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Influence of Government Funding on Prosthetics Research and Development

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Historically, tragically, warfare has been the major stimulant for the development of prosthetic devices. Much of the early history is traced in the introductory chapter of the *Orthopaedic Appliances Atlas, Volume 2,* published by the American Academy of Orthopaedic Surgeons in 1960. A fascinating source is the book *Historic Artificial Limbs* by the Italian surgeon Putti, published by Hoeber, New York, 1930, based upon the outstanding collection of artificial limbs in the Stibbert Museum at Florence, Italy. With that museum's distinguished collection of armor, it was perhaps natural that the byproduct of artificial hands, arms, and legs made by armorers for knights should also be assembled there. The story of the German knight Goetz von Berlichingen, commemorated in a drama by Goethe, stresses the knight's iron artificial hand.

Surgery generally and amputation surgery in particular were developed by the French surgeon Paré in connection with the religious wars in France; a corresponding development of artificial limbs was done by a locksmith known as "le petit Lorrain." Very likely only the relatively well-to-do knights and nobility were able to afford these early prostheses, with common people left to relatively crudely carved prostheses or crutches as illustrated, for example, by Breughel.

After the American Civil War, the government provided an allowance for artificial limbs for Union veterans. This financial incentive, plus the rapid increase of amputees from industry and railroads, led to great competition among private developers. In that era artificial limbs were essentially sold as commodities rather than fitted as professional services. Some interesting patents are cited in the *Orthopaedic Appliances Atlas, Volume 2.*

In World War I, countries among both the Central Powers and the Allies carried on simultaneous attempts to treat their patients and to develop better methods of surgery and fitting. Work in the Central Powers, notably in German military hospitals and in the Technical University of Berlin under Schlesinger, an engineering professor, was covered in great detail in the classic book *Ersatzglieder und Arbeitshilfen* (Substitute Limbs and Work Aids) published in 1919. Florent Martin worked extensively in Belgium, developing relatively early methods of fitting of temporary plaster-of-paris sockets on pylons for amputation of the lower extremity. His work was recorded particularly well in his critical analysis, *Artificial Limbs; Appliances for the Disabled,* published by the International Labour Office at Geneva in 1924. Efforts in England, including development of the specialty of limb fitting surgeon and the standardization of mechanical construction of a series of light metal limbs for many basic levels of amputation, are described in E. Muirhead Little's book *Artificial Limbs and Amputation Stumps,* published in England in 1922. During World War I, the Artificial Limb Manufacturers Association (ALMA) in the United States developed rapidly to advance the industry and cooperate with the government. Its descendant, the American Orthotics and Prosthetics Association (AOPA), along with the American Board for Certification (ABC), and the American Academy of Orthotists and Prosthetists (AAOP) continue today to develop the profession.

In World War II, the ALMA set up a small laboratory on the premises of the Rowley prosthetics facility in Detroit, under the name of the Research Institute Foundation. Its extremely limited financial and technical resources allowed very meager efforts.

Late in the war, partly because of growing demands from servicemen and unfavorable publicity, the Surgeon General of the United States Army asked the

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National Academy of Sciences (NAS) and its operating arm, the National Research Council (NRC), to select and standardize the best artificial limb designs. At a conference in 1945, the only unanimous agreement seemed to be on the concept that the best was not too good and that further improvements were needed on all aspects.

The Surgeon General then asked the NAS-NRC to organize a systematic program "to conduct with utmost dispatch research and development in the field of prosthetic devices." The resulting interdisciplinary Committee on Prosthetic Devices initially was financed by the wartime Office of Scientific Research and Development, then the Army briefly, and later the Army and Veterans Administration (VA) jointly. On July 1, 1947, it was reorganized as the Advisory Committee on Artificial Limbs to provide advice to other agencies which wished to conduct their own programs. The NRC committee structure underwent a variety of changes from 1945 to the mid-1970's but has now disbanded. AOPA-ABC-AAOP members were frequent members of committees, subcommittees, and technical groups in this structure.

The Army, Navy, and Veterans Administration each operated a laboratory. The VA, initially alone and later in parallel with other agencies, supported a series of projects with universities, industrial laboratories, and, in recent years, particularly through intramural projects in VA Medical Centers. After a change in its basic laws, the Office of Vocational Rehabilitation or its successors, now the National Institute of Handicapped Research (NIHR), has supported an increasing number of Rehabilitation Engineering Centers and projects.

In addition to stimulating a wide variety of basic studies on locomotion and arm and hand motions, phantom limb pain, and psychological aspects, and development of a wide range of devices for all levels of upper-and lower-limb prostheses, the total government-supported program became a major force in educational efforts and dissemination of information. The early suction socket schools brought together distinguished surgeons and prosthetists, teaching the surgeons about mechanisms and the prosthetists about anatomy and physiology, as well as fostering team work between the two professions, promptly involving therapists, and helping to upgrade the entire field. Follow-up of the early suction sockets led to organization of formal clinic teams. The suction socket certification program, operated by Orthopedic Appliance and Limb Manufacturers Association (OALMA) in conjunction with the NRC committee and recorded in the Veterans Administration, led to joint certificates and helped to pave the way for the founding of the American Board for Certification with its remarkable interdisciplinary board of directors. The suction socket schools led, in 1953, to organized university-level post-graduate education in prosthetics and later in orthotics.

Frustratingly slow as development often seems, nevertheless in retrospect it would appear that numerous major changes in devices, techniques, materials, and management methods were made in this continuing program. Voluntary cooperation was the key element in holding together this loose confederation. Diverse disciplines, many government agencies, some private foundations, separate organizations, sometimes competitive interests, and strong personalities worked together for the improvement of the lives of the disabled.

The fact that substantial government funding was available, though never on the scale needed for the awesome task of truly replacing human parts and functions, tended to minimize the importance of private funding for the research and development and even for the dissemination of results. One chronic problem, though, has always been the transition from a reasonably well-developed laboratory model with a very limited clinical experience on "professional" pilot wearers into a routinely available, commercially manufactured component available in high quality and at low cost to skilled and trained practitioners throughout this country and abroad for fitting to large numbers of individual patients.

Some devices were purchased in modest quantities for field tests through the National Academy of Sciences itself in the 1950's or through the Veterans Administration Prosthetics Center after that group was organized in 1956. Typically, AOPA was asked to suggest a group of potential bidders to make proposals for tooling and for construction of some modest number of models needed for a wide scale field trail or evaluation. Because of fiscal restraints and practical problems, numbers of copies were usually smaller, and statistical validity was low. (Early attempts to interest other organizations lacking experience and distribution facilities in the prosthetics field had been frustrating and largely disappointing.) Typically, the manufacturer of the initial test models has evolved into the principal, if not sole, manufacturer of the final device—if indeed it proved to be successful in the field trials. The field has been so small that there

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frequently has been no room for multiple manufacturers of a single relatively complex device, although other versions with somewhat comparable yet somewhat different functions sometimes evolve in parallel. Field trials should refine not only the hardware but the prescription, fitting, and training techniques, the manuals, and the maintenance procedures. All participants in a clinic team become familiar with the new development.

There has long been interest in stimulating private support of research and development, presumably based upon the results of fundamental studies conducted under government auspices. The government-supported program has sometimes received or purchased a few early test models of private inventions and has had its intramural or contract laboratories conduct studies with these test models, thereby providing a useful consulting service to the inventor or manufacturer which he probably could not readily obtain otherwise. This kind of independent evaluation may well become increasingly important under the medical device amendments in order to prove safety and effectiveness of new devices.

In any evaluation, there are problems in simultaneously assuring competence without bias and in providing constructive criticism in useful form which can be applied to improving the device for all disabled.

With the continuing and indeed increasing pressure upon government budgets, it would seem that the developers must increasingly come from private industry. Karl Vesper, the engineer and investment expert who organized the original Hosmer Corporation in the 1940's, was an early participant in the NRC and VA programs. He pointed out that as a private entrepreneur he could effectively estimate the potential strengths of competitors and their ability to develop and market new products within given time periods, so he could make his own choice of development expenditures wisely. Conversely, though, he could not predict what a government agency might do, particularly under political and other pressures. Though the existing government research and development projects are public knowledge, for example through progress reports published in the Bulletin of Prosthetics Research, private developments may well be "proprietary secrets." The net balance between these and other disadvantages and advantages for private development is hard to estimate. From the standpoint of the disabled of the world, one can only hope for a frank, friendly, and cooperative relationship between private entrepreneurs, government sponsors and regulators, government purchasing or using services at all levels, third-party purchasers, and the several professions concerned.

Meetings and Events

Please notify the National office immediately concerning additional meeting dates. It is important to get meeting notices in as early as possible. In the case of Regional Meetings, check with the National Office prior to confirming date to avoid conflicts in scheduling.

1982, April 16–17, AOPA Region I Meeting, Marriott Hotel, Worcester, Massachusetts.

1982, April 24, New York State Chapter, AAOP Seminar, Albany Medical College, Albany, New York.

1982, April 24–25, ABC Practitioner Certification Written Exam, New York City, San Francisco, Chicago, Atlanta and Dallas.

1982, April 29–May 1, AOPA Regions VII, VIII, X, XI Combined Meeting, Alameda Plaza, Kansas City, Missouri.

1982, May 6–9, AOPA Region IV Meeting, Radisson Plaza Hotel, Nashville, Tennessee.

1982, May 10–13, Advanced Course on Below-Knee and Through-Knee Amputations and Prosthetics, ISPO, Copenhagen, Denmark.

1982, May 27–29, AOPA Region V Meeting, Charleston House, Charleston, W. Virginia.

1982, June 1–3, Canadian Association of Prosthetists & Orthotists National Convention, Skyline Hotel, Ottawa, Ontario, Canada.

1982, June 4–6, AOPA Region IX, COPA, and the California Chapters of the AAOP Combined Annual Meeting, Harrah's, South Lake Tahoe, Nevada.

1982, June 10–13, AOPA Regions II and III Combined Meeting, Claridge Hotel, Atlantic City, New Jersey.

1982, June 17–20, AOPA Region VI and AAOP Midwest Chapter Combined Meeting, Indian Lakes Resort, Bloomingdale, Illinois.

1982, June 22–25, Orthopadie Technik '82 International Congress, Wiesbaden, Germany.

1982, July 30–31, AAOP Northwest Seminar, Portland, Oregon.

1982, August 13–14, AAOP Midwest Seminar, Kansas City, Kansas.

1982, September 8–10, Second Annual Advanced Course of Lower Extremity Prosthetics, Nassau County Medical Center, East Meadow, New York.

1982, October 19–23, AOPA National Assembly, Shamrock Hilton, Houston, Texas.

1983, January 26–30, AAOP Roundup Seminar, Hyatt Islandia, San Diego, California.

1983, April 21–23, AOPA Region IV Meeting, Jackson, Mississippi.

1983, May 12–14, AOPA Regions II and III Combined Meeting, Colonial Williamsburg, Williamsburg, Virginia.

1983, May 25–28, AOPA Regions VI, VIII, X and XI Combined Meeting, Hotel El Tropicano, San Antonio, Texas.

1983, June 3–5, AOPA Region IX, COPA, AAOP California Chapters Combined Annual Meeting, Harrah's, South Lake Tahoe, Nevada.

1983, September 5–9, The IV World Congress of the International Society for Prosthetics and Orthotics, Imperial College of Science and Technology, London, England.

Winter Honorarium

Peter A. Ockenfels, CPO has been awarded the $100 honorarium for his article, "Management and Construction Procedure of Bilateral Split-Bucket Type Hip Disarticulation Prosthesis."