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Visual outcomes of second surgery LASEK following aborted LASIK surgeries due to flap complications

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VISUAL OUTCOMES OF SECOND SURGERY LASEK FOLLOWING ABORTED LASIK SURGERIES DUE TO FLAP COMPLICATIONS

by

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DEDICATION

I would like to dedicate this work to my parents and brother.

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ABSTRACT

Refractive surgery is designed to minimize the need for glasses and/or contact lenses and is often used for convenience, cosmetic or occupational purposes. The two most common types of laser eye surgery are LASIK and LASEK. During LASIK, the first step is the creation of the corneal flap using either a femtosecond laser or a mechanical microkeratome. The femtosecond laser has been seen to create more uniform flaps that reduce the risk of intraoperative and postoperative flap complications compared to the mechanical microkeratome. The purpose of this study was to investigate the effect on visual outcomes of second surgery LASEK on patients following aborted LASIK surgeries due to Femtosecond laser flap complications.

LASIK was performed as planned and the corneal flap was created by the femtosecond laser but could not be lifted when a surgical cut was made. The procedure was aborted and LASEK was performed within a few weeks to attain the desired vision correction.

A total of 14 patients were identified over a 6-year period ranging from 2009-2015. Most patients underwent surface ablation within two weeks of the initial aborted procedure. 12 of the 14 patients had a UCVA of 20/20, while the remaining 2 patients had a UCVA of 20/25 at their last postoperative visit. None of the patients required

surgical enhancements despite the flap complications and no major postoperative complications were noted in any of the patients.

Provided the corneal flap was well centered and there was no evidence of microstriae or epithelial ingrowth, surface ablation LASEK can be performed within a week of the aborted LASIK procedure to minimize discomfort and trauma to the patient. LASEK is associated with a slightly longer healing time but no evidence of corneal or retinal issues were noted in these patients. None of the patients experienced any significant changes in refraction between surgeries and was thus a reliable indicator of refractive stability following the flap complication. No significant differences were noted with delaying the second surgery LASEK as several patients attained 20/20 vision when it was performed within a week. The most common flap complication was the formation of an incomplete flap that could not be lifted. The cause could not be identified.

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LIST OF ABBREVIATIONS

BCVA…………………………………………………Best Corrected Visual Acuity

BSS……………………………………………………..…Balanced Salt Solution

ICL……………………………………………………..Implantable Contact Lens

LASIK…………………………………………...….Laser In Situ Keratomileusis

LASEK…………………………………Laser-Assisted Sub Epithelial Keratomileusis

MMC…………………………………………………………………Mitomycin C

RSB…………………………………………………...Residual Stromal Bed

UCVA…………………………………………...…Uncorrected Visual Acuity

INTRODUCTION

Refractive surgery is an elective procedure designed to minimize an individual's need for visual aids including glasses and/or contact lenses. It permanently alters the shape and depth of the cornea to minimize refractive error and achieve vision correction. Refractive error occurs when the shape of the eye prevents light waves from focusing perfectly on the retina. The two main refractive errors are myopia (nearsightedness) and hyperopia (farsightedness). Myopia and hyperopia can be attributed to the shape and curvature of the cornea that disrupts the optimal bending of light waves. In myopia, the cornea is too steep and causes the bending of light waves such that the image is formed at a location in front of the retina (Li et al, 2016) while in hyperopia; the cornea is too flat which causes the light waves of the image to converge to a point behind the retina. Glasses and contact lenses help refocus the focal point and optimize the bending of light waves (Li et al, 2016). A diverging lens is used to reduce the bending of light and thus corrects myopia while a converging lens is used to increase the refraction of light in order to correct hyperopia (Adib-Moghaddam et al, 2016).

Another common refractive error that occurs in both myopes and hyperopes is a condition called astigmatism. This is caused by an irregular shape of the cornea or lens that prevents the light waves from focusing at any point resulting in distorted vision (Marcos et al, 2015). An astigmatism that is caused by the irregular shape of the cornea is called corneal astigmatism while one caused by a distorted lens shape is called lenticular astigmatism. A corneal astigmatism means one plane of the cornea is curved and shaped more than the adjacent plane (Marcos et al, 2015). Astigmatism can also be classified as a regular or an irregular astigmatism.

Today, refractive surgery is performed for a variety of reasons including convenience, cosmetic or occupational purposes. The surgery is designed to reshape the curvature of the cornea and correct any degree of astigmatism present. The cornea is a highly specialized tissue that has several layers. It does not contain any blood vessels to provide nutrients but is protected by tears present in the aqueous humor. The five layers of the cornea are the epithelium, Bowman's layer, the Stromal bed, Descemet's Membrane followed by a single cell layer of endothelium. The epithelium is the outermost layer and has a protective function as it serves as the first line of defense for the eye to foreign bodies and dust particles (Marino et al, 2016). It also has an absorptive function and can absorb oxygen and nutrients from the surrounding tears. Bowman's layer is composed of a strong protein called collagen and has the capability to form scars during a corneal abrasion (Kamma-Lorger at al, 2010). The majority of corneal thickness can be attributed to the stromal bed below Bowman's layer (Srinivasan, Herzig, 2007). Water comprises most of Bowman's layer with a small percentage of collagen proteins as well that gives the cornea a degree of elasticity and flexibility (Kamma-Lorger et al, 2010). Descemet's Membrane is another protective barrier against infection and injury and can regenerate after any abrasion or injury. The final layer is a single cell layer of endothelium that comprises the innermost layer of the cornea. The endothelium pumps excess fluid away from the cornea (Soh et al, 2016).

Laser in situ keratomileusis (LASIK) is currently the most common vision correction performed to minimize refractive error coupled with a short postoperative recovery (Jabbur, Myrowitz, Wexler, O'Brien, 2004). LASIK involves creating a corneal flap with the help of a laser, lifting the flap and performing the laser vision correction before restoring the flap back to its original location. For nearsightedness, the goal is to straighten out the cornea while for farsightedness, the goal is to steepen the cornea to achieve optimal bending of light waves and vision formation exactly on the retina (Adib-Moghaddam et al, 2016).

Common side effects of LASIK include dry eyes and halos at night that may sometimes interfere with activities such as driving vision and may cause some discomfort (Sun et al, 2013). Dry eyes may be treated with over the counter artificial tears in most cases, or by placing punctual plugs in the lower eyelids to block the drainage of tears via the tear ducts keeping the eyes well lubricated in more serious cases. Rare side effects include cells growing on the inside of the flap that may cause the vision to become hazy (Marino et al, 2016). The solution would be to re-lift the flap and scrape of the cells before repositioning the flap over the cornea. Patients with larger pupil sizes (>7mm) are at a higher risk of seeing halos and starbursts at night especially when driving (Scallhorn et al, 2015). Although the optical zone (the area of the cornea the laser corrects) may be increased (up to 7mm) to compensate for the bigger pupils, the risk of seeing halos still persists.

A potential treatment of laser eye surgery includes monovision. Individuals around 40 undergo a gradual change in their lens as its starts losing its ability to bring close objects into focus (Zheleznyak et al, 2015). Majority of the population are prescribed reading glasses at the age of 40 onwards to assist in daily activities including looking at cell phones, supermarket shelves or license plates. Monovision allows individuals to have the least dependency on glasses or contact lenses for reading vision by slightly under correcting the treatment for an eye. Under correcting the treatment means lowering the prescription by one to diopters (for myopes) or adding one to two diopters (for hyperopes). A drawback to monovision is that it may compromise depth perception and difficulty looking at objects in the intermediate distance range (Zheleznyak et al, 2015). Most people adapt to monovision but it requires a slight adjustment period for a few weeks. An individual's dominant eye is often chosen for distance vision while the non-dominant eye is corrected for monovision at the Boston Eye Group.

From an economic standpoint, the number of LASIK procedures performed in the USA has declined by 50% (Corcoran, 2015). LASIK is an elective cosmetic procedure not covered by medical insurance. Thus, patients pay the full amount out of pocket and have recently become extremely price-sensitive to such procedures. The number of LASIK procedures peaked in 2007 and a reported 1.4 million surgeries were performed (Corcoran, 2015). Interestingly, femtosecond lasers are also used in refractive cataract surgery and patients are more likely to pay for the use of a femtosecond laser assisted surgery when cataracts are obscuring their vision as their vision becomes blurry and cloudy and interferes with daily tasks (McAlister, 2016). This is clearly evident, as the number of femtosecond cataract surgery cases has increased compared to the conventional cataract surgery technique (McAlister, 2016). Furthermore, part of the cataract surgery is usually covered by an individual's medical insurance easing the financial burden on patients.

Laser-assisted subepithelial keratomileusis (LASEK) is a similar yet different type of laser vision correction that may be performed on patients. Patients who are not candidates for LASIK due to thin corneas or high and/or irregular astigmatism may still have vision correction performed. LASEK is a more conservative technique where the vision correction is performed on the surface of the cornea and does not require the formation of a corneal flap. LASEK is therefore seen to be a safer technique because of the lack of flap complications that is normally associated with LASIK. There is however a higher risk of infections, scarring and corneal haze formation (Li et al, 2016). Other disadvantages with LASEK include a longer recovery period as well as post-operative discomfort and pain until the overlying epithelium has healed completely (Li et al, 2016). LASEK patients have a longer post-operative drops regiment. With both LASIK and LASEK, no bandages or stitches are required nor is an overnight stay required.

Patients who are not candidates for LASIK or LASEK may be evaluated for an Implantable Contact Lens (ICL) instead. Individuals with high myopic or hyperopic prescriptions and/or low central corneal thickness are not suitable candidates for standard laser vision correction but could be candidates for an ICL. Placing an ICL is a more invasive surgery.

Deciding between LASIK and LASEK

The surgical protocol performed at Boston Eye Group for determining whether LASIK or LASEK should be performed depends on a variety of factors. For myopes, patients must have a refraction of less than -10 diopters to even be considered for LASIK or LASEK. Patients with a refraction of greater than -10 diopters are evaluated for an implantable contact lens. There is a tendency for the cornea to regress back to its original curvature and shape with high prescriptions and may lead to a partial loss of the benefit. The second most important factor is a patient's central corneal thickness. If the pachymetry or corneal thickness is less than 500 microns, the LASEK route is favored. Patients who have an inferior-superior keratometry ratio of greater than 1.5 as determined by the corneal topography are placed on the LASEK pathway even if the pachymetry is greater than 500 microns. Furthermore, the Residual Stromal Bed (RSB) must be greater than 300 microns or else the patient is considered for LASEK. If the pupil size is greater than or equal to 7mm, a larger optical zone is chosen and the corresponding ablation depth and residual stromal bed is calculated to determine whether LASIK or LASEK should be performed. In special circumstances, LASIK may be performed even if a patient has a thin cornea provided the corneal topography is within normal limits and the individual has a low prescription leading to a lower depth of ablation (Tomita, Watabe, Mita, Waring, 2014).

Deciding Between LASEK and ICL

Patients placed on the LASEK pathway also need to be carefully evaluated to determine if it is the best possible treatment plan or if they are better suited for ICL. An individual's Risk Factor Index (RFI) is calculated to aid the decision.

Table 1. Risk Factor Index Implemented at Boston Eye Group. (Boston Eye Group)

Risk	Risk Factor Index
Age < 26	0.5
Max K> 46	1.0
K Diff (OD:OS) >1.5	1.0
Family History of Keratoconus	1.0
Inferior-Superior Ratio	2.0
Total Score	

The first and foremost factor considered when deciding between LASEK and ICL is the pachymetry.

Pachymetry ≥ 520 microns

The RFI is calculated and if it exceeds 2.0, they are considered for an ICL. For individuals who have an RFI of 1.5 or below, the RSB is calculated and LASEK is performed in the RSB is greater than 400 microns.

Pachymetry < 520 microns

The RFI is calculated and if it exceeds 1.0, the individual is evaluated for an ICL. If the RFI is less than or equal to 1.0, the RSB is calculated and LASEK is performed if it exceeds 450 microns.

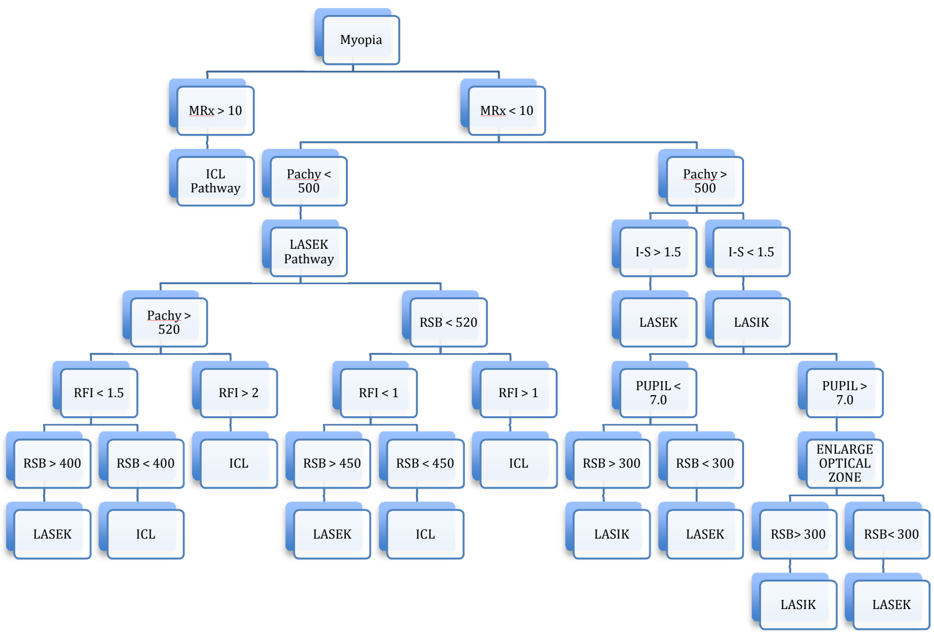

Figure 1. Refractive surgery pathway for myopes (Boston Eye Group).

The protocol for hyperopes is slightly different. Refractions must be less than +5 diopters to be considered. Patients with refractions greater than 5 diopters are evaluated for a clear lens extraction. Patients are considered for LASIK provided the pachymetry is greater than 500 microns and the I-S ratio is ≤ 1.5, while LASEK is chosen if the pachymetry ≤ 500 microns and/or the I-S ratio is ≥ 1.5.

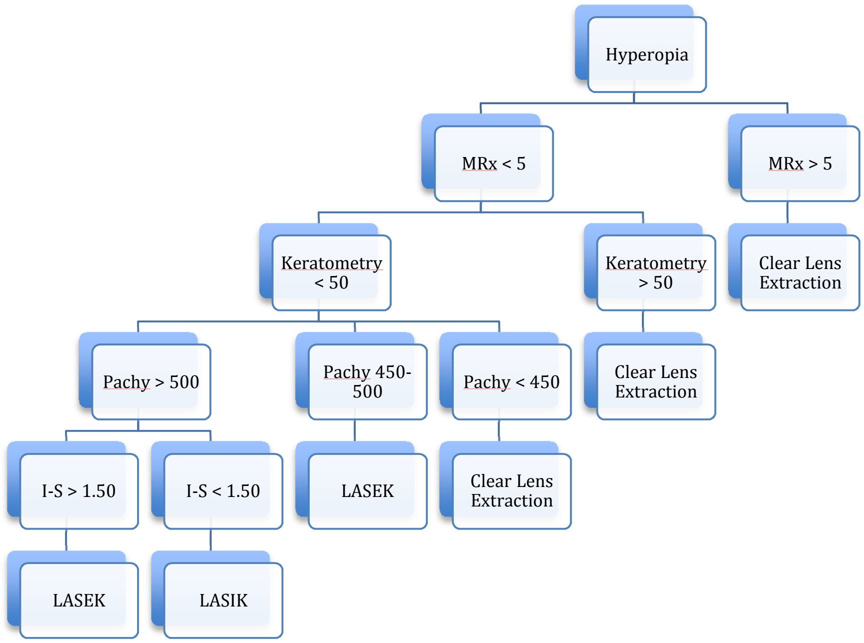

Figure 2. Refractive surgery pathway for hyperopes. (Boston Eye Group)

As successful as wavefront technology has become, it is sometimes necessary to perform a second surgery to correct any residual refractive error (Parikh, 2014). The second surgery enhancement is usually much quicker and relatively more straightforward than the initial one, requiring a lower depth of ablation to fine-tune the shape of the cornea (Broderick et al, 2016). A study showed that the need for enhancement correlated with higher preoperative age and higher degree of astigmatism (Mimouni et al, 2016). Patients who were hyperopic were also seen to have a higher rate of second surgery retreatment compared to myopes (Mimouni et al, 2016). Some of these risk factors may be corrected while others cannot be corrected. Other factors included temperature of the operating room and surgeon experience (Mimouni et al, 2016). Retreatment may also be necessary with patients who try monovision in the nondominant eye and are unable to adjust to it requiring further treatment to correct for full distance vision in both eyes. The enhancement occurs via the same procedure as the initial treatment via LASIK or LASEK. A key exception occurs if two years have elapsed from a LASIK procedure, surface ablation treatment is preferred to avoid a loss of tissue during the surgical side cut as it may lead to loss of reading lines (Vaddavalli et al, 2013).

A key step during the LASIK procedure is the formation of the corneal flap using a laser. There are two types of instruments that can create the flap: the mechanical microkeratome and the femtosecond lasers. Femtosecond lasers are favored because they are blade-free, require low energy and do not emit any thermal or shock wave transmission to surrounding optical structures and tissues (Farjo et al, 2013). Femtosecond lasers are also seen to produce better visual outcomes compared to the microkeratome (Durrie, Kezirian, 2005). A study showed that the femtosecond lasers allow patients to achieve a higher percentage of 20/20 uncorrected visual acuity with less astigmatism (Durrie, Kezirian, 2005). Studies also show greater flap placement accuracy along with greater adhesion to the surface with femtosecond lasers (Farjo et al, 2013). The microkeratome factors in corneal diameter and thickness, while the femtosecond laser does not, making the microkeratome susceptible to unique complications including buttonhole tears, irregular flaps, decentered flaps and higher rates of second surgery enhancements (Sharma, Ghate, Agarwal, Vajpayee, 2005). On the other hand, the femtosecond laser creates flaps with great accuracy and uniformity, which improves visual outcomes and reduces the risk of complications including microstriae and corneal ectasia (Espandar, Meyer, 2010).

The femtosecond laser however carries a unique set of intraoperative complications including bubbles in the anterior chamber, loss of suction in axis and decentered or thick flaps (Espandar, Meyer, 2010). Postoperatively, the flap may need to be recentered or corneal folds may develop if patients rub their eyes or squeeze their eyes over night. While some intraoperative complications, like bubbles in the anterior chamber or loss of suction, delay the procedure, other complications make it impossible to continue with the surgery and results in the procedure being aborted completely. These complications generally have very little effect on the overall visual outcome and most patients achieve the desired vision (Jadav et al, 2015). A case study conducted by the surgeon, Samir Melki, in 2014 showed the successful corneal flap creation following multiple suction losses before a surgical cut was made (Zeba, Melki, 2014). Instead of deciding to abort the procedure, the surgeon changed the suction ring while using the same docking cone as is advised by the manufacturer (Zeba, Melki, 2014). The patient had a UCVA of 20/25 at the 1-day follow up and 20/20 at the 2-month follow up (Zeba, Melki, 2014). The incomplete flaps considered in this study could not be lifted providing no other option for the surgeon but to abort the procedure. The study showed that attempting a second femtosecond laser pass did not affect a patient's visual outcomes compared to a single attempt pass. This encourages surgeons across the world to attempt multiple passes provided there is no trauma to the eye. There is no evidence to suggest that multiple passes to create the flap adversely affects the retina. Furthermore, while buttonhole flaps are common with the microkeratome, the equivalent for Femtosecond laser flaps is the vertical gas bubble breakthrough (VBB) (Srinivasan, Herzig, 2007).

Corneal abrasions and/or scarring and holes in Bowman's membrane increase the risk factor of vertical gas breakthrough (Srinivasan, Herzig 2007).

Intraoperative complications that result in the surgery being aborted increase the discomfort and inconvenience to the patient. Alternative methods of treatment need to be considered to allow the patient to achieve vision correction with minimal ocular complications. In this study we consider performing surface ablation within a week to achieve vision correction.

Objectives

As technology continues to progress there are newer lasers designed to minimize the risk of complications during LASIK. While the flap complications that occurred with the microkeratome are well known and widely reported, little is known about the flap complications produced by the Femtosecond Laser**.** Most practices have moved from the traditional microkeratome towards the Femtosecond laser. The Femtosecond laser is now available at various frequencies including 15, 30, 60 and 150kHz.

The specific aims of this study are:

1. To determine the types of flap complications that occur with the Femtosecond laser that cause a procedure to be aborted.
2. To investigate the visual outcomes of patients who experience the flap complication and the achievement of vision correction through second surgery LASEK as soon as possible.

We expect that this study will show:

1. The attainment of vision correction through second surgery LASEK without complication.
2. The possibility of performing LASEK within one week (or two weeks at most) of the initial aborted surgery instead of waiting several months and adding to the discomfort and trauma experienced by the patient.

METHODS

Consultation and Evaluation

The electronic medical records of patients undergoing LASIK surgery at the Boston Eye Group were retrospectively reviewed to identify patients who experienced flap complications during the procedure and resulted in the procedure being aborted. This led to performing a second refractive surgery at a later date once it was determined there were no flap issues, epithelial defects, corneal haze or microstriae.

The head surgeon, director and founder of Boston Eye Group, Samir Melki, performed the laser vision correction in Brookline, Massachusetts. 20 patient records and 20 eyes were identified and all procedures were performed between 2009-2015. Records were obtained from NEXTGEN EMR system.

All patients received a full ophthalmic evaluation and various parameters were measured to determine their candidacy for elective laser vision correction. Parameters included vision acuity, intraocular pressure, pupil size, keratometry and pachymetry, level of tear production. Pupil size was measured using a handheld Colvard and tear production was measured using zone quick strips placed in each lower lid for 15 seconds. Corneal topography was measured using the Pentacam Oculus (before February 2014) and Galilei G4 (after February 2014). A complete medical history including medications and allergies was obtained from patients to rule out contraindications and presence of rheumatoid arthritis, diabetes mellitus and keratoconus. Uncorrected visual acuity, best corrected visual acuity, eye dominance, manifest refractions were measured by an ophthalmic technician while the cycloplegic refractions, dilated fundus and slit-lamp examinations conducted by an ophthalmologist.

Pre-Operative for LASIK

Patients arrived at the clinic on the day of surgery and met with the head surgeon to ensure all questions were addressed and pre-operative instructions were given regarding information about the procedure, recovery time and post-operative care and treatment. All patients were required to have been out of contact lenses for at least a week prior to surgery. Manifest refractions and corneal topographies were repeated if 3 months had elapsed between the consultation and surgery day and/or if patients had worn contact lenses on the day of their initial evaluation. Patients were given 5mg of Valium to minimize any anxiety experienced during the procedure. All patients provided written informed consents and were informed of all potential risks involved with the procedure.

Intra-Operative Procedures During The Initial LASIK Surgery

The ocular surface of both eyes was sterilized using betadine. Patients were given anesthetic drops of 1% proparacaine hydrochloride in each eye before the procedure began while their eyes were prepped and draped. The patient is placed under the Femtosecond laser (Wavelight FS 200 or IntraLase FS 60) which created a corneal flap of about 100 or 110 microns. The depth of the corneal flap is determined using the patient's corneal topography and central thickness (Kim et al, 2011). The diameter, depth and position of the flap are reviewed and the patient is instructed not to talk and to stay as still as possible as the laser creates the flap for 10-15 seconds. The patient is docked off from the Femtosecond laser and moved towards the VISX laser (or Wavelight Ex 500). A lid speculum was placed to separate the eyelids and ensure the patient's eyes remained open throughout the procedure. The flaps were marked and a surgical cut was made with a lifter to expose the corneal stroma.

In an uncomplicated LASIK procedure, the vision correction is then performed by the VISX laser (Wavelight Ex 500) that fires pulses at a specific rate and frequency at this point. The ablation depth is calculated using Munnerlyn's formula. The formula states the depth of ablation per diopter of refractive error is equal to the optical ablation zone squared divided by 3. The optical ablation zone is measured in millimeters while the depth of ablation is measured in micrometers.

Following the laser vision correction, Balanced Salt Solution (BSS) is used to irrigate the area before the flap is carefully repositioned centrally over the cornea and excess BSS was drained out using Wexel tips. 3 drops of a steroid-antibiotic mixture containing a 50-50 mix of 1% prednisolone acetate and moxifloxacin were placed. All patients had a slit lamp examination 30 minutes following surgery to ensure the flap was intact and appropriately centered.

Surgical Complications and Observations During LASIK

The intralase applanation cone was inspected and found to be in good condition for all patients. Additional anesthetic drops such as 1% proparacaine hydrochloride were applied. The suction ring was centered over the pupil. The patient was moved under the Intralase and Docking performed without complications. The flap was recentered on the screen if needed at the surgeon's discretion. The femtosecond ablation was performed at a predetermined corneal flap diameter and depth. The patient was moved over to the

VISX laser and the eye was prepped and draped. A tegaderm film was placed over the upper eyelid and the flap was marked for orientation while the laser was armed and tested. An eyelid speculum was placed while additional anesthetic drops were administered. A large diameter corneal flap was excised but the flap was unable to be folded back due to various complications including loss of suction in axis, an incomplete flap or a decentered flap making it difficult to lift it completely. The surgery was then aborted only for the eye with the complication.

Post-Operative for Aborted LASIK

Aborted patients were examined at the slit lamp 30 minutes after the abandoned procedure and were required to come in for 1 day and 5 day follow ups to measure visual acuity and further slit-lamp examination to ensure the flap was centered and there was no epithelial defect or corneal haze. Patients were still required to complete a post-operative drop regiment consisting of Pred Forte and Vigamox. Patients were required to take 1 drop of Pred Forte every hour for the first 3 days (including the day of surgery) and then 1 drop 4 times a day for the next 2 days. Patients were required to instill 1 drop of Vigamox into the surgical eye 4 times a day for 5 days (including the day of surgery). All patients were instructed to avoid touching, rubbing or squeezing their eyes to prevent flap complications and further discomfort. Preservative free artificial tears were used as needed and patients were required to sleep with a corneal shield. At the 5-day follow up, the ophthalmologist decided to go ahead with LASEK if deemed appropriate.

Pre-Operative for LASEK

Manifest refractions and corneal topographies were repeated prior to surgery to ensure the corneal shape and depth was unchanged. New post-operative instructions were reviewed and 5mg of Valium was given to ease anxiety. All patients provided written informed consent.

Second Surgery LASEK W/ MMC

The ocular surfaces of both eyes were sterilized with betadine and an anesthetic drop of 1% proparacaine hydrochloride was administered. Tegaderm film was placed over the upper eyelid to open up the surgical area. An eyelid speculum was placed to keep the eye open and eye lashes away from the surgical field. 20% ethyl alcohol was placed through a ring well for 40 seconds and removed using a Wexel tip while the VISX laser was armed and tested. The corneal surface epithelium was removed to expose the corneal stroma. The VISX laser is docked on and performs the vision correction by firing at a specific depth and frequency and ablates using a predetermined depth calculated by Munnerlyn’s formula. Mitomycin C (MMC), an anti-scarring agent, is gently placed over the eye for 40-50 seconds depending on the depth of ablation and sterile water was used to wash away any residual debris. A bandage contact lens with a +0.50 prescription is placed over the eye to allow epithelial healing and minimize discomfort. 3 drops of the antibiotic-steroid mixture and a 1% dilating drop of cyclopentolate are placed in the patient’s operative eye.

Post-Operative for Second Surgery LASEK W/MMC

No slit lamp examination was required following the procedure and patients were allowed to go home. Post-Operative drops for LASEK included Pred Forte (prednisolone acetate 1%), Vigamox (moxifloxacin HCL 1%), and Nevanac (nepafenac 0.1%). Preservative free artificial tears were administered as needed to ensure the eyes were well lubricated. Tylenol with codeine was also prescribed to ease serious discomfort after surgery. Vitamin C (1g/1000mg) was also recommended for 3 months to prevent scarring. Patients were required to start the drop regiment 4 hours after the conclusion of surgery.

All patients were required to come in for 1 day, 1 week, 6 week and 1 year follow ups at the minimum to measure visual acuity and for a slit lamp examination. Patients were also required to wear corneal shields at night for one week and told not to rub or squeeze their eyes to prevent further discomfort. Patients were instructed to avoid heavy lifting and all contact sports for 2 weeks and to avoid jacuzzis, hot tubs and saunas for 2 weeks. Patients were told to refrain from wearing make-up and other substances around the eye including moisturizers and sunscreen lotion for 1 week. The contact lens was removed by the ophthalmologist at the 1-week follow up after epithelial healing. Intraocular pressure was not measured before the 6-week follow up.

RESULTS

A retrospective study conducted identified 14 eyes and 14 patients. The study identified cases through a six-year period ranging from January 2009 through December 2014 of LASIK eye surgeries performed at the Boston Eye Group. A prospective study was conducted on the patients that underwent flap complications in 2015.

Several measurements for the first LASIK surgery and second LASEK surgery taken included the age, sex and birth year of the patient, the operative eye and type of complication that occurred, manifest refraction before both surgeries, keratometry and pachymetry, uncorrected (UCVA) and best corrected visual acuity (BCVA) both preoperatively and postoperatively.

This study only included the set of eyes where the Femtosecond Laser made both a flap and an attempt was made at lifting the flap. The set of eyes where no attempt to lift the flap was made despite a complication was not included in this study. 6 other patients experienced similar flap complications that resulted in the surgery being aborted but were inconsistent with their follow-ups after the 1 week appointment. As a result, they were excluded from the study, as a required minimum of 3 follow up appointments were necessary to be included in this study.

Table 2. Type of Complication and Corresponding Number of Eyes Experiencing Complications.

Complication	Number of Eyes
Incomplete Flap	9
Decentered Flap	2
VBB Central	1
Loss of Suction in Axis	1
Thick Flap	1

The majority (64%) of flap complications occurred as a result of an incomplete flap while 14% of complications occurred due to a decentered flap. The remaining complications occurred due to a loss of suction in axis, the creation of a thick flap and VBB central.

Table 3. Summary of Pre-Operative Measurements and Surgical Details For First and Second Surgeries.

		Data for First Surgery								Data for Second Surgery				
Sex/Birth Year	Age	Eye	MRx before LASIK	Keratometry	Pachymetry	BCVA	UCVA	Flap Complication	Time	MRx before LASEK	Last post op VA	Final Follow Up	Year
M/1975	36	OD	-1.75, -2.00, 001	42.00/44.00	572	20/20	0	Loss of suction in axis	11 days	-	20/20	4 months	2011
F/1973	41	OD	-2.50, -0.25, 166	43.75/44.75	546	20/20	400	Incomplete	7 days	-2.75, -0.25, 125	20/25	3.5 months	2015
F/1966	45	OS	-5.75,-2.75, 150	45.25/47.75	518	20/20	400	Incomplete	2 months	-5.75,-2.75, 160	20/20-	1 year	2012
M/1979	35	OD	-1.25, sph	42.50/42.75	518	20/20	100	Incomplete	4 days	-	20/20	2 months	2015
M/1984	30	OS	-3.75, -0.75, 005	44.50/45.50	502	20/20	0	Incomplete	7 days	-4.00, -0.50, 005	20/15	2.5 months	2015
F/1969	46	OD	-6.25, -1.25, 090	45.25/45.75	548	20/20-	0	Too Thick	7 days	-6.25, -0.50, 095	20/25	4.5 months	2015
M/1958	56	OS	-4.25, -0.25, 147	46.00/46.75	611	20/20-	400	Decentered	21 days	-3.75, -0.50, 125	20/20	1 year	2015
M/1951	60	OD	0.25, -2.00, 085	44.00/44.75	574	20/20	50	VBB Central	28 days	PL, -1.75, 090	20/20-	5 weeks	2012
F/1988	26	OS	-6.50, -0.25, 059	44.25/45.00	516	20/20	0	Incomplete	4 days	-	20/20-	7 weeks	2015
M/1977	38	OD	-1.25, -1.00, 120	43.75/44.25	573	20/20	100	Decentered	7 days	-1.00, -1.00, 122	20/20-	2months	2015
F/1984	29	OD	-7.25, -0.50, 035	43.25/44.00	567	20/20	0	Incomplete	7 days	-7.25, -0.25, 010	20/20+	2 months	2014
F/1964	45	OS	-3.75,-1.25, 170	42.7/44.7	557	20/20	0	Incomplete	7 days	-	20/15	8.5 months	2010
M/1983	26	OS	-5.50, sph	43/43.2	573	20/20	400	Incomplete	12 days	-	20/20	6 months	2010
F/1983	26	OD	-2.50, sph	43.9/43.4	551	20/20	200	Incomplete	12 days	-	20/20	6 weeks	2009

Table 4. Duration Between LASIK and LASEK, Pre-Operative and Post-Operative Visual Outcomes.

Time Between Procedures	Number of Eyes	Preoperative LASIK BCVA	Last Postoperative UCVA
1 week	8	20/20 (8)	20/20 (6),20/25(2)
2 weeks	3	20/20 (3)	20/20 (3)
3 weeks	1	20/20	20/20
1 month	1	20/20,	20/20
2 months	1	20/20	20/20

Age/Sex/Eye

7 males and 7 females were found to have suffered flap complications of which 8 were right eyes and 6 were left eyes. The average preoperative age of patients was 38.5 (Range 26-60). The average age of males was 40.1 (Range 26-60). The average age of females was 36.9 (Range 26-46).

UCVA/BCVA

6 patients were unable to read the 20/400 line when uncorrected while another 3 patients could only read the 20/400 line, 1 patient could only read the 20/200 lines while 2 patients could only read the 20/100 line. Only one patient could read the 20/50 line

when uncorrected. All 14 patients were successfully able to read the entire 20/20 line during the preoperative manifest refraction before LASIK and before LASEK.

Manifest Refraction

13 patients included in the study were corrected for myopia and most corrected for some degree of astigmatism while only 1 patient was corrected for hyperopia. The one patient did have an overall myopic spheroequivalence with a significant astigmatism that was corrected for. Out of the 14 eyes included in the study, only 3 eyes were not corrected for astigmatism.

Monovision

2 patients opted to have monovision done in the flap complication eye but were both able to read at the 20/20 line for both reading and distance vision at their last postoperative visit.

Pachymetry

The average pachymetry was 551.8 microns (Range 502-611). All patients received another manifest refraction following the aborted LASIK surgery before the second surgery LASEK to ensure the corneal flap and aborted procedure did not affect the shape of the cornea.

Refraction Change Between LASIK and LASEK

6 out of the 14 eyes did not experience any changes in sphere, cylinder or axis between refractions at time of LASIK and LASEK, while 8 out of the 14 eyes experienced minor changes in the refraction. The minor changes were classified as anything less than a 0.50 diopter change in either direction in sphere or cylinder. Axial

changes were not considered significant if the spheroequivalence was unchanged or within a 0.5 diopter difference to the initial refraction in either direction. Only one patient had a 0.75 decrease in the cylinder value between refractions. This was also deemed insignificant and was seen as a positive side effect. Overall, all 14 eyes showed refractive stability between the initial aborted LASIK procedure and second surgery LASEK.

Time Between Procedures

The average duration between both procedures was 14 days (Range 4 days to 60 days). 8 of the 14 patients underwent the second surgery LASEK within a week, a further 3 patients underwent the LASEK within 12 days, with the remaining 3 patients waiting 3 weeks, 1 month and 2 months respectively. There were no significant differences in visual outcome or healing time between patients who waited a week versus patients who waited up to a month.

Table 5. Pre-Operative and Post Operative Visual Acuities.

Patient #	1 Day	1 Week	1.5-4 Months	Pre-Op BCVA
1	20/100	20/40	20/20	20/20
2	20/400	20/200	20/25	20/20
3	20/70	20/40	20/20	20/20
4	20/40	20/40	20/20	20/20
5	20/50	20/30	20/15	20/20
6	20/100	20/40	20/25	20/20
7	20/150	20/40	20/20	20/20
8	20/100	20/25	20/20	20/20
9	20/40	20/25	20/20	20/20
10	20/60	20/50	20/20	20/20
11	20/200	20/20	20/20	20/20
12	20/60	20/100	20/20	20/20
13	20/80	20/30	20/20	20/20
14	20/50	20/20	20/20	20/20

12 patients had a UCVA of 20/20 at their final follow up visit. All patients were required to come in for a 1 day; 1 week and 6 week follow ups at a minimum followed by annual ophthalmic exams. Not all patients followed the 6-week protocol so the results of the last postoperative visit varied between 1.5 to 4 months but all results are based of the last postoperative visit at the Boston Eye Group. Only 2 patients lost one line of reading and had a UCVA of 20/25. At 4 months postoperatively, all 14 eyes were corrected to 20/25 or better. 12 eyes did not lose a line of BCVA, 2 eyes lost one line of BCVA while no eye lost more than 1 line of BCVA.

Ablation Depth

Table 6. Ablation Depth and Corresponding Best Corrected Visual Acuity (BCVA) Lines Lost For Each Patient.

Patient	Depth of Ablation (Microns)	BCVA Lines Lost
1	52	0
2	30	1
3	67	0
4	23	0
5	80	0
6	89	1
7	50	0
8	32	0
9	84	0
10	27	0
11	111	0
12	46	0
13	84	0
14	47	0

The table above shows that there is no correlation with depth of ablation (measured in micro meters) compared to the number of BCVA lines lost after the second surgery LASEK. The depth of ablation is based off Munnerlyn's formula and accounts for the power and astigmatism of a patient's prescription. Higher prescriptions and higher degrees of astigmatism are associated with a higher depth of ablation. The table shows no clear trend between the two variables. The average depth of ablation was 58.7 microns and the range goes from 23-111 microns. At an ablation depth of 23 microns (lowest) there were no lines lost in BCVA, while at an ablation depth of 30 (third lowest) microns, there was one line lost of BCVA. Conversely, at higher ablation depths, there is no obvious trend either. At an ablation depth of 111 microns (the highest) there was no loss of BCVA, but at an ablation depth of 89 microns (second highest), there was one-line loss of BCVA.

Enhancement

At the 4-month postoperative mark, none of the patients required a surgical enhancement. The 2 patients who were reading the 20/25 line opted not to proceed with enhancements as they were satisfied with their vision and elected not to undergo a third procedure.

DISCUSSION

The aim of this study was to determine the visual outcomes of patients who suffered flap complications during LASIK surgery and thus needed to have LASEK at a later date to achieve the desired visual outcome. In all procedures, a flap was created and a surgical cut was made to attempt to lift the corneal flap. All surgeries in this study were aborted because the flap was unable to be lifted. All patients met the minimum criteria of 3 post-operative visits. Patients who did not meet these criteria were not included in the study.

Patients have to undergo the discomfort and trauma of epithelial scarring coupled with the dissatisfaction of the aborted surgery. Although studies have shown that the femtosecond laser creates the flap with great accuracy and precision, errors still occur leading to complications. The head surgeon, Samir Melki, has been performing LASIK surgeries since 2000 so the experience and learning curve of the surgeon was not considered to be a factor causing the complications. Studies have shown an increased likelihood of flap complication owing to the inexperience of a newly accredited surgeon (Jabbur, Myrowitz, Wexler, O'Brien, 2004) fellow or resident while others have shown high patient satisfaction and satisfactory visual outcomes with surgeons in training (Nehls, Ghoghawala, Hwang, Azari, 2014). This study only included complications that resulted in abandoning the procedure. Several other complications of the femtosecond laser are widely reported including bubbles in the anterior chamber, which delay the procedure but is ultimately completed successfully when the bubbles disappear (Soong, de Melo Franco, 2012). The bubbles interfere with the laser tracking of the center of the pupil and the laser would be unable to emit the necessary pulses of energy (Soong, de Melo Franco, 2012). Such flap complications that occurred without any attempts to make a surgical cut or delay the procedure were not included in this study.

The surgeon determined the duration between procedures depending on corneal appearance and refractive stability. 71% of patients (11/14 eyes) underwent LASEK within 12 days of the initial aborted procedure. There were no significant differences noted between patients who underwent LASEK in the first two weeks compared to those who waited longer than two weeks.

There was also no correlation between the types of flap complication along with the postoperative time for the desired visual outcome to be achieved. All the flap complications-incomplete, decentered, thick and loss of suction- were able to be corrected by LASEK and patients were able to read at the 20/20 line. There was no specific complication that delayed the healing process or caused a loss of reading line for distance vision. The most common flap complication was a loss of suction that led to the formation of an incomplete flap. The suction loss occurs as the intralase vacuum ring is placed over the eyeball causing an incomplete flap. Before the Femtosecond laser is docked on to the patient, the surgeon always checks to ensure good suction to minimize these complications from arising. The exact cause of suction loss during these procedures in unknown. Factors that may increase the chance of suction loss during such a procedure are keratometry readings of < 42, squeezing of the eyes and eyelid, and small palpebral apertures (Asano-Kato et al, 2002). Patient anxiety during the procedure leading to excessive head and face movements cannot be ruled out either. Generally, patients were given 5mg of Valium to easy anxiety during the procedure and patients were observed for calmness before being brought to the surgical room. Patients experiencing excessive anxiety are given a second dose of 5mg valium but this is relatively uncommon as patients are thoroughly informed about the procedure and given a step by step account during the procedure.

The second most common complication was the formation of a decentered flap. A potential way to overcome the problem of a decentered flap is to create a larger diameter flap which is permitted by the Femtosecond laser. A larger diameter flap would allow the surgeon to compensate for any decentration that may occur (Salamao, Wilson, 2010). However, it is hard to predict the risk of having a decentered flap on a patient. One of the patients suffered a Vertical Bubble Breakthrough (VBB) over the central area of the flap. This means there was a hole in the flap over the pupillary area and led to the surgery being aborted.

The efficiency of the Femtosecond IntraLase laser stems from the pulse rates it delivers. The slower the pulse rate, the greater the energy is required to create the corneal flap. The laser generates pulses at a wavelength that corresponds to the infrared region on the electromagnetic spectrum and is approximately 1053nm in wavelength (Salamao, Wilson, 2010). The laser also creates a more uniform flap in terms of thickness from the peripheral areas of the cornea towards the center while the microkeratome flap is meniscus shaped and thicker at the peripheral areas (Salamao, Wilson, 2010). Another key difference is that the overall thickness of the flap is thinner with the Femtosecond laser compared to the average depth of microkeratome flaps. LASEK was chosen as the best alternative route in these cases because no further surgical cut was needed and the risk of intersecting flaps would be eliminated. When complications such as buttonhole flaps occur with microkeratome flaps, there is often a longer time lag between surgeries to allow the flap to heal completely and ensure the epithelial defect heals completely (Al-Mezaine, Al-Amro, Al-Fadda, Al-Obeidan, 2009). Previously with the microkeratome, some surgeons preferred to delay the second surgery by a few months. Some surgeons repeated LASIK instead of performing LASEK (Al-Mezaine, Al-Amro, Al-Fadda, Al-Obeidan, 2011). This was not considered because of the increased risk of intersecting flaps with subsequent loss of vision. This would ultimately add to the distress and uneasiness for the patient and further complicate the procedure.

Essentially 100% of the eyes in this study did not experience a significant change in refraction between the two surgeries and did not experience a change in BCVA before LASEK. This was a good indicator to proceed with LASEK because the flap had not interfered with the bending of light rays through the eye. The corneal flap did not seem to interfere with the astigmatism of patients as well, which was another good indicator of refractive stability despite the aborted procedure. Only 1 eye was determined to have a slightly significant change in astigmatism as it decreased from -1.25 to -0.50. This was a positive side effect of the complication as the corneal flap was too thick in this patient. The patient only lost one line of UCVA and could successfully read the 20/25 line. The 0% enhancement rate was not a surprise given that surface ablation was not performed until refractive stability and satisfactory flap healing was determined in all patients. This was also a positive result as it fits in with the hypothesis that surface ablation can be done as soon as possible following serious flap complications. The average enhancement rate at Boston Eye Group for enhancements for both LASIK and LASEK is around 3% per year (Boston Eye Group Statistics).

There was no correlation observed between ablation depth and number of BCVA lines lost following surgery. This indicates that provided the flap has healed well, it would be advisable to proceed with the second surgery as soon as possible. We were able to conclude that surface ablation could be performed regardless of the patient's prescription of depth of ablation. Furthermore, there was no correlation observed with pre-operative age and final visual outcomes with patients of various ages were able to achieve 20/20 uncorrected vision.

None of the patients suffered any major post-operative complications and there were no reported cases of diffuse lamellar keratitis, which is a serious post-operative complication that is more common with Femtosecond lasers compared to the microkeratome. Common side effects included dryness and starbursts of light when driving at night but none of the patients reported serious discomfort with the side effects and were generally happy with the vision.

A key difference in methodology during the second surgery LASEK compared to conventional LASEK was that MMC was used for an extended period of time over the surface of the eye following the vision correction by the VISX laser. Although mitomycin C is often not used for low refractive errors (less than -6 diopters) by some surgeons due to its toxicity (Jabbur, Myrowitz, Wexler, O'Brien, 2004), the surgeon felt it was necessary to use it to prevent further scarring and discomfort to the patient. As an anti-scarring agent, it was placed over the surface of the eye for a slightly longer duration of 40 seconds to minimize further trauma to the eye and promote rapid epithelial healing. In conventional LASEK, the duration of MMC placed on the eye is proportional to the depth of ablation.

Overall, this is the first study to my knowledge to investigate the visual outcomes following Femtosecond laser flap complications and second surgery LASEK. Microkeratome flaps have been studied extensively and the purpose of this study was to provide an alternative form of treatment for Femtosecond flap complications. The study showed favorable results when performing surface ablation within one to two weeks of the initial aborted procedure. Over 85% of patients were corrected to 20/20 within 4 months of the aborted LASIK procedure. We thus advocate for surface ablation as soon as possible provided there are no postoperative flap complications from the aborted LASIK such as folds, microstriae or epithelial defects.

Evaluation of Study Design

The limitations with this study include the inconsistent follow ups by patients who missed their scheduled appointment. A likely cause of this would be the tendency to forget about the appointment if he/she is satisfied with their vision. All patients kept the 1 day and 1 week post operative appointments but came in at different times around the 6 week appointment (spanning from 4 weeks to 4 months). It would also be important to assess whether there are any long-term effects on the eye and whether patients experience drastic side effects such as regression. A second limitation would be the extent of differing flap complications involved in the study. Although 64% of patients experienced the same incomplete flap complication, the degree of incompleteness differed from each patient. Some patients suffered 1/3 or 2/3 flap defects in different spatial regions with some over the pupillary area and some in non-pupillary areas, so it would be important to classify those patients in a separate pool altogether. Further limitations include the sample size for the study, which could potentially skew the data. To increase uniformity between patients and minimize experimental bias, all surgeries were performed, Samir Melki, and only one type of Femtosecond laser was used.

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Education

Boston University School of Medicine, Boston Massachusetts August 2014-Present
Master of Science in Medical Sciences (Expected 05/16)
Emory University, Atlanta Georgia August 2010-May 2014
Bachelor of Science in Biology, Minor in Economics

Work Experience:

Emory Emergency Medical Services (EEMS) Atlanta, GA
Advanced Emergency Medical Technician (AEMT)
August 2013-Present

- On-call 25 hours a week for Emory EMS
- Perform life-saving skills including CPR and IV fluid administration
- Ability to work under pressure and communicate effectively with patients, bystanders and law enforcement personnel

Wake Forest Baptist Medical Center Winston Salem, NC
Intern
June 2012-August 2012

- Observed Dr G. Badlani, Dr. P Mufarrij, Dr. R. Terlecki (Urology), Dr. R. Jinnah (Orthopedics), Dr. C. Badlani (Neurology), Dr. M. Lovorn (Rehabilitation) and Dr. Siddiqui (Cardiovascular)
- Observed various surgeries including nephrectomies, a humpty-dumpty and stone manipulation surgeries via laser beams
  Assisted PT,OT and ST with simple tasks to aid patient treatment and recovery.

Oxford College of Emory University Oxford, GA
Introductory Biology and Chemistry Teaching Assistant
Aug 2011- May 2012

- Held bi-weekly review sessions and prepared practice exams for students
- Ensured safety during laboratory experiments and prepared lab for each day's experiments.

Academic Research:

Oxford College of Emory University Atlanta, GA
Psychology Research with Dr. Ken Carter
August 2011- April 2012
Research Scholar

- Constructed a general survey for professors to determine if their activities/demonstrations/teaching technique were effective.
- Collected data from 10 years of journals from the 'Teachings of Psychology' Journal about the most important questions asked.
- Research was displayed at American Psychology Association (APA) Conference

Chemistry Cancer Research with Dr. N. Powell Atlanta, GA
Research Scholar
Sept 2011-May 2012
- Synthesized various substituted chalcones and isoxazoles
- Observed their effects when introduced to a specific line of breast cancerous cells.

Volunteer work:
Winship Cancer Institute Atlanta, GA
- Read books to elderly patients as they receive chemotherapy every week
- Play word and board games with patients and families in waiting rooms

Oxford College of Emory University Oxford, GA
Orientation Leader
Aug 2011-Dec 2011
- Led incoming freshmen through orientation, assisted with their class registration and organized team-building games
- Facilitated a discussion based class called freshman seminar; Key issues such as socioeconomic class, race and racism and religion were discussed.

Up 'til Dawn Oxford, GA
Event Manager
Aug 2011-May 2012
- Organized monthly workshops and seminars to spread awareness about St. Jude's Research Hospital.
- Worked with peers to organize letter-writing events and multiple awareness weeks to raise $6,000 in donations for St Jude's Hospital.

Honors and Distinctions
- Dean's List: Fall 2010,2011, 2013; Spring 2011,2012,2013.
- Phi Eta Sigma Member (Honor society that represents the top 5% of the class)
- Alpha Epsilon Upsilon Member (Honor Society)
- Mu Epsilon Delta (M.E.D.) Member. (Honor society for distinguished pre-med students)

Additional:
Sophomore Class Gift Committee Executive Member
- Served on a 15-member board responsible for raising $10,000 to build a new room in the library.