

Evaluation of Variables Influencing Orbital Implant Motility

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Abstract

Purpose

To evaluate the variables influencing orbital implant motility following enucleation.

Methods

This was a single-centre observational, non-randomised, non-masked cohort study in 54 enucleated eyes. A standard ruler measured (SRM) vertical and horizontal movements to calculate a total motility score (TMS), comprising adduction, abduction, up-gaze, and infraduction. Variables assessed included implant size and type, presence of post-enucleation socket syndrome (PESS), and reason for enucleation. Student's T-test was used to analyse differences between variables influencing implant motility. Statistical significance was set at $P < 0.05$.

Results

Fifty-four eyes from 54 patients were assessed: 22 (40.7%) with acrylic implants and 32 (59.3%) with hydroxyapatite. Implant sizes were 18mm (3 patients), 20mm (17), and 22mm (28). Mean time since enucleation was 1,367 days, median 282 days. Motility differences between acrylic and hydroxyapatite implants were not statistically significant ($P = 0.36$), though acrylic showed higher motility (mean TMS = 14.1mm vs 12.8mm). Larger implants showed greater TMS. Patients with PESS had poorer motility (12.8mm vs 13.6mm, $P = 0.61$). Motility was better without trauma (13.6mm vs 12.5mm, $P = 0.38$).

Conclusions

Type and size of implant, PESS, and trauma influenced motility without reaching significance. Surgical technique may play a more prominent role in long-term motility.

Introduction

Orbital implants are used after enucleation to restore lost orbital volume, provide motility to the prosthesis, and achieve optimal symmetrical cosmesis with the fellow eye.(1) The idea of combining enucleation with orbital implants (orbital volume replacement) was first introduced by Mules in 1585.(2, 3) The various orbital implants are categorised into two main groups: integrated (porous) and non-integrated (non-porous).(4)

Non-integrated (non-porous) orbital implants do not allow ingress of fibrovascular tissues into the substance of the implant.(4) It was thought that disposition of the recti muscles over a non-integrated implant would enhance the orbital implant and prosthesis motility, in which the prosthesis would move

when the orbital implant moves, like a ball-and-socket joint.(4) However, as there is no direct coupling between the implant and prosthesis as they are disjointed by layers of imbricated muscles, Tenon's capsule, and conjunctiva, the efficacy of mechanical conduction is suboptimal from the orbital implant to ocular prosthesis.(4) One study has suggested that implant migration can result due to recti muscles imbrication over non-integrated implants.(5) One of the most commonly used non-integrated implants in practice is polymethyl methacrylate (PMMA) or acrylic orbital implant.(4)

Integrated (porous) orbital implants differ from non-integrated implants as they allow fibrovascular tissue ingress, theoretically providing better implant motility through better mechanical motility transmission. Pegging of the implant was thought to enhance motility by increased coupling of the prosthesis and implant; however, complications such as infection and extrusion have resulted in the abandonment of this technique.(6) Hydroxyapatite (HA) orbital implant is currently the most commonly used implant following enucleation.(5)The fibrovascular tissue ingrowth reduces infection risk, migration and extrusion.(7, 8) HA orbital implants need wrapping material (such as a mesh wrap method) to facilitate extraocular muscle reattachment, MRI study to assess implant vascularisation and, optionally, a peg placement via an additional drilling procedure with the subsequent alteration of the ocular prosthesis.(4) All of these factors may potentially lead to improved orbital implant motility and explain the higher cost, in comparison to acrylic implants.

An alternative to the HA implant is the porous polyethylene implant, which also permits the ingrowth of host fibrovascular tissue without the need of a wrapping substance. The recti muscles can also be attached directly to the orbital implant and it is less costly than HA.(4) Custer et al (9) reported that there was no significant impact based solely on the implant material, as long as the recti muscles are indirectly or directly attached to the orbital implant and the implant is non-pegged.

In this single site, single visit observational study, we attempt to measure objectively the degree of translational movement of orbital implant using standard rule measurements. We evaluate the factors that could affect orbital implant motility, such as orbital implant material type, orbital implant size, presence of PESS, enucleation after ocular trauma, and time since enucleation.

Methods

This single-centre, observational, non-randomised, and non-masked cohort study was conducted with enucleated patients attending routine appointments at the ocular prosthetics department of Moorfields Eye Hospital. Ethical approval was obtained from the Research Ethics Committee (reference 18/LO/1990). The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to participation in the study.

Patients Recruitment

Eligible patients attending the ocular prosthetics department at Moorfields Eye Hospital for routine follow-up were invited to participate by the chief ocularist or delegated staff. Patients were included if

they were adults, able to give consent and understand the study, able to cooperate by following instructions, and if orbital implant was inserted following enucleation. Our technique of enucleation surgery has been published previously, with implant choice made intraoperatively with socket sizers and chose according to the best fit.(10) Patients were excluded if they had a history of other socket procedures such as radiotherapy to socket, chemotherapy, Implant exposure repair, secondary orbital implant, concurrent socket pathology such as socket infection or exposure, giant papillary conjunctivitis, presence of ocular motility disorders on either side of the face, muscle restrictive disorders, previous trauma, idiopathic orbital inflammatory disease and neurological disorders for example cranial neuropathies, or multiple sclerosis. Evisceration cases were excluded from this study because orbital implant motility mechanisms differ between evisceration and enucleation. Including both could confound motility assessment.

Measurement of Orbital Implant Motility

The patient's eye socket was examined for implant exposure, infection, recurrence of disease and giant papillary conjunctivitis. If any of these conditions were discovered these were addressed and the patient excluded from the study. All motility measurements were based on images captured using a SRM, our technique that has been previously published.(11) Measurements were performed by a single observer to ensure consistency. A small dot mark was placed on the midline of the bridge of the nose (mid-canthal distance) of the patient using a surgical pen marker. This dot served as a reference point for measurements. A small dot was placed in the centre of the socket using a surgical ink marker to serve as another reference point for measurements. There was no need for the normal eye to be surgically marked but the pupil centre was used to measure eye movement. This allowed the reference and the excursion of the implant to be expressed as a numerical value.

A ruler with a 1 mm scale was held up in the same plane as the eye within the photograph (placed against the opposite cheek), and measurements of excursion were taken in four directions of gaze using the SRM method.

The patient was instructed to sit upright, keep their head still in the primary position, and follow a series of instructed gaze directions: straight gaze, adduction, abduction, supraduction, and infraduction. During infraduction, as the upper eyelids may obscure a front-on view of the eye, the researcher enlisted the help of an assistant to gently raise both upper eyelids.

At each gaze position, a photograph was taken. The degree of movement (excursion) was calculated by measuring the distance from the midline dot to the limbus/reference mark in straight gaze and deducting this from the measurement of the midline dot to the limbus/reference mark in the other gaze positions. Movement of the orbital implant was inferred from observation of eye socket movement and measured against the fellow normal eye.

Analysis of Associated Variables

We utilised the TMS concept to determine if any of the demographic variables were associated with motility. To do this, we focused only on the SRM. We also focused only on the measurements from the orbital implant, in order to reduce any confounding factors that might come from measurements with a prosthesis in place. We tested each variable individually to see if there was a significant association with TMS, which equals the total excursion of each eye in all directions of gaze (adduction, abduction, supraduction, and infraduction). Student's T-test (P-value) was conducted to analyse the significance difference between various variables that potentially might interfere with ocular implant motility. The criterion for statistical significance was P-value < 0.05.

Results

Patients Demographics

A total of 54 eyes in 54 patients were measured and tested for orbital implant motility following primary enucleation. Patients' age ranged from 18 to 85 years (mean, 54.9 years) and 24 right eyes (44.44%) and 30 left eyes (55.55%) were enucleated. Out of 54 patients (n = 54) who qualified for this study, 29 were female (53.7%) and 25 were male (46.2%). The enucleations were performed due to tumours (retinoblastoma, choroidal melanoma) in 34 eyes (62.9%), trauma in 13 eyes (24.0%), blind painful eyes in 5 eyes (9.2%) and infections in 2 eyes (3.7%). The mean (median, range) time since enucleation was 1,367 days, (282, 45–11,278). A total of 22 patients had received acrylic orbital implants while 32 had received hydroxyapatite. Among the 24 enucleated right eyes (44.4%), 13 received HA implants and 11 received acrylic implants. Among the 30 enucleated left eyes (55.6%), 19 received HA implants and 11 received acrylic implants. Three patients had received an 18mm implant (5.6%), 17 patients had received a 20mm implant (31.5%), 28 patients had received a 22mm implant (51.9%), and in six patients (11.1%) the implant size was unknown.

The variables that were analysed included orbital implant type, orbital implant size, presence of PESS, enucleation due to ocular trauma and the number of days since enucleation. Analysis was conducted by the Student's T-test (P-value) to define the significance of difference between various variables that could potentially interfere with ocular implant motility (Table 1).

Acrylic Implants versus Hydroxyapatite Implants

Implant motility measurements were assessed across all 54 patients using the SRM technique. In the subgroup of patients who had received acrylic implants (n = 22), the mean TMS was 14.1 mm. In comparison, for patients with HA implants (n = 32), the mean TMS was 12.8 mm. Overall, patients with acrylic implants demonstrated slightly greater mean TMS movements compared to those with HA implants though it did not reach statistical significance (P-value = 0.36). These findings are summarised in Table 1.

Orbital Implant Sizes

The range of the orbital implant sizes used were from 18 to 22 mm. Orbital implant size was 22 mm in 28 cases (51.9%), 20 mm in 17 cases (31.5%), 18 mm in 3 cases (5.6%), and in six patients (11.1%) the implant size was unknown. On analysing orbital implant size, 18mm orbital implants had a mean TMS of 10.7mm, 20mm orbital implants had a mean TMS of 12.8mm, and 22mm orbital implants had a mean TMS of 14.0mm. Among the 54 enucleated eyes, the larger orbital implants demonstrated greater motility than smaller implants. However, the difference in motility did not reach statistical significance (P -value = 0.64) (Table 1). However, increased implant motility does not necessarily imply greater prosthesis motility, as larger implants may reduce fornix depth and restrict prosthesis movement.

Post Enucleation Socket Syndrome

During orbital implant motility measurements, the socket condition was examined. A total of 17 of 54 patients suffered from PESS. Eleven patients (34.37%) with hydroxyapatite implant had PESS in contrast to 6 patients (27.27%) with acrylic implant. Patients with PESS had a mean implant TMS of 12.8mm, whereas patients without PESS had a mean implant TMS of 13.6mm. Even if the differences did not reach statistical significance (P -value = 0.61), our results indicate that patients without PESS had a greater motility than patients with PESS (Table 1).

Enucleation Secondary to Ocular Trauma

Patients whose enucleation was secondary to orbital trauma had a mean implant TMS of 12.5mm, while patients without orbital trauma had a mean implant TMS of 13.6mm. Patients without orbital trauma, therefore, had better motility than patients with orbital trauma, although the difference was statistically insignificant (P -value = 0.38) (Table 1).

Number of Days Since Enucleation

Our results indicated that there was no relationship between the number of days since enucleation and the TMS, which was verified by linear regression (P -value = 0.23) as illustrated in Fig. 1.

Discussion

The aim of this study was to evaluate the variables affecting HA and acrylic orbital implant motility following primary enucleation. To evaluate and compare the motility of HA and acrylic implants, a single centre observational study of ocular implant motility for patients attending routine visits at the ocular prosthetic department at Moorfields Eye Hospital was conducted. The enucleations were performed due to tumours (retinoblastoma, choroidal melanoma) in 34 eyes (62.9%), trauma in 13 eyes (24.0%), blind painful eyes in 5 eyes (9.2%) and infections in 2 eyes (3.7%). The mean time since enucleation was 1,367 days, the median was 282 days (range: 45–11,278). Two major orbital implant types are commonly used

currently at Moorfields Eye Hospital following primary enucleation: the hydroxyapatite orbital implant and polymethyl methacrylate/ acrylic orbital implant.

The important finding of our study was that acrylic orbital implants demonstrated slightly greater TMS mean movements compared to those with HA implants. Although acrylic implants demonstrated superior motility, the difference between the two groups did not reach statistical significance ($P = 0.36$), suggesting that there is no difference in terms of acrylic or HA motility (Table 1). These results are equivalent to those of Colen and colleagues,(12) Trichopoulos and colleagues, (13) in which most enucleations were performed for uveal melanoma despite various recording methods. Colen et al(12) reported no significant difference in vertical or horizontal saccadic amplitude of motility of the hydroxyapatite and acrylic implant at a mean follow up of 10.7 months. Trichopoulos et al(13) also documented no significant difference between acrylic (1.5% of 68 patients) and hydroxyapatite (2.1% of 190 patients) motility at a median follow up of 37.6 months. Similarly, Damato et al. reported no significant differences between HA and AC implants in terms of prosthetic motility ($p > 0.05$) at a follow up of ≥ 6 months.(6)

Table 1
Assessment of Variables affecting orbital implant motility (n = 54)

Implant Type: Acrylic: Mean Implant TMS: 14.1mm Hydroxyapatite: Mean Implant TMS: 12.8mm P-value (t-test, 0.36)
Implant Size: 18mm: Mean Implant TMS: 10.7mm 20mm: Mean Implant TMS: 12.8mm 22mm: Mean Implant TMS: 14.0mm P-value (ANOVA: 0.64, though an interesting trend, it is not significant)
Presence of PESS: PESS: Mean Implant TMS: 12.8mm NO PESS: Mean Implant TMS: 13.6 P-value (T-test, 0.61)
Etiology (Trauma vs. other): Trauma: Mean Implant TMS: 12.5mm N Trauma: Mean Implant TMS: 13.6 P-value (T-test, 0.38)
Days since enucleation: A plot of the Implant TMS vs. log (days since enucleation) demonstrates no relationship between the variables, something that is verified by linear regression (P-value = 0.23)

Large implant sizes scored higher in the TMS (18mm orbital implants showed a mean TMS of 10.7mm, 20mm orbital implants had a mean TMS of 12.8mm, and 22mm orbital implants had a mean TMS of 14.0mm), as larger orbital implants may allow the rectus muscles to be tauter around the orbital implant and enable them to be a more effective support for motility. Nevertheless, this did not reach statistical significance (P-value = 0.64), implying there is no difference between different orbital implant sizes (Table 1). Multiple factors must be considered in determining the suitable size of implant for a particular patient. Markedly large implants may raise the risk of extrusion, result in patient discomfort, or make prosthesis fitting difficult. Adequate space must persist in the socket to permit better prosthesis fitting with approximately 4 mm central thickness and at least 2 ml of volume.(1) Deep implantation without tissue restitution can avoid the risk of 'Cactus Syndrome' and allow adequate space for fitting of the prosthesis.(10) A UK nation-wide survey in 2007 of 243 ophthalmology consultants that performed

enucleations in the management of the anophthalmic socket revealed that 55% used porous orbital implants while 42% used acrylic orbital implants, indicating that porous spherical implants were the first choice, followed by acrylic spheres. Also, it was reported that 18-20mm orbital implants, 16 mm implants, 21 mm implant, and 22 mm implants were used by 70%, 6%, 3% and 7% of ophthalmologists respectively.(14) More recently, Mouris et al.(15) conducted a digital survey in 2015 of 58 ophthalmologists in 32 countries that performed enucleation in retinoblastoma patients. It was reported that 54.7% preferred using porous implants and only 37.7% preferred using nonporous implants. It is notable that the porous implants percentage documented in this study has the same estimate reported a decade ago from a UK ophthalmologists survey. (14, 15)

In this study, a total of 17 of 54 patients suffered from PESS. Post enucleation socket syndrome occurs following enucleation when the orbital volume may shrink in time in an anophthalmic patient as a result of orbital fat atrophy and loss of the surrounding connective tissue.(16) This in turn can potentially result in ocular prosthetic misfit and a disappointing cosmetic result.(16) This condition requires additional orbital volume augmentation.(16) Examples for orbital volume augmentation include secondary implant exchange, injectable augmentation or orbital floor implants.(16) Eleven patients (34.37%) with hydroxyapatite implants had PESS, in contrast to 6 patients (27.27%) with acrylic implants. Patients with PESS had a mean implant TMS of 12.8mm, whereas patients without PESS had a mean implant TMS of 13.6mm (P-value = 0.61). PESS was found to result in reduction in effectiveness of orbital implant motility. In this study, patients without PESS had a greater implant motility than patients with PESS (Table 1).

Moreover, patients who underwent enucleation following orbital trauma exhibited a mean implant TMS of 12.5 mm, compared to 13.6 mm in patients without a history of orbital trauma (P = 0.38). This indicates that patients without orbital trauma demonstrated superior motility; however, the difference did not reach statistical significance (Table 1). Furthermore, our findings suggest no correlation between the duration since enucleation and the TMS, as confirmed by linear regression analysis (P = 0.23), as illustrated in Fig. 1.

Furthermore, significant finding in our study is that, regardless of the great difference in cost between hydroxyapatite and acrylic orbital implants, there are no significant differences between them in terms of the outcome. Surgical technique of implantation is likely to be an important factor that negates the effect of material choice.

Attempts to improve movement conduction from the implant to the overlying ocular prosthesis have been made with various sizes and types of bio-integratable and quasi-integratable implant proposals. Different approaches for extraocular muscle attachment to the orbital implant (attachment to scleral cap or mesh wrapping, attachment to pre-existing holes in the implant) or to the conjunctiva (myo-conjunctival techniques) as well as diverse implant-prosthesis coupling methods have been attempted. Some of these procedures have fallen out of favour due to increased risk of complications such as implant-prosthesis coupling by way of a peg.(17)

Implant selection depends on the surgeon's preference, cost, availability, extrusion rates, desired motility and other factors.(18) However, the perfect ocular implant would be nonallergenic, nontoxic, mechanically stable, with satisfactory motility and no irritating immune response of the host tissue and an attractive value to price ratio.(19, 20)

Limitations

This study assesses variables affecting orbital implant motility using the SRM. This method ensured that measurements were based on a standardised, objective approach, rather than subjective evaluations by ocularists or patients, which are prone to bias. Nevertheless, our study relied on a single observer for both data collection and processing, which may have introduced an element of selection or observer bias.

Another limitation is the relatively small sample size, which may have influenced the statistical reliability and generalisability of the results. Additionally, not all variables were examined in isolation. For instance, patients with PESS, those undergoing enucleation for trauma, and variability in orbital implant size were present across both the acrylic and HA groups. These factors may have confounded the TMS outcomes, making it challenging to attribute differences solely to the implant material. Additionally, the heterogeneity of the implant sizes and underlying pathologies may have introduced confounding variable, limiting the ability to isolate single factors.

It is important to note that most previous studies investigating orbital implants have similarly suffered from methodological limitations, including small sample sizes, short follow-up periods, limited use of multivariate analysis, and the presence of many confounding factors, such as variable surgical experience, different surgical techniques, and the inclusion of multiple implant types.(19) In a Cochrane review of non-integrated versus integrated by Schellini et al (21), only 3 of a total 338 studies fulfilled the inclusion criteria for randomisation clinical trials. Wladis et al (20) more recently reported only 2 out of 25 fulfilled a level I evaluation (well-organisation, well-randomisation). Furthermore, measurements were performed by a single observer to ensure consistency; however, this may have introduced observer bias. Thus, there is a need for larger randomised clinical trials for further assessment of implant types.

We have recently assessed digital smartphone as well as analogue methods for measuring orbital implant motility and showed that some digital methods, such as Image J are closest to the gold standard of SRM.(11) We then completed a pilot assessment of movements of 3D-printed and hand-made ocular prosthetics and showed that motility in the 3D-printed prosthetics was non-inferior.(22) In the current report we show that orbital implant motility is not-significantly impaired by the choice of implant, history of PESS or trauma. This paves the way for our forthcoming randomised controlled crossover trial of fully digitally designed and manufactured 3D-printed prosthetics(23) versus analogue prosthetics (NCT05093348), which will use the foundations of these results in its study design.

Conclusion

This study highlights the variables influencing orbital implant motility following primary enucleation. While the type and size of orbital implants were found to have some influence, other factors, such as the presence of PESS and enucleation due to orbital trauma, also played a role, the differences did not reach statistical significance. Larger implants tended to have greater motility, and acrylic implants showed marginally better motility than hydroxyapatite implants, though the differences were not significant. These findings pave the way for studies on new manufacturing methods of ocular prosthetics using 3D printing. Within the constraints of this small and heterogenous cohort, the observed influences did not reach statistical significance. Larger clinical studies are needed for further evaluation variables affecting orbital implant motility.

Declarations

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Disclosure statement

All authors declare that they have no conflict of interest.

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Authors Contributions:

N.M.S. Performed the literature review, interpretation of the results and wrote the manuscript. S.B. conceptualised and led the study, contributed to data acquisition, analysis, and methodology refinement. B.P.G. participated in collecting data and manuscript editing. D.I.T.S. assisted in critical manuscript revisions. A.W.S. provided expertise in implant motility measurement methods and contributed to data analysis. D.C. supervised technical validation of measurements. M.S.S. conceived the study, assisted in study design, supervised the study, secured funding, and critically revised the manuscript. All authors reviewed and approved the final manuscript.

Ethics approval and consent to participate

Ethical approval was obtained from the Brent Research Ethics Committee (reference 18/LO/1990) and institutional review board at Moorfields Eye Hospital NHS Foundation Trust. The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to participation in the study.

Consent to publish

Not applicable.

Data Availability

The datasets generated and/or analysed during the current study are available from the corresponding author upon request.

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Figures

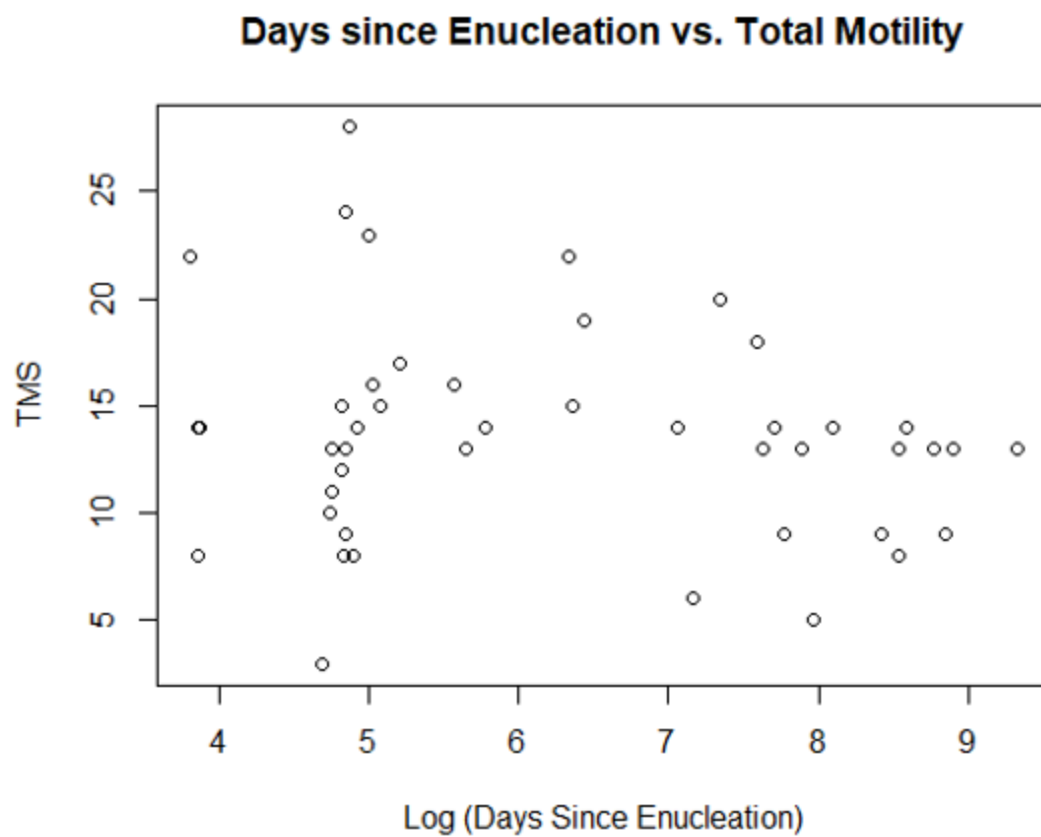


Figure 1

Relationship between TMS and the number of days since enucleation