Effect of autoclave sterilization upon mechanical properties of titanium miniplates used for internal fixation

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ABSTRACT

Titanium plates and screws are used for fixation of facial fractures and orthognatic surgery. That material is kept in proper boxes and receives multiple autoclave sterilization cycles. The present study evaluates the effects of those cycles upon mechanical properties of titanium miniplates (system 2.0, Engimplan). For that task four groups of fifteen plates were tested on a universal essay machine to verify the resistance to tension, flexion and compression. Group I received no sterilization, whereas Groups II, III, IV underwent one, ten and twenty cycles, respectively. After sixty destructive mechanical essays data were obtained concerning two variables: strength and deformation. The data were transformed into graphics plotting strength versus deformation, from which the calculus of the yield strength (σ_e) was obtained for each tested unit, so that a numeric result was gained in order to compare groups. Results were statistically treated to compare variables. Results did not show differences among groups for the tension and compressive tests. However, there were differences between groups for the flexion tests.

Keywords: bone plates, titanium, sterilization.

INTRODUCTION

Materials for fixation have evolved significantly in recent years. Most of the time, a few years ago, it was necessary to remove the fixation material shortly after the synthesis of some bony part in the head or neck with rigid fixation systems carrying additional costs to patients (Altobelli, 1992). Haug (1996), in his service, estimated in average US$ 338,520 the cost to remove such materials in a group of 260 patients/year.

To maintain stability and keep a dynamically functional while in the body, the material should have an adequate design, manufactured in biomaterial, show good biomechanic properties and good compatibility (Altobelli, 1992).

Biomaterials may by classified in three classes: metallic, ceramic and polymers (Idem).

In the practice of rigid fixation, metals are the sole materials to show adequate rigidity regarding all biomechanic demands of the facial bone frame. Commercially pure titanium and its alloy is the most modern material to be included as biomaterials due to its combination of strength, low molecular weight, resistance to corrosion and its biocompatibility. Because of that, titanium has arisen as a preference material for implants (Idem).

Only in 1940 medicine discovered titanium while introducing implants in laboratory animals with good results. Later, other studies have demonstrated its biocompatibility and high resistance to corrosion while in contact with body fluids (Leventhal, 1951; Clarke & Hickman, 1953).

Commercially pure titanium shows a hexagonal crystalline structure in room temperature. Small amounts of other elements, such as oxygen and iron, can be find in this presentation but do not account for more than 1%. Variations in the proportion of these impurities result in modifications in the mechanical properties of this metal (Williams, 1981).

The majority of metals form layers of oxide when exposed to the atmosphere. In theory, titanium may produce a variety of oxides such as TiO, TiO_2, and Ti2O3. Among them, TiO_2 is the most stable and the one that is most formed under physiological conditions.

These oxides may be spontaneously formed by contact with air. In a fraction of a second after exposition to air, a layer 10Å thick may be formed on the surface of pure titanium (Kasemo, 1983). Theoretically, this layer should not break under physiological conditions. The passive state of this material is caused by the low tax of dissolution of TiO_2 (Parr et al., 1985). This condition does not mean that titanium does not undergo corrosion but that the corrosion tax is significantly diminished due to the presence of the protective layer of oxide which, additionally, is responsible for the biocompatibility of this material (Brown, 1997).

The surgical use of titanium implant demands sterilization of the material. Stanford et al. (1994) state that the critical issue in implants is not the biological aspect, but the issues related to cleaning and ste-

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rilization of the surfaces as well as the layers of oxide. Lausmaa et al. (1985) verified that alteration in the layer interfere in the cell repair and in the process of bone remodeling.

Klauber et al. (1990) have demonstrated that autoclave sterilization of titanium implants induces the formation of layer of titanium oxide contaminated with ions N, F, Mg, Si and Cl. Braier et al. (1982) have arrived to a similar conclusion by demonstrating contamination of layers of vitalium and germanium oxide with hygroscopic salts and organic material.

Keller et al. (1990) have also observed modification from 3nm to 25 nm in the titanium oxide layer while in steam sterilization. They also discuss that modification in the surface color of these implants is due to this increase in thickness. Young (1988) has also demonstrated that alteration in the thickness of the oxide layer from 259 Å to 700 Å has also produced modification in the color of the surface of the metal.

Vezeau et al. (1996) mention that the multiple sterilization of pure titanium implants may interfere in the bioaceptability of the material as well as cause alteration in the implant surface. Sutton & Saunders (1996) assure that the plastic deformation of stainless steel due to high levels of stress, regarding function, may be partially attributed to the modifications of the properties of the material due to conventional steam sterilization.

Taking all these aspects into consideration, the aim of this study is to evaluate the effect of conventional steam sterilization on the mechanic properties of traction, compression and flexion in external fixation titanium miniplates, system 2,0mm.

MATERIAL E METHODS

Miniplates used in this study were obtained in the specialized trade[1]. Chemical composition of the surgical implants includes grade 2 titanium with low content of carbon. It was used sixty 2.00mm system plates with four holes (nº 220-04) of the 2.0 System (FIGURE 1) which were evaluated according to their mechanic properties for traction, compression and flexion (Hegtvedt et al., 1994), while submitted to sterilization cycles in autoclave. Such plates were ordered in four groups of 15 plates each. Group I was the control group that was not submitted to sterilization. Group II underwent one sterilization cycle, Group II 10 cycles and group IV, 20 cycles. Each group was divided in three sub-groups containing five plates each, referring to each of the mechanic assay undertaken.

1. ENGIMPLAN- Engenharia de Implantes Indústria e Comércio Ltda. Avenida 68, 227 V. Olinda - Rio Claro SP - Brasil.

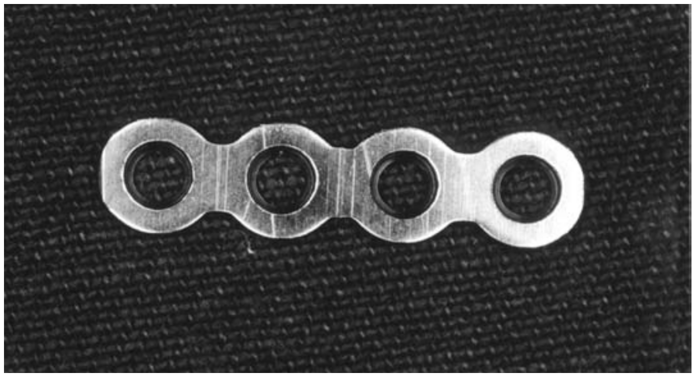

FIGURE 1 – Titanium miniplates system 2.0mm.

Prior to the selection of groups the 60 miniplates were measured in order to assure homogeneity of the sample. Then, the plates were selected at random in four groups being one of each of the treatments allotted to each of the sixty plates. These underwent sterilization in autoclave. For that, each plate was packed in a metallic container, common in parazitological examination, being the bottom lined with gauze to prevent direct contact between the titanium and the container. The specific treatment was identified in the container lid with a marking pen.

Since the lids were not perforated, containers were placed in the autoclave with the lid opened. The cycle was performed under 134ºC and 2.0 bar of pressure for 20 minutes when starting cold or 15 minutes if started hot. After drying for 15 minutes, a new cycle was initiated. Subsequent to it, plates were examined regarding the specific mechanic properties in a universal essay machine (FIGURE 2). After each essay, a strength versus deformation graphic was obtained (FIGURE 3) from which the flow limit was observed (σ_e), in a specific elongation or engineer deformation (&) of 0.2%. This means that the flow limit was fixed in a deformation of 0.2% of the initial length of the plate. After that, in the graphic, calculations were made to obtain the flow limit in each of the experimental units.

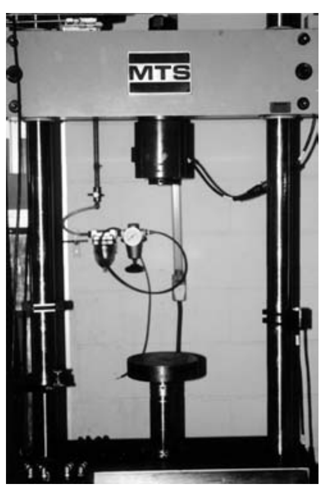

FIGURE 2 – Universal essay machine.

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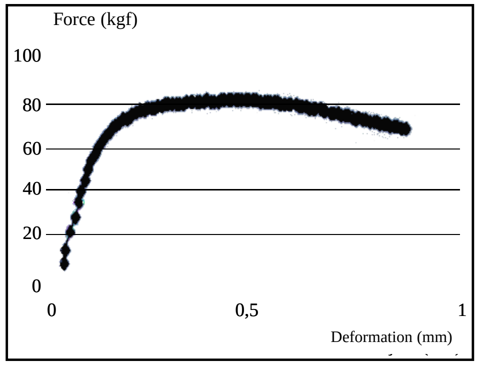

FIGURE 3 – Graphic force X deformation.

Evaluation of data was made by the non-parametrical method of Kruskal-Wallis while comparing two experimental groups. The test of multiple comparison: minimal significant difference – dms (Campos, 1983) was used when the result of the Kruskal-Wallis test was significant. The box-plot graphic was used to illustrate findings. Statistical calculation was made with the STATA[2] package.

RESULTS

The non-parametric analysis of σ_e values was carried through separately for each type of assay.

COMPRESSION

TABLE 1 shows the exploratory results for compression in the study.

TABLE 1 - Descriptive measures for compression and results of the statistical test for comparison among groups.

Group	Median (minimal value, maximum value)
I	33.00 (30.20 - 33.65)
II	33.65 (31.45 - 34.95)
III	32.80 (30.56 - 33.22)
IV	34.95 (33.22 - 34.95)

Result of the statistical test H = 6.837 (p = 0.0773)

2. STATA® Computing Resource center - STATA Reference Manual: Release III - 5 ed. Sta. Monica - California, 1992.

Result for Kruskal-Wallis test was not significant (H = 6.837 ; p = 0.0773). FIGURE 4 shows the results.

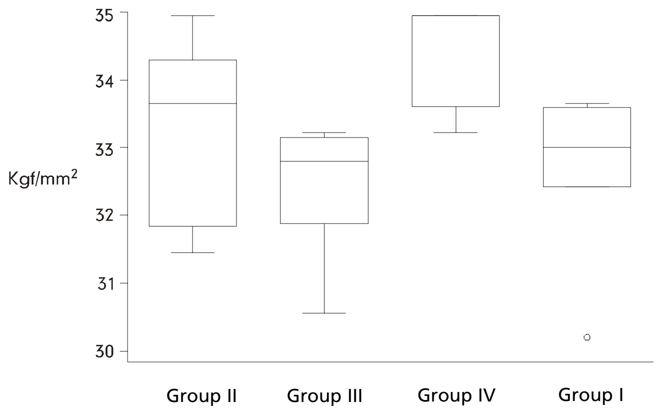

FIGURE 4 – Box plot diagram for σ_e values to the experimental units in the compression assay.

TRACTION

TABLE 2 shows exploratory results for traction values in the study.

TABLE 2 - Descriptive measures for traction and result of the statistical test for comparison among groups.

Group	Median (minimal value, maximum value)
I	42.71 (35.66 - 46.92)
II	38.38 (36.11 - 43.36)
III	42.56 (39.15 - 43.02)
IV	40.12 (38.44 - 41.56)

Result of the statistical test H = 4.254 (p = 0.2353)

Result for Kruskal-Wallis test was not significant (H = 4.254 ; p = 0.2353). FIGURE 5 shows the results.

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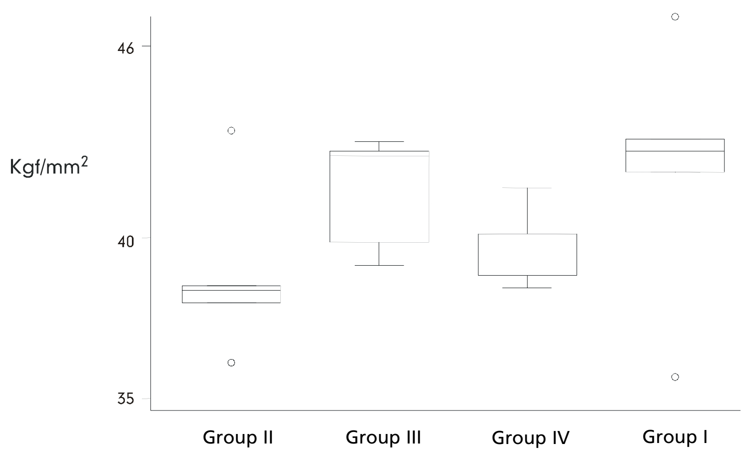

FIGURE 5 - Box plot diagram for σ_e values to the experimental units in the traction assay.

FLEXION

TABLE 3 shows exploratory results for flexion values in the study.

TABLE 3 - Descriptive measures for flexion and result of the statistical test for comparison among groups.

Group	Median (minimal value, maximum value)
I	16.95 ab (16.61 - 17.41)
II	17.10 a (16.34 - 17.25)
III	19.51 b (17.94 - 19.74)
IV	16.77 a (16.56 - 17.94)

Result of the statistical test H = 10.557 (p = 0.0144)

Result for Kruskal-Wallis test was significant (H = 10.557 ; p = 0.0144). FIGURE 6 display the results.

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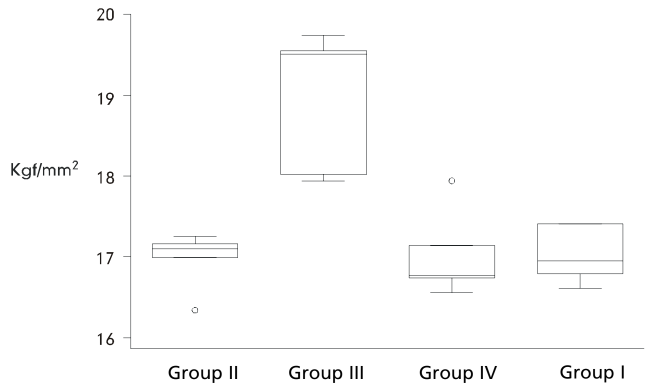

FIGURE 6 – Box plot diagram for σ_e values to the experimental units in the flexion assay.

DISCUSSION

Mechanical assays are emerging as important issues in the area of biomaterials. In the literature, there are examples of destructive essays such as those performed directly on the fixative devices, thus evaluating the mechanic properties offered by the geometry of the implant when submitted to any experimental condition (Hegtvedt et al.,1994; Tuncer et al., 1996) or by means of assays on fixation in osteotomies in bone removed from animals or in resin models (Ikemura et al., 1988; Anucul et al., 1992; Righi et al., 1996; Gosain et al., 1998).

The essays are about traction, compression and flexion since these combinations are these types of forces that act directly on the bone frame on the face.

Forces produced during chewing are dissipated through the mandibular process. Gibbs et al. (1981) verified that fully dentulous patients show an average masticatory force of 74 Kg. Colaizzi et al. (1984) observed average forces of 16 Kg for patients with superior and inferior total prosthesis. In the same way, Sposetti et al. (1986) obtained 23 Kg of force in patients with total superior prosthesis and inferior overdenture. Gibbs et al. (1986) reports the occurrence of limitrophe masticatory forces in patients with parafunction, varying from 234 a 443kg.

Hegtvedt et al. (1994) have demonstrated the resistance of vitalium miniplates till permanent deformation and observed that it is necessary a force of 92.03kg to obtain deformation in a traction assay, 127. 9 kg in compression assays and 2.65kg during flexion assays in the vertical direction.

The smaller values referred in these reports, when compared to ours, is due to the use of elastic deformation and not plastic deformation as a parameter and to the differences of size and the type of material since the miniplates have not the same commercial brand.

Gosain et al. (1998) concluded that titanium miniplates support forces of 350 N in compression as well as in traction, and therefore, there is no problems regarding the mechanical resistance since the maximum masticatory force is 296 N. This conclusion is also confirmed in the present study by comparing the necessary force to deform the plate with the masticatory force.

Sutton & Saunders (1996) asserted that sterilization in autoclave is responsible for alteration in the mechanical properties leading to plastic deformation in steel materials when submitted to high levels of stress. However, due to the low tax of dissolution of the titanium oxide, this metal shows a passive state and is, therefore, less prone to corrosion. In stainless steel, both corrosion and temperature contribute to the precipitation of carbonates in its microstructure leading to structural weakness that does not happen with titanium due to the apassivate layer of oxide (Williams, 1981;Chiarotti, 1997)

Commercially pure titanium shows some mechanical characteristics such as ductility and mechanical properties inferior to alloys. Regarding temperature, this metal shows a hexagonal structure while in room temperature – the so-called alpha phase. The first structural modification occurs at 882ºC when the metal shows a cubic structure of centered body called beta phase. In this last phase the titanium is hard and fragile, whereas in the alpha phase it is ductile and resistant. The next modification occurs at 1660ºC, which is its melting temperature (Lualdi & Minen, 1987).

The mechanical alteration in titanium occurs in high temperatures, around 882ºC, which are really high when compared to those in the sterilization process. Despite time and temperature, there is another factor to take into consideration during sterilization – humidity. This later is able to contaminate the layer of titanium oxide with ions F, Fe, Mg, Si, Cl, N, H, O (Stanford et al., 1994).

An increase in the percentage of ions H and O promotes a decrease in ductility of titanium leading to a smaller mechanical resistance (Brown, 1997). For that, these two ions (present in steam) need to penetrate the material matrix, which is only possible at temperatures of 560ºC (Haughes & Lamborn, 1961). This never happens in any sterilization process.

However, it was observed in the present study a significant statistical difference in the assay of flexion while comparing group III with the other groups. Therefore, there was a significant difference among flexion values regarding the experimental groups. Taking into consideration the test previously performed regarding the differences in miniplates measures, the values for thickness may have implications in the observed phenomenon. It is known that the greater the thickness, the greater the values for σ_e. Thus, observing these result for the covariable, it is interesting to note that the sum of the orders in the flexion essay has the same ordination as that of the study of the thickness of the miniplates. This could explain of the differences found among values in the assay for flexion.

Trivellato (1998), comparing four commercial brands of fixation systems, including the one used in the preset study, noticed problems related to the homogeneity of miniplates regarding the measures for both national systems.

Results obtained in the present study suggest that the studied material does not undergo alterations in its mechanical properties after sequential sterilization, thus this procedure can be done without deleterious effects.

CONCLUSIONS

1 - There was no differences in the mechanical properties (traction and compression) of miniplates when submitted up to 20 cycles of sterilization in autoclave.

2 - There was significant statistical difference to values of group III in the flexion essay when compared to the other experimental groups.

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