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Efficacy of digital otoscopy in telemedicine

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Efficacy of Digital Otoscopy in Telemedicine

Alexandra Short, B.S.

A dissertation submitted to the Graduate Faculty of

JAMES MADISON UNIVERSITY

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Abstract

With an average of 1 audiologist to every 20,000 people in developed countries and as many as 6.25 million people in developing countries, the need for audiology services in rural or underserved populations is evident (Swanepoel, et al., 2010). Telemedicine offers an affordable solution. Previous studies assessed digital otoscopy images for postsurgical follow-up (Kokesh, et al., 2008) as well as remote video otoscopy by telehealth technicians (Biagio, et al., 2013). These studies used traditional laptop based video otoscopes. The purpose of the present study was to determine whether more portable and less expensive systems, such as the CellScope and OTO App, could be used as effectively for referral and diagnosis of external and middle ear disease off-site (telemedicine). The study accomplished this by comparing diagnostic accuracy of CellScope images, determining rate of agreement for referral and obtaining an estimate of image quality.

Agreement within professional groups (audiologists – AUD, and otolaryngologists –ENT) and between professionals and the ‘gold’ standard were calculated from 195 comparisons. These agreement scores represented the accuracy with which both groups could specify a diagnosis. All groups were significantly different from each other ($p < 0.001$), but each had a high degree of agreement (greater than 90% agreement). The need for medical referral varied within and between professional groups as well as between CellScope images (pathology). However, two general trends were identified: 1. high agreement between ENTs and AUDs when need for referral was high; and 2. low agreement between the ENTs and AUDs when the need to refer was low. In general, the need for medical referral was rated as higher when the question

addressed “immediate referral” or “referral prior to hearing aid fitting/earmold impression” as opposed to need for referral before audiometric testing. All CellScope images were scored by both professional groups as having at least the same quality as manual otoscopy.

We conclude that CellScope images can be used effectively for telemedicine with a high degree of accuracy and with good agreement for referral between otolaryngologists and audiologists.

1. Introduction

Hearing loss is globally the most prevalent disabling condition, affecting more than 278 million people worldwide. With an average of 1 Audiologist to every 20,000 people in developed countries and as many as 6.25 million people in developing countries, the need for audiology services in rural or underserved populations is evident and rising (Swanepoel, et. al, 2010). Telemedicine offers an affordable solution to serve these populations.

Telemedicine, as defined by ASHA, is the “application of telecommunications technology to the delivery of audiology professional services at a distance by linking clinician to patient or clinician to clinician for assessment, intervention, and/or consultation.” Telemedicine offers a cost-effective and sustainable means of providing services with restricted or limited access. It has successfully been used in medical fields including: neurosurgery, radiology, dermatology, otolaryngology, psychiatry and pediatrics (American Speech-Language-Hearing Association, 2012; Heneghan, et al., 1999).

According to the American Academy of Audiology (AAA), telemedicine is a rapidly growing form of service delivery in the field of audiology because it offers four fundamental benefits: 1. Improved access, 2. Cost efficiencies, 3. Improved Quality, 4. Patient demand. Telemedicine improves access to medical services by reaching beyond the office walls, especially beneficial to patients in rural and underserved populations (American Academy of Audiology, 2015; Ferguson, et al 2008-9; Heneghan, et al., 1999). It is cost effective in that it reduces travel costs and time of hospital stays. Telemedicine has also been shown to maintain

the same quality of services and in some specialties improve the quality of services. Lastly, telemedicine is highly in demand because it reduces patient travel time and allows access to health care in places in which it might not be available otherwise (AAA, 2015; Ferguson, et al 2008-9).

Telemedicine can be delivered in one of two methods: synchronous and asynchronous. Synchronous telemedicine refers to the delivery of services in real time typically via on-line video streaming. Synchronous services can connect professionals to patients or professionals to technicians. Asynchronous telemedicine refers to image or data acquisition that is stored-and-forwarded to professionals for interpretation (ASHA, 2012; Heneghan, et al., 1999). Asynchronous telemedicine examples in audiology include testing results, video otoscopy, patient outcome measurements, post-surgical follow-up and more. However, both synchronous and asynchronous telemedicine methods have been studied and applied to a variety of audiology services (ASHA, 2012).

In particular, asynchronous methods have been used to assess the applications of digital otoscopy in telemedicine. Evidence suggests that reasonably accurate diagnosis of ear pathologies can be made remotely based on asynchronous video otoscopy performed by telehealth technicians and professional supervisors (Biagio, et. al, 2013). Similarly, asynchronous digital otoscopy has been shown to provide sufficient quality for accurate otologic post-surgical follow-up (Kokesh, et. al, 2008); indicating that asynchronous, or store-and-forward digital otoscopy images, are considered at least of equal quality to manual otoscopy performed onsite.

Thus, video otoscopy can yield reasonably-accurate remote diagnoses made by otolaryngologists and otoscopic still images can have a similar quality to manual otoscopy. However, there is no evidence supporting audiologists' role in video otoscopy for telemedicine. Further, there is little literature to show whether portable and inexpensive video otoscopy systems, such as an iPhone otoscope attachment, would yield reasonable quality images for remote diagnosis. Previous studies have used traditional video otoscopes to acquire images and while these devices provide excellent quality images, their expense [average retail cost = \$683.38 (Oaktree Products, 2015)] may be prohibitive for use by clinicians in rural, third-world or economically disadvantaged communities. Additionally, they are not easily portable (requiring external attachments to laptop computers and wireless internet connection) and so less likely to be used by professionals working at transient environments.

The current study was designed to determine whether digital otoscopy images obtained with an inexpensive, portable system were of sufficient quality to be used to accurately diagnose pathologies of the external ear canal, tympanic membrane and middle ear asynchronously (store-forward telemedicine approach) by audiologists and otolaryngologists. The system selected was a portable video otoscope App with an attachment for an iPhone (CellScope OTO.). This system is quite portable (fits on a cellphone) and inexpensive (current retail value < \$100). Our study addressed three specific research questions:

Research Question 1: How accurate are diagnoses made from digital otoscopy images compared to the gold standard*? **Hypothesis:** Both audiologists and otolaryngologists will have a high level of agreement with the gold standard

Research Question 2: Do Audiologists and Otolaryngologists agree regarding the need for referral based on digital otoscopy images? **Hypothesis:** There will be a moderate level of agreement between audiologists and otolaryngologists regarding the need to refer based on digital otoscopy images

Research Question 3: Is the quality of the digital otoscopy images at least equal to or better than manual otoscopy? **Hypothesis:** All images will be rated at least the same as manual otoscopy

*the gold standard was defined as the on-site diagnosis made by an otolaryngologist

2. Literature Review

2.1 Need and benefit of telemedicine in audiology

Telemedicine, a term that literally means “healing at a distance,” is defined by the World Health Organization as “the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities” (WHO, 2010).

Telemedicine and telehealth are often used as interchangeable terms; however, telemedicine refers specifically to the delivery of services by a medical professional while telehealth refers to the delivery of services by health care professionals (WHO, 2010). For the purpose of this document, telemedicine will be used to describe both telemedicine and telehealth.

Telemedicine can be delivered in two primary ways: synchronous and asynchronous. Synchronous telemedicine refers to the delivery of services in real time typically via on-line video streaming. Synchronous services can connect professionals to patients or professionals to technicians at a distant location. Asynchronous telemedicine refers to image or data acquisition that is stored-and-forwarded to professionals for interpretation. Images or data are stored electronically, forwarded and then retrieved at a later time by the professional for review. Both synchronous and asynchronous methods are appropriate applications of telemedicine as long as they are fully compliant with federal and

state privacy laws under the Health Information Portability and Accountability Act (HIPAA) of 1996 (American Speech-Language-Hearing Association, 2012; Ferguson, et al., 2008-9; Heneghan, et al., 1999). However, asynchronous telemedicine has proven to be the more cost-effective solution (Heneghan, et al., 1999).

Telemedicine has successfully been implemented in fields including but not limited to: radiology, cardiology, otolaryngology, neurosurgery, dermatology, etc. (Heneghan, et al., 1999; Swanepoel, et al., 2010). In relation to audiology, telemedicine refers to the “application of telecommunications technology to the delivery of audiology professional services at a distance by linking clinician to patient or clinician to clinician for assessment, intervention, and/or consultation” (ASHA, 2012). This document will address applications of telemedicine in audiology, which have also been referred to as “tele-audiology” and “telepractice” (ASHA, 2012).

Telemedicine was created, in part, out of need to make hearing health care globally available. A study by Swanepoel, et al. (2010) outlined the need of telemedicine in audiology and its potential to reach underserved countries. The study addressed 5 major areas: 1. Global burden of hearing loss, 2. Inadequacy of global hearing health care services, 3. Telehealth: a promising prospect for hearing health care, 4. Potential scope of tele-audiology, 5. Tele-audiology: a new era. The investigators found that permanent hearing loss is the number one most prevalent disabling condition globally (WHO, 2008). Permanent hearing loss affects over 278 million people rising to 642 million people (10% of the

global population) when including mild hearing loss (WHO, 2006a). Current estimates of the prevalence of hearing loss only include adult onset hearing loss and exclude permanent congenital and early-onset hearing loss suggesting that they underestimate the global burden of hearing loss. The most heavily burdened are low- and middle-income countries where services are often unavailable or unaffordable (Cohn & Cason, 2012; Swanepoel, et al., 2010).

Access to hearing health care varies from metropolitan cities like Washington D.C. to rural areas in the state of Alaska, from developed countries like the United States to developing countries like Kenya and from high- to middle- to low-income populations. However, overall hearing health care is “clearly inadequate for reaching the vast majority of people with hearing loss” as described in Swanepoel, et al. 2010. One reason for the discrepancy in the number of services available is the low number of hearing health care professionals available globally. It is estimated that the average ratio of audiologists to the general population in developing countries varies from between 1:500,000 to 6,250,000 and in developed countries is 1:20,000. Current audiological services are inadequate for reaching a large proportion of people with hearing loss globally; therefore the need to reach this population is high and increasing (Gladden, Beck, & Changler, 2015; Swanepoel, et al., 2010).

In order to address the inadequacy of hearing health care, solutions such as telemedicine have been proposed. Telemedicine offers a cost-effective and sustainable means of providing services to populations with restricted or limited access (Burgess, et al., 1999; Heneghan, et al., 1999; Swanepoel, et al 2010). A

prime example of telemedicine's cost-efficiency was reviewed in Ferguson et al. (2008-9) a retrospective study of telemedicine in remote Alaska. Alaska first started implementing telemedicine in 2001 and between the years of 2001-2007, saved an estimated 3.5 million dollars on health care costs. Specifically for otolaryngology [Ears, Nose and Throat specialist (ENT)] services, Alaska saved an estimated \$190,000 in 2007 alone. The increase in savings was largely a result of the decreased number of patients traveling to see a specialist as well as less reimbursable time for physicians. In 2007, only 10% of 2,080 referrals for ENT required an in-person consultation, which in turn reduced travel cost for 90% of patients. Therefore, by filtering all patients through a telemedicine consultation prior to an in-person consultation, the need for in-person office visits was reduced from 100% to 10% in 6 years. In the words of Ferguson, et al. (2008-9) "Telehealth has a 'trickle down' effect that improves specialty access for all patients even if their problems are not addressable by telehealth;" meaning that, even the patients who require in-person consultations benefit from telemedicine due to the reduced wait time to see specialists.

A second example of successful implementation of telemedicine into the delivery of audiology services can be seen within the audiology portion of the Department of Veteran Affairs (VA). In order to address the large population of veterans with hearing loss in a cost-efficient and timely manner, telemedicine applications were implemented in the VA at the beginning of 2009 (Jacobs & Saunders, 2014). Since implementation, telemedicine at the VA has seen a dramatic increase in service delivery jumping from 356 veterans in 2010 to over

15,000 veterans in 2014 (Gladden, Beck & Chandler, 2015). Currently, the VA offers both synchronous and asynchronous telemedicine services including: electronic consultations, mobile health records, remote hearing aid programming, and remote audiometry, with pilot programs exploring efficacy of remote cochlear implant programming and remote programming of hearing aids via smartphones (Gladden, Beck & Chandler, 2015; Jacobs & Saunders, 2014).

Asynchronous telemedicine has a clear cost-benefit when compared to synchronous telemedicine (Ferguson, et al., 2008-9; Heneghan, et al., 1999). For example: synchronous telemedicine requires: 1) a scheduler (typically an on-site technical facilitator) 2) specialist's clinic time (may result in "no show" appointments), 3) equipment and training (as do asynchronous methods), and 4) higher network bandwidth for live-streaming. The asynchronous method also allows for a faster turn-around time, where specialty consults can be provided within the same day the information is forwarded, instead of scheduling a time for specialist and patient to video-conference. It is, however, important to note that although asynchronous methods tend to be more cost efficient, there are services and application in which synchronous methods are superior, such as aural rehabilitation and therapy sessions (Ferguson, et al., 2008-9).

The need and potential for telemedicine are evident; however, there some barriers preventing full implementation. One barrier) is the limited availability of universal guidelines and standards (Gladden, Beck & Chandler, 2015; Swanapoel et al., 2010). Organizations like the American Academy of Speech-Language-Hearing Association (ASHA) and the American Academy of Audiology

(AAA) have basic guidelines for the USA but the standards for international and global guidelines are lacking. A second barrier is the lack of literature investigating the need, scope, and validation of telemedicine. A third barrier is the problems associated with areas of reimbursement, legislation and malpractice. Since telemedicine requires a sending and receiving site, reimbursement is an issue, particularly for the sending site. The sending site may not receive any reimbursement for creation and follow-up of telemedicine cases because the receiving-site provider performs the reimbursable service (Gladden, Beck & Chandler, 2015; Heneghan, et al., 1999). Although nothing is gained by the sending site, the patient and insurer benefit in terms of prevented travel and unnecessary follow-up costs (Ferguson, et al., 2008-9). Lastly, attitudes of both professionals and patients toward telemedicine may limit adaption of widespread use across professional services (Eikelboom & Atlas, 2005; Gladden, Beck & Chandler, 2015; Singh, et al., 2014). A 2014 study investigated practitioners' attitudes toward the delivery of "teleaudiology" services and found that although most indicated that teleaudiology would have a positive effect regarding accessibility to services, the willingness to provide telemedicine varied by type of service and patient population with the least willingness associated with diagnostic tasks performed on both young and elderly populations (Singh, et al., 2014).

Telemedicine is a rapidly growing form of service delivery in the field of audiology because it allows cost-effective and sustainable access to health care in places in which it might not be available otherwise (Ferguson, et al., 2008-9;

Heneghan, et al., 1999; Swanepoel, et al., 2010). Telemedicine improves access to medical services by reaching beyond the office walls, especially beneficial to patients in rural and underserved populations. It is cost effective in that it reduces travel costs and specialist's reimbursable time. Both synchronous and asynchronous methods can be utilized; however, asynchronous methods have proven to be the more cost-effective options (Ferguson, et al., 2008-9; Heneghan, et al., 1999). The available number of articles investigating telemedicine is limited, but the scope of telemedicine applications within the literature is large. These findings have been encouraging for utilization of telemedicine in a vast scope of audiology applications including screening, diagnostics, and intervention. Thus the potential of telemedicine is evident; however validation research for telemedicine applications is lacking and needs to be expanded prior to wide-spread implementation (Swanepoel & Hall, 2010).

2.2 Application of asynchronous video-otoscopy still images in telemedicine

As Swanepoel & Hall, (2010) discovered in their systematic literature review, there is limited literature validating the use of telemedicine applications in audiologic practice. There were three reports directly associated with asynchronous video-otoscopy up until 2010: Patricoski, et al. (2003); Eikelboom, et al. (2005); & Kokesh, et al. (2008). Patricoski et al. (2003) compared diagnosis of post-tympanostomy tube placement from an in-person microscopic examination to diagnosis made from asynchronous video-otoscopy still images

taken by two Otolaryngologists and found that diagnostic agreement, or concordance between the in-person and asynchronous methods was substantial. Results were similar across the all three of these studies.

A “proof-of-concept” study by Eikelboom, et al. (2005) compared the quality of in-person otoscopic examination to asynchronous video-otoscopy still images in order to validate the use of video-otoscopy images for diagnosis of ear disease in children. Otolaryngologists had the patient’s case history as well as the video-otoscopy images to make assessments of the ear. Researchers found that video-otoscopy images in combination with case histories were able to provide significantly comparable agreements for clinically important observations including otorrhea, perforation, retracted tympanic membrane and atrophy of the tympanic membrane, as well as, diagnoses of acute otitis media, chronic superlative otitis media with effusion and Eustachian tube dysfunction. However, rate of referral from asynchronous video-otoscopy was higher than that of in-person examination. They concluded that comprehensive telemedicine systems that include digital-otoscopy images, comprehensive case histories, audiological and tympanometric data can provide otolaryngologists with sufficient information to make accurate diagnoses of middle ear pathologies and provide management advice to the patient’s primary care provider.

Kokesh, et al. (2008) took a similar approach to the Eikelboom, et al. (2005) study by comparing asynchronous video-otoscopy images to in-person microscopic evaluation of follow-up after tympanostomy tube placement in a pediatric population. Otolaryngologists that reviewed the video-otoscopy still

images were provided with a simple case history that was not as comprehensive as the previous study. Kokesh, et al. (2008) found that the still images yielded comparable assessment to onsite examination, even without comprehensive case histories, and that this asynchronous method was acceptable for follow-up care of post tympanostomy tube placement.

In addition, and unlike previous studies, Kokesh, et al. (2008) used trained community health practitioners to obtain the video-otoscopy images instead of Otolaryngologists. Their results suggested that trained technicians/practitioners can perform initial video-otoscopy examination that can be stored and forwarded for acceptable medical evaluation. A more current research investigation by Biagio, et al (2013), further examined the validation of the use of telemedicine technicians in obtaining accurate video-otoscopy images from an adult population. Researchers found substantial agreement between judgment of TM surface structures and moderate agreement between diagnoses made from images by otolaryngologists versus technicians. Their results for video-image quality were comparable to previous studies described above, and also suggested that video-otoscopy by a telemedicine technician was equally effective for acceptable care and remote follow up.

Video-otoscopy still images obtained by otolaryngologists and trained technicians have been proven to yield sufficient quality and accurate diagnosis in both pediatric and adult populations. Asynchronous video-otoscopy still images can not only be used for remote ear examinations but also for post-surgical follow-up care. Although traditional video-otoscopy equipment has proven

comparable to manual otoscopy examinations, the cost and transportation of the equipment, which typically includes a laptop connected to the handheld-otoscope device, could be a potentially limiting factor when implementing video otoscopy into telemedicine. Therefore, a smaller, more portable and affordable video-otoscopy device could offer a more cost-efficient solution to implementing video-otoscopy in telemedicine procedures. The following discussion will focus on the literature available for one such a solution.

2.3 Evaluation of digital otoscopy obtained by an iPhone

As new technology emerges, validation studies need to be performed to investigate the efficacy of the device (Ferguson, et al., 2008-9). In the era of iPhones, technology has become smaller and more accessible through iPhone Applications (App). A recently developed iPhone App and external attachment (CellScope, Inc.) was designed to transform the case of the iPhone into an otoscope and utilize the camera of the iPhone through the App (OTO) to record video-otoscopy still images and videos. The CellScope device was developed in 2013 and became commercially available in 2015. Thus far, CellScope has only been reviewed and evaluated in three peer-reviewed publications: two which focused on the pediatric population (Rappaport, et al., 2015; & Richards, et al., 2015) and one which focused on an educational application (Sahyouni, et al., 2016).

In order for the CellScope to be implemented in telemedicine, the CellScope images need to be able to yield accurate diagnoses remotely (asynchronously). In the pediatric population, otitis media is the most common middle ear pathology and abnormal otoscopy is a primary finding. Rappaport, et al. (2015) evaluated the reliability and acceptability of CellScope in the diagnosis and management of acute otitis media (AOM) in children and found that the CellScope images were comparable to conventional otoscopy devices. Rappaport, et al. (2015) also reported high ratings for acceptability, image-capture, transmission and parental involvement through sharing of images. They concluded that CellScope has the potential to improve diagnosis and management of AOM and reduce costs related to AOM in children.

Richards, et al. (2015) took a similar approach to Rappaport, et al. (2015) and evaluated CellScope on tympanic membrane visualization and diagnostic precision compared to traditional otoscopy. Unlike Rappaport, et al. (2015), Richards, et al. (2015) collected data assessing physician, patient and parent device preference. The investigators found substantial agreement between diagnoses made with a traditional otoscope and the CellScope. Their results were consistent with findings from Rappaport, et al. (2015). In addition, Richards, et al. (2015) concluded that the use of CellScope changed diagnosis a significant number of times including clinically relevant changes to and from AOM, which increased diagnostic precision when compared to a traditional otoscopy. Lastly, findings from the survey indicated that the CellScope was preferred by physicians, patients and parents over traditional otoscopy. Physicians surveyed

agreed that the CellScope was easy to use, enhanced tympanic membrane visualization and diagnostic precision, and was a good teaching tool. Therefore, CellScope images can provide accurate diagnoses for AOM and is a preferred device to traditional otoscopes by both physicians and patients/parents.

Otoscopy is a common part of medical evaluations and is used in a variety of medical settings, including those outside of Otolaryngology. Patients in neurotrauma clinics typically undergo otoscopic examinations because of the high incidence of otologic symptoms after head trauma. Sahyouni, et al. (2016), studied the utility of CellScope in a neurotrauma clinic and in medical education of medical students, physician assistants, registered nurses and residents. Similar to Rappaport, et al. (2015) and Richards, et al. (2015), CellScope was evaluated to determine if CellScope enhances visualization of the tympanic membrane compared to traditional otoscopy, however, in this case, the patients were all adults. Sahyouni, et al. (2016) used pre- and post-surveys to assess the efficacy, usefulness, and value of standard otoscopy while the post-survey examined the same qualities for CellScope. For all groups (medical students, physician assistants, registered nurses, and residents) the CellScope was preferred and rated higher in all qualities over traditional otoscopy. The attending physicians reported that the CellScope was a beneficial tool that can enhance the education of medical and nursing trainees.

The practice of video-otoscopy performed by otolaryngologists and medical technicians in telemedicine has been supported in the literature (Biagio, et al., 2012; Eikelboom, et al., 2005; Kokesh, et al., (2008); & Patricoski, et al.,

2003). The CellScope device expands upon this practice and appears to be an acceptable device for telemedicine in restricted pediatric and adult populations (Rappaport, et al., 2015; Richards, et al., 2015; Sahyouni, et al., 2016). However, audiologists have been consistently absent in these studies, despite the inclusion of otoscopy in typical audiometric evaluations. Audiologists perform otoscopy on nearly every patient. Information obtained via otoscopy is used in conjunction with case history, tympanometry and audiometry for diagnosis of middle ear inner ear hearing loss (conductive versus sensorineural), selection of hearing aid devices (behind-the-ear, in-the-canal, thin tube, or receiver-in-the-ear), and referral recommendations. Therefore, it is conspicuous that audiologists have been overlooked in this area of literature.

2.3 Efficacy of digital otoscopy in telemedicine: the current study

The need for validation studies in telemedicine is evident, especially as new technology emerges (Ferguson, et al., 2008-9; & Swanepoel & Hall, 2010). Synchronous use of video otoscopy can yield reasonably-accurate remote diagnoses and otoscopic still images can have a similar quality to manual otoscopy. However, the current literature is limited to evaluations of video otoscopy still images performed by otolaryngologists and their ability to accurately diagnosis outer and middle ear pathologies. Thus, it is unknown whether audiologists can provide reasonably accurate remote diagnosis asynchronously.

Additionally, previous studies have used traditional video otoscopes to acquire images. While these devices provide excellent quality images, their expense [e.g. average retail cost = \$683.38 (Oaktree Products, 2015)] may be prohibitive for use by clinicians in rural, third-world or economically disadvantaged communities. Further, traditional video otoscopy systems require external attachments to laptop computers and a wireless internet connection to store-and-forward the digital images, thus these systems are not easily portable. Lack of portability, makes it less likely for video otoscopy systems to be incorporated into telemedicine, especially for telemedicine providers working at transient and/or rural environments. Therefore, an inexpensive and portable video otoscopy system is desirable to integrate into telemedicine.

CellScope, a new digital otoscope attachment for iPhone, has shown potential applications in telemedicine as it appears to be comparable to traditional manual otoscopy. Currently, evidence supporting the quality and efficacy of diagnosis using CellScope is primarily limited to the diagnosis of acute otitis media in a pediatric population (Rappaport, et al., 2015 and Richards, et al., 2015). Therefore, literature validating CellScope's use in non-pediatric populations and for a variety of pathologies would be valuable in justifying CellScope's efficacy in telemedicine. Further, the current literature is limited to asynchronous diagnosis made by otolaryngologists, thus, no studies have investigated asynchronous video-otoscopy performed by audiologists, accuracy of diagnosis nor need for otologic referral made by audiologists.

The present study was designed to determine whether digital otoscopy images obtained with the CellScope, an inexpensive, portable system, were of sufficient quality to be used to accurately diagnose pathologies of the external ear canal, tympanic membrane and middle ear asynchronously (store-forward telemedicine approach) by audiologists and otolaryngologists. Our study addressed three specific research questions:

Research Question 1: How accurate are diagnoses made from digital otoscopy images compared to the gold standard*? **Hypothesis:** Both audiologists and otolaryngologists will have a high level of agreement with the gold standard

Research Question 2: Do Audiologists and Otolaryngologists agree regarding the need for referral based on digital otoscopy images? **Hypothesis:** There will be a moderate level of agreement between audiologists and otolaryngologists regarding the need to refer based on digital otoscopy images

Research Question 3: Is the quality of the digital otoscopy images at least equal to or better than manual otoscopy? **Hypothesis:** All images will be rated at least the same as manual otoscopy

3. Methods

3.1 Materials and methods:

Digital otoscopic images were obtained from 32 participants currently under medical care for ear-related pathologies. Participants provided consent for their unidentified images to be used in the current research study prior to otoscopic image acquisition. The participants' primary care physician, an Otolaryngologist with over 30 years' of clinical experience, provided on-site diagnoses prior to image acquisition. No personally identifiable information was collected and all images were collected from patients at least 3 years of age (with the exception of 2 images all images were from adults). Fifteen of these images were included in a survey of Audiologists and Otolaryngologists to determine diagnoses and medical referral judgments as well as image quality.

3.2 Equipment:

A recently developed 2013 (released to public spring 2015) digital otoscopy application for the iPhone (CellScope) was used to obtain digital images from participants. The CellScope hardware and associated application (Oto version 1.1.0 and 1.1.01) was used in conjunction with an iPhone 5s for all otoscopy image acquisition. The CellScope system uses the camera and light source from the iPhone along with an attachment otoscope head with magnifying lens and disposable speculum. The software application is built specifically on an iOS platform and can only be used on devices with iOS 7.0 or higher.

CellScope was initially provided to the researchers as part of the “CellScope Pioneers Pre-Release Testers” group but later permission was provided from CellScope for the investigators to use the device for digital image acquisition in the current study. All CellScope images (through the Pioneer program or in the current study) were stored on the CellScope database. CellScope is fully compliant with federal and state privacy laws under the Health Information Portability and Accountability Act (HIPAA) of 1996. The researchers did not collect any personally identifiable information from any participants and the images were coded before being entered into the CellScope database. The Oto App allowed the user to store and forward both images and videos.

3.3 Image selection criteria

15 images were selected to be included in the survey from the 33 images obtained. Images were included: 1. if the diagnosis was included in the Oto App’s closed set of 24 pathologies 2. If there was not an object/hair in the ear canal, 3. If no more than 2 of the same pathology had already been selected, for instance, we had 7 images of venation tubes but only included 2 in the survey. The second criterion was important to note because if something, such as fungus or cerumen, was in the ear canal, then the camera would focus on the object in the foreground and the background would be blurred (only 1/33 images fit this exclusion criteria). More images could have been included in the study, however, due to the number of questions (15 images x 3 = 45 questions) researchers

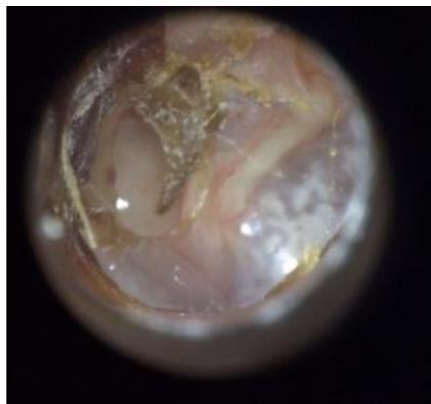
decided 15 was the maximum that could be included to ensure the survey would not be excessively time consuming.

3.4 Web-based exercise/ survey

The Qualtrics survey system was used to create a website survey that included a log-in screen, consent form and instructions screen. The survey directed raters through three main questions with 15 images per question. The questions were designed to evaluate accuracy of diagnosis, rate of referral agreement between raters, and determine quality of the images.

3.5 Survey Question 1: *“Based on the picture above, pick the correct diagnosis (may be more than one) from the list below. If the diagnosis is not listed please select ‘other.’”*

The survey was developed to display one image with a matrix below for all 15 images. The matrix had 13 possible diagnoses on the left column and the right column asked the raters to “Mark the CORRECT diagnosis (may be more than one).” Raters were able to select the correct diagnosis by clicking on the radio button and were able to unselect answers by re-clicking on the radio button. The survey was set to randomize the occurrence of the images to eliminate any effects of order. An example of Question 1 from the survey is shown below in Figure 3.1.



Based on the picture above, pick the correct diagnosis (may be more than one) from the list below. If the diagnosis is not listed please select "other."


	Mark the CORRECT diagnosis (May be more than one)
Normal	<input type="checkbox"/>
Acute Otitis Media	<input type="checkbox"/>
Otitis Media with Effusion	<input type="checkbox"/>
Tymp tube placement	<input type="checkbox"/>
TM perforation	<input type="checkbox"/>
Impacted Cerumen	<input type="checkbox"/>
Otitis Externa	<input type="checkbox"/>
Post-operative Tympanoplasty	<input type="checkbox"/>
EAC Exostosis	<input type="checkbox"/>
Cholesteatoma	<input type="checkbox"/>
Bullous Myringitis	<input type="checkbox"/>
Granulation Polyp	<input type="checkbox"/>
Other	<input type="checkbox"/>

Figure 3.1. Example screen shot of Survey Question 1 from Qualtrics.

3.6 Survey Question 2: *“Based on the picture above, how confident are you that a medical referral is needed for each condition on a scale of -10 (does NOT need referral) to 10 (needs referral).”*

The survey was designed so that there were three conditions per image (15 total images). The conditions were: 1. Recommend immediate medical referral 2. Medical referral prior to Audiometric testing (i.e. tymps, audiometry,

ect.) 3. Medical referral prior to ear mold impressions and hearing aid fitting. Each condition had an adjustable slider bar for the rater to move based on his/her opinion for referral. The survey randomized the presentation of the images. An example of Question 2 from the survey is shown below in Figure 3.2.



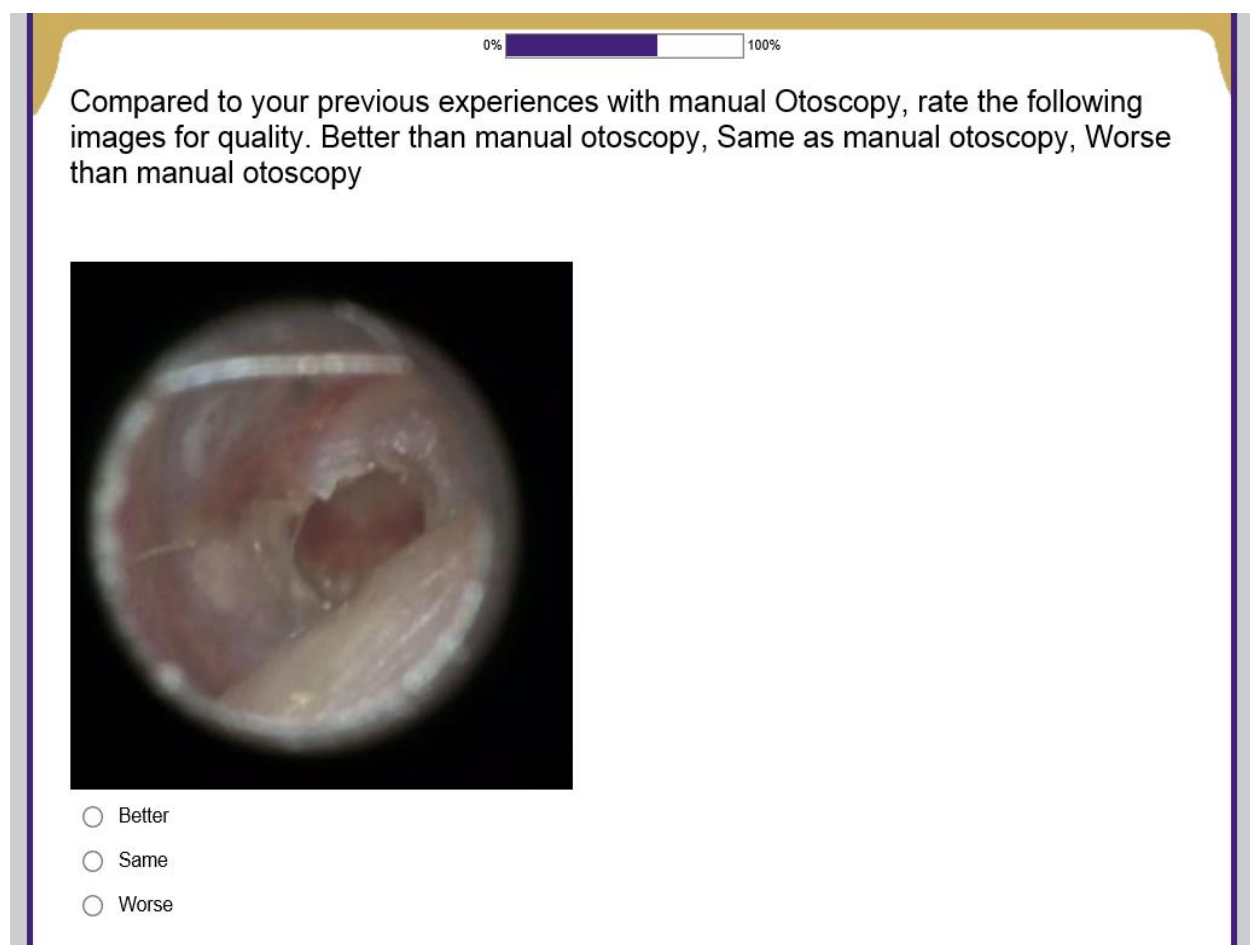
Based on the picture above, how confident are you that a medical referral is needed for each condition on a scale of -10 (does not need referral) to 10 (needs referral)?

	Do NOT need referral					NEED referral					
	-10	-8	-6	-4	-2	0	2	4	6	8	10
Recommend Immediate Medical Referral	[Slider bar with marker at 0]										
Medical referral prior to Audiometric Testing (i.e. tymps, audiometry, ect.)	[Slider bar with marker at 0]										
Medical referral prior to ear mold impressions and hearing aid fitting	[Slider bar with marker at 0]										

Figure 3.2. Example screen shot of Survey Question 2 from Qualtrics.


3.7 Survey Question 3: “Compared to your previous experience with manual otoscopy, rate the following images for quality. Better than manual otoscopy, Same as manual otoscopy, Worse than manual otoscopy”

The survey had each image with three radio buttons below. The rater had to select better, same or worse by selecting one of the corresponding radio buttons. Images were randomized. An example of Question 3 is shown below in Figure 3.3.



0% 100%

Compared to your previous experiences with manual Otoscopy, rate the following images for quality. Better than manual otoscopy, Same as manual otoscopy, Worse than manual otoscopy



Better

Same

Worse

Figure 3.3. Example screen shot of Survey Question 3 from Qualtrics.

At the end of the survey, raters were thanked for their participation and could then exit the survey or select the option of continuing to an incentive webpage. The incentive was a promotional code for 20% off the purchase of the CellScope (a \$60 value at the time). The incentive promotional code was provided by CellScope. 11 out of 42 raters opted to collect the incentive; however, it is not known how many out of the 11 used the promotion code to purchase the CellScope.

The survey was duplicated in the Qualtrics program so that one HTML link was sent to Audiologists and another HTML link was sent to Otolaryngologists in order to keep the group data separate. All responses were automatically saved and anonymous.

3.8 Survey participants/raters

“Raters” refer to Audiologists and Otolaryngologists asked to complete the survey. Invitations to participate were sent either via bulk e-mail through the Virginia Society of Otolaryngology Newsletter or through individual invitations to professionals (otolaryngologists and audiologists). Individual invitations included the additional suggestion to forward the invitation to any practicing colleague who they thought might be willing to participate. Reminder invitations were sent to Otolaryngologists 2 weeks after initial invitation. A total of 148 invitations were sent (52 individual invitations to audiologists and 21 individual and 75 bulk invitations to otolaryngologists).

3.9 Analysis of results

3.9a. Research Question 1: *How accurate are diagnoses made from digital otoscopy images compared to the gold standard?*

The data from Survey Question 1 was evaluated using rate of disagreement. Rate of disagreement, or the average disagreement within a group, was calculated by totaling the number of disagreements for every possible pair regarding diagnosis for each image. Every possible pair was compared (195 comparisons) to determine the number of disagreements for each pair. The number of disagreements per pair were then averaged for each of the 15 images in order to determine the mean rate of disagreement within a group. In order to determine the rate of disagreement, each diagnosis received a score of “0, 0” “0, 1” “1, 0” or “1, 1.” A disagreement was defined as every comparison in which one rater selected the diagnosis as true and the other rater selected the diagnosis as false. A score of “0, 1” and “1, 0” was disagreement on a diagnosis. For example, if Rater A selected “otitis media” and Rater B did not select “otitis media” for the same given image, then the score would be “1, 0.” A score of “1, 1” was agreement on a diagnosis. A score of “0, 0” was both raters agreeing that the diagnosis was not correct. For this study, the ENT who provided the on-site diagnosis is referred to as the Gold Standard.

3.9b. Research Question 2: *Do Audiologists and Otolaryngologists agree regarding the need for referral based on digital otoscopy images?*

In Survey Question 2, Raters were asked to indicate the need for medical referral (sliding scale -10=no need, +10 = greatest need) for three conditions per image. The first condition asked the rater to indicate need for “immediate referral,” the second condition asked for “referral prior to audiometric testing,” and the third condition asked for “referral prior to hearing aid fitting and/or ear mold impressions.” A Nested Repeated Measure ANOVA with possible interaction was calculated for all three conditions (questions). The within subject factors were: 1. refer immediate (Question 2 part A), 2. refer prior to testing (Question 2 part B), and 3. refer prior to hearing aid (HA) fitting/ ear mold impression (Question 2 part C). A Greenhouse-Geisser correction was used (for non-spherical data). The between subject factor was: AUD vs ENT.

3.9c. Research Question 3: *Is the quality of the digital otoscopy images at least equal to or better than manual otoscopy?*

In Survey Question 3, Raters were asked to score each image as “better,” “same,” or “worse” than manual otoscopy. Scores for “better” than and “same” as manual otoscopy were assigned a rating of “1” and scores for “worse” than manual otoscopy were assigned a rating of “0.” A One-Sample T-Test was used to determine if the images were rated significantly better than “0.”

4. Results

4.1 Participation rate

A total of 148 email invitations were sent to Audiologists (n=52 invitations) and Otolaryngologists (n=96 invitations). Forty-one audiology raters accepted the invitation and participated in the study but only 31 of these completed the survey (59.6% participation rate). Thirty otolaryngologists accepted the invitation and participated in the study but only 20 completed the survey (20.8% participation rate). Recruitment by bulk e-mail to otolaryngologists (n=75) was likely a factor in the lower participation rate. Total participation rate was 34.46%. A previous power analysis indicated that 26 subjects were necessary in each group to reach the conventionally accepted 0.80 power level for a large effect size; thus, the results from the ENT group should be interpreted with caution as there were 20 raters instead of the desired 26.

4.2 Completion time

In addition to each rater's response to the questions in the survey, the total amount of time it took each participant to complete the online survey was also automatically saved for off-line analysis. Raters were allowed to reopen the survey and no time limit was imposed on completion. Overall, the majority of raters completed the survey in under an hour. Audiologists' completion times averaged 22.8 minutes (ranging from 9-67 minutes) and Otolaryngologists' completion times averaged 16.7 minutes (ranging from 4-48 minutes).

Completion times exceeding 2 days and less than 3 minutes were not averaged as it is unlikely the survey was completed.

4.3 Research Question 1: How accurate are diagnoses made from digital otoscopy images compared to the gold standard?

In order to determine diagnostic reliability, a baseline for normal needed to be established. To accomplish this, two different images of normal ears were included. We found that the “normal” diagnosis was selected by 75% (image 13) and 82% (image 14) of raters. Thus diagnostic reliability for digital images of “normal” ears was not 100%. This suggests that diagnostic accuracy for raters is likely to be good (75% or greater) but not 100%. The most common misdiagnosis for normal was the selection of otitis media with effusion.

Mean rate of disagreement

Raters were given a closed set of 13 diagnoses from which to choose for each of the 15 images (195 possible selections). A One-Way Analysis of Variance (ANOVA) was used to examine differences between the mean rate of disagreement for all possible pairs of AUD vs AUD, AUD vs Gold Standard, ENT vs ENT, and ENT vs Gold Standard. There were significant differences ($p < 0.001$) between all groups (AUD vs AUD, AUD vs gold standard, ENT vs ENT, and ENT vs gold standard).

Otolaryngologists (ENT) had the highest level of accuracy (agreement with the Gold Standard) with an average number of 12.05 (± 4.785) disagreements out of 195 comparisons; the lowest disagreement average out of the four group comparisons (See Figure 4.1). ENT had good internal agreement (ENT vs ENT) with an average of 14.047 (± 4.15) disagreements. Audiologists (AUD) also had a high degree of accuracy with a mean of 16.16 (± 2.85) disagreements. Audiologists had the poorest internal agreement (AUD vs AUD) with an average number of 17.89 (± 3.78) disagreements. Although all groups were significantly different ($p < 0.001$), the mean number of disagreements for all four group comparisons was less than 10%; or an average of greater than 90% agreement for all four groups.. Figure 4.1 shows the results of Question 1 by group.

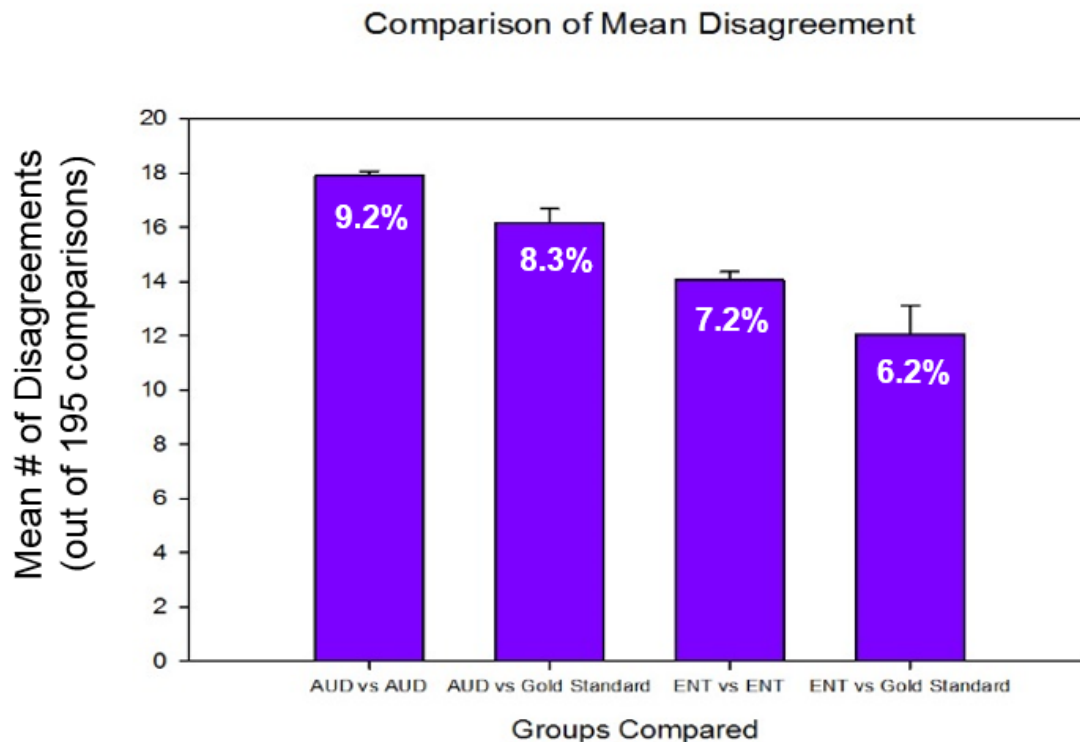


Figure 4.1. The mean number of disagreements \pm SEM. All groups are statistically different from each other. Numbers within each bar represent percent disagreement.

Cohen's kappa coefficient (generally regarded as a more robust indication of inter-rater agreement) was not calculated for two reasons. The first was because of the large number of possible decisions per image. Each rater had 13 possible decisions per image. This number of possibilities provided a large number of correct rejections (0, 0 - agreements) between professionals (i.e. professionals agreed the diagnosis was wrong in reference to a give image). Cohen's kappa coefficient of agreement would have been substantially

influenced by this large number of agreements and would have likely inflated the inter-rater agreement.

The second reason Cohen's Kappa was not calculated was because it is typically only a comparison of one rater to another. In the present study we compared agreement between 51 raters. Therefore, the most direct way to compare multiple raters was simply by using the rate of agreement/disagreement. The downside to this direct comparison is that the proportion of times raters would agree based on chance could not be taken into consideration.

4.4 Research Question 2: Do Audiologists and Otolaryngologists agree regarding the need for referral based on digital otoscopy images?

A Nested Repeated Measure ANOVA with possible interaction was calculated for the question "Based on the picture above, how confident are you that a medical referral is needed for each condition on a scale of -10 (does NOT need referral) to 10 (needs referral)." The Nested Repeated Measures ANOVA revealed a statistically significant 3-way interaction ($F_{10,31, 288.75} = 2.3, p=.011$), indicating no simple trend in the data.

4.4a.Part A

Figure: 4.2 below, shows images ranked from highest to lowest (1-15) need for "immediate referral" according to ENT. AUD responses were arranged in the ranked order according to the ENT responses. Analysis revealed a

complicated interaction; however, two general trends were identified in the data. The first showed high agreement between ENT and AUD when need for referral is high, i.e. the images are of pathological ears that require medical attention. This is true for images 1-8 where both AUD and ENT ranked the images over 6. The second showed low agreement between the ENT and AUD when the need to refer is low, i.e. the images are of pathological and non-pathological ears that do not necessarily require medical attention. For example this disagreement is seen in Figure 4.3 for image 10 (gold standard diagnosis = OME) where the ENT rated the image as having a moderate need for referral (3) but AUD rated the need as low (-7). In regard to the complicated interaction between images and professional group, there was a variation in the range of disagreements for the need to refer. Less disagreement can be seen between AUDs and ENTs for images 1-8 in Figure 4.3, in which the points for ear are fairly close together. Suggesting that for those particular images, there was good agreement regarding the need to refer. Conversely, large ranges of disagreement between groups can be seen for images 10, 11, and 12 in Figure 4.3. For images 11 and 12, the AUDs indicated a higher need for referral, however, for image 10 the AUD indicated a lower need for referral when compared to the ENTs. Therefore the need for referral cannot simply be predicted by image diagnosis or professional group alone.

Order of images ranked by mean ENT responses to Question 2A need for “Immediate Referral”



Figure 4.2. Images were ranked from 1 to 15 (highest to lowest) by ENT’s responses to need for “immediate referral”

It should also be noted that for images with the same underlying pathology, there was variability in professional assessment of need for referral, which could be related to the diagnostic variability. In the survey there were 3 pairs of images with the same diagnosis but from different ears, these include: normal (images 13 and 14), impacted cerumen (images 8 and 9) and perforation (images 6 and 7). For instance, images 13 and 14 are both of normal ears and need for referral was low for both groups; however, professional opinions varied scoring the images need for referrals between -3.6 to -8. This suggests that even when the diagnosis was the same, there was still professional variability in assessment of the need for referral.

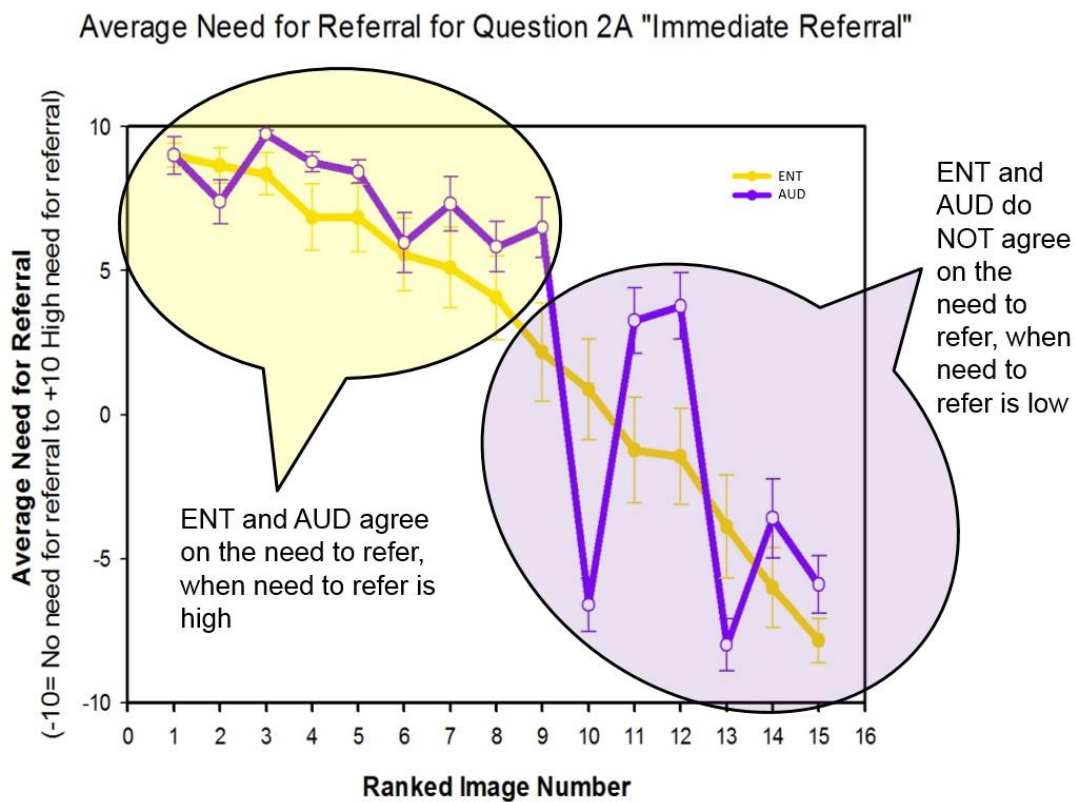


Figure 4.3. Average need for “Immediate Referral” (Question 2 Part A). Images were ranked from 1 to 15 (highest to lowest) by ENT responses to need for “immediate referral.”

4.4b. Part B

Nested Repeated Measures ANOVA results for mean slider position to the condition of need for “referral prior to audiometric testing.” A complicated interaction is present. In general both ENT and AUD indicated less need to refer prior to audiometric testing than both groups indicated for the “immediate referral”. Further, the agreement between rankings by AUD and ENT was better

(always in the same direction) than for the "immediate referral" condition, indicating that audiologists were able to determine, in good agreement with ENT, when audiometric testing could be performed for a variety of pathologies. In Figure 4.4 below, the image ranking was kept the same as Part A where the images were ranked highest to lowest (1-15) need for "immediate medical referral" by ENT. Figure 4.4 shows the mean rating of need for "referral prior to audiometric testing," which we see is generally less than the overall need for "immediate referral" seen in Figure 4.3 above.

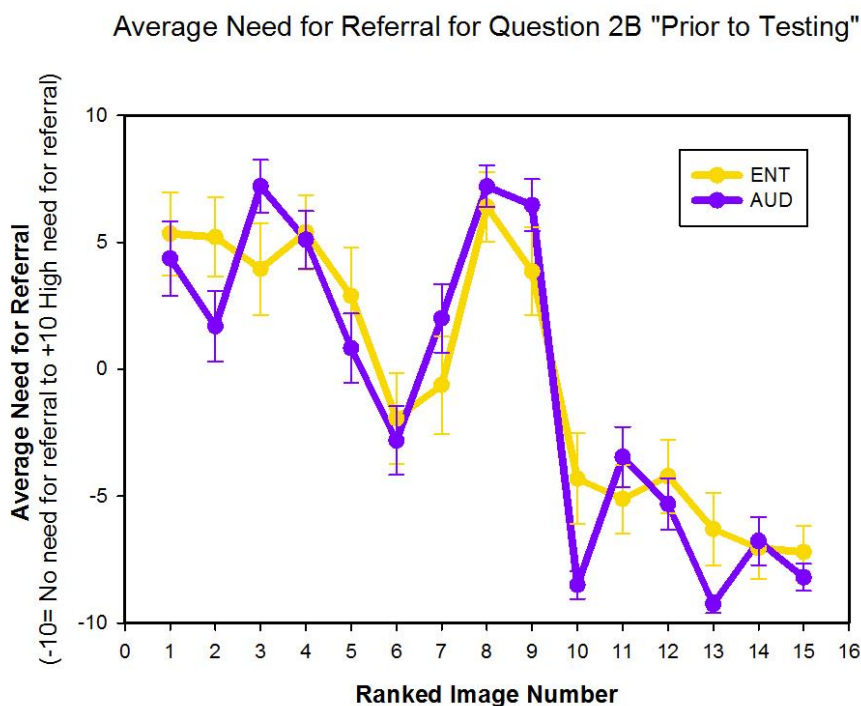


Figure 4.4. Average need for referral "Prior to Audiometric Testing" (Question 2 Part B). Mean slider position to the condition of need for "referral prior to audiometric testing."

4.4c. Part C

Nested Repeated Measures ANOVA for mean slider position to the condition of need for “referral prior to hearing aid fitting and/or ear mold impressions.” A complicated interaction is present meaning that the need for referral could not be predicted because it varied by professional group (AUD vs ENT) and image (variety of diagnoses). In general the mean slider positions for the need to refer in this condition are similar to the mean slider positions for the need to “refer immediately.” Two general trends were identified in the data (refer to Figure 4.5). The first showed high agreement between ENT and AUD when need for referral is high, i.e. the images are of pathological ears that require medical attention prior to hearing aid fitting and/or ear mold impressions. The second showed poorer agreement between the ENT and AUD when the need to refer is low, i.e. the images are of pathological and non-pathological ears that do not necessarily require medical attention prior to hearing aid fitting and/or ear mold impressions. In terms of the interaction between images and professional group, there was a variation in the range of disagreements for the need to refer. Large ranges of disagreement between groups can be seen below in figure 4.5 for images 11, 12, 14 and 15. In general for these four images, the AUD group recommended a higher need for referral than the ENT group. However, this pattern is opposite for image 10, indicating that the need for referral cannot simply be predicted by image diagnosis or professional group alone.

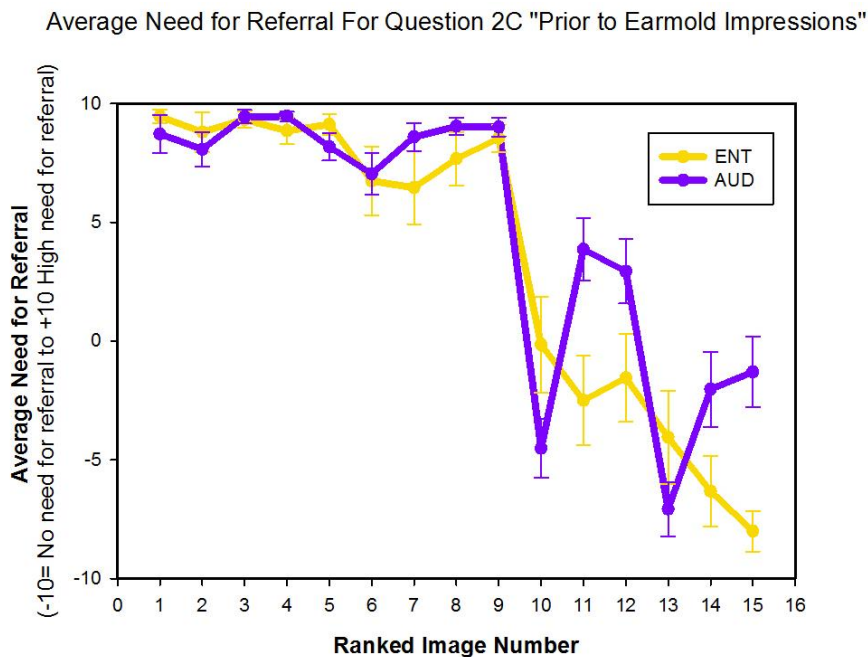


Figure 4.5. Average need for referral “Prior to EMI/HA” (Question 2 Part C). Mean slider position to the condition of need for “referral prior to hearing aid fitting and/or ear mold impressions.”

4.5 Research Question 3: *Is the quality of the digital otoscopy images at least equal to or better than manual otoscopy?*

A One-Sample T-Test was used to determine if the images were rated significantly the same or better than manual otoscopy. A rating of “1” indicated same/better than manual otoscopy verse a rating of “0” which indicated the image was worse than manual otoscopy. Ratings of better, same or worse were made for all 15 images. Analysis revealed that all images were significantly better than “0” ($p < 0.001$), suggesting that on average all images were scored at least as

good as manual otoscopy. A Bonferroni correction from multiple comparisons also yielded significance ($p=0.003$).

A Repeated Measure ANOVA was performed to analyze group effect with 15 within subject factors and 2 between subject factors (AUD vs ENT). There was a group by image interaction ($F_{7.584, 356.470} = 2.911, p=.004$), suggesting that on some but not all images the ENT and AUD ranked the images differently as seen in Figures 4.6 & 4.7 below. Despite ENT and AUD disagreement on some of the images' rankings, all images were rated significantly equal to or better than manual otoscopy.

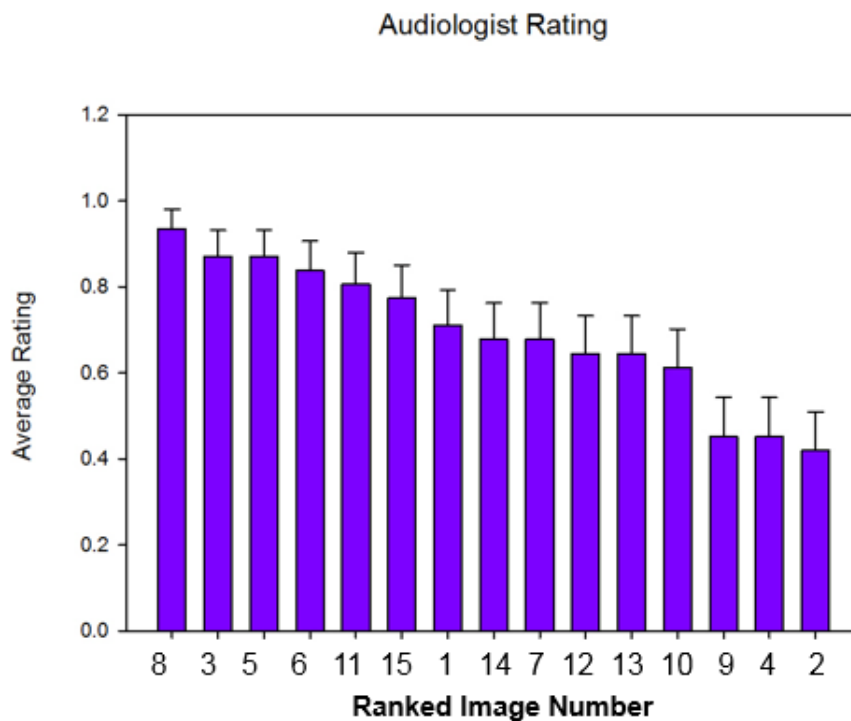


Figure 4.6. AUD mean scores of quality for digital images \pm SEM

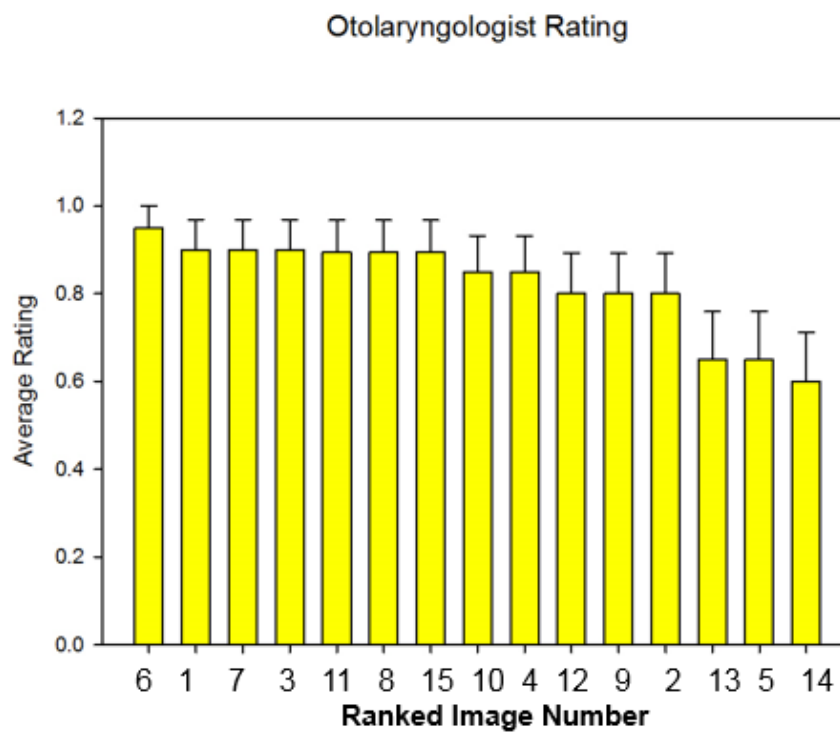


Figure 4.7. ENT mean scores of quality for digital images \pm SEM

5. Discussion

5.1 Research Question 1: *How accurate are diagnoses made from digital otoscopy images compared to the gold standard?*

A baseline for what raters considered normal was determined by incorporating two images of normal ears and evaluating the diagnoses selected. If the raters were 100% reliable to identify normal ears then we would not expect much variability in diagnosis. However, the raters were only 75-80% reliable (38-42 out of 51 raters) at identifying images of normal ears. The most common misdiagnosis was the selection of otitis media with effusion (accounting for 7-10 out of 51 raters). This suggested that images categorized as normal were actually variable and the spectrum of appearance may overlap with the appearance of other pathologies, particularly otitis media with effusion. Thus, the spectrum in the appearance of images with the same underlying pathology likely caused diagnostic variability for both audiologists and otolaryngologists.

Mean rate of disagreement

In order to determine diagnostic accuracy, audiologists and otolaryngologists responses were compared to the otolaryngologist, who provided on-site diagnosis, referred to as the “Gold Standard.” Otolaryngologists (ENT) had the highest level of accuracy (agreement with the Gold Standard) and ENT had good internal agreement (ENT vs ENT). This finding is in good agreement with previous studies using video-otoscopy. Thus the CellScope device provides otolaryngologists digital images that result in comparable

diagnostic accuracy to the traditional, more expensive and bulky video otoscopy systems. Audiologists (AUD) also had a high degree of accuracy (agreement with the Gold Standard) but AUD had the poorest internal agreement (AUD vs AUD). Audiologist's accuracy of diagnosis was not as good as the otolaryngologists; however, audiologists were still able to provide reasonably accurate (90.8% agreement) diagnosis for a variety of external and middle ear pathologies. It should also be considered that, unlike otolaryngologists, audiologists are unlikely to make a diagnosis solely from otoscopy, thus diagnostic accuracy would likely increase when combined with case history, tympanometry, and pure tone air and bone conduction audiometry information. Therefore, the digital images provided by CellScope can be expected to provide an efficient first step for use in tele-audiology in determining the diagnostic status of the external and middle ear. Further these results confirm that audiologists, like other trained health care professionals, can use digital otoscopy images with a high degree of accuracy.

It is difficult to directly compare the current results with previously published studies because most publications in this area use the Cohen's Kappa statistic to determine inter- and intra- rater concordance to determine the level of accuracy. However, Cohen's Kappa is not the appropriate statistic when comparing more than 2 raters and therefore, could not be used in the present study. Instead we used the most direct way to compare multiple raters by simply using the rate of agreement/ disagreement between the 51 raters (ENT and AUD) used in this study. A pitfall of this approach is that the proportion of times

raters would agree based on chance, as with Cohen's Kappa, could not be taken into consideration.

In retrospect, the format of the survey question complicated the data analysis. The question was arranged so that each rater was asked to look at the image and select the correct diagnosis from a closed set of 13 options. Since it was very unlikely that a rater would choose more than 2 diagnoses for a given image, the raters were likely to agree that 11-12 of the diagnoses for each image were not correct, therefore influencing the number of correct rejections (when 2 raters agreed that one diagnosis was wrong). In order to try to avoid this bias, mean disagreement was calculated between and within groups (AUD vs AUD, AUD vs Gold Standard, ENT vs ENT and ENT vs Gold Standard). Regardless of the number of correct rejection agreements, the mean disagreement between groups was low for all groups suggesting that there was good accuracy of diagnosis (agreement with the Gold Standard) for all groups. The diagnostic accuracy of both groups is likely underestimated when one considers that most telemedicine systems incorporate information regarding a case history and audiometric test results; in the present study no supplemental information was provided. Additionally, audiologists with access to the CellScope have an easy and convenient way to share otoscopy images with otolaryngologists, who can confirm the diagnosis remotely.

5.2 Research Question 2: *Do Audiologists and Otolaryngologists agree regarding the need for referral based on digital otoscopy images?*

In the first part of Question 2 (Part A) raters were asked to determine the need for “immediate medical referral.” For this condition, two general trends were identified: 1. When need for immediate medical referral was high (i.e. the images are of significantly pathological ears that require medical attention according to otolaryngologists’ judgments), the agreement between AUD and ENT was high (true for images 1-8; *refer to Results Section figure 4.2, p.33*), 2. Conversely when the need for immediate medical referral was low (i.e. the images are of pathological and non-pathological ears that do not necessarily require medical attention according to otolaryngologists’ judgments), the agreement between AUD and ENT was low (true for images 9-15; *refer to Results Section figure 4.2, p.33*). This suggested that audiologists were able to correctly identify ears, from CellScope images, that were in need of a medical referral, however, when a medical referral was not necessarily needed, audiologists may or may not have agreed with otolaryngologists. For all of the images where the otolaryngologists felt that the need for immediate referral was greater than 0 (moderate need) audiologists not only agreed but also felt a greater need to refer (as indicated by the more positive slider position). On the other hand when otolaryngologists felt the need for referral was less than 0 there was more variability in the audiologists’ recommendation. In conclusion it would be safe to say that CellScope images can be used most efficiently by audiologists when the pathology is more severe, but when the audiologists are less confident that a referral is needed (more variability), the most efficient thing would be to store-and-forward the image to an otolaryngologists for confirmation.

The images in which there was low agreement on the need for medical referral included the following diagnoses: otitis media with effusion, impacted cerumen, exostosis, normal (2), post-operative tympanoplasty, and ventilation tube with tympanic membrane scarring. ENT felt the need for referral was higher than AUD in the case of otitis media with effusion (OME) and normal and lower than AUD in the case of exostosis and post-operative tympanoplasty. Overall, AUD were more conservative in their recommendation for referral. For example, audiologists rated a high need (+5 to +10) for medical referral for impacted cerumen compared to otolaryngologist who indicated a moderate need (0 to +5) for referral.

The one exception to conservative referrals made by audiologists occurred for the image of OME in which audiologists rated almost no need (-6.6) for medical referral compared to otolaryngologist who indicated a moderate need (0.88) for referral. The audiologists' lack of referral for OME could reflect an inability to distinguish normal images from OME images. As discussed previously, the most common misdiagnosis for normal images made by audiologists and otolaryngologists was OME. Thus the inability to determine the presence of effusion would lead to a misdiagnosis of normal in which a medical referral would not be necessary. These results suggest that still images are not the most sensitive measure for distinguishing OME from normal and a more appropriate measure would include pneumatic otoscopy, which uses air pressure to determine movement of the tympanic membrane. Future studies should

evaluate the video format of the CellScope in combination with the pneumatic otoscopy attachment to determine sensitivity of distinguishing OME from normal.

Based on the variable diagnostic results from normal images, it was not unexpected that the images with the same underlying pathology yielded variable professional assessment for need for referral. Although the images were of the same final diagnosis, there was great variability in the appearance. For example, the two perforations (images 6 and 7 in results section Figure 4.2, p.) are not in the same place on the tympanic membrane, nor does the tympanic membrane texture resemble the other. Therefore, the spectrum in appearance of the same diagnosis likely influenced the professional assessment for need for referral.

Part B of Question 2 asked raters to determine the need for medical referral “prior to audiometric testing.” Although there was a significant interaction, a general trend was observed in the data. For this condition, both AUD and ENT indicated an overall decreased need for medical referral prior to audiometric testing (between -10 and +7) than both groups indicated for the “immediate referral” condition (between -8 and +10). Further the agreement between the rankings by AUD and ENT was better (in the same direction) than for the “immediate referral” condition. This would suggest that audiologists were able to make appropriate referrals for a variety of pathologies prior to doing any audiometric testing that could interfere with accuracy of diagnostic measurements. For example, audiologists and otolaryngologists consistently agree that audiometric testing can take place in the presence of some pathology – in fact we know that this is the role of many audiological evaluations - but that if

the pathology is such that immediate medical care is needed then that referral should take place prior to testing. These results suggest that audiologists practicing tele-audiology can be assured that CellScope digital images are effective (consistent with the otolaryngologists) in determining whether audiometric testing can move forward.

Part C of Question2 asked raters to determine the need for medical referral “prior to hearing aid fitting and/or ear mold impressions.” The rationale for this question was that these procedures were more invasive than standard audiometric testing and could be seen as putting the patient at risk for exacerbation of existing pathology. Thus we expected that both AUD and ENT would be more inclined to feel a need to refer for this situation than for the scenario in Part B – audiometric testing. Indeed, that was the case. Results were similar to Part A: need for “immediate referral,” in which the general need for referral was high (between +5 and +10) when pathology was severe and mild to low (0 to -9) when the pathology was less severe. In fact disagreement between ENT and AUD occurred for the same three images (images 10, 11 and 12 – otitis media with effusion, exostosis and post-op) when comparing results for “immediate referral” to “referral prior to hearing aid fitting/earmold impressions”. Similarly, ENT felt the need for referral was higher than AUD in the case of otitis media with effusion and lower than AUD in the case of exostosis and post-operative tympanoplasty. Thus, CellScope images can be used most efficiently by audiologists when the pathology is more severe, but when the audiologists determine that pathology is less severe, the most efficient thing

would be to store-and-forward the image to otolaryngologists prior to taking ear mold impressions or fitting a hearing aid.

5.3 Research Question 3: *Is the quality of the digital otoscopy images at least equal to or better than manual otoscopy?*

When verifying devices for telemedicine, the device should yield results comparable to the current standard used for in-person evaluations. Although otolaryngologists have magnifying otoscopes at their disposal, audiologists typically use manual otoscopes. Thus, the comparison of manual otoscopy to the CellScope images provided a more realistic comparison. Both audiology and otolaryngology raters were asked to rate the quality of the images. Any ratings of “better” or “same” were given a score of “1” and any ratings of “worse” were given a score of “0.” On average all images were scored at least as good as manual otoscopy.

Interestingly, otolaryngologists scored the images as having somewhat better quality than audiologists. This finding was interesting because otolaryngologists more commonly have access to magnifying otoscopy devices when compared to audiologists, yet the otolaryngologists scored the overall quality of the images higher than audiologists did. There was also a significant interaction between audiologist and otolaryngologist’s scores of image quality, indicating that for some images audiologists scored the quality higher, and for other images the otolaryngologists scored the quality higher. Although

otolaryngologists and audiologists did not consistently rate images the same, on average raters scored the quality of all the images as good as or better than manual otoscopy. Thus quality of digital images is adequate for telemedicine.

One disadvantage of comparing still digital images to a professional's memory of manual otoscopy is that with manual otoscopy the professional can move the otoscope around to observe different angles of the tympanic membrane. The CellScope has the ability for professionals to move the otoscope when recording a video, which could possibly be a more accurate comparison measure, however this was not evaluated. Despite this, our results were consistent with previous studies assessing traditional video otoscopy still images and confirmed their efficacy for both professionals.

5.4 Limitations

5.4a Equipment:

CellScope (OTO version 1.1.0. and 1.1.01) was evaluated in the present study in conjunction with an iPhone 5. It is important to note that only the CellScope PRO, for professionals, was evaluated in this study (CellScope HOME for parents was not assessed). Since the end of data acquisition, CellScope has upgraded to version 1.4.2 and has become available to iPhone 6 that requires iOS 8.0 or later. The software updates have addressed the following areas: refreshed design to improve ear exam flow, increased app stability, improved lighting for iPhone 6 users, improved upload mechanism, and other "bug fixes." A challenge to this study, and any other studies investigating smart phone

applications, is that the Apps continuously undergo updated revisions, which could possibly affect the efficacy of the device. However, we do not believe that any of the CellScope changes would reverse any of the present findings.

5.4b Image Selection Criteria:

15 images were selected to be included in the survey from the 33 images obtained. Images were included: 1. if the diagnosis was included in the OTO App's closed set of 24 pathologies 2. If there was not an object/hair in the ear canal, 3. If no more than 2 of the same pathology had already been selected, for instance, we had 7 images of venation tubes but only included 2 in the survey. The second criterion was important to note because if something was in the ear canal, the camera would focus on the object in the foreground and the background would be blurred (only 1/33 images fit this exclusion criteria). This has been addressed in the updated software version of CellScope OTO by the addition of adjustable lighting; however, this study was unable to use this feature.

5.4c Participation Rate:

Thirty-one audiologists completed the survey (59.6% participation rate); however, only 20 otolaryngologists completed the survey (20.8% participation rate). Recruitment by bulk e-mail to otolaryngologists was likely a factor in the lower participation rate. A previous power analysis indicated that 26 subjects were necessary in each group to reach the conventionally accepted 0.80 power

level for a large effect size; thus, the ENT group was slightly under powered. Therefore, the results from the ENT group should be interpreted with caution as there were 20 raters instead of the desired 26.

Although we were slightly under powered for the ENT group, our study is one of the only studies that used more than two physicians to assess the diagnostic accuracy of video otoscopy, with the exception of Rappaport, et al. 2013 who used 4 physicians. In the Biagio, et al., 2012; Eikelboom, et al., 2005; Kokesh, et al., (2008); Patricoski, et al., 2003 & Richards, et al., 2015 studies, one to two otolaryngologists were used to assess the diagnostic accuracy and image quality and data was statistically analyzed using the Cohen's Kappa static to determine inter- and intra- rater concordance. The Sahyouni, et al. 2016 study did not assess diagnostic accuracy but did assess subjective image quality through the use of a survey in which 18 medical professions (2 Attending Physicians, 5 Physician Assistants, 5 Medical Students, 5 Resident Physicians, and 1 Register Nurse). Therefore, our ENT n=20 is large in comparison to the existing literature.

5.4d Question 2:

In regard to referral agreement between professional groups (AUD vs ENT), there is no current literature in which to compare our results, thus complicating interpretation of our results. In the survey each rater had the opportunity to provide feedback. One particular comment regarding this research

question was of interest. One rater suggested that each condition (need for referral 1. Immediate medical referral, 2. Prior to audiometric testing, and 3. Prior to hearing aid fitting/ ear mold impressions) could be interpreted differently based on the wording of the question. For example, the rater suggested that the first condition of “immediate referral” could be interpreted as “do not do any further assessment” in which case it would make the following two conditions a moot point. This was possible, as wording of surveys can be tricky and can easily influence the rater’s response. We attempted to decrease misinterpretation by having a professor with experience in survey writing review the survey prior to data acquisition, however, differences in interpretation of the question was still possible.

5.5 Summary

We have provided evidence that CellScope images can be used effectively in telemedicine due to its ability to yield highly accurate remote diagnosis. The diagnostic accuracy of otolaryngologists was in good agreement with previous studies using video-otoscopy. Additionally, our results were consistent with Biajio, et al. 2013, who found that diagnosis could not be made from 4.3% of images recorded by the otolaryngologist and 10% of images recorded by the telemedicine technician, suggesting acceptable levels of quality for remote diagnosis. Furthermore, this is consistent with our findings from Research Question 1, where audiologists could not make an accurate diagnosis

for 9.2% of the CellScope images, indicating reasonably acceptable levels of quality for remote diagnosis.

Lastly, agreement regarding referral between professional groups could help control the number of otolaryngology referrals, in turn saving costs associated with follow-up care, consultation, and patient travel. CellScope offers an easily accessible and convenient way to obtain otoscopic images that could be stored-and-forwarded by audiologists to otolaryngologists, who can confirm or reject the referral. Our results suggest that the images can be used effectively and accurately by both otolaryngologists and audiologists regardless of the limitations experienced in this study. Future studies should consider these limitations during the experiment design phase.

5.6 Overall telemedicine implications:

The CellScope system is quite portable (fits on a cellphone) and inexpensive (current retail cost is less than \$100) making it an appealing device for telemedicine. In addition, it can record images and videos without Wi-Fi connection, which makes it an accessible device for rural populations.

Audiologists practicing tele-audiology should feel confident in their impression regarding medical referral when pathologies are severe and can use the store-and-forward function of the CellScope to confirm their impressions when the pathology is moderate or mild. The application of CellScope images to prevent unnecessary referrals would in turn reduce patient's travel, time and cost. Thus

our results suggest that audiologists and otolaryngologists providing services to rural or underserved population can use CellScope effectively to achieve objectives of telemedicine in a cost-efficient and portable manor.

5.7 Future Considerations:

Findings of this study support the use of the CellScope in telemedicine, however further research is needed to determine accuracy and agreement between otolaryngologists and audiologists for referral and diagnosis in a pediatric population for a variety of external and middle ear pathologies [currently only Acute Otitis Media has been assessed (Rappaport, et al., 2013 & Richards, et al., 2015)]. Prior to this study diagnostic accuracy and referral rates of audiologists have not been reported, therefore future research is needed to confirm our results for both pediatric and adult populations.

CellScope has potential in a variety of medical and non-medical settings, however, there have been few studies validating its use. It is especially important to assess the efficacy of the CellScope HOME device that is made for parents and guardians to ensure that parents receive adequate training to use the device safely and accurately. The pneumatic otoscopy attachment for CellScope PRO may increase sensitivity of detecting otitis media with effusion or small perforations remotely, however this should be confirmed. Since, otoscopy is performed in a variety of medical settings and performed by different levels of medical personnel; the quality of images could vary depending on their level of

training. As suggested in results from Biajio, et al. 2013, level of training could influence diagnostic accuracy. Therefore, although CellScope can provide acceptable quality images yielding accurate remote diagnosis from audiologists and otolaryngologists, there are many applications left to be investigated.

Appendix A

Bulk e-mail to audiologists and otolaryngologists

Dear Otolaryngology/Audiology Professionals,

I am a James Madison University Audiology doctoral student conducting research on a portable iPhone otoscope, as seen in the picture above. My dissertation is evaluating the use of the Cell Scope portable iPhone otoscope in tele-practice for Audiologists and Otolaryngologists. To do this, I have collected digital otoscopy images of pathological ears from a local Otolaryngologist's office and uploaded them onto a survey. The goal of our study is to see whether pictures taken with this instrument can be used in telemedicine. The results will provide support for continued research into telemedicine technologies as well as evidence for the clinical use of telemedicine by Audiologists and Otolaryngologists.

If you would like to participate in the survey please click this link:

http://jmu.co1.qualtrics.com/SE/?SID=SV_d5w7rjEoLyUlyuN The password to enter the survey is "guest." Please use your computer (not your smartphone or tablet) to take the survey. At the completion of the survey, you will have the option to be directed to a webpage with a **20% discount code for the CellScope** as a thank you from the researchers.

For more details about the purpose and methods of the study please visit the link above. If you have any further questions about the study please do not hesitate to contact Alexandra Short at shortab@jmu.edu.

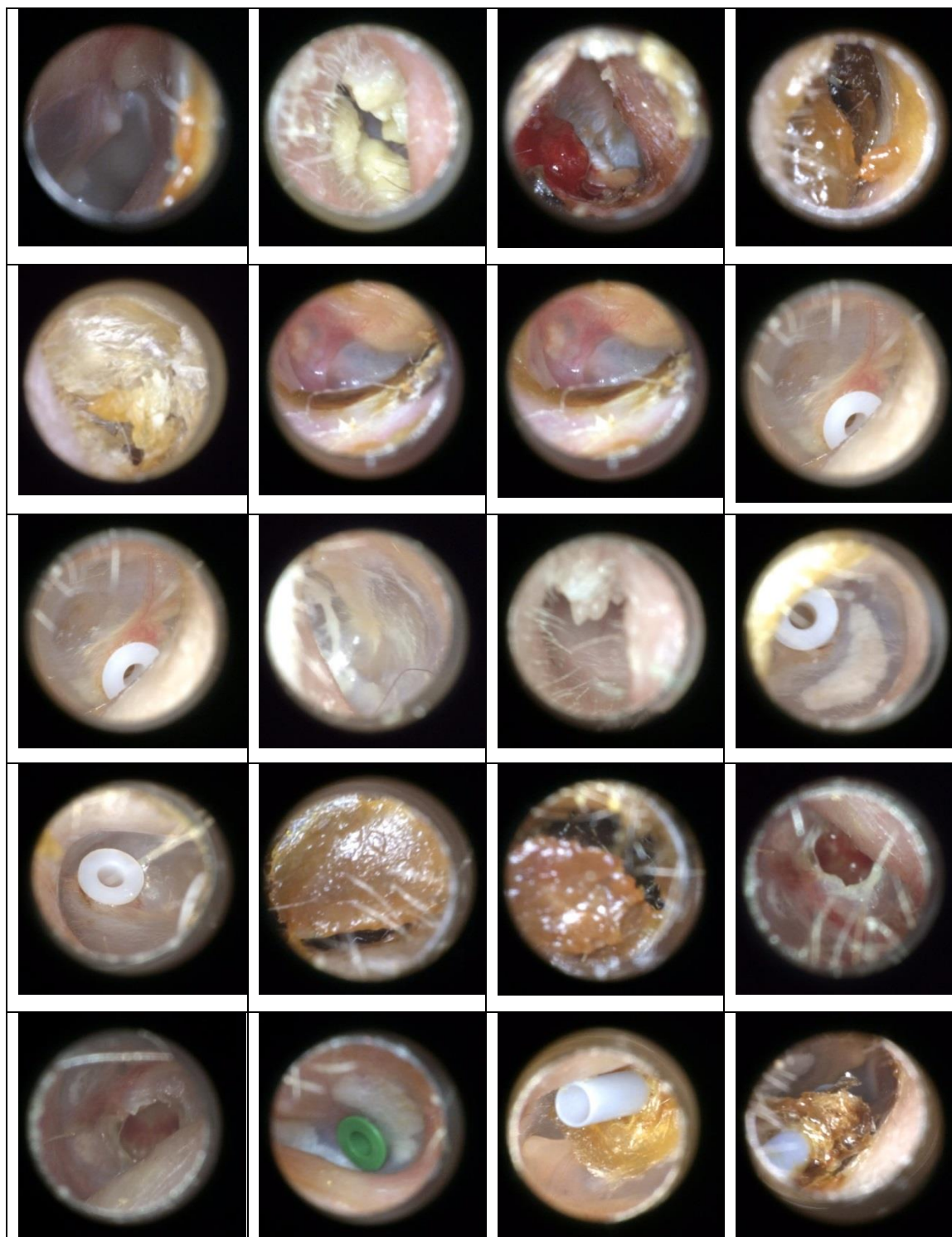
Your consideration is appreciated and we thank you for your time.

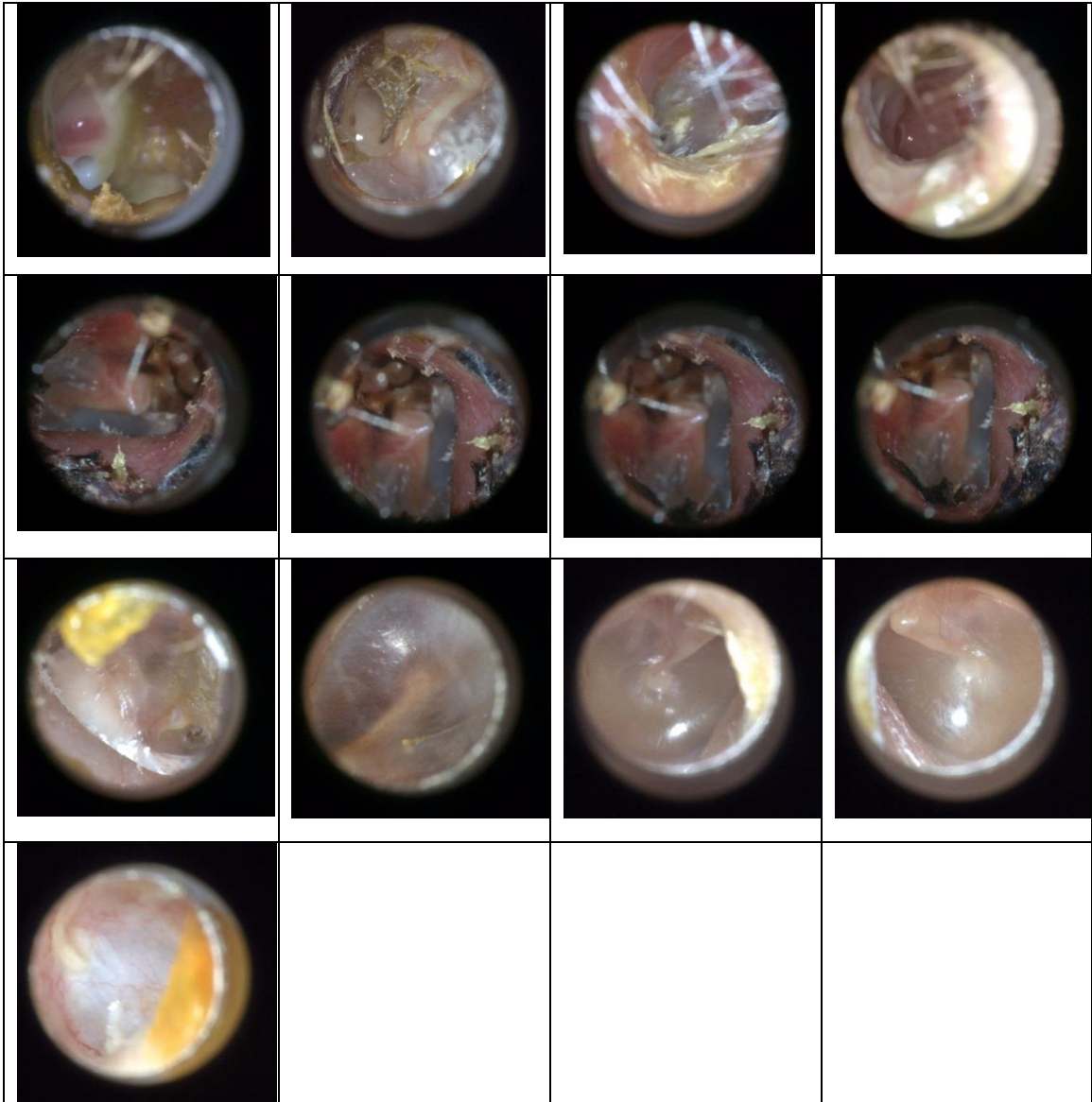
Sincerely,
Alexandra Short
Doctorate of Audiology Candidate
James Madison University
shortab@jmu.edu

Graduate Advisor:
Brenda M. Ryals, Ph.D.
James Madison University
Telephone (540) 568-3871
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Appendix B

All images acquired with the CellScope





Appendix C

Raw Data: Audiologists' Responses to Survey Question 1

Gold Standard Diagnosis: Otitis Externa													
	Normal	AOM	OME	Tubes	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbus Myringitis	Granulation Polyp	Other
1							1						
2							1						
3			1										
4							1						
5							1						
6							1						
7							1						
8						1							
9						1			1				
10							1						
11							1						
12							1						
13							1						
14							1						
15						1	1						
16							1						
17							1						
18							1						
19										1			
20							1						
21							1						
22						1	1		1			1	
23							1		1				
24							1						
25							1						
26							1						
27												1	
28							1		1				
29							1						
30							1						
31							1						
Sum			1			4	26		4	1		2	

Gold Standard Diagnosis: Bulbous Myringitis + Tube													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1		1		1									
2			1	1							1		
3			1										
4				1									
5											1		
6				1						1			
7				1		1							
8													
9				1							1		
10			1							1	1		
11				1								1	
12				1									
13			1										
14				1							1		
15			1	1									
16				1									
17		1											
18				1							1		
19			1	1									
20				1									
21			1	1									
22		1		1									
23				1									
24			1	1									
25				1				1					
26					1		1						
27			1										
28				1							1		
29												1	
30				1									
31			1	1									
Sum		3	10	22	1		1	1		2	7	2	

Gold Standard Diagnosis: Granulation Polyp													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Chosteatoma	Bulbous Myringitis	Granulation Polyp	Other
1											1	1	
2										1		1	
3											1		
4												1	
5									1				
6											1		
7										1			
8													
9												1	1
10												1	1
11											1		
12									1				
13								1					
14							1			1		1	
15					1							1	
16					1		1			1			
17													1
18										1		1	
19											1		
20													
21											1		
22													1
23												1	
24											1	1	
25								1					
26		1											
27								1			1		
28								1					
29													1
30											1		
31					1					1			
Sum		1			3		2	4	2	6	9	10	5

Gold Standard Diagnosis: Perforation (1)													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1					1								
2					1					1			
3					1								
4					1								
5					1								
6					1								
7					1								
8					1								
9					1								
10					1								
11					1								
12					1								
13					1								
14					1					1			
15					1								
16					1								
17					1								
18					1								
19					1								
20													
21					1								
22					1								
23					1								
24							1						
25					1								
26								1					
27					1								
28					1								
29					1								
30					1								
31					1								
Sum					28		1	1		2			

Gold Standard Diagnosis: Perforation (2)													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1			1										
2										1			
3					1								
4					1								
5										1			
6										1			
7					1	1							
8													
9					1					1			
10						1				1			
11	1												
12			1										
13					1								
14					1								
15			1		1								
16					1								
17			1		1								
18					1			1					
19			1										1
20													1
21										1			
22					1					1	1	1	
23								1					
24										1		1	
25										1			
26					1					1			
27					1								
28					1					1			
29			1										
30												1	
31					1					1			
Sum	1		6		15	2		2		12	1	3	2

Gold Standard Diagnosis: Otitis Media with Effusion (OME)													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1	1												
2	1												
3	1												
4	1												
5		1											
6		1											
7	1												
8	1												
9													
10	1												
11	1												
12	1												
13	1												
14	1												
15	1												
16	1												
17	1												
18	1												
19	1												
20	1												
21													1
22	1												
23	1												
24													1
25	1												
26	1												
27										1			
28	1												
29	1												
30	1												
31											1		
Sum	24	2								1	1		2

Gold Standard Diagnosis: Impacted Cerumen (1)													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1						1							
2						1							
3						1							
4						1							
5						1							
6						1							
7						1							
8						1							
9						1							
10						1							
11						1							
12						1							
13						1							
14						1							
15						1							
16						1							
17						1							
18						1							
19						1							
20						1							
21						1							
22						1	1		1				
23										1			
24						1							
25						1							
26						1							
27						1							
28						1							
29						1							
30						1							
31						1							
Sum						30	1		1	1			

Gold Standard Diagnosis: Impacted Cerumen (2)													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1						1							
2						1							
3						1							
4						1							
5						1							
6						1							
7						1							
8						1							
9						1							
10						1							
11						1							
12						1							
13						1							
14						1							
15						1							
16						1							
17						1							
18						1							
19						1							
20						1							
21						1							
22						1							
23						1		1					1
24						1							
25						1							
26						1							
27						1							1
28						1							
29						1							
30						1							
31						1							
Sum						31		1					2

Gold Standard Diagnosis: Cholesteatoma													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1									1				
2													1
3								1					
4										1			
5										1			
6										1		1	
7						1				1			
8													
9													1
10													1
11										1			
12					1								
13										1			
14												1	1
15					1					1			
16											1		
17										1			
18						1	1			1	1		
19					1							1	
20													1
21													1
22										1			
23										1			
24													1
25										1			
26									1				
27													
28													1
29		1											
30									1				
31										1			

29								1					
30								1					
31													1
Sum	2	4	8					8		1	3		7

Gold Standard Diagnosis: Perforation + AOM													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1										1			
2			1		1		1						
3		1											
4					1								
5			1										
6			1		1								
7					1								
8					1								
9		1											
10											1		
11					1		1						
12					1								
13					1								
14			1										
15					1								
16					1								
17											1		
18					1								
19					1								
20		1											
21					1								
22					1								
23					1								
24							1						
25					1								
26			1										
27			1										
28								1					

29		1											
30					1								
31													1
Sum		4	6		17		3	1		1	2		1

Gold Standard Diagnosis: Exostosis													
	Normal	AOM	OME	Tubes	Perforation	Impacted Cerumen	Otitis Media	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1										1			
2													1
3	1												
4		1											
5												1	
6												1	
7												1	
8													
9										1			
10									1				
11			1										
12										1			
13									1				
14									1				
15	1												
16											1	1	
17					1							1	
18									1				
19												1	
20	1												
21												1	
22											1		
23		1											
24													1
25												1	
26									1				
27		1											
28										1			

29										1			
30	1												
31													1
Sum	4	3	1		1				5	5	2	8	3

Appendix D

Raw Data: Otolaryngologists' Responses to Survey Question 1

Gold Standard Diagnosis: Otitis Externa													
	Normal	AOM	OME	Tubes	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbus Myringitis	Granulation Polyp	Other
1						1							
2							1						
3	1					1							
4							1						1
5							1						
6							1						
7							1						
8							1						
9						1							
10							1						
11						1	1						
12							1						
13							1						
14							1						
15							1						
16							1						
17							1						
18							1						
19							1						
20							1						
Sum	1					4	17						1

Gold Standard Diagnosis: Bulbous Myringitis + Tube													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1				1								1	
2				1									
3				1								1	
4				1								1	
5				1								1	
6		1		1								1	
7				1								1	
8				1								1	
9												1	
10		1											
11				1			1						
12				1								1	
13				1								1	
14				1								1	
15				1								1	
16				1								1	
17		1	1	1	1		1					1	
18				1								1	
19				1									1
20												1	
Sum		3	1	17	1		2					16	1

Gold Standard Diagnosis: Granulation Polyp													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Chosteatoma	Bulbous Myringitis	Granulation Polyp	Other
1												1	
2												1	
3													1
4												1	
5												1	
6												1	
7												1	
8										1		1	
9							1					1	
10												1	
11										1			
12												1	
13												1	
14												1	
15												1	
16												1	
17							1					1	
18												1	
19												1	
20												1	
Sum							2			2		18	1

Gold Standard Diagnosis: Perforation (2)													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1					1								
2					1								
3					1					1			
4					1								
5					1								
6					1					1			
7					1					1			
8					1								
9										1			
10						1							
11					1					1			
12					1								
13					1								
14					1								
15					1								
16					1								
17					1	1							
18					1								
19					1								
20								1					
Sum					17	2		1		5			

Gold Standard Diagnosis: Impacted Cerumen (1)													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1						1							
2						1							
3						1							
4						1	1						
5						1							
6						1				1			
7						1							
8						1							
9						1							
10						1							
11						1							
12						1							
13						1							
14						1							
15						1							
16						1							
17						1							
18						1							
19						1							
20							1						
Sum						19	2			1			

Gold Standard Diagnosis: Impacted Cerumen (2)													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1						1							
2						1							
3						1							
4						1							
5						1							
6						1							
7						1							
8						1							
9						1							
10						1							
11						1							
12						1							
13						1							
14						1							
15						1							
16						1							
17						1							
18						1							
19													1
20						1							
Sum						19							1

Gold Standard Diagnosis: Cholesteatoma													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1							1						
2													1
3										1			
4						1			1				
5										1		1	
6								1					
7										1			
8										1			
9			1				1						
10										1			
11										1			
12													1
13					1					1			
14										1			
15											1		
16										1			
17										1			
18											1	1	
19													
20											1		
Sum			1		1	1	2	1	1	10	3	2	2

Gold Standard Diagnosis: Normal (2)													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1	1												
2	1												
3	1												
4	1												
5	1												
6	1												
7			1										
8	1												
9	1												
10	1												
11	1												
12	1												
13			1										
14	1												
15	1												
16	1												
17	1												
18	1												
19	1												
20	1					1							
Sum	18		2			1							

Gold Standard Diagnosis: Post Op													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1								1					
2													1
3													1
4								1					
5	1												
6	1												
7								1					
8								1					
9			1										
10			1										
11			1										
12								1					
13			1										
14								1					
15			1			1							
16								1					
17			1										
18								1					
19													
20													1
Sum	2		6			1		8					3

Gold Standard Diagnosis: Perforation + AOM													
	Normal	AOM	OME	Tube	Perforation	Impacted Cerumen	Otitis Externa	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1								1					
2					1								
3					1								
4				1			1						
5					1								
6							1					1	
7							1					1	
8			1										
9		1											
10					1								
11							1						
12					1								
13							1						
14					1		1						
15					1								
16		1			1								
17					1								
18					1								
19													1
20					1								
Sum		2	1	1	11		6	1				2	1

Gold Standard Diagnosis: Exostosis													
	Normal	AOM	OME	Tubes	Perforation	Impacted Cerumen	Otitis Media	Post Op	Exostosis	Cholesteatoma	Bulbous Myringitis	Granulation Polyp	Other
1										1			
2									1				
3									1				
4					1					1			
5									1				
6	1												
7													1
8									1				
9													1
10											1		
11												1	
12									1				
13										1			
14													1
15										1			
16									1				
17													1
18	1		1										
19	1												
20									1				
Sum	3		1		1				7	4	1	1	4

Appendix E

Raw Data: Audiologists' Responses to Question 2 in which "Immediate" refers to Part A; "Prior Audio" refers to Part B; & "Prior HA" refers to Part C

DX:	Otitis Externa			Granulation Polyp			Bulbous Myringitis + Tube			Tube+ Other		
	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA
1	6	6	10	8	8	10	4	2	10	-6	-5	-5
2	10	10	10	10	10	10	10	2	8	-10	-10	-10
3	10	10	10	10	10	10	10	-10	10	-10	-10	10
4	10	10	10	10	10	10	10	10	10	-10	-10	-10
5	10	2	10	10	10	10	10	4	10	0	-10	-10
6	10	10	10	10	-10	10	10	-10	10	-10	-10	-10
7	10	-3	8	10	2	10	-2	0	1	-2	-4	-1
8	8	8	10	10	10	10	10	7	10	0	0	
9	10	6	10	10	6	10	10	6	10	8	-8	8
10	10	10	10	10	10	10	10	10	10	8	-8	10
11	10	10	10	10	10	10	10	10	10	-10	-10	-10
12	8	-4	8	10	2	10	4	2	10	-10	-10	8
13	10	-10	10	9	-8	10	9	-8	9	-10	-10	-10
14	6	7	10	10	10	10	10	10	10	-8	-8	4
15	10	10	10	10	10	10		-10	10	-10	-10	-10
16	7	7	10	10	10	10	-4	-4	-4	-6	-6	-6
17	10	10	10	10	10	10	10	10	10	-10	-10	-10
18	9	8	8	9	8	8	8	6	6	6	2	5
19	10	10	10	10	10	10	7	7	7	-6	-7	8
20	10	10	10	10	10	10	6	-5	6	-9	-10	4
21	10	10	10	10	-10	10	10	-10	10	-10	-10	10
22	10	10	10	-10	-10	-10	10	10	10	-10	-10	-10
23	4	2	7	5	-7	-5	-5	-6	-6	-7	-9	-8
24	10	2	10	10	-4	8	7		7	1		3
25	10	-10	10	10	-10	10	6	-10	7	-10	-10	-10
26	10	-6	6	10	10	10	10	10	10	-10	-10	5
27	6	-4	10	8	8	9	10	10	10	-8	-10	9
28	3	8	10	10	-10	10	10	9	10	0	-8	2
29	7	7	7	10	10	10	10	4	9	-7	-8	-7
30	10	10	10	10	10	10	6	-7	10	-9	-9	10
31	8	2	9	10	10	10	6		10	-8	-8	-8

DX:	Impacted Cerumen (1)			Perforation (2)			Cholesteatoma			Perf+ AOM		
	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA
1	3	10	10	4	4	10	10	10	9	8	8	9
2	10	10	10	10	-2	10	10	10	10	10	6	10
3	10	10	10	10	10	10	10	10	10	10	-10	10
4		10	9	10			10	10	10	9		
5	0	6	10	10	-1	10	10	10	10	10	-2	10
6	4	4	10	6	-10	10	10		10	10	2	10
7	-2	3	10	10	3	10	8	-4	6	3	-1	2
8	6	10	10	10	0	10	8	10	10	8	4	9
9	10	10	10	10	0	10	10	6	10	10	6	10
10	10	10	10	10	10	10	10	10	10	10	10	10
11	0	8	10	8	8	10	10	10	10	10	0	10
12	4	6	10	10	4	10	10	10	10	10	0	10
13	2	-2	8	6	-10	6	10	-10	10	4	-10	4
14	10	10	10	-6	-6	10	10	10	10	6	6	10
15		6	6		4	6	10	10	10	6	10	10
16	10	10	10	10	10	10	10	10	10	10	10	10
17	-6	-6	2	10	10	10	10	10	10	10	10	10
18	5	5	5	7	5	6	10	9	9	6	4	6
19	6	6	6				10	10	10	10	10	10
20	10	10	10	-10	-10	7	10	10	10	8	-7	7
21	10	10	10	10	-10	10	10	10	10	7	-10	10
22	10	10	10	10	10	10	10	10	10	10	10	10
23	5	4	5	-5	-5	-6	9	6		3	-5	-3
24	10	10	10	7		7	10	8	10	6		10
25	10	10	10	10	-10	10	10	-3	10	10	-10	10
26	10	10	10	10	10	10	10	10	10	10	-8	4
27	-4	-6	10	10	10	10	10	10	10		-4	6
28	10	10	10	10	10	10	10	-9	3	10	-10	3
29	7	9	9	6	4	5	7	3	6	9	7	8
30	0	10	10	10	10	10	10	10	10	10	-8	10
31	9	10	10	9	-2	8	10	10	10	10	6	10

DX:	OME			Perforation (1)			Impacted Cerumen (2)			Normal (1)		
	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA
1	-1	-1	-1	-10	-6	8	4	10	10	-10	-9	-9
2	-6	-10	-10	10	2	10	10	10	10	-10	-10	-10
3	-4	-10	-4	10	-10	10	10	10	10	-10	-10	-10
4	-10	-10	-10	10		9		10	10	7		
5	-10	-10	-10	10	-10	10		5	10	-10	-10	-10
6	0	-10	-10	-2	-10	4	0	4	10	-10	-10	-10
7	-10	-10	-10	2	-2	1	-1	4	9	2	-3	2
8	-8	-8	-8	8		8	10	10	10			
9	4	-6	4	10	-8	10	10	10	10	8	-8	10
10	-10	-10	10	10	0	10	10	10	10	-10	-10	10
11	-10	-10	-10	7	0	7	10	8	10	-10	-10	-10
12	4	0	4	2	2	10	4	2	10	-2	-2	-2
13	-10	-10	-10	-2	-10	4	-8	-10	6	-10	-10	-10
14	-10	-10	2	-2	-10	10	10	10	10	-10	-10	-10
15	-10	-10	-10	-10	-10	-10		6	6	-10	-10	-10
16	-10	-10	-10	10	10	10	10	10	10	-10	-10	-10
17	-10	-10	-10	10	10	10	-4	-2	2	-10	-10	-10
18	1	0	0	8	6	7	8	8	8	-8	-8	-8
19	-6	-6	-6	8	8	10	7	7	7	-10	-10	-10
20	-10	-10	7	10	10	10	10	10	10	-10	-10	-10
21	-10	-10	0	10	-10	10	10	10	10	-10	-10	-10
22	-10	-10	-10	10	10	10	10	10	10	-10	-10	-10
23	4	-6	-6	5	-7	-7	-8	-6	2	-10	-10	-10
24	2		5	5		5	10	3	10			
25	-10	-10	-10	7		6	10	10	10	-10	-10	-10
26	-10	-10	-10	10	-6	7	10	10	10	-10	-10	-10
27	-8	-10	8	6	-6	9		-8	10	-10	-10	8
28	-10	-10	-10	9	-9	2	10	10	10	-10	-10	-10
29	-10	-10	-10	8	-2	8	8	9	9	-9	-9	-9
30	-10	-10	-10	10	-8	10		10	10	-10	-10	-10
31		-8	5		-10	10	9	10	10	-10	-10	-10

DX:	Normal (2)			Post Op			Exostosis		
	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA
1	4	5	10	-9	-10	-10	10	2	10
2	-10	-10	-10	10	-6	-10	9	-6	-10
3	-10	-10	-10	0	-10	-10	10	-10	10
4	10	10	10						
5	-10	-10	-10	8	-8	10	10	-10	10
6	-10	-10	-10	6	-10	10	10	-10	10
7	4	-1	4	2	-3	2	-1	-6	3
8	-6	-6	-6	9		9	4	-2	4
9	8	-6	10	8	0	10	10	-6	10
10	-10	-10	10	8	-2	10	8	-10	10
11	-10	-10	-10	8	9	10	0	0	-6
12	4	2	10	10	2	10	8	2	10
13	-8	-8	-8	-2	-10	-2	-2	-10	-6
14	-10	-10	-10	-8	-10	2	-8	-10	4
15	-10	-10	-10	-10	-10	-10	-10	-10	-10
16	2	2	2	4	4	4	-2	-2	-2
17	-10	-10	-10	-10	-10	-10	2	-10	10
18	-8	-8	-8	6	3	4	7	5	5
19	-6	-6	0	6	-6	6	9	4	10
20	-10	-10	-10	-5	-10	5	4	8	-6
21	5	-10	10	0	-10	10	5	-10	5
22	-10	-10	-10	6	7	6	8	-10	6
23	-5	-5	-7	6	3		3	-7	-7
24				4		4	6		6
25	10	-10	10	0			6	-10	
26	-10	-10	-10	8	-8	6	-10	-10	-10
27	-10	-10	10	6	2	9	7	-4	8
28	9	-10	-4	7	-3	9	7	-10	4
29	3	-4	-4	0	-4	4	9	2	9
30	-10	-10	-10	10	10	10	-10	-10	-10
31	6	-8	10	10		10	4	-4	8

Appendix F

Raw Data: Otolaryngologists' Responses to Question 2 in which "Immediate" refers to Part A; "Prior Audio" refers to Part B; & "Prior HA" refers to Part C

DX:	Otitis Externa			Granulation Polyp			Bulbous Myringitis + Tube			Tube+ Other		
	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA
1	2	3	3	9	8	9	0	10	8	-3	5	4
2	10	10	10	10	10	10	10	10	10	-4	-4	-4
3	-10	10	10	10	10	10	10	10	10	-10	-10	-10
4	10	0	10	10		10	10	0	10	-10	-10	-10
5	10	-10	10	10	-10	10	10	-10	10	-10	-10	-10
6	10	10	10	9	5	10	10	8	10	-10	-10	-10
7	10	10	10	10	-10	10	10	-10	10	-10	-10	-10
8	10	10	10	10	10	10	10	10	10	-10	-10	-10
9	2	2	2	7	7	8	10	9	10	-9	-2	-9
10	2	4	10	10	10	10	10	10	10	-10	-10	-10
11	10		10	10	8	10	5	8	10	0	0	-10
12	8			6	10		6	0		-10	-10	-10
13	10	10	10	10	10	10	10	10	10	-10	-10	-10
14	10	10	10	10	10	10	10	10	10	-6	-6	-6
15	10	10	10	10			10	0	10	-8	-10	-8
16	2	9	8	7	8	8	8	9	9	-8	-8	-8
17	7	4	10	10	10	10	10	10	10	-10	-10	-10
18	4	5	5	3	5	5	4	6	6	-9	-9	-9
19	10	-10	10	10	-10	10	10	-6	-6	-10	-10	-10
20	10	10	10	9	5	10	10	10	10	0	0	0

DX:	Impacted Cerumen (1)			Perforation (2)			Cholesteatoma			Perf+ AOM		
	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA
1	7	7	7	7	8	7	10	10	10	10	4	3
2	10	10	10	10	10	10	10	10	10	10	10	10
3	-10	10	10	10	10	10	10	10	10	10	10	10
4	0		10	0	0	10	0	0	10	0	0	10
5	10	-10	10	10	-10	10	10	-10	10	10	-10	10
6	4	-8	10	6	-10	10	10	-10	10	0	-6	6
7	10	10	10	10	-10	10	10	-10	10	10	-10	10
8		10	10	8	10	10	10	10	10	6	10	10
9	3	3	3	7	7	7	6	5	5	7	6	6
10	-3	3	6	6	7	10	10		10	-10	-10	10
11	8	8	10	0	-6	10	10	10	10	4	6	10
12	4	10		-8	-8	4	0	10		6		
13	10	10	10	-10	-10	-10	10	10	10	10	10	10
14						10	8	0	10	10	10	10
15		10	10	10	0	10	10		10	10		10
16	6	9	9	7	8	8	9	9	9	7	9	9
17	-6	10	10	10	-10	10	10	10	10	10	-10	10
18	-4	3	3	-3	-7	-7	4	5	5			
19	10	10	-10	10	-10	-10	10	-8	8	10	10	10
20	10	10	10	7	9	10	10	10	10	10	10	10

DX:	OME			Perforation (1)			Impacted Cerumen (2)			Normal (1)		
	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA
1	-9	-9	-9	0	9	8	6	3	3	-3	-3	-3
2	8	8	8	10	10	10	10	10	10	-8	-8	-8
3	10	-10	10	10	-10	10	-10	10	10	10	10	10
4	-10	-10	-10	0	0	10	0	0	10	0	0	10
5	10	-10	10	10	-10	10	-10	-10	10	-10	-10	-10
6	6	-10	8	6	-8	10	2	-9	10	-10	-10	-10
7	4	-10	10	10	-10	10	10	-10	10	10	-10	10
8		-10	-10	6	10	10		10	10	-10	-10	-10
9	-6	-5	-6	4	-2	4	5	5	5	-10	-9	-10
10	-10	-10	-10	-10	-10	10	-4	4	6	-10	-10	-10
11	2	-4	-10	0	0	10	7	8	10	-10	-10	-10
12		-8		2	2	10		10			-10	
13	10	10	10	10	-10	-10	-10	10	10	10	10	10
14			10			10	10	10	10	-8	-8	-8
15	-7	-7	-7	10	0	0	10	10	10	-10	-10	-10
16	6	9	9	2	6	6	-4	2	4	-8	-10	-10
17	-10	-10	-10	10	-10	10	-5	-10	10	-10	-10	-10
18	4	4	4				2	4	4	3	-8	-8
19	7	-10	-10	10	-10	-10	10	10	10	8	-10	-10
20	0	10	0	10	8	10	10	10	10	-8	0	10

DX:	Normal (2)			Post Op			Exostosis		
	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA	Immediate	Prior Audio	Prior HA
1	-10	-10	-10	-10	-8	-8	0	6	6
2	-8	-8	-8	10	10	10	0	0	0
3	-10	-10	-10				-10	-10	-10
4	-10	-10	-10	0	0	0	0	0	10
5	-10	-8	-10	-10	-10	-10	-10	-10	-10
6	-10	-10	-10	-10	-9	-10	0	0	0
7	2	-10	4	-10	-10	-10	-10	-10	-10
8		-10	-10	-10	-10	-10	-10	-10	-10
9	-7	-7	-7	7	2	2	2	3	3
10	-10	-10	-10	4	-5	10	2	-3	10
11	-10	-10	-10	4	-2	10	10		10
12		-8			-6		-10	-10	-9
13	10	10	10	-10	-10	-10	10	10	-10
14	-8	-8	-8	-6	-6	-6	-8	-8	-8
15	-10	-10	-10	7		7	10		10
16	-8	-8	-8	-8	-8	-4	-10	-10	-8
17	-10	-10	-10	5	-10	-10	5	-10	9
18	3	-8	-7		-6	-6	-4	-4	-4
19	4	4	-6	10	-10	-10	8	-10	-10
20	-6	0	10	6	6	10	-4	0	0

Appendix G

Raw Data: Audiologists' Responses to Question 3 in which "3"=better, "2"=same, & "1"=worse than manual otoscopy

DX:	Ex	GP	IC1	OE	PEOTH	IC2	P1	BMPE	P2	PAOM	CH	OME	N1	N2	PO
1	3	1	2	2	1	2	1	1	1	1	1	1	1	1	1
2	2	3	2	2	2	3	2	2	2	2	3	2	2	2	3
3	3	1	2	2	2	2	2	1	1	2	2	1	1	1	1
4	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1
5	3	1	2	1	1	3	1	1	2	2	1	2	2	2	2
6	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3
7	3	1	2	2	1	2	2	1	2	2	1	1	1	1	3
8	2	2	2	2	2	2	1	1	1	1	2	2	2	2	2
9	1	3	2	2	3	3	3	2	2	3	3	2	2	2	3
10	3	1	2	2	2	2	2	2	1	3	3	2	2	2	2
11	2	2	3	2	2	3	2	2	2	3	2	2	2	2	3
12	2	2	2	2	2	2	2	2	1	2	3	2	2	2	2
13	3	1	2	2	2	3	2	1	1	3	1	2	2	2	3
14	2	1	2	1	1	2	2	1	1	2	2	2	2	1	2
15	1	2	2	2	2	2	2	2	2	3	2	2	2	2	3
16	3	1	2	2	2	2	1	2	1	2	2	1	1	1	2
17	1	1	1	2	2	2	2	1	1	3	1	2	2	2	2
18	3	1	2	2	1	2	2	1	1	2	2	1	1	1	1
19	2	1	2	1	3	2	1	1	1	2	1	2	2	2	2
20	3	2	1	1	1	2	2	1	2	2	2	1	1	1	2
21	2	2	3	2	2	3	2	2	2	3	2	2	1	2	2
22	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1
23	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3
24	3	1	2	2	2	2	2	1	1	1	1	1	2	1	2
25	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
26	3	1	2	2	1	2	2	1	1	3	1	1	1	2	1
27	3	1	2	1	1	3	1	1	1	3	1	2	2	2	2
28	3	1	2	2	2	2	1	1	1	2	1	2	2	2	3
29	2	2	2	2	2	2	3	3	2	2	2	1	2	1	2
30	2	1	2	3	3	3	2	3	2	3	2	2	2	2	3
31	2	2	3	3	2	3	2	2	3	3	3	2	2	2	3

Appendix I

Raw Data: Otolaryngologists' Responses to Question 3 in which "3"=better, "2"=same, & "1"=worse than manual otoscopy

	Ex	GP	IC 1	OE	PEOT H	IC2	P1	BMPE	P 2	PAO M	CH	OM E	N1	N2	PO
1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
2	2	2	3	2	2	2	2	3	2	3	3	2	2	2	3
3	2	2	2	2	2	2	2	2	2	3	3	1	1	3	2
4	2	2	2	2	2	2	3	3	2	3	2	2	2	2	2
5	2	2	2	2	2	2	2	2	2	3	2	2	2	2	2
6	1	2	2	2	2	2	2	1	2	3	3	2	2	2	
7	3	1	1	2	1	1	1	1	1	1	1	1	1	1	1
8	2	2	2	2	2	2	2	2	1	2	2	1	1	1	2
9	1	2	2	2	2	2	2	2	2	2	2	3	2	2	3
10	3	1	2	1	1	2	1	1	1	2	1	1	1	1	1
11	3	2	2	2	2	2	2	2	2	2	1	1	1	2	2
12	2	1	1	1	2	1	3	2	1	3	2	1	1	3	2
13	2	3	2	2	2	2	2	3	2	3	2	2	2	2	2
14	1	1	2	2	2	2	2	2	2	2	2	1	2	2	2
15	1	2	3	2	2	2	3	3	2	3	2	2	1	1	3
16	1	3	2	2	2	3	3	3	2	3	3	2	2	2	3
17	1	2	3	2	2	3	2	2	2	3	2	2	1	2	2
18	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
19	1	3	3		3		3	3	3	3	3	3	3	3	3
20	2	2	2	2	2	2	3	2	3	3	3	2	2	2	3

Appendix K

Question 2: Mean and Standard Error of the Mean (SEM) Data by Professional Group

AUD Average Need for “Immediate Medical Referral” (Part A)		
Image Dx	Mean	SEM
Otitis Externa	8.774194	0.355185
Granulation Polyp	9	0.658832
Bulbous Myringitis + Tube	7.4	0.761111
Tube + Other	-5.90323	1.009603
Impacted Cerumen (1)	5.827586	0.876999
Perfortation (2)	7.310345	0.946484
Cholesteatoma	9.741935	0.130848
Perf +AOM	8.433333	0.404711
Otitis Media with Effusion	-6.6	0.921011
Perforation (1)	5.966667	1.039908
Impacted Cerumen (2)	6.5	1.038503
Normal (1)	-8	0.904055
Normal (2)	-3.6	1.375874
Post Op	3.266667	1.133443
Exostosis	3.766667	1.148784

ENT Average Need for “Immediate Medical Referral” (Part A)		
Image Dx	Mean	SEM
Otitis Externa	6.85	1.155119
Granulation Polyp	9	0.416954
Bulbous Myringitis + Tube	8.65	0.617056
Tube + Other	-7.85	0.758737
Impacted Cerumen (1)	4.058824	1.448687
Perfortation (2)	5.105263	1.404821
Cholesteatoma	8.35	0.730435
Perf +AOM	6.842105	1.174972
Otitis Media with Effusion	0.882353	1.745257
Perforation (1)	5.555556	1.261373
Impacted Cerumen (2)	2.166667	1.707636
Normal (1)	-3.89474	1.787991
Normal (2)	-6	1.391813
Post Op	-1.23529	1.825237
Exostosis	-1.45	1.663821

AUD Average Need for referral “Prior to Audiometric Testing” (Part B)		
Image Dx	Mean	SEM
Otitis Externa	5.096774	1.134857
Granulation Polyp	4.354839	1.457465
Bulbous Myringitis + Tube	1.689655	1.399819
Tube + Other	-8.2	0.536325
Impacted Cerumen (1)	7.193548	0.820658
Perfortation (2)	2	1.347053
Cholesteatoma	7.2	1.041954
Perf +AOM	0.827586	1.355505
Otitis Media with Effusion	-8.5	0.5473
Perforation (1)	-2.81481	1.349063
Impacted Cerumen (2)	6.451613	1.024901
Normal (1)	-9.25	0.357817
Normal (2)	-6.76667	0.94376
Post Op	-3.46154	1.190056
Exostosis	-5.31034	1.01571

ENT Average Need for Referral “Prior to Audiometric Testing” (Part B)		
Image Dx	Mean	SEM
Otitis Externa	5.388889	1.464254
Granulation Polyp	5.333333	1.631369
Bulbous Myringitis + Tube	5.2	1.557732
Tube + Other	-7.2	1.012516
Impacted Cerumen (1)	6.388889	1.383622
Perfortation (2)	-0.63158	1.936284
Cholesteatoma	3.944444	1.811735
Perf +AOM	2.882353	1.907942
Otitis Media with Effusion	-4.31579	1.782007
Perforation (1)	-1.94444	1.787194
Impacted Cerumen (2)	3.85	1.716498
Normal (1)	-6.3	1.4409
Normal (2)	-7.05	1.209045
Post Op	-5.11111	1.346418
Exostosis	-4.22222	1.448927

AUD Average Need for Referral “Prior to Earmold Impressions and Hearing Aid Fitting” (Part C)		
Image Dx	Mean	SEM
Otitis Externa	9.451613	0.201199
Granulation Polyp	8.709677	0.791025
Bulbous Myringitis + Tube	8.064516	0.719531
Tube + Other	-1.3	1.474564
Impacted Cerumen (1)	9.032258	0.363479
Perfortation (2)	8.586207	0.580798
Cholesteatoma	9.433333	0.285559
Perf +AOM	8.166667	0.5776
Otitis Media with Effusion	-4.51613	1.235062
Perforation (1)	7.032258	0.876451
Impacted Cerumen (2)	9	0.393338
Normal (1)	-7.07143	1.144816
Normal (2)	-2.03333	1.578205
Post Op	3.857143	1.309042
Exostosis	2.931034	1.357085

ENT Average Need for Referral “Prior to Earmold Impressions and Hearing Aid Fitting” (Part C)		
Image Dx	Mean	SEM
Otitis Externa	8.842105	0.569204
Granulation Polyp	9.444444	0.289379
Bulbous Myringitis + Tube	8.789474	0.832326
Tube + Other	-8	0.855733
Impacted Cerumen (1)	7.666667	1.119883
Perfortation (2)	6.45	1.535377
Cholesteatoma	9.315789	0.35804
Perf +AOM	9.111111	0.446696
Otitis Media with Effusion	-0.15789	2.035758
Perforation (1)	6.736842	1.447608
Impacted Cerumen (2)	8.526316	0.579397
Normal (1)	-4.05263	1.965165
Normal (2)	-6.31579	1.476534
Post Op	-2.5	1.873688
Exostosis	-1.55	1.852591

Appendix L

SPSS Output for Question 2

```

GLM I7R1 I7R2 I7R3 I2R1 I2R2 I2R3 I3R1 I3R2 I3R3 I8R1 I8R2 I8R3 I1R1 I1R2 I1R3
I10R1 I10R2 I10R3 I5R1 I5R2 I5R3 I6R1 I6R2 I6R3
I9R1 I9R2 I9R3 I11R1 I11R2 I11R3 I15R1 I15R2 I15R3 I14R1 I14R2 I14R3 I12R1
I12R2 I12R3 I13R1 I13R2 I13R3
I4R1 I4R2 I4R3 BY Grp
/WSFACTOR=image 15 refer 3
/MEASURE=urgency
/METHOD=SSTYPE(3)
/PLOT=PROFILE(image*Grp*refer image*Grp image*refer*Grp)
/PRINT=DESCRIPTIVE ETASQ
/CRITERIA=ALPHA(.05)
/WSDESIGN=image refer image*refer
/DESIGN=Grp.

```

Within-Subjects Factors

Measure: urgency

image	refer	Dependent Variable
1	1	I7R1
	2	I7R2
	3	I7R3
2	1	I2R1
	2	I2R2
	3	I2R3
3	1	I3R1
	2	I3R2
	3	I3R3
4	1	I8R1
	2	I8R2
	3	I8R3
5	1	I1R1
	2	I1R2
	3	I1R3
6	1	I10R1
	2	I10R2
	3	I10R3
7	1	I5R1
	2	I5R2
	3	I5R3
8	1	I6R1
	2	I6R2
	3	I6R3
9	1	I9R1
	2	I9R2
	3	I9R3
10	1	I11R1
	2	I11R2
	3	I11R3
11	1	I15R1

	2	I15R2
	3	I15R3
12	1	I14R1
	2	I14R2
	3	I14R3
13	1	I12R1
	2	I12R2
	3	I12R3
14	1	I13R1
	2	I13R2
	3	I13R3
15	1	I4R1
	2	I4R2
	3	I4R3

Between-Subjects Factors

		N
Grp	AUD	19
	ENT	11

Multivariate Tests^a

Effect		Value	F	Hypothesis df	Error df	Sig.
image	Pillai's Trace	.942	17.276 ^b	14.000	15.000	.000
	Wilks' Lambda	.058	17.276 ^b	14.000	15.000	.000
	Hotelling's Trace	16.124	17.276 ^b	14.000	15.000	.000
	Roy's Largest Root	16.124	17.276 ^b	14.000	15.000	.000
image * Grp	Pillai's Trace	.604	1.636 ^b	14.000	15.000	.178
	Wilks' Lambda	.396	1.636 ^b	14.000	15.000	.178
	Hotelling's Trace	1.527	1.636 ^b	14.000	15.000	.178
	Roy's Largest Root	1.527	1.636 ^b	14.000	15.000	.178
refer	Pillai's Trace	.515	14.362 ^b	2.000	27.000	.000
	Wilks' Lambda	.485	14.362 ^b	2.000	27.000	.000
	Hotelling's Trace	1.064	14.362 ^b	2.000	27.000	.000
	Roy's Largest Root	1.064	14.362 ^b	2.000	27.000	.000
refer * Grp	Pillai's Trace	.049	.690 ^b	2.000	27.000	.510
	Wilks' Lambda	.951	.690 ^b	2.000	27.000	.510
	Hotelling's Trace	.051	.690 ^b	2.000	27.000	.510
	Roy's Largest Root	.051	.690 ^b	2.000	27.000	.510
image * refer	Pillai's Trace	.900	.322 ^b	28.000	1.000	.911
	Wilks' Lambda	.100	.322 ^b	28.000	1.000	.911
	Hotelling's Trace	9.020	.322 ^b	28.000	1.000	.911
	Roy's Largest Root	9.020	.322 ^b	28.000	1.000	.911
image * refer * Grp	Pillai's Trace	.923	.430 ^b	28.000	1.000	.862
	Wilks' Lambda	.077	.430 ^b	28.000	1.000	.862
	Hotelling's Trace	12.034	.430 ^b	28.000	1.000	.862
	Roy's Largest Root	12.034	.430 ^b	28.000	1.000	.862

Multivariate Tests^a

Effect		Partial Eta Squared
image	Pillai's Trace	.942
	Wilks' Lambda	.942
	Hotelling's Trace	.942
	Roy's Largest Root	.942
image * Grp	Pillai's Trace	.604
	Wilks' Lambda	.604
	Hotelling's Trace	.604
	Roy's Largest Root	.604
refer	Pillai's Trace	.515
	Wilks' Lambda	.515
	Hotelling's Trace	.515
	Roy's Largest Root	.515
refer * Grp	Pillai's Trace	.049
	Wilks' Lambda	.049
	Hotelling's Trace	.049
	Roy's Largest Root	.049
image * refer	Pillai's Trace	.900
	Wilks' Lambda	.900
	Hotelling's Trace	.900
	Roy's Largest Root	.900
image * refer * Grp	Pillai's Trace	.923
	Wilks' Lambda	.923
	Hotelling's Trace	.923
	Roy's Largest Root	.923

- a. Design: Intercept + Grp
 Within Subjects Design: image + refer + image * refer
 b. Exact statistic

Mauchly's Test of Sphericity^a

Measure: urgency

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon ^b
					Greenhouse-Geisser
image	.001	162.343	104	.000	.496
refer	.776	6.861	2	.032	.817
image * refer	.000	870.582	405	.000	.368

Mauchly's Test of Sphericity^a

Measure: urgency

Within Subjects Effect	Epsilon	
	Huynh-Feldt	Lower-bound
image	.700	.071
refer	.891	.500
image * refer	.621	.036

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.^a

- a. Design: Intercept + Grp
 Within Subjects Design: image + refer + image * refer

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Tests of Within-Subjects Effects

Measure: urgency

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
image	Sphericity Assumed	33102.749	14	2364.482	44.891	.000
	Greenhouse-Geisser	33102.749	6.947	4765.325	44.891	.000
	Huynh-Feldt	33102.749	9.804	3376.617	44.891	.000
	Lower-bound	33102.749	1.000	33102.749	44.891	.000
image * Grp	Sphericity Assumed	2423.949	14	173.139	3.287	.000
	Greenhouse-Geisser	2423.949	6.947	348.941	3.287	.003
	Huynh-Feldt	2423.949	9.804	247.253	3.287	.001
	Lower-bound	2423.949	1.000	2423.949	3.287	.081
Error(image)	Sphericity Assumed	20647.307	392	52.672		
	Greenhouse-Geisser	20647.307	194.504	106.153		
	Huynh-Feldt	20647.307	274.499	75.218		
	Lower-bound	20647.307	28.000	737.404		
refer	Sphericity Assumed	4890.318	2	2445.159	21.076	.000
	Greenhouse-Geisser	4890.318	1.633	2993.805	21.076	.000
	Huynh-Feldt	4890.318	1.783	2743.163	21.076	.000
	Lower-bound	4890.318	1.000	4890.318	21.076	.000
refer * Grp	Sphericity Assumed	91.430	2	45.715	.394	.676
	Greenhouse-Geisser	91.430	1.633	55.972	.394	.635
	Huynh-Feldt	91.430	1.783	51.286	.394	.653
	Lower-bound	91.430	1.000	91.430	.394	.535
Error(refer)	Sphericity Assumed	6496.782	56	116.014		
	Greenhouse-Geisser	6496.782	45.737	142.045		
	Huynh-Feldt	6496.782	49.916	130.153		
	Lower-bound	6496.782	28.000	232.028		
image * refer	Sphericity Assumed	1555.956	28	55.570	3.562	.000
	Greenhouse-Geisser	1555.956	10.312	150.882	3.562	.000
	Huynh-Feldt	1555.956	17.378	89.537	3.562	.000
	Lower-bound	1555.956	1.000	1555.956	3.562	.070
image * refer * Grp	Sphericity Assumed	1012.133	28	36.148	2.317	.000
	Greenhouse-Geisser	1012.133	10.312	98.147	2.317	.011
	Huynh-Feldt	1012.133	17.378	58.243	2.317	.002
	Lower-bound	1012.133	1.000	1012.133	2.317	.139
Error(image*refer)	Sphericity Assumed	12232.344	784	15.602		
	Greenhouse-Geisser	12232.344	288.748	42.363		
	Huynh-Feldt	12232.344	486.580	25.139		
	Lower-bound	12232.344	28.000	436.869		

Tests of Between-Subjects Effects

Measure: urgency

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	6964.594	1	6964.594	33.250	.000	.543
Grp	133.572	1	133.572	.638	.431	.022
Error	5864.983	28	209.464			

Appendix M

SPSS Output for Question 3

EorBtMO=Equal to or better than manual otoscopy followed by the image number

```

GET FILE='N:\UserG-L\graylc\Aud\Short\Q3.sav'.
DATASET NAME DataSet1 WINDOW=FRONT.
DATASET ACTIVATE DataSet1.
RECODE I15 (1=0) (2 thru 3=1) INTO EorBtMO15.
RECODE I14 (1=0) (2 thru 3=1) INTO EorBtMO14.
RECODE I13 (1=0) (2 thru 3=1) INTO EorBtMO13.
RECODE I12 (1=0) (2 thru 3=1) INTO EorBtMO12.
RECODE I11 (1=0) (2 thru 3=1) INTO EorBtMO11.
RECODE I10 (1=0) (2 thru 3=1) INTO EorBtMO10.
RECODE I9 (1=0) (2 thru 3=1) INTO EorBtMO9.
RECODE I8 (1=0) (2 thru 3=1) INTO EorBtMO8.
RECODE I7 (1=0) (2 thru 3=1) INTO EorBtMO7.
RECODE I6 (1=0) (2 thru 3=1) INTO EorBtMO6.
RECODE I5 (1=0) (2 thru 3=1) INTO EorBtMO5.
RECODE I4 (1=0) (2 thru 3=1) INTO EorBtMO4.
RECODE I3 (1=0) (2 thru 3=1) INTO EorBtMO3.
RECODE I2 (1=0) (2 thru 3=1) INTO EorBtMO2.
RECODE I1 (1=0) (2 thru 3=1) INTO EorBtMO1.

EXECUTE.
T-TEST
  /TESTVAL=0
  /MISSING=ANALYSIS
  /VARIABLES=EorBtMO15 EorBtMO14 EorBtMO13 EorBtMO12 EorBtMO11
EorBtMO10 EorBtMO9 EorBtMO8 EorBtMO7 EorBtMO6 EorBtMO5 EorBtMO4
EorBtMO3 EorBtMO2 EorBtMO1
  /CRITERIA=CI(.95).

```

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
EorBtMO15	50	.8400	.37033	.05237
EorBtMO14	51	.7059	.46018	.06444
EorBtMO13	51	.6471	.48264	.06758
EorBtMO12	51	.6471	.48264	.06758
EorBtMO11	51	.7059	.46018	.06444
EorBtMO10	51	.8824	.32540	.04556
EorBtMO9	51	.5882	.49705	.06960
EorBtMO8	51	.6078	.49309	.06905
EorBtMO7	51	.7843	.41539	.05817
EorBtMO6	50	.9200	.27405	.03876
EorBtMO5	51	.7647	.42840	.05999
EorBtMO4	50	.8200	.38809	.05488
EorBtMO3	51	.8824	.32540	.04556
EorBtMO2	51	.5686	.50020	.07004

EorBtMO1	51	.7843	.41539	.05817
----------	----	-------	--------	--------

One-Sample Test

	Test Value = 0					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
EorBtMO15	16.039	49	.000	.84000	.7348	.9452
EorBtMO14	10.954	50	.000	.70588	.5765	.8353
EorBtMO13	9.574	50	.000	.64706	.5113	.7828
EorBtMO12	9.574	50	.000	.64706	.5113	.7828
EorBtMO11	10.954	50	.000	.70588	.5765	.8353
EorBtMO10	19.365	50	.000	.88235	.7908	.9739
EorBtMO9	8.452	50	.000	.58824	.4484	.7280
EorBtMO8	8.803	50	.000	.60784	.4692	.7465
EorBtMO7	13.484	50	.000	.78431	.6675	.9011
EorBtMO6	23.738	49	.000	.92000	.8421	.9979
EorBtMO5	12.748	50	.000	.76471	.6442	.8852
EorBtMO4	14.941	49	.000	.82000	.7097	.9303
EorBtMO3	19.365	50	.000	.88235	.7908	.9739
EorBtMO2	8.118	50	.000	.56863	.4279	.7093
EorBtMO1	13.484	50	.000	.78431	.6675	.9011

DATASET ACTIVATE DataSet1.

*GroupEffectInQ3. Repeated measures anova with 0 meaning worse than manual, 1 meaning equal to or better than manual. 15 images.

GET

```
FILE='N:\UserG-L\graylc\Aud\Short\Q3.sav'.
DATASET NAME DataSet1 WINDOW=FRONT.
GLM EorBtMO15 EorBtMO14 EorBtMO13 EorBtMO12 EorBtMO11 EorBtMO10
EorBtMO9 EorBtMO8 EorBtMO7 EorBtMO6 EorBtMO5 EorBtMO4 EorBtMO3
EorBtMO2 EorBtMO1 BY Grp
/WSFACTOR=Image 15 Polynomial
/MEASURE=NotBad
/METHOD=SSTYPE(3)
/CRITERIA=ALPHA(.05)
/WSDESIGN=Image
/DESIGN=Grp.
```

[DataSet1] N:\UserG-L\graylc\Aud\Short\Q3.sav

Within-Subjects Factors

Measure: NotBad

Image	Dependent Variable
1	EorBtMO15
2	EorBtMO14
3	EorBtMO13
4	EorBtMO12
5	EorBtMO11
6	EorBtMO10
7	EorBtMO9
8	EorBtMO8
9	EorBtMO7
10	EorBtMO6
11	EorBtMO5
12	EorBtMO4
13	EorBtMO3
14	EorBtMO2
15	EorBtMO1

Between-Subjects Factors

		N
Grp	AUD	31
	ENT	18

Multivariate Tests^a

Effect		Value	F	Hypothesis df	Error df	Sig.
Image	Pillai's Trace	.519	2.622 ^b	14.000	34.000	.011
	Wilks' Lambda	.481	2.622 ^b	14.000	34.000	.011
	Hotelling's Trace	1.080	2.622 ^b	14.000	34.000	.011
	Roy's Largest Root	1.080	2.622 ^b	14.000	34.000	.011
Image * Grp	Pillai's Trace	.322	1.151 ^b	14.000	34.000	.354
	Wilks' Lambda	.678	1.151 ^b	14.000	34.000	.354
	Hotelling's Trace	.474	1.151 ^b	14.000	34.000	.354
	Roy's Largest Root	.474	1.151 ^b	14.000	34.000	.354

- a. Design: Intercept + Grp
 Within Subjects Design: Image
 b. Exact statistic

Mauchly's Test of Sphericity^a

Measure: NotBad

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon ^b
					Greenhouse-Geisser
Image	.001	277.954	104	.000	.542

Mauchly's Test of Sphericity^a

Measure: NotBad

Within Subjects Effect	Epsilon	
	Huynh-Feldt	Lower-bound
Image	.670	.071

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.^a

a. Design: Intercept + Grp

Within Subjects Design: Image

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Tests of Within-Subjects Effects

Measure: NotBad

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Image	Sphericity Assumed	7.625	14	.545	4.683	.000
	Greenhouse-Geisser	7.625	7.584	1.005	4.683	.000
	Huynh-Feldt	7.625	9.378	.813	4.683	.000
	Lower-bound	7.625	1.000	7.625	4.683	.036
Image * Grp	Sphericity Assumed	4.741	14	.339	2.911	.000
	Greenhouse-Geisser	4.741	7.584	.625	2.911	.004
	Huynh-Feldt	4.741	9.378	.506	2.911	.002
	Lower-bound	4.741	1.000	4.741	2.911	.095
Error(Image)	Sphericity Assumed	76.535	658	.116		
	Greenhouse-Geisser	76.535	356.470	.215		
	Huynh-Feldt	76.535	440.767	.174		
	Lower-bound	76.535	47.000	1.628		

Tests of Within-Subjects Contrasts

Measure: NotBad

Source	Image	Type III Sum of Squares	df	Mean Square	F	Sig.
Image	Linear	.367	1	.367	1.587	.214
	Quadratic	.001	1	.001	.008	.928
	Cubic	1.550	1	1.550	12.557	.001
	Order 4	.336	1	.336	2.163	.148
	Order 5	9.296E-6	1	9.296E-6	.000	.993
	Order 6	1.321	1	1.321	12.455	.001
	Order 7	.497	1	.497	5.278	.026
	Order 8	.085	1	.085	1.279	.264
	Order 9	1.017	1	1.017	12.841	.001
	Order 10	1.485	1	1.485	11.228	.002
	Order 11	.163	1	.163	1.552	.219
	Order 12	.289	1	.289	2.349	.132

	Order 13	.147	1	.147	2.091	.155
	Order 14	.368	1	.368	5.727	.021
Image * Grp	Linear	.012	1	.012	.054	.818
	Quadratic	.752	1	.752	4.939	.031
	Cubic	.110	1	.110	.895	.349
	Order 4	.167	1	.167	1.078	.305
	Order 5	.855	1	.855	6.812	.012
	Order 6	.991	1	.991	9.343	.004
	Order 7	.009	1	.009	.100	.754
	Order 8	.232	1	.232	3.488	.068
	Order 9	.095	1	.095	1.206	.278
	Order 10	.954	1	.954	7.209	.010
	Order 11	.004	1	.004	.042	.838
	Order 12	.534	1	.534	4.349	.042
	Order 13	.000	1	.000	.002	.962
	Order 14	.023	1	.023	.359	.552
Error(Image)	Linear	10.866	47	.231		
	Quadratic	7.157	47	.152		
	Cubic	5.801	47	.123		
	Order 4	7.298	47	.155		
	Order 5	5.900	47	.126		
	Order 6	4.984	47	.106		
	Order 7	4.426	47	.094		
	Order 8	3.130	47	.067		
	Order 9	3.721	47	.079		
	Order 10	6.217	47	.132		
	Order 11	4.932	47	.105		
	Order 12	5.776	47	.123		
	Order 13	3.307	47	.070		
	Order 14	3.020	47	.064		

Tests of Between-Subjects Effects

Measure: NotBad

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	388.081	1	388.081	374.551	.000
Grp	2.557	1	2.557	2.468	.123
Error	48.698	47	1.036		

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