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The Design of a Hard Contact Lens Insertion\ Removal Device

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ABSTRACT
One of the most common types of vision diseases is refractive eye diseases, such as farsightedness and nearsightedness, which prevent light from properly getting focused on the retina, producing blurry images, and thus unclear vision. In the United States of America, over 150 million people suffer from refractive eye diseases, which prevent light from properly getting focused on the eye retina, producing blurry images, and thus unclear vision. In both refractive eye diseases, corneal curvature plays a crucial role in correctly focusing light on the retina. Keratoconus is a chronic disease of the corneal ectasia that affects the corneal curvature of the eye. Corneal ectasia is the gradual thinning of the cornea and expansion outward due to internal pressure, which makes the cornea shaped like a cone, affecting visual acuity due to astigmatism. Keratoconus usually affects around 1 in every 200,000 of the general population and affects children from the age of 10 years old. Mainly, the treatment of Keratoconus is either by stopping the progression of corneal ectasia or by improving vision, or both. Improving the vision could be done by utilizing hard contact lenses, yet they are difficult to insert into the eye and require skills. To reduce the difficulty of such a procedure, several devices were made to be utilized in the process of insertion or removal of the hard contact lenses. Yet, Users need adequate training and skills to use such devices correctly. There is a need for a device that combines most of the advantages of previously made devices, such as single-handed operation, safety, and ease of use, and avoids most of their disadvantages such as the risk in using loaded springs and eye trauma, not containing spilled lens solution, and operating with both hands. In this project, ideation sessions and concept selection were performed utilizing the Pugh method. A design of a hard contact lens insertion/ removal device was proposed utilizing 3D computer-assisted design (CAD) software. Five main parts were designed: the housing, the roller, the plunger bracket, the eyelid bracket, and the eyelid fasteners. Furthermore, an alpha phase prototype of the five parts was 3D printed and assembled utilizing computer-assisted manufacturing (CAM) as a proof of concept.

Keywords: Hard Contact Lenses, Biomedical device design, Biomedical instrumentation, 3D CAD modeling, 3D printing; Innovation.

INTRODUCTION

Refractive Eye Diseases

One of the most common types of vision diseases is refractive eye diseases, such as farsightedness and nearsightedness [1]. In the United States of America, over 150 million people suffer from refractive eye diseases, which prevent light from properly getting focused on the eye retina, producing blurry images, and thus unclear vision [2]. Farsightedness (hyperopia) is seeing distant objects clearly while nearby objects are blurry. Farsightedness might be caused due to the eyeball being shorter than normal, and/ or the cornea being inadequately curved. Thus, the image is focused behind the retina. To treat such a refractive error, corrective glasses are utilized, or refractive surgeries are performed. Moreover, soft or hard (rigid gas-permeable) contact lenses are utilized to reduce corneal curvature [3]. Nearsightedness (Myopia) is a disease that affects the vision in which near objects are clear while far objects are blurry. This happens because the eyeball is too long rather than round, or the cornea is too steep in curvature, which causes light to refract incorrectly, resulting in the image being focused in front of the cornea instead of being focused on it [4]. As a treatment, there are non-invasive treatments used for myopia patients, such as corrective eyeglasses and contact lenses, and there are also invasive treatments that solve the problem of myopia, which are refractive surgeries [4]. In both refractive eye diseases, corneal curvature plays a crucial role in correctly focusing light on the retina.

Keratoconus

Keratoconus is a chronic disease of the corneal ectasia that affects the corneal curvature of the eye [5], [6]. Corneal ectasia is the gradual thinning of the cornea and expansion outward due to internal pressure, which makes the cornea shaped like a cone, affecting visual acuity due to astigmatism [6], [7]. Keratoconus usually affects around 1 in every 200,000 of the general population and affects children from the age of 10 years old [5], [8]. Moreover, keratoconus mostly affects individuals between 20 and 30 years old and has high rates in Middle Eastern and Asian ethnicities [7]. The causes of keratoconus are unknown, yet genetic factors are correlated; 1 in 10 people with keratoconus had a parent or a relative with the same disease [6]. Furthermore, keratoconus could be produced due to environmental factors such as eye rubbing, ultraviolet exposure, allergic diseases, and inflammation [6], [9].

Mainly, the treatment of keratoconus is either by stopping the progression of corneal ectasia or by improving vision, or both. Stopping the progression of corneal ectasia is done by corneal cross-linking to improve corneal stiffness. Improving vision is done by using eyeglasses or contact lenses. If none of the previous treatments worked, surgical intervention by Intrastromal corneal ring segments (ICRS) or corneal transplant would be the final solution [6]. The primary focus of this design paper will be on the application of contact lenses due to the difficulty and skills needed to wear them.

Contact Lenses

Contact lenses used to treat keratoconus are subdivided in terms of rigidity (stiffness) into soft, hard, and hybrid contact lenses [6]. Soft contact lenses correct blurry vision of keratoconus at early stages by altering the light refraction of the cornea's anterior surface. Yet, due to the elastic properties of soft contact lenses, they deform with the corneal deformation of keratoconus, creating an irregular refraction of the anterior surface of the cornea. Thus, a prescription needs to be changed regularly as the corneal shape changes [6]. Hard contact lenses have stiffer mechanical properties than soft contact lenses. Therefore, they are widely used to create a regular anterior surface for better light refraction [10]. Yet, hard contact lenses are less comfortable than soft contact lenses due to their rigid edges. Hybrid contact lenses combine soft and hard contact lenses, in which hybrid contact lenses are rigid at the center and soft at the edges. Such contact lenses offer the anterior regular surface for better light refraction, while soft edges for more comfort and easier insertion [7].

Hard Contact Lenses Insertion and Removal

Different rigidity of contact lenses requires different methodologies of insertion and removal of contact lenses for keratoconus patients. Soft contact lenses are widely spread and easy to insert or remove, yet stiffer contact lenses, such as hard and hybrid contact lenses, are more difficult to insert or remove, and require skills and special devices. Hard and hybrid contact lenses are inserted into the eye by first washing hands thoroughly to reduce the risk of eye contamination. Then, a hard or hybrid lens is put on the index finger facing upwards, and filled with a solution completely to eliminate bubble formation. Afterwards, the top lid of the eye is pulled upwards with the other hand, and the bottom lid of the eye is pulled downwards with the same middle finger of the same hand that has the contact lens. Then, the contact lens is pushed toward the corneal surface, ensuring there is minimal suction of the lens toward the cornea with no air bubbles in between. This procedure requires skills and training to be able to insert hard or hybrid contact lenses.

To reduce the difficulty of such a procedure, several devices were made to be utilized in the process of insertion or removal of the hard or hybrid contact lenses. One of the most widely used is the DMV silicon plunger. DMV plunger uses a suction cup to fasten the hard contact lens on one end and a hole that passes light through on the other end. Passing light through acts as a guide to focus the eye while inserting the hard contact lens. For removal, another silicon suction plunger is utilized to remove the contact lenses by putting the plunger on the lower one-third of the lens and pulling it out. The advantages of such plungers are the small size, ease of use, and simplicity. Yet, some of their disadvantages are that the insertion and removal of lenses are done with two separate devices. Furthermore, it is difficult to hold the eyelids open to insert the lens into the eye. Users need adequate training and skills to use a plunger correctly.

Moreover, many patents were found that utilize different techniques for inserting and removing hard contact lenses from the eye. Such patents range from 1977 up to 2019. Working principles in patents to insert a lens into the eye mainly depend on spring loaded cup [11], finger pressure on a rod [12], positive air pressure pumping [13], negative pressure (suction) [14], [15], or both positive and negative air pressure in the same device [16]. From the mentioned devices, some have several advantages such as preventing lens solution spills [11], lens insertion guidance [11], air puff for lens insertion [13], simplicity, and ease of use [14], [15], [16]. However, some have many disadvantages, such as the risk of using loaded springs and eye trauma [11], [12], [13], not containing spilled lens solution [12], [13], [14], [15], [16], and operating with both hands [11], [12], [13], [14], [15], [16]. There is a need for a device that combines most of the advantages, such as single-handed operation, safety, and ease of use, and avoids most of the disadvantages.

In this project, ideation sessions and concept selection were performed utilizing the Pugh method [17]. A design of a hard contact lens insertion/ removal device was proposed utilizing 3D computer-assisted design (CAD) software. Furthermore, an alpha phase prototype was 3D printed utilizing computer-assisted manufacturing (CAM) as a proof of concept.

MATERIALS AND METHODS

Clinical Needs Analysis

The author's personal experience with hard contact lenses was the source of initiating the clinical need. Furthermore, an optometry specialist and an optometry nurse at King Abdulaziz

University Hospital – Riyadh, Saudi Arabia, were interviewed to investigate further the need since they work with hard contact lenses regularly. A need statement was developed, which is: There is a need to develop a device for inserting and/ or removing hard contact lenses that is easier to use and does not require user skills in comparison to the currently existing devices.

Concept Generation and Selection

Three Ideation sessions on three different days and timings were conducted to generate ideas to develop a hard contact lens insertion/removal device [17]. Afterwards, initial concept selection was performed to reduce the number of initially generated concepts, and a mind map was drawn utilizing EdrawMind (version 9.0.10, Wondershare, Shenzhen, China). Then, User and Design Requirements were selected and weights assigned to each requirement to reflect its significance. For final concept selection, the Pugh method was used to compare the generated concepts' performance to the baseline performance [17]. Finally, scores were multiplied by user and design requirements weights, and final scores were obtained to quantitatively compare between generated concepts.

3D Computer-Assisted Design (CAD) Model

Notability (Ginger Labs, version 11.0.15, San Francisco, California, United States) was used to sketch the ideas on an Apple iPad. For the CAD model, Fusion 360 (Autodesk, educational version 2.0.12887, California, United States) was utilized. The design was divided into five main parts, then assembled into one assembly. The five parts are: housing, roller, plunger bracket, eyelid bracket, and eyelid fastener.

3D Computer Assisted Manufacturing (CAM) Model and Prototyping

To embody the proposed hard contact lens insertion/ removal device design, a 3D printed model was done utilizing Original Prusa i3 MK3S+ (Prusa, Prague, Czech). Prusa PLA filament (Prusa, Prague, Czech) was used with 0.15 mm of resolution. For the final version of the prototype, 20.11 m in length and 59.97 g in weight of filament was utilized; and the 3D printing duration was 8 hours and 26 minutes.

Testing

Each version was designed, 3D printed, and then assembled. Visual inspection of the insertion\ removal device was conducted to confirm parts fitting into the assembly. As a feedback loop, design iterations were made with altered measurements and features to correct any design or prototyping errors or faults from previous versions.

RESULTS AND DISCUSSION

Concept Generation and Selection

Three Ideation sessions on three different days and timings were conducted to generate concepts to develop a hard contact lens insertion/removal device [17]. Therefore, a total of thirty ideas were generated. One of them was selected by using the Pugh method [17]. As part of the Pugh method to select a concept, user and design requirements were determined to evaluate which of the ideas gets the highest total score to be selected. User and design requirements are requirements that are thought to increase the adoption of a new technology and make it more likely to sell. User and design requirements are summarized in Table 1, the concept must be able to insert and/ or remove hard contact lenses (R1), the concept must contain the spilled solution from the lenses (R2), the concept must be able to hold eyelids open

(R3) while inserting the hard contact lenses. Furthermore, the concept must contain a space to store hard contact lenses (R4), the concept must be easily cleaned and sanitized (R5), the concept must insert and/ or remove hard contact lenses without any contact with user hands or fingers (R6), and the concept must include a methodology that enables the end user to focus his eye on the center of the contact lens (R7).

Weights were assigned to each user and design requirement from the most significant (weight 5) to the least significant (weight 1). A weight of 5 means the requirement is highly significant, a weight of 4 means significant, a weight of 3 means medium significance, a weight of 2 means less significant, and a weight of 1 means the least significant requirement. Table 1 summarizes the user and design requirements and their weight scores.

Table 1: A summary of the user and design requirements (R1 to R7) with a weight scale (1 to 5), where 5 is the most significant and 1 is the least significant.

#	User and Design Requirements	Weight
R1	The concept must be able to insert and/ or remove hard contact lenses	5
R2	The concept must contain the spilled solution from the lenses	4
R3	The concept must be able to hold eyelids open	4
R4	The concept must contain a space to store hard lenses	1
R5	The concept must be cleaned easily	2
R6	The concept must insert/remove the hard contact lens without finger contact	3
R7	The concept must enable the user to focus on the center of the hard contact lens	5

To select the final concept to pursue as a design and a prototype, the Pugh method was utilized [17]. There were around thirty total generated concepts from which an initial concept selection was made, and only nine concepts were selected, labeled C1 to C9. Those nine concepts were abbreviated into one word for each functional part of the generated concept and summarized in Table 2. Plunger means to utilize the traditional DMV silicone plunger, tank is to preserve spilled contact lens solution in a reservoir, cotton is to absorb spilled lens solution with a cotton gauze, holder is to hold the eyelid, finger is an end designed like a human finger, light is adding a light source for the eye to be able to focus on the lens, storage is a space to store hard contact lenses, and cup is a dome-shaped cup to prevent spills of hard contact lens solution. As shown in Table 2, and following the Pugh method, scores assigned to the baseline are 0 for all user and design requirements. If the performance of the generated concept was better than the performance of the baseline in the specific user and design requirement, a score of +1 is assigned. If the performance of the generated concept was worse than the performance of the baseline in the specific user and design requirement, a score of -1 is assigned. If the performance of the generated concept was similar to the performance of the baseline in the specific user and design requirement, a score of 0 is assigned. Finally, scores were multiplied by the weight of each user and design requirement and combined for each generated concept to have a final total score at the bottom of Table 2.

Following the Pugh method mentioned above, and shown in Table 2, two concepts, C4 and C9, had equal total scores. Therefore, it was decided to use the functionality of both ideas and combine both concepts into one concept. As a result, it was determined to design a device that utilizes the traditional DMV silicone plunger, functions similarly to a human finger, and holds eyelids open as essential features in the proposed device.

Table 2: Pugh method final concepts selection table with requirements, weights, baseline, and generated concepts.

C9: Plunger +holder	C8: Plunger +finger	C7; Plunger +lens holder + focus point	C6: Plunger +cup +Focus point	C5: Plunger +light +storage	C4: Plunger + finger +holder	C3: Plunger +cotton +holder	C2: Plunger + cotton	C1: Plunger + tank	Baseline: DMV Silicon Plunger	Weight	User and Design Requirements
1	0	0	0	0	1	0	0	0	0	5	R1
0	0	0	1	0	0	1	1	1	0	4	R2
1	0	0	1	0	1	1	0	0	0	4	R3
0	0	0	0	1	0	0	0	0	0	1	R4
0	1	1	0	0	0	0	0	0	0	2	R5
0	1	1	0	0	0	0	0	0	0	3	R6
1	1	1	1	1	1	1	1	1	0	5	R7
14	10	10	13	6	14	13	9	9	0		Total

Hard Contact Lens Insertion\ Removal Device CAD Design

The final CAD design of the hard contact lens insertion\ removal device is composed of five main parts, which are then assembled into one device. The five parts are: housing, roller, plunger bracket, eyelid bracket, and eyelid fastener.

The housing is the main body of the proposed device (Fig. 1). It measures 74 mm in total length and 42.4 mm in diameter. The housing is composed of two different sections, an upper and a lower part. The upper part is inserted into the roller and measures 50 mm in height and 32 mm in diameter.

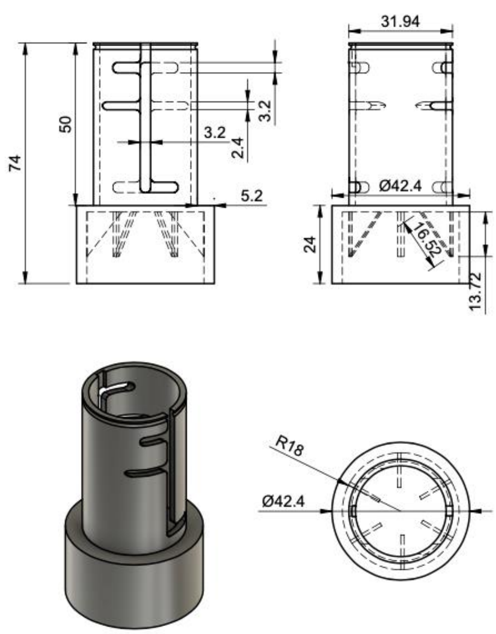

Fig 1: The housing CAD model illustrating the design and dimensions.

Also, the upper part consists of two open passages opposing each other, which act as a path for directing the pins of the plunger bracket and the eyelid bracket. Those open passages in the upper part of the housing are 3.2 mm in width. Additionally, those open passages include 3.2

mm wide ends to park the plunger bracket and a 2.4 mm wide middle passage to park the eyelid bracket and control its final protrusion height. The lower part of the housing is 24 mm in height and 42.4 mm in width. The lower part of the housing functions as a base for the proposed device and as a rotational controller, from which the end user can handle and rotate the device to insert or remove the hard contact lens.

The roller is the second designed part and the main controller to insert or remove the hard contact lens by controlling the protrusion of the plunger and eyelid fasteners (Fig. 2). The roller is 50 mm in height and 38 mm in outer diameter, and 33.5 mm in inner diameter. The roller contains two opposite spiral engraved passages on the inner side of it, which act as a guiding pathway for the plunger bracket and the eyelid bracket pins. Those engraved spiral passages lift both plunger and eyelid brackets upwards by their pins if rotated clockwise, and push both brackets downward by their pins if rotated counterclockwise. The roller is inserted on top of the upper portion of the housing as a sleeve and can rotate freely clockwise or counterclockwise, yet it is not free to move in any other direction on the XYZ planes.

Fig 2: The roller CAD model illustrating the design and dimensions.

The plunger bracket is the third component of the proposed device and functions as a bracket that holds the traditional silicon plunger (DMV) for hard contact lenses insertion or removal (Fig. 3). The plunger bracket is 31.5 mm in length and 26.6 mm in diameter. The upper part of the plunger bracket is hollow and measures 25.7 mm in length and 18 mm in diameter, and contains an opening on the top of it that is 6 mm in diameter and irradiates into four slits that are 15.85 mm in length and divide the top of the plunger bracket into four equal sections. This opening is to insert the DMV silicone plunger then the slits functions as springs to keep the DMV silicon plunger in place. The lower part of the plunger bracket is 6.3 mm in height and 26.6 mm in diameter. The lower part contains two protrusions (pins) that are 4.3 mm in length and 3.2 mm in diameter. Both pins are inserted through the open passages in the housing and the engraved spiral passages on the inner side of the roller. Pins are utilized to lift the plunger bracket upwards once the user rotates the roller clockwise, and pushes the plunger bracket downwards once the user rotates the roller counterclockwise.

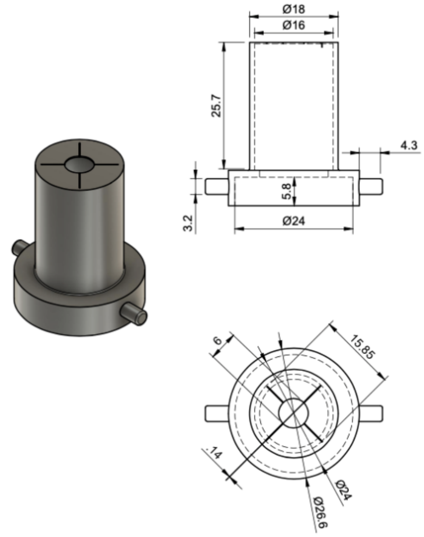

Fig 3: The plunger bracket CAD model illustrating the design and dimensions.

The eyelid bracket is the fourth component of the proposed device and functions as a bracket that holds the eyelid fasteners (Fig. 4). The eyelid bracket is 6.5 mm in thickness and 27 mm in diameter. The eyelid bracket contains an inner opening that is 18.4 mm in diameter, which allows the DMV silicone bracket and the upper portion of the plunger bracket to pass through. The eye lid bracket contains two small holes that are 2 mm in diameter to insert a 1.75 mm-thick rods that connect them to the eyelid fastener. Also, the eyelid bracket contains two protrusions (pins) that are 4.4 mm in length and 1.7 mm in diameter. Both pins are inserted through the open passages in the housing and the engraved spiral passages on the inner side of the roller. Pins are utilized to lift the eyelid bracket upwards once the user rotates the roller clockwise, then the pins park in the middle passage of the housing, then the eyelid bracket is pushed downwards once the user rotates the roller counterclockwise.

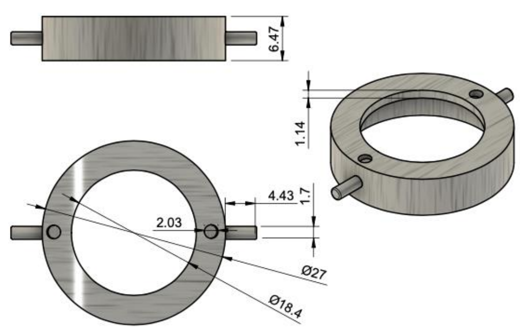

Fig 4: The eyelid bracket CAD model illustrating the design and dimensions.

The eyelid fasteners are two pieces, one for each eyelid, and are the fifth component of the proposed device. They are designed to fasten and hold open the top and bottom eyelids of the user's eye while inserting or removing hard contact lenses (Fig. 5). The eyelid fasteners are 34.5 mm in length, 4.15 mm in width, 3.24 mm in thickness, and their curvature is around 21 mm in radius. Each eyelid fastener contains a groove that is 32 mm in length, in which a rubber padding can be fitted inside to be in direct contact with the eyelids of the user. The eyelid fastener contains a small hole at the back that is 2 mm in diameter, in which the eyelid bracket is connected to the eyelid fastener via a 1.75 mm-thick rod.

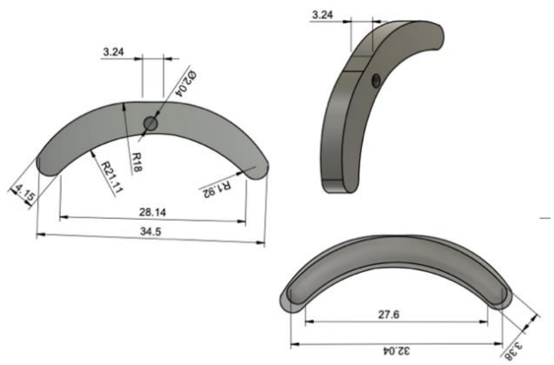

Fig 5: The eyelid fasteners CAD model illustrating the design and dimensions.

CAM Model and Prototype

A preliminary prototype (alpha phase) was 3D printed to visualize the design and structure of the proposed hard contact lens insertion/ removal device. Original Prusa i3 MK3S+ 3D printer and Prusa PLA filament were used with 0.15 mm of resolution to 3D print the CAM prototype. 20.11 m in length and 59.97 g in weight of filament was utilized; and the 3D printing duration was around 8 hours and 26 minutes.

Fig. 6 illustrates the 3D printed CAM model of the housing, showing the upper and lower portions previously mentioned. Moreover, both open passages, which function as pathways for pins of the plunger and eyelid bracket, and the ends, which function as a parking location for the pins of both brackets.

Fig 6: The 3D printed CAM model illustrating the housing of the proposed tool.

Fig. 7 illustrates the 3D printed CAM model of the roller, showing the two opposite spiral engraved passages on the inner side. Fig. 7A illustrates the final product, which shows the outer side of the roller without any opening and the inner side of the roller with engraved spiral passages. On the other hand, Fig. 7B shows the spiral passages open in the wall of the roller instead of just being engraved. This was done for visual representation only, from which the movement of the pins of the plunger and eyelid brackets in both the passages of the housing and the roller could be visualized in action while moving.

A **B**

Fig 7: The 3D printed CAM model illustrating the roller of the proposed tool. (A) Illustrates the final CAM model, while (B) does not include the outer layer to illustrate the working mechanism of the roller.

Fig. 8 illustrates the 3D printed CAM model of the plunger bracket, showing the upper and lower portions. It also shows the 6 mm diameter hole on the top surface of the plunger bracket to match the diameter of the traditional silicone plunger (DMV). Furthermore, the hole irradiates into four slits and divide the top of the plunger bracket into four equal sections. This opening enables the insertion of the DMV silicone plunger then the slits functions as springs to keep the DMV silicon plunger in place. The upper portion is high in higher for the plunger to reach the eye. Moreover, the prototype in Fig. 8 shows both pins on the sides of the lower portion of the plunger bracket, which are inserted into the open passages of the housing and the engraved passages of the roller to guide the movement of the bracket.

Fig 8: The 3D printed CAM model illustrating the plunger bracket of the proposed tool.

Fig. 9 illustrates the 3D printed CAM model of the eyelid bracket, showing the inner opening that will enable the plunger bracket to pass through. Furthermore, the prototype shows both pins on the sides of the eyelid bracket, which are inserted into the open passages of the housing and the engraved passages of the roller to guide the movement of the bracket. Also, the prototype shows the two 2 mm diameter holes on the top to insert the 1.75 mm thick rods that connect the bracket to the eyelid fasteners.

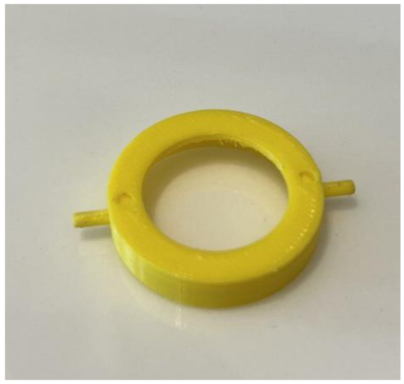

Fig 9: The 3D printed CAM model illustrating the eyelid bracket of the proposed tool.

Fig. 10 illustrates the 3D printed CAM model of the eyelid fasteners, showing the rubber padding (pink) inserted into the groove of the eyelid fastener (top eyelid fastener). Furthermore, Fig. 10 shows the 2 mm hole on the bottom of the eyelid fastener (bottom eyelid fastener) to insert the 1.75 mm thick rod that connects the eyelid fasteners to the eyelid bracket.

Fig 10: The 3D printed CAM model illustrating the eyelid fasteners (white color) of the proposed tool including the rubber padding (pink color).

Assembly and Operation

Assembling the proposed hard contact lens insertion/removal device is done by assembling all five designed parts, which are the housing, the roller, the plunger bracket, the eyelid bracket, and the eyelid fasteners (Fig. 11). First, the plunger bracket is inserted into the housing, in which both pins on each side are inserted through the open passages of the housing. Then, the DMV silicone plunger is inserted into the top opening of the plunger bracket. Second, the eyelid bracket is inserted on top of the plunger bracket, which passes through the inner opening in the eyelid bracket. Both pins of the eyelid bracket are inserted through the open passages of the housing. Third, the roller is inserted on top of the upper portion of the housing as a sleeve and can rotate freely clockwise or counterclockwise, yet it is not free to move in any other direction on the XYZ planes. It is important to make sure that both pins of the plunger and eyelid brackets are inserted into the engraved spiral passages on the inner wall of the roller. Fourth, a 1.75 mm diameter rod is inserted and glued in the top holes of the eyelid fasteners from one end and inserted and glued in the bottom holes of the eyelid fasteners from the other end. Doing so connects the eyelid bracket to the eyelid fasteners. Finally, the rubber paddings are inserted into the grooves on the top of the eyelid fasteners, making them ready to come in direct contact with the user's eyelids and operate.

To operate the proposed hard contact lens insertion/ removal device, the following steps should be followed. First, while the device is in the resting state (Fig. 11A), the hard contact lens is put on the DMV silicone plunger, facing downwards, where the concave side of the lens is facing upwards. Then, the hard contact lens is filled with lens solution to prevent the formation of air bubbles between the concave surface of the lens and the cornea of the eye. Second, the user tilts their head 90° degrees downwards, aligning their eye parallel to the hard contact lens and focusing on the lens to facilitate lens insertion. Third, the roller is rotated clockwise, which lifts the pins of both the plunger and the eyelid brackets upwards, hence moving the DMV silicone plunger and eyelid fasteners upwards (fig. 11B). By lifting the eyelid fasteners upwards, they move away from the plunger, and since they are in contact with eyelids, they will push eyelids open. Once the eyelid fasteners are in the appropriate position, holding the eyelids open, the eyelid bracket pins park in the middle open passages of the housing and do not move higher anymore. On the other hand, the plunger bracket keeps moving upwards to insert the hard contact lens into the eye. Once in the appropriate position, the plunger bracket's pins park at the end of the open passages of the housing and stop moving higher to prevent eye damage. Finally, the roller is rotated counterclockwise, where the plunger and eyelid fasteners get retracted, gently releasing the eyelids and returning the device into the resting state. For the removal of hard contact lenses similar process to what is mentioned above should be done again, except that the plunger does not include a hard contact lens on top of it.

A B

Fig 11: The assembled 3D printed CAM model of the hard contact lens insertion/removal tool. A) An illustration of the tool before inserting the hard contact lens into the eye (resting state). B) illustrates the tool when the plunger is elevated to insert the hard contact lens into the eye (expanded state).

Several difficulties may arise since the proposed device is a CAD model and an alpha-phase prototype. For instance, it is difficult to insert the DMV silicone plunger vertically due to the flexibility of silicone rubber and being compressed by the opening and four slits on top of the plunger bracket. Moreover, if the 3D printing is not high in resolution, the round features' surfaces become rough and not smooth. Hence, the pins passing through the engraved passages on the inner wall of the roller get stuck, which prevents the roller from rotating smoothly. Moreover, some features might be 3D printed in the wrong manner if not designed correctly.

For example, the engraved spiral passages in the roller were 3D printed incorrectly when it has a round cross-sectional design. To avoid such an issue, a square cross-sectional design was used for the engraved spiral passages. Other difficulties may arise due to the variability among users, such as the size of the eye and eyelids requires altering the dimensions of the eyelid brackets to function properly without injuring the user.

CONCLUSION

In summary, one of the most common types of vision diseases is refractive eye diseases, such as farsightedness and nearsightedness, which prevent light from properly getting focused on the eye retina, producing blurry images, and thus unclear vision [1], [2]. In both refractive eye diseases, corneal curvature plays a crucial role in correctly focusing light on the retina. Keratoconus is a chronic disease of the corneal ectasia that affects the corneal curvature of the eye [5], [6]. Corneal ectasia is the gradual thinning of the cornea and expansion outward due to internal pressure, which makes the cornea shaped like a cone, affecting visual acuity due to astigmatism [6], [7]. Mainly, the treatment of Keratoconus is either by stopping the progression of corneal ectasia or by improving vision, or both. Improving the vision could be done by utilizing hard contact lenses, yet they are difficult to insert into the eye and require skills. To reduce the difficulty of such a procedure, several devices were made to be utilized in the process of insertion or removal of the hard contact lenses. Yet, Users need adequate training and skills to use such devices correctly. There is a need for a device that combines most of the advantages of previously made devices, such as single-handed operation, safety, and ease of use, and avoids most of their disadvantages. In this project, ideation sessions and concept selection were performed utilizing the Pugh method [17]. A design of a hard contact lens insertion/ removal device was proposed utilizing 3D computer-assisted design (CAD) software. Furthermore, an alpha phase prototype was 3D printed and explored utilizing computer-assisted manufacturing (CAM) as a proof of concept. Further investigation, development, and testing on actual users of hard contact lenses are required to improve the proposed device and to provide a minimum viable product (MVP).

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