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ORIGINAL ARTICLE

Customized Liquid Ocular Prosthesis for Anophthalmic Patients suffering from Dry Eye: A Clinical Research

[1]Rubina Gupta, [2]Richa Aggarwal, [3]Arjun Bharat, [4]Sushil Nijhawan

ABSTRACT

Problem: Prosthetic eyes often cause dryness, irritation, and inflammation of the anophthalmic sockets.

Purpose: To reduce the discomfort caused due to dryness of ocular prosthesis by a custom-made hollow ocular acrylic prosthesis, which is filled with lubricant drops slowly and systemically released into the ophthalmic cavity upon blinking.

Materials and methods: Thirty-eight patients wearing unilateral artificial eye for a period of more than 6 months were evaluated. An innovative customized hollow prosthesis is described, which was incorporated with a hollow reservoir containing a combination of a tear substitute along with cyclosporine A (0.05%) acting as the lubricant. The patients were then evaluated with the help of a questionnaire, regarding the comfort, dryness, soreness, and the ease of use of prosthesis. A self-formulated grading system was used to record the scores.

Results: Postinsertion of this hollow prosthesis, there was a marked reduction in the dryness, irritation, discomfort, and signs of inflammation.

Conclusion: It was concluded that the continuous flow of the lubricant onto the dry prosthetic eye helps in reducing dryness, irritation, soreness, and inflammation.

Clinical implications: A hollow ocular prosthesis that can continuously discharge lubricant onto the dry prosthesis can help in increasing patient's acceptance and comfort.

Keywords: Hollow ocular prosthesis, Lubricating prosthesis, Maxillofacial prosthesis, Prosthesis for dry eyes.

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INTRODUCTION

"It is the God given right of every human being to appear human."

Since the 16th century prosthetic reconstruction is employed to restore anatomy, function, and esthetics of acquired surgical defects (Chalian et al).[2]

[1]Associate Professor, [2,3]Assistant Professor, [4]Professor and Head

[1-4]Department of Dental Surgery, Muzaffarnagar Medical College and Hospital, Muzaffarnagar, Uttar Pradesh, India

Corresponding Author: Rubina Gupta, Associate Professor Department of Dental Surgery, Muzaffarnagar Medical College and Hospital, Muzaffarnagar, Uttar Pradesh, India, Phone: +9101396252702, e-mail: dr.guptarubina@gmail.com

Among various paraoral structures, eye is the most important organ. Most patients experience significant stress, primarily due to adjusting to the functional disability caused by the eye loss, and due to societal reactions to the facial impairment.[1,2] Thus, ocular prosthesis should be provided as soon as possible for the psychological well-being of the patient.[3]

An ocular prosthesis can be either ready-made (stock) or custom-made. Stock prosthesis comes in standard sizes, shapes, and colors. They can be used for interim or postoperative purposes.[4-7]

Custom eyes have several advantages over stock prosthesis, including better eyelid movements; even distribution of pressure due to equal movement thereby reduces the incidence of ulceration, improved fit, comfort, and adaptation to improved facial contours; and enhanced esthetics gained from the control over the size of the iris, pupil, and color of the iris and sclera.[8-10]

Patients wearing prosthetic eyes often complain of dryness, irritation, discomfort, and discharge.[11] This makes wearing prosthetic eye very uncomfortable. An innovative method of fabricating custom-made hollow prosthesis is described and studied so as to check its acceptance and comfort level.

MATERIALS AND METHODS

Thirty-eight patients who had undergone anophthalmic surgery in 1 eye and had been wearing artificial eyes for a period of more than 6 months were included. Subjects with contracted sockets, or other known lid disorders, were excluded.

Subjects reported with the chief complaint of dry eyes, irritation, and discomfort. Custom-made acrylic ocular prosthesis was fabricated for the subjects. The prosthesis was incorporated with a hollow reservoir, which contains tear substitute, takes up minimal space, and slowly releases the lubricant onto the dry ophthalmic prosthesis.

The procedure for prosthesis fabrication is as under:

- A tray of self-cure acrylic resin was made in the shape of the eye socket. It was checked for the fit and trimmed if required. The front end of the needle cap was cut and fixed at the center of the acrylic tray (Fig. 1). The irreversible hydrocolloid impression material was mixed with excess water until it is very free flowing, as suggested by Barlett and Moore.[12] The material was

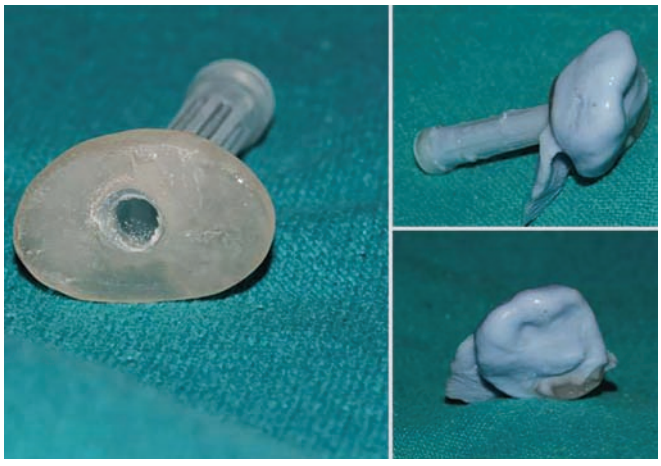

Fig. 1: Customized acrylic tray for impression making and irreversible hydrocolloid impression of the anophthalmic socket

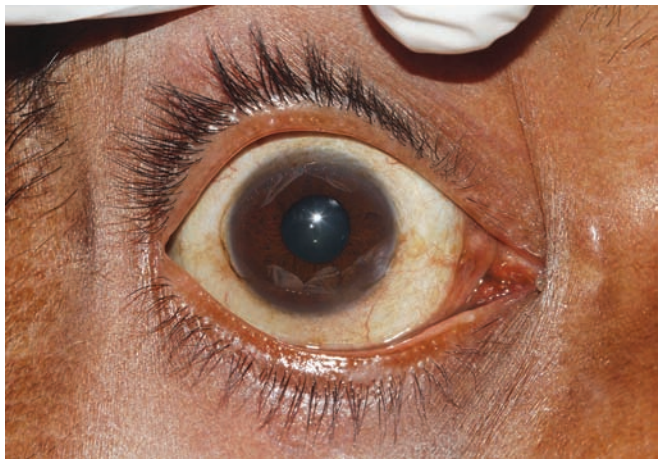

Fig. 2: Digital view of the patient's iris made

then injected into the socket with the help of the cap. Once filled, the head was moved back to the vertical position and the patient was directed to move his eyes up and down. This will facilitate the flow of the impression material to all aspects of the socket. Patient was asked to look at a distant spot at eye level with his gaze maintained in a forward direction. After the material was set, cheek, nose, and eyebrow regions were massaged to break the seal. Impression was removed and checked for accuracy. Excess material was trimmed.[13]

- The color for the sclera portion was selected using the tooth-color acrylic shade guide.[14]
- A digital photograph of the patient's iris was made using a digital camera (SLR camera, Canon 60D). The shutter speed was set at 1/5 seconds with an aperture of F32, and the film sensitivity was set at International Organization for Standardization 200 sensitivity mode with 1:1 lens magnification. In order to calibrate the red, green, and blue (RGB) values of the images, the white balance was set to customized "preset mode" by following the manufacturer's instructions using a standard grey card. Using graphics software (Adobe Photoshop, version 8.0; Adobe Systems Inc., San Jose, California, USA), the image was adjusted for slight differences in color, brightness, contrast, or hue, and formatted (Fig. 2).
- Final image was printed on 130 gsm white paper with differing brightness, contrast, and intensity using a laser printer with a color-ink print cartridge. The paper iris was covered with cyanoacrylate to make it water resistant.[9]
- The impression was poured in dental stone. Four pyramid shaped keys were then made on the base of set cast and a plaster index was pored. The stone cast was then cut into two using the die preparation saw, facilitating the removal of the wax pattern from the cast.

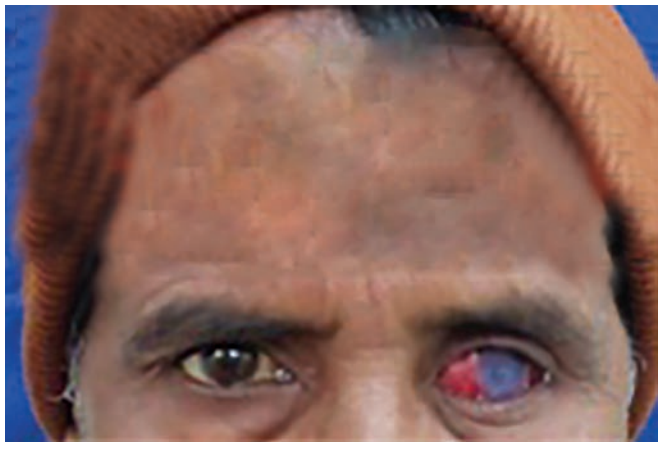

Fig. 3: Base plate wax trial with attached paper iris

- Base plate wax was then molded in the shape of the eye and tried in the patient's socket (Fig. 3). The wax pattern was modified in order to achieve patient comfort, appropriate anterior/posterior dimension, palpebral fissure curvature, and iris center position. It was also examined for the size, contour, esthetics, support from tissue, simulation of the eye movement, and eyelid coverage. The iris plane and pupil point were evaluated by drawing guide lines on the patient's face. This was confirmed with the contralateral normal eye. Care was taken to see that the eyelid closed over the scleral blank is normally like the contralateral normal eye. The paper iris is attached to the wax pattern.
- After the try-in is complete, a two-part mold is constructed using dental gypsum within a stainless steel or brass flask. The anterior portion of the mold is invested, and a separating medium is applied. Four and five small pieces of 26 gauze wire were placed around the iris peg in the wax pattern. The posterior portion of the mold is then invested and dewaxing is carried out (Fig. 4).
- The flask is then opened. The wire pieces are attached to the posterior portion of the mold (Fig. 5). While

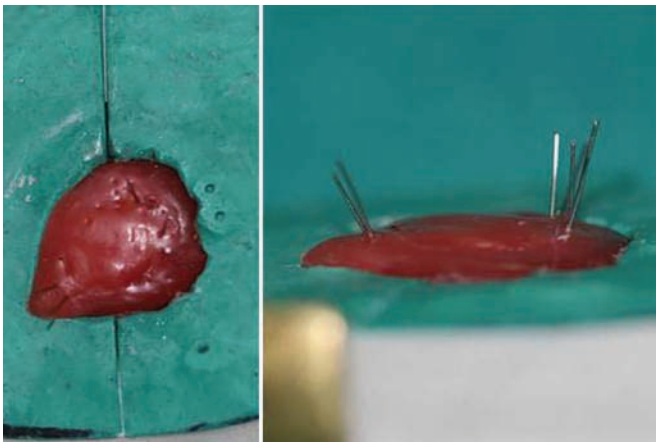

Fig. 4: During flasking 4 to 5 small pieces of 26 gauze wire placed around the iris peg in the wax pattern

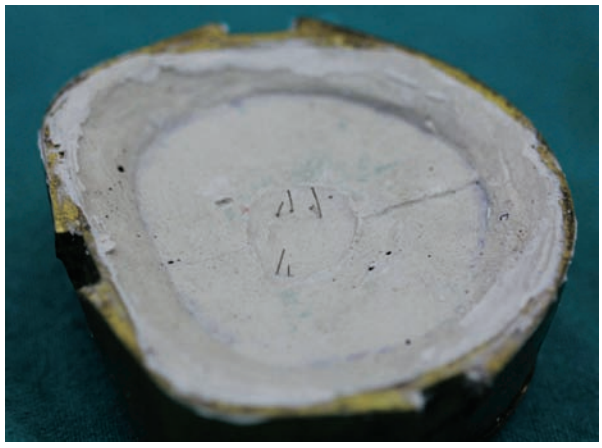

Fig. 5: The wire pieces attached to the posterior portion of the mold after dewaxing

Fig. 6: Packing of the heat cure PMMA with salt crystals between two layers

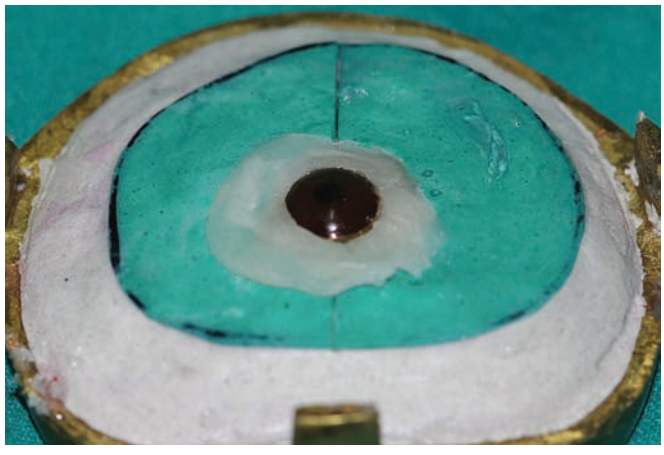

Fig. 7: Ocular prosthesis after polymerization

preparing the white posterior section of the prosthesis, the above-mentioned two-part mold is cleaned and examined, and a liquid separator is applied to each gypsum section. These wire pieces helped in making minute holes on the anterior surface of the prosthesis so as to facilitate the drainage of lubricant onto the anterior surface of prosthesis.

- Half of the heat cure polymethyl methacrylate (PMMA) (Trevalon, Dentsply India Pvt Ltd) in dough stage was positioned accurately over dewaxed mold and then salt crystals were placed over it (Fig. 6). The remaining heat cure was placed over it and packed. The mold is placed in a mechanical or hydraulic press and excess PMMA is squeezed out; the mold is then placed in a curing device and heat is applied until polymerization is complete (Fig. 7).
- After curing, the prosthesis is removed from the mold. A small hole was drilled in the posterior section of the prosthesis. The salt is flushed out by injecting water under high pressure. A wax impression of the hole is made and invested in cold cure PMMA to form a removable cap over the hole (Fig. 8).

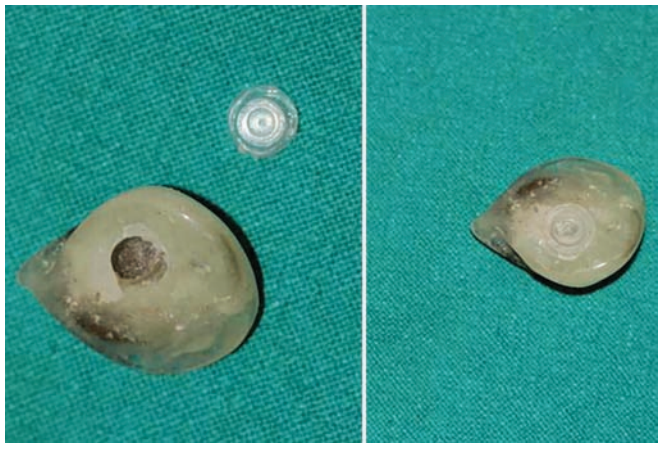

Fig. 8: A small hole drilled in the posterior section of the prosthesis with removable cap

- The prosthesis is then smoothed with a paste of pumice flour and water. Progressively, finer abrasives are used until all surfaces are smooth and show no scratches[15] (Figs 9 and 10).
- Prior to insertion of the finished prosthesis, it was disinfected using 70% isopropyl alcohol and 0.5% chlorhexidine solution. After thoroughly cleaning the

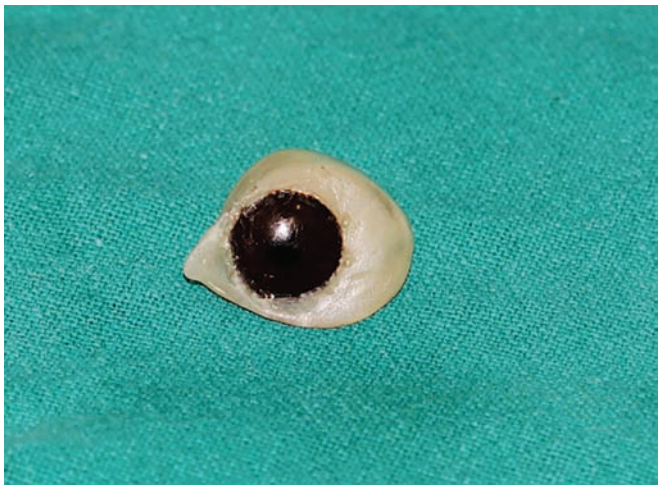

Fig. 9: Final prosthesis after finishing and polishing

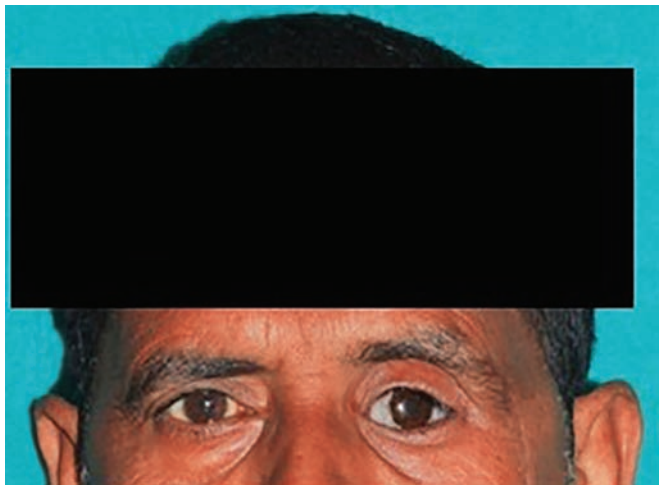

Fig. 10: Final prosthesis post-insertion

prosthesis with saline solution to prevent chemical irritation, it was inserted and checked for fit, contour, and movements.[16]

- Periodic recall appointments were scheduled at 1, 3 weeks, and 3 months after the insertion of the prosthesis.
- Patient was advised to clean the internal surface of the reservoir by forcefully injecting the water through the openings every day and once in 15 days with 7% sodium hypochlorite solution to prevent any growth of microorganisms.[17]

The patient was asked to fill a questionnaire twice: One on the 1st appointment to evaluate already worn prosthesis and the second on the scheduled appointment 3 months after the delivery of custom-made hollow prosthesis.

The questionnaire consisted of questions regarding the type of prosthesis worn (stock or custom-made), dryness, whether using any lubricants, frequency of lubricant use, irritation, discomfort, and for any soreness and pain. Patients were asked to assign the severity of their symptoms on a scale of 1 to 5; 1 being the least and 5 being the maximum.

The signs of inflammation were also checked and graded using the same scale.

The statistical analysis was done by using "chi-sqaure" statistic and a 5% level of significance had been used ($p < 0{\cdot}05$ is taken as statistically significant).

RESULTS

Out of 38 subjects included in the study, 25 were wearing stock prosthesis while 13 were custom-made ocular prosthetic wearers for a period of minimum of 6 months. The chief complaints included dryness, irritation, discomfort, soreness, pain, and inflammation.

In this questionnaire-based investigation, it was found that about 25 patients were using lubricant drops 4 to 5 times daily, but were not satisfied. The average scale of dryness was 4.29 for nonlubricant users, while it was approximately 3.75 for lubricant users. Artificial tear drops were the most commonly used lubricants. Postinsertion of hollow prosthesis, this dryness scale reduced to an average of 0.55. Three patients complained of excessive flow postinsertion.

Irritation scale was directly proportional to dryness scale. An average of 4.34 was found with the 1st prosthesis. Patient also complained of increased irritation toward the end of the day. Begley et al[18] have found similar results in contact lens wearers.[19] As with dryness, the irritation scale also reduced to an average of 1.18 postinsertion of hollow prosthesis.

The feeling of discomfort was more common among stock eye wearers than the custom-made prosthetic wearers. Same were the results of soreness and pain. This may be due to poor fit and improper pressure distribution of stock prosthesis. The average scale of discomfort was about 3.61 (4.32 in stock eye and 2.90 in custom eye), while it was average 3.14 (3.84 in stock eye and 2.45 in custom eye) for soreness and pain. This may be due to constant fiction (due to mechanical rubbing) between the sensitive ocular tissues and the prosthetic eye. Both the discomfort and soreness scales reduced to about 0.81 in custom-made hollow prosthesis.

Similarly the signs of inflammation (redness and discharge) of the tissues also reduced from average of 3.60 (3.71 in stock eye and 3.50 in custom eye) to about 1.52. The inflammation symptoms reduced further to 1.21 when cyclosporine A 0.05% was also used along with the artificial tear substitutes.

DISCUSSION

An anophthalmic socket has a different anatomical and physiological environment, as compared with a normal eye. Allen et al[20] reported that prosthetic eye wearers did

not produce as much tear fluid as people with normal eyes do. Sung et al also found that mean tear meniscus depth, tear meniscus area, and tear meniscus volume also were significantly lower in artificial eyes than in normal eyes.[21]

It was suggested that the mechanism of reduced tear production involved the absence of a corneal reflex. Reflex tears supply most of the aqueous components of tears, which is important in the self-cleansing mechanism of the normal eye.[22] Decreased aqueous production on the dry surface of the ocular prosthesis inhibits self-cleansing mechanism in the anophthalmic socket, leading to mucoid discharge.

Kim et al[23] reported that decreased goblet cell density and an increased nucleus-to-cytoplasm ratio resulted in decreased mucus production in anophthalmic patients wearing an ocular prosthesis. They attributed these cytological changes to the constant irritation of prolonged prosthesis wear.

In practice, many prosthetic eye patients with ocular discomfort are prescribed artificial lubricants to relieve from their ocular symptoms. Artificial tears provide palliative relief to eye irritation in patients with aqueous tear deficiency, but do not prevent the underlying inflammation or reverse conjunctival squamous metaplasia.[24] Cyclosporine A 0.05% is a topical immunomodulatory compound with antiinflammatory properties that has been demonstrated to have certain benefits in the treatment of dry eye symptoms.[25-28]

In the present study, an innovative technique is described for fabrication of a hollow custom-made ocular prosthesis. "The lost salt technique" was used for fabricating hollow prosthesis.[29] The hollow prosthesis was light in weight even after filled with lubricant. This increased patient comfort and ease of wearing.

The delivery of lubricant into the oral cavity from a hollow prosthesis has been a recognized method for more than two decades.[30-34] The reservoir in the ocular prosthesis is used to store liquid artificial lubricants and cyclosporine A 0.05%. The liquid is discharged on the anterior surface of the prosthesis by minute holes. During the blinking of the eyelids, this liquid spreads on the complete surface by capillary action. The liquid helped in keeping the eyes wet, thus reducing the dryness, irritation, and discomfort. The equal distribution of pressure and continuous lubrication helped in reducing the soreness and pain in the eye. Lastly, use of cyclosporine A 0.05% and lubricating eye drops helped in reduction of socket inflammation by reducing mechanical rubbing of the prosthesis and ophthalmic tissue and medicinal action.

Accurate iris reproduction in the fabrication of ocular prosthesis in order to match the remaining eye is a key factor to mask the loss and achieve an esthetic outcome for anophthalmic patients. The iris is reproduced with the help of digital imaging. Thus complete resemblance to the adjacent eye is achieved.[35] The color for the sclera portion was selected using the tooth-color acrylic shade guide.[14] Thus high esthetics was achieved leading to good patient acceptance.

Ocular prosthesis installation may allow the adherence of fungi and/or bacteria due to the superficial characteristics of the prosthesis material, or because the void located between the internal portion of the prosthesis and the anophthalmic cavity mucosa. Hence the patient was asked to clean the prosthesis regularly and visit the doctor every 6 months.

CONCLUSION

The eye is a vital organ not only in terms of vision but also being an important component of facial expression. Loss of eye has a crippling effect on the psychology of the patient. The use of custom-made ocular prosthesis has been a boon to the average patient who cannot afford the expensive treatment options available. The esthetic and functional outcome of the prosthesis is superior to the stock ocular prosthesis. A technique of fabricating a custom-made hollow ocular acrylic prosthesis is presented here, which had acceptable fit, retention, and esthetics. The reservoir in the prosthesis is filled with lubricant drops that helped in reducing dryness, irritation, discomfort, soreness, and inflammation, thereby increasing patient's acceptance and comfort.

The fabrication of extraoral prosthesis is as much an art as it is science. Prosthesis form, coloration, and texture must be as indiscernible as possible from the surrounding natural tissues. Rehabilitation efforts can be successful when patients appear in public without fear of attracting unwanted attention.

REFERENCES

1. Lubkin V, Sloan S. Enucleation and psychic trauma. Adv Ophthalmic Plast Reconstr Surg 1990;8:259-262.
2. Barnett MO, Chalian VA. Psychological and economic aspects of maxillofacial patients. Baltimore (MD): The Williams & Wilkins Co; 1972.
3. Taylor TD. Clinical maxillofacial prosthetics. Chicago, London: Quintessence Publishing; 2000. p. 233-276.
4. Goel BS, Kumar D. Evaluation of ocular prosthesis. J All India Ophthalmol Soc 1969 Dec;17(6):266-269.
5. El-Dakkak M. Problem solving technique in ocular prosthetic reconstruction. Saudi Dent J 1990;2(1):7-10.
6. Kale E, Meşe A, Izgi AD. A technique for fabrication of an interim ocular prosthesis. J Prosthodont 2008 Dec;17(8): 654-661.
7. Smith RM. Relining an ocular prosthesis: a case report. J Prosthodont 1995 Sep;4(3):160-163.
8. Beumer J, Zlotolow I. Restoration of facial defects. In: Beumer J, editor. Maxillofacial rehabilitation: prosthodontic and surgical considerations. St. Louis (MO): Mosby; 1996. p. 350-364.

9. Artopoulou II, Montgomery PC, Wesley PJ, Lemon JC. Digital imaging in the fabrication of ocular prostheses. J Prosthet Dent 2006 Apr;95(4):327-330.
10. Ow RK, Amrith S. Ocular prosthetics: use of a tissue conditioner material to modify a stock ocular prosthesis. J Prosthet Dent 1997 Aug;78(2):218-222.
11. Pine K, Sloan B, Stewart J, Jacobs RJ. Concerns of anophthalmic patients wearing artificial eyes. Clin Exp Ophthalmol 2011 Jan;39(1):47-52.
12. Barlett SO, Moore DJ. Ocular prosthesis: a physiologic system. J Prosthet Dent 1973 Apr;29(4):450-459.
13. Adarsh N, Pradeep, Suresh BS, Yogesh RB, Rachana KB. Ocular prosthesis made easy a case report. Int J Dent Clin 2011 Jan-Mar:3(1):105-106.
14. McArthur DR. Aids for positioning prosthetic eyes in orbital prosthesis. J Prosthet Dent 1977 Mar;37(3):192-193.
15. Shah FK, Aeran H. Prosthetic management of ocular defect: esthetics for social acceptance. J Indian Prosthodont Soc 2008 Apr;8(2):66-70.
16. Gunaseelaraj R, Karthikeyan S, Kumar MN, Balamurugan T, Jagadeeshwaran AR. Custom-made ocular prosthesis. J Pharm Bioallied Sci 2012 Aug;4(Suppl 2):S177-S179.
17. Arora V, Kumar D, Legha VS, Kumar KV. Management of xerostomia patient with salivary reservoir designed in upper complete denture and lower cast partial denture. J Contemp Dent 2014;4(1):56-59.
18. Begley CG, Caffery B, Nichols KK, Chalmers R. Responses of contact lens wearers to a dry eye survey. Optom Vis Sci 2000 Jan;77(1):40-46.
19. Brennan NA, Efron N. Symptomatology of HEMA contact lens wear. Optom Vis Sci 1989 Dec;66(12):834-838.
20. Allen L, Kolder HE, Bulgarelli EM, Bulgarelli DM. Artificial eyes and tear measurements. Ophthalmology 1980 Feb;87(2):155-157.
21. Kim SE, Yoon JS, Lee SY. Tear measurement in prosthetic eye users with Fourier-domain optical coherence tomography. Am J Ophthalmol 2010 Apr;149(4):602-607.
22. Adams AD. The morphology of human conjunctival mucus. Arch Ophthalmol 1979 Apr;97(4):730-734.
23. Kim JH, Lee MJ, Choung HK, Kim NJ, Hwang SW, Sung MS. Conjunctival cytologic features in anophthalmic patients wearing an ocular prosthesis. Ophthal Plast Reconstr Surg 2008 Jul-Aug;24(4):290-295.
24. Lin H, Yiu SC. Dry eye disease: a review of diagnostic approaches and treatments. Saudi J Ophthalmol 2014 Jul;28(3): 173-181.
25. Byun YS, Rho CR, Cho K, Choi JA, Na KS, Joo CK. Cyclosporine 0.05% ophthalmic emulsion for dry eye in Korea: a prospective, multicenter, open-label, surveillance study. Korean J Ophthalmol 2011 Dec;25(6):369-374.
26. Wilson SE, Perry HD. Long-term resolution of chronic dry eye symptoms and signs after topical cyclosporine treatment. Ophthalmology 2007 Jan;114(1):76-79.
27. Kunert KS, Tisdale AS, Gipson IK. Goblet cell numbers and epithelial proliferation in the conjunctiva of patients with dry eye syndrome treated with cyclosporine. Arch Ophthalmol 2002 Mar;120(3):330-337.
28. Han JW, Yoon JS, Jang SY. Short-term effects of topical cyclosporine A 0.05% (Restasis) in long-standing prosthetic eye wearers: a pilot study. Eye 2014 Oct;28(10):1212-1217.
29. Aggarwal H, Jurel SK, Singh RD, Chand P, Kumar P. Lost salt technique for severely resorbed alveolar ridges: an innovative approach. Contemp Clin Dent 2012 Jul;3(3):352-355.
30. Vergo CT, Kadish SP. Dentures are artificial saliva reservoirs in the irradiated edentulous patient with xerostomia: a pilot study. Oral Surg Oral Med Oral Pathol 1981 Mar;51(3):229-233.
31. Vissink A, Gravenmade EJ, Panders AK, Olthef A, Huisman MC, Visch LL. Artificial saliva reservoirs. J Prosthet Dent 1984;52: 710-715.
32. Toljanic JA, Schweiger IW. Fabrication of an artificial reservoir denture system for xerostomia management. Quint Dent Tech 1985 Jun;9(6):355-358.
33. Pankhurst CL, Dunne SM, Rogers JO. Restorative dentistry in the patient with dry mouth. Part 2. Problems and solutions. Dent Update 1996 Apr;23(3):110-114.
34. Frost PM, Shirlaw PJ, Walter JD, Challacombe SJ. Patient preferences in a preliminary study comparing an intra-oral lubricating device with the usual dry mouth lubricating methods. Br Dent J 2002 Oct 12;193(7):403-408.
35. Jayaswal GP, Dange SP, Khalikar AN. Restoration of an atrophic eye socket with custom made eye prosthesis, utilizing digital photography. Indian J Dent Res 2011 May-Jun;22(3): 482-485.