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Customizing a cryolite glass prosthetic eye

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TITLE:

Customizing a Cryolite Glass Prosthetic Eye

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SUMMARY:

This manuscript shows each step of customizing a cryolite glass prosthetic eye including some major advantages of the use of cryolite glass for manufacturing an eye prosthesis compared to poly(methyl methacrylate). In addition, this manuscript gives ophthalmologists better insight into the ocularistic care that could improve interprofessional collaboration.

ABSTRACT:

In Germany, Austria, and Switzerland, over 90% of ocularists still manufacture customized prostheses using cryolite glass from Thuringia. The present manuscript demonstrates this long-forgotten technique in detail. This manuscript shows some major advantages of manufacturing prosthetic eyes using cryolite glass in comparison to poly(methyl methacrylate) (PMMA). These advantages include a lighter weight of the prosthesis, higher levels of patient satisfaction, and only one appointment necessary for the customized manufacturing. Potential risk of breakage seems not to be a critical disadvantage for glass prosthetic eye wearers. However, in some patients, manufacturing a well-fitting prosthetic eye is not possible or reasonable due to anophthalmic socket complications such as post nucleation socket syndrome, scarred fornices, or an orbital implant exposure. This article gives ophthalmologists a better insight into ocularistic care in order to improve the essential interprofessional collaboration between ocularists and

ophthalmologists.

INTRODUCTION:

The purpose of the present manuscript is to comprehensively demonstrate the technique of manufacturing a customized cryolite glass prosthetic that is long forgotten outside the German-speaking countries (**Figure 1**). This manuscript also focuses on major advantages of this technique. These include a very smooth surface of the prosthesis due to fire polishing, the light weight of the prosthesis due to the hollow design, high levels of patient satisfaction, and the need of only one appointment for manufacturing of the customized prosthesis[1-5]. This article also gives ophthalmologists better insights into ocularistic care in order to improve essential interprofessional collaboration[1-5].

In 1832, the glassblower Ludwig Uri Müller from Thuringia, Germany, developed the cryolite glass prosthetic eye based on the class-leading models made in France[4]. Benefits of cryolite glass included a better look, better tolerability, easier processing, and longer durability than previous glass eyes[4,6-8]. Herman Snellen, a Dutch eye surgeon, used this cryolite glass to produce a lightweight hollow prosthetic eye in 1880[4,6-8]. This lightweight prosthetic eye, the Snellen 'reform eye', increased the volume of prosthetic eyes, resulting in better fitting into larger eye sockets following the introduction of enucleation procedures made possible by the development of anesthesia and asepsis[4,8]. Twenty years later, cryolite glass had become the most commonly used material for prosthetic eyes. Germany developed into the manufacturing center of prosthetic eyes globally[2,4,5,7,8]. At the start of the second world war, German cryolite glass eyes became unavailable outside of the German-speaking area. Therefore, (poly)methyl methacrylate (PMMA) became a substitute material for prosthetic eyes[4,7,8], and today PMMA is the most commonly used material for prosthetic eyes globally[4,5,8]. Notwithstanding, in German speaking countries, over 90% of ocularists still manufacture customized prostheses using the cryolite glass from Thuringia[2-5,7-13]. Each customized cryolite glass prosthetic eye is produced in two major steps: the first step is to produce a "half-done" cryolite glass eye that conforms to a white sphere with an iris and a pupil (**Figure 2**). The second and decisive step is to customize the "half-done" cryolite glass prosthetic eye for the respective patient. To that end, a "half-done" cryolite glass eye is selected from thousands (**Figure 3**) based on the best matching iris color to the patient's healthy fellow eye.

The following protocol presents customizing a selected "half-done" cryolite glass eye for a specific patient. This step lasts about 25–35 min.

PROTOCOL:

All procedures performed in the following protocol involving human participants were in accordance with the ethical standards of the institutional research committee of the University of Cologne and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

1. Prosthetic eye customization

1.1. Select one of the "half-done" cryolite glass eyes based on the best matching iris color to the healthy fellow eye of the patient (**Figure 3**).

1.2. Examine the fitting of the current prosthetic eye. To do so, let the patient look straight ahead and then alternate in all lines of sight. Pay special attention to the retention of the prosthesis, the viewing direction, the motility, the eye lid contour (ptosis, entropion, and ectropion), as well as to the size and volume (exophthalmos and enophthalmos) of the current prosthesis.

1.3. Remove the current prosthetic eye with help of a contact lens suction cup for hard contact lenses.

1.4. Examine the anophthalmic eye socket without the prosthesis and pay attention to a potential inflammation of conjunctiva, the volume filling of the orbital implant, if the orbital implant is visible through the conjunctiva, and if the fornices and sulci are deep enough for a good fitting prosthesis. If there are any major concerns regarding one of these points, an examination by an ophthalmic surgeon should be performed before manufacturing a new prosthesis.

1.5. Take the selected "half-done" cryolite glass eye with the ocularist forceps and in the other hand take a hollow skewer that will be used later as a mouthpiece for blowing the glass prosthesis. Heat both slowly to 600 °C with a Bunsen burner while continuously rotating it, and melt the skewer at the open end of the "half-done" cryolite glass eye. Open the forceps and lay it down.

1.6. Heat the "half-done" cryolite glass eye continuously (**Figure 4**). Using the healthy fellow eye as a model for the color, shape, and quantity of the conjunctival vessels, draw the vessels on the white sclera with heated glass stems in different colors (mostly red, brown, or yellow) (**Figure 5**).

1.7. Heat the whole "half-done" cryolite glass eye while continuously rotating it so that the drawn vessels merge with the white cryolite glass and to produce a very smooth surface.

1.8. Modify the shape and the volume of the of the cryolite glass prosthetic eye by suction and blowing in the mouthpiece. Keep rotating the glass eye in the flame of the Bunsen burner from time to time. Use the old prosthesis as a template for this step, but if necessary, modify the shape and the volume of the new prosthesis based on the findings of the previous examinations.

1.9. Heat a transparent glass stem and melt it at the pupil of the cryolite glass prosthetic eye while continuously rotating the glass eye (**Figure 6**).

1.10. While continuously rotating the "half-done" glass prosthetic eye, melt the glass at the rear of the prosthesis (**Figure 6** and **Figure 7**) and reduce the volume of the rear by suction with help of the mouthpiece so that the back side shape is nearly equal to the sample prosthesis or the desired shape.

1.11. Melt the glass stem at the front side away and heat the front side of the prosthesis again to produce a very smooth surface (**Figure 8**).

1.12. Take the front side of the prosthesis with the forceps again, form the final shape of the back side with help of the skewer (**Figure 9**), and then melt the skewer away (**Figure 10**).

1.13. Heat the whole prosthesis for fire polishing again, especially at the back side and rotate the prosthesis until the surface is very smooth all over.

1.14. Put the prosthesis in a preheated metal container and let it slowly cool down (**Figure 11**).

1.15. Insert the prosthesis and check the fitting as described in step 1.2 (**Figure 12**).

1.16. If necessary, modify the shape of the prosthesis again (repeat steps 1.8–1.15).

REPRESENTATIVE RESULTS:

Optimal results include a new prosthetic cryolite glass eye that fits very well, is comfortable, has a good motility, and the appearance with the prosthetic eye, including the eye lid contour, is nearly symmetrical to the healthy fellow eye (**Figure 12**).

Suboptimal results can result if the new prosthetic cryolite glass eye fits and is comfortable, but there are concerns regarding the cosmetic results. If a prosthesis does not fit perfectly, the appearance, including the eye lid contour, might not be symmetrical to the healthy fellow eye. In this case, the prosthesis can be redesigned eventually. Another reason for a suboptimal result despite a well-fitting prosthesis is post nucleation socket syndrome (PESS). PESS can result in an asymmetrical appearance of the prosthetic eye compared to the healthy fellow eye. In addition, due to a reduced motility of the orbital implant the motility of the prosthesis itself might not be optimal. However, fitting a new ocular prosthesis in these cases is possible and reasonable.

Complicated results include the manufactured prosthesis not fitting, or if wearing it is painful. In this case, the prosthesis has to be redesigned or completely renewed. In addition, in some patients manufacturing a good fitting cryolite glass prosthetic eye is not possible or reasonable due to complications of the anophthalmic socket. Complications such as a proceeded post nucleation socket syndrome, scarred fornices, or an orbital implant exposure prevent good ocularistic care. These patients have to be examined comprehensively by an ophthalmologist, and surgical socket reconstruction has to be performed by an ophthalmic plastic surgeon.

FIGURE AND TABLE LEGENDS:

Figure 1. Three different cryolite glass prosthetic eyes in different colors and shapes.

Figure 2. A "half-done" cryolite glass eye, already merged with the hollow skewer, that is used as a mouthpiece. In the background the Bunsen burner is visible.

Figure 3. Some "half-done" cryolite glass eyes in different colors.

Figure 4. The "half-done" cryolite glass eye after consistent heating.

Figure 5. Various preproduced glass stems in different colors.

Figure 6. Melting and shaping the back side of the prosthesis.

Figure 7. A second image showing melting and shaping of the back side of the prosthesis. For good stabilization, a transparent glass stem was merged with the front side of the pupil before.

Figure 8. Melting away the glass stem at the front side.

Figure 9. The ocularist takes the front side of the prosthesis with the forceps and forms the final shape of the back side with help of the skewer.

Figure 10. Melting away the skewer at the back side.

Figure 11. After completion of prosthesis, the glass eye is placed with help of the ocularists forceps in a preheated metal container in order to cool down slowly.

Figure 12. Optimal result. The new prosthetic cryolite glass eye fits very well, is comfortable, has good motility, and the appearance with the prosthetic eye, including the eye lid contour, is nearly symmetrical to the healthy fellow eye.

Figure 13. Front surface of the old prosthesis (template prosthesis) and the new prosthesis of the same patient. The shape of the prosthesis was copied with a very high precision by the ocularist. However, the shape of the new prosthesis was slightly modified by the ocularist due to changes of the anophthalmic socket over time for an optimal fit.

Figure 14. Back surface of the old prosthesis (template prosthesis) and the new prosthesis of the same patient. The shape of the prosthesis was copied with a very high precision by the ocularist. However, the shape of the new prosthesis was slightly modified by the ocularist due to changes of the anophthalmic socket over time for an optimal fit.

DISCUSSION:

Following enucleation with an orbital implant, a conformer has to be inserted for two weeks (**Figure 1**) in order to prevent scarring of the conjunctival fornices and subsequent inserting of a prosthesis[2-4,7,12,13]. Because an early ocular prosthesis insertion improves quality of life after enucleation and ensures better rehabilitation, cryolite glass prosthetic eye wearers get their first eye prosthesis two weeks after their operation[2,4,14]. This cryolite glass eye prosthesis is handmade but not fully customized for the fitting due to major changes of the anophthalmic socket in the first weeks and months after operation[2,4]. Promptly, six weeks after enucleation,

patients get a second glass prosthesis[2,4]. As of this date all cryolite glass prostheses are fully customized[2,4].

The process of customizing the "half-done" cryolite glass eye includes some critical steps[2,7]. The first critical steps within the protocol include examination of the fitting of the current prosthesis (step 1.2) and examination of the anophthalmic socket without the prosthesis (step 1.4)[11]. The ocularist has to check the current fitting of the prosthesis as well as the anophthalmic socket in detail, because on the basis of this examination the shape of the new customized prosthesis will be possibly changed compared to the old prosthesis[2,7] (**Figure 13** and **Figure 14**). In addition, the ocularist has to check whether there are other points, such as extrusions of orbital implants requiring surgical interventions prior to adequate ocularistic care[2,7]. Another critical step is the slow heating and continuous rotation of the half-done cryolite glass eye. If the glass eye is not rotated continuously and evenly, it gets warped when heated. Heating or cooling the glass eye too quickly will result in breakage of the glass eye[2,5,7]. Furthermore, the temperature during shaping of the cryolite glass eye has to be in the correct range (nearly 600 °C) for an optimal result[5]. All of these steps are a matter of practice and experience resulting from over 6 years of training for ocularists.

The technique described in the protocol is used for manufacturing a hollow, double walled cryolite glass eye, a so-called 'reform eye'[2,7]. These reform eyes are used especially for patients after enucleation or evisceration, when they need more volume replenishment through the prosthesis[2,7]. When volume replenishment is not necessary, for example in phthisic eyes or in patients with microphthalmos, the technique can be modified and the cryolite glass prosthetic eye can be made very thin and single-walled. Therefore, the back wall is melted off during the customizing process[2,7].

In case the customized prosthesis glass eye does not fit initially, it can be heated once more, and the shape can then be modified by the ocularist. However, reheating of the glass prosthesis eye is only possible in the first days after production[2,5,7]. After a wearing time of several days, the first hydrolytic material changes, and material stress occurs, and a reheating results mostly in a breakage of the prosthesis[2,5,7]. Of course, in some rare cases, the prosthetic eye has to be reproduced from the beginning due to a fitting error that cannot be corrected anymore (for example, when the prosthesis is too small, or the material is too thin).

Essentially, using the technique described here allows the production of cryolite glass prosthetic eyes of nearly all shapes and sizes[2,7]. The limitations of our technique depend on the anophthalmic socket[2,3,11]. In patients with a pronounced postenucleation socket syndrome (PESS) or scarring of the fornices, it is not possible or useful to customize a prosthetic eye[2,7]. These patients benefit more from an initial surgical reconstruction of the anophthalmic socket with following ocularistic care[2,7].

After six months, patients receive a new customized glass prosthesis based on the changes of the eye socket over time[2,4]. Afterwards, according to the current recommendations, most adult patients in Germany get a new customized prosthesis at least once a year, primary due to

hydrolytic surface changes resulting in an inflammation of the anophthalmic socket[2,4,11]. It is not possible to polish cryolite glass prostheses[2,4,5]. Of course the fitting and the design of the yearly, newly made prosthesis is adjusted and improved from time to time by the ocularist because of the patients' experiences and wishes[2,4].

In contrast, PMMA prosthetic eye wearers only get one prosthesis about 6 weeks following eye loss and wearing a conformer[2,4]. This prosthesis is usually worn for the next 5 or 6 years[2,4]. PMMA prosthetic eyes have to be repolished every year due to surface changes but there is in some cases no improvement in the fitting or the design over the years[2,4,5]. These different approaches in the manufacturing of the prosthesis immediately following eye loss seem to result in higher levels of patient satisfaction in the cryolite glass prosthetic eye wearers compared to PMMA prosthetic eye wearers[2,4,15]. However, the exact reasons for these divergences between both groups remain unclear[2,4,15,16].

One very important point for prosthetic eye wearers is mucoid discharge[2,4,11,17-22]. The reason for this discharge is a conjunctival inflammation, among other things caused by the irritation of the anophthalmic socket by the ocular prosthesis[2,4,11,17-22]. Clinical studies show that the fire-polished surface of cryolite glass prosthetic eyes is smoother than those of PMMA prosthetic eyes[2,4,11,23]. This could be a potential advantage of the cryolite glass compared to PMMA, but some studies show that there was no difference in mucoid discharge between cryolite glass and PMMA prosthetic eye wearers[2,4,11]. Therefore, further studies are needed to investigate this in detail[2,4,11].

Another aspect is the durability of both materials (PMMA vs. cryolite glass) [2,4,5]. At first glance, the potential breakage of cryolite glass prosthetic eyes seems to be a problem for anophthalmic patients[2,4,5]. However, the mean rate of breakage is very low and amounts to only one prosthesis per 26.63 years of wear[2,4,5]. Damage (94%) occurs during removal or cleaning of the glass eye[2,4,5]. Therefore, removing and cleaning of the prosthetic eye should be done over a filled sink[2,4,5]. In case of damage or loss, almost all cryolite glass prosthetic eye wearers have at least one suitable replacement prosthesis[2,4,5]. To avoid the very rare case of damage to the prosthetic eye inside the socket and of course also to protect their healthy fellow eye, patients should wear protective glasses all the time[2,4,5]. In summary, a potential higher breakage rate of cryolite glass seems to be of subordinate importance and not to be a disadvantage in everyday life for the patients[2,4,5].

Another advantage of the use of cryolite glass is the weight of the prosthesis[2,4,5,7,24]. While the Snellen 'reform eye' made of cryolite glass is hollow and therefore lightweight, most of the PMMA prosthetic eyes are solid and heavier than cryolite glass prostheses with the same volume[2,4,5,24]. According to the experience of the authors, these heavier prostheses might cause sagging of the lower eye lid in the course of the postenucleation socket syndrome. Of course, there are some innovative approaches to manufacturing hollow PMMA prostheses. However, these techniques are still not used in standard care[2,4,5,24].

In addition, only one appointment is needed to manufacture cryolite glass prosthetic eyes[2,4,5]. After one hour, patients can leave the ocularist with their new prosthesis, while PMMA prosthetic

eye wearers need 3–4 appointments at their ocularists and get their new PMMA prosthesis a few weeks after the first appointment[2,4,5,24].

So far the recommended care regime for glass prosthetic eyes includes removal and cleaning on a daily basis while for PMMA prosthetic eyes removal and cleaning between 1–6 months is recommended[11,17,18]. However, the results of the newest studies suggest that cryolite glass prosthetic eyes should not be removed daily for cleaning and that further research is needed to develop a cleaning protocol[11]. This protocol would recommend a minimum period of wear between cleaning sessions and should consider individual conditions, such as climatic, psychological, and environmental factors[11].

In recent decades, some improvements of this technique have focused on the working conditions of the patients, such as air conditioner use, ergonomic workstation designs and, in a few cases, newer devices such as novel Bunsen burners[2,4,5,7]. However, in the last few years some potential further developments have been described in the literature[25,26]. New surface coatings with antibacterial or with more hydrophilic properties are one of the main subjects of current research regarding prosthetic eyes[25,26]. However, these new coatings will probably be used especially for PMMA prosthetic eyes because the coating procedures mostly require very high temperatures or high pressure, very likely resulting in breakage of the glass prostheses. Another innovative approach to improve the prosthetic eyes is to fabricate a hollow ocular prosthesis with a functional lubricant reservoir to increase the artificial eye comfort[27]. This technique is not established, and further studies are needed to define the clinical outcome. A big issue of this suggested improvement could be the growth of bacteria within the hollow prosthesis. Thus, further studies are a high priority.

In summary, this manuscript shows each step of customizing a cryolite glass prosthetic eye, including some major advantages of the use of cryolite glass for manufacturing an eye prosthesis compared to PMMA, and gives ophthalmologists a better insight into ocularistic care. These insights help to improve the essential interprofessional collaboration between ocularists and ophthalmologists. In addition, some divergences between the PMMA and cryolite glass prosthetic eyes have not yet been identified in detail, especially the impact of the material itself, remain unanswered, and should be addressed in further studies.

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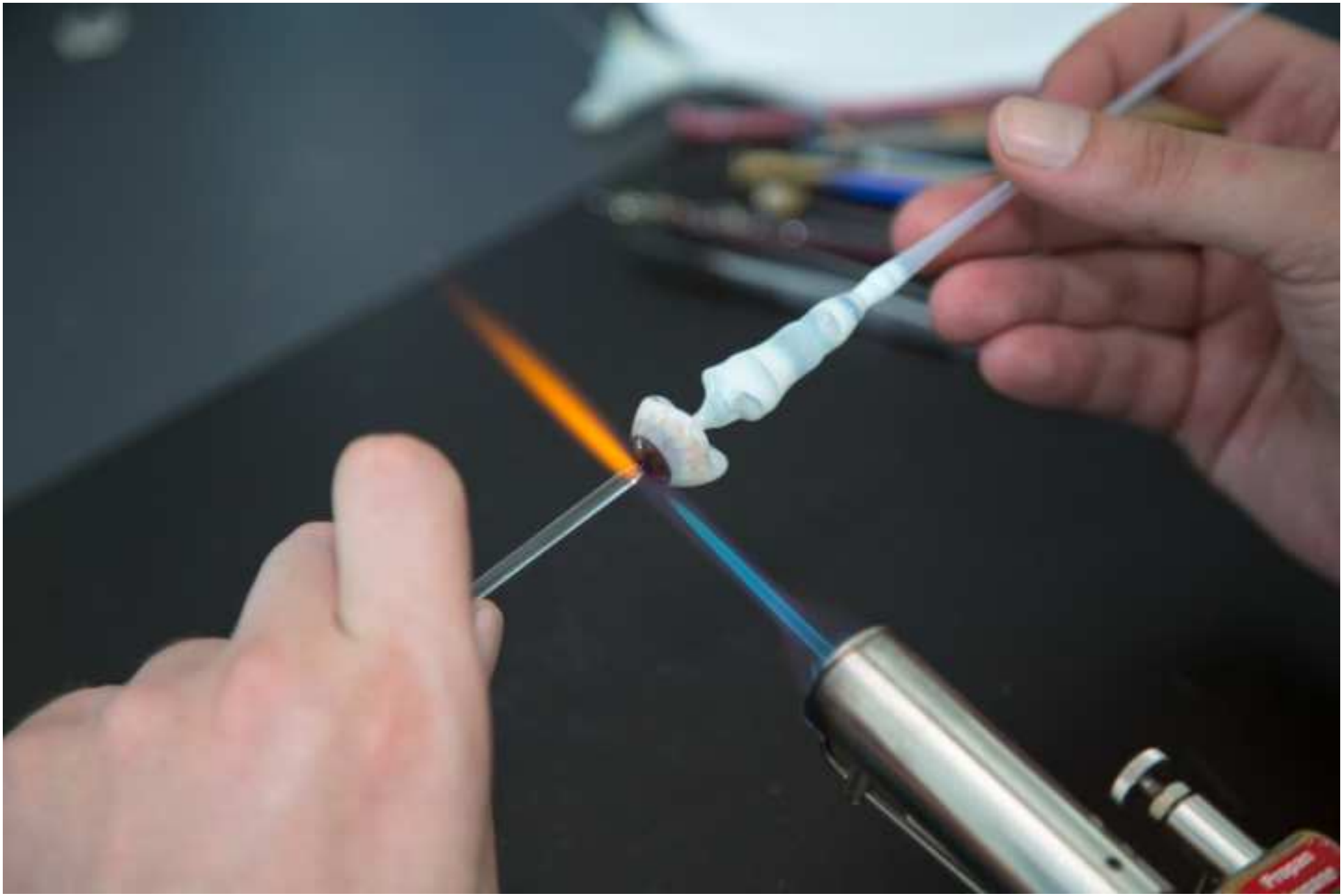

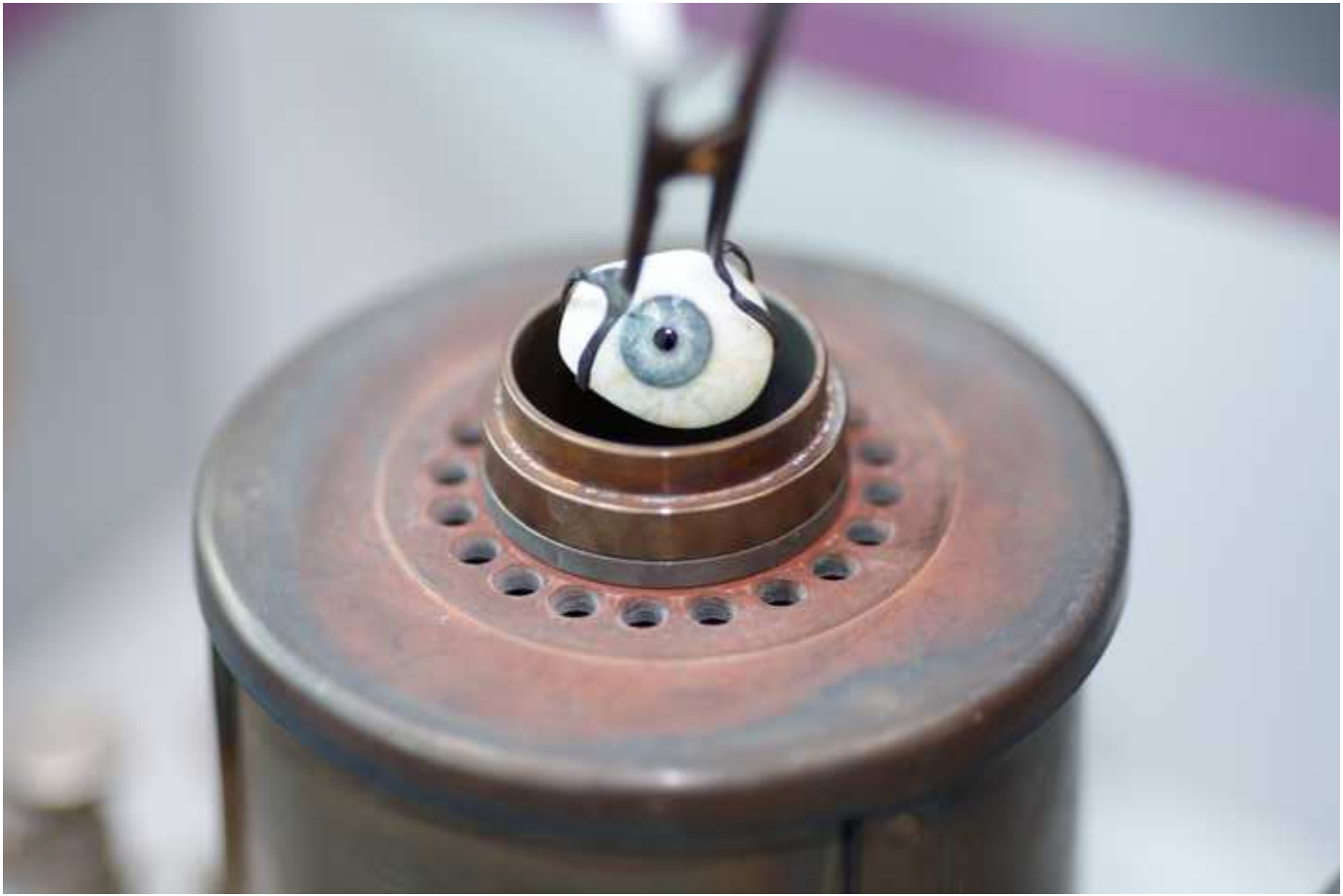

Name of Material/ Equipment
Bunsen burner with gas and air flow over a fire-resistant worktop made from anodised stainless steel
Hollow skewer
Ocularist forceps
Preheated metal container to 500 degree celsius
Pre-produced "half-done" cryolite glass eye
Transparent glass stem
Various preproduced glass stems in different colors

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I. Editorial comments:

Changes to be made by the author(s):

1. Please take this opportunity to thoroughly proofread the manuscript to ensure that there are no spelling or grammar issues. The JoVE editor will not copy-edit your manuscript and any errors in the submitted revision may be present in the published version.

Thank you for this amendment. All spelling or grammar issues were corrected.

2. Please revise lines 41-53 and 264-268 to avoid previously published text.

Thank you for this amendment. We revised the lines 41-53 and 264-268 to avoid previously published text. Therefore, we changed the manuscript as follows:

"Herman Snellen, a Dutch eye surgeon, used this cryolite glass to produce a lightweight hollow prosthetic eye in 1880. This lightweight prosthetic eye, the Snellen 'reform eye' increased the volume of prosthetic eyes resulting in better fitting into larger sockets following the introduction of enucleation procedures made possible by the development of anesthesia and asepsis. 20 years later, cryolite glass had become the most commonly used material for prosthetic eyes. Germany developed into the manufacturing centre of prosthetic eyes globally. At the start of the second world war, German cryolite glass eyes became unavailable outside the German-speaking area. Therefore (poly)methyl methacrylate (PMMA) became a substitute material for prosthetic eyes, and today PMMA is the most commonly used material for prosthetic eyes globally. Notwithstanding, in German speaking countries over 90% of the ocularists still manufacture the customized prostheses using the cryolite glass from Thuringia."

"Another aspect is the durability of both materials (PMMA vs. cryolite glass). In the first glance, the potential breakage of cryolite glass prosthetic eyes seems to be problem for anophthalmic patients. However, the mean rate of breakage is very low and amounts only one prosthesis per 26.63 wearing years. The damages (94%) occur during removing or cleaning the glass eye . Therefore, removing and cleaning of the prosthetic eye should be done over a filled sink. In case of damage or loss, almost all cryolite glass prosthetic eye wearers have at least one suitable replacement prosthesis."

3. Authors and affiliations: Please provide an email address for each author.

Thank you for this important information. We provided email addresses for each author:

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4. Abstract: Please expand to include an overview of the method and a summary of its advantages, limitations, and applications. Please do not include references here.

Thank you for this important information. We expanded the abstract as follows:

"In Germany, Austria, and Switzerland, over 90% of the ocularists still manufacture customized prostheses using cryolite glass from Thuringia. The present manuscript demonstrates this technique - long forgotten in other countries – in detail. This manuscript shows some major advantages of manufacturing prosthetic eyes using cryolite glass in comparison to PMMA, such a lighter weight of the prosthesis, higher levels of patient satisfaction, and only one appointment for the customized manufacturing. Potential risk of breakage seems not to be a decisive disadvantage for glass prosthetic eye wearers. However, in some patients manufacturing a good fitting prosthetic eye is not possible or reasonable due to anophthalmic socket complications such as post enucleation socket syndrome, scarred fornices or an orbital implant exposure. This article gives ophthalmologists a better insight into the ocularistic care in order to improve the essential interprofessional collaboration between ocularists and ophthalmologists."

5. Introduction: Please expand to include the advantages of the presented method over alternative techniques with applicable references to previous studies, description of the context of the technique in the wider body of literature and information that can help readers to determine if the method is appropriate for their application.

Thank you for this important information. We expanded the introduction as follows:

"The purpose of the present manuscript is to comprehensively demonstrate the technique of manufacturing a customized cryolite glass prosthetic eye that is long forgotten outside the

German-speaking area (Figure 1). In addition, this manuscript focuses on major advantages of this technique described in the protocol resulting in a very smooth surface of the prosthesis due to fire polishing, the light weight of the prosthesis on the basis of the hollow design, high levels of patient satisfaction and the need of only one appointment for manufacturing of the customized prosthesis. This article also gives ophthalmologists better insights into the ocularistic care in order to improve the essential interprofessional collaboration.

In 1832, the glassblower Ludwig Uri Müller from Thuringia, Germany, developed the cryolite glass prosthetic eye based on the class-leading models made in France. Benefits of cryolite glass included a better look, better tolerability, easier processing, and longer durability than previous glass eyes. Herman Snellen, a Dutch eye surgeon, used this cryolite glass to produce a lightweight hollow prosthetic eye in 1880. This lightweight prosthetic eye, the Snellen 'reform eye' increased the volume of prosthetic eyes resulting in better fitting into larger sockets following the introduction of enucleation procedures made possible by the development of anesthesia and asepsis. 20 years later, cryolite glass had become the most commonly used material for prosthetic eyes. Germany developed into the manufacturing centre of prosthetic eyes globally. At the start of the second world war, German cryolite glass eyes became unavailable outside the German-speaking area. Therefore, (poly)methyl methacrylate (PMMA) became a substitute material for prosthetic eyes, and today PMMA is the most commonly used material for prosthetic eyes globally. Notwithstanding, in German speaking countries over 90% of the ocularists still manufacture the customized prostheses using the cryolite glass from Thuringia. Each customized cryolite glass prosthetic eye is produced in two major steps: The first step is to produce a "half-done" cryolite glass eye what conforms nearly to a white sphere with an iris and a pupil (Figure 2). The second and decisive step is to customize the "half-done" cryolite glass prosthetic eye for the respective patient. To that end a "half-done" cryolite glass eye is selected from thousands of them (Figure 3) on the basis of the best matching iris color to the fellow eye of the patient.

The following protocol presents customizing a selected "half-done" cryolite glass eye for the specific patient. This step lasts about 25-35 minutes. All procedures performed in the following protocol involving human participants were in accordance with the ethical standards of the institutional research committee of the University of Cologne and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards."

6. Please include an ethics. statement before the numbered protocol steps, indicating that the protocol follows the guidelines of your institution's human research ethics committee.

Thank you for this important information. We included an ethics statement:

"All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional research committee of the University of Cologne and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards."

7. Lines 72-79: Please move the introductory paragraph of the protocol to the Introduction, Results, or Discussion (as appropriate).

Thank you for this important information. We moved the named paragraph to the introduction. Please see point 5.

8. 1.03: What is used to remove the current prosthetic eye?

Thank you for this important amendment. We changed the manuscript as follows:

"1.03. Remove the current prosthetic eye with help of a contact lens suction cup for hard contact lenses."

9. Representative Results: Please include at least one figure or table to show the effectiveness of your technique backed up with data.

Thank you for this important amendment. We included a figure to show the effectiveness of our technique. Please see the pictures.

10. Please reference Figure 8 in the manuscript.

Thank you for this important amendment. We referenced figure 8 in the manuscript.

"Heat both slowly to 600 degrees with a Bunsen burner (Fig. 8) while continuously rotating it and melt the skewer at the open end of the "half-done" cryolite glass eye. Open the forceps and lay it down."

11. JoVE articles are focused on the methods and the protocol, thus the discussion should be similarly focused. Please revise the Discussion to explicitly cover the following in detail in 3-6 paragraphs with citations:

a) Critical steps within the protocol

b) Any modifications and troubleshooting of the technique

c) Any limitations of the technique

d) The significance with respect to existing methods

e) Any future applications of the technique

Thank you for this important amendments. We revised the discussion as follows:

"The process of customizing the half-done cryolite glass eye includes some critical steps. The first critical steps within the protocol include examination of the fitting of the current prosthesis (1.02) and examination of the anophthalmic socket without prosthesis (1.04). The ocularist has to check the current fitting of the prosthesis as well as the anophthalmic socket in detail, because on the basis of these checks the shape of the new customized prosthesis will be possibly changed compared to the old prosthesis. In addition, the ocularist has to check whether there are other points, such as extrusions of orbital implants requiring surgical interventions prior to adequate ocularistic care. Another critical step is the slow heating including a continuous rotation of the half-done cryolite glass eye. If the glass eye is not rotated continuously and evenly, the glass eye gets warped uncontrolled when heated. Heating or cooling the glass eye too quickly will result in a breakage of the glass eye. Furthermore, the temperature during shaping the cryolite glass eye has to be in the correct range (nearly 600 degrees Celsius) for an optimal result. All these steps are just a matter of practice and also a question of experience resulting in an over 6-years training period for ocularists."

"The technique described in that protocol is used for the manufacturing a hollow, double walled cryolite glass eye, a so-called 'reform eye'. These reform eyes are especially used for patients after enucleation or evisceration when they need more volume replenishment through the prosthesis. When volume replenishment is not necessary for example in phthisic eyes or in patients with microphthalmos, the technique can be modified and the cryolite glass prosthetic eye can be produced very thin and single-walled. Therefore, the backwall is melted of during the customizing process.

In the case the customized prosthesis glass eye does initially not fit, it can be heated once more, and the shape can then be modified by the ocularist. However, reheating of the glass prosthesis eye is only possible in the first days after production. After a wearing time of some days the first hydrolytic material changes and material stress occur and a reheating results mostly in a breakage of the prosthesis. Of course, in some rare cases the prosthetic eye has to be reproduced from the beginning due to a fitting error that can`t be corrected any more, for example when the prosthesis is too small, or the material is too thin.
Essentially using the technique described here allows to produce cryolite glass prosthetic eyes in nearly all shapes and sizes. The limitations of our technique depend on the anophthalmic socket. In patients with a pronounced PESS or scarring of the fornices, it is not possible or useful to customize a prosthetic eye. These patients benefit more from an initial surgical reconstruction of the anophthalmic socket with following ocularistic care. "

"In recent decades some improvements of this technique have prevailed, especially with focus on the working conditions such as air conditioners and ergonomic workstation designs and, in a few cases, newer devices such as novel Bunsen burners. However, in the last years some potential further developments have been described in the literature. Especially, new surface coatings with antibacterial or with more hydrophilic properties are one of the main subjects of the current research regarding prosthetic eyes. However, these new coatings will probably be used especially for PMMA prosthetic eyes, because the coating procedures mostly require very high temperatures or high pressure resulting very likely in breakage of the glass prostheses. Another innovative approach to improve the prosthetic eyes is to fabricate a hollow ocular prosthesis with a functional lubricant reservoir to increase the artificial eye comfort. This technique is not established until today, and in addition further studies are needed to define the clinical outcome. A big issue of this suggested improvement could also be the growth of bacteria within the hollow prosthesis. Also with regard to this point, further studies are a high priority."

12. References: Please do not abbreviate journal titles.

According to the journal's guidelines, we updated all references without abbreviations.

13. Table of Materials: Please also provide company and catalog number for each item in separate columns and sort the items in alphabetical order according to the name of material/equipment.

Thank you for this amendment. However, it is not possible to list the catalogue numbers or the companies. All parts of the equipment and also all parts for producing are customized or partially self constructed or handmade many years ago by firms that do not exist anymore. We sorted the equipment and material alphabetical.

Reviewers' comments:

Reviewer #1:

1. The customisation process is listed in summary at points 1.01 through to 1.16. I was expecting that the protocol which is to be captured on video would be highlighted in yellow but as there is no highlighting, I am presuming that the protocol that is to be presented in the video is that listed after the "PROTOCOL" heading in the manuscript.
Thank you for this important information. The reviewer is right that the protocol that is to be presented in the video is that listed after the "PROTOCOL" heading in the manuscript. We highlighted the text in yellow.

2. The discussion section that follows the protocol is NOT initially related to the protocol. Instead the discussion briefly describes the process by which a patient is handled following surgical enucleation of an eye and the surgical insertion of an orbital implant. The discussion describes how a conformer is inserted into the inter-palpebral space to prevent scarring while the conjunctiva heals and to maintain the conjunctival fornices following during the healing process. At this point the authors describe how a progression of glass prosthetic eyes need to be fitted at intervals while swelling recedes.
We fully agree with the reviewer and revised the discussion with more focus on the protocol as follows:
"The process of customizing the half-done cryolite glass eye includes some critical steps. The first critical steps within the protocol include examination of the fitting of the current prosthesis (1.02) and examination of the anophthalmic socket without prosthesis (1.04). The ocularist has to check the current fitting of the prosthesis as well as the anophthalmic socket in detail, because on the basis of these checks the shape of the new customized prosthesis will be possibly changed compared to the old prosthesis. In addition, the ocularist has to check whether there are other points, such as extrusions of orbital implants requiring surgical intervention prior to adequate ocularistic care. Another critical step is the slow heating including a continuous rotation of the half-done cryolite glass eye. If the glass eye is not rotated continuously and evenly, the glass eye gets warped uncontrolled when heated. Heating or cooling the glass eye too quickly will result in a breakage of the glass eye.

Furthermore, the temperature during shaping the cryolite glass eye has to be in the correct range (nearly 600 degrees Celsius) for an optimal result. All these steps are just a matter of practice and also a question of experience resulting in a over 6-years training period for ocularists.

The technique described in that protocol is used for the manufacturing a hollow, double walled cryolite glass eye, a so-called 'reform eye'. These reform eyes are especially used for patients after enucleation or evisceration when they need more volume replenishment through the prosthesis. When volume replenishment is not necessary for example in phthisic eyes or in patients with microphthalmos the technique can be modified and the cryolite glass prosthetic eye can be produced very thin and single-walled. Therefore the back wall is melted of during the customizing process.

In the case the customized prosthesis glass eye does initially not fit, it can be heated once more and the shape can then be modified by the ocularist. However, reheating of the glass prosthesis eye is only possible in the first days after production. After a wearing time of some days the first hydrolytic material changes and material stress occur and a reheating results mostly in a breakage of the prosthesis. Of course, in some rare cases the prosthetic eye has to be reproduced from the beginning due to a fitting error that can`t be corrected any more, for example when the prosthesis is too small, or the material is too thin.

Essentially using the technique described here allows to produce cryolite glass prosthetic eyes in nearly all shapes and sizes. The limitations of our technique depend on the anophthalmic socket. In patients with a pronounced post enucleation socket syndrome (PESS) or scarring of the fornices, it is not possible or useful to customize a prosthetic eye. These patients benefit more from an initial surgical reconstruction of the anophthalmic socket with following ocularistic care. "

"In recent decades some improvements of this technique have prevailed especially with focus on the working conditions such as air conditioners and ergonomic workstation designs and, in a few cases, newer devices such as novel Bunsen burners. However, in the last years some potential further developments have been described in the literature. Especially, new surface coatings with antibacterial or with more hydrophilic properties are one of the main subjects of the current research regarding prosthetic eyes. However, these new coatings will probably be used especially for PMMA prosthetic eyes because the coating procedures mostly require very high temperatures or high pressure resulting very likely in breakage of the glass

prostheses. Another innovative approach to improve the prosthetic eyes is to fabricate a hollow ocular prosthesis with a functional lubricant reservoir to increase the artificial eye comfort. This technique is not established until today, and in addition further studies are needed to define the clinical outcome. A big issue of this suggested improvement could be the growth of bacteria within the hollow prosthesis. Also with regard to this point further studies are a high priority."

3. At 6 months post enucleation a final glass prosthesis is fitted and this is expected to last for 12 months before the level of surface etching requires a new prosthesis. This reviewer is aware that some ocularists extend the time between renewal of glass prostheses to well beyond 12 months.

Our newest data (Rokohl et al. - Cryolite Glass Prosthetic Eyes – The Response of the Anophthalmic Socket) show that most of the patients have a big inflammatory response of the anophthalmic socket. This inflammatory response seems to be stronger in patients with longer wearing time (of the same prosthesis). Most patients seem to benefit from a newly made prosthesis every 9 months. However, the reviewer is also right: in individual cases it is of course possible to extend the time between renewal of the glass prostheses to well beyond 12 months. It is very difficult to state general recommendations for all patients, but the German recommendation is in these days to renew the prosthesis at least all 12 months, also for preventing other inflammation related complications. We changed the manuscript as follows:

"Afterwards, according to the current recommendations, most adult patients in Germany get a new customized prosthesis at least once a year, primary due to hydrolytic surface changes resulting in an inflammation of the anophthalmic socket."

4. The discussion then turns to prostheses made from PMMA and the authors begin their comparison between prostheses made from each material. The authors state that PMMA prostheses are not made until 6 weeks after enucleation and that the PMMA prosthesis is then worn for the next 5 to 6 years without improvement in fit and with only annual re-polishing. The inference is that PMMA prostheses are therefore at a disadvantage. This reviewer is aware that there are ocularists who do fit PMMA prostheses earlier than 6 weeks and also that there are ocularists who willingly modify the PMMA prosthesis (e.g. by adding

material or by removing material - which is not possible with glass) to correct any fitment issues.

We fully agree with the reviewer and we revised the discussion as follows:

"PMMA prosthetic eyes have to be repolished every year due to surface changes but there is in some cases no improvement of the fitting or the design over the years."

5. The discussion continues with a comparison of the level of smoothness and the hydrophilicity of the cryolite glass and the PMMA prosthesis surface. The authors are correct that the glass surface has advantages (but this may be limited to when the prosthesis is new). They are correct when they state that more research is needed in this area.

Thank you for this information. Of course, newly made prostheses have smoother surfaces. This applies to both PMMA and glass prostheses. However, Clodius et al. (1981-Artificial Eyes: Surface Changes Following Use, as Observed by the Scanning Electron Microscope) showed that the smoother surface of glass prostheses compared to PMMA is not limited to the new unworn prostheses.

6. At lines 274 to 276 the authors make the inference that the heavier PMMA prosthesis will irritate the conjunctiva, increase mucous discharge, increase discomfort, redden the eye lids, cause overburdening and sagging of the lower eyelid which is part of PESS. The authors cite references 5, 6, 8, 22, and 23. In my reading of these articles I did not find direct evidence that the weight of the prosthesis was a significant cause of PESS. In my view the statement that the weight of the prosthesis was a cause of lower lid sagging would be best worded as simply the opinion of the authors without direct evidence.

Thank you for this important amendment. The reviewer is right. We adjusted the manuscript as follows:

"According to the experience of the authors these heavier prostheses might cause sagging of the lower eye lid in the course of the post enucleation socket syndrome."

7. The authors make, as their final point of comparison between glass and PMMA prosthetic eyes, the time involved in the fitting process. They are correct that the number of in-office visits and time required to manufacture PMMA prostheses is much longer. The authors do not comment on the differences in patient care requirements (how frequent

is the removal and cleaning for each) for cryolite glass prosthetic eyes and PMMA prosthetic eyes. This is a significant oversight and should be included.

Thank you for this important amendment. We included patient care requirements and changed the manuscript as follows:

"So far the recommended care regime for glass prosthetic eyes included removal and cleaning on a daily basis while for PMMA prosthetic eyes removal and cleaning at an interval between monthly and six-monthly was recommended. However, the results of newest studies suggest that cryolite glass prosthetic eyes should not be removed daily for cleaning and that further research should be undertaken to develop a cleaning protocol. This protocol would recommend a minimum period of wear between cleaning sessions and should consider individual conditions, such as climatic, psychological, and environmental factors."

8. ABSTRACT

The abstract presents the aims of the manuscript succinctly

SUMMARY

The summary statement does NOT mention that the topic of this publication is the in-office protocol for customising a cryolite glass prosthetic eye for a patient.

Thank you for this important amendment. We changed the manuscript as follows:

"This manuscript shows each step of customizing a cryolite glass prosthetic eye including some major advantages of the use of cryolite glass for manufacturing an eye prosthesis compared to PMMA. In addition, this manuscript gives ophthalmologists a better insight into the ocularistic care what could improve the interprofessional collaboration."

9. Major Concerns:

It is not clear from the manuscript what the protocol is that is to be presented in video format. There is no yellow highlighting.

We fully agree with the reviewer. The protocol that should be presented in the video is that listed after the "PROTOCOL" heading in the manuscript. We now highlighted in yellow.

10. Assuming that the content for the video is ALL that is listed under the heading "PROTOCOL" then it is important that 1) the steps involved in production of the "half-dome" cryolite glass prosthetic eye initially are fully covered at the start of the video.

then 2) the steps involved in customising the half dome cryolite glass prosthetic eye to a patient would then be the second part of the video.

Thank you for this important information. Unfortunately, it is not possible to present both main steps in one and the same manuscript or video due to length restrictions. Pre-producing the "half-done" prosthetic eye is very elaborate, and therefore a separate video and manuscript would be necessary. In addition, most ocularists focus on this second step and buy the half-done prosthetic eyes from a supplier that focus on producing these half-done prosthetic eyes. Furthermore, the procedure reported here is the most critical step in respect to individual patients' care and seems to be the most interesting issue for the ophthalmologists.

11. The major discussion topic is a comparison of prosthetic eyes made from the two materials a) cryolite glass, and b) PMMA. This comparison should include the care that needs to be exerted by the patient in maintaining the prosthesis between annual visits to the ocularist. I understand that the recommended care regimes are

(i) for glass prosthetic eyes is removal and cleaning on a daily basis.

(ii) for PMMA prosthetic eyes is removal and cleaning at an interval between monthly and six monthly.

Thank you for this important amendment. We included patient care requirements and changed the manuscript as follows:

"So far the recommended care regime for glass prosthetic eyes included removal and cleaning on a daily basis while for PMMA prosthetic eyes removal and cleaning at an interval between monthly and six-monthly was recommended. However, the results of newest studies suggest that cryolite glass prosthetic eyes should not be removed daily for cleaning and that further research should be undertaken to develop a cleaning protocol. This protocol would recommend a minimum period of wear between cleaning sessions and should consider individual conditions, such as climatic, psychological, and environmental factors."

12. Minor Concerns:

The spelling and grammar is difficult in places and needs revision.

Thank you for this amendment. All spelling or grammar issues were corrected.

Reviewer #2:

1. Manuscript Summary:

Need a revision of technique illustrations and results achieve

Thank you for this important amendment. We included various figures to show each step of the technique more detailed and to show possible results of our technique. Please see the pictures.

2. Major Concerns:

Technique defined by Author not clear, how the conforming of shape with other shapes being done

Thank you for this important amendment. The ocularists form the shape of the prosthesis based on the model of the existing prosthetic eye with sense of proportion. All these steps are just a matter of practice and also a question of experience resulting in an over 6-years training period for ocularists. We changed the manuscript as follows:

"1.10. While continuously rotating the "half-done" glass prosthetic eye, melt the glass at the backside of the prosthesis (Figure 6) and reduce the volume of the backside by suction with help of the mouthpiece so that the backside shape is equal to the sample prosthesis or the desired shape."

3. No Pre and post picture which shows typical a custom eye prosthesis does look, and how the replica or transfer of the posterior surface is done and with what level of precision Images should be ideally attached, as the technique described by author is already being used in dusty over 100 Years.

Thank you for this important amendment. We included various figures to show the technique and the level of precision more detailed and to show possible results of our technique. Please see the pictures.