

EVALUATION OF MOTILITY OF SOLID VERSUS HOLLOWED OCULAR PROSTHESIS. A DOUBLE BLINDED RANDOMIZED CLINICAL TRIAL

Mahmoud Abdelrahman H ^{*ID}, Hassan, Doaa T ^{**ID} and Agamy, Emad M T M ^{***ID}

ABSTRACT

Purpose: To evaluate the motility of solid and hollowed ocular prostheses in cases with eviscerated eye defect who received orbital implants more than 6 weeks.

Materials and methods: The study was conducted at prosthodontic department, Minia University. Ten patients with unilateral eye defect were selected from the out-patient clinic of Ophthalmology Department Minia University Hospital. The study design was a double blinded randomized controlled trial where neither the patients nor the evaluators knew the type of appliance in question. Each patient received two types of ocular prostheses (hollowed and solid) one at a time in a random sequence. A novel technique is used for the fabrication of the hollow prostheses. The patients were blinded regarding the type of prosthesis used at each sequence. Three evaluators blindly evaluated the motility in horizontal and vertical gaze (movement) using a standard millimetric ruler (Custer's method).

Results: The median for motility in vertical movement for sum of the evaluators was 5 mm for solid and hollowed prostheses. The median for motility in horizontal movement for sum of evaluators was 3 mm for solid and hollowed prostheses. The Mann-Whitney test was used for non-parametric quantitative data evaluation between the two groups (p-value was set to be ≤ 0.05). The results of Mann-Whitney test revealed non-significant difference between the two groups either in horizontal or vertical gaze (p-values ranged from 0.728 to 0.817).

Conclusion: under the limitations of the current study, it may be concluded that the method of prosthesis construction either hollowed or solid does not affect its mobility. Solid and hollowed ocular prostheses have essentially the same range of motility. Thus, reducing their weight may not have a benefit for their motility.

KEYWORDS: Ocular prosthesis, hollow ocular prosthesis, artificial eye motility, custom ocular prostheses.

* B.D.S. (2013), MSc Student (2017) Faculty of Dentistry Minia University,

** Lecturer of Prosthetic Dentistry, Faculty of Dentistry, Minia University.

*** Professor of Prosthetic Dentistry Faculty of Dentistry, Minia University Dean of Faculty of Dentistry, Delta University

INTRODUCTION

Each year approximately 50000 individuals lose an eye due to trauma, or surgical procedure to treat an infection, a tumor or a painful blind eye⁽¹⁾. Surgical treatment may include one of the three approaches: evisceration, enucleation, or exenteration. The minimal surgical procedure is evisceration by removal of the contents of the globe, leaving the sclera and the cornea intact. Enucleation is the surgical removal of the globe and a portion of the optic nerve from the orbit. While exenteration; the most radical, is removal of the entire contents of the orbit.⁽²⁾

To rehabilitate the patient after such surgical procedures, custom-made prosthetic devices in the form of ocular prostheses is the first choice. Ocular prostheses will help these patients gain professional and social acceptance and alleviate other problems. The aim of an ocular prosthesis is mainly to restore esthetics, preserve muscle tonicity of the upper eyelid (preventing it from shrinking due to lack of function), conduct tears to their physiological ducts (prevent lashes from sticking and drying the conjunctival area), and protect the orbital mucosa from debris and dust.⁽³⁾

A large ocular prosthesis within large socket defect would temporarily ease the problem but inevitably leads to: lower lid laxity and deep superior sulcus owing to its considerable weight, further compromising retention, esthetic appearance, and function. So, a hollow ocular prosthesis would be lighter and yet large enough to occupy the evident residual ocular space.

MATERIALS AND METHODS

Study design:

Ten patients were selected with unilateral eye defect from out-patient clinic of Ophthalmology Department Minia University Hospital. Diagnostic sheet was filled for each patient to include personal data, past medical history, past surgical history, and chief complain. Then the steps of ocular prosthesis were carried out at the department of Prosthodontics,

Minia university. Two prostheses (solid and hollowed) were fabricated for each patient.

Construction of the solid ocular prosthesis:

Primary impression was taken with irreversible hydrocolloidⁱ injected into the defect (anophthalmic) socket. The impression was poured in dental stoneⁱⁱ to obtain primary cast for studying the case and fabrication ocular special tray. Double layers of modeling waxⁱⁱⁱ were adapted to the cast and a mixing tip of rubber base impression material was fixed to the outer surface to form an impression channel. The waxed tray was flaked to fabricate custom special tray from heat cure acrylic resin^{iv} according to manufacturer instructions.

After deflasking, finishing, and polishing; disinfection of custom ocular tray was done. Injection of light polyvinyl siloxane impression material^v was done through the hollowed handle of the special tray to obtain final impression. The impression was poured in dental stone to obtain master cast and wax was sculptured to resemble future prosthesis.

The wax try-in was inserted in the socket and modified to reach proper contour guided by the contralateral eye. The wax try-in was flaked, eliminated by heat and the resultant mold was packed with scleral acrylic resin. The packed flask was cured, then the prosthesis was retrieved, finished and polished similar to any prosthetic appliance. The obtained prosthesis was painted^{vi} followed by application of a layer of clear acrylic resin^{vii}. Then the prosthesis was delivered to the patient who was given the proper instruction (fig.1a).

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- i. Zhermack s.p.a via bovazecchino ,10045021 badia polesine (rovgo) Italy
 - ii. Ata Alci San.ve Tic.as.paris cad. No:9/206540 kavaklidere Ankara
 - iii. Bilkim chemical company Izmir / Turkey
 - iv. Acrostone acrylic resin, Egypt
 - v. Hugel borkstrass 10.48136 Muenster, Germany
 - vi. Amestrdam acrylic colors p.o box4,apeldorn'NL
 - vii. Polymer type 12,IP white 012 E 3007. Esschem Co, Essington, PA



Fig. (1) Illustrates same patient have solid prosthesis. (1a) (left figure) and hollowed prosthesis (1b) (right figure)

Construction of the hollow ocular prostheses:

All the steps involved in the fabrication of solid ocular prosthesis were repeated till the final wax try-in step. Wax try-in was flaked, then the flask was opened after wax elimination. For each flask compartment, separating medium was painted to the stone surface and a layer of wax was added to build either the outer or the inner surface of the prosthesis. Each half of the flask was mounted to another flask part. In this way, two flasks were obtained, one with outer polished part of the prosthesis containing the iris button in proper position; and the other flask contained the inner finished part of the prosthesis. The two flasks obtained were completely invested in stone followed by wax elimination, packing and curing. In this way the prosthesis was created in two separate parts that can be reassembled guided by the original flask parts.

Heat acrylic resin^{vii} was added to the periphery of the polished (anterior) and fitting (posterior) surfaces. Then the two compartments of flask were reattached to form hollowed ocular prostheses. Curing, finishing, and polishing were done as conventional manner. The hollowed prosthesis was delivered to the patient who was given hygiene instructions (fig.1b).

Each patient received -in a blind random way- one of the ocular prostheses to use for two weeks after that motility was measured. The prosthesis was retrieved from the patient who was instructed for a wash period of 14 days before the insertion of the new one. After that, the patient received the

other type of prosthesis for another two weeks then motility was measured.

During motility analysis, the patient -wearing the appliance- was asked to look in primary gaze at a fixed object and the center point of the prosthesis was marked by a felt-tip pen. The patient was then instructed to look in four extreme gaze positions (superior, inferior, medial, and lateral), and the excursion of the mark was measured using a standard millimetric ruler. Motility evaluation was in horizontal and vertical gaze using Custer's method⁽⁴⁾. Three examiners evaluated this motility separately in a blind protocol, where no one of them was informed about the prosthesis type.

RESULTS

Three evaluators measured the motility of two types of ocular prostheses in horizontal and vertical gaze using Custer's method. Table (1) shows the median motility for the two prostheses in horizontal and vertical gaze for 3 evaluators.

The median motility in horizontal movement for the three evaluators was 3 mml for solid and hollowed prostheses. The median motility in vertical movement for the three evaluators was 5 mml for solid and hollowed prostheses.

As the data is nonparametric type; Mann-Whitney test was used for quantitative comparison between the two groups and p-value was considered significant if equal to or less than 0.05. The results showed no significant differences between the groups either in horizontal or vertical movement (table 1, figs 2 and 3).

TABLE (I) Comparison of motility between three evaluators in horizontal and vertical direction for solid (type A) and hollowed (type B) ocular prosthesis.

		Type A No. = 10	Type B No. = 10	p value
Horizontal motility				
Evaluator 1	Median	3.0	3.0	0.784
	(IQR)	(2.0 - 3.6)	(2.0 - 3.3)	
Evaluator 2	Median	3.0	3.0	0.817
	(IQR)	(2.0 - 3.6)	(2.4 - 3.6)	
Evaluator 3	Median	3.0	3.0	0.784
	(IQR)	(2.0 - 3.3)	(2.0 - 3.6)	
Vertical motility				
Evaluator 1	Median	5.0	5.0	0.728
	(IQR)	(4.5 - 6.1)	(4.0 - 6.0)	
Evaluator 2	Median	5.0	5.0	0.815
	(IQR)	(4.5 - 6.0)	(4.8 - 6.0)	
Evaluator 3	Median	5.0	5.0	0.784
	(IQR)	(4.0 - 6.0)	(4.8 - 6.0)	

Mann-Whitney test for non-parametric quantitative data between the two groups.

*: significant level at $p \text{ value} \leq 0.05$

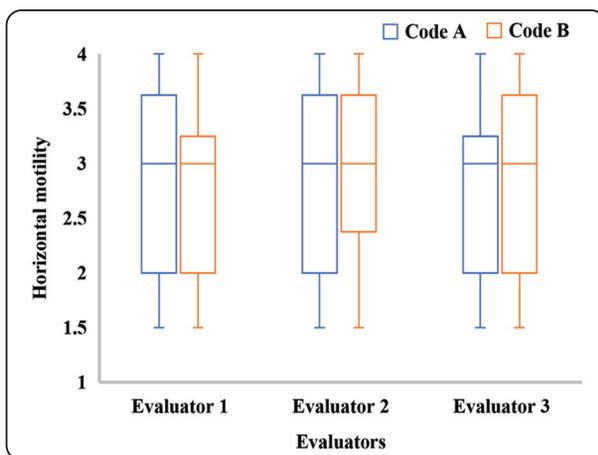


Fig. (2) Boxplot of horizontal motility for type A&B by the three evaluators.

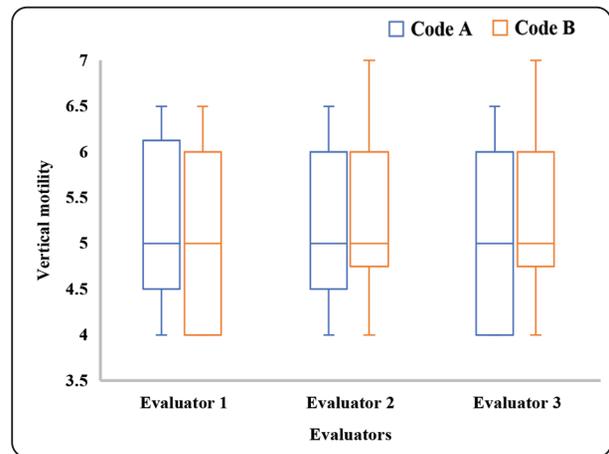


Fig. (3) Boxplot of vertical motility for type A&B by the three evaluators.

DISCUSSION

The aim of this study was to evaluate hollow ocular prosthesis compared to solid one. The evaluation for motility in horizontal and vertical gaze was done for two types of ocular prostheses. Ocular prostheses are designed to fit discreetly in the eye socket, so they should be as lightweight and comfortable as possible for the patient and can be well-tolerated by patients who have little or no orbital tissue support. They can also accommodate more natural movement and blinking of the eyelid, making them appear more realistic ⁽⁷⁾

Hollowing of the ocular prosthesis creates a lightweight artificial eye that reduces the pressure on the eye socket and enhances comfort. The process also allows for the creation of a natural eyelid movement and the ability to wear cosmetic contact lenses. Since they are hollow, they allow for more air circulation to prevent irritation or discomfort. ⁽⁵⁾

Some of author's like **khamis** have found that the lighter ocular prosthesis has more motility than heavier one but for a conclusive statement evaluation of motility of different prostheses should be carried out for the same anophthalmic socket. So, the current study was conducted in this manner.

The minimum sample size was calculated to be 8 sockets to get valid results so ten patients were selected to overcome any lost patients during the study and or follow up period.⁽⁶⁾

The authors in this study selected patients who received orbital implant. it improve motility of prosthesis as reported in most of researches as **smith et al., 1990** who measured the motility of ocular prostheses in patients with primary base-ball implant after enucleation, secondary base-ball implant and patients without implant. Smith concluded that motility of ocular prosthesis improved markedly in orbital implant .⁽⁷⁾

In this study patient with evasciration not enucleation were selected. The evasciration improve motility rather than enucleation .According to **yong-yi et al., 2009** who make Comparison of orbital prosthesis motility following enucleation or evisceration with sclerotomy with or without a motility coupling post in dogs .And they found that When dogs underwent evisceration with sclerotomy, the motility of the implant was significantly increased compared to enucleation.⁽⁸⁾

Although motility coupling post (MCP) improve ocular prosthesis motility according to most of authors, Authors in this study excluded patients with MCP . Because it transmit the highest amount of movement from orbital implant to prosthesis so any prosthesis would move the same movement .**Guillinta et al., 2003** measured and compared prosthetic motility in pegged versus unpegged orbital implants. They founded that prosthetic motility increase in horizontal gaze after motility peg placement..⁽⁹⁾

When Patients delivered the prostheses, they were blinded to prostheses as they didn't know any information about type of prosthesis to decrease the bias for judgment on prosthesis for the patient . Also all evaluators didn't know any information about type of prosthesis during their evaluations.

One of limitations of this blindness in the study was the weight of the prostheses . Patient could feel the light weight of hollow and could guess that the hollow is lighter than the other one. This limitation couldn't be overcome

The time of evaluation of motility was two weeks after delivery of prosthesis as ten days were enough to muscles' adaptation to the prosthesis .Also the wash out period was two weeks , which is a good time for muscles to return to its normal coordination.

Acustom special tray was fabricated for each patient from only heat cure acrylic resin due to excess residual monmer of self cure which cause irritation to conjunctiva and discomfort to patient.

Aggarwal H. et al.,2014 suggested a new technique for fabricating a pneumatic custom ocular prosthesis for large ophthalmic cavities by using lost wax technique, aiming to reduce the weight of the prosthesis and thus improving mobility, comfort and aesthetics apart from preventing lower lid distortion and/or asymmetrical alignment of the entire palpebral fissure . In this technique they immersed the prosthesis in the steam cleaner to remove the wax. There is some difficulty to insure complete wax removal and no evidence for complete wax removal .also they used self cure acrylic resin to seal the holes which have excess residual monomer with its harmful effect on conjunctiva.⁽¹⁰⁾

Jyotsna Vimal et al .,2020 used lost Salt technique, in order to reduce the weight of the prosthesis for fabricating a pneumatic custom ocular prosthesis for large ophthalmic cavities but this technique need very large eye defect to create space for salt sac .

In the current study, a novel technique in hollowing of ocular prosthesis was used which was easy, simple, applicable and better than other methods as heat cured acrylic resin was used to decline the effect of the residual monomer that may cause irritation to conjunctiva leads to patient discomfort⁽¹¹⁾.

Patients wear prostheses two weeks after that three evaluators use **custar** method to measure the motility it was simply to put small mark in the center of prosthesis. The patient was then asked to look in extreme gaze positions, while the horizontal and vertical excursions of the marked prosthesis were measured with a standard millimeter ruler. **Mouritis et al., 2016** described new method to measure artificial eye motility using I view x system. It consists of 2 computers and 3 monitors connected to each other through a direct network connection. The system, with adjusted software, was tested with patients wearing one prosthetic eye. The system was accurate and noninvasive but the **custar** method is less cost and easy to be applicable. ^(12,13)

All data for every patient was coded and collected from the patients and evaluators by candidate and were put in sealed envelopes. After finished collecting data, the data was sent to biostatistical analysis.

The current study founded that there was non-significant difference between hollow and solid ocular prostheses in motility. This can be explained by that the two prostheses were custom prosthesis and highly fitted to conjunctiva. So any movement transmitted from orbital implant to ocular prosthesis. The hollow prosthesis was easy in movement but the same in range of movement as solid prosthesis.

The current study doesn't support **Khamis et al., 2008** who founded the more weight of prosthesis the less motility. **Khamis** compare motility of custom prosthesis in different patients so the different sockets are considered another factor that affect the motility. We compared motility in the same socket with two prostheses.

Khamis compared between custom ocular prosthesis and ready made ocular prosthesis. His results can be explained by that the motility of prosthesis affected by close contact between prosthesis and conjunctiva. As in ready made prosthesis there is already space between conjunctiva and prosthesis but custom made is good fitted to conjunctiva.

So custom made prosthesis have greater motility than ready made prosthesis, which explained the result in our study where both prostheses were custom made and the difference only in its weight. ⁽⁶⁾

Current study matched the finding with **Lucci et al., 2007** who reported that the efficiency of transmitting movement from the implant to prosthesis determine the degree of prosthetic motility. ⁽¹²⁾

CONCLUSION

Under the limitations of the current study, it may be concluded that the method of prosthesis construction either hollowed or solid does not affect its mobility. Solid and hollowed ocular prostheses have essentially the same range of motility. Thus, reducing their weight may not have a benefit for their motility.

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