Microbial Contamination of Immersion Biometry Ultrasound Equipment

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Purpose: To investigate the prevalence of microorganisms on ultrasound biometry equipment and cleaning habits.

Design: Observational case series.

Participants: Thirty-four university-based and private ophthalmology clinics.

Methods: In a prospective multicenter study, clinics representative of every region of the country sampled their fixed immersion biometry equipment (i.e., ultrasound probe, immersion shell, and infusion tubing) for bacteria and fungi. Assessment of the cleaning habits for this equipment was conducted by way of a standard questionnaire that included type of fluid and delivery method, frequency of fluid change, method of cleaning the probe and shell, and frequency of tubing change and/or cleaning.

Main Outcome Measures: Frequency (prevalence), descriptive statistics, and type of microorganisms.

Results: Eighteen samples (53% [18/34]) grew organisms from either the probe/shell or tubing. Positive cultures were found in 32% (11/34) of the immersion shell/probes and in 31% (10/32) of the infusion tubing samples. The bacteria most commonly cultured from both probe/shell and tubing was coagulase-negative *Staphylococcus,* whereas *Penicillium* species was the most commonly cultured fungus (exclusively from the probe/shell). Overall, fungi (*Penicillium* and *Alternaria* species) were cultured in 12% of the probe/shell samples. Only 14% of the study sites adequately disinfected the probe/shell according to Centers for Disease Control and Prevention (CDC) guidelines, which recommend a 5-minute soak in antiseptic.

Conclusions: The bacteria and fungi that colonize biometry equipment are not being adequately eliminated by the cleaning/disinfecting techniques employed in most ophthalmology clinics. These results also may apply to contact biometry, pachymetry, and tonometry equipment as well. Clinicians should follow the CDC recommendations for disinfecting instruments that come in contact with the eye, and the infusion tubing should be changed after each patient. *Ophthalmology 2005;112:e13–e18 © 2005 by the American Academy of Ophthalmology.*

During the last several years, refractive expectations for cataract surgery have been increasing steadily. Because patients have come to view cataract surgery as both a rehabilitative and a refractive procedure, for better or for worse, surgeons are now being judged mainly for their refractive outcomes.[1] This has driven changes in cataract surgery and biometry techniques to improve postoperative refractive outcomes.[2]

The accuracy of ocular axial length measurements is a critical element in matching the postsurgery refractive outcome with the presurgical intraocular lens (IOL) calculation[3] such that a measurement error of just 1 mm can result in a 3-diopter refractive surprise. Mistakes in axial length determination have been shown to account for 54% of all sources of IOL errors.[4] Although the majority of ophthalmology practices still measure axial length using applanation (i.e., contact method) A-scan ultrasonography, multiple studies (Invest Ophthalmol Vis Sci 44:e-abstract 212, 2003)[2,5–11] have shown the immersion technique[12,13] to be superior in accuracy to the applanation method. Inherent to immersion biometry is the suspension of the ultrasound probe in a fluid coupling medium, avoiding physical contact with the cornea,[2] thus eliminating corneal compression. In contrast to the optical coherence biometry (OCB) technology employed by the IOL Master (Carl Zeiss, Rochester, NY), immersion ultrasound biometry with the fixed immersion shell (e.g., Prager Shell, ESI, Inc., Plymouth, MN) is

Originally received: September 22, 2004.
Accepted: January 12, 2005. Manuscript no. 2004-128.

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Data presented in part at: American Society of Cataract and Refractive Surgery Annual Meeting, May 1, 2004; San Diego, California.

This study was supported, in part, by grants from Research to Prevent Blindness, Inc., New York, New York; National Eye Institute, Bethesda, Maryland (core grant no.: EY10608); and the Hermann Eye Fund, Houston, Texas.

Drs Prager and Hardten have a financial interest in ESI, Inc., Plymouth, Minnesota. None of the other authors has a proprietary or financial interest in any ultrasound product.

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ISSN 1549-4713/05/$–see front matter
doi:10.1016/j.ophtha.2005.01.030

not hindered by dense cataracts,[14] and the clinical accuracy is equivalent to the OCB technology.[3,14,15]

A cited disadvantage of the immersion technique is the potential for infection, because the shell comes in direct contact with the sclera[16–19] and microorganisms in solution could bathe the cornea. However, it can be postulated that the potential for microorganisms to move between patients also exists for applanation biometry, tonometry, or pachymetry, because these methods involve *direct* contact with the cornea. The Centers for Disease Control and Prevention (CDC) has established guidelines[20] for instruments that come into direct contact with the external surfaces of the eye, and these recommendations should be considered by every ophthalmologist who uses immersion shells, contact biometry probes, or even applanation tonometers. The CDC states that the equipment should be wiped clean and then disinfected by (1) a 5- to 10-minute exposure to a fresh solution of 3% hydrogen peroxide, (2) a fresh solution containing 5000 parts per million (milligrams/liter) free available chlorine—a 1/10 dilution of common household bleach (sodium hypochlorite), (3) 70% ethanol, or (4) 70% isopropanol. Lastly, the device should be thoroughly air dried or rinsed in sterile water and dried before reuse.

A MEDLINE literature search did not reveal any studies identifying clinic-to-clinic variation in immersion shell hygiene, or the type of microorganisms that grow from biometry equipment. The goal of this investigation is to determine the kind of organisms found on ultrasound equipment. In this report, the cleaning habits of 34 clinics performing immersion ultrasound biometry employing a fixed immersion shell were assessed by questionnaire, and cultures were taken to identify the microorganisms present in the shell/probe and infusion tubing.

Materials and Methods

Thirty-four samples were obtained from ophthalmology offices representing every region of the country. All respondents used the fixed immersion technique, and physicians/technicians were asked to sample their biometry equipment for bacteria and fungi and queried regarding their biometry cleaning habits. Culturing was requested after biometry. University-based departments and private practice clinics were included in the cohort. Questionnaires and culture kits were sent to the respective study sites and returned directly to the University of Texas Medical School's Department of Pathology for processing. Institutional review board approval was not required for this study. Questionnaire data were entered into a spreadsheet, and study site identifiers were stripped from the records. The questionnaire was composed of 4 primary questions:

1. What type of fluid is used (tap water or balanced salt solution [BSS]) when performing biometry, and what was the delivery method?
2. What was the frequency of fluid change?
3. What was the method of probe and shell cleaning?
4. What was the frequency of tubing change and/or cleaning?

All sites were given detailed sampling instructions that included pictorial examples, and all participants were asked to maintain their usual biometer hygiene program. Not all sites answered the questionnaire or sampled both the immersion shell/probe and tubing. Thus, the denominator varies, and this is noted throughout the report.

Table 1. Organisms Cultured and Associated Eye Diseases

Environmental
Fungi *Acinetobacter* species (keratitis,*† endophthalmitis‡)
Fungi *Penicillium* species (keratitis,§ endophthalmitis‖)
Burkholderia pickettii (keratitis¶)
Pseudomonas oryzihabitans (endophthalmitis#)
Roseomonas species (keratitis**)
Alternaria species (keratitis,†† endophthalmitis‡‡)
Skin, oral, or respiratory flora
Micrococcus species (keratitis,§§ endophthalmitis‖‖)
Coagulase-negative *Staphylococcus* (keratitis,¶¶ endophthalmitis##)
Staphylococcus aureus (keratitis,*** endophthalmitis##)
Streptococcus not *pneumoniae* (keratitis,††† ‡‡‡ endophthalmitis##§§§)
Organisms cultured *not* associated with eye disease
Sphingomonas species (water‖‖‖)

*Kau HC, Tsai CC, Kao SC, et al. Corneal ulcer of the side port after phacoemulsification induced by *Acinetobacter baumannii*. J. Cataract Refract Surg 2002;28:895–7.

†Wang AG, Wu CC, Liu JH. Bacterial corneal ulcer: a multivariate study. Ophthalmologica 1998;212:126–32.

‡Gopal L, Ramaswamy AA, Madhavan HN, et al. Postoperative endophthalmitis caused by sequestered *Acinetobacter calcoaceticus*. Am J Ophthalmol 2000;129:388–90.

§Panda A, Sharma N, Das G, et al. Mycotic keratitis in children: epidemiologic and microbiologic evaluation. Cornea 1997;16:295–9.

‖Lyratzopoulos G, Ellis M, Nerringer R, Denning DW. Invasive infection due to *Penicillium* species other than *P. marneffei*. J Infect 2002;45:184–95.

¶Holland SP, Mathias RG, Morck DW, et al. Diffuse lamellar keratitis related to endotoxins released from sterilizer reservoir biofilms. Ophthalmology 2000;107:1227–33, discussion 1233–4.

#Yu EN, Foster CS. Chronic postoperative endophthalmitis due to *Pseudomonas oryzihabitans*. Am J Ophthalmol 2002;134:613–4.

**Tabin G, Danenhower C, Reardon D, et al. Opportunistic *Roseomonas* keratitis [letter]. Cornea 2001;20:772–3.

††Zahra LV, Mallia D, Hardie JG, et al. Case report. Keratomycosis due to *Alternaria alternata* in a diabetic patient. Mycoses 2002;45:512–4.

‡‡Rummelt V, Ruprecht KW, Boltze HJ, Naumann GO. Chronic *Alternaria alternata* endophthalmitis following intraocular lens implantation [letter]. Arch Ophthalmol 1991;109:178.

§§Kent HD, Cohen EJ, Laibson PR, Arentsen JJ. Microbial keratitis and corneal ulceration associated with therapeutic soft contact lenses. CLAO J 1990;16:49–52.

‖‖Cartwright MJ, King MH, Weinberg RS, Guerry RK. *Micrococcus* endophthalmitis [letter]. Arch Ophthalmol 1990;108:1523–4.

¶¶Wong T, Ormonde S, Gamble G, McGhee CN. Severe infective keratitis leading to hospital admission in New Zealand. Br J Ophthalmol 2003;87:1103–8.

##Benz MS, Scott IU, Flynn HW Jr, et al. Endophthalmitis isolates and antibiotic sensitivities: a 6-year review of culture-proven cases. Am J Ophthalmol 2004;137:38–42.

***Cosar CB, Cohen EJ, Rapuano CJ, Laibson PR. Clear corneal wound infection after phacoemulsification. Arch Ophthalmol 2001;119:1755–9.

†††Ormerod LD, Smith RE. Contact lens-associated microbial keratitis. Arch Ophthalmol 1986;104:79–83.

‡‡‡Nauheim RC, Nauheim JS. Contact lens-related *Streptococcus viridans* keratitis presenting as an epithelial defect [letter]. Arch Ophthalmol 1991;109:1354.

§§§Oshitari K, Hirakata A, Okada AA, et al. Vitrectomy for endophthalmitis after cataract surgery [in Japanese]. Nippon Ganka Gakkai Zasshi 2003;107:590–6.

‖‖‖White DC, Sutton SD, Ringelberg DB. The genus *Sphingomonas*: physiology and ecology. Curr Opin Biotechnol 1996;7:301–6.

Sampling Procedures

Both the ultrasound probe and the immersion shell were sampled using a nasopharyngeal swab dipped in a sterile tube of trypticase

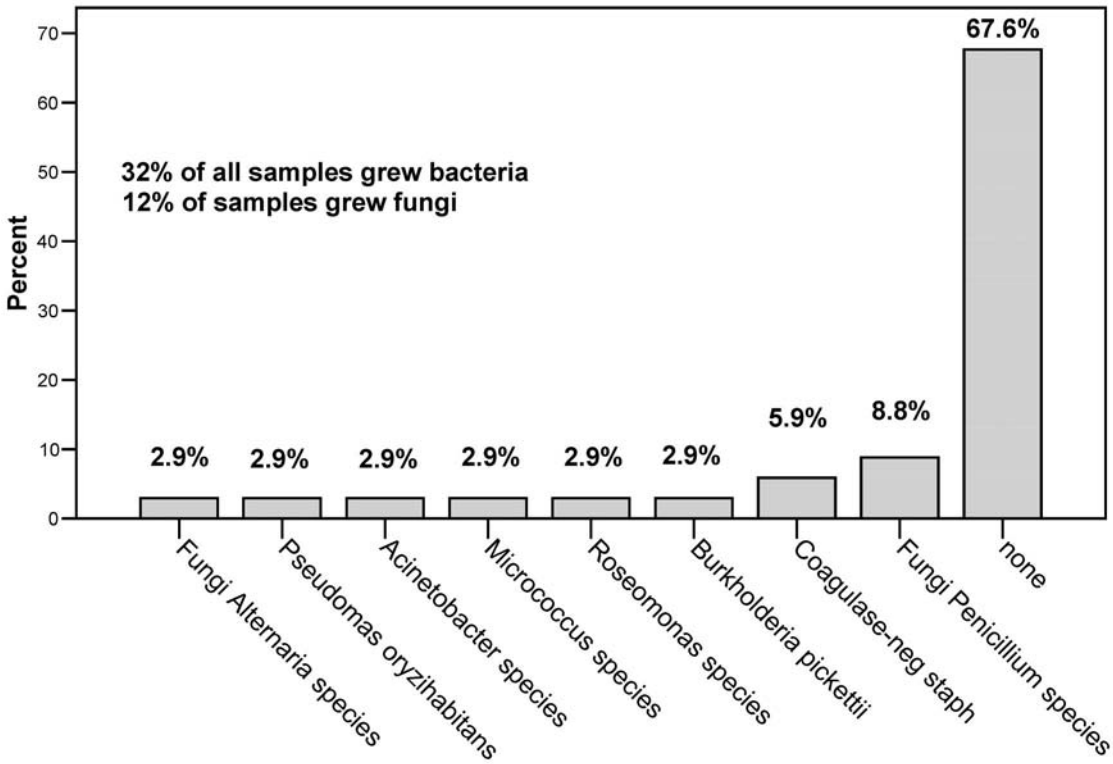

Figure 1. Organisms grown from probe/shell cultures and percents.

soy broth. The swab was then placed back into the culturette for transport. The fluid expressed from the Luer fitting and tubing (1 cm^3) was also collected and placed into the tube of trypticase soy broth. Both the swab and the tube of broth were transported overnight to the University of Texas Department of Pathology Laboratory for processing.

Processing of Samples

The broth was incubated at 35 °C for 24 hours, and then subcultured onto blood agar, chocolate agar, and sabouraud dextrose agar. The nasopharyngeal culturette was swabbed onto the same culture media. The blood and chocolate agars were incubated at 35 °C for 48 hours, and the sabouraud dextrose agar at 30 °C for 7 days. All organisms were identified by routine microbiological methods. Fungi were identified by colonial and microscopic morphology.

Results

Organisms were commonly found in cultures from both the probe/shell and tubing. Eighteen of the total 34 samples (53%) grew organisms from either the probe/shell or tubing. There were data on 32 samples in which *both* probe/shell and tubing cultures were taken. In 7 (22%) sites, organisms were retrieved from the probe/shell cultures, and 7 (22%) sites yielded organisms from the tubing cultures. Three sites (9%) retrieved organisms from both probe/shell and tubing cultures.

Microorganisms fell into 2 broad groups: *environmental,* usually found in water or soil, and *skin, oral, or respiratory flora.* Table 1 lists the specific organisms found grouped by category as well as associated eye disease. T1

Figures 1 and 2 show frequency distributions by organism, for probe/shell cultures (Fig 1) and for tubing cultures (Fig 2). In 11 of 34 (32%) probe/shell samples and 10 of 32 tubing samples (31%), organisms were cultured. It should be noted that after soaking a probe/shell for 5 minutes in alcohol, no organisms grew nor were there positive cultures when BSS was expressed from new sterile tubing, a finding that was replicated twice. F1-2

Most sites, 93% (27/29), used BSS as the coupling agent when performing immersion biometry, but 7% (2/29) employed tap water. From a total of 29 respondents using BSS, 52% reported that the fluid was changed after every patient, and 21% refreshed the fluid at least daily. The remaining 28% waited until the BSS bottle or syringe of fluid was empty.

Tubing change behavior varied across the 29 sites reporting. With the modal response, 45% reported changing tubing after every patient, whereas another 21% replaced tubing at least daily. However, 35% waited until the tubing was no longer functional.

The entire cohort of 29 respondents cleaned their shell with some type of disinfectant, and as depicted in Figure 3, the overwhelming majority, 86%, used an alcohol wipe, whereas the minority, 14%, soaked the probe/shell in alcohol for 5 minutes. F3

Chi-square tests (nonparametric analyses of frequency data) were performed to establish an association between category of shell fluid changes (after each patient, daily, or when bottle is empty) and presence of organisms in the subsequent cultures. Due to small cell size, the 3×2 analysis was not significant ($P = 0.48$). Small cell size also produced no significance when analyzing tubing change (after each patient, daily, or when tubing wears out) ($P = 0.26$). Thus, definite conclusions cannot be drawn from these analyses.

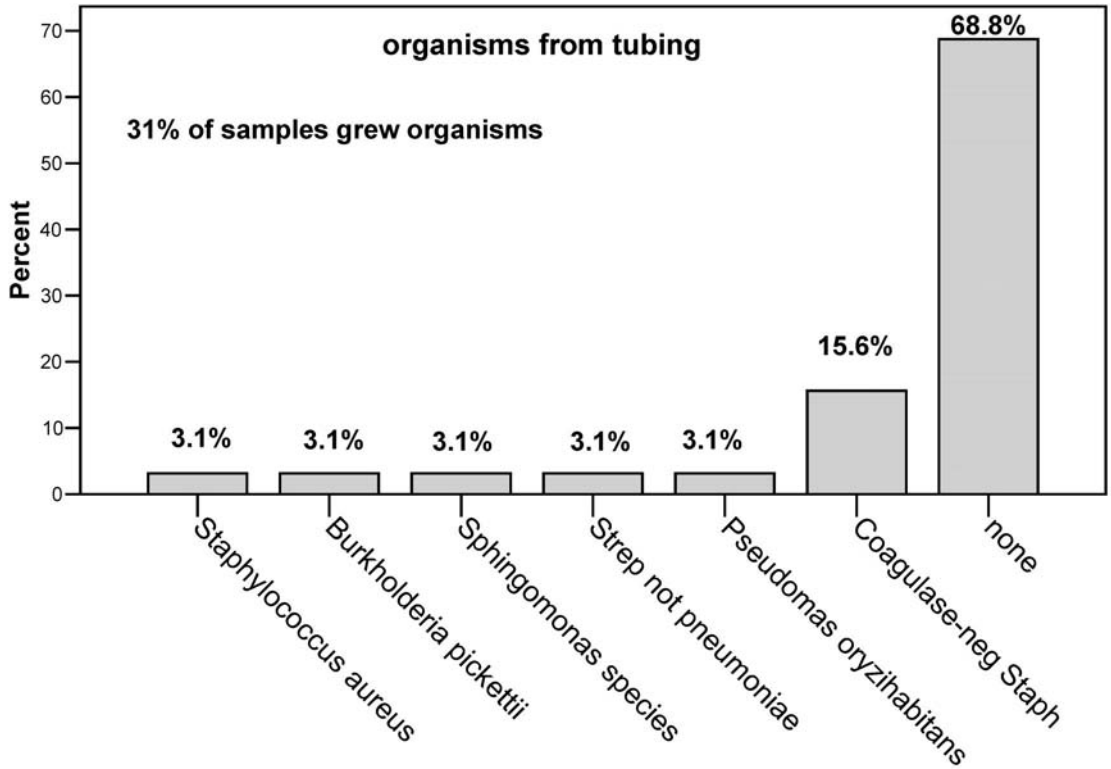

Figure 2. Organisms grown from tubing cultures and percents.

Discussion

In this study, 53% of all samples grew organisms from either the immersion shell/probe or the infusion tubing. The probability of finding organisms was equally likely in shells or tubing. Thirty-five percent of the study sites changed tubing when it was no longer functional, and only 13.8% adequately soaked the shell in alcohol. Our findings suggest that most biometry laboratories do not meet the CDC recommendations for cleaning instrumentation that comes in contact with the eye.

This investigation demonstrates that bacteria and fungi colonize the immersion shells/probes and/or infusion tubing in most clinics, and if the biometry equipment is not cleaned well, microorganisms can survive in the absence of rigorous cleaning or changing tubing between patients. One relevant consideration is that the immersion ultrasound equipment may serve as a potential vector for transmission of normal microbial flora between patients, and these microbes can be opportunistic pathogens in the right host. Although this assumption is logical, rarely occurring outcomes are difficult to investigate prospectively, especially when there is a latency period between exposure and infection. Notably, all but one (*Sphingomonas*) of the organisms cultured from either the probe/immersion shell or tubing have been shown to cause ocular disease, as summarized in Table 1. Of greater concern is the utilization of immersion or contact biometry shortly before cataract extraction, in which inadvertent inoculation of microbes from the tubing, shell, or probe may occur, with the potential for entry into the eye. Coagulase-negative staphylococci are the microorganisms most commonly found in the conjunctiva and eyelid skin,[21] and it has been reported that the primary source of bacteria in culture-positive cases of endophthalmitis is the patient's ocular surface and periocular skin flora.[22,23] Among our pathology samples, the prevalent bacteria identified was coagulase-negative *Staphylococcus,* the most common cause of postoperative endophthalmitis.[24]

Although viral contamination was not assessed in this study, previous studies have confirmed that viruses may be transmitted between patients via Goldmann tonometer and pneumotonometer tips, resulting in outbreaks of epidemic keratoconjunctivitis.[25–27] The likelihood of growing human immunodeficiency virus would be very low in these cases. However, other viruses such as adenovirus, herpes simplex virus, influenza, and hepatitis A and C can survive on inanimate objects for extended periods of time.[28–31] Microorganism transmission is not limited to the immersion technique, but is likely in contact biometry. In a direct analogy to biometry with an applanation probe (contact technique),[31] hepatitis C virus RNA contamination on Goldmann tonometers was reduced by only 11% (89% of contamination remained) after a 5-second isopropyl alcohol wipe (the preferred cleaning method in 86% of the respondents in this report), but only 2% remained when the CDC guidelines were followed. Smith and Pepose also have shown that a 5-minute soak in alcohol or peroxide is effective in the disinfection of viruses such as hepatitis C virus and organisms such as acanthamoeba.[32] The time soaking the probe/shell can be spent explaining the procedure to the patient and logging relevant information.

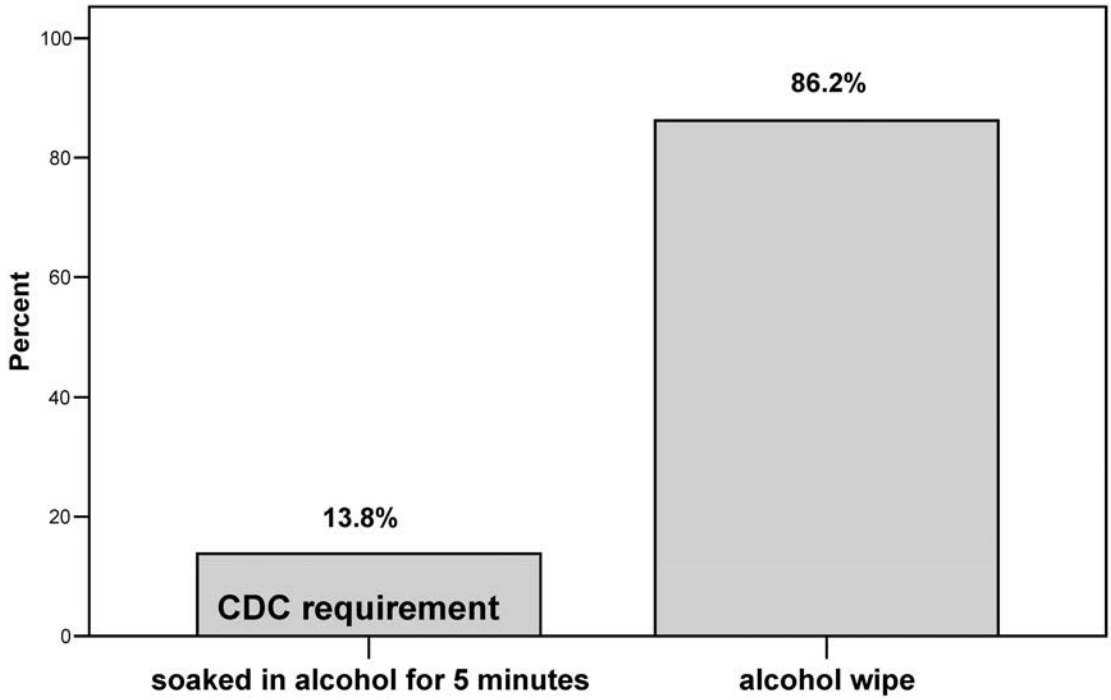

Figure 3. Method of probe/shell cleaning. CDC = Centers for Disease Control and Prevention.

Some of the centers in this study used tap water to fill the immersion shells. Tap water potentially harbors pathogenic organisms such as acanthamoeba.[33] Eliminating the presence of organisms is important in situations where patients have active skin or eye infections, or if a patient is immunosuppressed either systemically or locally (i.e., with topical steroids). This study may present some bias and represent a best-case situation because all the study centers were aware that they were being evaluated, even though the protocol asked that the routine cleaning procedures remain unchanged and that culturing take place before the biometry measurement. All centers may not have complied with the latter protocol requirement, as 4 cultures grew bacteria from sterile tubing, suggesting that sampling may have taken place after biometry or that the sample was somehow contaminated by handling. In our laboratory, following CDC guidelines, fluid expressed from sterile tubing did not grow contaminates, a result that was replicated several times.

To prevent the spread of organisms, universal precautions are important, and subjecting the immersion shell and probe to an aseptic soak in a beaker for 5 minutes and changing tubing/BSS between patients are straightforward. The relative cost to initiate this prophylactic precaution currently represents $2.30 per patient, and is a small fraction of the Medicare reimbursement for biometry. Clinic personnel can quickly, efficiently, and economically reduce the likelihood of bacterial contamination and help prevent bacterial spread to other patients.

Immersion biometry is very accurate, reproducible, fast, well tolerated by most patients, and easy to learn (Invest Ophthalmol Vis Sci 44:e-abstract 212, 2003).[14,19,34,35] Nevertheless, there are still some misconceptions about this technique. Among surgeons and staff alike, it is perceived as technically difficult, time consuming, and uncomfortable for the patient.[1] In our experience, nonetheless, the learning curve is only a few patients, and the procedure is well tolerated. Although OCB has emerged as a new modality for biometry[16] whose accuracy compares very closely to immersion ultrasound biometry,[3,14,19,34,36] there are associated drawbacks. One advantage is that OCB is not subject to cross-contamination because it is a noncontact procedure, but visual acuity must be equal to or better than 20/200.[3] Further, OCB does not allow reliable measurements in the presence of any significant axial opacity (e.g., corneal scars; keratopathy; severe tear film problems; dense posterior subcapsular cataracts; brunescent cataracts; vitreous hemorrhage, neovascular membranes, maculopathy, and retinal detachment).[3,15,36,37] Optical coherence biometry cannot be performed when the subject has tremor, respiratory distress, nystagmus, or lid abnormalities, or when he or she cannot fixate on a target.[3,38] Consequently, eyes of 8% to 17% of patients cannot be measured with OCB.[3,15,35,37,38] In addition, instrumentation is expensive. Thus, there will always be a role for immersion biometry in the foreseeable future.

The findings reported also would apply to contact applanation probes—the open cylinder design (Hansen Ophthalmics, Iowa City, IA) for immersion biometry as well as the fixed immersion shells (Prager Shell, ESI, Inc., Plymouth, MN). The findings of organisms on biometry equipment are prevalent, and this may increase the risk of infection. However, this risk can be reduced by following the CDC recommendations of soaking the shell/probe in an antiseptic solution for at least 5 minutes and changing tubing/BSS for each patient.

Acknowledgements. The authors thank Karen Pawlowski, BS, MTASCP, and Steven Hightower, BS, from the University of Texas Medical School–Houston Department of Pathology, who processed the samples.

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