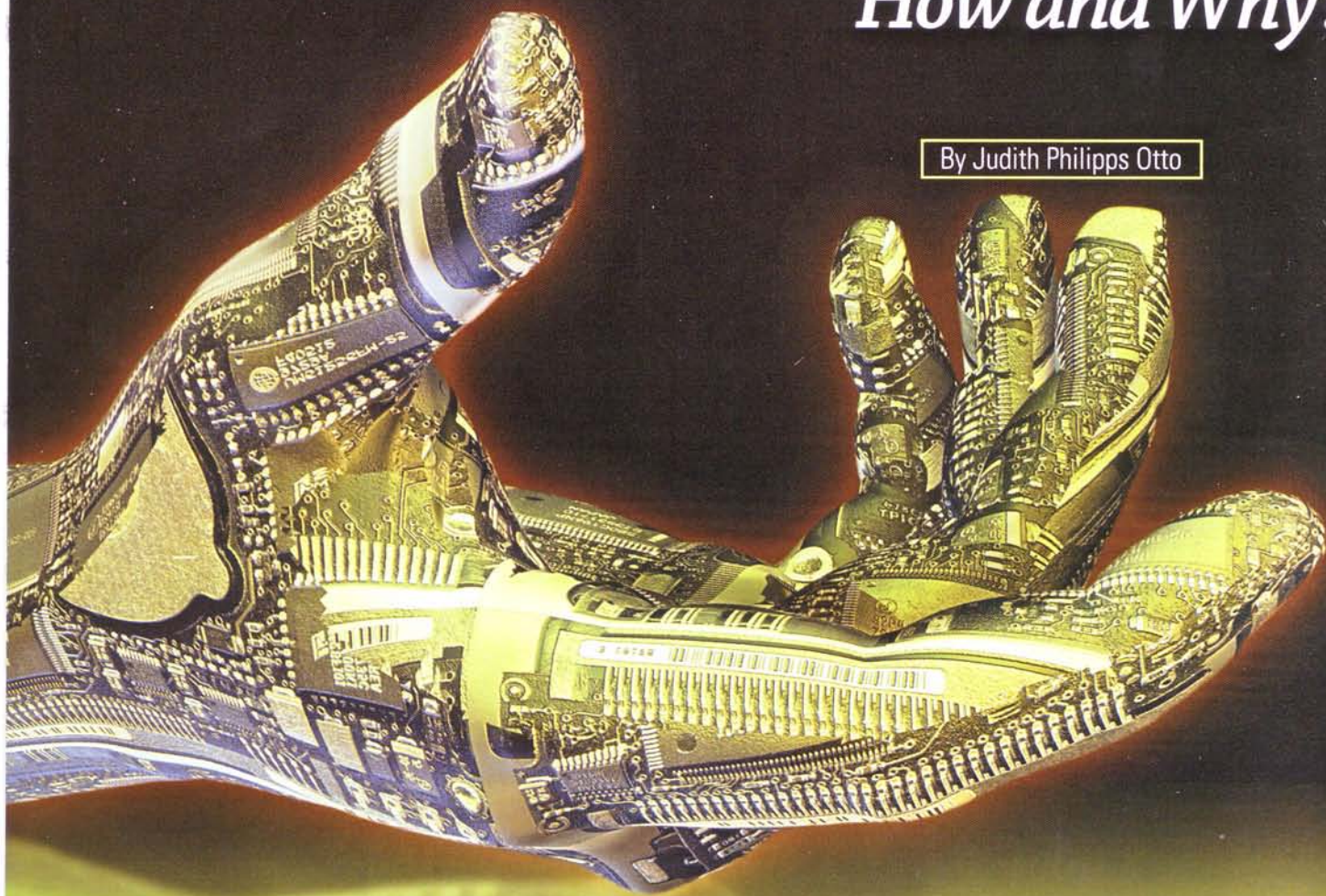


# DARPA

## Revolutionizes Prosthetics

*How and Why?*

By Judith Philipps Otto



## Times change. Perceptions change.

*Once upon a time, not so long ago, only a relatively small ratio of the population had experienced limb loss or amputation, and only a few dedicated manufacturers and individuals with limited resources focused on research and development of new prosthetic solutions.*

As healthcare improved, people began living longer and surviving traumatic limb loss and elective amputations resulting from vascular disease. Improved sockets and liners, microprocessor knees, and smart ankles appeared to meet the demands of a growing population of lower-limb amputees.

Still, only one amputee in 13 was an upper-limb amputee. That changed after 9/11, when the Middle East conflicts started to take a terrible toll on young American servicemen and servicewomen because of improvised explosive devices (IEDs) and other instruments of war. The sudden upsurge in amputations—both upper and lower limb—motivated the Department of Defense (DoD) to become involved, specifically through DARPA (Defense Advanced Research Projects Agency).

Since its birth in 1958, DARPA has been using its formidable brainpower and virtually bottomless financial reservoir to keep the U.S. military's technology ahead of its enemies. Along the way, it developed the Internet, the Global Positioning System (GPS), night-vision goggles, titanium, Gore-Tex®, and unmanned vehicles, to name just a few.

**Col. Geoffrey Ling, MD, PhD**, former professor and acting chair of the Department of Neurology at the Uniformed Services University of the Health Sciences (USUHS), Bethesda, Maryland, currently serves on the critical care staff at Walter Reed Army Medical Center (WRAMC), Washington DC, and Johns Hopkins Hospital, Baltimore, Maryland. He also serves as the manager of DARPA's Revolutionizing Prosthetics program, which is largely responsible for the explosion of recent advances in upper-extremity prosthetics.

### Why the Focus on the Upper Arm?

"First," says Ling, "it's doggoned hard—and that's what DARPA is all about. Our job is to show that things that are thought to be impossible are, in fact, possible."

Existing upper-extremity prostheses are vastly inferior to lower-extremity prostheses in terms of functionality, largely due to the complexity of a five-fingered hand with an opposable thumb that allows 27 separate ranges of motion.

While soldiers can and have chosen to go back to duty wearing a C-Leg®, the best thing available for upper-limb amputees was a hook hand and maybe a powered elbow, Ling discovered. "That's not nearly enough functionality for young people. The goal here is to provide enough functionality so that they can go back to active duty if they so choose. Our country is based upon choices, and we sure like to give choices back to these young people who have sacrificed so much."



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Ling ticked off a list of needs: a five-fingered hand; an elbow that can actually lift a decent amount of weight; a wrist that moves; and a shoulder. "When you look at science right now—based upon myoelectric control that uses residual muscles—you simply don't have enough residual muscles to move all of the fingers and the thumb. Even if you were Bill Gates and you wanted to buy it, it just doesn't exist."

The mechanical arm doesn't exist because there would be no way to control one if it did. With insufficient available muscle, myoelectrics can't do it. The natural answer, says Ling, is to tap into the person himself for the control. "You need the person's nervous system—their own thinking—to drive the arm." A simple desire or intent—not a conscious focus on the mechanics of each function—should drive movements.

Creating a brain-controlled arm that functions like a real one—weighing only eight pounds, matching the dimensions and appearance of a natural arm, waterproof, with on-board power—was a tall order that no one else was equipped to tackle—not the U.S. Department of Veterans Affairs (VA), and not the National

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Institutes of Health (NIH). And yet, says Ling, “we now had an increasing number of very fine service people who needed it.

“That’s when DARPA stepped in. We are the impossible guys. Fortunately we had a program ongoing, called HAND—Human Assisted Neural Devices—that was started back in the late ’90s.” Its objective was to translate the patient’s intent into a way of controlling assistive devices like wheelchairs. Ling cites the groundwork done by Miguel Nicolelis at Duke University, Durham, North Carolina, and Andy Schwartz at the University of Pittsburgh, which inspired DARPA to create a new program to develop a robot arm that is controlled by the wearer’s intent.

“That was the genesis of this prosthesis program,” explains Ling. “It wasn’t until the work of Nicolelis and Schwartz and several others showed us that such an arm was now in the realm of the possible that we launched our Revolutionizing Prosthetics program.”

Ling, who directs the program, is one of about 100 such program managers recruited by DARPA. “Program managers are only brought in for a very short time. The mean is six years. During that time, our job is to invent new programs, not to run legacy programs as other government agencies do.”

After several years of coming up with far-out ideas, these professional visionaries are replaced with new recruits with fresh ideas, who will in turn be replaced by fresher minds several years in the future.

“We’re purely a funding agency,” says Ling. “We don’t do the research in-house. We come up with the ideas, and then we go out

and find the very best people to execute the work for us. The way we convince them to work for us is...we’ve got the money! How much money do we have? We have a lot of money. The exact number is classified, but I will tell you it’s in the billions of dollars.”

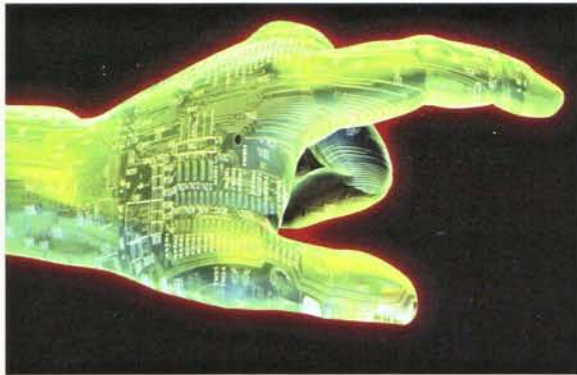
And DARPA is not stingy with that money, says Ling. “It’s very difficult to convince someone to take on an unprecedented challenge with a budget of ten cents. You have to give them the resources. We never say, ‘This is how much money we’re going to give you.’ We always ask, ‘How much money do you need?’—and negotiations begin from there.”

Unlike the rest of the DoD, DARPA is not constrained by a need for requirements documents, which express a need/desire for an item or solution. “Here,” says Ling, “we do purely what our imaginations tell us to do.”

The choice of which visions are pursued is up to the director and deputy director of each of the eight program offices within DARPA; the Revolutionizing Prosthetics program falls within the Defense Sciences Office.

Ideas with enough merit to pass muster are packaged by the program manager, the program office director, and the deputy director. They are then brought before DARPA Director Anthony J. Tether, a National Intelligence Medal and DoD Civilian Meritorious Service Medal winner, who makes all final decisions, says Ling.

There’s no limit to the number of projects that can be pursued simultaneously. “We pursue all that have merit,” says Ling. “We have enough money here to pursue most things, and some of it is really way-out, crazy stuff. But it’s an incredible investment.”



### Industry Perspective



**John Michael, CPO, FAAOP**, isn’t certain that Defense Army Research Project’s (DARPA) ambitions for the brain-powered arm will succeed within its short-term project parameters, but he promptly agrees with Col. Geoffrey Ling, MD, PhD, manager of DARPA’s Revolutionizing Prosthetics

program, that the agency’s ambitious projects mean progress, especially for the O&P industry overall.

“The short-term perspective of the DARPA project, like all short-term projects,” explains Michael, “sends the development in a certain direction. For example, the choice of compressed gas as a power source for the upper-limb prostheses may or may not prove to be a realistic choice in 2010. If it isn’t, then it is quite plausible that the commercial partners would revert to the widely accepted electromechanical motors [and] scale down the strength and the speed of whatever has been developed, but retain many of the other valuable features.

“So it’s quite possible that what DARPA has developed will

not be widely available commercially in a practical sense, but it still might represent a huge leap forward because spin-offs or related developments might then come to light that would otherwise have taken a decade or two or more to come to the forefront.”

Funding and availability will continue to be issues, in any case. “That’s not DARPA’s problem,” Michael says. “If we only offered—at least initially—a DARPA-level development to people with bilateral involvement, the market is so small that it would probably be much less threatening to Congress and to third parties, and there might be a realistic chance that level of care could move forward. Like all developments over time, as these advanced prostheses become more reliable, manufacturable, and more cost-efficient, such technology may very well begin to become available to unilateral amputees as well.”

DARPA has done a good job of involving multiple experts from across the commercial and academic landscapes, he points out, spreading their seeds widely.

“That substantially increases the likelihood that the knowl-

## What Specific Strategy Does DARPA Employ in Determining What's Reasonable to Pursue and What's Not?

DARPA's business is high-risk, high-payoff research, Ling notes, but it is possible to mitigate risk by only pursuing those ideas that have scientific validity. "We don't take risks based upon stupidity. That doesn't mean there has to be preliminary data or proof of principle. We don't ask for that. We just ask that the engineering rationale make sense. The question then becomes, 'Have you assembled the right expertise?'—and that's very critical because a lot of people have good ideas, but they can't execute them because they don't have the experience."

DARPA often creates teams that didn't previously exist. "We are very good at cross-disciplines; for example, getting a mathematician to work with a biologist, or an engineer to work with a materials scientist. These experts often don't know each other, so we pair them up."

DARPA establishes very rigid milestones, keeping its experts on track and on schedule. "If you don't achieve step one, there's no way you're going to get to step two, three, or four. Granted, those milestones are open to discussion because science is still science. But still, it gives us a framework."

Even if the project doesn't succeed, it is critical to have learned something along the way, Ling stresses. "Every journey is worth taking. Although you may not get to the ultimate goal, you may have learned a lot along the way that will then be helpful for something else."

Unlike NIH or other agencies, DARPA gives its program managers a tremendous amount of leverage, says Ling, all based upon contract money. "We can always terminate a contract, so it's highly motivating."

## What about Timeframes? Can Genius be Rushed—or Held to Deadlines?

"Sometimes we establish deadlines, sometimes not," Ling says. "In the case of the brain-controlled upper-limb prosthesis, we want an advanced mechanical platform in two years, and in four years we want the thing neurally controlled."

What happens if they can't do that?

"Then we find out why they didn't do it," Ling explains. "If it was because they didn't have a resource or a piece of technology available, we try to get it to them before we get to the failure point. On the other hand, if the science just doesn't merit it, we will know ahead of time and we'll disengage."

"And if it's because they're just not good performers, we will have taken their money away from them long ago because my team is 'in their shorts,' meeting with them once a week. And once every couple of months, I pay them a visit. We are watching every move, so if things are starting to slip, we know. But in this case, both performers—DEKA Research and Development [Corporation] and the Johns Hopkins University Applied Physics Lab—have not only met their milestones, they're actually ahead of schedule."

Although Tether oversees everything within the agency, from finances to procedures, DARPA's program managers require minimal oversight, says Ling. "The vast majority of program managers here have at least one doctoral degree—I myself have two. There's only a certain amount of control that you need to leverage on these people. If you leverage too much control, you actually squash their independent thinking."

DARPA experiences no difficulty in locating performers to execute the programs it conceives, according to Ling. "Many people seek us out, but in most cases, we send out an Internet announcement specifying in very detailed terms what we want."

edge being developed will serve as the foundation for future developments that will be a clinical step forward. I think DARPA is reaching very wide, very high, but I think it's a good direction to go, and I'm personally delighted that they're willing to undertake these endeavors."



**John Miguelez, CP, FAAOP**, points out that funding DARPA-developed high-tech prostheses might not be as difficult as we think.

"Ten years ago, when the C-Leg<sup>®</sup> first appeared, people feared that it was way too expensive for a knee system, and insurance companies wouldn't pay for it," Miguelez says. "It may not be the standard knee being fit today, but it's certainly mainstream, and a lot of patients have access to it."

Making a case for reimbursement for high-dollar high-tech items is not difficult, Miguelez believes. "As long as that emerging technology is medically necessary, and we can document that it will have a positive impact on the patient's medical out-

comes, insurance companies are, to a certain extent, required to fund the treatment. It's really all in the approach."

As the provider of upper-extremity prosthetic services for Walter Reed Army Medical Center (WRAMC), Washington DC, Miguelez is involved in the beta testing of new DARPA-developed technology designed to benefit recovering amputee soldiers. "It's a very aggressive plan that has developed a new upper-extremity prosthetic system and new controls in just four years," Miguelez says. "Although some really impressive new technology has appeared over the last ten years, we have never seen it evolve to this degree this quickly."

Miguelez describes another DoD benefit in the making. He is one of several prominent experts nationwide who have been commissioned to write specialized chapters for a book titled *Care of the Combat Amputee*—which should be available in early 2008.

"This is something else that has not happened historically—a gathering of experts sharing their knowledge and experience for the benefit of our prosthetic patients."

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Generally, only the very best respond because these are very daunting challenges. People respond to our calls for proposals because they know there's a lot of money there. Most universities and industry are constantly trolling our website to see what pops up."

### Does DARPA Follow Projects Long-Term—Making Them Commercially Available to the General Public?

"In the Revolutionizing Prosthetics program, we're very involved with getting these advances to the public," says Ling. "We knew that at the end of the day, somebody is going to have to make this thing. So every single proposal that made it to the critique level had a commercial partner. It was mandated in our call for proposals that one of the partners must be a commercial entity that knew how to transition the product.

"This is not a secret. We expect this to go out into the civilian community worldwide. I think this is going to be another wonderful thing America is going to give to the world."

In addition, Ling says he has worked closely with the FDA, which has helped him review the proposals and examine the devices. "They have been intimately involved even before anyone has asked them for approvals, so they know ahead of time that this technology is coming down the pipe." The fact that the FDA



officers themselves are already part of the oversight of this program could help to streamline the FDA approval process.

One day, when they have shown that the impossible is possible, DARPA's involvement in the project will end, says Ling. At that point, someone will have to take over the task of packaging and manufacturing it. "My guess would be that our transition partners are likely to be the U.S. Army and, I hope, the VA. The 'Big Army' [U.S. Army Medical Research and Material

Command] is generally our best transition partner; they usually take it over once we've done all the high-risk front-end."

Since its inception, DARPA has proven its worth many times over, to the extent that other government agencies—the U.S. Department of Health and Human Services (HHS) and the Department of Energy (DOE)—are developing mini-DARPA's of their own, says Ling. In the future, who can predict what might come from the wildly imaginative, creative, futuristic, and visionary brain trust the agency continues to recruit. If we could predict it, we wouldn't need them. After all, these are the 'impossible guys.' **WEB QUICK FIND: EDPEAT1107**

*Judith Philipps Otto is a freelance writer who has assisted with marketing and public relations for various clients in the O&P profession. She has been a newspaper writer and editor and has won national and international awards as a broadcast writer-producer.*

An advertisement for Prosthetics Research Specialists, Inc. (PRS). The image shows several containers of prosthetic materials: two large blue jugs labeled 'Stretch EZ', two smaller blue jugs labeled 'E-Z SKIN', and two white jugs labeled 'E-R Part J Resin'. To the right, there is a prosthetic leg in a white skin sleeve, a prosthetic foot in a brown boot, and a prosthetic foot in a tan shoe. The background is a light yellow gradient.

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