REDUCING THE FAILURE RATE OF OCULAR PROSTHESIS AT HOSPITAL SULTANAH AMINAH

Muhamad Imran Abdulah[1], Ikmal Abdul Hakim[1], Rosni Amin[1], Rosliza Parumo[1], Ma Bee Chai[1], Rolzilah Rohani[2], Noraziyah Abdul Aziz[3], Hisyam Zainal Abidin[3]

[1]Oral Maxillofacial Surgery Department
Hospital Sultanah Aminah, Johor Bahru, Johor

[2]Oral Health District Office, Johor Bahru, Johor

[3]Oral Health Division, State Health Department, Johor

Corresponding Author: Muhamad Imran Abdullah
Email: emilioversache@gmail.com

Abstract

The Department of Oral & Maxillofacial Surgery at Hospital Sultanah Aminah, Johor Bahru started managing patients who lost their eyeballs with ocular prosthesis in 2013. Unfortunately, there was an increasing trend of failed ocular prosthesis from 2013-2015. The failure rate went from 28.6% in 2013 to 40% in 2014 and increased to 44.4% in 2015. Failed ocular prosthesis not only leads to dissatisfied patients but also an increase in cost due to redoing of prosthesis. The objective of this project was to reduce the incidence rate of failed ocular prosthesis. A failed case is when the prosthesis does not pass the issue stage and has to be redone from the beginning. The standard failure rate is 0%, as the average number of cases per year is only about 10 cases. We determined the contributing factors of failed ocular prosthesis by analysing retrospective data from patients' dental and lab records. This was followed by a self-administered questionnaire on reasons for failed cases which was distributed among the dentists and lab technicians in our department. The contributing factors that were identified included insufficient knowledge or skill of dentist and lab technicians in the construction of the ocular prosthesis, as well as improper screening of new cases which was the main factor of all the failed cases. The strategies for change included improving the process of care by creating a checklist for proper screening of new patients, mentoring of new staff, and continuous training on construction of ocular prosthesis, Fabricated Iris Mould innovation technique and early referral for insertion of eye conformer. The interventions that were implemented reduced the failure rate to 20% in 2016 followed by 0% in 2017, 2018 and 2019. Ongoing efforts are being done to replicate this project in other Oral & Maxillofacial Surgery clinics in Johor.

KEYWORDS: Ocular prosthesis, failure rate, Fabricated Iris Mould, eye conformer

Problem

Hospital Sultanah Aminah, Johor Bahru (HSAJB) is the official state hospital of Johor. HSAJB accepts referrals from primary and secondary level government healthcare centres, as well as from private healthcare centres. In our Oral and Maxillofacial Surgery (OMFS) department at HSAJB, we receive referrals from external and internal sources, including from the ophthalmology department for ocular prosthesis for patients who have undergone evisceration, enucleation or exenteration of the eye. Our department receives an average of 10,000 patients per year with variable conditions and illness related to OMFS, but the number of patients referred for ocular prosthesis averages only about 10 per year.

Despite the small number of patients referred for ocular prosthesis, we noticed an increasing trend of failed cases of ocular prosthesis. Total patients with failed ocular prosthesis increased from 28.6% (two out of seven) in 2013, to 40% (four out of ten) in 2014. In the year 2015, the failed ocular prosthesis rate increased to 44.4% (four out of nine). This showed an exponential increase in the failure rate of ocular prosthesis from the year 2013 to 2015.

A failed ocular prosthesis may lead to dissatisfied patients, which could affect their social and psychological wellbeing, and they could become a potential complaint or file a lawsuit against our department. A failed ocular prosthesis could also be a potential source of infection and irritation and lead to a significant increase in cost due to repairing or redoing the prosthesis. The cost of constructing an ocular prosthesis can amount up to MYR 5,000.00, thus, redoing an ocular prosthesis case would double the cost. Previously, patients had to pay a MYR 100.00 fee for the construction of an ocular prosthesis. Fortunately, this fee is currently fully subsidised and patients do not need to pay for the ocular prosthesis construction according to the Fee Order (Medical) 2017 Ministry of Health Malaysia. This highlights the vast gap in the cost needed to construct one ocular prosthesis, compared to the zero-amount charged to patients to obtain one. Therefore, it is crucial not to have a failed ocular prosthesis, which would lead to an increase in the already high cost. The process of constructing an ocular prosthesis is very complicated especially during the lab processing stage and requires a skilled dental technician who have undergone OMFS post basic training. The aim of this study was to decrease the failure rate of ocular prosthesis at HSAJB to zero percent within one year.

Background

Eye loss resulting from congenital malformation, tumour treatment, or trauma may lead to social, family and psychiatric problems. A mutilated face can affect the patient's self-esteem due to difficulty in establishing emotional ties, new life style, insecurity, and rejection, as shown in a study where an average of 60% of patients suffering from eye loss exhibited these symptoms (1). An ocular prosthesis, artificial eye or glass eye, is a type of craniofacial prosthesis that replaces an absent natural eye following an orbital enucleation, orbital evisceration, or orbital exenteration (2,3). Ocular prosthesis differs from ocular or orbital implants where an ocular prosthesis is made purely from polymethylmethacrylate (PMMA) material with no points for implant insertion. A study done in South Korea showed that 71.8% of the patients were satisfied with their initial ocular prosthesis post-evisceration or post-enucleation (4).

Limited literature is available on the average failure rate of ocular prosthesis in a community. However, according to Leatherbarrow et al., out of 44 patients who received ocular prosthesis at a hospital in Manchester, Britain, six patients presented with failed ocular prosthesis (13.6% failure rate) where the reason of failure was their eye socket anatomy and they needed a secondary surgery to repair the eye socket

to redo the ocular prosthesis successfully (5). Another study done at Jules Stein Eye Institute; Los Angeles showed a zero percent failure rate (zero out of nine patients) who were reviewed on average of four years (6). Compared to these studies, our department had an alarmingly high failure rate at 44.4%. As stated previously, only a few studies on successful ocular prosthesis has been reported in literature, hence providing limited evidence on successful ocular prosthesis strategies.

Measurement

The general objective of this project was to reduce the incidence rate of failed ocular prosthesis at HSAJB. The specific objectives included identifying contributing factors of failed ocular prosthesis, implementing remedial actions that address the contributing factors and evaluating the effectiveness of the remedial actions taken.

The indicator used in this study was the failure rate of ocular prosthesis at HSAJB. The calculation formula for the indicator was:

$$= \frac{\begin{array}{c}Number\ of\ failed\ cases\ of \\ ocular\ prosthesis\ issued \\ for\ a\ particular\ year\end{array}}{\begin{array}{c}Total\ number\ of\ all\ selected\ cases \\ for\ ocular\ prosthesis, \\ for\ the\ same\ particular\ year\end{array}}\ x\ 100\%$$

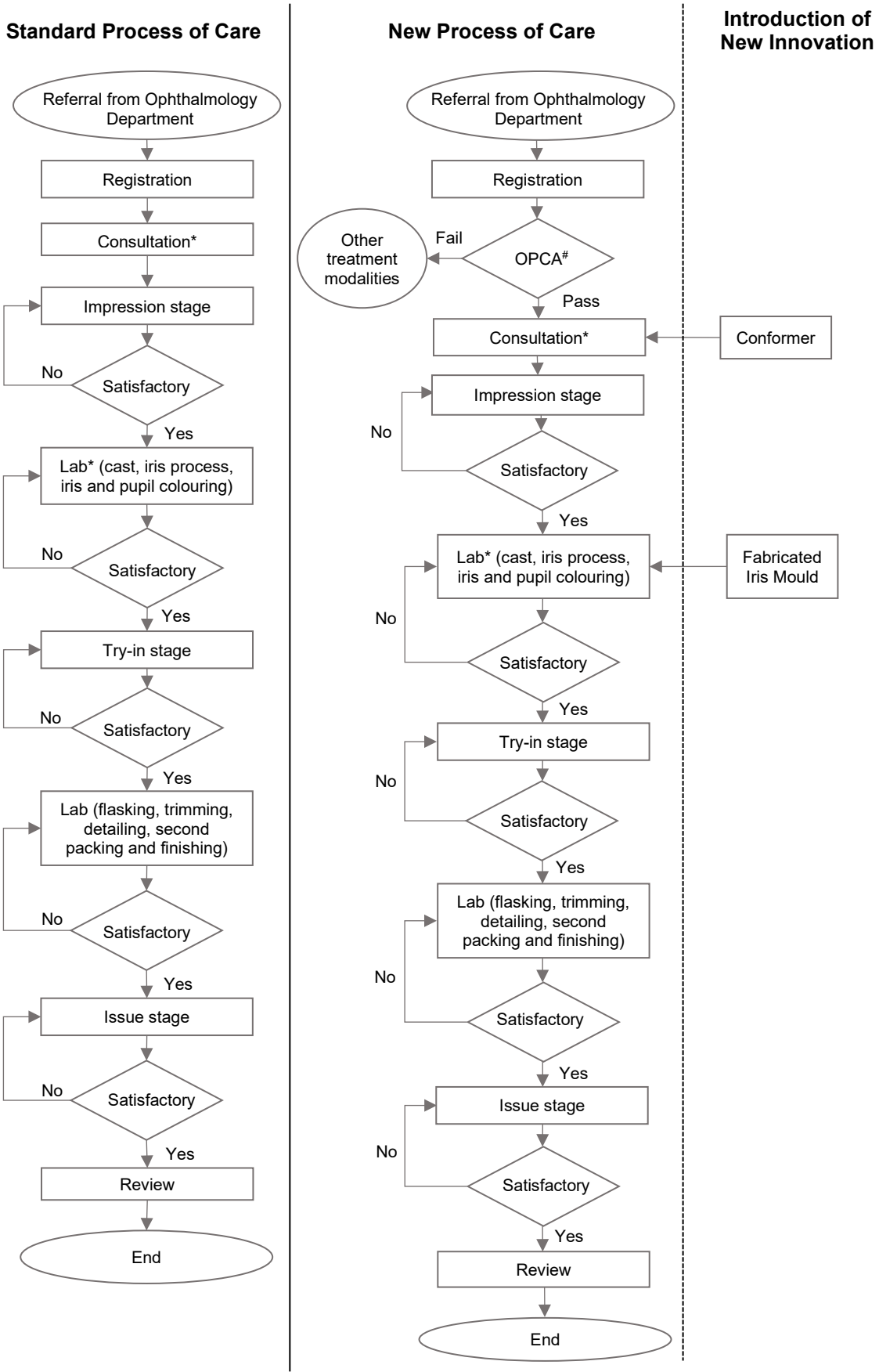
According to DM Meisler et al., (7) an ocular prosthesis fails when it causes irritation or infection in an eye socket. In our department, an ocular prosthesis was considered failed when an ocular prosthesis did not pass the issue stage (as stated in the Process of Care (POC), Figure 1) of the prosthesis and the whole clinical and lab process must be repeated to re-issue the ocular prosthesis. According to our Model of Good Care (MOGC, Table 1), during the issue stage, the dentist and dental technician need to ensure that the ocular prosthesis fits well in the patient's eye socket, appears natural, the color, shape and position of the iris on the ocular prosthesis is similar to the adjacent eye, and the ocular prosthesis does not cause irritation to the patient. The standard failure rate is 0% as the total number of issued ocular prosthesis averages to only about 10 cases per year. The standard was determined by our Head of Department with the consensus of our OMFS specialist.

This quality improvement study was conducted in the OMFS Department in HSAJB from June 2015 to December 2019. Data was collected by reviewing dental records of ocular prosthesis patients from 2013 to 2019 (LP6 Dental Laboratory card and LP8 Dental Clinical card). Data was also collected every time an ocular prosthesis patient came for their appointment. The inclusion criteria included any ocular prosthesis cases in HSAJB, which was referred to our department. Exclusion criteria was any ocular prosthesis cases in HSAJB where the patient failed to attend their appointment during any stage of their treatment.

Initial Assessment of the Problem

A verification study was done from June 2015 to November 2015 where the failed ocular prosthesis cases were analysed to determine the reasons of failure by reviewing the patients' dental records. It was determined that 90% (nine of out 10 cases) of the failed cases were due to anatomical reasons, while 10% (one out of 10 cases) of the failed cases were because of psychological reasons (Table 2). Further analysis was done on poor anatomical eye socket cases to determine the factors that caused this problem.

In December 2015, a survey was conducted by distributing the questionnaire among the three specialists, seven Dental Officers, Officers, seven First Year Dental Officers (FYDO) and three Dental Technicians from the OMFS department (total n=20). The questionnaire listed four potential contributing factors where the respondents had to score each factor from one to five, with five score being the highest potential factor.



* *Critical steps*
\# *Ocular Prosthesis Criteria Assessment*

Figure 1: Standard Process of Care versus New Process of Care.

Table 1: Comparison of Model of Good Care Before and After Remedial Measures.

No.	Process	Criteria	Standard	Verification	Cycle 1	Cycle 2
1.	Registration	Ensure the correct patient is referred to the OMFS department	100%	100%	100%	100%
		Ensure the details of the patients are properly registered and documented	100%	100%	100%	100%
2.	Consultation	To determine if patient is both physically and mentally fit for ocular prosthesis treatment	100%	50%	100%	100%
		To examine the condition of the eye socket prior to treatment.	100%	50%	70%	100%
3.	Impression stage	Impression taken using alginate	100%	70%	70%	100%
		To ensure all borders of the eye socket taken properly	100%	70%	70%	100%
4.	Lab (cast, iris process, iris & pupil colouring)	To cast impression with methacrylate resin	100%	70%	70%	100%
		To fabricate iris & pupil by taking into account the appearance of the adjacent eye	100%	50%	50%	100%
5.	Try-in stage	To ensure the wax try-in fits properly in the eye socket and does not displaced	100%	70%	70%	100%
		To ensure position, colour and shape of iris is the same as the adjacent eye	100%	70%	70%	100%
6.	Lab (flasking, trimming, detailing, second packing & finishing)	To invest, cure, detailing, second invest process and finishing of prosthesis	100%	70%	80%	100%
		To ensure anatomical characterization was done using acrylic paints to simulate the veins and follow the actual colour of adjacent eye	100%	70%	80%	100%

7.	Issue stage	Ensure the ocular prosthesis fits well in the eye socket and appear natural	100%	70%	75%	100%
		Ensure the colour, shape and position of the iris on the ocular prosthesis is similar to the adjacent eye	100%	76%	85%	100%
		Does not cause irritation to patient	100%	70%	80%	100%
8.	Review stage	To review the patient's compatibility with the ocular prosthesis	100%	100%	100%	100%
		To see if any problems arise such as irritation, looseness of ocular prosthesis or others	100%	100%	100%	100%

Table 2: Category of failed ocular prosthesis at HSAJB 2013-2015.

Year	MRN Patient	Age	Type of ocular prosthesis	Reason of Failure
2013	A1	8	Left eye prosthesis	Growth in eye socket
2013	A2	9	Left eye prosthesis	Too shallow eye socket
Total number of failed ocular prosthesis in 2013: 2. Total issued: 7				
2014	B1	59	Right eye prosthesis	Socket not properly healed
2014	B2	30	Right eye prosthesis	Too deep eye socket
2014	B3	64	Left eye prosthesis	Growth in eye socket
2014	B4	10	Right eye prosthesis	Patient mentally ill
Total number of failed ocular prosthesis in 2014: 4. Total issued: 10				
2015	C1	35	Left eye prosthesis	Eye socket space too big
2015	C2	11	Left eye prosthesis	Sutured eye socket
2015	C3	44	Right eye prosthesis	Eyeball still present in socket
2015	C4	16	Right eye prosthesis	Too much eye discharged
Total number of failed ocular prosthesis in 2015: 4 Total issued: 9				

The cumulative points for each question would determine the importance of the contributing factor. From the survey, it was determined that improper screening process was the main contributing factor (90 points), followed by lack of knowledge in construction of ocular prosthesis (75 points), poor skills in clinical procedure (60 points) and finally, poor material used for ocular prosthesis (30 points).

The POC (Figure 1) was also evaluated and we found two most critical processes in the POC that did not comply with the MOGC standard (Table 1). The first was Consultation, where the clinical operator was supposed to determine if the patient was both physically and mentally fit for ocular prosthesis treatment, as well as examine the condition of the eye socket prior to treatment. We only managed to achieve 50% for this process. The second critical process, Lab (cast, iris process, iris and pupil coloring) is where the Dental technician needed to cast an impression with methacrylate resin (achieved only 70%) and fabricate the iris and pupil by taking into account the appearance of the adjacent eye (achieved only 50%). Other critical steps in the MOGC also did not obtain 100%.

After analysing all the data, the main contributing factors were determined. The first contributing factor was the improper screening process; there was no guideline on proper screening for ocular prosthesis cases, which led to cases of patients with improper orbital anatomy and poor psychological condition being accepted for ocular prosthesis. We also had other issues such as immature post-operative referral and high patient's expectations upon initiation of treatment. The second contributing factor was the lack of knowledge or skill in construction of ocular prosthesis, inexperienced Dental Technicians, and complicated lab procedures. Finally, the third contributing factor was insufficient skill or experience in taking impression for ocular prosthesis, and inexperienced Dental Officers. The lack of Continuous Dental Education (CDE) was also apparent for all the contributory factors, which led to improper screening, lack of skill during impression taking and during construction of ocular prosthesis.

Strategy

We conducted two phases of remedial measures. The first phase was from January 2016 to December 2016 and the second phase was from January 2017 to December 2017.

a) First Phase:

During the first phase of remedial measure, we tackled the improper screening process factor by having a CDE in January 2016 on proper screening of patients suitable for ocular prosthesis. This CDE involved New Dental Officers from the OMFS department as well as new Medical Officers from the Ophthalmology Department, HSAJB. This was followed by a screening checklist, Ocular Prosthesis Criteria Assessment (OPCA, Appendix 1), that was created and distributed to the OMFS department on 10 January 2016, which functioned as a guideline in referring patients for ocular prosthesis. This checklist was reviewed and approved by our OMFS Head of Department and Specialists. The OPCA screening checklist acted as a "gatekeeper" where any patients that required an ocular prosthesis must pass the checklist before they could be listed on our waiting list for construction of the ocular prosthesis. The checklist contained two sections; the first section assessed the patient's psychosocial and physical state to determine if he or she was mentally stable and in good physical state to be selected for ocular prosthesis treatment. The second section was an assessment of the eye socket to evaluate if it was in optimal condition for ocular prosthesis. Patients with conditions such as residual, growth, tissue tag or sutures in the eye socket were considered non-optimal and should not be issued with ocular prosthesis. Depth of eye socket and width of the eye fissure was also considered in the checklist. This ensured the patient's eye socket was in an optimal condition prior to the start of the treatment.

Next, we tackled the lack of knowledge or skill in construction of ocular prosthesis factor by having a CDE in April 2016 on construction of ocular prosthesis for new dental technicians involved in ocular prosthesis construction. We also started a mentoring program for new staff, where the new staff (usually dental technicians) would be mentored and supervised by a senior staff (supervisor). The mentoring program was carried out throughout 2016.

b) Second Phase:

After re-evaluation of the first phase, despite the interventions done, we noticed that there were still cases with improper orbital anatomy, and complicated lab procedures were still an issue. So, in the second phase, we continued all remedial measures that were conducted in the first phase with an addition of two new remedial measures. The first strategy tackled the improper orbital anatomy by having patients being referred earlier for insertion of eye conformer, especially for patients with post evisceration or enucleation of the eye. By having an eye conformer (pre-shaped clear acrylic shell) inserted immediately post evisceration or enucleation of the eye (within two weeks), it helped hold the shape of the eye socket for easy insertion of the ocular prosthesis later upon construction. The second remedial measure tackled the complicated lab procedures factor by the innovation of a prefabricated iris mould, Fabricated Iris Mould (FIM, Table 3). During the iris process stage of the ocular prosthesis construction in the lab, the iris sizes are usually limited due to the limited resources in purchasing the original cast to create the synthetic iris. By having this FIM innovation, where we created our own synthetic iris with variable iris sizes, we not only drastically reduced the overall cost of the ocular prosthesis but also eased the lab procedure as the FIM method was a less sensitive technique. By the end of the second phase, we had created a new, more efficient POC (Figure 1) compared to the standard POC.

Results

The first remedial measure phase was completed in December 2016 and was evaluated in January 2017. The failure rate reduced from 44.4% from the previous year to 20% (three out of 15) in 2016. Despite the lower failure rate, we still did not manage to obtain our target, thus the failed cases were re-evaluated. Two cases had shallow eye socket (improper orbital anatomy) as reasons of failure, and one case had improper size of iris (limited iris size available in the lab). Reassessment of the MOGC (Table 1) showed improvement but it was still not optimal. Since we were unable to achieve a zero percent failure rate, we proceeded with another remedial measure phase for another year.

After implementation of two additional remedial measures during the second phase, we managed to obtain zero percent failure rate (zero out of 8). Re-evaluation of critical steps implementation in the MOGC also showed 100% achievement for all steps (Table 1). All remedial measures were continued in the subsequent years and we managed to maintain zero percent failure rate in 2018 and 2019 (Figure 2).

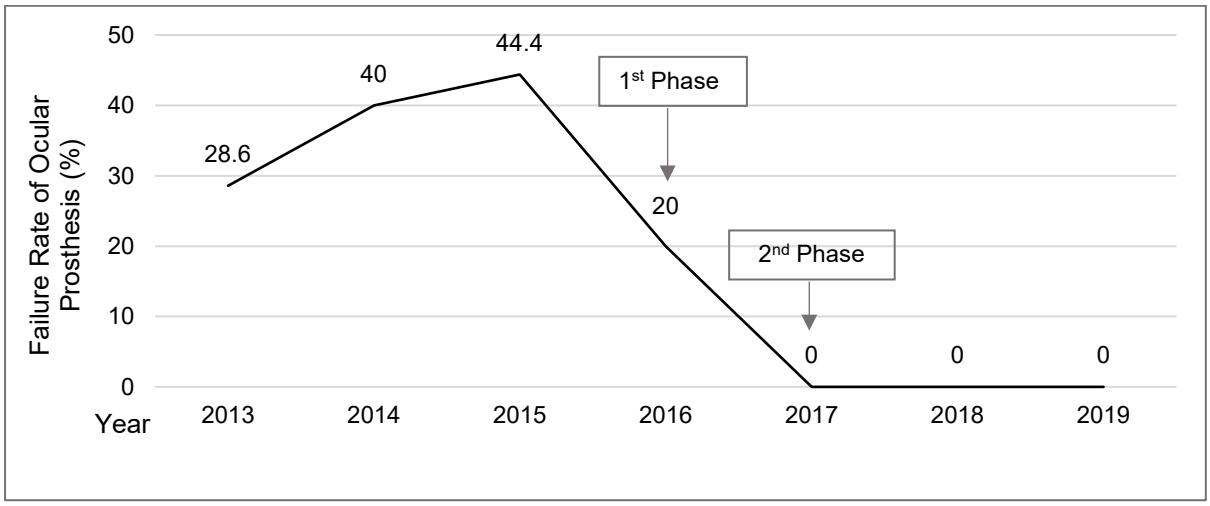
Lessons and Limitations

This project highlighted the many issues that our OMFS department faced in providing ocular prosthesis treatment for patients, which caused an increase in failure rate of ocular prosthesis at HSAJB during the first few years. This was perhaps due to fact that the OMFS department just started ocular prosthesis treatment in 2013, where all the staff and doctors were new to this treatment. There was also no national guideline in ocular prosthesis referral of treatment which led to this problem. By initiating this QA project, we managed to improve the treatment of ocular prosthesis patients, thus increasing patients' satisfaction and their overall quality of life.

Table 3: Comparison between standard lab method with FIM method.

Before FIM	After FIM
	
Limited iris size	Variable iris size
High risk of iris post breakage	Eliminate risk of iris post breakage
Difficulty in iris removal from mould	Simplified iris removal from mould (less technique sensitive)
Whole process of iris construction cost MYR 3,007.60	Whole process of iris construction cost MYR 5.70

FIM: Fabricated Iris Mould.



Year	2013	2014	2015	2016	2017	2018	2019
No. of issue	7	10	9	15	8	11	8
No. of failure	2	4	4	3	0	0	0
Failure rate	28.6%	40%	44.4%	20%	0%	0%	0%

Figure 2: Failure rate of ocular prosthesis at HSAJB from 2013 – 2019.

By having a zero percent failure rate, we managed to save a huge amount in constructing ocular prosthesis. Since the project started, we managed to save up to MYR 50,000, and by the end of the project we reduced the cost of one ocular prosthesis from approximately MYR 5,000 to MYR 2,000, effectively saving around MYR 3,000 per ocular prosthesis.

We also acknowledge certain limitations in our project where our remedial measures might only be applicable to our department and hospital. Further review of feasibility and suitability of the remedial measures will be needed if implementation of these remedial measures at higher level (for example national level) is to be considered. Our data is also limited to be used in Malaysia as the treatment of constructing ocular prosthesis in other countries is not limited to the OMFS Department.

Conclusion and Next Steps

This project managed to identify the factors that led to the increasing failure rate of ocular prosthesis at HSAJB. By formulating and implementing relevant remedial measures that tackled the identified factors, we managed to reduce the failure rate from 44.4% to the standard of zero percent. By doing so, we not only managed to provide the best treatment for patients in need of an ocular prosthesis, but also reduced the overall cost of constructing the ocular prosthesis via the FIM innovation. By having zero percent failure rate, we also prevented doubling the cost of constructing an ocular prosthesis for the same patient.

To maintain zero failure rate for ocular prosthesis, the project is still being conducted and monitored. Therefore, ongoing efforts must be maintained to further enforce and advocate the preventive measures, as well as maintain zero percent failure rate of ocular prosthesis. This project was presented to all Johor District Dental Officers on 8 April 2019 for suggestion of project implementation in all OMFS departments in the state of Johor. This project will also be evaluated by the headquarters for potential national-level replication.

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Conflict of Interest

None.

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Appendix 1

OCULAR PROSTHESIS CRITERIA ASSESSMENT (OPCA)

NAME	:		AGE	:
NRIC NO.	:		RACE	:
SEX	:		OCCUPATION	:
ADDRESS	:		DATE	:
EYE HISTORY	:	TRAUMA/NON-TRAUMA (OTHERS: ……)		

SECTION A: PATIENT'S PSYCHOSOCIAL & PHYSICAL STATE

- Mentally Stable ☐
  - Functioning at satisfactory level of emotional and behaviour with/without underlying mental illness (able to work and live)
- Cooperative ☐
  - Able to obey command and adapt to changes
- Loss of unilateral eye ☐

*Patient has to **fulfil all criteria** in **Section A**. Kindly reassess the need or appropriateness for ocular prosthesis if criteria are not met.*

SECTION B: CONDITION FOR EYE SOCKET FOR OCULAR PROSTHESIS

I. a. Residual eye in socket ☐
   b. Growth of soft tissue/present of tissue tag in eye socket ☐

For patient with above criteria, surgical removal and review is needed, patient need to be referred back.

II. a. Sutured eye socket ☐
    b. Eye socket swelling ☐

For patient with above criteria, to be referred back for further review.

III. a. Eye socket too deep (socket depth >12mm) ☐
     b. Eye socket swelling ☐

For patient with above criteria, need implant prior ocular prosthesis

IV. a. Drop lid ☐
    b. Eye size too small compare to contralateral (socket depth/fissure width <8mm) ☐

For patient with above criteria, ocular prosthesis can be made but with unfavourable aesthetic. Explanation to patient is needed prior to start of treatment.

Attending Doctor
