

Factors affecting dimensions of the 3D ocular prosthesis in patients rehabilitated at Mahidol University

Hai Phan Hoang, Kajohnkiart Janebodin, Kanokwan Charoonpatrapong,
Waqas Tanveer, Kawin Sipiyaruk, Natdhanai Chotprasert

Objective: This study aimed to evaluate three factors affecting dimensions of the '3D ocular prosthesis' in patients rehabilitated at Mahidol University.

Materials and Methods: A cross-sectional study was conducted on non-irradiated and healthy anophthalmic patients, including 82 subjects aged above 15 years old. All 82 standardized ocular prostheses, fabricated following the Mahidol University's patent, were measured with a digital caliper (Mitutoyo 573 Digimatic Absolute Point Caliper) in horizontal, vertical, and anteroposterior (thickness) dimensions. Three main factors (age, gender, and surgical techniques) were evaluated in relations to the ocular prosthesis. The data were statistically analyzed using multifactorial ANOVA ($p < 0.05$).

Results: The multifactorial ANOVA showed no significant differences in vertical and horizontal dimensions among all those three factors ($p > 0.05$). However, regarding thickness consideration, statistically significant difference was found in accordance to the surgical technique factor ($p = 0.012$).

Conclusion: This study presents the first set of data for the 3D ocular prosthesis in patients rehabilitated at Mahidol University. The factors of age and gender might not affect in all three dimensions of the ocular prosthesis, however the surgical technique could influent thickness of the ocular prosthesis.

Keywords: Customized ocular prosthesis, Enucleation, Evisceration, Ocular defect, Ocular prosthetic dimension, Stock ocular prosthesis

How to cite:

Introduction

The facial components, especially eyes, are the most prominent characteristic of each individual in non-verbal communication. Therefore, loss of an eye could leave a psychological wound, esthetic disfigurement, and financial difficulties to an individual.¹⁻⁴ The restorative strategies for such ocular defect patients primarily include rehabilitating ocular deformities by replacement of lost orbital portions, recovering orbital esthetics, and preventing surrounding tissue contraction following evisceration or enucleation.^{5,6} Evisceration is a surgical approach for removing

the intraocular contents of the globe, leaving the entire sclera intact, whilst enucleation is a removal of an eye globe including a portion of the optic nerve from an orbit.⁷ These surgical techniques, currently, are accompanied by a placement of intraorbital implants to restore a lost volume, to reduce a size of future ocular prostheses, and to improve a movement of ocular prosthesis.^{8,9} Therefore, a management in these patients requires a collaborative effort of ophthalmologists, ocularists and maxillofacial prosthetists.¹⁰

Ocular dimensions and ocular volume vary in different age groups due to changes in hard and soft tissues.¹¹⁻¹³ In addition, dimensional changes of an eye globe are related to volume

Correspondence author: Natdhanai Chotprasert

Maxillofacial Prosthetic Clinic, Department of Prosthodontics Faculty of Dentistry, Mahidol University, Bangkok, Thailand

Tel: 02-200-7737 Email: cnatdhanai@hotmail.com

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increase, which rapidly grows from birth to two years of age and then gradually changes until 30 years old before starting to decrease;^{14,15} the growth of an orbit ceases by 11 years of age in female and 15 years of age in male.^{16,17} During the stable period, the enlargement of a bony orbit is mainly because of an increased resorption and volume loss of a midface bone.¹⁸ This consideration was analyzed by Pessa in normal and healthy male skulls.¹² According to sex consideration, average orbital volumetric changes with respect to this factor are controversial; however, larger orbital volumes were found in men than women in some studies.^{17,19} Furthermore, soft tissues surrounding a bony orbit expand until 13 years old for female and 15 years old for male before undergoing the same atrophic process with the loss of elasticity, contributing to orbital wrinkle, crow's feet, and sagging of upper and lower eyelids.^{20,21}

An intact eye globe plays a crucial role in the development of an orbit.¹⁷ Therefore, an anophthalmic socket results in a significant orbital asymmetry and disfiguration.^{22,23} There had been evidence that orbital volume tended to reduce following enucleation in children and adults.²⁴ Therefore, the placement of an intraorbital implant of appropriate volume at the time of enucleation or evisceration followed by replacement of ocular prostheses can stimulate the orbital growth in ocular defect patients.²⁵

There had been many studies regarding the measurement of a bony orbit in eviscerated and enucleated sockets, focusing on the size of an intraorbital implant and pre-prosthetic procedures; however, no study took in account ocular prosthesis dimensions.^{24,26,27} This study aimed to evaluate the factors effecting dimensions of the '3D ocular prosthesis' in patients rehabilitated at Mahidol University.

Materials and Methods

This cross-sectional study was carried out at the Maxillofacial Prosthetic Clinic, Prosthodontics Department, Mahidol University, Thailand. Subjects included ocular defect patients aged above 15 years old who were rehabilitated with custom made ocular prostheses from January to July 2017. A total of 82 patients (36 females and 46 males aged 40.33 ± 3.74 years) were recruited into this study after hospital record screening and clinical examination. Participants who had healthy anophthalmic sockets due to either evisceration or enucleation without receiving a radiation therapy in head and neck region were included in this study.

Demographic data of all patients, including age, gender, etiology of defect, type of surgery, and history of orbital implant rehabilitation, were recorded. All 82 custom made ocular prostheses, '3D ocular prosthesis', were fabricated according to the Mahidol University's patent (Patent number: 36414). The specimens were measured with a digital caliper (Mitutoyo 573 Digimatic Absolute Point Caliper) in horizontal, vertical, and anteroposterior (thickness) dimensions; these data were then recorded.

The study protocol was approved by the Faculty of Dentistry and the Faculty of Pharmacy, Mahidol University, Institutional Review Board (MU-DT/PY-IRB), reference number: MU-DT/PY-IRB 2016/092.

Statistical analysis

The three main factors, including gender, patient's age group, and surgical technique, were analyzed using multifactorial ANOVA (SPSS version 20.0, IBM, Chicago, IL), with $p < 0.05$ taken as a significant difference.

Results

The means of horizontal width, vertical height, and thickness were 23.82 ± 0.25 , 22.98 ± 0.38 , and 22.98 ± 0.3818 , respectively (presented in Table 1). Gender and age group did not significantly affect the dimensions of the prostheses ($p > 0.05$). In contrast, surgical

techniques significantly affected the thickness of ocular prostheses ($p = 0.012$); the thickness of the prosthesis in the enucleation group was significantly greater than that of the evisceration group (mean = 9.435 and 8.213 mm, respectively), as presented in Table 1 and Fig. 1. However, the surgical techniques did not significantly affect horizontal and vertical dimensions of the ocular prosthesis ($p > 0.05$).

Table 1 The means of three-dimensional ocular prostheses and the three main factors

Dimension (mm) mean \pm SD	Genders	<i>p</i> -value	Surgical techniques	<i>p</i> -value	Age groups	<i>p</i> -value
Horizontal width 23.816 \pm 0.247		0.289		0.917	15-20 21-30	0.168
Vertical height 22.977 \pm 0.381	M = 46 F = 36	0.224	Evisceration Enucleation	0.800	31-40 41-50	0.887
Thickness 8.824 \pm 0.241		0.836		0.012*	51-60 > 60	0.986

* Significant difference ($p < 0.05$) according to multifactorial ANOVA

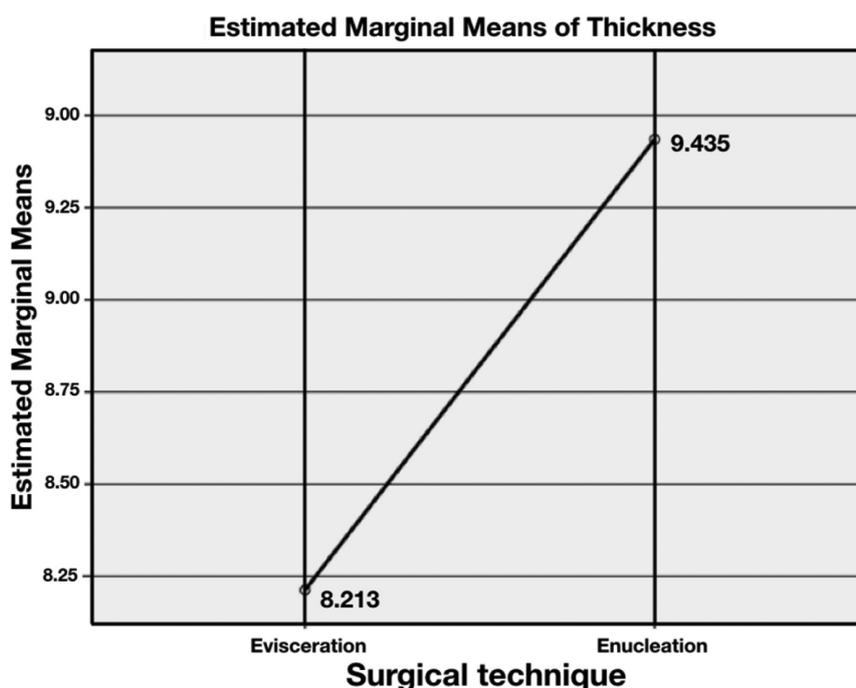


Figure 1 The means of ocular prosthesis thickness in evisceration and enucleation

Discussion

The data of this research were collected at Maxillofacial Prosthetic Clinic, Faculty of Dentistry, Mahidol University. In this study, the authors collected all data in patients over 15 years old when growth of an eye globe as well as orbital hard and soft tissues had ceased.²⁸

According to a report in 2001, insertion of orbital implants and ocular prosthesis after enucleation was necessary for the adequate development of an affected orbit.²⁵ Furthermore, insertion of an ocular prosthesis soon after surgical removal of an eye followed by constant replacement of ocular prosthesis in growing age helped to prevent growth retardation of the orbit. Analysis of effective volume replaced with adequate ocular prostheses (2 - 4 ml) is meaning in the successful rehabilitation for ocular defect patients.^{29,30} This

conception, however, has not appeared to be significantly applicable in clinical practice, as relying solely on referential volume of prostheses cannot fabricate those in proper three-dimensional forms. Based on the results of our research, an ocular prosthesis was an oval-shaped hemisphere with a concave posterior base facing the tissue bed of ocular defects; an average ocular prosthesis, consequently, has dimensions of 23.82, 22.98, and 8.82 mm in horizontal width, vertical height, and thickness, respectively (Fig. 2). As a result, the mean of prosthetic volume was commonly less than 3 ml, which was slightly larger than an ideal prosthetic volume of 2.2–2.3 ml in cases of 14 mm to 22 mm implant diameters as reported in a previous study.³¹ However, these parameters were surveyed in ocular defect patients either with or without an implant placement, and the purpose of the article mainly focused on the effect of age and gender on ocular prostheses.

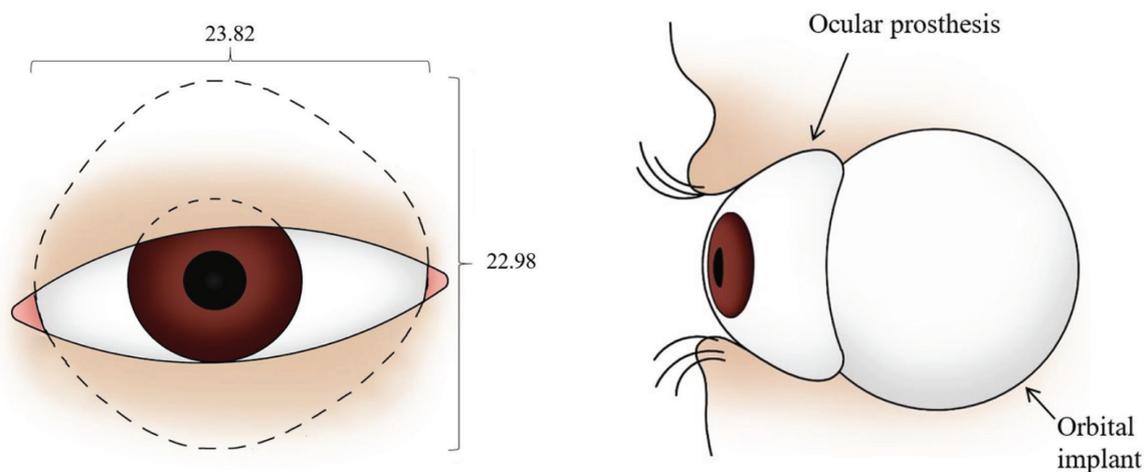


Figure 2 Schematic diagrams show an oval-shaped hemisphere ocular prosthesis with a concave posterior base over the tissue covering orbital implant.

The number of males was slightly higher than the number of females in this study. This observation was similar to previous reports carried out in China (2008) and in Italy (2013).^{32,33} This quantity imbalance may be due to high risk of eye loss in males related to ocular or orbital injuries. Based on the result analysis, these parameters can be applied generally in ocular defect patients with different genders and various ages of adulthood. Although publications showed that normal ocular dimensions in adults varied with age and gender among different biometric parameters,^{13,34} vertical and horizontal diameters were not found much different between males and females at any ages.²⁸ There was also no clear evidence to explain variation in ocular dimensions with gender, but that might be due to differences in genetic and environmental factors.³⁵ Most of the patients in the study had been using either stock ocular conformer or ocular prosthesis after surgical removal of their eye, leading to reduction of orbital socket volume, as opposed to regular replacement with custom made ocular prosthesis.^{24,25} This could be a reason why there were no significant differences among all measured dimensions with increasing age.

This research had focused only on adult age groups; therefore, the real influence of age on a size of ocular prostheses was inadequately evaluated. Moreover, this research did not consider duration of eye loss since an eye removal and effects of an intra-orbital implant on an available volume for future ocular prosthetic rehabilitation.

In conclusion, this research demonstrates the first three-dimensional data of ocular prosthesis, in patients rehabilitated after a surgical removal of an eye. Previous studies were done to evaluate the prosthetic volume replacement, which had theoretical significance rather than clinical application. Based on the data of this

research, a new set of stock ocular prosthesis will be fabricated. However, further studies are required with focuses on a quality of life in ocular defect patients upon using different dimensions of stock ocular prostheses in order to fulfill the clinical application.

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