Biomedicine: Revolutionizing Prosthetics—Guest Editors' Introduction

Dexter G. Smith and John D. Bigelow

In early 2006, APL was awarded a contract to start the first phase of the Revolutionizing Prosthetics 2009 (RP2009) program, a multi-year, multi-million-dollar effort to develop an advanced upper-extremity prosthetic limb. This advanced limb would be designed to allow a user to button a shirt, tune a radio, and feel the warmth of a loved one's hand; such a limb might even provide the warfighter with the opportunity to return to active duty. The RP2009 project was an enormous scientific research and advanced development effort that enabled APL to not only develop many exciting new technologies but also to attract the highest quality staff from inside and outside of the Laboratory. This issue will recreate the history of this amazing program and highlight many of its challenges, successes, and derivative technology applications.

INTRODUCTION

A long and illustrious history of APL biomedical research and systems engineering contributions, dating back to 1965, has been detailed in previous volumes of the *Johns Hopkins APL Technical Digest*.[1–7] These technologies, developed through internal investment, independent research and development (IR&D) funds, license fees, and modest external funding, represent several collaborative projects with the Hopkins medical community that have led to innovations in clinical practice and military casualty care.

In late 2004, former APL Director Dr. Richard Roca established the Biomedicine Business Area with the challenge of developing a solid and sustainable funding base for performing important and impactful biomedical programs for the government. Dr. Roca also stressed that the direction of the business area had to be strategically focused and had to complement the rest of the Hopkins enterprise.

From the Biomedicine Business Area Executive's perspective, it was clear that the path to long-term success was for this business area to look and act like the other business areas at the Laboratory. Of utmost importance was for the business area to develop a realistic business strategy that included sponsor engagement, independent research and development investments, capital equipment, and human capital investment.

A cross-enterprise strategic planning effort focused on biomedical research and development in areas critical to national defense was initiated. A cross-enterprise team of both technical and business personnel was assembled and met regularly. After some iteration, it became apparent that ambitious business development goals were at odds with internal resource constraints. The solution that emerged was to have very focused and attainable short-term goals in concert with broader and more ambitious long-term goals. The team proposed that the individual warfighter be the focus of the business area and that the business area concentrate on warfighter protection, sustainment, and performance spanning predeployment through combat casualty care and finally to long-term rehabilitation.

During this same period, the Defense Advanced Research Projects Agency (DARPA), in response to the growing number of warfighters injured by improvised explosive devices, began developing a Broad Area Announcement for research and development into technologies that would vastly improve upper-extremity prosthetics by providing a replacement device that would mimic human performance in terms of appearance, function, and natural control. This DARPA effort fit perfectly into the business area's strategy of using the Laboratory's strengths in systems engineering; management of large-scale, multi-discipline, multi-organizational projects; development of complex technology; and comprehensive test and evaluation. Almost every department in the Laboratory, as well as The Johns Hopkins University School of Medicine, The Johns Hopkins University Whiting School of Engineering, the Johns Hopkins Bloomberg School of Public Health and many other organizations, played a part in developing the proposal for this effort (see the Appendix).

APL's proposal was chosen as the winner from a field of 14 submittals from world-leading competitors in prosthetics, neuroscience, and neuroprosthetics. The government indicated that our systems perspective, the strength of our team, and the team management paradigm were key factors in the award. In early 2006, APL was awarded a $30.4 million contract to start the first phase of the RP2009 program, a 4-year, $68 million effort to develop an advanced upper-extremity prosthetic limb. This advanced limb would be designed to allow a user to button a shirt, tune a radio, and feel the warmth of a loved one's hand; such a limb might even provide the warfighter with the opportunity to return to active duty.

The RP2009 project was an enormous scientific research and advanced development effort that enabled the business area to not only develop many exciting new technologies but also to attract the highest quality staff from inside and outside of the Laboratory. This issue will recreate the history of this amazing program and highlight many of its challenges, successes, and derivative technology applications.

THE ARTICLES

First, the systems engineering challenges of a project of this magnitude and complexity are detailed in the article by Burck et al. They describe the system engineering challenges and the tools, techniques, and processes used to overcome them. The article focuses on the factors that led to success in a team environment that included collaborators from many different technical disciplines, parts of the world, and organizational cultures. This model has been successfully exported as an exemplar to other biomedicine and healthcare delivery programs.

Next, the real-time Virtual Integration Environment is explored by Armiger. et al. This concept revolutionized neuroscience and prosthetics research and development by creating a common playing field that researchers and developers around the world could use to simulate and test new ideas. The Virtual Integration Environment is used to visualize and monitor performance of various design approaches, pilot neural signal analysis algorithms, simulate emerging mechatronic elements, train end users to control real or virtual neuroprosthetic devices, and configure and customize clinical and take-home devices. The authors provide a comprehensive description of the system, as well as a summary of its applications for myoelectric control and neural research at multiple academic institutions.

From the effort to prove that an advanced prosthetic device is possible through Prototype 1 to the technology candidate elimination process undertaken for Prototype 2, the history of the process that was followed to arrive at the unique design and architectural characteristics of the Modular Prosthetic Limb (MPL; see Fig. 1)

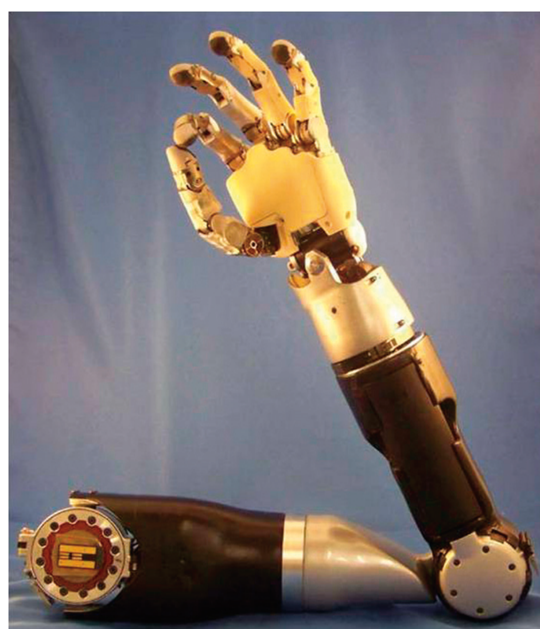

Figure 1. This final prototype of the MPL, successfully demonstrated to DARPA in December 2009, offers 22 degrees of freedom.

is remarkable. The next article by Johannes et al. highlights the developmental process that has resulted in the MPL as it exists today.

A multi-degree-of-freedom prosthetic limb system is only as functional as the controls system inputs and the resultant control strategies. The next article by Bridges et al. provides an overview of the human–machine interface between the MPL and the patient and discusses how the inherent flexibility of the MPL's control architecture is able to support various human–machine interface paradigms.

Natural and intuitive control was one of the driving requirements for the program and was achieved through "neural integration." The neuroscience framework was developed to support a myriad of conventional, myoelectric, and neural signal input sources and is a key component for robustly controlling a lifelike prosthetic limb. Levy and Beaty describe the high-level architecture implemented within the Virtual Integration Environment consisting of a neural interface to provide the link between the prosthetic limb and a user's nervous system and motor decoding, sensory feedback, and decision fusion algorithms.

Certainly one of the most significant technical challenges for the program was to directly interface with the body's nervous system for limb control and sensory feedback. The program explored a wide variety of devices capable of acquiring electrical signals at their source locations: nerves and neuronal cells. Team members focused much of their efforts on evaluating the state of these devices as well as advancing the state of the art of a select few that were found to have the best chance of being transitioned for human use. The article by Tenore and Vogelstein provides a summary of these efforts to identify optimal devices for neural signal acquisition and provides a glimpse into the future.

From the beginning of the program, it was clear from our discussions with patients and clinicians that "comfort" was a critical consideration for the eventual everyday use of an upper-extremity prosthetic. No matter how functional the ultimate limb system would be, if it could not be worn comfortably for an extended period of time, it would not be used. The body interface, or socket, became the nexus for addressing the comfort of the end system. Moran's article highlights the most novel socket concepts, prototypes, and socket accessory tool designs developed to support the MPL.

The next article provides a discussion of the social (appearance) and functional interface of the MPL—the cosmesis. A cosmesis fulfils multiple functions, from providing a lifelike cosmetic cover to improving the grip capability of a prosthetic hand. This article by Biermann explores the additional requirements imposed on the cosmesis for the program and looks at the solution path that evolved during the development and testing program.

In addition to all the research, technology development, and team management challenges, the program also had to address the nuances of providing a viable regulatory and commercial transition path. It was apparent early on that the upper-extremity amputee market alone would not sustain this advanced technology and that derivative and dual-use applications would help drive volume up and costs down. One such derivative application is in dexterous robotics. Currently, in the robotics field, enormous effort is spent developing interfaces whereby a user can manipulate various multi-degree-of-freedom "robotic arms" in fairly unnatural ways. These interfaces are nonintuitive, time-consuming to learn, and tiring to use. If the robotic arm were to perfectly mimic a human arm, have an intuitive interface, use the same tools that humans use, and provide haptic sensory feedback, it would be a great leap in capability. The last article in this issue by Hinton et al. covers this concept and its first funded application in explosive ordnance disposal robotics.

The Revolutionizing Prosthetics program has been widely recognized and has received considerable attention. Notably, the team's early efforts were recognized by the scientific community and the media, including nomination as a finalist for DARPA's 2007 Most Significant Technical Achievement Award, selection by the International Academy of Science as one of the top 10 Technical Achievements of 2007, and receipt of a *Popular Mechanics* 2007 Breakthrough Award.

Beyond this program, the business area constantly evaluated its strategy and organizational structure and aggressively executed sponsor engagement activities. These sponsor engagement activities concentrated on battlefield trauma and combat casualty care. The business area judiciously invested its capital and independent research and development funds in biomechanics, traumatic brain injury, neuroscience, dexterous robotics, and numerous biomedical systems applications building upon the Revolutionizing Prosthetics model. A future issue on biomedicine at the Laboratory will elaborate on many of these other exciting program areas and projects.

CONCLUSION

During periods of conflict, we are accustomed to seeing advances in warfighting strategies, tactics, offensive weaponry, and defensive systems. As a result of this evolution, we also see dramatic changes in warfighter injuries, coupled with significant advances in trauma care, recovery, and rehabilitation. The proliferation of improvised explosive devices in today's conflicts has severely affected many of our nation's warfighters and their families. The Biomedicine Business Area, established to make important contributions to our nation's defense, is making positive contributions in warfighter survivability and recovery in response to today's threats.

Through strategic planning and execution, the business area transitioned from a principal investigator-based business model to a problem-solving business model focusing on the individual warfighter as a system. The business area won and then leveraged a very large science and technology program while continuing to develop a sustainable business model. Everyone involved in this area at the Laboratory should be proud of its contributions and the solid foundation it developed. The work of the business area since its formal inception in 2004 has positioned the Laboratory to continue to pursue significant, large-scale efforts in the biomedical sciences. Future issues of the *Digest* will cover these efforts.

REFERENCES

[1]Massey, J. T., and Johns, R. J., "A Short History of the Collaborative Biomedical Program," *Johns Hopkins APL Tech. Dig.* **2**(3), 141–142 (1981).

[2]Friedman, M. H. (ed.), "Science and Technology in Biomedicine Issue," *Johns Hopkins APL Tech. Dig.* **2**(3), 139–230 (1981).

[3]Friedman, M. H. (ed.), "Science and Technology in Biomedicine—II Issue," *Johns Hopkins APL Tech. Dig.* **4**(2), 63–136 (1983).

[4]Friedman, M. H. (ed.), "Science and Technology in Biomedicine—III Issue," *Johns Hopkins APL Tech. Dig.* **9**(1), 1–70 (1988).

[5]Grant, D. G. (ed.), "The Johns Hopkins University Applied Physics Laboratory–Medical School Collaborative Biomedical Program Issue," *Johns Hopkins APL Tech. Dig.* **12**(2), 101–218 (1991).

[6]Ko, H. W. (ed.), "Biomedical and Biochemical Technology at APL," *Johns Hopkins APL Tech. Dig.* **24**(1), 41–51 (2003).

[7]Yanek, S. P. (ed.), "Biomedical Engineering Issue," *Johns Hopkins APL Tech. Dig.* **25**(3), 181–280 (2004).

APPENDIX. RP2009 TEAM

The RP2009 team, comprising university, government, medical, and business partners from across the United States, Canada, and Europe, worked under close coordination within a novel virtual enterprise framework. The full list of RP2009 partners follows.

First-Tier Subcontractors

- Arizona State University
- California Institute of Technology (CalTech)
- Duke University
- Hunter Defense Technologies (New World Associates)
- Johns Hopkins Medicine
- Johns Hopkins University
- Martin Bionics
- McGill University (Canada)
- National Rehabilitation Hospital
- Northwestern University
- Oak Ridge National Laboratories
- Orthocare Innovations
- Otto Bock Healthcare (Austria)
- Rehabilitation Institute of Chicago
- Rutgers, The State University of New Jersey
- Scuola Superiore Sant'Anna (Pisa, Italy)
- Stanford University
- Umeå University (Sweden)
- University of California, Irvine
- University of Chicago
- University of Michigan
- University of New Brunswick (Canada)
- University of Rochester Medical Center
- University of Southern California
- University of Utah
- Vanderbilt University

Second-Tier Subcontractors

- BioSTAR, Inc.
- FlexSys, Inc.
- Fraunhofer IZM (Germany)
- Harvey Mudd College
- Kinea Design, LLC
- Ripple, LLC
- Sigenics, Inc.

Other Collaborators

- Advanced Arm Dynamics
- Alfred E. Mann Foundation for Biomedical Engineering
- Massachusetts Institute of Technology (MIT)
- NASA–Johnson Space Center
- NASA–Langley Research Center (LRC)
- NASA–LRC, National Institute of Aerospace (NIA)
- National Institutes of Health (NIH)
- U.S. Army Natick Soldier Research, Development, and Engineering Center (NSRDEC)
- U.S. Army Brooke Army Medical Center (BAMC)
- U.S. Army Medical Research and Materiel Command–Telemedicine and Advanced Technology Research Center (USAMRMC-TATRC)
- U.S. Army Research Institute of Environmental Medicine (USARIEM)
- U.S. Army Walter Reed Army Medical Center (WRAMC)
- U.S. Department of Veterans Affairs (VA)
- University of Pittsburgh
- Zyvex

The Authors

Dexter G. Smith

John D. Bigelow

Dexter G. Smith is an associate dean of engineering in The Johns Hopkins University Whiting School of Engineering responsible for the Engineering for Professionals program. Dr. Smith is a former member of APL's Principal Professional Staff and in 2004 became the first Business Area Executive for the Biomedicine Business Area. He played a key role in organizing, staffing, and writing the largest DARPA proposal ever awarded to the Laboratory, RP2009. **John D. Bigelow** is a member of APL's Principal Professional Staff and the acting Branch Supervisor for the Research and Exploratory Development Department. His previous position was as the Biomedicine Business Area Branch Supervisor and acting Program Area Manager. On the Revolutionizing Prosthetics program, he was the Assistant Program Manager responsible for structuring and executing this dynamic and challenging program. For further information on the work reported here, contact John Bigelow. His e-mail address is john.bigelow@jhuapl.edu.

The *Johns Hopkins APL Technical Digest* can be accessed electronically at **www.jhuapl.edu/techdigest**.