Using oxygen to sterilise medical implants could save time and money

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International researchers led by the University of Bath have demonstrated a cheap, effective and environmentally-friendly way to sterilise medical implants without changing their properties, in contrast to some techniques.

This inexpensive technology could save time and money while effectively sterilising medical implants, does not require extensive training and produces no waste products

Scientists from the University of Bath's Department of Pharmacy & Pharmacology and Centre for Regenerative Medicine and from the Faculty of Pharmaceutical Sciences, University of São Paulo, Brazil, showed that ozone gas, obtained by passing electricity through oxygen, effectively sterilises one of the most common types of polymer used in medical implants.

Polymer implants, such as screws, pins and stents, are commonly used in surgical treatments, and there is an increasing use of implantable polymers in fields such as drug delivery, regenerative medicine and tissue engineering.

These materials must be sterile before use, but some methods of sterilisation alter their physical or chemical properties, potentially reducing performance.

The researchers showed that exposing the implants to as few as two

controlled 'pulses' of ozone gas could sterilise the polymer, called poly(lactic-co-glycolic acid) (PLGA), killing spores of the Geobacillus stearothermophilus bacteria, the most common biological indicator used for validation of sterilisation processes.

Ozone treatment caused no changes in the PLGA and no loss of function, with cells still able to grow on the polymer scaffold, as they would in treatments.

This contrasts to methods such as gamma or electron beam radiation which are expensive and can damage the polymer. Other techniques also include risks to the polymer due to the heat, pressure and toxicity involved.

Ozone is cheap, safe and environmentally friendly because its only by-product is atmospheric oxygen, and is able to kill viruses, bacteria and fungi.

Dr Paul De Bank, Lecturer in Pharmaceutics at the University of Bath, said: "A significant worldwide effort is being made to create implantable polymeric matrices for a number of medical and surgical applications.

"Maintaining sterile manufacturing facilities is extremely costly, so the ideal scenario is to sterilise the matrix post-manufacture. Unfortunately, many sterilisation techniques adversely affect the physical or chemical properties of the materials used in the scaffolds, and this can alter their overall performance.

"We decided to investigate pulsed ozone gas as an alternative sterilisation method and chose PLGA as it's perhaps the most widely used implantable polymer.

"We decided to look at nanofibers specifically as they are extremely fine

and allowed us to easily determine if the sterilisation treatment affected the scaffold's structure. The fact that ozone performed so well suggests it could be routinely used to sterilise not only PLGA, but a wide range of materials used in clinical implants."

Carolina Rediguieri, a PhD student from São Paulo who carried out the work during a six month visit to Dr De Bank's laboratory in Bath, said: "Sterility is a critical attribute of implantable materials that needs to be met in order to be applied in vivo. Our findings suggest that sterilisation by ozone gas is very likely to work for other implantable polymers as well, especially other polyesters."

The study Ozone Gas as a Benign Sterilization Treatment for PLGA Nanofiber Scaffolds is published in the journal *Tissue Engineering Part C: Methods*.

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