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Analyzing the Lenticule Created During the Small Incision Lenticule Extraction (SMILE) Procedure and Creating a 3D Model

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Abstract:

Purpose: To analyze the symmetry and adherence to the attempted end parameters of the lenticule formed during the Small Incision Lenticule Extraction (SMILE) procedure and create a 3D model of the lenticule using the MATLAB platform.

Methods: Three human donor corneoscleral buttons were each mounted on an artificial anterior chamber maintainer and received the SMILE procedure. Immediately following treatment, these corneas underwent imaging on the Avanti OCT to obtain lenticule pachymetry data. The data was then extracted and exported into Microsoft Excel, as well as a program written in MATLAB that compiles and displays the data as a 3D model of the lenticule. Statistical analysis was performed in Microsoft Excel.

Results: Attempted maximum lenticule thickness was 107 µm as reported by the VisuMax laser with a minimum thickness of 15 µm at 3.25 mm from the center. Post-treatment lenticule data showed an average central lenticule thickness of 117.24 µm, a minimum central thickness of 99 µm and a maximum central thickness of 128 µm. Lenticule thickness, when measured at the same radial distance within the same meridian varied by 9 µm on average and had an average standard deviation of 6.936 µm.

Conclusions: Lenticules formed during a SMILE procedure to treat a -6D refractive error using the VisuMax femtosecond laser were shown to be radially symmetric within 9 µm, having an average standard deviation of all points measured at each radial distance of 6.936 µm.

The symmetry of the lenticule formed during the SMILE procedure shows that small incision lenticule extraction is an effective treatment for those eyes without astigmatism. However, the measured post-treatment lenticule data showing the lenticule to be 10 µm thicker than the attempted lenticule thickness necessitates special consideration to be taken when treating an eye that presents with thinner than ideal pachymetry data. Due to the symmetric nature of the lenticule, it may be a viable option for the correction of high hyperopia without astigmatism by implanting it in a created pocket or under a flap.

Introduction

Refractive laser surgery, specifically laser-assisted in situ keratomileusis (LASIK), has offered an attractive solution for those seeking spectacle independence. During this procedure, surgeons employ the use of lasers to physically change the shape of the transparent front part of the eye known as the cornea. This is done by first making a flap of tissue with an excimer laser, then lifting the flap to reveal the stromal tissue beneath. The eye is then positioned below the femtosecond laser and tissue is ablated away, thus reshaping the cornea.

Potential complications following the LASIK procedure may include flap dislocation[1], decreased biomechanical stability of the cornea leading to corneal ectasia[2–4], decreased corneal innervation leading to dry eye[5–7], and more.

In recent years, a new less invasive and flapless variant of refractive surgery has been introduced under the name of small incision lenticule extraction (SMILE). Rather than using both an excimer and femtosecond laser like LASIK, the SMILE procedure utilizes only a femtosecond laser to create a disc of stromal tissue below the surface, called a lenticule. This removes the need to make a flap. The lenticule is then extracted by the surgeon through a small incision. Due to the flapless nature of the surgery, the number of vertical cuts in the cornea is reduced, which increases preservation of corneal innervation and biomechanics. The preservation of corneal innervation can lead to a decrease in dry eye symptoms.

The lenticule formed during the SMILE procedure is ordinarily discarded following the treatment, but it could potentially be preserved for re-implantation into the pocket, thus allowing the treatment to be reversable[8,9]. Alternatively, the lenticule could be used for another patient as donor tissue used to treat various other refractive conditions such as high hyperopia, or presbyopia. This is conceptually similar to an existing technology called implantable hydrogel inlays.

There have been various studies concerning the use of hydrogel inlays for the correction of hyperopia and presbyopia[10–13], but the implantation of human donor tissue to correct these issues is not yet widely practiced. These studies have shown that artificial inlays can have a negative impact on nutrient transfer within the cornea[11,12]. It is possible that implanting a lenticule made from corneal stroma tissue will mitigate nutrient transfer issues while achieving similar refractive corrections. To the best of our knowledge, very few case reports of patients who have undergone lenticule implantation have been published, so the visual outcomes, both in the long- and short-term are largely unknown[7,14,15].

Before the technique of lenticule implantation can be widely practiced, it is important to understand the properties and fine details of the lenticule. It is for this reason we are investigating the symmetry and adherence to the attempted end parameters of the lenticule formed during the SMILE procedure.

Methods

Corneoscleral buttons that were deemed unsuitable for human transplant were obtained from Utah Lions Eye Bank (Salt Lake City, Utah, United States). All the obtained corneas had good opacity, no ulcers, and no significant corneal edema. The corneoscleral buttons were received in Optisol storage medium and soaked in glycerin for five minutes prior to rinsing and mounting on an artificial anterior chamber maintainer (AAC; Moria Inc., Doylestown, Pennsylvania, United States). Balanced salt solution (BSS) was used to pressurize the chamber to simulate appropriate physiological intraocular pressure (IOP), about 15 to 25 mmHg. A Tono-Pen Avia tonometer (Reichert Inc., Dewport, New York, United States) was used to monitor pressure. The corneoscleral buttons were kept in this configuration for the duration of the surgery and scans.

The mounted corneoscleral buttons first underwent corneal imaging on the Pentacam (Oculus, Arlington, Washington, United States) and the Avanti OCT (Optovue, Inc., Fremont, California, United States). The keratometry and pachymetry data obtained from the Pentacam scan was used to provide the required values for the VisuMax prior to treatment.

To ensure consistent orientation and centration for all scans, an AAC holder was custom made (Figure 1 A-C). By mounting the AAC in the holder, we were able to achieve a consistent axial orientation, a reference for the center of the cornea, and a stabilizing mechanism to ensure quality, in focus scans. These details are crucial to maintain the integrity of the data.

The VisuMax 500 kHz femtosecond laser was used to perform the SMILE treatment using the following surgical parameters: a correction of 6 diopters of sphere, cap thickness of 120 µm, and cap diameter of 7.5 µm. Lenticule diameter was set to 6.5 mm, with a minimum lenticule thickness of 15 µm. Spot separation for the lenticule was 3 µm and 2.5 µm for the lenticule side-cut. The side-cut incision was 5.89 mm long and placed at 90º. The laser-bed energy was set at 145 nJ. The above settings the VisuMax predicted a maximum central lenticule thickness of 107 µm.

Standard SMILE procedures were followed throughout, with few exceptions. The AAC holder was placed horizontally on the headrest and the cornea was raised to the applanation glass of the femtosecond laser. The applanation glass used was specially designed for preparation of corneal grafts and does not apply suction to the cornea as a standard applanation glass would. The lack of suction aids in maintaining the appropriate IOP of the corneoscleral button on the AAC. Once the cornea was centered and good applanation was achieved, the laser was activated. The lower interface of the lenticule was created first, followed by the upper interface and the small incision used to access the lenticule. The laser portion of the treatment lasted for approximately 35 seconds [6].

Once lenticule formation was complete, the bed was moved below the surgical microscope. A Johnston flap applanator was used to force the formed gas bubbles out through the small incision to aid in achieving higher quality OCT measurements and a clearer lenticule interface.

Following the treatment, the corneoscleral button was imaged again on the Avanti OCT. While the AAC mount provided a stable base, it was still impossible to achieve a perfect centration on the scan. As such, efforts were made to correct for any misalignment through the data collection process.

Data collection from the Avanti OCT was done by using the built-in caliper tool in the software to measure from the posterior surface of the lenticule to the anterior surface.

The demarcation of the lenticule profile was clearly visible as a white line of remaining gas bubbles (Figure 2A). Thickness measurements were acquired at 0.0 mm, 0.50 mm, 1.00 mm, 1.50 mm, 2.00 mm, and 3.00 mm measured radially out from the center of the lenticule (Figure 2B) along each meridian. The Avanti OCT collects data along eight meridians that are separated by 22.5º. Data along each meridian is collected two separate times.

Care was taken to locate the center of the 6.5 mm diameter lenticule to mitigate any alignment error. This was done by locating the end of the cut on either side, then taking the center point. The data was saved into an Excel spreadsheet and imported into a MATLAB (The MathWorks, Inc., Natick, Massachusetts, United States) program that compiles the data and displays it in a 3D model (Appendix). Statistical analysis was performed in Microsoft Excel.

Results

Thickness values of the lenticules can be seen in Tables 1-3. Columns 1-8 represent the data collected from the first pass along the eight meridians. The data from the second pass is represented in columns 9-16. The difference between two mirrored points on the same meridian (eg. 2 mm left of center and 2 mm right of center) was calculated for each radial distance and averaged over the 16 measurements for each lenticule, then averaged again over the three lenticules. The averaged difference in mirrored points was found to be 9 µm with an average standard deviation of 6.936 µm. Maximum lenticule thickness was similarly calculated: each of the meridian’s central measurement was averaged, and again averaged over the three lenticules, yielding an average maximum lenticule thickness of 117.24 µm, 10.24 µm higher than the anticipated thickness of 107 µm as calculated by the VisuMax femtosecond laser.

Discussion

This study was aimed to examine the symmetry and adherence to attempted end parameters of the lenticule formed during the SMILE procedure. It was found that the formed lenticule exhibits radial symmetry immediately following formation and while still within the intact cornea. It was also found that the formed lenticule is approximately 10 µm thicker than anticipated.

The effect of dissection and removal of the lenticule from the corneal pocket was not examined. It was demonstrated that a good applanation leading to an even ablation yields a symmetric lenticule prior to extraction. Supposing a clean extraction of the lenticule is achieved, it is hypothesized that thickness and symmetry of the lenticule will not be significantly different following extraction. If an uneven ablation pattern is observed, tearing of the cap, bed, or lenticule may occur during extraction, leading to a decrease in lenticule symmetry.

Lenticule reimplantation aimed to reverse the procedure has been examined in rabbits and monkeys[8,16]. These studies have found that the central corneal pachymetry, keratometric, and topographic indices returned to near preoperative status, showing the potential reversibility of a lenticule extraction procedure. However, the biomechanical response of reimplanting a lenticule into the pocket whence it came is not necessarily the same as implanting a lenticule into a newly created pocket. Ex-vivo studies in human corneal tissue have shown that lenticule implantation for correcting hyperopia generally results in under correction when the lenticule's refractive power is similar to the intended correction [7,14,17]. The thickness of the lenticule certainly has a drastic effect on the refractive outcome, through both the power of the lenticule as well as inducing changes in the anterior and posterior curvature of the cornea.

There were several limitations to this study, the most prominent being the small sample size, quality of tissue, and learning curve. Having a larger sample size would have provided us with greater statistical power and more accurate data on average. While we did seek out the best tissue available to us, the overall quality was far from perfect; pachymetry data was incongruous between tissues and the age of tissue was varied. Having more pristine tissue samples may provide more accurate, consistent results. Lastly, the learning curve associated with SMILE, especially when operating on a corneoscleral button that is mounted on an AAC, in conjunction with multiple surgeons may have slightly affected the data.

Improvements

A recent study showed that lowering the laser energy level to 125 nJ yielded improved visual acuity with fewer corneal aberrations in the early postoperative period following SMILE[18]. As further investigation is done, lowering the energy level may make the lenticule interface more smooth and crisp, allowing increased precision of lenticule thickness measurements.

Further study needs to be conducted concerning the actual power of the lenticule based on the curvature of the lenticule. The anterior curvature of the lenticule will be equivalent to the applanation glass' curvature, as the anterior cut of the lenticule is always 120 µm from the cornea's anterior surface. Investigating the power of the lenticule based on collected data may shed more light on the achieved visual outcomes of procedures involving lenticule implantation. Progress has been made on this front, though not enough to include it in the body of this paper. Notes and calculations that were written in Wolfram Mathematica are included in Appendix B.

Conclusion

This study showed the lenticule formed during the SMILE procedure with the VisuMax femtosecond laser to be radially symmetric but thicker than anticipated. The symmetry of the lenticule indicates that the SMILE procedure is an effective treatment to correct refractive error in eyes without astigmatism. However, the thicker than attempted lenticule thickness necessitates special consideration to be taken with regards to biomechanical stability. Additionally, the symmetric nature of the lenticule lends itself well to be a possible instrument in the correction of high hyperopia without astigmatism by implanting it in a created pocket or under a flap.

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Tables and Figures

Lenticule 1 Thickness Values (µm)

Distance from center (mm)	Meridian 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
-3.0	36	38	42	44	45	46	45	42	46	49	38	36	35	46	38	46
-2.0	73	69	73	79	65	66	68	66	70	79	82	88	70	79	76	76
-1.5	86	77	99	90	70	66	88	83	91	86	87	96	73	83	88	83
-1.0	94	98	102	90	103	86	87	86	107	98	99	99	90	91	87	95
-0.5	111	115	111	111	111	104	99	107	111	119	115	94	111	115	116	113
0.0	120	124	111	123	115	119	115	111	115	119	128	128	102	115	115	111
0.5	120	115	120	111	111	119	111	107	107	112	115	119	111	111	119	115
1.0	117	108	117	103	94	102	102	98	107	103	115	111	111	115	111	107
1.5	117	84	98	99	87	94	94	85	87	82	109	104	99	103	115	86
2.0	82	62	74	87	84	87	83	74	66	72	94	91	86	87	90	74
3.0	45	42	42	40	40	42	46	46	48	42	50	54	44	42	46	40

Table 1: Lenticule 1 thickness values measured in micrometers. Meridians 9-16 are repeated measurements of meridians 1-8.

Lenticule 2 Thickness Values (µm)

Distance from center (mm)	Meridian 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
-3.0	36	36	58	50	38	36	46	32	44	40	32	50	40	44	38	56
-2.0	88	80	86	77	83	66	91	83	74	99	96	73	74	79	70	98
-1.5	90	86	98	94	86	104	116	109	90	99	103	90	90	99	104	101
-1.0	99	94	119	102	94	111	103	112	90	115	111	98	98	107	116	111
-0.5	115	102	111	115	132	119	115	115	102	115	119	119	115	111	111	120
0.0	128	99	111	111	111	111	128	119	111	124	111	120	116	119	115	123
0.5	119	112	103	107	111	94	115	119	108	115	103	112	103	111	115	111
1.0	107	103	99	126	105	104	107	112	104	116	105	108	104	108	108	107
1.5	110	105	94	114	90	96	88	109	106	102	92	98	91	96	95	104
2.0	94	96	68	96	76	74	88	87	86	96	76	74	72	72	83	74
3.0	64	56	38	38	45	45	36	42	49	56	38	49	40	42	42	42

Table 2: Lenticule 2 thickness values measured in micrometers. Meridians 9-16 are repeated measurements of meridians 1-8.

Lenticule 3 Thickness Values (µm)

Distance from center (mm)	Meridian 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
-3.0	46	43	39	38	46	55	49	62	44	44	-	50	49	56	32	35
-2.0	91	77	80	87	84	94	94	95	79	83	-	80	78	86	92	96
-1.5	107	88	91	104	104	101	105	105	102	90	-	111	102	105	99	112
-1.0	119	108	97	108	113	103	108	113	115	106	-	103	113	103	107	109
-0.5	115	118	111	115	115	128	115	108	124	111	-	120	119	120	112	124
0.0	120	121	123	119	115	123	123	111	119	115	-	120	119	115	119	119
0.5	112	113	105	120	120	115	111	111	116	115	-	115	115	115	115	119
1.0	113	112	101	103	116	108	111	103	108	116	-	114	104	104	107	111
1.5	98	99	91	101	96	94	91	98	96	106	-	90	94	91	99	104
2.0	86	94	96	84	82	78	83	87	86	84	-	84	94	70	87	87
3.0	55	58	58	38	45	49	42	38	59	52	-	46	45	35	52	44

Table 3: Lenticule 3 thickness values measured in micrometers. Meridians 9-16 are repeated measurements of meridians 1-8. The OCT was unable to acquire data for meridian 11.

Standard Deviation of Thickness Measurements

	Distance from center *-3.0 mm*	*-2.0 mm*	*-1.5 mm*	*-1.0 mm*	*-0.5 mm*	*0.0 mm*	*0.5 mm*	*1.0 mm*	*1.5 mm*	*2.0 mm*	*3.0 mm*	*Average*
Lenticule 1	4.502	6.560	8.928	6.633	6.473	6.816	4.449	6.850	11.057	9.347	3.928	6.868
Lenticule 2	7.962	10.071	8.594	8.914	7.057	7.637	6.652	6.205	7.907	9.899	7.848	8.068
Lenticule 3	8.096	6.801	7.126	5.640	5.581	3.432	3.852	4.978	4.853	6.457	7.769	5.871
												6.936

Table 4: Standard deviation of lenticule thickness measurements between all values measured at a specific radial distance.

Figure Legends

Figure 1 A: The artificial anterior chamber maintainer (AAC) holder is designed to produce a stable positioning and alignment when performing scans by holding the AAC in a consistent orientation. **B:** The Moria AAC is held in constant orientation with easy access to the pressurizing ports. **C:** The AAC holder uses the chin rest of the device when performing scans to minimize minute movements.

Figure 2 A: OCT image of a 6D lenticule created after the SMILE procedure using the VisuMax femtosecond laser. **B:** OCT image of a 6D lenticule that was measured by using the Avanti's built-in caliper tool at radial distances of 3.00 mm, 2.00 mm, 1.50 mm, 1.00 mm, 0.50 mm, and 0.00 mm.

Figure 1

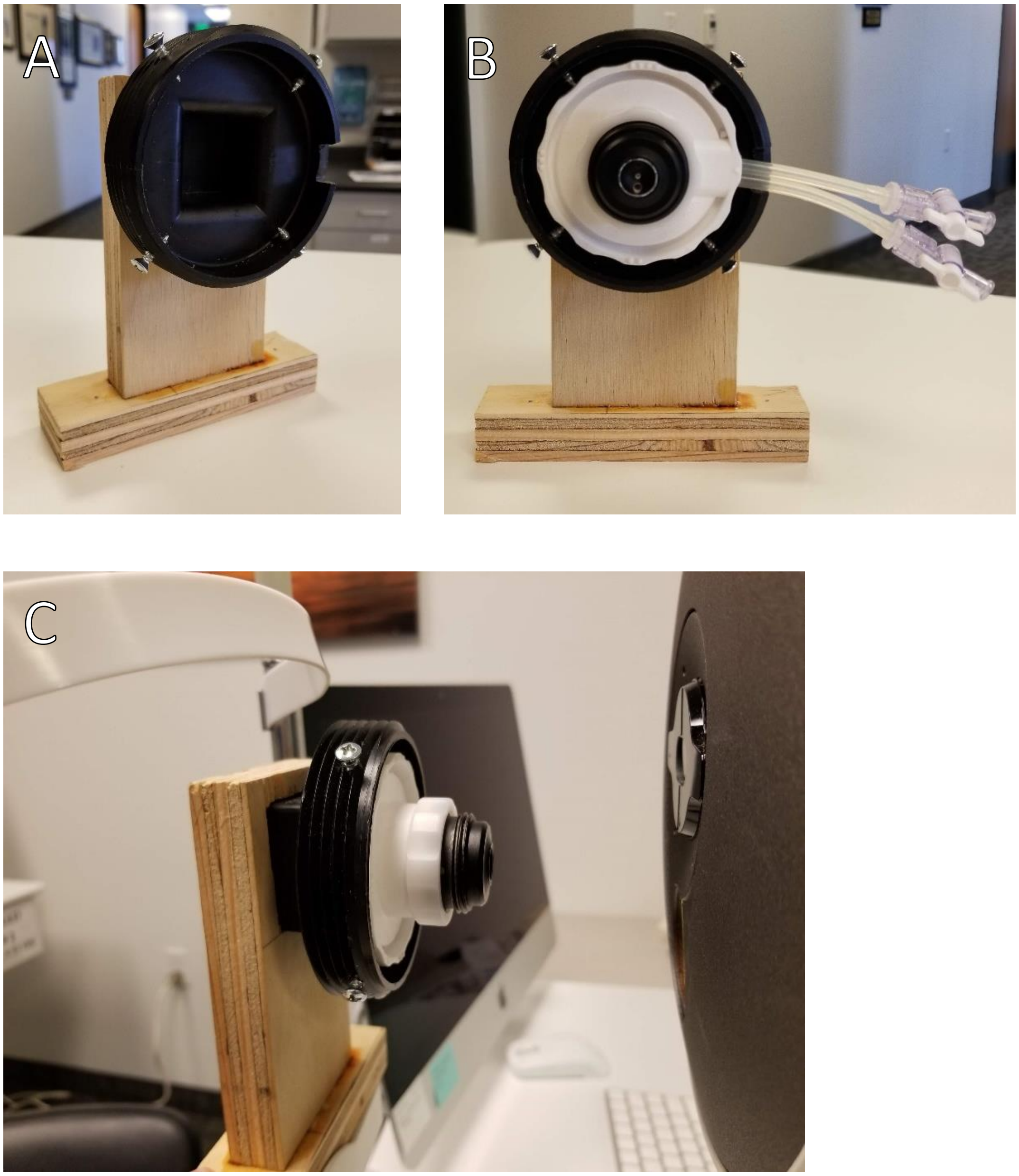
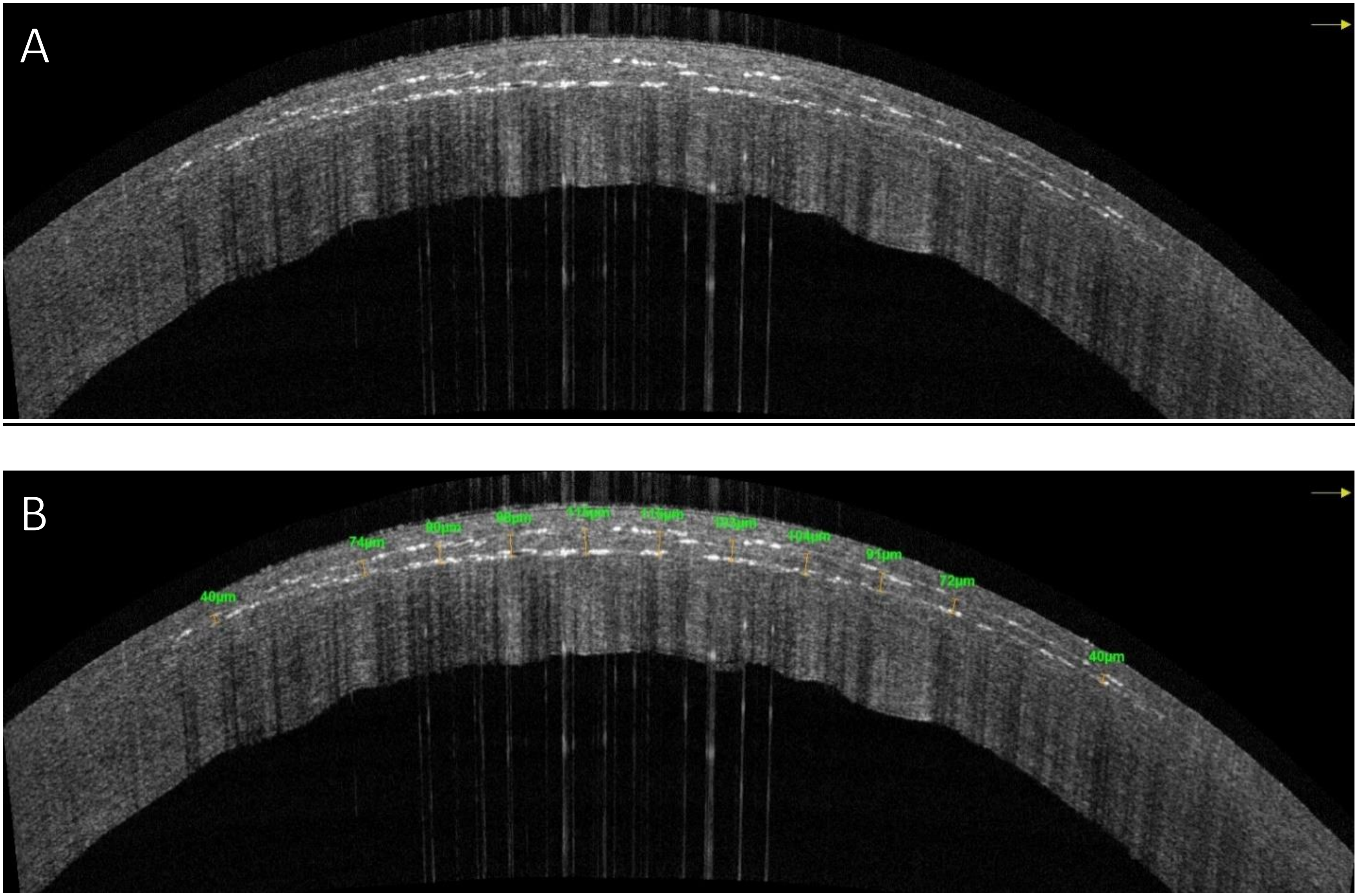
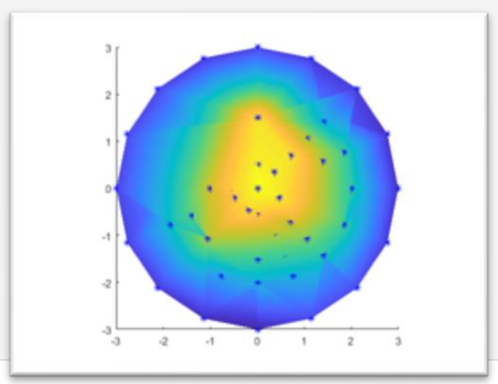


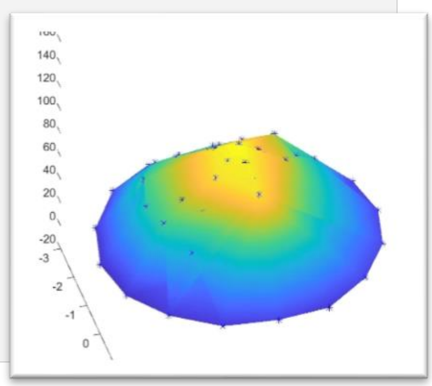
Figure 2



Appendix A

```
%Enter lenticule thickness data into the t matrix to produce a plot of it.
close; clearvars -global;

%t is thickness data. Enter data along each meridian as a single row of the t matrix
t = [%0/180 degrees-
    36, 73, 86, 94, 111, 120, 120, 117, 117, 82, 45;
    %22.5 degrees-
    38, 69, 77, 98, 115, 124, 115, 108, 84, 62, 42;
    %45 degrees-
    42, 73, 99, 102, 111, 111, 120, 117, 98, 74, 42;
    %67.5 degrees-
    44, 79, 90, 90, 111, 123, 111, 103, 99, 87, 40;
    %90 degrees-
    45, 65, 70, 103, 111, 115, 111, 94, 87, 84, 40;
    %112.5 degrees-
    46, 66, 66, 86, 104, 119, 119, 102, 94, 87, 42;
    %135 degrees-
    45, 68, 88, 87, 99, 115, 111, 102, 94, 83, 46;
    %157.5 degrees-
    42, 66, 83, 86, 107, 111, 107, 98, 85, 74, 46;];

%r is radial distance of measuremnts
r = [-3, -2, -1.5, -1, -0.5, 0, 0.5, 1, 1.5, 2, 3];

%make empty slots for the data to go into
[x,y] = size(t);
for c=1:size(t)
    %loops through and plots the measured t at the associated r
    for i=1:length(r)
            theta = [0, deg2rad(22.5), deg2rad(45), deg2rad(67.5), deg2rad(90), deg2rad(112.5),
deg2rad(135), deg2rad(157.5)];
            x(c,i) = r(i).*sin(theta(c));
            y(c,i) = r(i).*cos(theta(c));
    end
end
hold on
%plot all iterations
plot3(x,y,t,'b*')

%Makes a surface plot
tri = delaunay(x,y,t);
h = trisurf(tri,x,y,t);
axis vis3d
shading interp
```





Published with MATLAB® R2017b

Appendix B

In[681]:= (*

This code is used to perform various calculations to aid in figuring out the curvature and location of the posterior sphere used to form a lenticule. The code also displays a cross-section view of the cornea.

Issues to solve:

The 6.5 mm lenticule diameter is not defined as the location where the two offset spheres intersect, but rather where they are 15 microns

apart. The laser sets a minimum thickness of 15 microns, not 0 microns.

Lenticule thickness is dependent on both curvature and spacial positioning of the posterior sphere. While the spacial positioning can be calculated based on central lenticule thickness, the curvature still needs to be found.

The curvature must be such that the separation between spheres is 15 microns at a radial distance of 3.25 mm.

Define the variables.

r1 is the anterior curvature. This is determined by applination cone.

r2 is is the posterior curvature. An estimation is made based on the thin lens equation and the assumption that the lenticule is indeed +6 diopters.

a is the linear distance between the two intersecting circles. It is

calculated from the arc length of lenticule □assumed to be 6.5 mm□.

t is lenticule thickness.

*)

```
Clear["Global`*"]

(*Define Variables*)

r1=20;
r2=31.099;
a=6.451;
mm=1000;

(*Solve for separation of the center point of the two spheres*) sols=Values□
    Solve□a==1□d*Sqrt□□-d+r2-r1□*□-d-r2+r1□*□-d+r2+r1□*□d+r2+r1□□,d□//N□;
sep=Part[sols,1,1];

Print["calculated sep= ", sep, " mm"]
```

```
(*calculate max lenticule thickness*) t=□sep-r2+r1□*mm;
Print["calculated central t= ", t, " mm"]

(*calculate lens power based on radii*) power=1000*.336*□1□r1-1□r2□;
Print["Lens power= ", power," D"]

(*calculate expected separation from expected lenticule thickness □107 microns□ *)
Values□Solve□t/.t→107==□distance-r2+r1□*mm,distance□□;
Print["expected sep= ",Part[%,1,1]//N," mm"]

(*Graph the two radii to show lenticule profile. The vertical red lines show where *)



circle1=Circle[{0,0},r1]; circle2=Circle[{0,-11.22},r2];
pts=Solve[{x,y}∈circle1&&{x,y}∈circle2,{x,y}]

Graphics[{circle1,circle2,{Red,PointSize[Large],Point[{x,y}/.pts]},

    {Red,Line[{{3.25,0},{3.25,20.2}}]},{Red,Line[{{-3.25,0},{-3.25,20.2}}]}},

  PlotRange→{{-3.5, 3.5},{19.4,20.2}},Axes→True,ImageSize→Full]
```

```
calculated sep= 11.1931 mm

calculated central t=

94.0877 mm Lens power=

5.99579 D expected sep=

11.206 mm
```

Solve: Solve was unable to solve the system with inexact coefficients. The answer was obtained by solving a corresponding exact system and numericizing the result.

Out[697]= {{x→-3.65081,y→19.664},{x→3.65081,y→19.664}}

Out[698]=