Total or subtotal replacement of tarsal plate by novel silicone plate for upper eyelid reconstruction in malignant tumors

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Purpose: To evaluate the cost, safety, surgical outcome, and efficacy of modified Cutler–Beard eyelid reconstruction utilizing a novel silicone plate as a tarsal plate replacement in the repair of 60% to 100% eyelid defects following the excision of large malignant tumors. Methods: A prospective, noncomparative, interventional study of 30 eyes was done over 3 years. Fourteen patients were female, and 16 patients were male. In all the cases, a silicone plate, the synthetic, artificial tarsal plate, was utilized for a total or subtotal replacement of the tarsal plate. The created defect was measured in mm (length and width) and later expressed in percentage. Pre- and postoperative action of levator palpebrae superioris (LPS) was measured. Pre- and postoperative measurements of the margin-to-margin reflex distance (MRD1) were noted. Results: Preoperative LPS action was 1.23 ± 1.35 mm, whereas postoperative LPS actions at the end of 1 week and 18 months were 11.8 ± 0.88 mm and 13.53 ± 0.73 mm, respectively. Preoperative MRD1 was 3.0 ± 1.144 mm, whereas postoperative MRD1 values at the end of 1 week and 18 months were 2.18 ± 0.27 mm and 4.16 mm ± 0.35, respectively. The mean created defect after the removal of the tumor was 87.3% ±11.10. The mean length of the silicone plate implanted in this study was 27.53 ± 2.48 mm. The follow-up period for the study participants was 18 months. Conclusion: The synthetic novel silicone plate was successful as a tarsal plate replacement. A second surgical site for ear cartilage harvesting is avoided. Cadaver transfer of Achilles tendon carries the risk of transmission of communicable diseases, for example, hepatitis B and HIV. Silicone is an inert, nonreacting, and tissue-tested material, thus eliminating the possibility of graft rejection. This material is readily available and cost-effective. The novel silicone plate is considered to be the most promising alternative material as a tarsal replacement in the future generation.

Key words: Malignancy, reconstruction, silicone plate, tarsal plate

The eyelids are structures that protect the anterior surface of the eyeball. Additional functions of the eyelids include tear film maintenance over the cornea by blinking, tear outflow by the lacrimal pump, and regulation of light entering the eye. The eyelids have cosmetic value too, and thus, any tumor involving the eyelids must be dealt with utmost care and vigilance for an aesthetic outcome (Image -1a, 5a). Normally the eyelids close every 6 seconds by reflex action. Although small defects can be reconstructed using a direct closure, larger defects after removal of large malignant tumor require more extensive surgery. Often it is a life-saving as well as a vision-saving intervention that restores the normal anatomy. This helps the patient to achieve normal stability, mobility, and functionality of the eyelids. An oculoplastic surgeon faces a major challenge in restoring eyelid anatomy and function while maintaining satisfactory cosmetic outcomes.

Aims

The aims of the study were to determine the efficacy of the silicone plate as a tarsal replacement in modified Cutler–Beard procedure for the repair of 60% to 100% upper eyelid defects created after the removal of large malignant tumors, to evaluate the cost and safety of using a silicone plate as an alternative for tarsal plate replacement and lid reconstruction, and to appraise the recurrence of the disease along with the functional and cosmetic outcomes.

Methods

This is a prospective, noncomparative, interventional study conducted over 3 years. The total number of patients was 30, of which 14 were females and 16 were males. The Institutional Ethical Committee clearance was obtained with reference no. MC/Kol/Non-spon/638/11-2017. Informed written consent was taken from each patient recruited in the study in accordance with the Declaration of Helsinki. In this study, the inclusion

Special Focus, Ophthalmic Plastic Surgery, Original Article
criteria were all upper eyelid malignant tumors, upper eyelid defect of 60% to 100% created after the removal of the tumor, and patients having informed consent. The exclusion criteria were regional lymph node involvement; hepatic, pulmonary, or brain metastasis; concomitant lower eyelid tumor; gross corneal infiltration; and tumor infiltrating the orbit. Computed tomography (CT) scans and magnetic resonance imaging (MRI) were advised to determine the invasion of the tumor in the orbital cavity or to assess any scleral involvement. In all the cases, the silicone plate was obtained from a commercially available 279 scleral buckle. Moreover, the silicone plate is radio-opaque and is a safe material in MRI.

The specification of the novel silicone artificial tarsal plate and its clinical application are as follows [Fig. 1]: (1) Length: 30 mm, (2) shape: elliptical, (3) thickness: 0.75 mm (ultra-thin), (4) multiple boreholes through the plate, (5) central width: 6 mm, (6) angulation of curvature from the midplane: 30°, (7) material: silicone, (8) weight: 0.8 to 0.12 g, and (8) applied for usage as the promising material for a tarsal plate substitute.

Surgical procedure

In this study, all the surgeries were performed by a single, experienced surgeon with the same settings under general anesthesia. In the first stage of the Cutler–Beard procedure, the upper eyelid large malignant tumor was excised with the frozen section biopsy to confirm tumor-free margin all around. The incision line went beyond the 4 mm clear margin in cases of sebaceous gland, porocarcinoma, and squamous cell carcinoma [Fig. 3a], and the 3 mm clear zone in cases of basal cell carcinoma and amelanotic melanoma, for the safety of the patients to prevent a recurrence. Thus, tumors involving less than 60% of the upper eyelid ultimately involve more than 60% of the upper eyelid when a full-thickness rectangular defect is created after complete excision of the tumor. The then a full-thickness horizontal incision was made 4 to 6 mm below the lower lid margin, followed by two vertically oriented incisions and joined to make a rectangular flap [Fig. 3a]. Thus, the lower lid tarsal plate was preserved. The lower eyelid advancement flap was dragged below the hammock flap and aligned with the rectangular defect in the upper eyelid. The advancement flap was now split into anterior and posterior laminae [Fig. 3c and d]. The anterior lamina consists of the conjunctiva and capsulopalpebral fascia. The anterior lamina consists of orbicularis oculi muscle and skin. A similar separation of the remaining upper eyelid margin was performed into anterior and posterior laminae. The posterior lamina consists of the conjunctiva and the aponeurosis of levator palpebrae superioris (LPS) muscle and orbital septum. Normally, in upper lid gray-line splitting, the orbital septum is not included in the posterior lamina; it remains with the anterior lamina. But in this study, the orbital septum was deliberately included in the posterior lamina for two reasons. At first, when the tumor was excised with the full thickness of the upper lid, the gray line was totally lost, and during the splitting of the upper lid, we followed the tough glistening layer (the orbital septum), and it was easy to split from the overlying layers of the upper lid. Second, the newer implant was fixed over a tough fibrous layer of the lid to prevent extrusion or migration of the implant. The skin with orbicularis oculi forms the anterior lamina of the upper lid. The posterior lamina of the advancement flap and the upper lid are sutured with interrupted 5-0 polyglactin, thus making the posterior lamella. The majority of the rectangular upper lid–created defect was covered by a posterior lamella of the upper lid and the minority by a posterior lamina of the lower lid. The novel silicone plate was then positioned over the posterior lamella and fixed with 5-0 polyglactin sutures all around [Figs. 3c and 5c]. The anterior lamina of both the lids was then sutured together [Fig. 3d]. This bridge flap was maintained for the next 6 weeks [Fig. 3e]. In the second stage of the Cutler–Beard procedure, the lid spatula was used to lift the bridge flap to protect the cornea. Then, it was incised with the convexity.

Figure 1: Schematic diagram of novel silicone artificial tarsal plate
downward skin incision; it went tangentially more toward the conjunctival layer. The chief object was that the conjunctival layer was more in length than the skin so that the margin can be covered by a smooth conjunctival surface. Interrupted 6-0 double-armed polyglactin sutures were applied to reform the lid margin. Here, the knots were placed over the skin surface to prevent suture-related corneal complications. Thus, the newly made upper eyelid was created. The smoothness and regularity of the newly formed upper eyelid margin were essential for the maintenance of a healthy ocular surface and tear film also. The lids were then individually restored as usual. Prime importance was given to the re-creation of the lid margin [Fig. 3f].

Preparation of novel silicone plate from 279 retinal buckle
A 30-mm long rectangular piece was cut out from the 360° 279 scleral buckle [Fig. 4a and b]. The total width was 8.5 mm of which the central groove was 2.5 mm and both sides were 3 mm each (2.5 + 3 + 3 = 8.5) [Fig. 4c]. The elevated edges of the central groove of the buckle were made smooth and leveled with even curvature, sliced by the sharp blade under microscope [Fig. 4d]. The surface was scraped to make the thickness about 0.75 to 0.50 mm [Fig. 4e]. It was then fashioned into an elliptical shape with a central width of 6 mm and an angle of curvature with the horizontal at the midplane being 30°. This coincided with the angle of curvature of the upper eyelid. Multiple full-thickness holes were made on the surface of the plate [Fig. 4f].

The evaluation parameters were defect created after surgical excision was measured in mm (length and width) and documented as a percentage; the action of LPS and margin reflex distance (MRD1) were measured both pre- and immediate postoperative at 1 month, 6 months, and 18 months, respectively; and postoperative entropion, ectropion, any lid shrinkage, lagophthalmos, lid thickening, and lid margin irregularity were measures. In each case, the corneal

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**Figure 2:** (a) Preoperative image of upper lid tumor. (b) Postoperative image of upper lid tumor

**Figure 3:** Steps of modified Cutler–Beard procedure with tarsal plate replaced by artificial synthetic novel silicone plate for upper lid reconstruction in malignant tumors. (a) Rectangular skin marking performed. (b) Tumor excised with a 4 mm wide healthy margin. (c) Artificial synthetic silicone plate (artificial tarsal plate) is introduced between the anterior and posterior laminae. (d) The wound closes and sandwiches the silicone plate with anterior laminae of both upper and lower lids. (e) Second stage of Cutler–Beard procedure after 6 weeks. (f) Upper lid margin creation performed
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Figure 4: Steps of preparation of the novel silicone plate from 279 retinal buckles (a and b) A 30-mm long rectangular piece was cut out from the 360° 279 scleral buckle. (c) The total width was 8.5 mm of which the central groove was 2.5 mm and both sides were 3 mm each (2.5 + 3 + 3 = 8.5). (d) The elevated edges of the central groove of the buckle were made smooth and leveled with even curvature, sliced by the sharp blade under microscope. (e) The surface was scraped to make the thickness about 0.75 to 0.50 mm. It is elliptical shape with a central width of 6 mm. (f) The angle of curvature with the horizontal plane is 30°. This coincided with the angle of curvature of the upper eyelid. Multiple full-thickness holes were made on the surface of the plate.

Figure 5: (a) Preoperative right upper lid tumor. (b) Postoperative lid thickness, contour, and height are similar to the opposite eyelid. (c) Partial replacement of tarsal plate by the silicone plate. (d) Immediate postoperative period at the time of separation of upper lid in the second stage of the Cutler–Beard procedure.

Examination was mandatory to exclude suture-related or margin-related complications.

Serial photographs were taken, and each patient was assessed for complications, for example, wound infection, necrosis, tumor recurrence, graft extrusion, and corneal surface disorder. The statistical data analysis was done with the help of IBM SPSS statistics, Version 25.0. Descriptive statistical analysis was performed to calculate the mean, median, and standard deviation. The means were compared with paired t test, and P < 0.05 was considered to be statistically significant.

Results

After the exclusion criteria were met, there were a total of 30 patients, of which 14 were females (47.5%) and 16 males (52.5%). The age of the patients ranged from 40 to 86 years, and the mean age was 71.5 ± 8.4 years. The median age was 73 years [Table 1]. In this study, the types of malignancy were as follows: 76.7% sebaceous gland carcinoma, 10% squamous cell carcinoma, 6.7% basal cell carcinoma, and 3.3% porocarcinoma (eccrine sweat gland carcinoma) and amelanotic melanoma [Fig. 8].

The involvement of the lid tumors was measured from edge to edge without margin clearance. It ranged from 43.3% to 73.3%, and the mean was 60.7% ± 10.5 [Table 1]. The median lid involvement was 63.3%. The created defect size ranged from 60% to 100%, and the mean was 87.3% ± 10.5 [Table 1]. The median defect size was 90%. The preoperative MRD1 ranged from –4 to –1 mm (mean = −3 ± 1.14 mm, median = −3 mm). Immediate postoperative MRD1 at the end of the first week ranged from 1 to 3.5 mm (mean = 2.18 ± 0.5 mm,
Figure 7: Showing the comparison of preoperative mean LPS** action with postoperative mean LPS action among the study population (n = 30). **LPS: Levator palpebrae superioris.

Discussion

In this study, we propose a novel silicone plate repurposed from a model 279 scleral buckle as a tarsal plate substitute. The dimension and architectural support are similar to the tarsus and stabilize a newly reconstructed upper eyelid when performed with a modified Cutler–Beard procedure. Depending on the tumor size and the amount of tissue excised, there has to be careful planning of the surgery. For large upper eyelid defects, the Cutler–Beard procedure is the most useful intervention. However, complications such as entropion, dermatochalasis, and cicatrix have been reported with the traditional procedure. There is a need for a suitable support to the lid in the absence of the tarsal plate.[5-8]

Several studies were conducted and different materials were tried as tarsal plate substitutes. Nasal septal cartilage grafts were used with some success.[9] Werner et al. describes the use of composite tarsoconjunctival grafts from the...
Table 2: Comparison of preoperative parameters with postoperative parameters among the study population (n=30)

| Evaluation Parameter | Preoperative mean with standard deviation | Immediate postoperative mean with standard deviation | 18 months postoperative mean with standard deviation | Unaffected eye |
|----------------------|------------------------------------------|---------------------------------------------------|---------------------------------------------------|----------------|
| Margin reflex distance 1 (MRD1) | -3±1.14 mm | 2.18±0.5 mm | 4.16±0.35 mm | 4-4.5 mm |
| LPS action* | 1.23±1.35 mm | 11±0.78 mm | 13.53±0.73 mm | 14-16 mm |
| Entropion upper lid | Nil | 2 | Nil | Nil |
| Ectropion lower lid | Nil | 4 | Nil | Nil |
| Lagophthalmos | Nil | 2 | Nil | Nil |
| Unusual Hypertrophy | Nil | 2 | Nil | Nil |

*LPS: Levator palpebrae superioris

opposite eyelid as a tarsal plate substitute in the affected eye. Acellular dermal graft (AlloDerm) was used by Hayek B, et al. with some success, but two patients had residual exposure keratopathy. Rotational upper eyelid flaps were also tried but were found to be more suitable for smaller-sized defects. Holloman et al. in 2005 used an Achilles tendon from cadaveric donors. Kadoi et al. used donor sclera as a tarsal plate replacement graft. The main issue with both the above studies was disease transmission and proper harvesting and preservation of the graft. Hard palate mucoperiosteal graft was utilized by Ito et al. in 2001. Jordan et al. in 1997 performed eyelid reconstruction with an irradiated human tarsal plate and aorta. Yoon et al. in 2009 used the MEDPOR® sheet as a substitute material for tarsal plate in upper eyelid reconstruction. In a recent study in 2015 by Mandal et al., autogenous auricular cartilage was used for lid reconstruction, with quite a satisfactory outcome. Chen et al. in 2020 uses three-dimensional printed poly-caprolactone scaffolds modified with biomimetic extracellular matrices for tarsal plate tissue engineering. However, the main drawbacks were the requirement of a second surgical site, the uneven thickness of harvested cartilage, and the curvature of the auricular cartilage not coinciding with the lid curvature. Although tissue acceptance and tissue adaptability were excellent in the postoperative period, there was increased thickness of the newly created upper lid, cosmetically not up to the mark. Moreover, it was a time-consuming procedure. During the time of harvesting cartilage, it needed good assistance and excellent skill, sometimes the cartilage might break, or ear skin perforation might occur. Hence, no ideal tarsal plate substitute was found as every material had its own drawbacks.

Improper upper eyelid reconstruction may crop up with serious complications such as keratitis, esthetic deformities, recurrent conjunctivitis, ectropion, entropion, and so on. Careful assessment of the size and percentage of upper eyelid involvement is required for preplanning the reconstruction of the full-thickness defect. For tumors affecting more than 60% of the upper lid such as in our patients, procedures such as Cutler–Beard, inverted semicircular flap, multiple composite eyelid grafts, lid switch flap, malar cheek flap, or medial or temporal forehead flaps can be employed. Several studies have shown upper eyelid reconstruction with switch flap technique, but it involves additional lower eyelid reconstruction. In cases where adequate facial tissues are not available for grafting, as in severe facial burns, free dorsalis pedis graft supported by nasal septal cartilage or an ear helix flap or a two-stage lamellar rotation procedure can be performed. However, these have additional challenges such as establishing proper venous drainage. With the above-mentioned procedures, the introduction of a silicone plate or any tarsal plate substitute for an upper lid tarsal plate replacement to provide architectural support is not possible. Cutler–Beard procedure is the only surgical procedure where it can modify and successfully implant the silicone plate safely with excellent architectural support and stability in the long term.

Proper eyelid reconstruction requires a tarsal plate substitute. Multiple previous studies have modified the Cutler–Beard procedure by using various materials as tarsal plate substitute grafts, including donor sclera, cadaver Achilles tendon, hard palate mucoperiosteal autograft, nasal septal graft, bioengineered tarSys, MEDPOR®, and autologous auricular cartilage. All these procedures involved a second surgical site or a cadaveric donor, increasing the risk for postoperative morbidity, increasing the risk of transmission of diseases from donor to recipient and the cost of graft harvesting/storage, and thus increasing the operating time. For example, the cost of Achilles tendon grafts ranges from $700 to $1100, the cost of donor sclera ranges from $300 to $600, and the cost of bioengineered tarSys is $385. The cost of the silicone plate is not estimated to date because it is a new, innovated material, clinically applied for the past 3.5 years over 30 patients. It is not commercially marketed or available so far. It is secured from 279 retinal buckles [Fig. 4]. The estimated cost of a single 279 retinal buckle is 1,450 INR (19.51$). From one retinal buckle, approximately three silicone implants can be fashioned out. Each silicone plate costs around 483 INR (6.56$). The silicone plate was made inside the sterile operation theater with strict asepsis measure. Then, it is sent for packed ethylene oxide sterilization and preservation. Silicone is a well-tolerated material known to cause minimum long-term complications. Its tissue adaptability has been shown by its various uses such as prosthesis in breast reconstruction postmastectomy, scleral buckles for retinal detachment, tarsofrontalis sling for ptosis correction, and silicone plate for orbital plate fracture.

When examining our patient outcomes, 6.6% (2) patients developed upper lid entropion, 13.3% (4) patients developed lower lid ectropion, and 6.6% (2) patients developed unusual hypertrophy of the upper lid in the reconstructed area; initially all the patients had mild margin irregularity, and 6.6% (2) cases developed transient lagophthalmos [Table 2]. In one case, the affected eye scleral show was 1 mm, and the difference in the lid height of both the eyes was 3 mm. In another case, the affected eyelid margin was at the limbus, and the difference of the lid height of both the eyes was 2 mm. Peculiarly, this mild lagophthalmos appeared when the patient looked actively in primary gaze.
The traditional Cutler–Beard reconstruction is an effective implant used in upper lid reconstruction. It needs longer plate infection. The silicone plate is a newer artificial synthetic substitute with good cosmetic and functional outcomes. Moreover, this is a promising technique with good initial results but further experience and long-term follow-up are needed.

**Video link**
https://youtu.be/rbdkvnqbpN4

**Personal interest statement**
Dr. Salil Kumar Mandal, has a copyright and a patent of the product “SILICONE PLATE ”. The product may be freely distributed to eyelid cancer patients with an e-mail request at salil_dum@live.com.

**Consent for image publication**
Informed written consent was taken from all the patients whose clinical photograph and or clinical data have been published in this study.

**Acknowledgments**
I acknowledge all the doctors of Medical College Calcutta, especially Dr. Anvesha Maitra, Dr. Paulami Roy, Dr. Sudip Roy, the staff of the Department of Ophthalmology and Operation Theatre, and the nursing staff who contributed significantly to this study. Last, but not least, thanks to R.I.O., Professor, and Dr. James Christian Fleming and Dr. Brain T. Fowler of the Hamilton Eye Institute, Memphis, USA, who helped us present this article at the 2018 annual meeting of the Association for Research in Vision and Ophthalmology at Honolulu, Hawaii, USA.

**Financial support and sponsorship**
Nil.

**Conflicts of interest**
There are no conflicts of interest.

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