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Effects of repeated cycles of sterilisation on the mechanical characteristics of titanium miniplates for osteosynthesis

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Abstract

Aim: This study investigates the changes occurring in the mechanical characteristics of osteosynthesis titanium miniplates when exposed to repeated sterilization cycles.

Methods: For this study Medicon ©titanium miniplates were used. The characteristics of miniplates were evaluated using the Penetration Resistance test, MSC/Pal2 Software, and the Finite Elements Method (F.E.M.). Surface roughness measurements were also carried out. Statistical analysis was conducted using the One way ANOVA model. The significance level was set at >0.05.

Results: The one way ANOVA analysis between HV value and increased sterilization cycles showed $P > 0.029$; between the Ra value and increased sterilization cycles it was $P > 0.325$; between the Rq value and increased sterilization cycles it was $P > 0.703$. The Finite Element Model shows an amplified deformed shape of the miniplate at a load of 196 [N]. At this load value the equivalent 'von Mises stress' reaches the value of σ *P0.2*, shown by the ASTM F 67–95 standard. Stress distribution comparison between the six-holed plate and the equivalent straight miniplate shows more consistent behaviour for the Medicon ©miniplate. The rigidity of the Medicon ©miniplate is 14.46, lower than that for the equivalent straight miniplate ($R = 23.4$). The ANOVA analysis between the break load and increased sterilization cycles showed $P > 0.175$; between the break position and increased sterilization cycles it showed $P > 0.016$.

Conclusions: Experimental static tests have shown that all tested miniplates did not have notable differences and this suggests that sterilization cycles do not affect mechanical characteristics.

Keywords: Osteosynthesis Miniplates; Finite Elements; Mechanical Characteristics; Sterilization

Introduction

During previous years, the fixation of maxillofacial fractures has evolved from Luhr's method,[1,2] to miniplates with titanium screws and to other methods being developed such as alloy chips with shape memory[3] and biodegradable plates of polylactic acid[4].

Pure titanium and other α + β titanium alloys were originally designed for use in general structural materials, particularly for aerospace structures, and only later adopted for biomedical applications.[5]

Titanium has become the biomaterial of choice for these systems, as it meets the requirements of resistance, adaptability, and biocompatibility.

Fracture of a miniplate is a rare complication, but the exact mechanism is still not well explained.[6–8] Tuncer et al.[9] reported an experimental trial in dogs, in which they compared new with removed and reused miniplates and showed no mechanical difference.

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Titanium miniplates can be sterilised many times before a given plate is implanted into the body, yet there is only one report that documented the material integrity of these multiply-autoclaved materials.[10]

Because sterilisation is one of the final surface preparations before placement of titanium plates, a study of the mechanical and surface changes is pertinent. This is particularly true because many plates are left in place indefinitely.[11]

The aim of this study was the analysis of changes that occur in osteosynthesis titanium miniplates when they are exposed to repeated cycles of sterilisation. In particular, we have focused on changes in the mechanical characteristics on variations in temperature and pressure.

Material and methods

For this experimental study titanium miniplates Medicon ©, mod. 68.70.16, were used. These are made from a titanium alloy, according to technical specifications ASTM F67-77 (Grade 2)[12].

The mechanical characteristics of these miniplates are: yield strength, 400 [MPa]; ultimate tensile strength 500 [MPa].

The characteristics of the miniplates were evaluated using penetration resistance tests; the mechanical characteristics were evaluated with MSC/Pal2 software, using the Finite Elements Method (FEM); and the surface roughness was also measured.

The tests were made on four sets of two miniplates that had had increased sterilisation cycles. A typical sterilisation cycle was one inside a standard autoclave, and corresponded to the exposure of each element to a water jet steam at 403 K lasting 30 minutes, not being otherwise specified by the manufacturer.

Penetration resistance

In the technological field, for metallic alloys, hardness is proportional to the resistance of a surface to pressure exercised by a penetration of conventional dimension and shape, to which a defined force is applied.

The Vickers hardness test uses a square-based pyramid diamond with an angle of 136° between opposite faces as an indenter (22° between the indenter face and surface). It is based on the principle that impressions made by this indenter are geometrically similar regardless of load. Accordingly, loads of various magnitudes are applied to a flat surface, the loads depending on the hardness of the material to be measured. The Vickers pyramid number (HV) is then assessed by the ratio **F/A** where **F** is the force applied to the diamond and **A** is the surface area of the resulting indentation.

The corresponding units of HV are then expressed as kilogram force/square mm (kgf/mm^2).

The impressions are read using a microdurometer with a 400× enlarging lens. The tests on the Medicon ©miniplate were conducted using a piezoelectric based load cell (sensitivity equal to 2.942 pC/N). Impressions for measurement of hardness are microscopic and do not damage the miniplate, so the tests were conducted in series on the same miniplate loaded with increased sterilisation cycles.

Surface roughness

The contact between titanium and steam produces a surface protective film (passivation film) of titanium oxide. The measurement of surface roughness with increasing sterilisation cycles is important to evaluate whether the tests of hardness are influenced by geometrical changes in the surface of the miniplate with increasing sterilisation cycles.

The measurement was made with a portable Surtronic 3+ instrument, which gives measures of centimetric mean roughness (Ra) and depth of roughness (Rt), together with other measurements not discussed here.

Ra indicates the mean of the scatter of the surface profile from its mean value.

Rt is the mean of the distances between peaks and valleys, along the length being measured.

Finite element analysis (FEA)

In general a finite element model is defined by a mesh network, which is made up of the geometric arrangement of elements and nodes. Nodes indicate points at which features such as displacements are calculated. Elements are bounded by sets of nodes, and define the localised mass and stiffness of the model.

Traction test

The mesh used for the structural model *F.E.M.(MSC/Pal)* led to a definition of 527 structural nodes and 384 quadrangular elements (Fig. 1). The element used is the classical thin plate bending element. One of the main aspect which needs to be studied, for a static analysis, is the correct simulation of the proper boundary conditions and the corresponding application of the load. As final result of this study, the structure was locked up in the centre (node 495) and constraints were considered to avoid translation along the y-axis, ensuring symmetrical behaviour.

The total traction load, 392 N, was distributed to four nodes that indicated the most stressed part of the structure itself in real conditions.

According to this distribution, a negative load of 98 N was applied on the two nodes (141 and 152), from one side of the plate, while an opposite load of 98 N was applied on symmetrical nodes(379 and 390), on the other side, as shown in Fig. 2.

Bending test

To understand the structural behaviour of the miniplates better, we also made a numerical analysis in the presence of a