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Long-Term Mental Health after High-Density Polyethylene-Based Porous Orbital Implant in Enucleated and Eviscerated Patients

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Abstract: Objectives: To assess the overall mental health of enucleated or eviscerated patients after high-density porous polyethylene OCULFIT implantation and external prosthesis over a 1-year follow-up. Methods: Patients with an indication of enucleation or evisceration with OCULFIT implantation were included in a prospective study. The patients completed four questionnaires regarding mental health at three different visits (baseline, 3–6 months, and 9–12 months post-surgery). The questionnaires used were the following: SF-12 for multidimensional health-related quality of life (scale 0–100); Rosemberg self-esteem scale (scale 0–40); Patients Health Questionnaire-4 (PHQ-4) (scale 0–6); and a Lifetime Major Depression and Anhedonia questionnaire (categorised in groups with/without symptoms). Results: A total of 33 patients (16 enucleations and 17 eviscerations) were included in the study. The physical domain of the SF-12 questionnaire did not change between visits, but the mental domain significantly improved from the baseline to the last visit (41.71 $\pm$ 12.72 vs. 46.80 $\pm$ 10.68, $p = 0.04$). The number of patients with high, moderate, and low self-esteem (Rosemberg scale) was similar between the baseline and the last visit. The depression and anxiety scores of the PHQ-4 were not significantly different among visits. The number of patients with no symptoms (depression or anhedonia) improved from the baseline (42.2%) throughout the follow-up (66.7% at the last visit). Conclusions: OCULFIT orbital implant and external prosthesis placement maintained and/or improved the quality of life related to mental health in eviscerated and enucleated eyes. The number of patients with no symptoms improved from the baseline throughout the follow-up. The patients' self-esteem was already high before implantation and remained stable over the follow-up.

Keywords: mental health; quality of life; enucleation; evisceration; orbital implants

Citation: Garrido-Hermosilla, A.M.; Martínez-Alberquilla, I.; Díaz-Ruiz, M.C.; Monge-Carmona, R.; Méndez-Muros, M.; López-Díaz, Á.; Sánchez-Margalet, V.; Gutiérrez-Sánchez, E.; Relimpio-López, M.I.; Rodríguez-de-la-Rúa-Franch, E. Long-Term Mental Health after High-Density Polyethylene-Based Porous Orbital Implant in Enucleated and Eviscerated Patients. *Prosthesis* **2024**, *6*, 979–988. https://doi.org/10.3390/prosthesis6050071

Academic Editors: Marco Cicciu and Gabriele Cervino

Received: 24 June 2024
Revised: 19 August 2024
Accepted: 20 August 2024
Published: 27 August 2024

1. Introduction

The eyes are a key part of interpersonal communication. The loss of an eye itself not only affects visual perception, visual field or binocularity; eye amputation (EA) also has a marked negative impact on patients' quality of life and social interactions, and entails enormous physical and mental consequences for those who suffer from it [1–4].

In the context of ophthalmologic surgery, the importance of addressing mental health outcomes cannot be overstated. Visual impairments and changes in appearance resulting from EA not only alter the physical capabilities of the patient but also profoundly affect their psychological well-being. Mental health is a critical component of overall health. This is particularly significant for EA patients, who often experience a decline in self-confidence and self-image, leading to lower scores in health-related quality of life and self-rated health, and higher levels of stress compared to the general population [2].

Appearance-related distress, emotional problems, mental health issues, anxiety, and depression are some of the symptoms reported by EA patients [2,5–8]. Additionally, these disorders seem to be underdiagnosed in these patients [5]. Given the profound influence of mental health on the overall quality of life, it is crucial to assess and address these issues in EA patients to provide comprehensive care and improve their long-term outcomes. Accordingly, questionnaires are a powerful tool for assessing patients' quality of life, self-rated health, and disability.

It is known that to restore the lost volume and to enhance motility and aesthetic appearance after enucleation or evisceration procedures, orbital implants are placed in the anophthalmic socket [9–11]. Within the wide variety of orbital implant materials and designs, high-density porous polyethylene (HDPE) implants have been the most used in recent decades [12]. HDPE implants have shown excellent performance and low rates of complications, along with excellent patient satisfaction after external prosthesis placement [13,14].

Most research has focused on assessing the performance and complications of orbital implants, and few have focused on assessing mental health disorders and quality of life after implantation. Once their safety and efficacy are known, it would be interesting to study their impact on EA patients' emotional state. Therefore, this study aimed to assess the overall mental health of enucleated or eviscerated patients after HDPE-manufactured OCULFIT implantation and external prosthesis placement through several questionnaires over a 1-year follow-up.

2. Methods

2.1. Study Design and Population

A prospective study was carried out in the Hospital Universitario Virgen Macarena (Seville, Spain). Patients eligible for inclusion in the study were those with a clear medical indication for enucleation or evisceration, coupled with the need for OCULFIT orbital implant placement. The specific indications for these procedures included advanced intraocular malignancies, severe untreatable ocular pain, blind painful eyes, or irreparable ocular trauma. The patients were thoroughly evaluated by the ophthalmology team to confirm that enucleation or evisceration was the most appropriate surgical intervention.

Patients with an indication of enucleation or evisceration with OCULFIT implantation were included in the study. Exclusion criteria included severe orbital infection or severe trauma with the possibility of orbital infection. The study conformed to the principles of the Declaration of Helsinki and was approved by the hospital ethics committee. Informed consent was delivered to all patients. Enucleation/evisceration and orbital implant placement were performed in the usual way and in the same surgical procedure. To ensure consistency in surgical technique and outcomes, all procedures were performed by the same experienced surgeon (AM.G.H) from 2021 to 2022.

Questionnaires were handed to patients in three different visits throughout the follow-up: at baseline (before enucleation/evisceration and OCULFIT implantation), at Visit

1 (from 3 to 6 months post-implantation), and at Visit 2 (from 9 to 12 months post-implantation). Visits 1 and 2 were carried out after external prosthesis placement.

2.2. Orbital Implant

The OCULFIT orbital implant (AJL Ophthalmic S.A., Vitoria, Basque Country, Spain), manufactured in HDPE, presents a smooth anterior surface with four points for its fixation and a more porous posterior surface, theoretically minimising the risk of long-term exposure. It is characterised by its interconnected and opened porous structure [15]. Biocompatibility, fibrovascular growth, high tensile strength, and malleability are some of the features of this implant. It also allows the suturing of the extrinsic muscles directly from the implant [9,13,14]. It presents a pore size > 100 µm and a porosity of 45%. Sterilisation is performed in ethylene oxide, and the implants present a 5-year expiration. Sphere diameters range from 12 mm to 23 mm. Figure 1 shows the OCULFIT implant and injector.

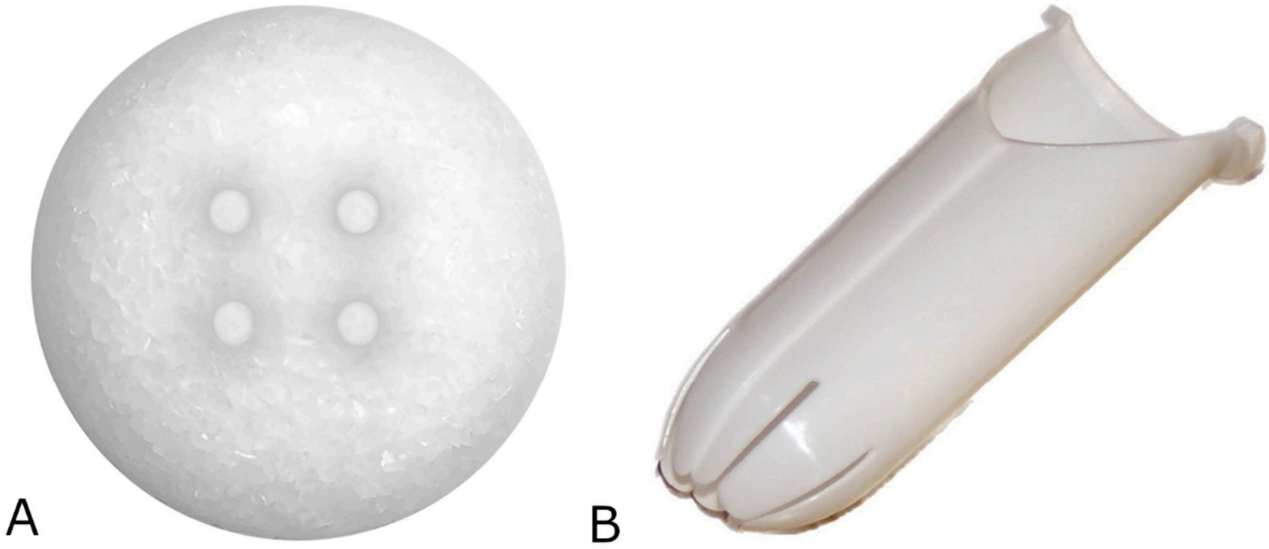

Figure 1. Images of the OCULFIT system. (**A**) OCULFIT implant; (**B**) OCULFIT injector.

2.3. SF-12 Questionnaire

The SF-12 questionnaire, the shorter version of SF-36, evaluates the multidimensional health-related quality of life through 12 questions [16]. SF-12 consists of 2 main components evaluating 8 dimensions of health: Physical Component Summary (PCS) and Mental Component Summary (MCS). PCS evaluates physical functioning, role-physical, bodily pain, and general health scales, whereas MCS evaluates vitality, social functioning, role-emotional, and mental health scales. The response options form Likert-type scales (where the number of options varies from 3 to 6 points, depending on the item), which evaluate the intensity and/or frequency of patients' health status. The score goes between 0 and 100, where the highest score implies a better quality of life related to health. The SF-12 questionnaire has proved to be a valid and reliable instrument, with significant correlations between the short and long versions [17–20], and has been validated in Spanish [20].

2.4. Rosemberg Self-Esteem Scale

The Rosemberg self-esteem scale was used to explore personal self-esteem, understood as feelings of personal worth and self-respect. It consists of 10 items that are scored using a 4-option Likert scale, where 1 means "Strongly disagree" and 4 means "Strongly agree". Items 1, 3, 4, 7, and 10 are worded positively (e.g., "I have a positive attitude towards myself"), and items 2, 5, 6, 8, and 9 are worded negatively (e.g., "there are times when I think I'm useless"). A sum is made that determines the level of self-esteem on a scale from 0 to 40. A total of 25 points or less means low self-esteem, 26–29 points moderate self-esteem, and 30–40 high self-esteem.

This questionnaire has been validated in Spanish, with an internal consistency between 0.76 and 0.87, and a reliability of 0.80 [21].

2.5. Patient Health Questionnaire-4 (PHQ-4)

PHQ-4 is an ultra-shorter version of PHQ-9, consisting of two items to evaluate depression (PHQ-2) and two items to evaluate anxiety (GAD-2) [22]. Scores are 0: never; 1: several days; 2: more than half the days; and 3: almost every day. PHQ-2 determines the frequency over the last 2 weeks of (1) the presence of a depressed mood, and (2) a loss of interest or pleasure in routine activities. The depression cut-off point is 3, with a maximum value of 6. On the other hand, GAD-2 determines the level of anxiety by two different questions: (1) the presence of a state of nervousness, anxiousness or tension, and (2) the inability to control or stop worrying. The anxiety cut-off score is 3, with a maximum value of 6.

2.6. Lifetime Major Depression and Anhedonia

Lifetime major depression episodes (MDE) were assessed through a 4-item questionnaire [23]. Participants were asked about a history and frequency of depressed mood and/or anhedonia lasting several days or longer. Answers were divided into four groups: those reporting both symptoms, those reporting one of the two symptoms, and those reporting neither of the symptoms.

2.7. Statistical Analysis

Statistical analysis was performed using the IBM SPSS statistics software version 25.0 (SPSS Inc., Chicago, IL, USA). After assessing the normality of each variable, numeric variables were analysed with the ANOVA test, and categorical variables were analysed with the Chi-Square test. The patients were also divided into different groups according to demographic factors. The effect these factors might have on the questionnaire outcomes was assessed. Differences among subgroups were analysed with the ANOVA test. Data are expressed as mean ± standard deviation and percentages. The statistical significance was set at 95% ($p < 0.05$).

The sample size was calculated using the Granmo v.7.11. sample size and power calculator. The sample size calculation is based on the rate of one of the most serious complications with this type of implant as the primary endpoint, which is the development of an ocular infection. According to the previous literature regarding the rate of this complication, which has a value of 2%, and assuming a minimum difference to be detected of 5% and a confidence level of 95%, the minimum number of evaluable eyes would be 29.

3. Results

3.1. Demographic Data

A total of 33 patients (16 enucleations and 17 eviscerations) were included in the study. The mean age was 65.6 ± 12.0 years (range 30–85). The main cause of EA was the presence of a tumour (48.5%), mostly choroidal melanoma; 33.3% required EA due to postsurgical complications, 12.1% had glaucoma and 3% required surgery because of an infection. Concerning employment status, the vast majority of patients were retired (66.7%), followed by salaried employees (15.2%), unemployed (12.1%), and self-employed (3%).

No postoperative complications related to either enucleation/evisceration or OCULFIT implantation were found. During the follow-up, two eyes (6%) required an advancement of levator aponeurosis surgery (7 and 9 months after surgery) because of aponeurotic ptosis with full recovery, and one eye (3%) required horizontal eyelid shortening and lateral canthoplasty surgeries because of recurrent moderate palpebral laxity (9 and 12 months after surgery). These conditions were present before the preoperative visit.

3.2. SF-12 Questionnaire

The SF-12 results about multidimensional health-related quality of life were divided into physical (PCS) and mental component summaries (MCS). Table 1 shows the results of this questionnaire for each visit. PCS did not change between visits, but MCS was significantly better in Visit 2 compared to the baseline, which means the quality of life related to mental health improved over time.

Table 1. SF-12 questionnaire results for all visits.

Visits	Physical Component Summary	Mental Component Summary
Baseline	42.68 ± 9.39	41.71 ± 12.72
Visit 1	43.95 ± 11.35	44.4472 ± 11.18
Visit 2	42.46 ± 11.41	46.80 ± 10.68
p-value	0.67	0.04 *

* Statistical significance.

3.3. Rosemberg Self-Esteem Scale

Table 2 shows the results for the Rosemberg self-esteem scale for every visit and the mean score. The mean score was "high" (>30) for all visits and did not significantly change between them ($p = 0.53$). The number of patients with high, moderate, and low self-esteem was similar among visits ($p > 0.05$ all).

Table 2. Rosemberg self-esteem results for all visits.

Visits	High Self-Esteem N (%)	Moderate Self-Esteem N (%)	Low Self-Esteem N (%)	Mean ± Standard Deviation
Baseline	22 (66.7)	5 (15.1)	6 (18.2)	32.21 ± 5.98
Visit 1	17 (51.5)	10 (30.3)	6 (18.2)	31.67 ± 6.36
Visit 2	24 (72.7)	4 (12.1)	5 (15.2)	31.82 ± 5.82
p-value	0.18	0.13	0.93	0.53

To assess if the main cause for eye amputation affected baseline self-esteem, the Rosemberg scale results were divided into different groups. Patients with a preoperative tumour (mainly choroidal melanoma) obtained 33.44 ± 4.99 points; those who suffered from postsurgical complications obtained 30.09 ± 5.58, and those who had glaucoma obtained 30.75 ± 10.24 ($p = 0.10$).

3.4. Patient Health Questionnaire-4 (PHQ-4)

Depression scores (on a scale from 0: low to 6: high) were 2.30 ± 1.88 at baseline, 2.18 ± 2.04 at Visit 1, and 1.82 ± 1.96 at Visit 2, not being significantly different among visits ($p = 0.17$). On the other hand, anxiety scores were 2.23 ± 1.89 at baseline, 2.06 ± 1.69 at Visit 1, and 1.85 ± 1.70 at Visit 2 ($p = 0.6$).

3.5. Lifetime Major Depression and Anhedonia

Table 3 shows the number of patients reporting the different classifications (no symptoms, depression, anhedonia, or both symptoms). The percentage of patients with no symptoms improved from the baseline (42.2%) through the follow-up (66.7% at the last visit). Only one patient experienced depression and anhedonia separately at the last visit. The percentage of patients suffering from both symptoms simultaneously decreased from the baseline (45.5%) to the last visit (27.3%), although the results were not significantly different among visits ($p > 0.05$ all).

Table 3. Major depression and anhedonia results for all visits.

Visits	No Symptoms N (%)	Depression N (%)	Anhedonia N (%)	Depression + Anhedonia N (%)
Baseline	14 (42.4)	4 (12.1)	0 (0.0)	15 (45.5)
Visit 1	20 (60.6)	0 (0.0)	0 (0.0)	13 (39.4)
Visit 2	22 (66.7)	1 (3.0)	1 (3.0)	9 (27.3)
p-value	0.12	0.09	0.36	0.30

3.6. Demographic Factors Affecting Questionnaire Outcomes

Table 4 summarises the results of all questionnaires at the last visit divided by demographic data, such as gender, type of surgery, marital status, level of education and employment status, and the differences among the subgroups. Regarding PSC results, females, widowed, divorced/separated, and non-educated subjects reported significantly worse physical health-related quality of life than the other subgroups in each demographic factor. Subjects with primary education reported significantly lower self-esteem than other levels of education. The type of surgery and employment status did not affect questionnaire outcomes.

Table 4. Questionnaire outcomes at the last visit divided by demographic data.

Demographic Data	*N* (%)	PCS (SF-12)	MCS (SF-12)	Rosemberg Self-Esteem Scale	PHQ-4 Depression	PHQ-4 Anxiety
Gender						
○ Male	14 (42.4)	47.3 ± 8.1	47.8 ± 12.3	32.5 ± 4.8	1.5 ± 1.8	1.4 ± 1.6
○ Female	19 (57.6)	38.9 ± 12.4	46.1 ± 9.6	31.3 ± 6.6	2.1 ± 2.1	2.2 ± 1.7
p-value		0.034 *	0.652	0.572	0.432	0.157
Type of surgery						
○ Enucleation	16 (48.5)	44.9 ± 11.4	48.1 ± 9.7	32.2 ± 5.6	1.9 ± 2.0	1.9 ± 2.2
○ Evisceration	17 (51.5)	40.1 ± 11.3	45.6 ± 11.7	31.5 ± 6.2	1.8 ± 1.5	1.8 ± 1.8
p-value		0.237	0.512	0.730	0.932	0.875
Marital status						
○ Widowed	6 (18.2)	31.7 ± 12.1	47.0 ± 10.8	30.0 ± 3.1	1.7 ± 2.3	2.0 ± 2.1
○ Single	5 (15.2)	46.9 ± 8.7	43.1 ± 16.5	32.2 ± 7.4	2.0 ± 2.8	1.4 ± 1.7
○ Married	21 (63.6)	45.1 ± 10.1	47.3 ± 9.6	31.9 ± 5.0	1.9 ± 1.8	1.9 ± 1.7
○ Divorced/separated	1 (3.0)	30.1	54.9	40.0	1.0	2.0
p-value		0.031 *	0.764	0.479	0.971	0.941
Level of education						
○ No education	3 (9.1)	34.8 ± 13.3	54.7 ± 4.0	34.0 ± 5.3	1.3 ± 2.3	2.0 ± 2.0
○ Primary education	16 (48.5)	37.4 ± 10.2	42.8 ± 10.9	28.7 ± 5.2	2.6 ± 1.9	2.5 ± 2.0
○ Secondary education	7 (21.2)	50.3 ± 7.3	48.5 ± 11.4	34.9 ± 3.9	1.1 ± 2.2	0.7 ± 1.0
○ Professional training	3 (9.1)	44.8 ± 13.1	55.0 ± 4.0	36.0 ± 6.9	1.0 ± 1.0	1.3 ± 1.2
○ University education	4 (12.1)	53.0 ± 5.2	48.0 ± 10.9	34.3 ± 6.6	0.8 ± 1.5	1.5 ± 1.7
p-value		0.012 *	0.207	0.044 *	0.249	0.202
Employment status						
○ Retired	22 (66.7)	39.3 ± 11.7	46.5 ± 10.2	32.2 ± 6.1	2.0 ± 2.0	2.1 ± 1.8
○ Salaried employed	5 (15.2)	43.8 ± 7.8	46.2 ± 14.3	32.4 ± 7.8	1.4 ± 1.5	1.4 ± 1.9
○ Self-employed	1 (3.0)	57.8	54.1	33.0	1.0	0.0
○ Unemployed	4 (12.1)	50.9 ± 6.4	46.6 ± 14.1	30.3 ± 2.1	2.0 ± 2.8	1.5 ± 1
○ Others	1 (3.0)	56.6	49.5	26.0	0.0	1.0
p-value		0.113	0.971	0.851	0.848	0.655

* Statistical significance. PCS: Physical Component Summary; MCS: Mental Component Summary.

4. Discussion

After enucleation or evisceration, orbital implants are usually placed in the anophthalmic socket to restore the lost volume and enhance motility and aesthetic appearance. Despite having surgical success, excellent biocompatibility results and low complication rates [13,24], aesthetic impact is crucial regarding social interactions and health-related quality of life [1–4]. The final aim of orbital implants and external prostheses is to provide a successful long-term rehabilitation, that includes, to the extent possible, an overall lack of mental health disorders. Thus, this study aimed to compare preoperative and postoperative mental health issues after OCULFIT HDPE orbital implantation and external prosthesis placement in enucleated and eviscerated patients.

The outcomes showed that OCULFIT orbital implant and external prosthesis placement provided satisfactory overall quality of life and mental health results. The SF-12 questionnaire showed scores below 50 for both physical and mental domains (PCS and MCS) at every visit. PCS did not change over time but remained constant during the follow-up. On the other hand, MCS scores improved from baseline to Visit 2 (9 to 12 months), which means that patients' mental health became better over time.

Rasmussen [2] used the SF-36 questionnaire (the longer version of SF-12) in patients with EA or the secondary implantation of an orbital implant and found a poorer health-related quality of life, self-rated health, and more perceived stress than the general population in all dimensions of the questionnaire. Moreover, Heindl et al. [5] investigated anxiety and depression levels in 295 prosthetic eye-wearing patients. It should be noted that almost half of the sample was retired (49.3%). The mean SF-12 PCS and MCS domains for all anophthalmic patients were 47.76 $\pm$ 10.0 and 52.98 $\pm$ 8.81, respectively. As expected, patients with anxiety and depression obtained lower scores for both physical and mental domains. These results are comparable to those obtained in our study. Heindl et al. [5] reported mean PCS scores for patients with anxiety and depression of 46.09 and 43.81, respectively, and our study reported a score of 42.46 at Visit 1. On the other hand, Heindl et al. [5] reported mean MCS scores for patients with anxiety and depression of 44.97 and 44.74, and our study reported a score of 46.80 at Visit 2. These variations could be due to differences in sample sizes and follow-up times.

Regarding self-esteem, the Rosemberg scale showed no significant differences in mean scores among visits, all of them with high self-esteem results (30–40 points) even before surgery. The percentage of patients reporting high self-esteem before the operation was 66.7%, which decreased to 51.5% at Visit 1 (3–6 months) and improved again to 72.7% at Visit 2 (9 to 12 months). These findings are in accordance with the literature. Rasmussen [2] found that adjusting to life after EA wearing an artificial eye can happen during the first 6 months for the vast majority of patients, which could explain the decreased percentage of high self-esteem patients on that first visit. Additionally, Pine et al. [3] studied the level of concern after 2 years of wearing artificial eyes. The main concerns, such as the ability to judge distance, reduced peripheral vision, a change to appearance, and the movement of the artificial eye, decreased after 2 years.

In our study, patients whose main cause for eye amputation was a tumour reported a higher self-esteem (33.44 over 40 points on the Rosemberg scale) than those who suffered from glaucoma, postsurgical complications or infection, although there was no statistically significant difference. A recent investigation also reported that patients after enucleation because of uveal melanoma highly rated their postoperative cosmetic outcome, even with a higher score than by investigators [25]. This can be explained by the feeling of relief and comfort after tumorous ocular removal. Moreover, all groups in our study reported high average self-esteem under baseline conditions. In fact, many patients expressed gratitude because of the lack of pain and improved aesthetics at the end of the follow-up.

Regarding the PHQ-4 questionnaire, the mean depression (PHQ-2) and anxiety (GAD-2) scores did not significantly change among visits. It should be noted that patients already had good depression and anxiety scores even before surgery. This fact could be explained by the work status of the patients. It has been found that patients whose

occupations involved face-to-face contact were more prone to experience concerns about their appearance [3]. Here, the vast majority of the sample (66.7%) was retired, which might influence health-related results. Additionally, it must be kept in mind that patients did not see themselves with an empty socket, given that eye amputation and OCULFIT implantation were performed in the same surgical procedure, which could have yielded different results. Although the results were not significant, a tendency to lower depression and anxiety levels with time can be observed. Depression scores improved from 2.30 at baseline to 1.82 at Visit 2, whereas anxiety scores improved from 2.23 to 1.85, respectively (scale from 0 to 6). Heindl et al. [5] studied 295 anophthalmic patients wearing prosthetic eyes, and found a mean PHQ-9 score (scale from 0 to 27) of 3.01 $\pm$ 3.83 and a mean GAD-7 score (scale from 0 to 21) of 2.90 $\pm$ 4.34. Those patients with depression (24.1%) and those with anxiety (22.4%) reported higher levels of both PHQ-9 and GAD-7 scores compared to patients with no symptoms. However, no comparison can be made with the present study due to the different questionnaires used.

Finally, the major depression and anhedonia questionnaire showed excellent results. Patients with no symptoms improved from 42.2% at baseline to 60.6% and 66.7% at Visits 1 and 2, respectively. At the same time, patients reporting both depression and anhedonia decreased over time, from 45.5% at baseline to 39.4% and 27.3% at Visits 1 and 2, respectively, although the results were not significantly different. These outcomes, along with those of the PHQ-4 questionnaire, suggest that depression levels improved during the follow-up after OCULFIT implantation. The overall results of this study agree with Wang et al. [26] who studied 26 patients after hydroxyapatite orbital implant and prosthesis wearing 6 months post-implantation. Orbital implant and prosthesis placement were associated with less anxiety about one's appearance. Social relations and psychological quality of life domains also improved after implantation, with significant improvements in psychological functioning.

Additionally, the effect demographic factor might have on questionnaires results was analysed. Interestingly, men reported better physical component results of the SF-12 questionnaire than females. This finding could be explained by different cultural and social expectations about physical appearance between genders, and differences in self-esteem, body image perception and emotional expression, although this finding might be multifactorial. The widowed and divorced/separated subject also reported the worst results in this questionnaire, maybe due to the emotional impact of grief and loss, social isolation, or the changes in identity and self-worth they might experience.

Subjects with higher levels of education, such as secondary education and university studies, reported better results and higher self-esteem. People with higher levels of education typically have better health literacy, which means they have a better understanding of medical conditions, treatments, and the implications of health changes. This can lead to more effective coping strategies and a more positive outlook on their condition, which could improve their perceived quality of life.

Although the questionnaires used in this study are well-validated tools and relevant to the research, their limitations must be acknowledged. Specifically, they may not fully encompass the unique psychosocial dimensions experienced by patients undergoing EA. Future research could benefit from incorporating more specialised instruments that focus on body image and appearance-related distress. Moreover, the limited and uneven sample size of the different subgroups should be noted, which should be stated as a limitation.

The clinical relevance of our findings lies in the potential for the OCULFIT orbital implant to be considered as an option for enhancing mental health-related quality of life in EA patients. Practitioners can use this information to guide decision-making processes in ocular surgery, particularly when discussing treatment options with patients. The knowledge that the OCULFIT implant supports stable self-esteem and reduces symptoms of anxiety and depression can be a critical factor in patient consultations, especially for those who are at risk of experiencing depression or anxiety following EA.

The findings of this study underscore the critical role of mental health in the overall well-being of patients undergoing EA. Given the higher prevalence of mental disorders and the poorer health-related quality of life observed in this population, the integration of a multidisciplinary support team is essential. Such a team could proactively address mental health concerns, ensure the early identification and management of psychological issues, and ultimately enhance patient outcomes and satisfaction. Future research should focus on further exploring the long-term psychological impacts of EA and the effectiveness of targeted mental health interventions in this context. Clinically, these results highlight the need for a holistic approach to patient care, where mental health is given equal importance alongside physical recovery.

In conclusion, OCULFIT orbital implant and external prosthesis placement improved the quality of life related to mental health and maintained a stable patients' self-esteem over the follow-up. The number of patients with no symptoms improved from the baseline throughout the follow-up, and the percentage of patients simultaneously suffering from depression and anhedonia decreased at the last visit.

Author Contributions: Conceptualization: A.M.G.-H., E.G.-S., M.I.R.-L. and E.R.-d.-l.-R.-F.; methodology: A.M.G.-H., M.C.D.-R., R.M.-C., M.M.-M., Á.L.-D. and V.S.-M.; formal analysis: A.M.G.-H. and I.M.-A.; investigation: A.M.G.-H. and I.M.-A.; data curation: A.M.G.-H. and I.M.-A.; writing-original draft: A.M.G.-H. and I.M.-A.; preparation: R.M.-C., M.M.-M., Á.L.-D. and V.S.-M.; writing-review and editing: A.M.G.-H., I.M.-A., E.G.-S., M.I.R.-L. and E.R.-d.-l.-R.-F. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by AJL Ophthalmic S.A. (Vitoria, Basque Country, Spain).

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of Hospitales Universitarios Virgen Macarena (protocol code 0104-N-21 and date of approval 15/03/21).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest: The authors declare no conflict of interest.

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