Project for Sustainable Eye Care

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Mech 402: Senior Design

Professor Charles Kim

Final Report

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Contents

1 Executive summary

The Project for Sustainable Eye Care (ProSEC) is a multi-disciplinary team consisting of engineering and management students and professors, a local optometrist, members of Christ Wesleyan Church, and engineers in San Pedro, Guatemala. The goal of the project is to provide affordable, sustainable eye care to the developing world. This goal will be achieved by providing locally manufacturable tools made using locally available materials, a method for accurate diagnosis, and a support system to maintain a constant source of supplies for the local optometrist.

The major task that the Senior Design team was tasked with was developing a system to diagnose a patient's prescription without needing a formally-trained optometrist. The chosen system consists of a diagnostic tool and a detailed procedure for the patient and optometrist to follow. Within the constraints of low-cost and high accuracy, the tool can be manufactured locally for less than $13 with an accuracy of +/- 0.5 diopters in the myopic range.

Given the materials developed by the team, combined with other yet to be developed aspects of the project, a local entrepreneur with basic craftsmanship knowledge has the potential to open a fully functioning optometry shop in less than a week for less than $100. As opposed to diagnostic techniques commonly used in the developed world, the optometrist will simply operate the tool and determine the diagnosis based on feedback from the patient. This change allows for the optometrist to have minimal training while still achieving results that will effectively correct the vision of the patients. Additionally, patients with astigmatism, a common problem in the equatorial region, can also have their vision corrected.

The process for diagnosis was equally as important as the physical embodiment of the tool. The process was refined both to maximize accuracy and lessen the burden on the patient. After entering the office, the patient can be diagnosed in less than 15 minutes.

In order to be able to provide a full system to a local entrepreneur, an edger still needs to be refined to shape the lenses. Additionally, a supply system needs to be implemented to ensure that the entrepreneur can obtain bulk lenses and frames.

2 Introduction and Motivation

An estimated 153 million people in the world need corrective lenses and do not have access to them [1]. Access is restricted by a lack of local and available optometrists, high cost solutions and, in some cases, a patient's lack of knowledge of their vision problems. The overall goal of our team is to give a business to an entrepreneur in a developing country.

Our team consists of Professors Charles Kim and Jamie Hendry, optometrists Bob and Sherri Lipski, graduate student Adam Andersen, and our senior design team. Additionally, we work with Immer Ramirez, leaders of Christ Wesleyan Church, and Pedro Navichoc, a mechanical engineer in San Pedro, Guatemala.

Our part of the project is to develop a diagnostic tool for the entrepreneur to use to determine a patient's prescription. Management members of the team are working to develop relationships with lens and frame manufacturers to have a constant supply of low cost, high quality supplies for the entrepreneur.

The entrepreneur will receive a variety of equipment and instructions in order to start the business. A general qualification for the entrepreneur will be to have access to simple tooling. The entrepreneur will receive detailed instruction manuals to teach him how to fabricate the parts and how to accurately diagnose a patient's prescription.

Currently, the problem with diagnostic tools is that they are too expensive. Additionally, some tools require extensive operator training, which reduces the amount of time they can spend producing glasses and making money.

The main objectives of the project were to design a tool that is inexpensive, accurate, and locally manufacturable. It is imperative that the tool be affordable, otherwise it cannot be used to create a viable business in the developing world. Accuracy is needed to ensure proper diagnoses. Also, having the tool be locally manufacturable will empower the local community and make the project more sustainable.

3 Optics

3.1 Background

The human eye consists of three major components: the cornea, the lens, and the retina. Light enters the eye through the cornea and is refracted. It then passes through the lens and is refracted further. The curvature of the lens is adjustable to make sure that the light is focused effectively on the retina. The light that strikes the retina forms the image that one sees [2].

Globally the most common cause of poor vision is refractive error [3]. An eye with a refractive error is unable to focus light on the retina, thus producing an image that is out of focus. A person who does not have a refractive error is considered to be emmetropic (Figure 1a), where light focuses on the retina. Myopia (Figure 1b), or nearsightedness, occurs when the optical power of the eye is too strong and light is focused in front of the retina. Hyperopia (Figure 1c), or farsightedness, occurs when the optical power of the eye is too weak and light is focused behind the retina.

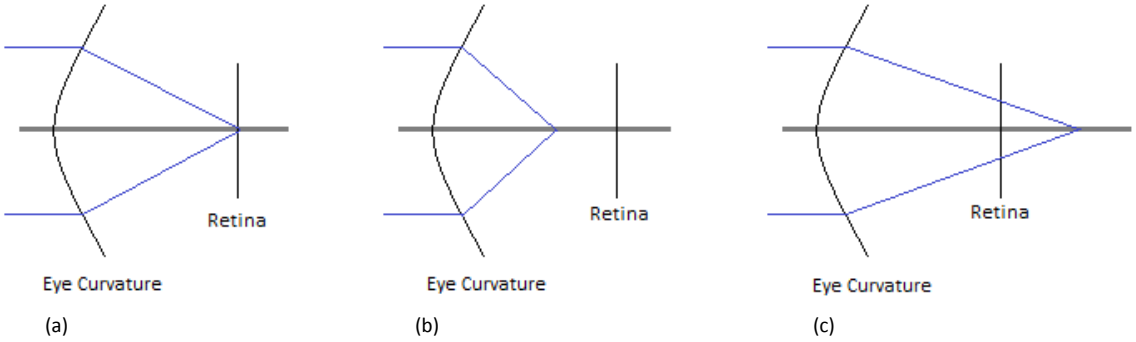


Figure 1: Light as it is refracted by the eye for a) emmetropia, b) myopia, and c) hyperopia

Lenses are used to correct for refractive error. When light passes through a convex lens, it is converged to a point. The focal length of a convex lens is the distance from this point to the lens. A concave lens diverges light. The focal length is determined by tracing the diverged light rays back to an intersection point, resulting in a negative focal length. The ray diagrams showing the focal lengths for convex and concave lenses are shown in Figure 2 (a) and (b), respectively, with the light shown entering from the left. The outward facing arrows represent a convex lens and the inward facing arrows represent a concave lens.

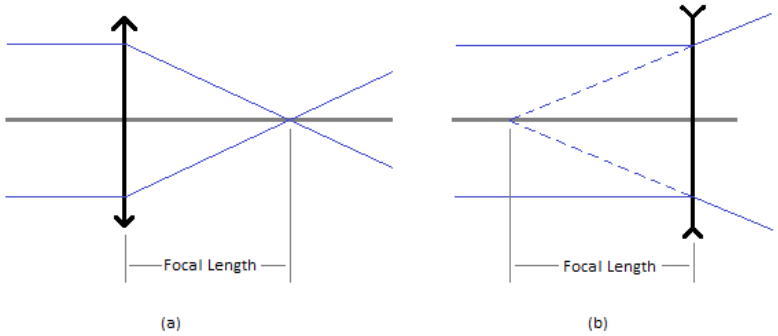


Figure 2: Ray diagrams showing focal lengths for (a) convex lens and (b) concave lens

The optical power of a lens is measured in diopters (Equation 1). A smaller radius of curvature in a lens corresponds to a higher power.

$$D = \frac{1}{f} \qquad (1)$$

where: D is the diopter of the lens, in inverse meters, and
f is the focal length of the lens, in meters.

Refractive error can be addressed with corrective spherical lenses. For a hyperopic patient (Figure 3), a convex lens is used to converge the light. Figure 4 shows the effect of using a convex lens for the same patient. The red and blue lines represent light entering the eye in perpendicular planes.

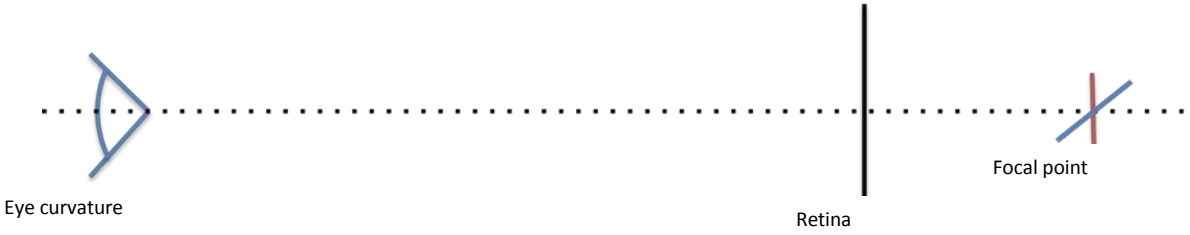


Figure 3: Patient with simple hyperopia

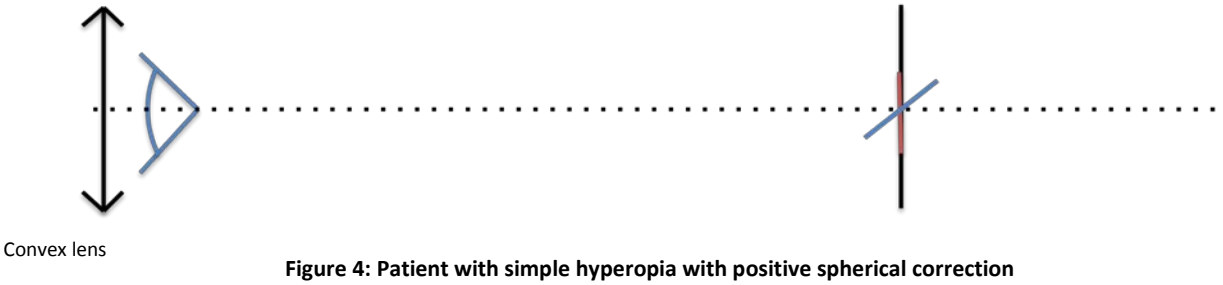


Figure 4: Patient with simple hyperopia with positive spherical correction

For a myopic patient (Figure 5), a concave lens is used to diverge the light. Figure 6 shows the effect of a concave lens on the same patient.

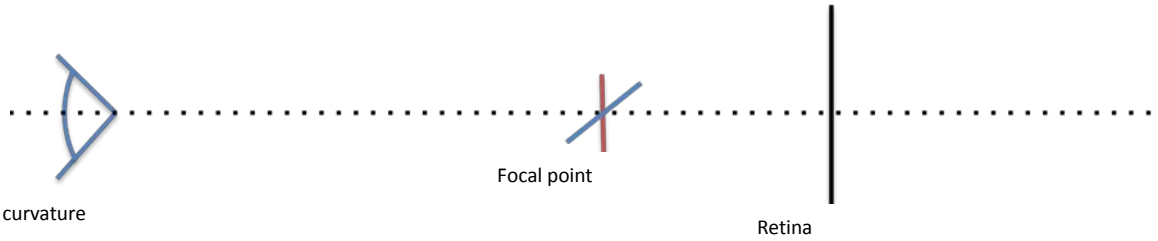


Figure 5: Patient with simple myopia

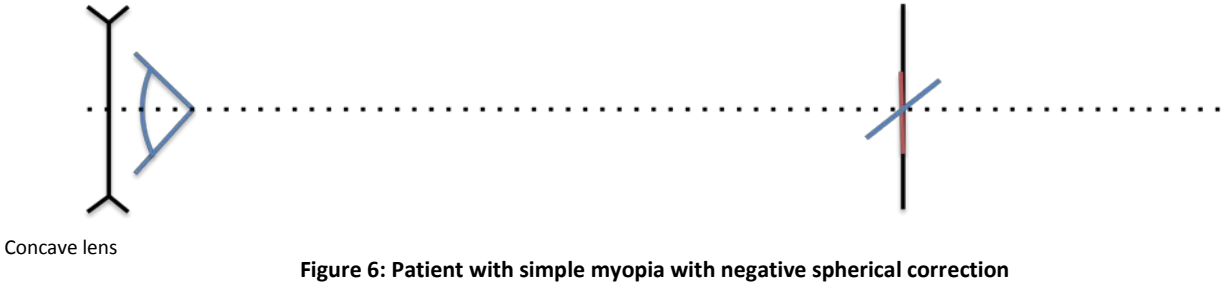


Figure 6: Patient with simple myopia with negative spherical correction

Another common vision problem is astigmatism, which causes rays of light in perpendicular planes to focus at different points, rather than coinciding at the retina. Cylindrical lenses are required to correct for astigmatism. A cylindrical lens compresses an image in one direction while leaving it unaltered in the perpendicular direction. Figure 7 represents a patient with a compound hyperopic astigmatism. The red and blue lines do not intersect, as they do with simple hyperopia, indicating the need for cylindrical correction as well as spherical correction.

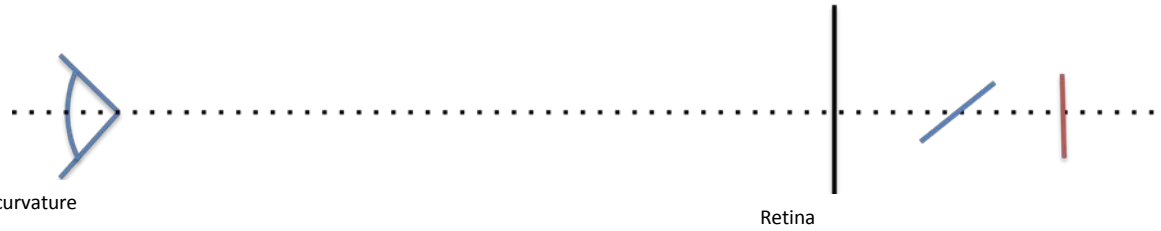


Figure 7: Patient with a compound hyperopic astigmatism

Figure 8 represents a patient with a compound myopic astigmatism. Again, the perpendicular light does not intersect, necessitating cylindrical correction.

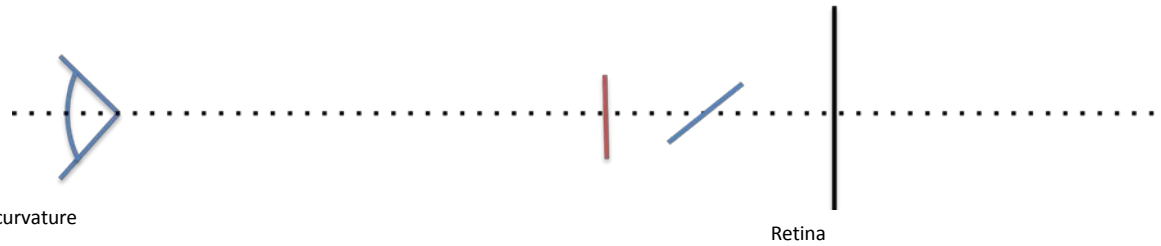


Figure 8: Patient with a compound myopic astigmatism

3.2 Parametric Analysis

In an effort to quantify results found through experimentation, parametric analysis was performed on the lenses. The initial goal of the analysis was to determine the separation between the objective and ocular lenses for an emmetropic patient. The other goal was to determine the increment between diopters for different lens combinations. The data from the analysis is used to determine which lenses are optimal.

3.2.1 Governing Equations

The nominal separation of the lenses in the apparatus is determined by the difference in the focal lengths of the lenses (Equation 2a). For the purposes of our design, it is more convenient to express the nominal separation in terms of the diopter of the lenses (Equation 2b). Equation 3 shows the expression for the focal error of the system as a function of lens diopter and the separation of the lenses. The focal error of the system is equivalent to the focal error of the patient's eye, and the lens separation is read from the apparatus by the optometrist. Figure 9 physically describes the system, including the variables.

$$d_0 = f'_{obj} - f_{oc} \tag{2a}$$

$$d_0 = \frac{1}{D_{obj}} + \frac{1}{D_{oc}} \tag{2b}$$

$$D_e = \frac{D_{obj} + D_{oc} - dD_{obj}D_{oc}}{dD_{obj} - 1} \tag{3}$$

where: d_0 is the nominal separation of the lenses, in meters
f'_{obj} is the focal length of the objective lens, in meters
f_{oc} is the focal length of the ocular lens, in meters
D_{0bj} is the diopter of the objective lens, in inverse meters
D_{0c} is the diopter of the ocular lens, in inverse meters
D_e is the diopter error, in inverse meters
d is the separation of the lenses, in meters

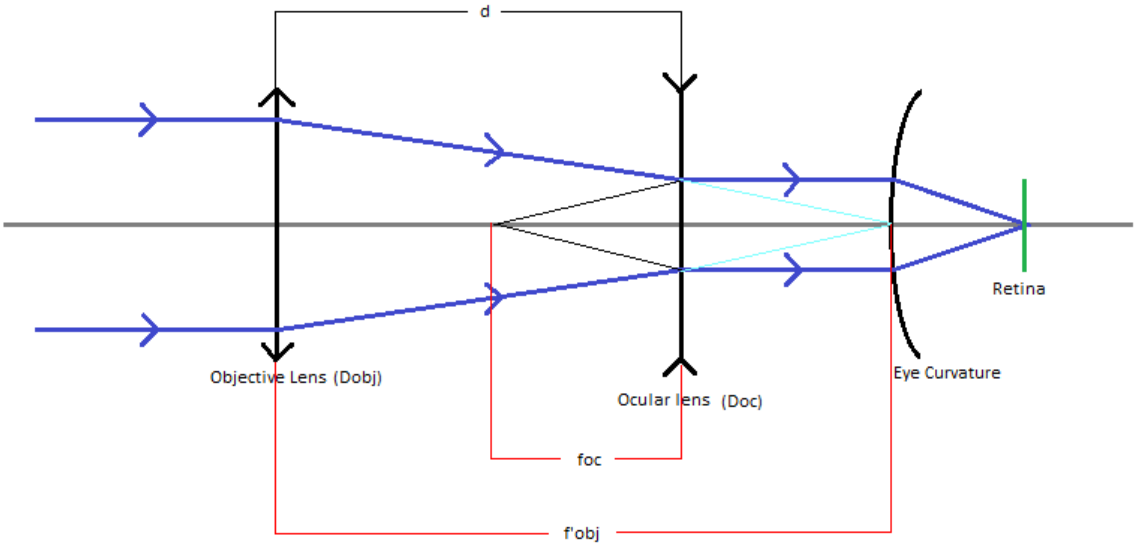


Figure 9: Ray diagram with description of variables

3.2.2 Ray Diagrams

This section contains ray diagrams for each type of refractive error. For each diagram, parallel light enters from the left. The light is assumed to be parallel because it is greater than 20 feet away [4]. For each case, light from the test object enters the objective lens and is converged. When it reaches the ocular lens, it diverges toward the eye of the patient.

Figure 10 shows a ray diagram for a patient with perfect vision. With the lenses at their nominal spacing, the light focuses directly on the retina.

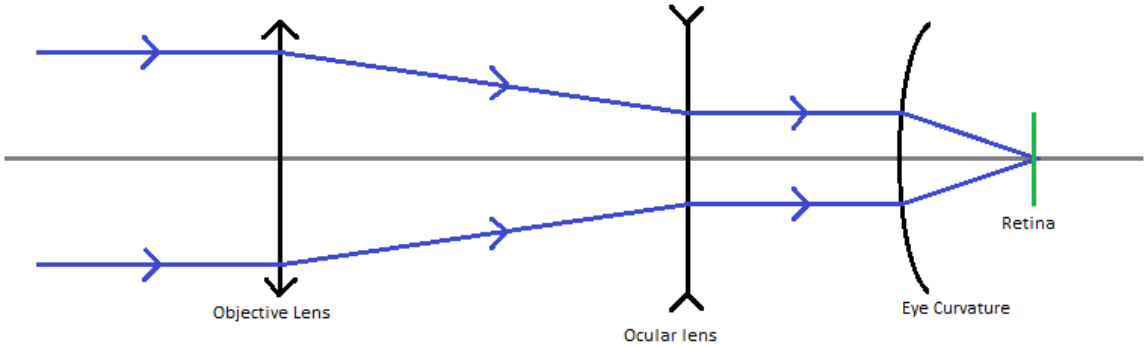


Figure 10: Ray diagram for apparatus with emmetropic patient

Figure 11 shows the correction necessary for a hyperopic patient. This requires a greater spacing between the lenses to bring the focal point of the light onto the retina.

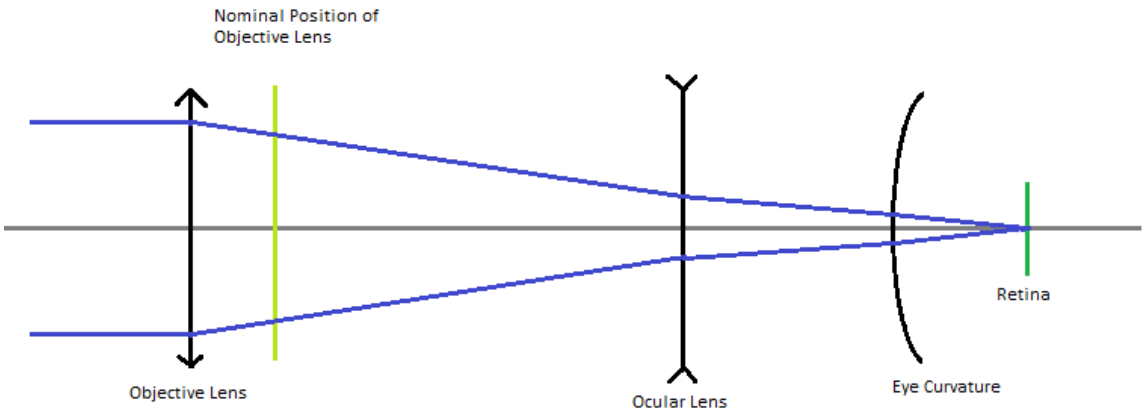


Figure 11: Ray diagram for apparatus with hyperopic patient

Figure 12 shows the correction for a myopic patient. Decreasing the spacing is necessary to bring the focal point of the light back toward the retina.

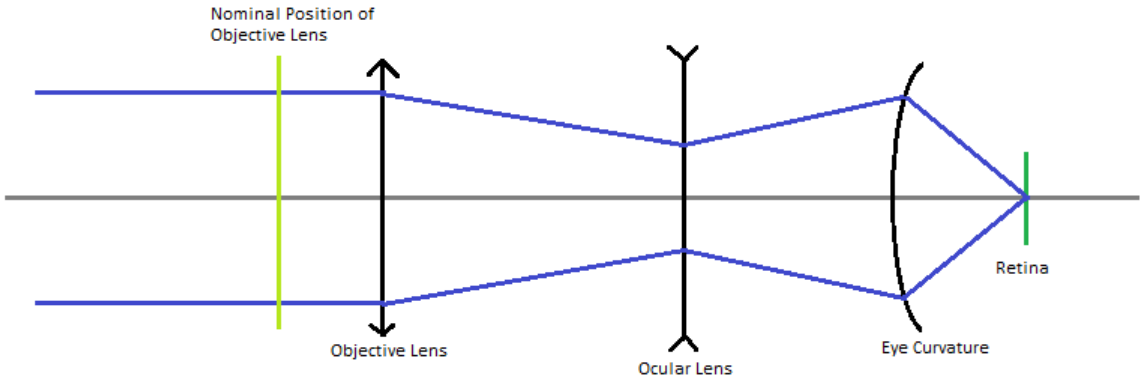


Figure 12: Ray diagram for apparatus with myopic patient

3.2.3 Parametric Analysis Results

Using the above equations, tables were created to show the nominal separation and increments between diopters. Table 1 shows the nominal separation based on ocular and objective lens powers. It shows the general trend that as the ocular lens becomes more negative and the objective lens becomes more positive, the nominal separation increases. Empty cells occur when the nominal separation is less than 0 cm.

Table 1: Nominal separation based on ocular and objective lens power

D_{obj} \ D_{OC}	-1	-2	-3	-4	-5	-6	-7	-8	-9	-10	-11	-12	-13	-14	-15	-16
1	0	50	66.6667	75	80	83.3333	85.7143	87.5	88.8889	90	90.9091	91.6667	92.3077	92.8571	93.3333	93.75
2		0	16.6667	25	30	33.3333	35.7143	37.5	38.8889	40	40.9091	41.6667	42.3077	42.8571	43.3333	43.75
3			0	8.3333	13.3333	16.6667	19.0476	20.8333	22.2222	23.3333	24.2424	25	25.641	26.1905	26.6667	27.0833
4				0	5	8.3333	10.7143	12.5	13.8889	15	15.9091	16.6667	17.3077	17.8571	18.3333	18.75
5					0	3.3333	5.7143	7.5	8.8889	10	10.9091	11.6667	12.3077	12.8571	13.3333	13.75
6						0	2.381	4.1667	5.5556	6.6667	7.5758	8.3333	8.9744	9.5238	10	10.4167
7							0	1.7857	3.1746	4.2857	5.1948	5.9524	6.5934	7.1429	7.619	8.0357
8								0	1.3889	2.5	3.4091	4.1667	4.8077	5.3571	5.8333	6.25
9									0	1.1111	2.0202	2.7778	3.4188	3.9683	4.4444	4.8611
10										0	0.9091	1.6667	2.3077	2.8571	3.3333	3.75
11											0	0.7576	1.3986	1.9481	2.4242	2.8409
12												0	0.641	1.1905	1.6667	2.0833
13													0	0.5495	1.0256	1.4423
14														0	0.4762	0.8929
15															0	0.4167
16																0

Nominal Separation (cm)

Table 2 shows the increments between lenses based on ocular lens power and patient prescription. After examining Equation 4, it can be seen that the increments are not dependent on objective lens power, because the increment is only affected by the second term of the expression.

$$d = \frac{1}{D_{obj}} + \frac{1}{D_{oc} + D_e} \qquad (4)$$

To read the table, as an example, for a -4 diopter ocular lens, moving from a patient prescription of 0 to -1 would move the lens 5.00 cm. Moving from -1 to -2 would move the lens an additional 3.33 cm.

Table 2: Increments between patient prescription based on ocular lens diopters

D_e \ D_{OC}	-1	-2	-3	-4	-5	-6	-7	-8	-9	-10	-11	-12	-13	-14	-15	-16
-12	0.64	0.55	0.48	0.42	0.37	0.33	0.29	0.26	0.24	0.22	0.20	0.18	0.17	0.15	0.14	0.13
-11	0.76	0.64	0.55	0.48	0.42	0.37	0.33	0.29	0.26	0.24	0.22	0.20	0.18	0.17	0.15	0.14
-10	0.91	0.76	0.64	0.55	0.48	0.42	0.37	0.33	0.29	0.26	0.24	0.22	0.20	0.18	0.17	0.15
-9	1.11	0.91	0.76	0.64	0.55	0.48	0.42	0.37	0.33	0.29	0.26	0.24	0.22	0.20	0.18	0.17
-8	1.39	1.11	0.91	0.76	0.64	0.55	0.48	0.42	0.37	0.33	0.29	0.26	0.24	0.22	0.20	0.18
-7	1.79	1.39	1.11	0.91	0.76	0.64	0.55	0.48	0.42	0.37	0.33	0.29	0.26	0.24	0.22	0.20
-6	2.38	1.79	1.39	1.11	0.91	0.76	0.64	0.55	0.48	0.42	0.37	0.33	0.29	0.26	0.24	0.22
-5	3.33	2.38	1.79	1.39	1.11	0.91	0.76	0.64	0.55	0.48	0.42	0.37	0.33	0.29	0.26	0.24
-4	5.00	3.33	2.38	1.79	1.39	1.11	0.91	0.76	0.64	0.55	0.48	0.42	0.37	0.33	0.29	0.26
-3	8.33	5.00	3.33	2.38	1.79	1.39	1.11	0.91	0.76	0.64	0.55	0.48	0.42	0.37	0.33	0.29
-2	16.67	8.33	5.00	3.33	2.38	1.79	1.39	1.11	0.91	0.76	0.64	0.55	0.48	0.42	0.37	0.33
-1	50.00	16.67	8.33	5.00	3.33	2.38	1.79	1.39	1.11	0.91	0.76	0.64	0.55	0.48	0.42	0.37
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1		-50.00	-16.67	-8.33	-5.00	-3.33	-2.38	-1.79	-1.39	-1.11	-0.91	-0.76	-0.64	-0.55	-0.48	-0.42
2			-50.00	-16.67	-8.33	-5.00	-3.33	-2.38	-1.79	-1.39	-1.11	-0.91	-0.76	-0.64	-0.55	-0.48
3				-50.00	-16.67	-8.33	-5.00	-3.33	-2.38	-1.79	-1.39	-1.11	-0.91	-0.76	-0.64	-0.55
4					-50.00	-16.67	-8.33	-5.00	-3.33	-2.38	-1.79	-1.39	-1.11	-0.91	-0.76	-0.64
5						-50.00	-16.67	-8.33	-5.00	-3.33	-2.38	-1.79	-1.39	-1.11	-0.91	-0.76
6							-50.00	-16.67	-8.33	-5.00	-3.33	-2.38	-1.79	-1.39	-1.11	-0.91
7								-50.00	-16.67	-8.33	-5.00	-3.33	-2.38	-1.79	-1.39	-1.11
8									-50.00	-16.67	-8.33	-5.00	-3.33	-2.38	-1.79	-1.39
9										-50.00	-16.67	-8.33	-5.00	-3.33	-2.38	-1.79
10											-50.00	-16.67	-8.33	-5.00	-3.33	-2.38
11												-50.00	-16.67	-8.33	-5.00	-3.33
12													-50.00	-16.67	-8.33	-5.00

Increments (cm/Diopter)

3.2.4 Parametric Analysis Conclusions

Using the data in the tables, -12 and +4 lenses were chosen for the ocular and objective lenses, respectively.

The main focus of the secondary concepts was on constraint of the lenses relative to each other. The desired precision was within 0.1 cm. As a result of the parametric analysis, we found that the spacing between negative diopters is larger than expected, allowing for a desired precision of 0.5 cm. This means that precise linear movement is not necessary for an accurate diagnosis. While precision is still a design consideration, it is now secondary to the orientation of the lenses. Through experimentation, we saw that small angular deflections caused misdiagnosis. For this reason, the final design concepts focus heavily on the orientation of the lenses relative to each other.

4 Design Evolution

While the physical design of the tool did not change significantly since the final prototype was made last semester, major changes were made to the procedure to increase accuracy of the tool. Large-scale testing produced unsatisfactory results, requiring a major overhaul of the diagnostic procedure. Only minor modifications were made to the tool, such as adding more electrical tape to allow the inner tube to slide more smoothly between the outer tube, and extending the lengths of the tubes to prevent the tubes from frequently separating.

4.1 Testing

4.1.1 Test Plan

A test plan was developed to validate the accuracy of the tool. To ensure all Bucknell policies were followed and to make sure the testing did not risk the safety of any subject, a proposal was submitted and approved by Bucknell's Institutional Review Board. The proposal can be found attached to the report in the Appendix. The main component of the proposal was the test plan. In an effort to make the process as efficient and consistent as possible, a script was developed to read to each subject:

a. "This is the tool you will use to diagnose your prescription. While using the tool, you will be asked to determine when the image becomes most "clear." Clear should be when the image is sharp and well-defined. Be sure to differentiate between size and clarity. Please play with the tool, resting the fat end on your RIGHT brow-bone (the bone under your eyebrow), moving it in and out to determine for yourself what clear means."
b. **Let subject use tool for a minute or 2.**
c. "To determine your prescription, you will start with the tube in the fully extended position. Rest the fat end of the tube on your RIGHT brow-bone. Slide the inner tube toward your eye until the image becomes clear. Do not go past the initial clear point. If you go past the initial clear point, repeat the process, rather than trying to adjust."
d. **Have subject use tool until 3 results are given for RIGHT EYE.**

After completing using the tool on their own, the subject proceeded to a room where Dr. Bob Lipski used retinoscopy to determine their prescription. As mentioned previously, the specification for accuracy on the tool is that each patient's diagnosis should be within +/- 0.5 diopter of Dr. Lipski's diagnosis.

4.1.2 Results

The testing produced unsatisfactory results. 48 subjects went through the procedure. After removing patients with astigmatism, those who had LASIK, and those who were out of the range of the tool, 31 subjects were valid. When compared with Bob's results, 17 were within 0.5 diopter, while 14 fell outside of that range. 14 subjects were diagnosed too positive, with a maximum error of 3 diopters, while 8 subjects were diagnosed too negative, with a maximum error in the negative direction of -2 diopters. Figure 13 shows a plot of the patient's error as a function of their actual prescription. The green represents the results within the desired accuracy range. The full results of the testing can be found in the Appendix. This plot shows the tool's relative inaccuracy in the 0 to -2 range, while it tends

to be more accurate at more negative prescriptions. This valuable observation will serve to change the tool and the process.

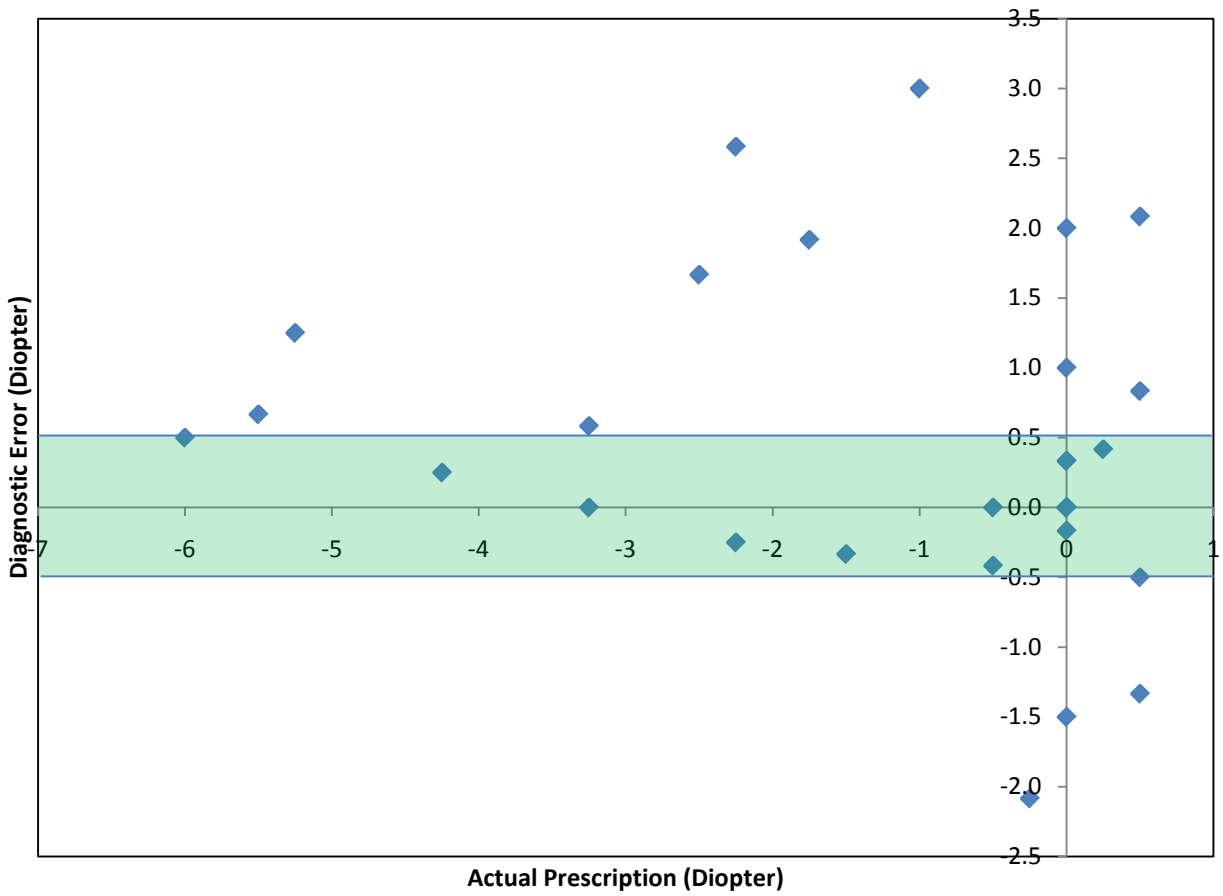


Figure 13: Diagnostic error based on actual prescription (diopter)

4.2 Modifications

4.2.1 Tool Modifications

After reviewing comments the subjects left in their post-test survey, two minor modifications were made to the tool. First, the length of the tubes was extended so that each tube was 1 foot long. This change ensures that the tool does not fall out as frequently and allows a greater distance before the tool comes into focus, providing greater accuracy around the zero point. This increase in length stemmed directly from the observations made from the above plot. The second change simply involved adding more electrical tape to the inner tube to make it easier to slide. This was a low-cost solution that solved the issue of the tool not sliding smoothly.

4.2.2 Procedure Modifications

4.2.2.1 Operation

One of the major comments from the subjects in the testing was on the difficulty of operating the tool and focusing on the object at the same time. The team investigated the benefits of having the tool being user operated versus being operated by the optometrist. The benefits to being user operated are that the patient can stop immediately when the image becomes clear, as opposed to having the optometrist operate it, resulting in a slight delay. However, when the patient is operating the tool, it looks very uncomfortable (Figure 14) and results in unsatisfactory diagnosis.

Figure 14: User operating the tool

Conversely, the benefits of the tool being optometrist operated are plentiful. First, the optometrist can slide the tool at a constant, slow rate. This will allow for more accurate diagnoses because the patient will not be able to speed through their prescription. Second, the patient can direct all of their attention toward focusing on the object. A final advantage over user operation is that the optometrist can use his judgment to move the tool around the focal point so that he can ensure the patient truly is at the clearest point when they say they are. The benefits of optometrist operation clearly outweigh the benefits of user operation, making optometrist operation an easy choice. Figure 15 shows the improved situation with the optometrist operated procedure.

Figure 15: Optometrist operating the tool

4.2.2.2 Focal Object

Another issue with the initial testing was the object that the subject was using to focus on. The eye chart used in testing was improperly scaled, which led to inaccurate results. After examining various options, including using a device similar to a viewfinder, the team chose to use two different focal objects. All patients will look at an astigmatic clock to determine whether they have astigmatism. If the patient has astigmatism, they will continue using the clock. Those without astigmatism will switch to a properly scaled Snellen Eye Chart (Figure 16). This eye chart is the commonly used eye chart in an optometrist's office, and will help to provide the most accurate diagnosis.

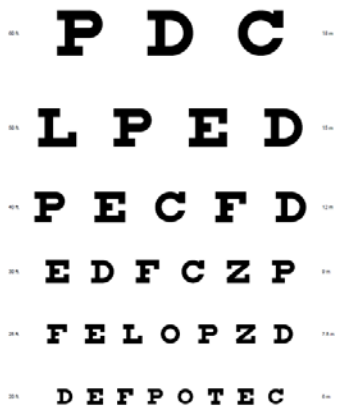


Figure 16: Snellen eye chart

Different variations of the astigmatic clock were examined. Based on the Lensometer, a device used to determine the power of a lens, a clock with “triple-lines” was developed. This clock, shown in Figure 17, proved to have too many lines on it, resulting in inaccurate astigmatism diagnoses.

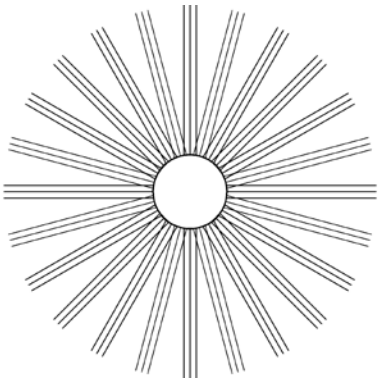


Figure 9: "Triple line" astigmatic clock

For this reason, a clock, which still had lines at every “half hour,” was designed with only single lines in each direction. This clock, shown in Figure 18, provides the accuracy of smaller angles between each line with the increased accuracy of single lines. Clock numbers were added at every 30 degree mark to make it easier for the patient to convey to the optometrist which line is most prominent.

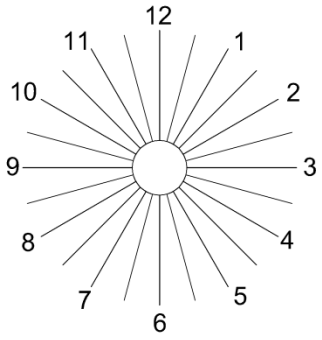


Figure 18: Astigmatic clock

4.2.2.3 Familiarity with Diagnostic Tool

As testing progressed and the team tested various other people, it was discovered that there was a strong correlation between accuracy of diagnosis and the amount of time the patient spent with the tool. In the initial testing, there was too much focus on quantity over quality. For this reason, time is purposefully spent allowing the patient to become more familiar with not only the function of the diagnostic tool, but also the various images they can expect to see.

For the astigmatic clock, the patient will be asked to look through the tool while the operator slowly traverses through the full range of the tool. This will allow them to see when the image becomes most clear, and help them to distinguish between size and clarity. If the patient has astigmatism, they will see

the sudden change between blurriness, one line being clear, blurriness, and then the perpendicular line being clear. In addition to familiarizing the patient with the tool, their feedback will immediately let the optometrist know whether or not the patient has astigmatism. If the patient has astigmatism, the optometrist can continue with testing to determine the patient's power and axis.

If the patient does not have astigmatism, the optometrist can proceed to explain the eye chart to the patient. During the actual testing, the patient will be instructed to stop the optometrist each time a line becomes visible. This will continue until the patient can accurately read the bottom line. Familiarizing the patient with the eye chart will consist of slowly pulling the tool inward, letting the patient see how each line progressively comes into focus. This out- and inward motion should continue until the patient feels confident that they know what clear means and can see the difference between size and clarity.

4.2.2.4 Tool mounting

Movement of the tool during testing was a cause for significant error, based both on the patient not being able to keep the tool aligned with the chart and simply being another aspect on which the patient had to focus. The tool is now mounted on a tripod to eliminate unnecessary tool movement from the process. In the developing world, the tripod can be replaced by an inexpensive, easy to build wooden support. While seemingly an insignificant change, removing any variability makes the process inherently simpler and improves accuracy. Figure 19 shows the diagnostic tool mounted to the top of a tripod.

Figure 19: Diagnostic tool mounted on a tripod

4.2.2.5 Removing one lens

Based on previous calculations, it was found that the size of the scale only varies by the objective lens. The position of the scale varies by the ocular lens. For this reason, the scale can be shifted by removing one of the (-)6 lenses from the ocular side to increase the accuracy around the zero point. This shift results in a distance of approximately 1.35 inches between 0 and (-)1 diopter as opposed to the previous distance of only approximately 0.35 inches. This increased distance will result in far greater accuracy for patients close to zero error.

4.2.2.6 Dr. Bob Lipski's Recommendations

Dr. Lipski provided valuable insight into virtually every aspect of the project. A few of his points that will affect diagnosis and what prescription the optometrist gives the patient follow [4]:

- The patient should cover their other eye with their hand instead of closing it. Closing their eye could affect the focus of the measured eye or cause that eye to squint.
- The angle of the patient's head can affect the angle of diagnosis for the cylindrical axis. It is not necessary to build a device to level the head. Rather, simply having the optometrist instruct the patient to keep their head straight and constantly monitor it is sufficient.
- It is better to "under-minus" someone than to "over-minus" them. This means that if a patient has a (-)5 diopter prescription, if the optometrist is to err, they should err by giving a (-)4.5 prescription as opposed to a (-)5.5 diopter. This is because "over-minussing" will result in worsening the patient's vision.
- If the patient's cylindrical correction is between 0 and (-)1 diopter, their astigmatism can be corrected by simply adding (-)0.5 diopter to their spherical correction. If a patient is diagnosed to have a (-)4 spherical with a (-)0.5 cylindrical axis 60 prescription, they can be prescribed a (-)4.5 diopter spherical correction.

4.3 Solar Calibration

4.3.1 Zero Point Calibration

An alternate form of determining the positioning of the scale on the tool was explored as a means of calibration. When light is shone into one end of the tool, it will create a predictable projected image on the other side. When the lenses are the nominal distance apart (d_0) light rays entering the tool parallel will also exit the tool parallel; this is the zero position. If the light rays exit the tool parallel through the objective lens then the projected image created will be the exact size and shape of the small aperture of the inner tube (Figure 20). Because the light is traveling parallel, the size of the projected image will not be affected by the distance between the tool and the projected image.

Figure 20: Aperture on small tube

The sun was selected for use as the light source because it is free and easily accessible. Also, it is guaranteed that the light from the sun will be entering the tool parallel as, for all intents and purposes, it is infinitely far away. Figure 21 shows the ray diagram for solar calibration of the zero point, where *r* represents the radius of the small aperture. To calibrate the tool, it needs to be aligned with the ocular end facing directly toward the sun. A surface should be aligned perpendicular to the axis of the tool to display the projected image. The tool should be set to the marked zero point and the projected image should be measured. The projected image should be measured at several distances from the end of the tool to confirm that it is of consistent size. If the projected image is not the correct size, then the scale on the tool is not positioned correctly and needs to be moved.

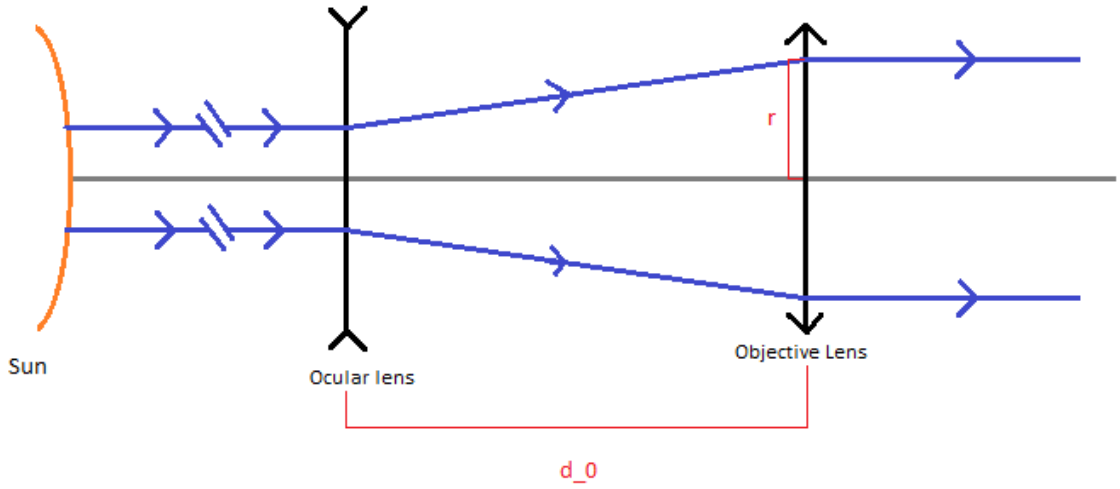


Figure 21: Ray diagram for solar calibration of zero point

4.3.2 Scale Validation

4.3.2.1 Direct Method

In addition to confirming the position of the zero point, confirming the spacing of the scale was explored using the sun as well. The theoretical size of the projected image was calculated. Figure 22 shows a ray diagram used for this calculation. First the angle of refraction (Θ) for the objective lens at the radius of the small aperture of the device was calculated. When the device is at the zero point, the light will be entering and exiting the tool in parallel rays. Therefore, using simple trigonometry, Θ can be calculated as long as the following three variables are known: the radius of the aperture of the inner tube (r), the nominal displacement of the lenses (d_0), and the focal length of the ocular lens (f1). Similarly, the angle of refraction of the ocular lens (Φ) can be calculated for a ray of light passing through the same point on the objective lens given a new lens displacement (d'). Subsequently, the radius of the projected image can be calculated given the two angles and a specific length from the objective lens to the projected image (L). Calculations were performed given L = 3 feet and at the position on the tool for diagnosis of (+)6 diopters. Experimental trials showed that the precision of the calculation was not high enough to be effective, as the resulting tolerance was too wide to accurately confirm the scale within a diopter. For this reason, an alternative validation method was explored.

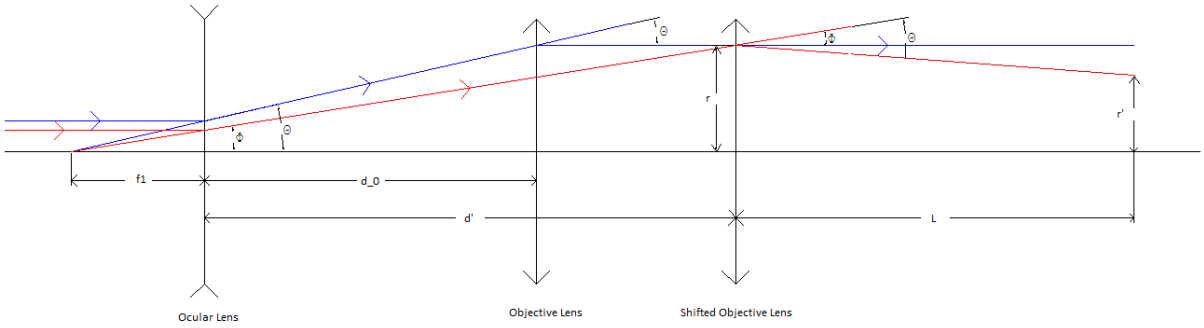


Figure 22: Ray diagram for calculating the size of projection

4.3.2.2 Trial Lens method

It was determined that the scale could be confirmed using the previous method of calibrating the zero point in conjunction with trial lenses. By placing a trial lens directly in front of the ocular lens the power of the ocular is adjusted and the effective zero point of the tool is offset. This allows the tool to be confirmed at any point on the scale if the corresponding trial lens is available. For example, if a (-)3 diopter lens is placed in front of the ocular lens and the tool is set to (+)3 diopters, then the projected image should be the size and shape of the small aperture. After confirming the zero point, this procedure was carried out for multiple points along the scale. All of the tested points aligned, indicating that the scale was delineated correctly. Because this test corroborated the analysis, future iterations can be confirmed by simply measuring the spacing between lines on the scale with a ruler or caliper. Afterward, the placement of the scale should be confirmed using solar calibration of the zero point.

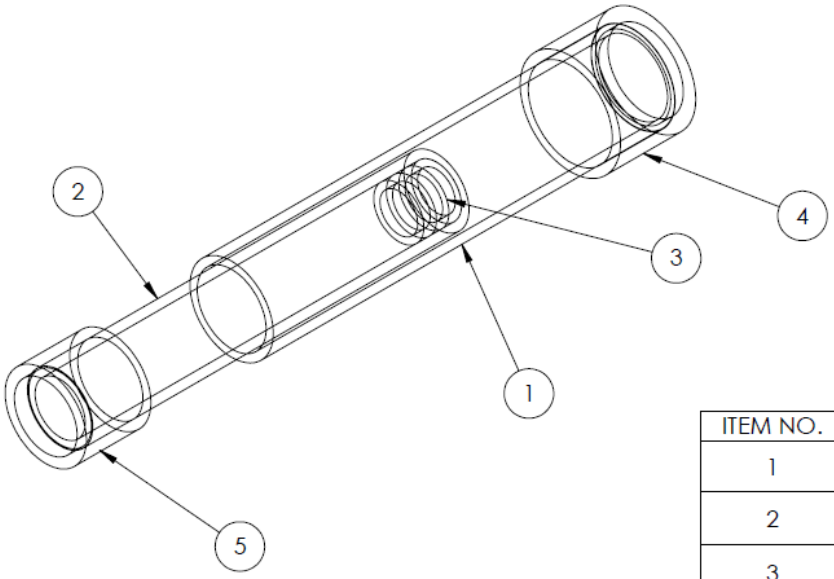
4.3.3 Multiple Lens Confirmation

Solar calibration was also used to examine the difference between using two (-)6 diopter lenses or a single one for the ocular lens of the tool. Testing showed that nesting lenses does not interfere with refractivity. The same scale can be used in either case. However, solar calibration should be performed with both one and two lenses to confirm scale location.

5 Final Design

5.1 Embodiment

The final design of the diagnostic tool consists of two pieces of PVC piping, each 1 foot long, nested inside of one another (Figure 23, items 1 and 2). It is important that they fit snugly but are able to slide. Smooth tape, such as electrical tape, is added as needed to help the tubes slide more smoothly within each other. The ocular lens of the tool is created using two (-)6 diopter lenses, resulting in an effective (-)12 diopter ocular lens. These lenses are mounted on one end of the outer tube by the lens holder cap (Figure 23, item 4). The objective lens—(+)4 diopter—is held inside one end of the inner tube by the two objective lens constraints, which are press fit into the inner tube on either side of the lens (Figure 23, item 3). The end of the inner tube with the objective lens is inserted into the outer tube. An end cap is placed on the other end of the inner tube to form a positive stop, preventing the lenses from hitting each other (Figure 23, item 5). Full engineering drawings for each part can be found in the Appendix.



ITEM NO.	PART DESCRIPTION	QTY.
1	Outer Tube	1
2	Inner Tube	1
3	Objective Lens Constraint	2
4	Lens Holder Cap	1
5	Positive Stop	1

Figure 23: Assembly model of the final design

5.2 Use

The design constrains the lenses about the same focal axis and keeps them parallel to each other. The outer tube should be mounted on a tripod or fixed to a stable surface. The inner tube is then free to slide within the outer tube, allowing the lenses to translate with respect to each other.

5.3 Manufacturing Process

5.3.1 Diagnostic Tool Fabrication

Required Tools:

Hacksaw, tape measure/ruler, drill, hole saws (1 ⅛, 1 ½ inch), rough and fine grit sandpaper, razor knife, vise/clamp

1. Cut each tube to a length of 12 inches. Clean the cuts using light grit sandpaper, and wipe away any dust or debris.
2. Secure the 1 ¼ inch PVC fitting in a vise. Drill a 1 ½ inch through hole into the cap side of the fitting. Clean the hole with light grit sandpaper, and wipe away any debris.
3. Secure the 1 inch PVC fitting in a vise. Drill a 1 ⅛ inch through hole into the cap side of the fitting. Clean the hole with light grit sandpaper, and wipe away any debris.
4. Using heavy grit sandpaper, sand the outer surface of a ¾ inch male pipe fitting. Reduce the outer diameter such that the male end of the fitting can be inserted into the 1 inch tube tightly.
5. Cut two discs from the male end of the fitting, at least ¼ inch wide. These will serve as the lens mounts on the inside of the 1 inch tube.
6. One disc should have a manufacturer-made edge, which should be oriented toward the objective lens. Insert this disc, keeping the smooth edge toward the objective lens, into the 1 inch tube. Leave enough room near the end of the tube that both the objective lens and outer disc can be placed inside the tube.
7. After cutting the objective lens to the same diameter as the inner diameter of the tube, insert the lens into the 1 inch tube, pressing until the lens sits flush with the smooth edge of the inner disc. Visual inspection of the lens should show that it is mounted flush with the smooth edge of the inner disc, as well as perpendicular to the inner surface of the 1 inch tube.
8. Insert the outer disc into the tube, pressing it in until it sits against the objective lens.
9. Mark on the outside of the tube where the axial center (thickness) of the objective lens is located.
10. After cutting both of the ocular lenses to the inner diameter of the 1 ¼ inch PVC cap, insert the lenses into the cap, with the curve of the lens bulging toward the eye.
11. Press the 1 ¼ inch tube into the cap firmly, checking for a tight fit between the lenses, cap, and tube end (Figure 24).

Figure 24: 1 ¼ inch tube with end cap attached

12. Press the end cap onto the 1 inch tube at the end opposite the mounted lens.
13. In order to provide a tighter fit, electrical tape can be placed axially along the outer surface of the 1 inch tube. 4 strips, placed 90 degrees apart, will provide adequate material. However, if there is still significant deflection between the tubes as the inner tube is extended, a second layer of electrical placed on top of the original will add the necessary material (Figure 25).

Figure 25: 1 inch tube with end cap and electrical tape attached

5.3.2 Calibration/Scale Placement

1. In order to place the scale, first mark the axial centers of each lens (the thickness of the lens).
2. Measure 16.7 cm from the center of the ocular lens along the tube, and mark the spot on the outer surface.
3. Measure the distance from the mark to the open end of the tube.
4. From the axial center of the objective lens, measure along the tube, and mark the distance from step 3.
5. The mark made on the 1 inch tube in step 4 is the zero point. After printing the scale and checking it using a ruler, lay the scale down on the outer surface of the 1 inch tube.
6. Align the zero point on the scale with the zero point marked in step 4, and secure using clear packing tape.
7. Check that, when aligned at the zero point, the diagnostic tool shows a clear, crisp image at a distance of 20 feet.

5.4 Final Procedure

The final procedure was developed based on all of the above modifications to the previous test plan. Table 3 shows the test procedure, with the significance of each step in the column next to it. Depending on which market the tool is delivered to, the procedure can be translated to a different language. A video of the test procedure can be found at http://www.youtube.com/watch?v=0C0VcH6V2wM.

Table 3: Test procedure and significance

Test Procedure	Significance
1) Show tool to patient, giving a brief demonstration of how the tool slides.	1) Familiarize patient with operation of tool.
2) Align tool with astigmatic clock	2) Ensure patient will be looking at the correct thing
3) Ask patient to look into tool, and take note of the changes to the image as the tool is slid in and out as optometrist slowly adjusts tool	3) Familiarize patient with what they can expect to see as the image comes in and out of focus
4) After patient has an understanding of when the image is clear/ blurry, big/small, sharp/dull, show them astigmatic clock.	4) Gives preliminary determination of presence of astigmatism and axis
5) If patient sees one line clearer than another, make note of which line. If 2 lines are clear, rotate clock until only one is clear, then make note of which line is clear and the angle the clock was rotated by. If patient sees all lines equally, continue procedure.	5) The line that comes into focus should be the patient's astigmatism axis. Multiply time by 30° to get correction. Axis will be confirmed in later steps. If all are equally clear, patient does not have astigmatism. This will be confirmed in step 7.
6) Again ask patient to look into tool. Make certain that the patient's head is aligned; have them adjust as necessary.	6) Head needs to be perfectly vertical to ensure axis is correct
7) Ask patient to tell you immediately when a line becomes clear. Slowly pull tool inward until patient says a line is clear. a. If only 1 line comes into focus and is sharp, proceed to step 8. b. If 2 lines come into focus simultaneously, rotate astigmatic clock slightly until one line comes into focus and is sharp. Proceed to step 8. c. If all lines come into focus and are sharp, proceed to step 13.	7) One line coming into focus means the patient's astigmatism axis is exactly aligned with a "hand" of the clock. Multiple lines coming into focus means their axis is between two "hands." Rotating the clock will provide one clear, sharp line for an accurate axis diagnosis. If all lines come into focus simultaneously, patient does not have astigmatism.
8) Ask patient which "time" is clear, and note location on scale.	8) Linear location of first clear line on scale will later determine spherical correction. Time can be used to determine axis.
9) Ask patient to tell you when the line	9) The linear location of the second clear

perpendicular to that time is clear. Slowly pull tool inward until patient says perpendicular line is clear. 10) Determine which "time" is clear. Mark down location on scale and which line is clear. (Axis of astigmatism is measured from left side of x-axis, rotating clockwise) 11) After determining which "time" is clear, adjust correction +/- 0.5 diopter from "time," and ask patient to determine which is clear. a. Ex: Patient's correction is determined to be near -3.0 diopter. Shift to -2.5 diopter and ask patient to compare. "Is location A(-3.0 diopter) or B(-2.5 diopter) more clear?" Repeat comparison test, varying which location is A and B, and which location is a stronger or weaker prescription. 12) Repeat process 3 times, until 3 consecutive readings give results within +/- 0.5 diopter and same axis. Mark down the location and time of first stop and second stop. a. Spherical correction is first stop b. Cylindrical correction is the difference between first stop and second stop. Cylindrical axis is the angle of line at second stop (measured from left side x-axis). Can also multiply first line's "time" by 30°. i. Note: If cylindrical power <1 proceed to step 13 as if patient does not have astigmatism 13) If the patient does not have astigmatism, then refocus tool on eye chart. Ask patient to stop you each time they can read a new line. Mark location of tool when patient can read the 20 ft line. 14) Repeat step 13 until 3 consecutive readings give results within +/- 0.5 diopters. 15) Patient's prescription is read directly from tool.	line is used to determine the cylindrical correction. 10) The time is used to determine the axis of the astigmatism. 11) Adjusting and asking patient which correction is better will ensure that patient gets the most accurate prescription possible by giving them better and worse options. 12) Repeating the process will ensure more accurate results. 13) Reading each line ensures that the patient does not get over-diagnosed because the tool will stop periodically and move slowly. 14) Again, repeating the process will help achieve more accurate results

6 Ethical, Safety, and Sustainability Issues

6.1 Ethical

The only major ethical concern with the project is misdiagnosing a patient. Providing an inaccurate diagnosis would risk further worsening a patient's vision and would allow the patient to waste money that would otherwise be spent feeding their family. It is our responsibility to ensure that the tool is accurate to within +/- 0.5 diopter so that we fulfill our obligation to the patients.

6.2 Safety

There are three minor health and safety concerns associated with the use of the diagnostic tool. The first is the transmission of an eyeborne disease from patient to patient. A disease, such as conjunctivitis, could be transferred from one patient to another if the tool makes direct contact with the patients' eyes. To alleviate this concern, the optometrist will wipe the front face of the tool (including the lens) with an alcohol swab to remove any possibly harmful substances.

The other two concerns deal with damaging a patient's eyes. As mentioned in the ethics review, over-minussing a patient can result in worsening their vision. Additionally, if the patient somehow manages to look at the sun with the tool, they could possibly sustain eye damage. This, however, is not a serious concern because they could sustain eye damage simply by looking at the sun with the naked eye. When using the sun to calibrate the tool, the optometrist needs to be aware of looking through the tube directly at the sun. Again, with a small amount of caution, this should not be an issue.

6.3 Sustainability

Sustainability has a two-fold meaning within the project. The first meaning requires the tool to be made with materials whose supply is not restricted and whose components can be reused in the future. The diagnostic tool complies with this because all of the PVC components, both tubes and caps, are readily available in most hardware stores, and all of these components can be reused in various applications if the tool ever needs to be disassembled.

The second, more important, meaning of sustainability within the project concerns the business perspective. Sustainability of the business means that the tool needs to be designed with materials that are locally available, and with processes that are available in local machine shops. This aspect will ensure that an entrepreneur within a developing country can continue to produce the product without support from developed countries.

7 Validation of Engineering Specification

A list of engineering specifications was created at the beginning of the project and is shown in Table 4.

Table 4: Engineering Specifications

Primary "Customer" Requirement	Constraint Number	Primary Source (customer, competition, etc)	Design Specification/ Constraint	Target Value or Range	Validation Method(s)
Basic:	1	Patient/Entrepreneur	Weight	5 pounds	Make SolidWorks model Weigh with a scale (once prototype is fabricated)
	2	Patient/Entrepreneur	Dimensions	handheld	Make a proof of size prototype
	3	Entrepreneur	# injuries per product made	0	Use machine safety statistics
Performance:	4	Entrepreneur	Cost of equipment	<40 USD	Compile list of item costs based on conceptual design Make a prototype for <40 USD
	5	Entrepreneur	Training time	1 week (retinoscope) 1 day (self-diagnosis)	Train a student at Bucknell with no knowledge of optometry to perform eye exams
	6	Entrepreneur and patient	Time needed with patient	15 minutes	Accurately perform an eye exam in under 15 minutes
	7	Patient	Prescription accuracy	+/- 0.5 diopter	Use proven equipment and/or process to validate results
	8	Entrepreneur	Time to make the product	1 week	Use previous prototype fabrication times to estimate Measure amount of time needed to make in PDL
Excitement:	9	Entrepreneur	Tools unavailable in Pedro's shop	0	Ask Pedro if he has specific tools
	10	Entrepreneur	Materials needed from Guatemala City	0	Ask Pedro if he has specific materials

1. The target value for weight was 5 pounds, and the final prototype weighed just less than 1 pound.
2. The tool must be handheld. With the outer tube being made of 1 ¼ inch PVC and the entire tool being just over a foot long, the tool is portable and very manageable, meeting this specification.
3. The manufacturing process for the tool is easy and safe; if the manufacturing tools are operated by someone who is trained to use them, no injuries should result from manufacturing the tool.
4. The cost of production is one of the most important specifications. The limit on total cost was set at 40 USD. The cost of manufacturing the final prototype was just under 13 USD. Table 5 shows a complete cost listing for all materials used in the final prototype. The decision to add 2 (-)6 diopter lenses to make a (-)12 diopter lens was based on cost. While using a single lens would have been simpler and required less confirmation of accuracy, the cost of the (-)6 lenses are significantly less than that of the (-)12.

Table 5: Cost of materials

Item	Supplier	Quantity	Unit Cost($)	Cost per Prototype($)
Charlotte 1" OD sch40 PVC Pipe(10ft)	Coles	1	3.49	0.35
Charlotte 1-1/4" OD sch40 PVC Pipe(10ft)	Coles	1	4.99	0.50
LASCO 1"PVC Cap	Coles	1	0.79	0.79
LASCO 1-1/4" PVC Cap	Coles	1	0.99	0.99
LASCO 1" PVC Plug	US Supply Co	1	1.01	1.01
(-)6 diopter lens blank	Ballaster Optics	2	3.07	6.14
(+)4 diopter lens blank	Ballaster Optics	1	3.07	3.07
			TOTAL:	$12.85

5. The amount of time required to train someone to use the device was set at one day. After watching a brief instructional video, reading through the testing procedure, and experimenting with the tool, an entrepreneur should be a fully transitioned to an optometrist within a day.
6. The target for the amount of time that the operator would need to spend with the patient was set at 15 minutes. During testing no patients needed to stay longer than 15 minutes to be diagnosed. Some test subjects, like those who were emmetropic, could even be diagnosed in less than 5 minutes.
7. The target for prescription accuracy was a tolerance of ±0.5 diopters. The tolerance was kept at ±0.5 diopters for the myopic range. However, it was later adjusted to ±1 diopter in the hyperopic range because a precise prescription is not as important for farsighted patients. The

specified precision proved more difficult to achieve than anticipated. These problems were addressed by stringent revisions to the testing procedure rather than redesigning the tool itself.

8. The time to produce the tool was set at 1 week, but the final design can easily be manufactured in less than a day by a moderately skilled craftsman.
9. Further specifications were established beyond the general ones to evaluate the feasibility of the tool in San Pedro, Guatemala, because this is the first place that the diagnostic tool will be implemented. The specifications were that all of the tools as well as all of the materials necessary for manufacturing are available in San Pedro. Local mechanical engineer Pedro has all of the tools necessary for making the diagnostic tool.
10. It is possible to obtain all of the materials necessary to build the tool in San Pedro. If some of the materials are unavailable as specified, alternate materials are available in the town that would still serve the same function. The available materials do not include the lenses which will be ordered from the US, but will be edged to size locally.

8 Conclusion

ProSEC's goal is to provide inexpensive, prescription eyeglasses to the developing world. This takes input from engineers, management people, and traditionally trained optometrists. The project is multi-dimensional and the Senior Design team's task was to develop a diagnostic method. After exploring various diagnostic methods and considering attempting to reproduce a traditional tool for lower cost, the team decided to develop a new tool and a new method. In the end, the team discovered that the process used to diagnose prescriptions is just as important as the diagnostic tool itself.

The team successfully designed and built a diagnostic tool that is less than half the cost constraint, can be manufactured locally, and is accurate to within ±0.5 diopters in the myopic range. While failure to meet other constraints could have led to the tool seeming less desirable, it was essential that these three constraints were met. As mentioned previously, a high cost would be prohibitive for entry into the business. Local manufacturability is essential so that if something breaks, the entrepreneur can fix and/or replace the broken parts. Finally, accuracy is critical. While the glasses will likely be offered for less than 5 USD, that is a significant expense for those in the developing world. It would not only poorly affect their vision if they were misdiagnosed, but it would also waste precious resources that could be spent on food or clothing.

The process for diagnosis was developed through various stages of testing and changed frequently to reflect feedback from patients. The final process provides sufficient redundancy to ensure a patient is properly diagnosed. While initial testing took 3 minutes instead of the current time of up to 15 minutes, the extra time spent results in more accurate diagnoses.

In the future, the lens edger needs to be redesigned such that it will be able to cut lenses to any shape quickly and accurately. Additionally, the tool and procedure will be constantly updated. Whether adding another strip of tape to the tool, or modifying how the objective lens is mounted, the local optometrist will use his craftsman knowledge and experience to make adjustments to reflect his environment. The optometrist will also develop procedural tendencies as he spends weeks, months, and years providing eyeglasses. This should be encouraged, as he will become experienced and discover steps that cause problems with patients. However, the optometrist should be cautioned to not adjust too much and risk providing an inaccurate diagnosis.

As a whole, ProSEC will help to provide eyeglasses to the developing world. While 153 million people in need of glasses is an incredibly large number, the system needs to be implemented one step at a time. Ideally, with the help of the diagnostic tool designed by the team, ProSEC will allow entrepreneurs in the developing world to have a meaningful impact on their communities in the near future.

9 References

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10 Appendix

10.1 Institutional Review Board Testing Proposal

10.2 Testing Results

10.3 Full engineering drawings

10.4 Memos

10.1 Institutional Review Board Testing Proposal

IRB Project Proposal Summary

Tracking Number: 1112-080
Principal Investigator: Andrew Klein
Co-PI(s): Gregory Epremian, Tyler Campbell
PI Status: Student
Submitted By: apk006
Submit Time: 2/2/2012 at 17:49
Title: Eyeglasses for the Developing World
Sponsor: cjk019
Department: Mechanical Engineering
Department Rep:
Address: C-0457
Phone: 412-478-5345
Email: apk006@bucknell.edu
Review Type: EXEMPT

Answers To Part I:

1) The research DOES NOT involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.

2) The research DOES NOT involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3) The research DOES NOT involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4) The research DOES NOT involve subjects under the age of 18.Note: Research involving children cannot be classified as Exempt if the research involves: SurveyInterview proceduresObservations of public behavior when the investigator participates in the activities being observed.Research involving children can be considedered as Exempt if the research involves only educational tests and observation of public behavior where the investigator does not participate in the activities being observed and meets the other conditions of 45 CFR 46.101(b)(2). These conditions stipulate that the information obtained cannot be recorded in a manner such that subjects can be identified, directly or through identifiers linked to the subjects. For example, because audio-or videotapes allow subjects to be identified, using such a data source would make it impossible for a study to be considered as exempt. Please refer directly to CFR 46.101(b)(2) for additional details.Studies that include minors are typically considered at either the expedited or full level of review depending on the level of risk involved in the study.

5) The research DOES NOT involve deception.

6) The procedures of this research are generally free of foreseeable risk to the subject.

Answers To Part I (continued):

7) The research WILL NOT be conducted in established or commonly accepted educational settings and will involve normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).

8) The research WILL NOT involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. Information will be recorded anonymously (i.e., so that the human subject cannot be identified, directly or through identifiers linked to the subject).[NOTE: Survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is exempt whether or not data collection is anonymous].

9) The research WILL NOT involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources are either publicly available or the information will be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

10) The research WILL NOT be conducted by or subject to the approval of federal department or agency heads, and is designed to study, evaluate, or otherwise examine:(i) public benefit or service programs (e.g., social security, welfare, etc.);(ii) procedures for obtaining benefits or services under those programs;(iii) possible changes in or alternatives to those programs or procedures;(iv) possible changes in methods or levels of payment for benefits or services under those programs.

11) The research WILL NOT involve taste or food quality evaluations or consumer acceptance studies and the tested products are wholesome foods without additives or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the US Department of Agriculture.

Answers To Part II:

1) What is the purpose of the proposed study (the research question) and what is the research hypothesis?

The purpose of the study is to test the effectiveness of a new tool to diagnose refractive error in patients. The patient will use the tool designed by our team to determine their prescription, then will be tested in the traditional way by Dr. Bob Lipski, a local optometrist. As a result of the study, we hope to confirm that our diagnostic tool gives the same results as Dr. Lipski¿s traditional diagnostic method. Using Dr. Lipski¿s advice, our tool will be successful if it diagnoses patients to within +/- 0.5 diopter. A diopter is the unit of measurement in eyeglasses.

2) Describe the proposed subject sample. If subjects under the age of 18 will participate in your research, indicate the expected age range of the samples. If your research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects, you must indicate clearly why the use of these subjects is scientifically necessary.

The subject sample will consist of Bucknell students. All of the subjects will be over the age of 18, and will be mentally and physically healthy. Approximately 50 subjects will be used.

3) How will subjects be recruited and selected?

Subjects will be recruited from fellow members of our Senior Design class, other engineers, and, if necessary, recruited through various social organizations on campus.

Describe fully the following:

4a) all research methods and procedures that will be employed in this study.

After being recruited, students will be assigned a time to report for the study. They will be advised to wear their glasses instead of contacts, if they have them. Upon arrival, if they are still wearing their contacts, there will be a station set up with hand sanitizer, contact cases, and contact solution. Additionally, they will be given a subject number that will be stored in a private file only accessible by our team and will be used to match their prescription from our diagnostic tool to Dr. Lipski¿s prescription.
The first station the subjects will move to is to try the new diagnostic tool. Subjects will be given simple instructions on how to operate the tool, and will proceed to use it three times. Each time, a member of our research team will record their prescription from the dial. If the subject¿s three trials vary by more than 1 diopter, the subject will then repeat the procedure until they can get three trials within 1 diopter of each other. After each subject, the team member will wipe the tool with rubbing alcohol to clean it.
After successfully using the tool, the subject will move to Dr. Lipski¿s station, where he will proceed to use his preferred method of retinoscopy to diagnose the subject¿s prescription. Dr. Lipski will record the subject¿s prescription.
Subjects will be asked to fill out a simple survey regarding ease of use and ergonomics of the diagnostic tool. Subjects will then be thanked for their participation.

4b) approximately how much time each subject is expected to devote to the research.

Each subject will spend approximately 15 minutes on the research (5 with the diagnostic tool, 5 with Dr. Lipski and 5 with consent forms and post-diagnosis survey).

4c) how data will be collected and recorded (with or without identifiers? what instruments, materials, or equipment will be used? Will audio or videotapes be employed in data collection?). In the final step of this form, please append electronic copies of all written instruments and/or describe any apparatus with which subjects will be in direct contact.

For the initial diagnosis, subjects will use our diagnostic tool to determine their prescription. Figure 1 in the appendix shows an image of the diagnostic tool. After each subject uses it, rubbing alcohol will be applied with cotton balls to disinfect the surface and to ensure no eyeborne illnesses can be transferred. This is the commonly used method in Optometrist¿s offices.
Dr. Lipski will use his retinoscope and lens kit to determine the subject¿s prescription. He will maintain his equipment and bring any necessary materials from his office.
Data will be recorded from the diagnostic tool by a member of our team into an excel file with the subject¿s ID number. Dr. Lipski will record his diagnosis into another excel file, again using the subject¿s ID number.

4d) methods for obtaining informed consent or assent in the case of minors. For minors, indicate how the consent of parents or legal guardians will also be obtained. In the final step of this form, append electronic copies of all materials used to obtain informed consent or assent.

Subjects will sign a simple consent form (see attached) ensuring they understand the minimal risks involved in this study. No minors will be used in the study.

4e) use of deception in the proposed study and justification for its use.

There will be no deception in the study.

4f) methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records at the conclusion of the research).

The subject¿s ID numbers will only be saved in a password-protected, private file, and consent forms will not contain the subject¿s ID number.

5) Indicate any benefits that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.

Subjects are not expected to gain benefit from this study. The only perceived benefit would be if they are diagnosed with a refractive error that they were previously unaware of.

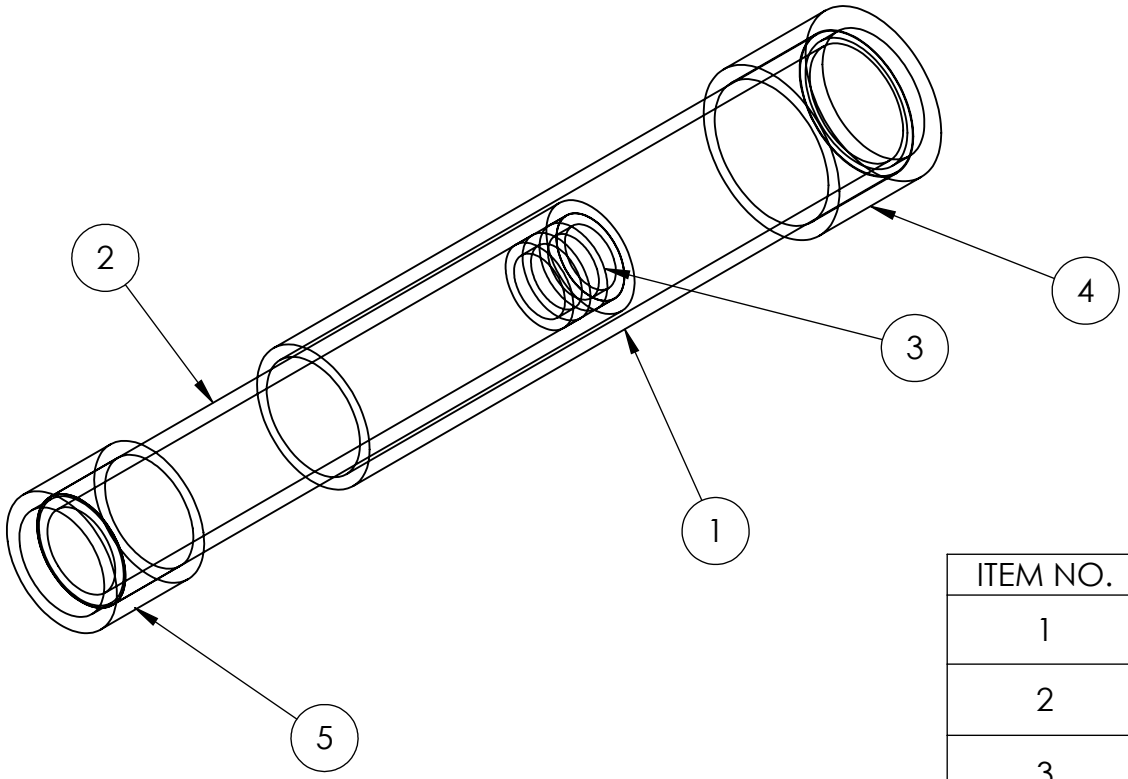
6) Describe any relationship between researcher and subjects, such as: teacher/student; superintendent/principal/teacher, employer/employee. If such a relationship exists, how will it affect the subject's ability to participate voluntarily and how will the Principal Investigator handle it?

Subjects will be acquaintances of the student members of the team, but there will be no pressure to participate.

10.2 Testing Results

ID	Age	Sex	Correction	Tool	Trial 1	Trial 2	Trial 3	Average	Bob' Result	Cylinder	Difference
47	29	M	Y	2	-1	-1	-0.5	-0.83	-2.5	0	1.67
44	21	M	Y	1	-4	-4	-4	-4.00	-4.25	0	0.25
45	22	m	N	2	2	2	2	2.00	-1	0	3.00
42	22	M	N	1	1	1.5	1.5	1.33	0.5	0	0.83
40	21	M	Y	1	0	0	0	0.00	0	0	0.00
37	22	M	N	2	0	0.5	0.5	0.33	0	0	0.33
35	21	M	N	2	0	0	0	0.00	0	0	0.00
33	30	F	N	2	2	2	2	2.00	0	0	2.00
31	21	F	N	2	0	1	1	0.67	0.25	0	0.42
30	18	F	N	2	-1	0	-0.5	-0.50	-0.5	0	0.00
27	18	F	N	2	0	0	0	0.00	0	0	0.00
26	21	M	N	2	0	0	0	0.00	0	0	0.00
25	19	F	Y	2	0	0.5	0.5	0.33	0	0	0.33
24	20	F	Y	1	-4	-4	-4	-4.00	-5.25	0	1.25
20	21	M	Y	2	1	0	-0.5	0.17	-1.75	0	1.92
18	21	M	Y	2	-1.5	-2	-2	-1.83	-1.5	0	-0.33
19	20	M	N	2	1	1	1	1.00	0	0	1.00
15	21	F	N	2	0	0	0	0.00	0	0	0.00
13	22	M	Y	1	-2.5	-2.5	-2.5	-2.50	-2.25	0	-0.25
12	21	M	N	2	1	-1	0	0.00	0.5	0	-0.50
11	21	M	Y	2	-1	-1.5	-1	-1.17	-3.25	0	2.08
10	24	M	N	2	0.5	0.5	0.5	0.50	0.5	0	0.00
9	21	M	N	1	-2.5	-2	-2.5	-2.33	-0.25	0	-2.08
8	23	M	Y	2	-5.5	-5.25	-5.75	-5.50	-6	0	0.50
7	32	F	Y	1	-3	-2.5	-2.5	-2.67	-3.25	0	0.58
6	21	M	N	2	-2	-1.5	-1	-1.50	0	0	-1.50
2	22	F	Y	1	0.5	0	0.5	0.33	-2.25	0	2.58
3	21	M	Y	2	-0.5	-1	-1	-0.83	0.5	0	-1.33
1	20	M	N	2	-1	-1.25	-0.5	-0.92	-0.5	0	-0.42
4	21	M	Y	1	0	0	-0.5	-0.17	0	0	-0.17
5	22	M	Y	2	-5	-5	-4.5	-4.83	-5.5	0	0.67
										MAX	3.00
										Average	0.41
39	23	M	N	2	0.5	0.5	0	0.33	0	LASIK	0.33
32	22	M	Y	2	out of range				-11	RANGE	11.00
21	20	F	N	2	1.5	1.5	2	1.67	0	LASIK	1.67
17	22	M	Y	2	-7	-6.5	-7	-6.83	-8	RANGE	1.17
14	20	M	Y	2	-0.5	-1	-1	-0.83	-2.5	ASTIG	1.67
46	21	F	Y	1	0	0	0	0.00	-1	-.75X165	1.00
43	21	M	Y	2	-2.5	-2.5	-2.5	-2.50	-4.5	-1.75X160	2.00
41	19	M	Y	2	-2	-2	-2	-2.00	-2.25	-1.5x105	0.25
38	22	M	Y	1	3	2	2	2.33	0	-1.5X90	2.33
36	20	M	Y	1	-2	-2	-2	-2.00	-3	-1.5X5	1.00
34	22	M	Y	2	-2.5	-2.5	-2.5	-2.50	-3.25	-.5X90	0.75
29	19	M	N	2	1	1	1	1.00	0.25	-1.25X110	0.75
28	20	M	N	2	1.5	1	1	1.17	0.5	-.5X180	0.67
48	19	M	Y	1	-1	-0.5	-0.5	-0.67	-1	-.5X100	0.33
23	20	F	Y	2	-4	-4.5	-4	-4.17	-5	-.75X105	0.83
22	20	M	Y	1	-1.5	-1	-1	-1.17	-2.75	-.5X45	1.58
16	22	F	Y	2	-5	-5	-5.5	-5.17	-5.5	-1X45	0.33

10.3 Full engineering drawings



ITEM NO.	PART DESCRIPTION	QTY.
1	Outer Tube	1
2	Inner Tube	1
3	Objective Lens Constraint	2
4	Lens Holder Cap	1
5	Positive Stop	1

Drawn By: Greg Epremian

Reviewed By: Andy Klein

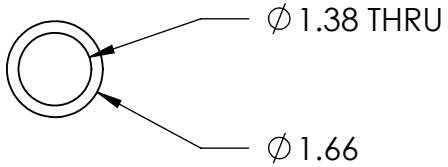
Date: 10 Feb 2012

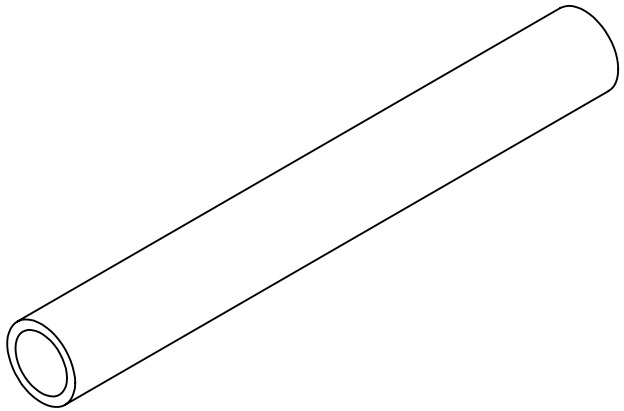
Eyeglasses Project

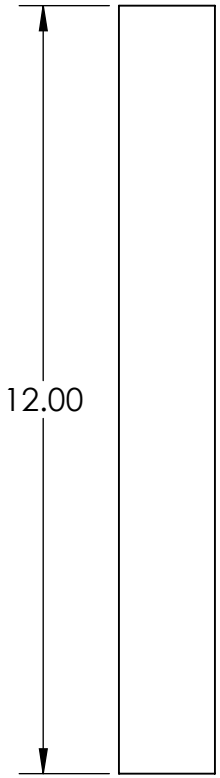
Bucknell University
Mechanical Engineering Department

SIZE A | Drawing Name: Assembly | REV. 2

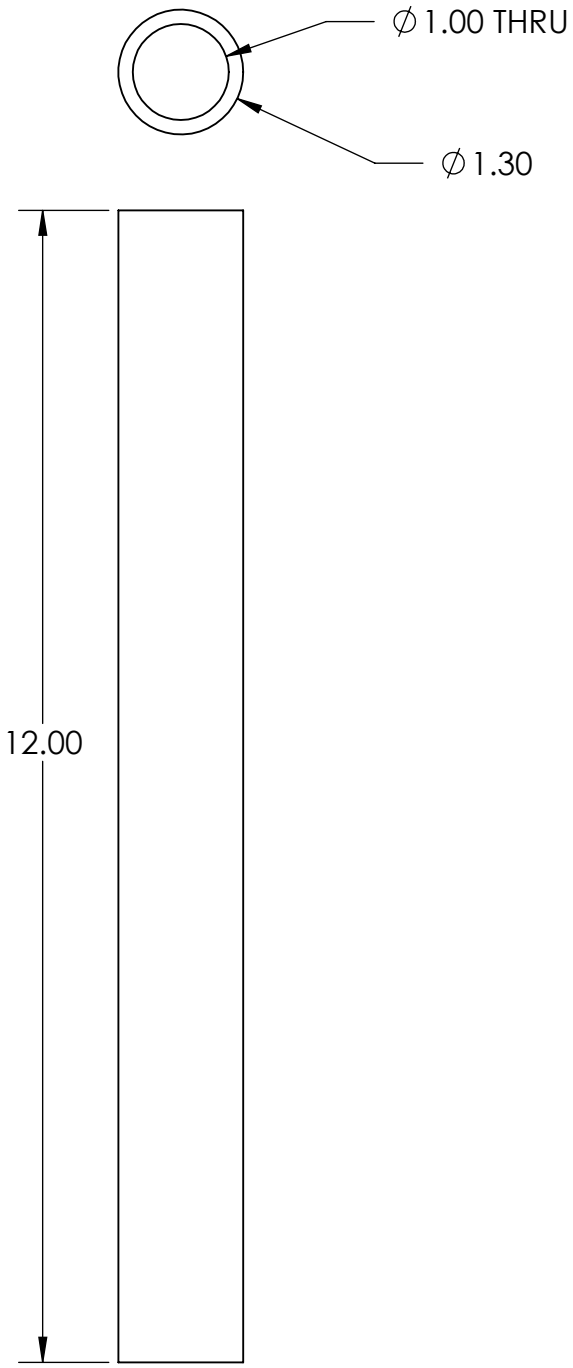
SCALE:1:4 | Materials: S40 PVC | SHEET 1 OF 1

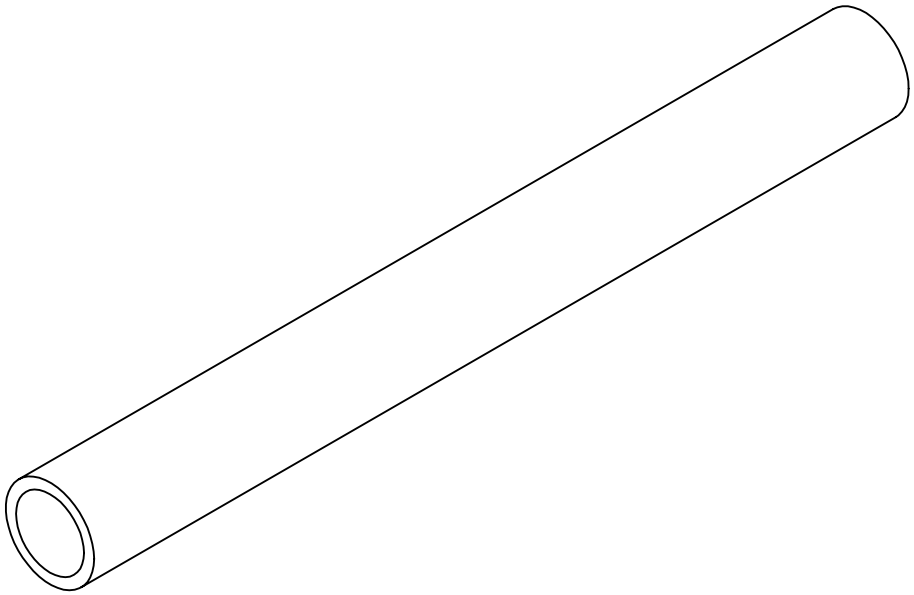




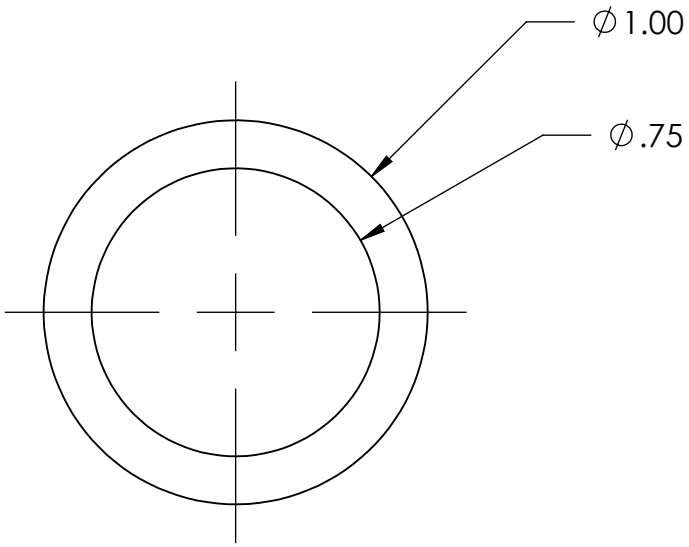


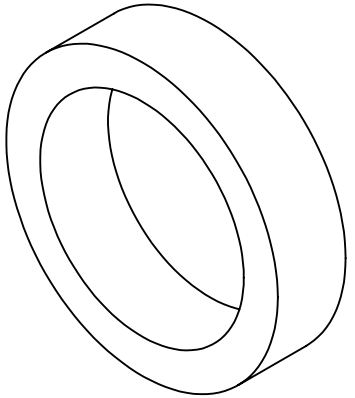
Drawn By: Andy Klein Reviewed By: Greg Epremian Date: 25 April 2012	Tolerances: .xx +/- 0.06 Units: inches Part #: 1	Eyeglasses Project Bucknell University Mechanical Engineering Department SIZE A | Drawing Name: Outer Tube | REV. 6 SCALE:1:5 | Materials: S40 PVC | SHEET 1 OF 1

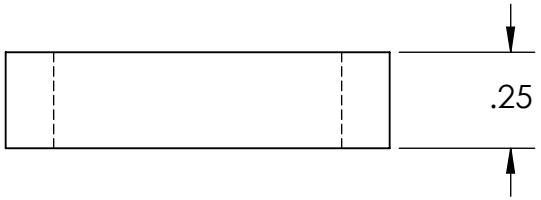




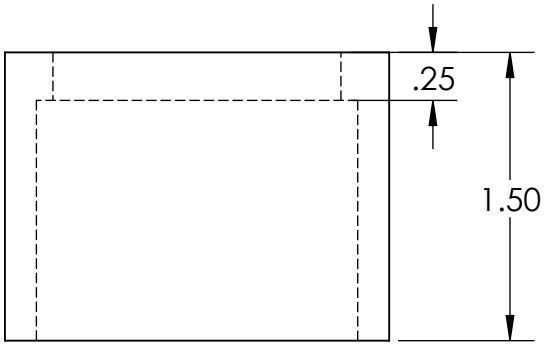
Drawn By: Greg Epremian Reviewed By: Andy Klein Date: 25 April 2012	Tolerances: .xx +/- 0.06 Units: inches Part #: 2	Eyeglasses Project Bucknell University Mechanical Engineering Department SIZE A | Drawing Name: Inner Tube | REV. 2 SCALE:1:5 | Materials: S40 PVC | SHEET 1 OF 1

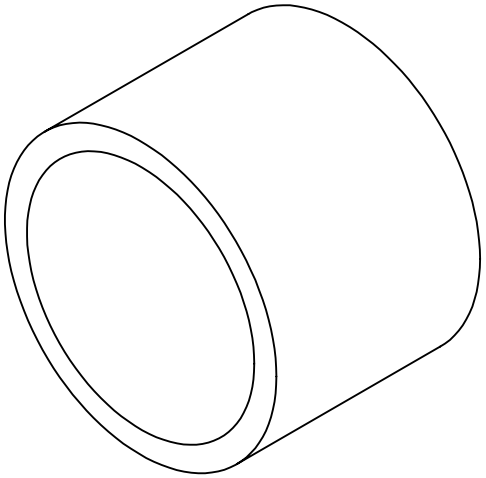


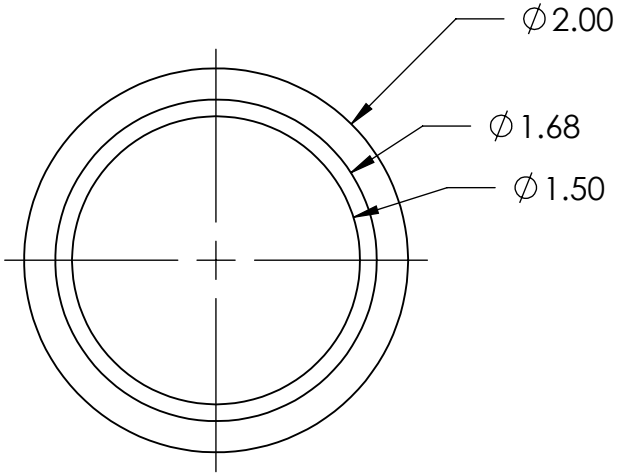


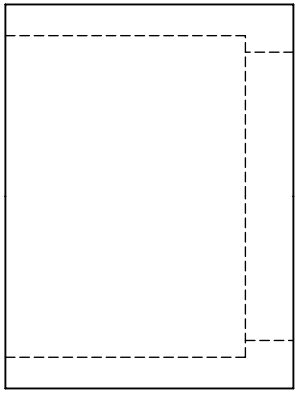


Drawn By: Greg Epremian Reviewed By: Andy Klein Date: 25 April 2012	Tolerances: .xx +/- 0.06 Units: inches Part #: 3	Eyeglasses Project Bucknell University Mechanical Engineering Department SIZE A | Drawing Name: Objective Lens Constraint | REV. 2 SCALE:2:1 | Materials: S40 PVC | SHEET 1 OF 1

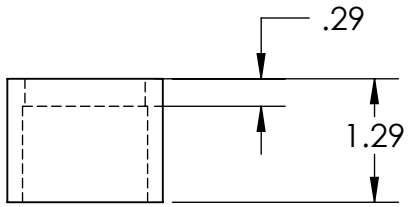


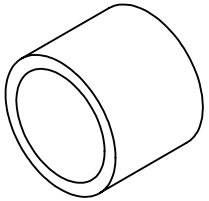


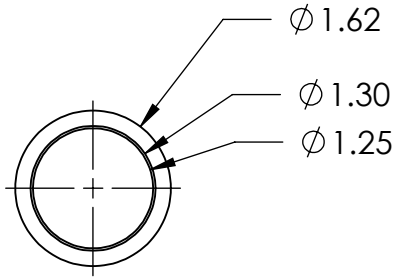


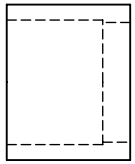


Drawn By: Greg Epremian Reviewed By: Andy Klein Date: 10 Feb 2012	Tolerances: .xx +/- 0.06 Units: inches Part #: 4	Eyeglasses Project Bucknell University Mechanical Engineering Department SIZE A | Drawing Name: Lens Holder Cap | REV. 3 SCALE:1:1 | Materials: S40 PVC | SHEET 1 OF 1









Drawn By: Tyler Campbell Reviewed By: Andy Klein Date: 10 Feb 2012	Tolerances: .xx +/- 0.06 Units: inches Part #: 5	Eyeglasses Project Bucknell University Mechanical Engineering Department SIZE A | Drawing Name: Positive Stop | REV. 3 SCALE:1:2 | Materials: S40 PVC | SHEET 1 OF 1

10.4 Memos

To: Prof. Kim, Prof. Stryker, and Dan Johnson
From: Project for Sustainable Eyecare - Greg Epremian, Tyler Campbell, and Andy Klein
Date: 10 February 2012
Re: Memo 1: Prototype of Final Design

Introduction

This memo summarizes the work that our team did since the final report submitted at the end of last semester. We have completed the design of the diagnostic tool. Materials were purchased and the device was manufactured. We calibrated the device and are now ready for testing.

Previous Work

We finalized the design of the diagnostic tool. Technical drawings were created for each component of the device. A bill of materials was written to expedite the purchasing of materials at the beginning of this semester. PVC was selected as the material for the body of the device because it is easily accessible and inexpensive. The lenses required for the device were more expensive, bringing the anticipated total cost of each device to around $20.

Current Work

As we attempted to fabricate the prototype, most aspects went according to plan, while others had to be adjusted. The modified bill of materials for the final prototype is shown in Table 1.

For the size of the PVC we had initially planned to nest a ¾ inch and 1 inch tube but found that the ¾ inch tube was too narrow to function properly. For this reason, we changed to a 1 inch tube nesting in a 1 ¼ inch tube.

Another change dealt with the constraint of the objective lens. Initially, the design called for one small slice of a ¾ inch PVC fitting to serve as an angular constraint for the lens. This proved to be insufficient to constrain the lens, so a second section of the fitting was placed on the other side of the lens, constraining it from both directions. This press-fit served as a sufficient constraint for the objective lens.

Due to availability of the PVC, only type L schedule 40 was used. Therefore electrical tape was used to add thickness to the inner tube. The tape provided enough additional thickness to appropriately constrain the tubes within each other.

The scale was applied to the prototype using the calibration from Fall 2011. We then performed preliminary tests on the prototype to ensure that it was ready for formal testing. Figure 1 shows the scale drawn on the inner tube, while Figure 2 shows the final assembly.

Table 1: Bill of materials

Item	Supplier	Quantity	Unit Cost($)	Cost per Prototype($)
Charlotte 1" OD sch40 PVC Pipe(10ft)	Coles	1	3.49	0.35
Charlotte 1-1/4" OD sch40 PVC Pipe(10ft)	Coles	1	4.99	0.50
LASCO 1"PVC Cap	Coles	1	0.79	0.79
LASCO 1-1/4" PVC Cap	Coles	1	0.99	0.99
LASCO 1" PVC Plug	US Supply Co	1	1.01	1.01
(-)6 diopter lens blank	Ballaster Optics	2	3.07	6.14
(+)4 diopter lens blank	Ballaster Optics	1	3.07	3.07
			TOTAL:	$12.85

Figure 1: Inner tube with scale

Figure 2: Fully assembled prototype

Future Work

With the final prototype constructed, the next step is to begin testing. We are developing a plan to test the device on a set of subjects. We will be working closely with Bob Lipski to validate the accuracy of the device. We are also beginning to make plans for the trip to Guatemala in March.

Attachments

Technical drawings for the final design

To: Prof. Kim and Prof. Stryker
From: Project for Sustainable Eyecare - Greg Epremian, Tyler Campbell, and Andy Klein
Date: 23 March 2012
Re: Memo 2: Testing and Evaluation

Introduction

This memo summarizes the test plan, testing, and evaluation of the diagnostic tool. From preliminary examination, we found that the tool was accurate after a person used it for a significant amount of time. The formal testing proved this point, as some subjects were in a rush and used the tool too quickly, resulting in inaccurate diagnoses. We do not believe there are significant design flaws with the tool, but rather with the clarity of the instructions and the amount of guess-work that is left to the subject. Additionally, the focal target was inconsistent and could have led to error. Future changes include revising the instructions with a pointed emphasis on clarity, and researching new focal targets for the subjects.

Previous Work

Before a test plan could be developed and testing could be completed, the tool was fabricated and used by members of the team and other people associated with the Mechanical Design Lab to attain preliminary validation of the accuracy of the tool.

Current Work

Prior to testing, an extensive test plan had to be written, and the procedure had to be approved by Bucknell's Institutional Review Board (IRB). This process delayed the implementation of the testing, but ensured that there was minimal risk to subjects and that we complied with all necessary institutional procedures. The test plan, along with the entire IRB application can be found attached to this report.

Per the IRB application, implementation required the team to recruit approximately 50 subjects, as well as to coordinate a time with Bob Lipski so that he could validate the diagnostic tool's results. 48 subjects were tested using the tool and then sent to Bob for professional diagnosis. Testing ran very smoothly overall, and there was limited backup at any time. A second diagnostic tool was fabricated before the testing to effectively accommodate all test subjects.

Local Testing

Out of the 48 subjects that were tested, 31 of them produced data that was useful. Subjects who had an astigmatism, had previously had LASIK surgery, or were out of the tool's diagnosable range were removed from the pool. Of the 31, 17 were within 0.5 diopter, while 14 were outside of the 0.5 diopter goal. 14 subjects were diagnosed too positive, 8 were too negative, and 9 were identical to Bob's diagnosis. The maximum positive error was 3, while the maximum negative error was -2. The average positive error was 1.2, while the average negative error was -0.8. Figure 1 shows the subject's prescription on the horizontal axis with the diagnostic error on the vertical axis. It shows a general trend that as subjects' prescriptions moved more negative, the error decreased. Additionally, subjects were not over-minused as their prescriptions moved more negative. According to Bob, over-plussing is more

of a concern than over-minusing, so this error is favorable. However, around zero diopter, subjects tended to have a much wider range of values from the diagnostic tool.

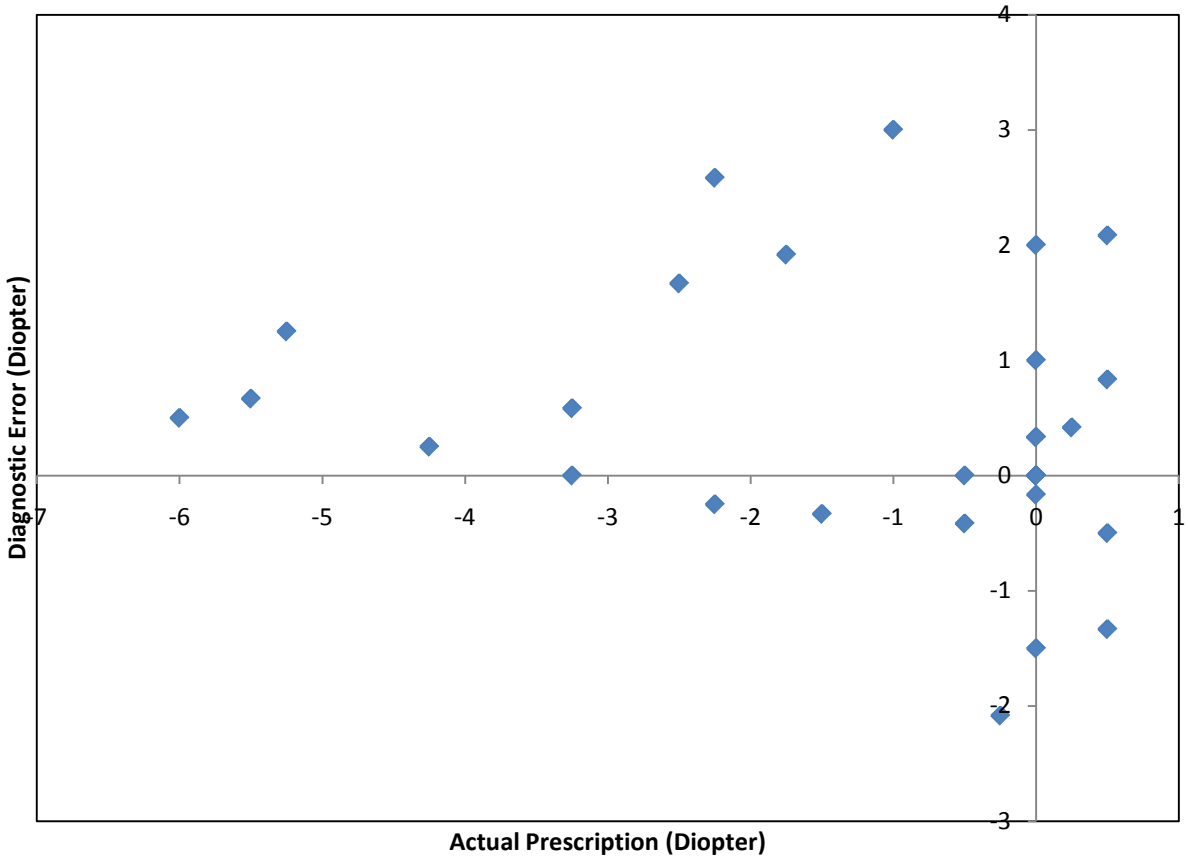


Figure 1 - Diagnostic error based on actual prescription (diopter)

Reflections and Modifications

Stemming from the relative success of the tool, some minor changes have been made to the test plan to improve performance. The instructions were updated to purposefully allow the subject more time to get acquainted with the tool. From experiences letting other members in the lab use the tool, this increased familiarity with the diagnostic tool will improve accuracy of the diagnoses. Additionally, the size of the letters the patient was asked to focus on will be smaller, fixing the problem of over-plussing.

To increase accuracy for an emmetropic patient, a longer tool was developed that will allow for the ocular lens to be changed. By removing one of the minus 6 lenses, the scale will be shifted. The shift of the scale gives a much larger increment between 0 and -2 diopters. This change should allow the tool to be more accurate around 0 diopter.

Guatemala Trip

A trip was taken to San Pedro, Guatemala in order to perform local testing of the diagnostic tool. The testing required that our instructions be translated into Spanish. This was completed prior to working

with the test subjects. 20 students from a school in San Juan were tested because prior data was collected by Bob Lipski on those students. The testing procedure was as follows:

Groups of two students were brought to the translator and read the instructions. Then, the students were directed to stand on a line facing a wall with an eye chart on it 20 ft away. After the tool's function was demonstrated, the students were given the tool and told to focus on the letters until they were as clear as possible.

The results of the tests varied widely. Most of the students were able to find a clear point at which to stop, but with accuracy no greater than +/- 1 diopter. Two students were unable to use the tool effectively, and did not report seeing any clear point in the tool's range.

Throughout the testing, it became clear that lighting, focal target, and instruction clarity all played a vital role in the accuracy of the diagnosis. Issues to address in future trials include proper lighting for testing, as well as the most effective focal target. While the team's instructions were translated into Spanish, the verbose nature and length of the instructions will be changed in order to make the directions simpler and more effective.

While in San Pedro, a diagnostic tool was created using local materials. The schedule 40 PVC specified in the original design was not locally available (although it was available in Guatemala City), so schedule 26 PVC was used. Some modifications to the original design were necessary in order to create a snug tube fit, but the overall design remained the same. The lenses used in the diagnostic tool were ground using the lens grinder designed in summer 2011. While the tubing and fixtures were made with relative ease, the lens grinding took significant time.

Through the experience, it became obvious that our drawings were effective in communicating form to Pedro (a local Guatemalan engineer), but were not effective in communicating function. In order for the project to be successfully implemented, communicating function will be necessary.

Future Work

Immediate tasks are to fabricate a new diagnostic tool that will be modifiable based on the severity of the refractive error of the patient. The instructions given to patients need to be reexamined for clarity and effectiveness.

To validate the changes to the tool, we will ask some of the test subjects to be tested again. Additionally, we may ask some new subjects to use the tool following our revised procedure.

Another major aspect that needs to be figured out is diagnosing astigmatism. According to Bob, astigmatism is a major issue in Guatemala and other developing countries, so we hope to use an astigmatic clock to accurately diagnose astigmatism. This method is a generally accepted means to diagnose astigmatism, so we simply need to prove that it works for our project.

Attachments

IRB Application

To: Prof. Kim and Prof. Stryker
From: Project for Sustainable Eyecare - Greg Epremian, Tyler Campbell, and Andy Klein
Date: 23 April 2012
Re: Memo 3: Refining tool calibration and astigmatism analysis

Introduction

This memo summarizes work done toward accurately determining a patient's astigmatism and refining the diagnostic tool to achieve more accurate results. We examined a variety of possible changes, including procedural changes, instructional changes, and physical changes to the tool. In the end, it was a combination of the three that will ultimately lead to more accurate results. Additionally, with the help of Bob Lipski, a patient's astigmatism will be able to be diagnosed within +/- 0.5 diopter and within 10°.

Previous Work

As was discussed in the previous memo, the diagnostic tool was extended to be 1 foot long to prevent the inner tube from frequently coming out of the outer tube. Also, the trip to Guatemala proved valuable in providing feedback on the procedure for how to best utilize the diagnostic tool.

Current Work

Procedure

A major cause of inaccuracy in the testing was the procedure used to test patients. Based on positive results from testing in Guatemala, the tool will now be operated exclusively by the optometrist. This will allow the patient to focus solely on determining clarity, and not have to worry about translating the tool. Additionally, the tool will be mounted on a tripod (or similar mounting device). Stabilizing the tool will further remove inaccuracy from the procedure.

Another area of change was to investigate the image that the patient will focus on and the procedure they will use. A variety of astigmatic clock designs were explored, including one based off of the "triple line focus" used in the lensometer, and clocks with markings at every 15°. The triple lines were too cluttered and did not increase accuracy, so the chosen astigmatic clock has single lines at every 15° (Figure 1).

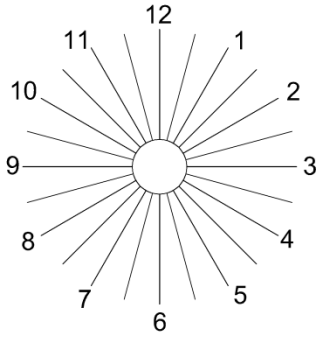


Figure 1: Astigmatic clock

It was decided that the patient will initially be asked to focus on the astigmatic clock. If one line comes into focus, the tool will then continue to be slid inward until the line perpendicular to the first line comes into focus. The location of the first line will be the spherical correction, and the difference between the first and second will be the cylindrical correction. The axis of the cylindrical correction will be measured clockwise from the left side of the x-axis (9 o'clock) to the second line focus.

If all of the lines come into focus at the same time, the patient will then move to use the eye chart (Figure 2). The optometrist will slowly pull the tool inward, and the patient will be instructed to stop the optometrist each time they can read a new line. A detailed procedure can be found at the end of the memo.

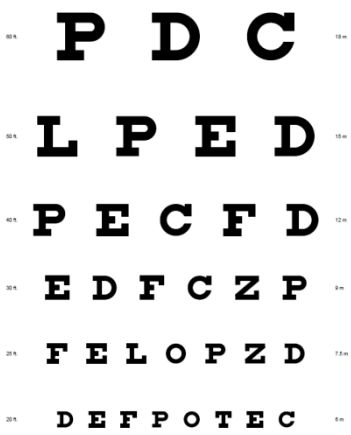


Figure 2: Snellen eye chart

Bob Lipski provided very valuable information for increasing accuracy of the procedure. Bob stated that if a patient has a cylindrical correction of less than 1 diopter, their eyes can be corrected by simply adding (-)0.5 diopter to their spherical prescription, and forgoing cylindrical correction. Additionally, Bob refined the procedure for reading a patient's astigmatism, allowing an accurate determination of the patient's axis.

Calibration

In order to independently verify that the scale on the tool is accurate, a separate means of calibration was explored. It was determined that the sun can be used to calibrate the device. The correct position of the zero point can be found by aligning the ocular end of the device with the sun and measuring the projected image. The projected image should be the same size as the aperture within the small tube and should remain at constant size regardless of the distance between the projected image and the end of the device. The spacing of the scale was verified using a similar method. Trial lenses were placed in front of the ocular lens, and the projection was measured at the corresponding position on the scale. All of the points tested corresponded with the size of the aperture. This confirmed that the scale was optically correct and can be verified by measurement with a ruler in the future.

Future Work

In the next week, in addition to completing the final report, the procedure for diagnosis will be finalized and a secondary means to express function of the tool will be provided. This secondary means will either include a video, pictures, or a combination of the two.

Attachments

Test procedure