Personalized 3D ocular prosthesis vs Conventional prosthesis

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The aim of this study is to compare the 3D designed prosthesis with the conventional made prosthesis.Study questions:- How is the 3D designed prosthesis compared to the conventional prosthesis? The final chosen workflow and settings will be applied...

Ethical review	Approved WMO
Status	Pending
Health condition type	Ocular injuries
Study type	Interventional

Summary

ID

NL-OMON56495

Source
ToetsingOnline

Brief title
3D designed ocular protheses

Condition

- Ocular injuries

Synonym
Post enucleation/evisceration

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: KIKA

Intervention

Keyword: Artificial eye, Ocular prosthesis, Retinoblastoma

Outcome measures

Primary outcome

Well-being of the patient is measured by a validated quality of care and life questionnaire. Three domains will be assessed; wearing comfort, physical appearance and motility and psychosocial functioning. Each domain has 5 questions with answers from fully agree to fully disagree on a 5-point Likert scale. Outcomes per subdomain are obtained by summing all scores in that subdomain and can range from 5 to 25. The total score is obtained by summing the three subdomain scores and can range from 15 to 75. We choose for a difference of 15 points on the total score between the 3D designed prosthesis and the conventional prosthesis to be clinically relevant as non-inferiority margin. This number is chosen because the total number of questions is 15 and the average interquartile range is approximately 1 point for each question.

Two prostheses (one conventional made and one 3D designed version) will be compared, the patients already wear the conventional and the newly designed prosthesis will be worn for 3 weeks. At the end of each period the participant is asked to fill out a questionnaire. The researcher will check (optional: telephone, whatsapp) with the patient that he/she actually fills out the form.

Comparative analysis between 3D vs conventional scores will be done by estimating the 90% confidence interval of the difference. In case the lower

bound of this confidence interval is above a score difference of -10, the 3D designed prosthesis is proven to be non-inferior compared to the conventional prosthesis.

Secondary outcome

Facial symmetry measurements will be done using a 3D laser scanner. Scans will be scored on defined prosthetic fitting parameters:

- pretarsal show symmetry (mm),
- superior sulcus volume symmetry (mm displacement),
- upper lid position (MRD1) symmetry,
- lower lid position (MRD2) symmetry,
- horizontal palpebral fissure symmetry (mm);
- lagophthalmos symmetry(mm with eyelids closed).

Individual parameters will be compared using a paired t-test with significance at 0.05. By visual inspection of the results (histograms) we will check whether the data are normally distributed. If the results are not normally distributed a Wilcoxon signed-rank test will be used

Motility of the artificial eye(s) is measured using an eyetracker

-the eyetracker measures eyemovements in 4 directions of gaze (superior, inferior, nasal and lateral)

- before the measurements the eyetracker is calibrated on both the healthy eye, and the artificial eye; The artificial eye is calibrated with help of a gimbal that holds the prosthetic eye, and which is directed at pre-set gaze directions with a laser pointer

- the directions will be compared for each of the 4 directions between the conventional vs 3D designed prosthesis

- all results will be expressed as the percentage of movement of the affected eye vs the normal healthy eye

-Analysis will be done in SPSS. Comparison between the 3D designed prosthesis and the conventional produced prosthesis will be done using a paired t-test for each direction of gaze, and also for the sum of the four gaze directions. Individual directions, and the total sum will be compared and tested using a paired t-test with significance at 0.05. By visual inspection of the results (histograms) we will check whether the data are normally distributed. If the results are not normally distributed a Wilcoxon signed-rank test will be used.

Subjective prosthesis opinion

The prosthetic surface will be evaluated with 2D photographs using a 5-point likert scale: the reviewers will be blinded for the 3D/conventional prosthesis and asked to score on:

- Balance iris/sceral show - corresponds with the healthy eye - strongly disagree, disagree, neither disagree or agree, agree, strongly agree)

- iris colour/details - corresponds with the healthy eye - strongly disagree, disagree, neither disagree or agree, agree, strongly agree)

- sclera colour - corresponds with the healthy eye - strongly disagree, disagree, neither disagree or agree, agree, strongly agree)

- number of veins - corresponds with the healthy eye - strongly disagree, disagree, neither disagree or agree, agree, strongly agree)

Data will be analyzed using a paired t-test with significance at 0.05. By visual inspection of the results (histograms) we will check whether the data are normally distributed. If the results are not normally distributed a Wilcoxon signed-rank test will be used

Overall subjective professional opinion (5-point Likert scale)

Short movies will be made to test the appearance in the most realistic setting. The movies will be blinded for the 3D/conventional prosthesis. Professionals are asked if the prosthesis looks disturbing giving these 5 answer options; Strongly disagree, disagree, neither disagree or agree, agree, strongly agree. Using a paired t-test with significance at 0.05. By visual inspection of the results (histograms) we will check whether the data are normally distributed. If the results are not normally distributed a Wilcoxon signed-rank test will be used.

Study description

Background summary

Retinoblastoma is one of the most common eye tumors in childhood. Most children are very young during diagnosis (<5 years). In the Netherlands annually 10-12 children get diagnosed with retinoblastoma. It can occur at both eyes or at one eye. The visual acuity can be decreased with large tumors or tumors with a position in the macula. Survival prognosis is good with timely diagnosis and treatment, 90% of patient lives 5 years after diagnosis. Treatment consists of one of the following options; Removal of the affected eye (enucleation), local therapy (laser- or cryotherapy) chemotherapy (local or systemic) or

radiotherapy (local or external). The eye will be removed in case the eye is filled with tumor, no vision is possible and/or chance of metastasis. After enucleation an orbital implant is placed that fills the volume loss, and subsequently a prosthesis is made by the ocularist.(1).

Their remaining life these children will become dependent on a prosthesis. Our earlier studies showed that retinoblastoma patients can experience a decreased quality of life because of bullying for their deviant appearance with the artificial eye.(2). In another study of our group(3) it was shown that in 56.7% of patients an improvement of appearance can be obtained with adaption of the prosthesis, and possible surgical correction. As children grow, frequent adaption of the prosthesis is needed for an optimal result. In the first year after the eye removing operation frequent renewal is needed for every patient because of the volume decrease in the first year after operation. But also after the first year alterations of the socket occur meaning that also in adulthood the prosthesis need frequent renewal. Our experience learns that small alteration can have a big influence on the patients wellbeing and satisfaction if the alteration result in a more natural looking eye. (4-7).
The production of an ocular prosthesis is a manual process with trial and error till the correct fit is found. This process requests much patience, especially with children what can be a tough situation. The results can then be disappointing(8). For everyone and especially with children it is beneficial if the process of making a fitting prosthesis is quicker and more target based. Beside the model, the colours and textures are an important aspect for a natural looking prosthesis. The natural eye reflects light on a different ways with different environmental lights. Thise is due to the 3 dimensional aspect of the iris with its crypts and folds where the colour pigments are divided on different layers of the iris. The colour of an iris is conventionally made on a 2 dimensional surface with paint and the pupil is made by a black spot in the centre of the iris
In our experience with microphthalmia children we experienced that 3 dimensional planning can be an important tool in developing prostheses for children born without or with a too small eye. In these situations we have the advantage that a MRI scan is made where the imprint of the eye socket is scanned. With these images the ocularist can design a first prosthesis taking the maximum values of the orbital dimensions and total surface of the prosthesis into account. Using analysis we calculated the needed size-upscale for subsequent prostheses in the treatment of these patients. A downside is that it is only possible to print these 3 dimensional designed prostheses in one colour. In this group we accept it because the primary objective is to obtain a sufficient growth of the eye socket.

Study objective

The aim of this study is to compare the 3D designed prosthesis with the conventional made prosthesis.

Study questions:

- How is the 3D designed prosthesis compared to the conventional prosthesis? The final chosen workflow and settings will be applied to retinoblastoma patients who are in need of a new prosthesis. They will both receive a conventional made model and a new 3D designed model and be asked to use both for several weeks. The hypothesis is that the 3D produced eye is not inferior to a conventional created prosthesis (cosmetics and comfort) and is faster in production with lower burden to the patient. Subjective patient satisfaction the main outcome measurement. We will also do objective measurements to compare symmetry between artificial eye and the fellow normal eye, for both the 3D designed eye and the conventional artificial eye. The motility will be compared using eyetracker-based motility measurements.

Study design

Single group crossover intervention study

Intervention

Participants will receive an impression of the eye socket (which is already being done in complicated eye socket cases). Additionally, participants will be provided with a photo of the healthy eye to replicate its colors and structures (this is also already done in regular practice). Afterward, participants will return to test the 3D designed prosthesis. We will perform a 3D measurement and eye movement analysis using an eyetracker for both the 3D designed prosthesis and the conventional prosthesis. (Both examinations have already been conducted and tested on participants with eye prostheses in a previous study).

Study burden and risks

The fitting process will be no different from a standard fitting process, including a mould of the socket, an iris picture and a fitting-trial for the contour and comfort.
- Current normal practise is a visiting number of 2-3 visits to receive the final prosthesis. In the trial the patients need to come 3 times.
- The extra burden during the visit consists of extra imaging with a hand-held 3D scanner (1 minute per scan, three in total), and extra motility tests with an eye-tracker (max 30 minutes).
- 3D designed prosthesis for 3 weeks. At the end of the 3 weeks the patient is asked to fill out a quality of life questionnaire.
- Rarely, a patient reacts to an ocular prosthesis with an allergic reaction, notable as a red, irritated socket. Since the patient is already wearing an acrylic prosthesis, it is not expected that there will be a difference with respect to allergies.
- It can occur that the patient will have to wait several weeks before the

batch of 3D designed prostheses is finalized. Yet the patient will remain wearing his/her original prosthesis.

There is no absolute risk, except that the patient is asked to wear an ocular prosthesis for 3 weeks that in the worst case is not optimal comfortable. Yet, with the final fitting trial we will adapt the shape to a maximal comfortable fit. Also, the procedure is not different from the normal situation where the patient is fitted with a new prosthesis. The benefit can be that the 3D designed prosthesis is be better appreciated than a conventional prosthesis, and when that is the case, the patient can keep the prosthesis. Also the data regarding colour and geometry is saved so that a future prosthesis can be replicated easily with or without small adaptations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 16 or older
Able to understand the study information and instructions
Patients already using an ocular prosthesis for at least 6 months
Cases after enucleation, evisceration, or a prosthesis worn over the own blind eye

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
Newly eviscerated or enucleated patients
Socket pathology (cyst, infection, exposure, contraction)
Not able to understand the study information and instructions

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-10-2023
Enrollment:	34
Type:	Anticipated

Medical products/devices used

Generic name:	Ocular prosthesis
Registration:	No

Ethics review

Approved WMO Date:	19-12-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85034.018.23