? If the patients were adequately informed about these risks why did they consent to the study as the 5 s steam cleaning did not offer advantages, which would justify its usage? These questions have weighed heavily on my mind over the last couple of months, and I am happy to finally share them with EJOI readers.

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