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ORIGINAL RESEARCH

# Accelerated physical deterioration of *in vitro* ocular prostheses

## *Deterioro físico acelerado de las prótesis oculares* in vitro

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**ABSTRACT**

Ocular prosthesis is a facial prosthesis mode destined to alloplastically repair partial or total loss of the ocular globe as well as its several malformations. It is well established that the best prosthetic rehabilitation has been obtained with acrylic resin ocular prosthesis. The aim of this study was to determine aqueous absorption and solubility, as well as accelerated physical deterioration degree such as change of color of characterized and non characterized ocular prostheses. Thirty eye shapers were manufactured following the flasking and characterizing UNAM technique. Aqueous sorption, solubility and accelerated deterioration tests were carried out. Turkey test and ANOVA analysis were applied to the results and a frequency graph was as well performed. Non characterized samples were reported as having greater sorption. Characterized samples were reported as having greater solubility; greater color changes were observed in the clear surface.

**RESUMEN**

La prótesis ocular es una modalidad de prótesis facial que va a reparar aloplásticamente las pérdidas parciales o totales y deformaciones diversas del globo ocular. Está claro que la mejor rehabilitación protésica se ha logrado con las prótesis oculares de resina acrílica. El objetivo de este trabajo fue determinar la absorción acuosa y solubilidad y, el grado de deterioro físico acelerado determinado como cambio de color de prótesis oculares caracterizadas y sin caracterizar. Se fabricaron bajo la técnica de enmuflado y caracterizado (UNAM) 30 conformadores oculares. Se realizaron pruebas de sorción acuosa, solubilidad y deterioro acelerado. A los resultados se les aplicó análisis de Anova y prueba de Tukey y se realizó una gráfica de frecuencias. En los resultados de sorción acuosa se reportó mayor sorción en los no caracterizados. En solubilidad se reportó mayor solubilidad en los caracterizados, cambios mayores de color se observaron en la superficie transparente.

**Key words:** Ocular prosthesis, aqueous absorption, solubility, accelerated deterioration.
**Palabras clave:** Prótesis ocular, absorción acuosa, solubilidad, deterioro físico.

## INTRODUCTION

Ocular prostheses are facial prostheses procedures destined to the alloplastic repair of partial an total loss of the ocular globe, as well as its various deformities. The psychological effect triggered in patients by the loss of one or two ocular globes is devastating. This justifies the seeking of a prompt and qualified solution to the problem.

The first report to appear in scientific literature of an ocular globe prosthesis belongs to Ambroise Paré, 1591, with the description of two types of ocular prostheses: the Hyplèpharon and the Ecblèpharon, the first fitted under the eyelids in the conjunctival sac, and the second one consisting on a strip of leather, with eyes and eyelids painted upon it, which was held with a metallic band around the head.[1]

In 1947 the first official plastic ocular prosthesis was presented at the French Ocular Prosthesis Center. Advantages of plastic over glass were thus established, for this reason, in our days, all prostheses are made of methyl-methacrylate material.[2]

The best material for prosthetic rehabilitation has been achieved with ocular prostheses made with acrylic resin. In these prostheses, color and individual characteristics can be reproduced. It is pertinent to point out that skill and time are required to replicate iris and sclera.[3]

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These prostheses are manufactured with the help of a shaper which has the anatomical shape and proper volume characteristics required to replace the loss of the ocular globe, which is specific for each patient.

At the Maxillofacial Prosthesis Clinic of the National School of Dentistry, National University of Mexico, UNAM, prostheses are manufactured with a muffle, and characteristics of the ocular globe are reproduced with the help of the «UNAM Technique for the Manufacture of Ocular Proshteses».[4] These prostheses are manually manufactured on plaster casts obtained from copies of the sites to be reconstructed.

When adhering to this technique, the time required for the manufacture of an individual prosthesis, from the manufacture of the prosthetic shaper, characterization of its components and proper finishing, is from 6 to 8 hours, divided into three sessions. The useful life of these prostheses can be indefinite, as long as proper care, such as cleansing in non chlorinated water is observed. Manufacturing costs are relatively low, although some clinics charge excessive fees.

This study presents the hypothesis that pigments used in the manufacturing of ocular prostheses, can be the factor inductive of deterioration. This deterioration becomes evident when a conspicuous change of color is observed.

The aim of this study was to determine the aqueous absorption, solubility and accelerated physical deterioration degree that these prostheses experience when exposed to different factors such as temperature, humidity and *in vitro* UV rays.

## MATERIAL AND METHODS

Thirty eye shapers were manufactured following the UNAM muffle technique for manufacturing ocular prosthesis: a sample shaper was manufactured with clear thermal polarizing acrylic (Nic tone, Mexico®) Pigmented with white oil paint (ATL, Mexico®).The proportion being 0.5mg per 10mL of monomener (The master shaper ) has a diameter greater than 2.65 cm ± 0.30cm and a parable over 1.2 cm high. Twenty shapers were characterized with ferrous oxide pigments (ATL®, Mexico), brown iris at an 11 mm diameter circumference, limbo pigmented with oil paint (Atl®, Mexico) combined with blue and black colors applied in two coating and sclera pigmented with two coatings of oil paint (ATL ®Mexico) color blue and ocher applied with one brushstroke each. Vascularization was characterized with 60 fibers of red rayon (IRIS, Mexico) each. The remaining 20 shapers were not characterized.

**Solubility and Aqueous sorption test:** 10 characterized and ten non characterized samples were placed in a dessicator with silica gel at 37 ± 1 °C. After 24 hours they were withdrawn and weighed in a scale (Analytical scale, Model GA 200, Ohaus Corp. Florham Park N.J.) This cycle was repeated until a constant weight was obtained (weight variation not larger than 0.1 mg in a 24 hour period); this was reported as Mass 1 ($m_1$). These samples were later placed in water at 37 ± 1 °C for 7 days in 50 mL of bi-distilled water per sample. After 7 days, samples were withdrawn, washed with water and drained up to the point when no humidity could be observed on the surface. Samples were aired, and weighed one minute after being withdrawn from the water; this was determined as Mass 2 ($m_2$). After weighing, samples were placed on the desiccator, using the previously described cycle; this was reported as Mass 3 ($m_3$). Values were calculated according to the following formula:

$$\frac{m_2 - m_3}{m_2} \times 100 = \% \text{ aqueous sorption}$$

$$\frac{m_1 - m_3}{m_1} \times 100 = \% \text{ solubility}$$

Results were subject to Anova analysis and Tukey test.

**Accelerated deterioration test:** 10 characterized samples were placed under the UV light produced by a 375 watt bulb. Samples were positioned at a 12 cm distance from the light source and relative humidity conditions of 95 ± 5% and temperature of 70 ± 5 °C, at 30 and 60 days periods. For observation purposes, samples were digitally photographed in an Intel microscope with 10 augmentations. Photographs were taken before initiating procedure, at 30 days and at 60 days of being subject to accelerated aging conditions.

One single observer performed the comparison of color change experienced by the characterized samples. This subject assessed in the photographs, the presence or absence of changes in the pupil, iris, limbo and sclera. Observation of changes was performed comparing photographs of initiation with 30 and 60 days photographs in a state of accelerated deterioration.



## RESULTS

Table I. Shows results of aqueous sorption in %.

Table II. Shows results of solubility in %.

Table III and figure 1. Shows results of frequency analysis of samples with changes in color with respect to time and observed site.

## DISCUSSION

Greater solubility was observed in characterized samples and greater absorption was discerned in non characterized ones. This could be due to the solubility of pigments present in characterized samples. Percentages of aqueous sorption found in this study are not within ADA Norm Number 2 parameters[5] for acrylic resins. This is due to the size of samples, which, being of larger bulk is directly proportional to the amount of solubilized material as well as in the sorption case.

**Table I.** Aqueous sorption in %.

| | Mean | Standard deviation | Variation coefficient |
|---|---|---|---|
| Characterized | 0.00103 | 0.0000511 | 0.0000162 |
| Non characterized | 0.00108 | 0.0000374 | 0.0000118 |

There is a statistically significant difference with P = 0.039

**Table II.** Solubility in %.

| Mean | Standard deviation | Variation coefficient | |
|---|---|---|---|
| Characterized | 0.000414 | 0.0000278 | 0.00000879 |
| Non characterized | 0.000383 | 0.0000296 | 0.00000936 |

There is a statistically significant difference with P = 0.27

**Table III.** Of samples with changes during evaluation period.

| Days | Pupil | Iris | Limbo | Sclera | Surface |
|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 |
| 0-30 | 2 | 6 | 7 | 1 | 7 |
| 30-60 | 0 | 1 | 2 | 1 | 7 |
| Total | 2 | 7 | 9 | 2 | 14 |

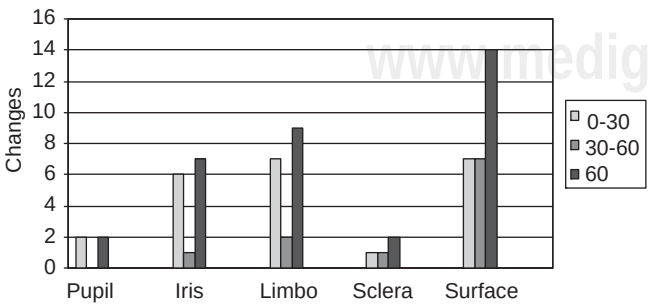


**Figura 1.** Graph of samples with changes during evaluation period.

Samples were photographed before and after procedure. This aimed at assessing changes at 30 and 60 days (following methodology used in studies to determine changes on the surface of restorative materials).[5,6]

Thus, (comparing photographs taken before and after procedure) it could be observed that the prostheses suffered the greater amount of changes in their surface. It could also be observed that the lesser amount of changes was found in the prostheses pupil and the sclera. This might be due to the fact that any of the elements found under the surface of the clear acrylic are tightly sealed and this avoids contact with the external environment.

It is proposed to carry out research on the different types of pigments to determine their deterioration and solubility in the state they present when preparing a prosthesis. According to the results thus obtained, recommendation can then be made to use the one showing the lesser deterioration or solubility to decrease risks in biocompatibility. This is dictated by the fact that, although exposition to solubility is minimal for the time when it is in contact with the ocular cavity, solubility and aqueous sorption is present in greater percentages in patients with compromised lachrymal ducts.

Results of this study are similar to those found in the paper «Observación del deterioro físico del silicón grado médico tipo «A» e industrial (dow corning) expuestos a tres y seis meses al medio ambiente de la Ciudad de México» (Observation of physical deterioration of industrial and medical «A» type silicon (dow corning) exposed to three and six month periods to the Mexico City environment).[7] These observed changes are mainly loss of surface gloss. This could be due to the fact that surface is the first component of the prosthesis to be exposed to environmental agents. Nevertheless, we beg to point out that in that study, there were no ultraviolet radiation level, humidity and temperature controls, and in this it differs from our present paper.

In the present study ocular prostheses could be kept at accelerated deterioration state at 70 ± 5 °C temperatures, and 95 ± 5% relative humidity, at a constant exposition of 375 watts ultraviolet light, as mentioned in ADA Norm 18 accelerated deterioration tests[8] pertaining to impression materials and alginates, ADA Norm 12 was observed for changes in color,[9] achieving thus tighter control on test conditions.



## CONCLUSIONS

When following this methodology, non characterized prostheses showed greater aqueous sorption as

well as lesser solubility. Changes observed in characterized samples were greater than those discerned in sclera and pupil. Exposition time to accelerated deterioration increases color changes in characterized prostheses.

According to results gained in this paper, it is suggested that, although these prostheses are definitive, the clinical operator should assess and value all changes, so as to recommend substitution in cases so warranted.

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