INTRODUCTION

Advances in battlefield trauma care and improved body armor for soldiers have combined to increase the survivability of injuries experienced in the wars in Iraq and Afghanistan. Although the body armor protects the torso and internal organs, the soldier’s limbs remain vulnerable to blast and ballistic injuries, which are often caused by the use of improvised explosive devices. These injuries can subsequently lead to amputation. Surprisingly, the familiar images of restored limbs from Star Wars or i, Robot do not actually exist. Most upper-limb amputees choose a simple, effective, hook-like device that has not advanced much in 400 years. Spurred to restore quality of life to injured warfighters and aware of the complexities of the arm and hand, the Defense Advanced Research Projects Agency (DARPA) sponsored the Revolutionizing Prosthetics 2009 program to develop a new generation of upper-extremity prostheses. APL formed and led an international team of more than 30 corporate, government, and academic partners to develop this system to mimic the human limb. In January 2005 the Defense Advanced Research Projects Agency (DARPA) issued a request to develop the world’s most advanced prosthetic limb. It was required that this limb have the strength, sensation, weight, comfort, and appearance of a native human limb. In addition, this limb system had to be neurally controlled using the patient’s mind—as opposed to by traditional methods involving body movements, switches, force-sensitive devices, and inputs from the patient’s remaining muscles. APL won the right to meet this need after a competitive bid process. We had 4 years to complete this challenge and create a limb that was ready to go into clinical trials at completion of the program. This article describes the systems engineering challenges the Revolutionizing Prosthetics 2009 team faced and the tools, techniques, and processes they used to overcome these challenges over the course of this unique program. We focus on the factors that led to success in a team environment with a diversity of technical disciplines, geography, and organizational cultures.
• The system needed a natural appearance, with a size and weight comparable to those of the native limb and a lifelike cosmetic covering. In addition, it needed to move naturally with lifelike motion and resistance to motion regardless of the underlying limb structure.

• The system needed natural control like the native limb it was replacing. Instead of nonintuitive controls, this system would be neurally integrated, tapping into the body’s natural pathways for motor control and sensory feedback. Furthermore, because we use our limbs to explore our environments—to touch and feel—the system also needed a sense of touch (force, pressure, and vibration), temperature (heat flux and relative hot and cold), and proprioception (our sense of limb position in space).

• A very important requirement was that the system needed to be comfortable—one would need to be able to wear it all day, every day with no discomfort. This led to a wealth of research and advances in the very challenging area of body attachment technologies—methods of securing this highly dynamic and powerful robotic limb system to one’s residual limb or torso while maintaining comfort.

• Finally, despite pushing the envelope in most research and technology areas, the system had to be reliable. Users cited reliability and comfort as the main reasons to opt for less functional but more reliable systems today.

Figure 2 illustrates the overall process pursued during the program to satisfy these goals.

TEAM MAKEUP

APL assembled and led an international a team of more than 30 partners spread across the United States, Canada, and Europe (see the Appendix for a list of partner organizations). At peak periods, we had nearly 400 individual team members. Maintaining the vision and focus across this team was a significant challenge.

Program skill sets spanned technology development, science, and clinical disciplines. Engineering specialties included systems, electrical engineering, mechanical engineering, software engineering, signal analysis, controls, wireless communications, power-sensitive applications, human factors, materials (cosmesis), reliability, manufacturability, and project and program management. Scientific specialties were neuroscience, sensory feedback and haptics, neural motor decoding, neural stimulation, and research studies. Clinical disciplines included surgery, clinical/research prosthetics, physical therapy, occupational therapy, and human subjects research including institutional review boards and other regulatory requirements.
the added cost and complexity. Similarly, clinical and human factors team members introduced patient-centered requirements that the engineering team had not considered. These energetic transdisciplinary debates built an integrated team with a strong sense of mutual respect. In a fabled instance at one of our early design reviews, our mechanical lead had just completed briefing the electromechanical limb design, with detailed analyses of the relative merits of cycloidal and planetary drives. The next presenter, a world-renowned researcher, opened with, “Well, I’m just a neuroscientist.” While it certainly provided comic relief, it also showed the mutual respect for all disciplines across the team and the realization that everyone’s contributions were essential to success.

Continuous risk management was at the heart of the program. Risk management practices were crucial to fusing the exploratory nature inherent in the scientific efforts with the engineering aspects of producing a limb ready to transfer to manufacturing and poised for clinical transition. We developed and maintained traditional risk matrices, and we structured the entire program to manage risk incrementally, with progressive research and prototypes being evaluated at gating reviews. As expected for a program this large, systems requirements management was crucial. We tracked traditional metrics of correctness, completeness, traceability, and baselines. Also, given the unique challenge and team, it was important to capture requirements at a useful and practical level of abstraction. This level was a balance between allowing the team to know when they had reached their goals while still keeping those goals flexible enough to support the dynamic nature of the research portions of the program. Beyond the mission to develop a neurally integrated prosthesis, DARPA supplied a few pages of top-level performance requirements. From this seed, the program created a comprehensive System Requirements Specification that eventually led to more than 50 subsystems, each with requirements and design documents.

Engineering processes were crucial to preparing for FDA approval and clinical trials. Common documents and well-defined interfaces were the team’s lingua franca. Team document reviews and program-level design reviews provided opportunities to assess and improve quality. The proper level of process had to

Organizational cultures were also quite diverse. These broadly aligned with skill sets in terms of engineering, science, and clinical practice. Engineering teams familiar with broad collaboration and process were less familiar with merging ongoing science and research into an engineering program. Scientific collaborators were familiar with dynamic environments and open-ended research efforts but were less familiar with disciplined engineering processes, deliverables, and schedules. Finally, clinical team members were, as appropriate, patient focused but less accustomed to integrating into the larger team.

GUIDING PRINCIPLES

To integrate such a diverse team, we systematically applied systems engineering and management principles. Key among them were communication, continuous risk management, requirements management, and engineering processes.

We followed the communication tenants of hiding nothing from any team member and taking nothing for granted. Given the diverse team, solutions to problems could come from many areas. Open information sharing could only increase our chance of success. Also, because our team members came from a broad cultural spectrum, we could not assume common process knowledge. Team communication and cross-pollination were key to getting engineers to think like practitioners, scientists to think like systems engineers, technologists to think about production, and the like. Although challenging, this open program communication created a productive collaborative environment where interteam diversity converged on solutions balancing engineering, scientific, and clinical factors. For example, our clinical researchers were adamant about the number of powered finger joints needed for “dexterity,” but our industry partners resisted

![Figure 2. Overall systems engineering process performed on Revolutionizing Prosthetics 2009.](image-url)
strike a balance between the rigor needed to assure quality while allowing progress and innovation to proceed apace within an aggressive schedule. Processes were created to generate FDA 820.30 Design Controls artifacts, all quickly trainable to the team. Liberal use of templates for reviews and documents was critical.

**PROGRAM STRUCTURE**

The program was strategically structured to continuously mitigate risk; it consisted of Phase 1 and Phase 2 (see Fig. 3), which were 2-year phases with some activities overlapping the entire program.

Phase 1 focused on capability assessment, concept exploration, and solution validation. The team had minimal time to identify needed research and technology threads and then implement research programs and prototype technology. This phase’s goal was to provide the fundamental pioneering neuroscience research, develop the multimodal neural integration framework, gain clinical experience, and demonstrate key technologies. Phase 1 culminated with an in-depth System Integration Plan capturing the results of these efforts and providing the systematic weighted trades for the Phase 2 program plan.

Phase 2 centered on solution implementation of Phase 1 results. This phase was more of an engineering development effort, but it also continued critical threads of neuroscience research. This phase also had elements of solution validation geared toward performance verification of the engineering implementation, neuroscience framework, and algorithm performance.

The Virtual Integration Environment (VIE) underlay the program. This environment proved critical to team collaboration as a virtual modeling framework and repository for mechanical engineering, controls, neuroscience, signal analysis, algorithm development, system performance validation, and design compliance. The VIE provided a common communication framework, supported algorithm consolidation among team members from various institutions, and served as the facilitator for team integration. By providing this universal framework, the VIE could be distributed to multiple researcher sites and used for development. Once algorithms were proven, the tools used within the VIE allowed the algorithms to be quickly and confidently ported into the complete system model and ultimately into the embedded environment. It included an end-to-end simulation consisting of the following: patient signal acquisition, signal analysis for determination of intent, controls for realization of intent, a model of the physical and electromechanical properties of the limb (the plant) for limb simulation, and a 3-D visualization of the state of the limb. The VIE also had a clinical interface for patient training and therapeutic use. Finally, the VIE provided a user interface for the limb and neural system configuration that would ultimately be needed for clinical use. Figure 4 shows some of the capabilities provided by the VIE.

Understanding the challenge of rapidly integrating our diverse and distributed team into a cohesive and

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**Figure 3.** Strategic program schedule. IDE, Investigational Device Exemption; UEA, Utah Electrode Array; USEA, Utah Slant Electrode Array.
focused unit, the project team structure was a crucial component for success. The project organization needed to facilitate the contributions of all members, assure timely and accurate communications, and build unity within individual disciplines and across the broader team. The core was a management team of program/project management, systems engineering, and quality assurance. Subsystem development teams (SDTs), which were aligned to support the strategic program structure as shown in Fig. 3, surrounded this core. Each SDT organization included a lead to oversee and integrate major thrust areas such as the mechanical limb, VIE, neural interfaces, signal analysis, etc., and each team contained technical experts from multiple organizations. These SDTs were similar to a traditional engineering organization shaped around functional subsystems. The program organization included integration working groups orthogonal to the SDTs. These integration working groups provided program oversight for clinical and patient needs, including test and evaluation for performance validation, safety, human subjects, and quality of life. The integration working groups worked across the SDTs and the program to assure the program addressed these needs at the system level. The program also engaged a medical advisory board to oversee research, patient needs, human subjects testing, institutional review boards, and regulatory issues. Finally, a critical observer versed in team interactions gave feedback at major reviews and helped the entire team function more effectively.

**PHASE 1**

From the very beginning of Phase 1 and continuing throughout the program, formal communications channels guided daily, weekly, and monthly activities. The SDTs started weekly teleconferences from the program’s outset. The program established a SharePoint site, a web-based collaboration solution, on APL’s unclassified network for all partners to share information. The SharePoint site included a mirror of our configured document area to give all partners easy access to program documents. Program-wide and SDT areas on SharePoint contained design information and artifacts and materials from meetings, presentations, and teleconferences.

This phase (concept demonstration through engineering design) explored approaches to limb actuation, haptic feedback, neural interface devices, neural decode and encode algorithms, communications, power, and control for the final MPL. These explorations were evaluated using systems engineering tools such as dem-

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**Figure 4.** Capabilities of the VIE. The capabilities ranged from embedded model framework (a), patient algorithm training (b), virtual environments and basic gaming (c), and patient data acquisition/prosthetic control (d).
subject-matter experts could not produce the data so the program initiated a detailed study to track arm movements of office and nonoffice workers to gather data for power analyses needed by the electrical and mechanical teams for implementation.

In parallel with these explorations, APL and our collaborators developed Prototype 1, a fairly low-risk limb with 7 DOF. The team built, verified, and validated Prototype 1 with patients using the VIE within a year of the program’s start. This prototype had three objectives: to gain early clinical and patient experience, to rapidly force the team through the stages of team development (forming, storming, norming, etc.), and to provide early success and visibility to benefit the team and

![Figure 5. Evolution of Prototype 2 limb from early concepts to final designs at major reviews.](image)

![Figure 6. Prototype 2 intrinsic and extrinsic approaches. DOM, degrees of motion.](image)
prosthetic community. Prototype 1 encouraged communications between our technology development team members and our clinical team members. Although it was a prototype, its systems requirements specification, which was derived from sponsor requirements, provided design rigor and on-the-job training for team members. This systems requirements specification struck a balance between team direction and formality and hence no further derivation of requirements was done for this prototype. Prototype 1 was subjected to preliminary and critical design reviews attended by a broad cross section of the team, which encouraged expertise sharing.

Prototype 2 was developed in parallel with Prototype 1 to validate that electromechanical actuation could meet MPL requirements (forces, speeds, weight, volume, etc.) and provide technology risk reduction. A systems requirements specification was derived from sponsor requirements and balanced the need for rigorous requirements definition against constraining a still-dynamic requirements specification. Again, design reviews served as decision gates throughout the development. These reviews often led to improvements in the plan. Figure 5 illustrates the Prototype 2 design progression. Finally, as competing approaches progressed through design and early prototyping, we decided to build a single upper arm and two hand designs (see Fig. 6) to determine which would best meet our needs. One of these designs, the Intrinsic Hand, had all motors in the hand. This solution was perhaps more complex and less desirable for weight distribution, but it was more modular, allowing a central processor to be placed in the palm of the hand, and therefore it could serve more patients, including transradial (between the elbow and wrist) amputees. The other design, the Extrinsic Hand, had all motors in the forearm in a cooperative robotic (cobotic) drive unit controlling a tendon-actuated hand, similar to our human hand. This solution was perhaps more elegant and lighter and had better weight distribution, but it was not suitable for transradial amputees.

Concurrent with MPL technology efforts, neural researchers developed and demonstrated neural implant devices, decode algorithms, and full-featured system designs in a scalable and extensible architecture. From the start, there was lively debate on the merits of various neural techniques: whether to stay with standard noninvasive surface electrodes, use more invasive wireless intramuscular implants, or attempt more aggressive peripheral nerve or cortical implants. These debates proved that there was no near-term “one size fits all” solution. Each approach had risks and rewards, and ultimately the choice should be made by the patient and his/her clinician. As a result, we created a multimodal neural integration framework design to use one or more of these approaches in synergy with each other. Through the program, researchers in basic neuroscience at several institutions looked for the best way to acquire and decode peripheral and cortical motor signals. Ground-breaking research also occurred in sensory feedback and demonstrated the direct stimulation of the peripheral nerve and the somatosensory cortex. Over the 4-year program, we demonstrated the viability of all neural interface methods for control of the MPL.

Phase 1 culminated in the System Integration Plan that captured the results of all research and development paths and provided the systematic weighted trades resulting in the program development plan for Phase 2 (see Fig. 7 for an example).

**PHASE 2**

One of the core program requirements was that the final limb system be modular so that the full range of upper-extremity amputees could benefit from the technology. Although the systems created during Phase 1 of the program kept this requirement in mind, this requirement was key during Phase 2. In fact, what had formerly been the Final Limb was renamed to the Modular Prosthetic Limb as Phase 1 wound to a close. This led to a renewed focus on clearly defining the interfaces between components so that a clinician could create a limb...
system suitable for their particular patient. Figure 8 illustrates the required levels of amputation that the system needed to support, and Fig. 9 shows the eventual set of system components that met this need.

The MPL portion of Phase 2 focused on solution implementation of Phase 1 outputs. As such, it was structured more traditionally than Phase 1. A key product of this phase was documentation to support moving to clinical trials and manufacturing. Given this need, processes were more formal during this phase of the program. SharePoint was used to support distributed Formal Peer Reviews for designs. We used Telelogic’s Dynamic Object-Oriented Requirements System (DOORS), a requirements management tool, to manage requirements creation, maintenance, allocation, and traceability between the 50 or so electrical, mechanical, software, and neural subsystems. Unified Modeling Language architectural models were used to allocate interfaces among interface control documents (ICDs). These ICDs captured the all-important interfaces between subsystems to support system integration and an open, modular system. The MPL progressed through a series of major system reviews before proceeding into implementation and integration.

The first review was the Design Approach Review, during which the team assessed the preliminary system architecture. A critical activity leading up to the initial architecture was identification of the key components

Figure 8. The MPL required a modular approach that could serve patients of various levels of amputation, ranging from shoulder to wrist. Therefore, the system was designed in modules that can be assembled in any combination for use with different amputation levels.

Figure 9. Modular components of the MPL.
The team developed specifications for these major CIs and allocated requirements from these specifications to their subsidiary CIs. This process was performed with (and probably would have been impossible without) a requirements management tool. The preliminary ICDs for this review covered the numerous mechanical, electrical, and messaging interfaces in the system. Defining these interfaces was important for the team to understand the system as a whole. The team repeated this process until all key functions had an associated CI and the major scenarios were satisfied. Engineers used Unified Modeling Language diagrams to capture the CIs and the interfaces among them at the electrical (power, electrical interfaces), mechanical (mechanical connections), and logical (messaging interfaces) levels (see Fig. 10 for an example).

The Preliminary Design Review followed the Design Approach Review. Activities leading up to this review included updating the architecture, refining performance objectives, developing CI specifications and ICDs, drafting test plans and test specifications, and creating prototypes for candidate components. Controls and software designers also defined major modes and states of the system (see Fig. 11 for an example). As part of specification development, engineers allocated requirements from the System Requirements Specification to the major CIs: Neural Interface, Socket, Limb, and VIE. The team developed specifications for these major CIs and allocated requirements from these specifications to their subsidiary CIs. This process was performed with (and probably would have been impossible without) a requirements management tool. The preliminary ICDs for this review covered the numerous mechanical, electrical, and messaging interfaces in the system. Defining these interfaces was important for the team to understand the system as a whole.

**Figure 10.** Unified Modeling Language was used to capture component relationships and the interfaces between them. HW, hardware; L, logical; M, mechanical; MEL, mechanical/electrical/logical; MHW, mechanical hardware; SW, software.

**Figure 11.** Software state transitions during system operation. Each rounded rectangle represents a system state: boot loader, INIT (initialization), NOS (normal operations), PRG (programming), and FS (fail safe). Arrows represent transitions between states and the event that causes the transition.
faces and allocating responsibilities among them was a key systems engineering activity at this time. Thoroughly defined interfaces would eventually lead to reduced design effort, common parts, and a shorter assembly time. One of the key lessons learned during Phase 1 of the program was that wiring crossing joints such as the base of each finger or across the elbow led to components that were difficult and time consuming to assemble and disassemble. These wires also led to components that were not modular. To remedy this, the team focused on designing electromechanical interfaces between components such as the fingers and the palm or the elbow and the forearm that had electrical connections embedded within them (see Fig. 12 for an example of consolidated mechanical/electrical interfaces used in the upper arm).

The final gating review was the Critical Design Review. In preparation for this review, all components progressed to the point where they could be fabricated, prototypes to characterize key design metrics were created and tested, anticipated system integration issues were identified, and mitigation approaches for these issues were developed. It was particularly important to baseline and track changes to the system from this point forward so that changes in one component could be adequately addressed in any interfacing components. Component and integration tests were created in preparation for final system integration.

At the conclusion of Phase 2, the MPL team produced the final limb shown in Fig. 13. This limb has 25 DOF (17 actuated), sensors throughout the hand, and impedance control. It can curl more than 18 kg at the elbow. The MPL effort culminated in demonstrations to the sponsor and community.

In parallel with limb development, the neural team continued to develop wireless neural implants (see Fig. 14) and neural decode and sensory encode algorithms. The team designed a Motor Decoding Engine to host a wide variety of decoding algorithms. All neural team members implemented their algorithms in the VIE and documented their inner workings in Algorithm Description Documents and Experiment Description Documents—
mimic the human arm and hand despite significant technical, organizational, and cultural challenges. As a result of this success, DARPA has funded Phase 3 of the Revolutionizing Prosthetics program, currently under way, to take the MPL created at the end of Phase 2 into clinical trials. Consistent application of sound systems engineering principles with a large, diversified, and distributed team continues to provide the ability to successfully meet these extreme challenges and create an extraordinary technology base that holds the promise to dramatically improve the quality of life for upper-extremity amputees.

ACKNOWLEDGMENTS: We acknowledge the significant editorial contributions made by Alan Ravitz of APL. The views expressed are those of the authors and do not reflect the official policy or position of the Department of Defense or the U.S. government.

Figure 14. Neural interfaces ranged from electrode arrays containing up to 100 arrays within a 16-mm² area to custom application-specific integrated circuits and custom-designed coils for wireless power and data transmission. INI-R/INI-S, implantable neural interface recording/implantable neural interface stimulation.

CONCLUSION

The Revolutionizing Prosthetics program successfully met DARPA’s challenge to create a prosthetic limb to mimic the human arm and hand.

Reference

APPENDIX. REVOLUTIONIZING PROSTHETICS 2009 PARTNER ORGANIZATIONS

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 (USAMMRTC-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

James M. Burck is a systems engineer in APL’s Research and Exploratory Development Department. Jim served as the Revolutionizing Prosthetics 2009 Systems Engineer for Phase 1 and Phase 2, providing system, subsystem, and process guidance. He also served as the project manager for the VIE during Phase 1 of the program. John D. Bigelow is the Research and Exploratory Development Department’s Acting Branch Head.

On Revolutionizing Prosthetics 2009, John performed program management, structuring, and execution of this dynamic and challenging program. Stuart D. Harshbarger is currently Chief Technology Officer at Contineo Robotics. Stuart served as the system architect and provided program/technical leadership, coordinating research and development activities across all collaborators. For further information on the work reported here, contact James Burck. His e-mail address is james.burck@jhuapl.edu.

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