

Residents Prefer Traditional Over Virtual Slides

BY SHERRY BOSCHERT

SAN FRANCISCO — Medical residents made similarly accurate diagnoses using virtual microscopy or traditional glass microscopy, but said they'd prefer glass slides when being tested, results of a randomized study of 132 residents found.

The dermatology and pathology residents at 14 institutions diagnosed neoplastic and inflammatory skin conditions after examining slides in virtual (computerized) and glass format. Each of 20 cases appeared in both virtual and glass slides, but the order in which the residents saw them varied among randomized subgroups of participants.

Residents correctly diagnosed a mean of 5.5 cases on glass slides and 5.6 cases on virtual slides, Dr. Laine H. Koch and associates reported at the annual meeting of the American Society of Dermatopathology.

The order in which slides were viewed did not change diagnostic accuracy between groups. The rate of correct diagnoses increased with each additional year of residency, but did not differ between same-level residents based on the use of virtual or glass microscopy, said Dr. Koch of Eastern Virginia Medical School, Norfolk.

When asked their opinions of the experience in an 11-item questionnaire, however, 79% of residents said they think virtual microscopy is useful for learning, but only 47% said it is useful for testing.

Approximately 40% complained of one or more problems during virtual microscopy.

Complaints from 31% of residents pointed to fuzzy images on the computer screen, while 10% reported poor color on the screen, 9% said the image froze on

the screen, and 8% complained of poor contrast. Four complaints each were reported by less than 5% of participants: difficulty starting the computer, inability to adjust the screen, computer failure, or power failure.

At one institution, all residents complained of problems with image clarity, while another institution produced no complaints about clarity, and responses varied from the other 12 institutions. It may be that fewer image problems occurred when all residents completed the exam in a computer lab, compared with using the technology on a computer of their own choice, Dr. Koch said.

Glass slides have been considered the highest standard for diagnosis and for medical education in histology and pathology. They are easy to prepare and are part of learning to use light microscopes, but can be expensive to purchase, maintain, store, and distribute for educational purposes. Virtual slides can be duplicated endlessly and inexpensively, stored and catalogued easily, and can be made available to many people in a variety of locations.

As a result, medical schools increasingly are incorporating virtual microscopy into curricula, and in some programs virtual microscopy has replaced traditional microscopy entirely, Dr. Koch said.

At the start of the study, 23% of residents reported some experience with virtual slides, usually from online or Internet sources.

Diagnostic accuracy after examining virtual slides in the study did not differ significantly between residents who had or had not used virtual slides before.

Few studies have looked at the performance of students using virtual or glass microscopy. One study that randomized first-year dermatology and pathology residents from 14 institutions found no significant differences in test scores (*Clin. Anat.* 2007;20:565-70).

The 132 students in the study were given a randomized combination of 10 virtual and 10 glass slides of dermatopathology disorders and were asked to correctly select the diagnosis from a list of foils. They were also asked to report their subjective experiences with virtual microscopy.

Investigators in the current study prepared glass slides using standard hematoxylin and eosin staining techniques. Virtual slides were created using a slide-scanning machine and were distributed to the medical schools on compact discs. Dr. Koch and her associates have no association with the company that makes the scanning machine, but are considering negotiating an educational discount to obtain one, she said.

One dermatology resident in the audience who participated in the study said the main problem with virtual microscopy was the slow speed of loading images. "Any time you moved around [in an image], it was like waiting for the dial-up connection to have your Internet," she said. "It was really cumbersome. Once that's straightened out, I think it will be super." ■

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Dermatology Lexicon Web Site to Be Launched by AAD

BY ALICIA AULT

The American Academy of Dermatology is launching an online dictionary of common terms that it hopes will aid dermatologists, primary care physicians, and other practitioners in communicating, securing reimbursement, and reporting adverse events.

DermLex grew out of a 5-year grant issued by the National Institute of Arthritis and Musculoskeletal and Skin Diseases in 2001 to Dr. Art Papier and Dr. Lowell Goldsmith at the University of Rochester (N.Y.) dermatology department to develop a universal dermatology lexicon. Five years later, the AAD took over the project, and the initial version 1.0 was expected to be live on its Web site (www.aad.org/research/lexicon) at press time.

Dr. Mark Pittelkow, chairman of the AAD's Medical Informatics Committee, said that the most important goal of DermLex is to create a common language among dermatologists but also between specialties. It should help make coding more accurate, he said in an interview. DermLex will also contribute to better patient care and improve provider education, said Dr. Pittelkow.

Eventually, DermLex should have online tools so it seamlessly integrates into an electronic medical record, said

Dr. Pittelkow. The compendium is similar to SNOMED-CT (Systematized Nomenclature of Medicine—Clinical Terms), which was developed by the College of American Pathologists and is owned, maintained, and distributed by the International Health Terminology Standards Development Organisation (IHTSDO), a not-for-profit association in Denmark.

Dr. Pittelkow said that hopefully, DermLex will be used as a companion to SNOMED-CT.

Currently, DermLex is primarily a compendium of terms organized in a hierarchical fashion, he said. The Medical Informatics Committee still is working on formal definitions for all the terms.

The database will be open to the public, but AAD members will likely get additional tools that will not be available to nonmembers, Dr. Pittelkow said.

The AAD is providing the technical and financial support for the project, although it has been a largely volunteer effort up until this point. The need for ongoing support will be great, he said.

"Some may view (DermLex) as a sort of stamp collecting, but it's supposed to be very alive and dynamic," said Dr. Pittelkow. He made no disclosures. ■

Biologics Data Exclusivity Debate: No End in Sight

BY DENISE NAPOLI

Follow-on biologics legislation without a long period of data exclusivity for the original drug would significantly hinder future innovation, according to one economist.

Meanwhile, legislators' insistence that incentives for innovation be balanced with generics' promise of affordability means that a regulatory pathway for the drugs could remain uncharted in 2009.

Data exclusivity for follow-on biologics is the "period of time after [a biologic drug's] approval before a follow-on biologic can enter the market with an abbreviated filing" that relies on the original drug's safety and efficacy data, said Henry G. Grabowski, Ph.D., at a recent audioconference sponsored by Avalere Health LLC, a health care consultancy.

Because a "typical" new biologic drug might cost up to \$1.2 billion in research and development, the "data exclusivity [period] acts as an insurance policy to ensure that there is adequate incentive" to produce the drugs in the first place, said Dr. Grabowski, a professor of economics and director of the program in pharmaceuticals and health economics at Duke University in Durham, N.C.

Ann Witt, a health care adviser to Rep. Henry Waxman (D-Calif.), who cosponsored the 1984 generic drugs legislation,

disagreed with Dr. Grabowski's assessment. "Many of the arguments we heard here today were also made in 1984 by the then-manufacturers of small molecule drugs, who insisted that innovation would come to an end" with the advent of generics, she pointed out. Since then, "I have never heard anyone claim that that bill reduced innovation in the pharmaceutical industry," she said.

The Food and Drug Administration's stance seems to side with Dr. Grabowski and the drugmakers. A Sept. 18, 2008, letter from the FDA's then-chief scientist, Dr. Frank M. Torti, states: "The Agency believes that sponsors that develop innovative biotechnology products should be eligible for a significant period of market and/or data exclusivity, independent from any patent protections that might be applicable to the product, to ensure continued innovation."

Dr. Torti has since taken over as the FDA's acting commissioner.

The letter was addressed to the chairman of the House Subcommittee on Health, Rep. Frank Pallone Jr. (D-N.J.). The subcommittee is a division of the House Committee on Energy and Commerce, of which Rep. Waxman was recently appointed chairman. Ms. Witt said that legislation supporting a follow-on biologics pathway would be a high priority for the committee in 2009. ■