OPTIPOINT™ CORNEAL TEMPLATE How an innovative device is helping surgeons optimize their NearVision CK outcomes

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NearVision CK (Conductive Keratoplasty) for the correction of hyperopia and presbyopia on the surface appears to be a relatively simple procedure. But, as we and hundreds of other experienced CK surgeons have learned during 150,000 NearVision CK procedures, there are a few technical challenges that a surgeon must overcome to achieve optimal refractive results. These challenges include:

- Proper centration and marking of treatment
- Appropriate hand position
- Correct placement and depth of Keratoplast tip
- Accurate amount and consistency of pressure on the comea

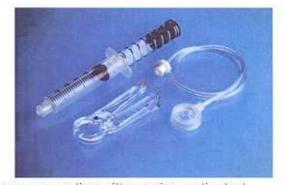
To help the NearVision CK surgeon acquire requisite skills quickly, Refracted has developed an innovative new device, the OptiPoint corneal template. This device addresses all the inherent challenges of NearVision CK, making it easier to learn and perform the procedure consistently. Additionally, patients find the procedure quite easy to tolerate with the OptiPoint corneal template in place.

STEPS FOR USING THE OPTIPOINT CORNEAL TEMPLATE

The OptiPoint corneal template is designed to fixate the eye, and provides a centration feature for ease of placement of the device on the entrance pupil. It also guides spot marking and the location on the cornea subsequent surgical manipulation and placement of the Keratoplast® fip.

The product is packaged in a sterile pouch and tray that includes the following components: one OptiPoint corneal template with flexible tubing; one OptiPoint gripper (a handle to help with application of the template on the eye); and one luer-lock syringe.

To perform the NearVision CK procedure using the OptiPoint corneal template, the surgeon must first insert a Lieberman-style speculum (that is designed for use with the ViewPoint CK System); the Lieberman speculum is important to insure that the patient's palpebral fissure is open enough to accommodate template placement. The surgeon then marks the center of the pupil by making a small mark with a Sinskey hook. The center opening of the OptiPoint template is centered over the



surgeon's mark and applied to the eye using light vacuum suction with a spring-activated syringe,

The template has three rings of eight pre-drilled spot holes at 6.0 mm, 7.0 mm and 8.0 mm, providing precise locations for spot placement using the Keratoplast fip. The CK treatment is applied in a circular pattern. The surgeon must select the appropriate CK treatment plan based on their own personal nomogram, just as they would with the freehand CK technique.

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OVERCOMING THE CK LEARNING CURVE

The OptiPoint corneal template addresses at least four common challenges with the procedure: centration, alignment or placement of spots, depth of treatment, and application of pressure on the cornea.

- Centration: Using the freehand technique, an erroneous initial mark using an inked CK corneal marker can result in a decentered CK treatment. The standard CK corneal marker creates inked hash marks on the comea at the 6.0-, 7.0- and 8.0-mm optical zones, making it difficult to re-mark if they aren't quite centered. With the OptiPoint template, it is very easy for the surgeon to line up the device with the pupil center mark (made using a Sinskey hook). Once suction is activated and the template is adequately secured on the cornea, the template spot holes are perfectly centered relative to the central mark. Of course, one should make sure that the template does not slip or move on the cornea; if there is any movement, you would see through the translucent template that the central mark was off center or not visible.
- Placement: For ideal results with CK, all of the spots need to be of equal distance from the
 center of the cornea, perpendicular to the cornea, and tangential to one another. The
 angle of approach with the Keratoplast tip and the surgeon's hand position or hand stability
 can affect spot placement when the treatment is applied using the freehand technique, but
 the OptiPoint template stabilizes the eye and ensures proper treatment application.
- Depth of treatment: When the Keratoplast tip is inserted completely through the OptiPoint
 corneal template hole this is very easy to visualize through the translucent template the
 radiofrequency energy is delivered to the same depth at every CK treatment spot. Because
 of this, we achieve consistency across all CK spots that we expect this may improve the
 stability of the CK treatment.
- Pressure: In recent years, we have realized the importance of pressure on the cornea during CK procedures. We realized that the harder the surgeon pressed, the less effect they got with the CK treatment. The resulting Light Touch technique provided improved and more robust outcomes greater treatment effect by applying fewer spots but requires a surgeon to judge the size of the corneal indentation to determine whether pressure is adequate. Distinguishing a 2.0 to 3.0-mm dimple from a 5.0 to 7.0 mm one (as was used in the conventional CK technique) is not always easy. In addition, we have always instructed surgeons to "follow the cornea down" as it shrinks away from the Keratoplast tip after the first few spots in a LightTouch procedure.

The OptiPoint corneal template offers one less thing—the amount of pressure applied on the cornea – for the surgeon to monitor. Once the OptiPoint template is activated, the surgeon really can't press too lightly or too hard with the Keratoplast tip; the surgeon will obtain the same application of pressure as long as the Keratoplast tip is inserted all the way through the pre-drilled holes of the template. This should greatly reduce any variability in the pressure from spot to spot or from surgeon to surgeon, thereby also improving the consistency of effect and reducing cylinder induction.

These factors are important because performing all these properly reduces the likelihood of inducing astigmatism. Conductive keratoplasty works by shrinking the corneal collagen. When the CK spots are applied in a perfect circle, we get an even thermal effect that forms a belt around the cornea to steepen it. But if one of the "belt loops" is not in the correct place, or if the tension forces between spots are uneven for some reason, the treatment effect may be reduced or astigmatism may be induced. This is very similar to what we see with corneal sutures in transplants.

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RESULTS USING THE OPTIPOINT CORNEAL TEMPLATE

We, along with a few other colleagues, have performed over 50 NearVision CK procedures using the OptiPoint corneal template from September 2006 to March 2007. Below is a summary of the six month results using the OptiPoint template.

Results with OptiPoint Corneal Template
Treatment Pattern – 16 spots at 7 and 8 mm OZ

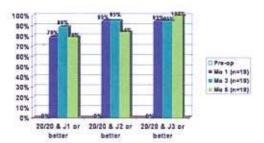
| | Month 1 | Month 3 | Month 6 |
|----------------------------------|----------------|----------------|----------------|
| Number of patients DSD HLM | 22 19 | 20 11 | 15 4 |
| Mean effect DSD HLM | 1.88D 1.83D | 1.54D 1,54D | 1.39D 1,38D |
| 1.00 DC DSD HLM | 9% 1% | 5% 0% | 0% |

While using the template, we have found that the device offers the following benefits:

- Greater consistency with each CK treatment spot delivered and from procedure to procedure
- Procedure easier to perform because of standardizing technique
- May improve consistency of CK refractive outcomes and standardize CK surgical plan from surgeon to surgeon

We found the current design of the OptiPoint corneal template to work on most typical CK cases. We also believe that we are seeing good stability of the CK effect and a possible reduced rate of induced astigmatism. As with any refractive surgery, we would encourage surgeons to monitor their own data and refine their own nomogram based on their outcomes using the OptiPoint corneal template and the CK freehand technique.

Binocular UCVA- Distance 20/20 & Near OptiPoint Comeal Template



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THE NEARVISION CK PROCEDURE USING THE OPTIPOINT CORNEAL TEMPLATE - SIMPLER AND FASTER

Using the OptiPoint corneal template will likely shorten the learning curve for new surgeons adopting NearVision CK. Learning how to use the OptiPoint template may take just one or two cases. During the new surgeon's initial procedures, the surgeon can make sure the corneal template is centered and is adequately affixed to the cornea before the surgeon begins the procedure, making it an ideal learning tool.

In fact, we originally conceived the OptiPoint corneal template as something CK surgeons would discontinue after gaining experience with the CK procedure. However, both of us, as well as Dr. Antonio Mendez-Gutierrez, who invented the CK procedure, prefer using the OptiPoint template over the freehand CK technique. Although we found the template initially slowed down the procedure time slightly, it now makes the procedure go faster because the surgeon can apply the CK treatment spots in a clockwise fashion, instead of in a cross-cornea pattern that is required with the freehand technique to balance CK's effect on the cornea.

We have also found that patients really like the OptiPoint corneal template. The device obscures the patient's vision a little bit during the procedure, similar to what patients experience during a microkeratome pass. We inform patients that their vision may get a little fuzzy, and they

OptiPoint Corneal Template - Durie & Milne (continued)

will see some light, but just to stare straight ahead. This seems to eliminate concerns about where they should look during the CK treatment.

The OptiPoint corneal template represents an advance in the NearVision CK procedure for both the doctor and the patient. Surgeons will find that it addresses many of the technical challenges that might have caused anxiety in performing CK previously. Although we await definitive results from our study, we are confident that the OptiPoint corneal template will improve CK results by reducing variability and improving consistency of treatment.