

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

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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 customized 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 dimensions of an ocular prosthesis. The data were statistically analyzed using an independent *t*-test and a one-way ANOVA.

Results: An independent *t*-test showed that a horizontal dimension was significantly greater in males than females ($p=0.020$), and a thickness dimension was significantly different in surgical techniques, which enucleation technique showed thicker ocular prosthesis compared with evisceration technique ($p=0.024$). However, one-way ANOVA showed that all dimensions of an ocular prosthesis were not significantly different among age groups ($p>0.05$).

Conclusion: This study presented the first set of data for the 3D ocular prosthesis in patients rehabilitated at Mahidol University. Gender had an effect on horizontal dimension whilst surgical technique had an effect on the thickness of ocular prosthesis.

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

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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

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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 an intraorbital implant placement to restore a lost volume, to reduce a size of future ocular prostheses, and to improve a movement of ocular prosthesis.^{8,9} Therefore, 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 of hard and soft tissues.¹¹⁻¹³ In addition, dimensional changes of an eye globe are related to volume 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 each patient, including age (age groups 15-20, 21-30, 31-40, 41-50, 51-60, or >60), gender (male or female), and type of surgery (evisceration or enucleation), were collected. 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 data were analyzed using SPSS version 20.0. Differences in horizontal, vertical and thickness dimensions were analyzed separately between genders and surgical techniques as well as among age groups. An independent *t*-test was used to analyze whether there are any differences in each dimension between genders and surgical techniques, whilst a one-way ANOVA was used to analyze dimensional difference among age groups.

Results

The means of horizontal width, vertical height, and thickness were 23.82 ± 0.25 , 22.98 ± 0.38 , and 8.82 ± 0.24 mm, respectively (presented in Table 1 and Figure 1). Gender and surgical technique factors significantly affected the horizontal width ($p=0.020$) and thickness ($p=0.024$) of "3D ocular prostheses", respectively. In contrast, age groups were not significantly affected to all dimensions of "3D ocular prosthesis" ($p>0.05$). The thickness of the prosthesis in the enucleation group was significantly greater than that of the evisceration group (means = 9.44 and 8.21 mm, respectively), as presented in Fig. 2. However, the surgical techniques did not significantly affect horizontal and vertical dimensions of the ocular prosthesis ($p>0.05$). In addition, the horizontal width in the male group (24.45 mm) was significantly greater than that of

the female group (23.40 mm), ($p=0.020$).

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 volume replacement by orbital implant and ocular prosthesis is required for successful rehabilitation in 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. 1). 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.

Table 1 Means of the three dimensions of ocular prostheses and the three main factors

Factors	Number of samples	Horizontal width		Vertical height		Thickness	
		Mean ± SD (mm)	p-value	Mean ± SD (mm)	p-value	Mean ± SD (mm)	p-value
Gender							
Male	46	24.45 ± 2.02	0.020 ^{A*}	23.54 ± 2.75	0.136 ^A	8.94 ± 2.02	0.460 ^A
Female	36	23.40 ± 1.94		22.59 ± 2.92		9.26 ± 1.82	
Surgical technique							
Evisceration	26	24.05 ± 2.31	0.868 ^A	23.36 ± 2.79	0.603 ^A	8.38 ± 1.25	0.024 ^{A*}
Enucleation	56	23.96 ± 1.93		23.01 ± 2.89		9.41 ± 2.11	
Age group							
15-20 yrs	14	23.65 ± 1.58	0.418 ^B	23.43 ± 3.73	0.877 ^B	9.23 ± 1.44	0.995 ^B
21-30 yrs	10	24.69 ± 1.16		23.29 ± 1.63		9.08 ± 1.77	
31-40 yrs	19	24.61 ± 1.58		23.48 ± 3.07		8.90 ± 1.92	
41-50 yrs	14	23.53 ± 2.98		22.36 ± 2.60		9.24 ± 2.15	
51-60 yrs	14	23.43 ± 2.00		22.75 ± 3.04		9.13 ± 2.54	
>60 yrs	11	24.01 ± 2.46		23.41 ± 2.44		8.95 ± 1.85	

* Significant difference (p<0.05) according to independent t-test and One-Way ANOVA

^A Independent t-test

^B One-Way ANOVA

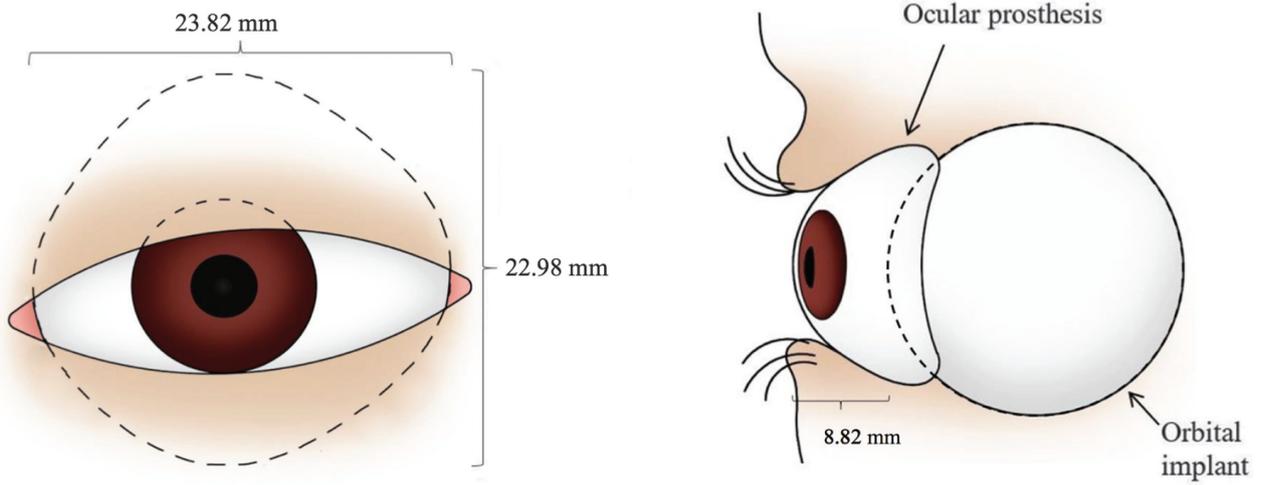


Figure 1 Schematic diagrams show dimensions of an oval-shaped hemisphere “3D ocular prosthesis” with a concave posterior base over the tissue covering orbital implant.

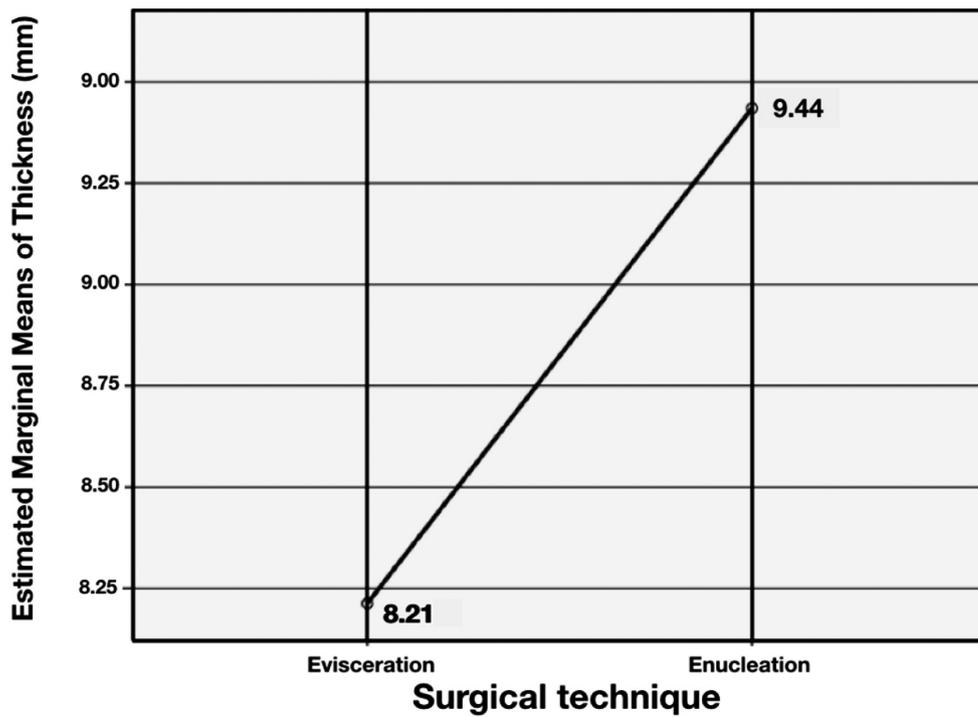


Figure 2 The means of ocular prosthesis thickness in evisceration and enucleation.

In terms of the dimensional differences between the two surgical techniques, this research demonstrated that the thickness in the enucleation group was significantly greater than the evisceration group. Although these two surgical techniques produce similar esthetic and functional outcomes,³² evisceration remains Tenon's capsule and leaves sclera intact, which minimizes the amount of fat atrophy after surgical removal providing 0.5 ml greater than enucleation.³³ This could lead to a dimensional difference in thickness of an ocular prosthesis. According to the horizontal width and vertical height, our findings showed no significant difference between the two surgical techniques; this could be explained by an argument that no differences in both fornices and canthi were found between both surgical techniques.³³

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).^{34,35} 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,^{13,36} vertical and horizontal diameters were not found much different between males and females at any ages.²⁸

Our study found that gender had an influence on the horizontal width of an ocular prosthesis, which the male group showed 1 mm significantly greater than the female group. Although there was a statistical difference, it was not much significant in terms of clinical considerations. The statistical significance might result from a large number of samples with a low standard deviation. Literature also revealed that an orbital volume was greater in boys compared to girls although they shared a

similar growth pattern during the first five years of development.¹⁶ Although the orbital dimensional differences in terms of gender are still controversial, there is evidence of a greater orbital volume in males, compared to females women.^{17, 19}

According to an age consideration, our study found no effect of age in all dimensions of an ocular prosthesis. This study had focused only on adult age groups due to the limited of clinical management in children; therefore, the real influence of age on a size of ocular prostheses was inadequately evaluated. Moreover, this study 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 addition to the duration of eye loss, future research on other factors such as age of eye removal, effects of radiation, intraorbital implant size and location, and an anophthalmic socket in a congenital defect is required for a proper protocol of an ocular prosthetic rehabilitation.

The data of our study will be used to fabricate a new set of stock ocular prostheses to be used in Mahidol University. However, further research is required to gather information regarding a relationship between a pupil and an ocular prosthesis as well as colors of iris and sclera. Further multicenter research is also recommended in order to further develop the set of stock ocular prostheses for the future use in other areas. Finally, the evaluation of quality of life in patients using the stock ocular prosthesis should be taken into a consideration.

In conclusion, this research demonstrated the first three-dimensional data of ocular prosthesis in patients rehabilitated after a surgical removal of an eye at Mahidol University. Based on the findings of this research, the surgical technique had an effect on thickness and gender had an effect on horizontal width of the ocular prosthesis, however, age group did not affect all three dimensions of the ocular prosthesis.

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