

Report concerning the outcomes obtained with corneal cosmetic surgery of new design with the pigments of Biotic Phoceia, previously CE mark

Background:

Over the last 11 years the group that I lead in the Miguel Hernandez University, Alicante, Spain and Vissum Corporation has developed extensive studies on the development of a new type of corneal surgery based on the use of pigments applied either intralamellarly, inside the cornea, or from the corneal surface. Both types of techniques have been developed by us, investigated in an experimental animal model and applied for the last 11 years on human patients, aiming to restore inadequate cosmetic appearances or to resolve functional disabilities of the eye that were unable to be treated in any other more conservative way.

Recently, the pigments of Biotic Phoceia have lost their CE mark and the purpose of this report is to illustrate our experience and evolution with the use of the pigments of this company.

Experimental experiences:

We have been looking for pigments for the purpose of corneal pigmentation for over 10 years. This was the reason for initially using pigments that were obtained from different sources, first in the experimental animal and later in patients. We quickly realized in the experimental animal model that the toxicity and other possibly related complications such as teratogenicity were related to the purity of the pigments and the redox composition of the metals. None mineral pigments were soon discarded from our experiments and later on with the evidence micronized pigments became those to be further investigated. In the experimental animal model we selected different types of pigments and, finally selected for these studies, brown, black and blue, and white, were used selectively in the initial patients. The purpose was to restore normal cosmetic appearance for functional disabilities of diseased eyes.

The results of our experimental and clinical experiences have been published in the literature, and recently have been the subject of a book, the first published on the topic, published on an international basis. At the end of this report we list our scientific references, which have all been made in scientific journals with a very high impact factor.

At this moment, we are testing different types of pigments in experimental animal models in order to further implement their composition, based on micronized metals which are already available and proven in safety and the redox condition that have to be used for the purpose of minimizing the recovery time of the patient and to improve their biointegration.

Clinical experimental experiences:

The main complication that is related to the use of inadequate pigments, especially those from vegetal origin and/or organic, is the high risk of infection. Mineral pigments, if micronized, do not induce foreign body reaction and are well tolerated as the redox composition is properly established. The pigments have to be developed with extreme purity and no contaminants should be included. If these rules are not properly adhered to, problems such as corneal opacity, neovascular corneal ingrowth and corneal irritation might occur.

The pigments of Biotic Phoea, listed with CE mark in this company until recently, have been tested by us with full success as proven in our references which are below.

Human experiences:

Over our 11 years of experience, we have edited and published several scientific papers on the topic. We are the authors of the following techniques:

Intrastromal femtosecond assisted keratopigmentation

Superficial keratopigmentation

Functional keratopigmentation

Cosmetic keratopigmentation (cosmetic cornea)

These papers have raised the evidence on the tolerance and evolution of the patients. We are able to solve in an extremely conservative way, avoiding mutilations such as evisceration or enucleation, many cases which with the longterm experiences in over 350 cases prove the safety of the technique. Over the last 2 years we have been using exclusively the pigments of Biotic Phoea with no complications and, again, this has been the subject of publications that are listed below.

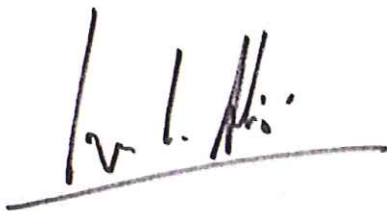
Conclusion:

It is our experience, proven by the evidence that is published in the scientific literature by our group that the pigments of Biotic Phoceia are safe, stable and convenient for human use. We need to use these pigments in order to minimize and even to eliminate aggressive surgeries such as corneal transplantation, esvisceration and enucleation in diseased eyes, even blind, which need cosmetic reparation. Functional problems such as traumatic aniridia, congenital aniridia, colobomas, and albinism have no solutions so far other than cosmetic keratopigmentation or risky operations which are at this moment abandoned by us.

Since the availability of the Biotic Phoceia CE mark pigments, we have been using them on an open basis with all the clinical standards that are used in good clinical practices. Our experience in over 350 patients is outstandingly good and we have to make it evident that these pigments are necessary for our practice and for our patients.

We are ready to complete this report with any complementary evidence necessary on request for the purpose of the continuation of the previously CE labelled pigments for keratopigmentation of Biotic Phoceia.

I am signing this report with no commercial or financial interest in the company, nor am I consultant for it and under my free and independent scientific and academic opinion.



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Alió J.L Amesty M.A.; Rodriguez A.; El Bahrawy M
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Keratopigmentation to Change the Apparent Color of the Human Eye: A Novel
Indication for Corneal Tattooing.

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Corneal tolerance to micronised mineral pigments for keratopigmentation.

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Femtosecond-assisted keratopigmentation double tunnel technique in the management
of a case of Urrets-Zavalía syndrome.

Alió JL, Rodriguez AE, Toffaha BT, El Aswad A.
Cornea. 2012 Sep;31(9):1071-4. doi: 10.1097/ICO.0b013e318243f6b1

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J Cataract Refract Surg. 2011 Oct;37(10):1744-7. doi: 10.1016/j.jcrs.2011.08.003. Epub
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Keratopigmentation (corneal tattooing) for the management of visual disabilities of the
eye related to iris defects.

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Tolerance and biocompatibility of micronized black pigment for keratopigmentation
simulated pupil reconstruction.

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