VA, DoD Meet to Forge Ties on Prosthetics Research

[VA R&D COMM./NOV. 20, 2003]

With an increasing number of soldiers suffering limb loss due to combat in Iraq and Afghanistan, prosthetics researchers and clinicians from the Department of Veterans Affairs (VA) and Walter Reed Army Medical Center (WRAMC) met on Nov. 17 and 18 in Arlington, Va., to outline joint initiatives to further prosthetics research and improve care for military and veteran amputees. The conference, sponsored by VA's Rehabilitation Research and Development Service and also attended by industry and university experts, fostered discussion on several proposed projects now under consideration by VA and WRAMC, such as the development of a shared database on military and veteran amputees and rigorous clinical trials comparing high-tech artificial limbs to less costly conventional devices.

"I hope this is the beginning of a 'beautiful friendship' between VA and the Department of Defense," said Mindy Aisen, MD, a neurologist and deputy chief research and development officer for VA, noting it was perhaps the first such joint research conference on prosthetics between the two agencies. Aisen said that by working together to develop shared outcome measures and data collection systems—among other initiatives—the two departments "will have a much more powerful way to provide a continuum of care and answer the important questions that beg investigation about early, late and long-term interventions for people with limb loss."

A highlight of the two-day event was a talk from Secretary of Veterans Affairs Anthony J. Principi, who cited a directive from President Bush that VA and DoD cooperate in projects such as the development of a joint formulary and medical record-keeping system. He said his resolve to strengthen VA-DoD ties was affirmed by recent visits to seriously wounded patients at WRAMC in Washington and the National Naval Medical Center in Bethesda, Md.

"I am deeply touched by their strength of will, their determination to overcome their wounds, and their unflagging trust in the medical professionals treating their often horrific injuries," said Principi, who himself led river patrols in Vietnam and whose two sons, both Air Force captains, have served in Iraq. "My visits increased my determination to help make these heroes whole again—particularly youngsters, who have lost arms and legs, at a time in their lives when society beckons them to be full participants." He pledged to make VA resources available to expand research, training and care in prosthetics and to explore relevant new technologies, such as microelectronics.

Testing the C-Leg

One topic of lively discussion at the meeting was the much-publicized "C-Leg," an artificial leg with a sophisticated microprocessor-controlled knee that costs around $50,000 and is widely regarded as state of the art. The leg, however, has never been tested in randomized, double-blinded clinical trials—the gold standard of medical decision-making.

VA, DoD and Medicare currently authorize the leg for above-knee amputees when appropriate. In fact, recent media articles profiled soldiers who had been fitted with the leg at WRAMC. But questions remain about whether some patients—particularly those who are less active—would do just as well with a lower-tech device.

Lt. Joseph Miller, CP, MEd, chief prosthetist at WRAMC, led a workgroup that developed a tentative plan for a crossover trial at WRAMC that would have amputees wear the C-Leg for three months and an older, hydraulic-powered model for three months. Attendees debated whether the study could enroll enough participants to produce meaningful data; whether it would be feasible to "blind" the research; and whether soldiers' preconceptions of the C-Leg's superiority would bias the study.

Miller asserted that while his patients do tend to perceive the C-Leg as the "best" on the market, they also know its limitations—the need to recharge it every night, for example, and shield it from grime. "Our guys want to get out in the mud and the dirt sometimes, and they know the C-Leg is not a tool for that," he said.

Is expensive always better?

At several points in the meeting, VA's Aisen emphasized that medical practice—as well as health-care policymaking and reimbursement—should be driven only by hard data from well-designed experimental studies. Regarding the C-Leg, she said, "We don't yet have bullet-proof data showing these devices are worth the money."

Making a similar point with regard to upper-limb prostheses, T. Walley Williams, a private-industry bioengineer who works on shoulder systems, said, "There's very little in the way of 'this device works better than this device' numbers to justify where we are, and where we want to go. … We get enamored by the 'sexy' new stuff, and don't do a good job of looking at what's already out there that works very well."

Steven Gard, PhD, director of the VA Chicago Motion Analysis Research Laboratory, added: "Expensive is not always the best. At this point, we don't know what the best is."

Williams expressed frustration over high-end components that are engineering marvels but do not come into wide use because of their prohibitive cost: "If we can't afford to get it on the amputee, why did we bother going through this exercise?"

Investing in CAD/CAM

The meeting also featured lively exchanges on the merits and drawbacks of Computer Aided Design and Manufacture (CAD/CAM), widely accepted as the quickest, most cost-effective means of producing the sockets into which prosthetic legs are fitted. VA installed CAD/CAM equipment at 36 clinics in the mid-1990s, but the system hasn't been widely used, partly due to technology incompatibilities and a lack of education. Moving to reverse this trend, VA initiated a dialogue earlier this year with Otto Bock Healthcare to perform a systems analysis pilot study on updated equipment and to brainstorm ways to expand CAD/CAM training for VA practitioners.

Currently, many VA staff or contract prosthetists still use the manual method of production, in which plaster is used to create a negative mold of the residual limb. The mold is then filled with more plaster to make a positive model, which is carefully hand-sculpted and rasped into final form. The socket is then laminated or vacuum-formed over the model.

With CAD/CAM, imaging technology is used to create a digital representation of the "topography" of the residual limb. The digital image is brought up on the computer screen, where it can be modified with special software. The data is then fed to an automated carving, or milling, apparatus that shapes the residual-limb model out of foam or a mixture of plaster and corn starch.

Some prosthetists at the VA-DoD meeting expressed a personal preference for the older method, seeing it as a delicate art form that cannot be replicated by machinery, computers and templates. Alvin Pike, a prosthetist at the Minneapolis VA Medical Center, said what is needed is not further investment in CAD/CAM, but better training in manual methods: "We are losing the art of prosthetics, because we no longer have a mentoring system."

But more typical were comments on the "incredible time-saving" features of CAD/CAM, or its ability to produce precise and replicable results. "Prosthetists can't measure what they're doing. CAD/CAM can," said David Allen Boone, CP, MPH, a prosthetist at Hong Kong Polytechnic University.

Cheryl Stetler, RN, PhD, an independent consultant in translational research, stressed that any VA training effort—whether in CAD/CAM or other areas—had to incorporate what she called "evidence-based strategies" for bringing about changes in attitudes and practice. "Passive education—that is, without context, facilitation, and ongoing use of the information—is unlikely to result in sustained change," she said.

On the horizon: Osseointegration

Another focus at the meeting was osseointegration, a technique developed in Sweden whereby prostheses are affixed to a special titanium bolt anchored directly into the bone of the residual limb, rather than by means of a custom-designed hard-plastic socket and silicone or urethane liner fitted over the stump. The principle is widely applied for dental implants, and for amputees is said to eliminate many of the complications of sockets, such as skin sores, sweating and pain.

Rickard Branemark, MD, PhD, son of the originator of the method and today its leading proponent, was accompanied at the VA-DoD meeting by Erik Ax of Sweden, one of about 50 amputees worldwide who Branemark said are currently benefiting from the technology.

Ax answered questions from attendees and at one point lifted his artificial leg up at the knee and moved it around in circles to show how he could control the limb. Responding to a question on infections, he explained how twice daily he cleans the area where the bolt extrudes from the skin, and said the routine was no more complicated than "brushing your teeth."

A workgroup at the meeting sketched out a proposed VA clinical trial of the procedure. According to Joseph Czerniecki, MD, assistant chief of rehabilitation for the VA Puget Sound Health Care System, the trial might incorporate imaging technologies such as MRI or CT-scans to track and evaluate the integration of the titanium into the bone. Czerniecki said one goal of the trial would be exploring ways to shorten the time between initial surgery and actual prosthesis-fitting, which can be 12 to 18 months.

Standardizing measurement across VA, DoD

Attendees also proposed an agenda to standardize the way clinicians and researchers measure functioning and outcomes for amputees, so data can be more easily shared among VA and DoD practitioners. Examples of the various outcome measures currently used are the Six Minute Walk Test and the Prosthetics Evaluation Questionnaire, developed by outcomes researcher Gayle E. Reiber, PhD, MPH, and her team at the Puget Sound VA.

The conference participants agreed on the need for more objective and consistent measures of gait—how a person walks—to determine how well lower-limb components are performing. Gene Alexander, PhD, a VA researcher from the Palo Alto VA with an appointment at Stanford University, discussed his work using motion-capture technology like that used in the video-game industry to record and precisely replicate, through computerized animation, the movements of celebrity athletes. He showed a video of rehabilitation patients wearing form-fitting bicycling jerseys or black spandex pants with bright reflective markers. The markers are picked up by high-speed video cameras and translated into electronic graphs showing musculoskeletal movement.

An additional area of consensus among the researchers, clinicians and engineers at the meeting was the need for lighter-weight and more versatile upper-extremity prostheses. Williams, the bioengineer, said his field needs better access to lightweight, super-strong materials, such as the boron fiber-reinforced alloys used mainly in the space industry.

The importance of a team approach

Another central theme at the meeting was the importance of a team approach to prosthetics care—in particular, engineers working closely with clinicians to ensure that devices are designed to fit the needs of patients.

Danielle M. Kerkovich, PhD, acting assistant director of VA Rehabilitation Research and Development and coordinator of the conference, touched on the importance of physical therapists in the prosthetics team: “We can add all the componentry we want, but if people are not rehabilitated properly, it goes nowhere.”

Lt. Col. Paul Pasquina, MD, chief of physical medicine and rehabilitation at WRAMC, pointed to the diverse range of disciplines that work together to care for military amputees, from battlefield evacuation and surgery all the way through therapy and rehabilitation. He provided a stark reminder of the harsh, jarring reality of traumatic injury when he spoke about incoming U.S. casualties and showed graphic clinical slides of amputees’ wounds, taken at Army field hospitals. Pasquina described the amputees as highly motivated and eager to return to a

physically demanding lifestyle—even active military duty in many cases—and underscored the need for durable, functional prostheses.

The two-day conference allowed ample time for participants to exchange information and ideas with colleagues in their field and those from different disciplines and work settings. Army physiatrist Jeff Gambel, MD, raised a question about the durability of components for amputees who wish to return to active duty and may face extreme weather. Boone, the Hong Kong-based prosthetist, informed the group about a website hosted by Monash University in Australia, providing extensive information on that issue.

"The Australians are very rough on their components," commented Boone. "A lot of users are in the outback and very active."

In her closing remarks, Aisen urged the participants to continue their dialogue and approach VA for support of their projects, both in terms of funding and assistance with study design. "There's a lot of collaboration that needs to continue beyond these few days," she said. "We want to work together in any way we can—even if you've got an unusual idea, send it our way and we'll try to make it work."

Slide presentations and other materials from the meeting can be viewed on the VA Rehabilitation Research and Development website at www.vard.org.

###