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Transfer of Rehabilitation Research and Development Results into Clinical Practice

by Margaret Giannini, M.D.*

The Veterans Administration, Rehabilitation Research and Development Service (Rehab R&D) funds approximately 100 projects a year aimed at developing new methods or improving existing techniques for assisting disabled veterans. The program was created by a Congressional mandate, U.S.C. 38, Sec. 4101, (c)(1) and (2), which directs that the VA "carry out a program of medical research including prosthetics research. Prosthetics research should include research and testing in the field of prosthetic, orthotic and/or orthopedic appliances and sensory devices."

A review of Rehab R&D scientific and engineering accomplishments provides insight into the VA/Rehab R&D technology-transfer programs. Some of the recent and ongoing research conducted under this sponsorship includes: maxillofacial restorations—to include use of biomaterials and their clinical applications; development and evaluation of robotic aids for the severely disabled; seat cushions for the paralyzed to prevent decubitus ulcers; functional electrical stimulation (FES) systems for upper extremity control; physiological effects of FES on paralyzed muscles; walking restored in a paralyzed man using FES; a motion-guiding load-bearing external frame for the knee; possible myoelectric controlled above-knee prosthesis; oprimum prosthetic foot characteristics for the dysvascular below-knee amputee.

In addition to sponsoring such research in the past, Rehab R&D has established a program concerned with the transfer of research into clinical practice. This program consists of the following six parts:

1. Establishing clinically relevant research priorities.
2. Insuring that the significant research encompasses clinically relevant factors.
3. Dissemination of research findings to the scientific community.

*For more than thirty years, Dr. Margaret Giannini has been a pioneer in creating programs for the diagnosis, treatment, education, rights and affairs of the mentally retarded, developmentally disabled and the handicapped.

In 1950, Dr. Giannini founded and directed the Mental Retardation Institute at New York College. In 1980, she accepted a Presidential appointment as the first Director of the National Institute of Handicapped Research, a branch of the U.S. Department of Education. In April, 1981, Dr. Giannini took over the position of Director for the VA Rehabilitation Research and Development Service (Rehab R&D).

In addition to these positions, Dr. Giannini is past-president of the American Association on Mental Deficiency and past-president of the American Association of University Affiliate Progams, two of the most influential organizations concerned with the mentally and physically handicapped.

Dr. Giannini is the recipient of many awards from varying organizations in recognition of her professional and humanitarian services and achievements. She also has authored and co-authored numerous publications; presented many lectures, papers, keynote addresses; and participated in panel discussions and workshops throughout the world.

A native of New York, Dr. Giannini is married to Louis J. Salerno, M.D. and has raised four sons. Dr. Giannini is scheduled to speak at the Academy Annual Meeting in Orlando on January 26, 1984.

4. Evaluation of research results for suitability for transfer to clinical settings.
5. Support to private industry to make new devices and equipment commercially available.
6. Dissemination of new methods to clinical practitioners.

Each of these is examined at length in the remainder of this paper.

Establishing Clinically Relevant Research Priorities

In the past, the VA had only general research priorities for award of Rehab R&D funds. Oftentimes researchers focused proposals on esoteric topics which were of little or no clinical significance while major clinical issues went unaddressed. To remedy this situation, a series of workshops were held with consumers and clinical leaders to develop priorities for research on clinically significant issues.

Many of the workshops sponsored by RESNA and the VA have been published. Workshop topics have included sensory aids, functional electrical stimulation, and prosthetics/amputation. Rehab R&D also has participated in meetings of the International Standards Organization (ISO) which established specific priorities within the areas of prosthetics/amputation, spinal cord injury (including wheelchairs), and sensory aids. Rehab R&D now has a policy of soliciting and approving funding for only those proposals which fall within these priorities.

Ensuring that Research Addresses Relevant Clinical Issues

There is a vast distance between research and clinical application of methods and devices. Rehab R&D has the responsibility not only to fund research, but also to initiate and support the development of the clinical methods necessary for effective application. For example, the outstanding work done by Ernest Burgess, M.D., in Seattle, and others on immediate postoperative fitting requires new and complex clinical procedures. A necessary step in promoting clinical application of this method has been the development of a clinical procedures manual and the training of practitioners and patients.

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Dissemination of Research Findings

The new VA *Journal of Rehabilitation R&D* replaces the earlier *Bulletin of Prosthetics Research* with a number of major changes. Aimed at the entire scientific community, and charged with following the highest standards of scientific quality, the *Journal of Rehabilitation R&D* is designed to offer an interdisciplinary vehicle for publication of technical materials which can most directly reach rehabilitation professionals. In addition to the *Journal,* the first edition of a new annual publication *Rehabilitation R&D Progress Reports,* is now in press. This publication is aimed at providing a comprehensive overview of research and development now in progress both in the United States and internationally. One of the publication's functions will be to serve as a guide to sources of information within the areas of Rehab R&D priorities.

Rehab R&D, in the planning stage of developing, will work in coordination with professional organizations in the field to facilitate the translation of scientific results into technical clinical information of direct relevance to practicing clinicians.

Evaluation of Research Results

The Chief Medical Director of the VA has given approval to establish the Development and Evaluation Program (DEP) for the evaluation of research and development findings to determine their suitability for adoption into clinical practice. The program is designed to stimulate, evaluate, and acquire and disseminate information, including the development of educational guidelines and technical manuals.

The educational guidelines will be coordinated between the Continuing Education Resources Service and the Prosthetics and Sensory Aids Service (PSAS). Thus, both the people who will prescribe and/or use these new devices, techniques, or concepts, will be trained. Rehab R&D will not actually provide the training, but it will provide the data and/or research scientists as instructors for the training program. This Rehab R&D program is currently limited to devices specifically developed in VA or other federally funded R&D projects.

Rigorous evaluation will provide objective and comprehensive information to the key decision makers related to clinical adoption. Information will be provided to funding agencies—including the VA—which must formally approve reimbursement of the devices or use of procedures in clinical practice; to industry so they can decide whether to add the devices to their commercial lines; and to clinicians who must decide on how to apply the new methods or devices. VA responsibility for evaluation will be shared cooperatively between Rehab R&D on new research, and by the VA's Prosthetics and Sensory Aids Service on devices which are already commercially available, but have not been previously evaluated.

Support to Private Industry to Make New Devices Commercially Available

No matter how good research and engineering results are, they are of no value unless they become available to clinicians. Many useful devices which have resulted from research are not commercially available. To overcome this

gap, discussions have been held with industrial leaders who have offered advice on the nature of the rehabilitation market, which is just one impediment. Based upon the input of these industrial leaders, commercial availability is being attacked on two fronts.

First, an interagency agreement with the Department of Commerce has been developed to assist small minority business firms in tooling-up for offering new products as a part of their commercial lines. Specifically, the interagency agreement provides for the study of marketing and development methods to fully utilize the research and development of new devices for the disabled. The purpose of this interagency agreement is to utilize existing programs in the Minority Business Development Agency (MBDA) and stimulate marketing for devices that result from VA-sponsored R&D.

The National Commission of Technology Transfer, of the Department of Commerce, is in the process of offering funding in order to:

- plan for an international conference on making prosthetic and orthotic devices and sensory aids readily available to the handicapped population;
- identify and develop potential markets and financing for such devices;
- examine the use of microcomputers and other high technology areas;
- examine the impediments to obtaining funding for high-technology products; and,
- develop a process that leads to the commercialization of technology researched and developed by the VA, with emphasis on providing access to these markets for minority entrepreneurs.

Arrangements have been made to encourage private industry to adopt the results of individual reseach products which are judged to have particular merit. As a result of these efforts, the Johns Hopkins Manipulator will soon be commercially available. Other negotiations are continuing. To facilitate this process, VA Rehab R&D has assisted in the creation of a National Commission for Technology Transfer, which is concerned with making research results commercially available to handicapped people.

New Directions

Future plans by VA Rehab R&D to assist in the transfer of technology from research to clinical practice are as follows:

- Continued publication of the *Journal of Rehabilitation R&D* and the *R&D Progress Reports;*
- Publication and distribution of papers on subjects potentially relevant to future clinical practice (e.g. training manual for use of robotic systems for the severely disabled);
- Design and implementation of a formal research program, based at the Office of Technology Transfer, to evaluate and improve the transfer of technology, including:
  1. The collection of clinical practice data from VA facilities to give a chronological picture of the gap between state-of-the-art devices and actual clinical practice;
  2. A series of consumer surveys to determine their needs and to uncover problems or frustrations with existing rehabilitation procedures and equipment; and,
  3. A series of surveys among clinical practitioners to collect data on clinical needs, problems and priorities.
- A periodical and/or a technical communication in existing periodicals for clinicians, designed in cooperation with PSAS, the Academy, AOPA, AAOS, Paralyzed Veterans of America, Disabled American Veterans, National Institute of Handicapped Research, and other organizations to further enrich the transfer of new research findings to clinicians in a format tailored to their practical needs. In the long run, a computerized reference system may be developed;
- Seminars on selected topics between recognized clinical leaders and senior researchers who have achieved scientific breakthroughs relevant to clinical practice; and,
- Access to national and international scientific and clinical literature.

These thrusts are ambitious and will take time, but they convey the depth of Rehab R&D commitment to technology transfer.

Prosthetic-Orthotic Research—A New Thrust is Needed: A Clinician's Perspective

Charles H. Epps, Jr., M.D.*

Since the prime supporter of research, the federal government, has sharply reduced some areas of funding, the efforts of many established investigators and programs have been curtailed. Hardest hit has been the young aspiring investigator without a track record, who has found it virtually impossible to acquire funding for initial research efforts. Basic research as well as clinical research has suffered. Prosthetic and orthotic research programs which have never had abundant or even adequate funding also have been adversely affected.

In the area of upper extremity prosthetics, much research remains to be done. For the patient who wears a prosthesis, cosmesis is still a major concern. Cosmetic acceptability must be improved and sensory feedback must be developed; sockets must be made more comfortable and suspension must be improved. Myoelectric control systems and other methods of external power must be made more functional, more compact, and more economical.

In the lower extremity, newer materials and techniques must be developed to make prostheses lighter in weight, especially for the geriatric wearer. Although there seems to be less enthusiasm today for skeletal attachment of prostheses, the concept remains a challenge. The mechanical integrity and durability of knee devices can be improved along with fitting and alignment techniques.

Because of basic lack of knowledge about the effects of forces on bone, ligaments and tendons, the need for orthotic research is even greater than in prosthetics. More

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needs to be known about the magnitude and patterns of forces that are necessary and safe to orthotic applications. Workers in kinesiology and gait laboratories around the country are endeavoring to find more answers to diagnostic problems and to collect useful data for orthopaedic assessment and even surgical treatment. New materials offer the orthotist new versatility. The pneumatic orthosis, a new concept, is ready for full development. Electrical applications are at an embryonic stage in the stimulation of paralyzed muscles, inducing therapeutic exercises, and providing afferent or feedback systems. New interest has developed to improve powered mobility devices to replace the conventional electric wheelchair for the high level spinal cord injured patient. Specially adapted vans can be operated safely by paralyzed, limb deficient patients and other severely handicapped. In view of the potential offered by computer applications and rapidly improving robot technology, environment control devices are on the threshold of great advances. So much remains to be done in prosthetic-orthotic research that even the casual observer must be concerned.

At the same time that public research dollars have decreased, private research dollars have not increased sufficiently to fill the void. Obviously, research needs offer a challenge to orthopaedic surgeons who must increase the amount of personal time and funds given for research. At least one encouraging sign of private sector philanthropy exists. Bristol-Meyers/Zimmer U.S.A. has donated 1.2 million dollars to the Orthopaedic Research and Education Foundation (OREF) for the 1983–1984 Campaign. To date, more than 150 orthopaedic surgeons have given $1,000 each to OREF for the current campaign. This is in sharp contrast to the previous years' total of $200,000 from all sources. Other members of the industrial community should duplicate and even surpass the example set by the Zimmer group.

If this instance of giving by the orthopaedic surgeons and a prime industrial supplier is replicated by prosthetic-orthotic practitioners and members of the corresponding industrial manufacturing community, the funding for prosthetic-orthotic research can be adequately raised to support needed research programs.

From Research Lab to Consumer: The Manufacturers' Point of View

Carlton Fillauer, CPO*
Charles H. Pritham, CPO†

The matter of transferring new developments from the researcher to the consumer is one that has bedeviled the American prosthetic-orthotic establishment for years. The researcher, the agency that funds the research, the manufacturer, the clinician, and the patient are all, of course, interested in seeing new products brought to market, and all stand to benefit. Financially, the manufacturer is the one who stands to benefit the most from the successful introduction of a new product. Only by such means does a manufacturer expand his base and increase earnings. If the incentives are greatest for a manufacturer, the risks are also proportionately greater. In making a decision to produce a new product, the manufacturer must weigh the risks against the potential benefits and make a decision about committing his resources. It should be obvious that once resources of time, effort, and money are lost backing an unsuccessful product, they are lost forever. What is not so obvious is the fact that the loss is threefold.

Potentially, at least, the resources expended for backing a losing product could have been invested in a successful one, turning a loss into a profit. Also, in making the decision to back a new product the manufacturer commits his prestige and credibility. A positive result resounds to his credit, attracting new attention to products currently being produced and assuring a positive reception for future products. A negative result has the opposite effect, tarnishing the image of other items in the manufacturer's product line and damaging his credibility. That the investment in a new product can be a high one should not be discounted, therefore.

A small group of highly skilled and motivated individuals (or an inventor working alone) can, with a relatively low investment in machinery, produce complicated prototypes efficiently and with a low rejection rate. When the time comes to produce the same object in large numbers, the factors are fundamentally different. Production workers are seldom so skilled or motivated. Oftentimes, to overcome bottlenecks in production and to achieve consistent results, a product must be redesigned. The cost of this redesign must be borne by the manufacturer. To achieve productivity and consistent results, the manufacturer will develop tools, dies, and molds with which to produce a device. Resorting to such an alternative can enable relatively unskilled personnel using inexpensive materials to produce products of great appeal and excellent quality. While the material costs of such objects can be measured in the cents, the cost of the molds and dies can frequently run in the thousands of dollars each. If it is necessary to produce the device in a range of sizes and in right and left, the cost can be prohibitive. It should also be borne in mind that the researcher or inventor frequently has only partially tested the prototype and further testing and development must precede redesign for production. The direct expense of manufacturing an object, however, is only a portion of the cost.

In order to sell a product it must be promoted and advertised. The total expense of attending a convention (often far from home), renting space to exhibit, and obtaining a suitable display is not cheap. Commissioning the art work and copy of an advertisement, and obtaining space for it in a journal are, similarly, of considerable expense.

The organization that makes all this possible (research and development, production, and promotion) can fre-

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quently be quite large and demand a sizable indirect labor force to administer the resources and personnel involved. The total expense of all factors involved in developing a new product is a figure to be reckoned with and can be justified only if the product has the potential of selling in sufficient quantities to recoup the original investment and earn a favorable rate of return. It is in connection with this that the greatest stumbling block is encountered. Whatever the merits of a design may be, a manufacturer can not afford to devote the resources to its development if it will not sell in a large enough volume to enable him to sell it at a reasonable cost.

Despite the optimistic expectations of a developer, the market for his new object is seldom as large as he hopes. All researchers and developers seeking federal research money are asked to project the number of individuals for whom their work will be applicable. As all involved will admit, it is a fundamental fact of the way that health care is funded in the United States and the way that health care statistics are gathered that the best of projections are crude estimates. What statistics are available point to the fact that the total market for any one product is small. This market is rendered smaller because not all members of that market are in the marketplace at one time, or even interested in the new product.

A new product must compete for a share of the market with existing products that do the same thing. It should be kept in mind that few, if any, developments are so radically different as to have no potential competiton for market share. The price at which established products are sold limits the price for which a new product can be sold. For a new product to rapidly gain market share, it must be reasonably priced versus the competition, potentially much better than the competition, and current users must be very dissatisfied with the competing product.

On a practical level, the people to whom a product must be marketed are not the ultimate consumer, but the prosthetist-orthotist who will render that product into a form suitable for a particular patient, and who must also frequently convince the physician to prescribe the device.

At any one time, there are said to be about 2,000 practicing prosthetists-orthotists; that is hardly a mass market. Prosthetists-orthotists as a group are not the easiest group to introduce to a new product. Most of them have experience with one or more products that, despite the manufacturer's best efforts, were released before all the problems were worked out. Like the car buyer who chooses not to buy a car during its first model year, they prefer to wait and see. Others, while interested in trying a new product are "waiting for just the right patient." On the other hand, a disconcerting number are all too ready to rush in without thought.

Battling for preeminence in every prosthetist-orthotist's lexicon of adages to live by are the two:

1. If all else fails, read the instructions.
2. Don't force it, get a bigger hammer.

Every manufacturer can recount instances of practitioners who provided a device to a patient for whom it was specifically contraindicated, or who neglected one or more crucial precautions in fabricating the completed device. This can result in a wave of negative word of mouth publicity despite a manufacturer's best efforts to promote a new product and educate the profession about its proper use. The end result may be passive indifference, or active rejection whatever the positive merits of a new device are when it is properly prescribed and utilized.

A developer of a new object has a vested interest in making it work successfully and will go to considerable pains to make it do so. It is a well recognized fact that a product, when transferred to even the best motivated and prepared practitioners, seldom works as well as it does for the developer.

In summary, then, the following points can be made:

1. The following factors are sizable expenses:
   a. Research and development of the original idea to a workable prototype
   b. Production design
   c. Tooling
   d. Manufacturing

Questionnaire

1. Do you believe the amount of public funds available is adequate for prosthetics and orthotics research?

   Yes _____ No _____

2. Do you believe appropriate research and development is conducted?

   Yes _____ No _____

3. In each of the three categories below, indicate your personal priorities for research that needs funding. (1 being the highest priority)

PROSTHETICS

_____ External power for upper extremity prosthetics
_____ Sensory feedback upper extremity prosthetics
_____ Improved body power for upper extremity prosthetics
_____ Better lower extremity prosthetics for geriatrics
_____ Extra-ambulatory advance performance lower extremity prosthetics for younger amputees
_____ Alignment and gait analysis for lower extremity prosthetics
_____ Cosmesis
_____ Other _____

ORTHOTICS

_____ Upper extremity orthotics
_____ Lower extremity orthotics
_____ Spinal orthotics
_____ Gait analysis for lower extremity orthotics
_____ Seating
_____ Other _____

GENERAL

_____ Materials
_____ Fabrication technology
_____ Basic science as related to prosthetics and orthotics
_____ Other _____

4. Additional Comments: _____

_____

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e. Quality control and testing
f. Marketing

2. Considerable uncertainty surrounds the business of gauging market size and reception for a new product.

3. However well an object sells, the field of prosthetics and orthotics can hardly be said to constitute a mass market of sizable proportions.

4. Experience has repeatedly shown that it takes three years to achieve a profitable volume of sales once a new product is introduced.

The result of these facts is that the manufacturers of items for use in the prosthetic and orthotic market are confronted with the need to make sizable initial investments for a rather small market that is oftentimes slow to adopt new products of even the greatest merit. Considerable uncertainty surrounds the decision to make the investment and it can take many years for a return on the investment to be realized and the decision to be vindicated. Given these facts, it is understandable that manufacturers differ from developers and their backers about the utility and acceptability of many developments, and that they are slower to adopt new products than others might wish.

Flexible Prosthetic Socket Techniques

H.R. Lehneis, Ph.D., CPO*, Don Sung Chu, M.D.*, Howard Adelglass, M.D.*

The continuous development and availability of new materials of various kinds, e.g., elastomers, copolymer thermoplastics, and composite materials have brought a potentially revolutionary development in the design, configuration, and fitting principles of prosthetic sockets, especially for above-knee prostheses. All of this may result in greater patient comfort, physiological, and psychological advantages.

Improvements in socket comfort with concomitant physiological and psychological benefits are not only due to the materials themselves, but rather, the inherent characteristics of the various materials used permit socket configurations heretofore not possible. For example, socket fenestrations over selected or entire stump surface areas are now possible. The desirability and principle of permitting greater flexibility over muscular areas than is possible in a rigid, laminated socket were appreciated more than 25 years[1] ago in the fitting and design of the "Flexicage" socket[2] which consisted of nylon cords strung between the proximal brim and the distal end of the socket. McCollough, et. al.,[3] as early as 1968, attempted fenestrations over selected socket areas. These attempts, however, were not generally successful because of the potential and real problems with window edema and the properties of the material used. These problems now have been overcome through the availability of materials which can be used as elastic or semi-elastic inserts, preventing window edema, yet permitting removal of the outer rigid socket shell in selected areas.[4,5]

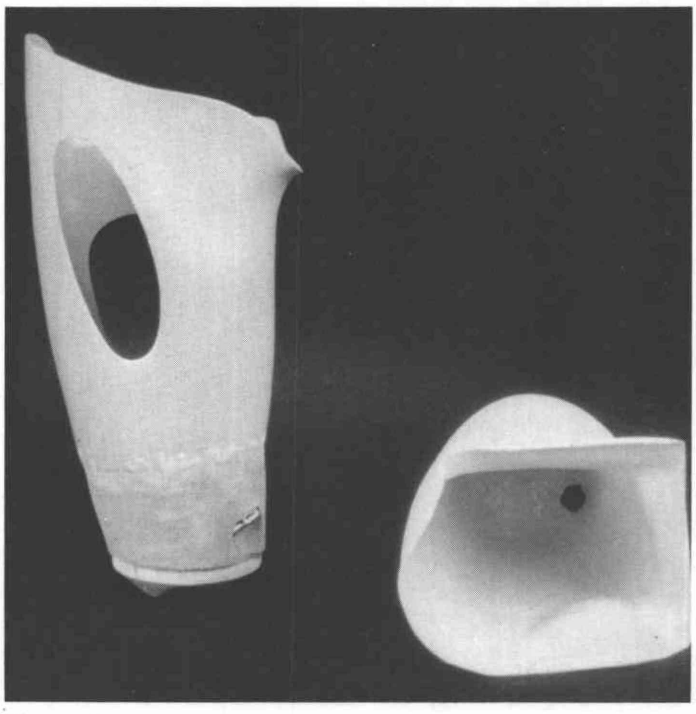

Figure 1.

Below are described several approaches allowing flexible or semi-flexible stump containment, while maintaining the essential biomechanical characteristics required for interface stability to transfer body weight through the prosthesis to the ground, and for dynamic and safe control of the prosthesis.

Two systems are curently used at the Institute of Rehabilitation Medicine at NYU Medical Center (IRM-NYU) to provide the characteristics described above. The first system consists of an inner socket laminated of Perlon fiber and silicone elastomer contained in a rigid plastic laminated socket (Figure 1). The laminated silicone elastomer has nearly perfect memory and permits fenestrations of the rigid outer socket over the posterior area (Figure 2), rectus femoris (Figure 3) and the adductor group, without causing window edema. This design permits greater muscle expansion than the designs described below because of the elasticity of the silicone material. It also provides enhanced sensory feedback, particularly when sitting, i.e., the patient is able to feel the surface of the chair or seat. The soft liner is also a boon to improved comfort, particularly in geriatric amputees and those with a history of general socket discomfort.

The second design utilized at IRM-NYU is a Surlyn™ inner socket (Figure 4) which permits removal of even more of the hard outer laminated socket (Figure 5). The reason larger areas of the hard socket can be removed is the lesser flexibility of Surlyn™. Thus, more rigid material can be eliminated without compromising the integrity of known biomechanical principles (Figure 6).

A more recent design developed in Iceland and further refined in Sweden and at New York University, known as the ISNY socket, consists of a medical rigid frame only, leaving the rest of the polyethylene socket semi-flexible.

For below knee amputations, similar systems have been developed at IRM-NYU and in Belgium by Van Rolleghm

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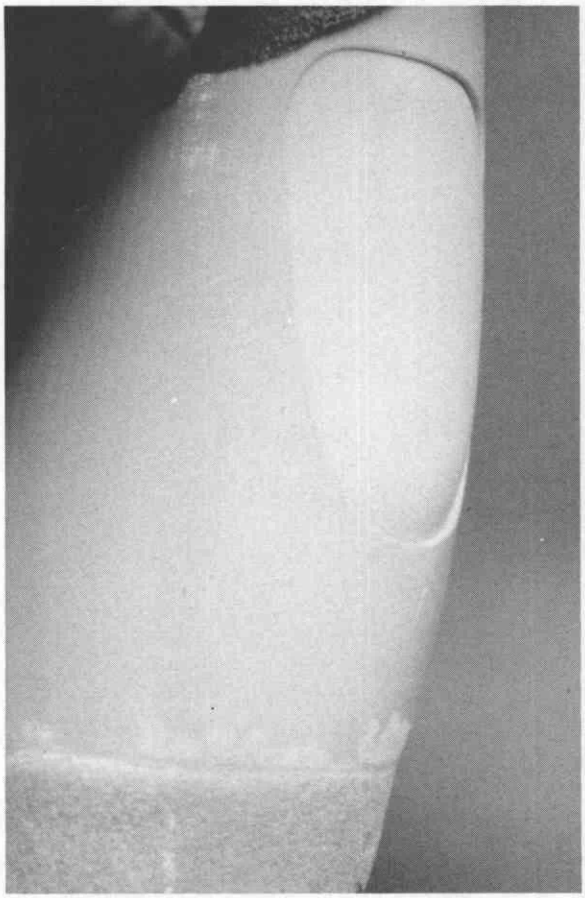


Figure 2.

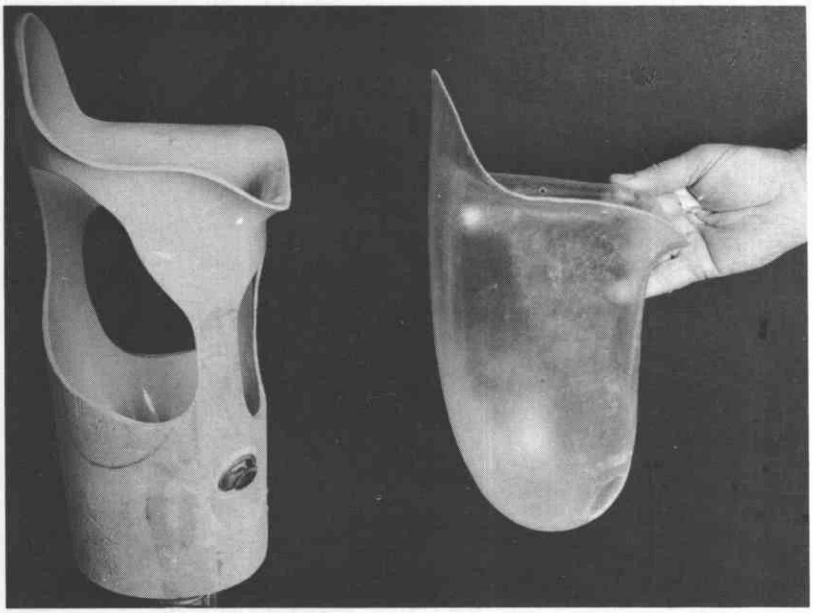
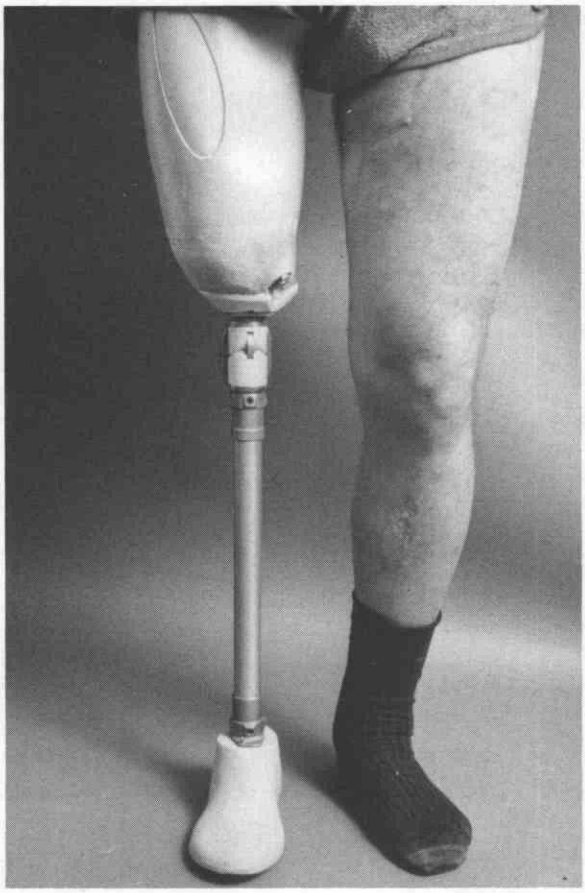


Figure 4.

of CEBELOR.[6] In the IRM-NYU system, a Surlyn™ inner socket permits removal of material in the outer laminated socket over bony or pressure sensitive areas (Figure 7). This permits easy inspection of these areas and ease of adjustment by heating the inner socket to further relieve painful areas.

The CEBELOR consists of a silicone laminated soft socket insert for the SP-SC below-knee prosthesis. Thus, it is self-suspending, provides improved comfort, and permits selected fenestration over pressure sensitive



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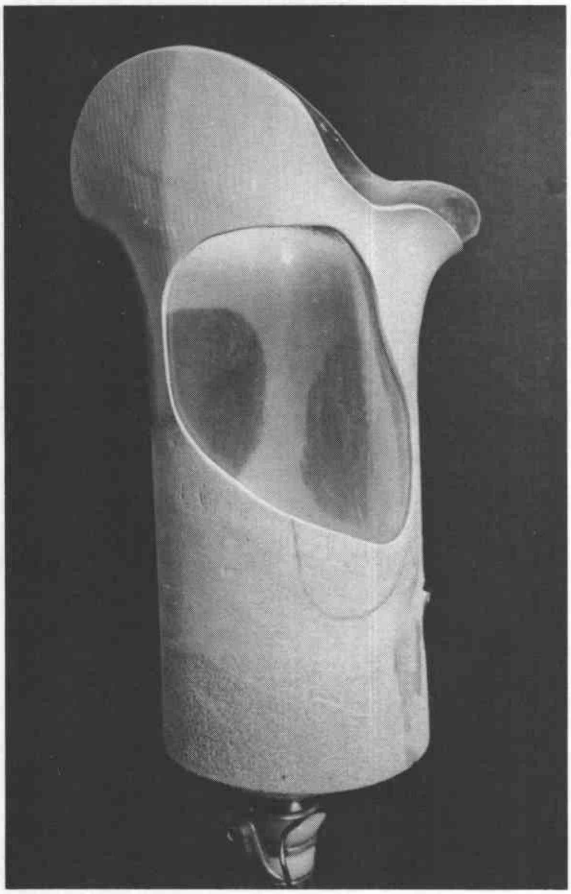

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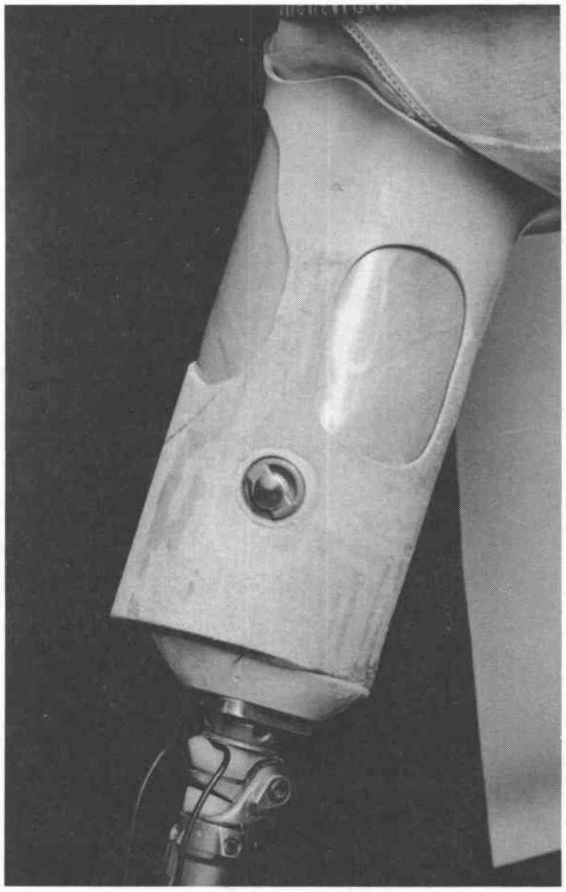

Figure 6.

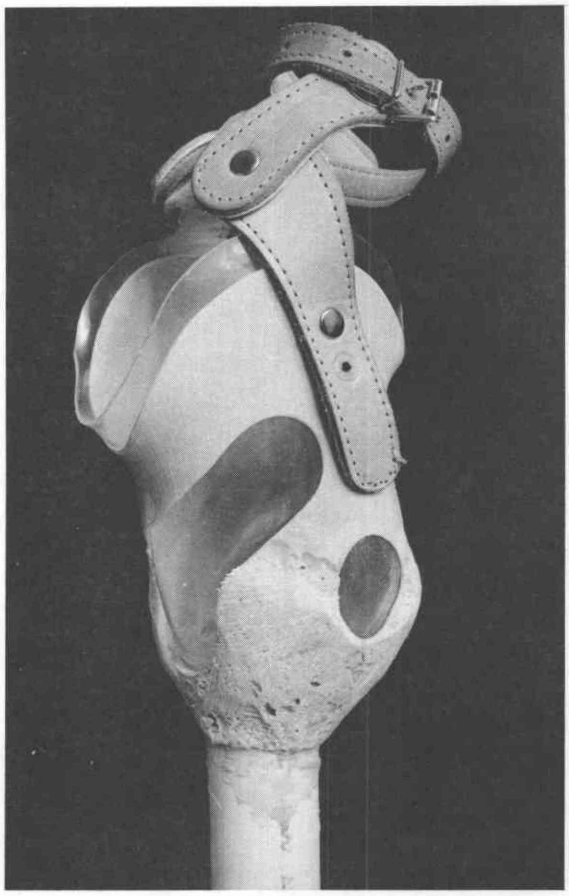

Figure 7.

areas, e.g., head of the fibula, distal end of the tibia. To prevent slippage and rotation of the inner silicone socket, distal and posterior plugs are laminated as an integral part of the soft socket to fit into female counterparts in the plastic laminated socket.

Summary

While the various systems described above employ different materials and socket configurations, certain characteristics are common to all systems. These are: improved muscle physiology due to greater socket flexibility; enhanced sensory feedback; quicker heat dissipation due to thinness of the flexible stump containment material; and improved comfort, especially in the IRM-NYU and CEBELOR systems with the soft silicone liner.

All these are important improvements which were made possible through the use of flexible or semi-flexible materials. Yet, the biomechanical principles of providing stump containment, weight transfer, and control of the prosthetic limb are not compromised. In the ISNY System, however, it is not clear how lateral and anterior/posterior stability of the femur is achieved, since there are no structural components in areas conventionally considered to provide such stability. This question, however, will be addressed in studies to be conducted in the near future.

Acknowledgments

The participation of Donald Fornuff, CP, and Roger Chin, CPO, in the development of the IRM-NYU systems is gratefully acknowledged.

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Results of Questionnaire on Professionalism

There were seven respondents who replied as follows:

1. Do you believe the profession's Carons of Ethical Conduct benefit the public?
   Yes—6 (85%) No—1 (14%)

2. Do you believe they are adequately enforced?
   Yes—0 No—7 (100%)

3. Do you believe that society has benefited from the presence of various governmental bodies in the area of self-regulation (of all professions)?
   Yes—4 (47%) No—3 (43%)

4. Define professionalism
   A. "Treating people in courteous, candid, and knowledgeable fashion in accordance with our most current state-of-the-art and in harmony with the physician's prescription."
   B. "Professionalism means conducting your actions and interactions in such a way that people respect you whether they agree with you or not."
   C. "Having a commitment to ethical conduct within a certain job or industry."

5. Other comments
   A. "Notify funding agencies of our concern that non-credentialed people are providing services."
   B. "It seems that all professions have a few who are looking out for their own best interests. It seems that greed and the awareness that a strong enforcement agency does not exist to put them out of business motivates these few."

A Case History

Clinical Indication for Flexible Above-Knee Prosthetic Socket

Howard Adelglass, M.D.*, Don Sung Chu, M.D.*, H.R. Lehneis, Ph.D., CPO*

R.W. is a 62 year old male with a 32 year history of insulin dependent diabetes mellitus. He was in a normal state of good health until August, 1982 when he developed gangrene of the first three toes of his left foot. A left femoral popliteal bypass was performed unsuccessfully. He then underwent a left below-knee amputation which also was unsuccessful and, in October, 1982, a left above-knee amputation was done. In December, 1982, he was admitted to the Institute of Rehabilitation Medicine, NYU Medical Center(IRM-NYU) for a prosthetics rehabilitation program. At that time, his stump became infected and dehissed, requiring stump revision.

In July, 1983, he was readmitted to IRM-NYU and started on gait training with an AK prosthesis with a semi-suction socket, hip joint and pelvic belt, polycentric knee joint (Lang) and SACH foot (Figure 1). During the course of his rehabilitation training, he began complaining of pain at the distal stump. The socket was adjusted numerous times by alternately relieving painful areas distally and placing padding above these areas, but with little success. Subsequently, x-rays taken of the stump revealed a small amount of soft tissue calcification distally with a small spur at the posterior lateral side of the femur (Figure 2). The patient was started on anti-inflammatory agents which provided a moderate amount of pain relief. However, he still had difficulty ambulating secondary to stump pain.

A lateral pad above the distal end was inserted into the prosthesis which relieved some of the pain. However, within a few days, the patient developed a skin break-

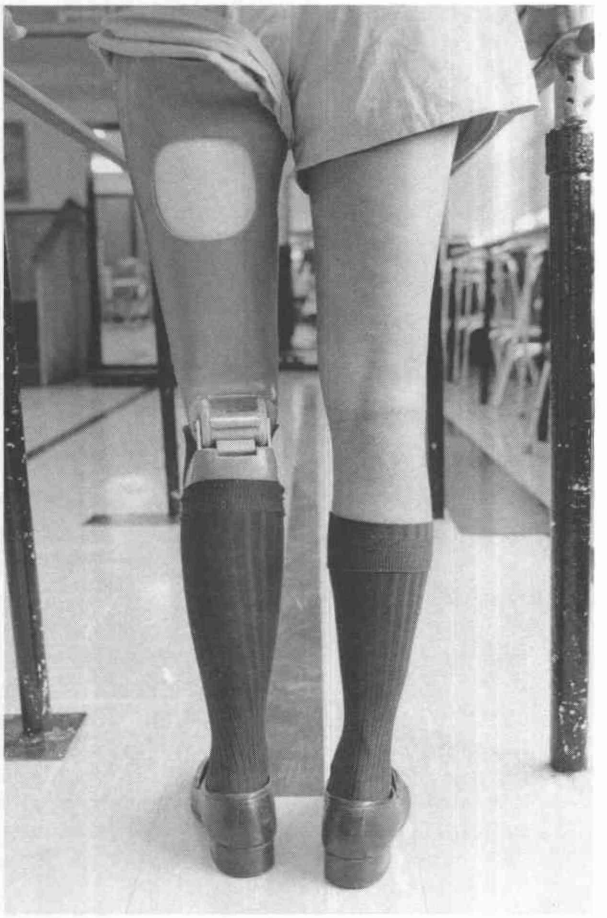

Figure 1.

*Institute of Rehabilitation Medicine, NYU Medical Center (IRM-NYU).

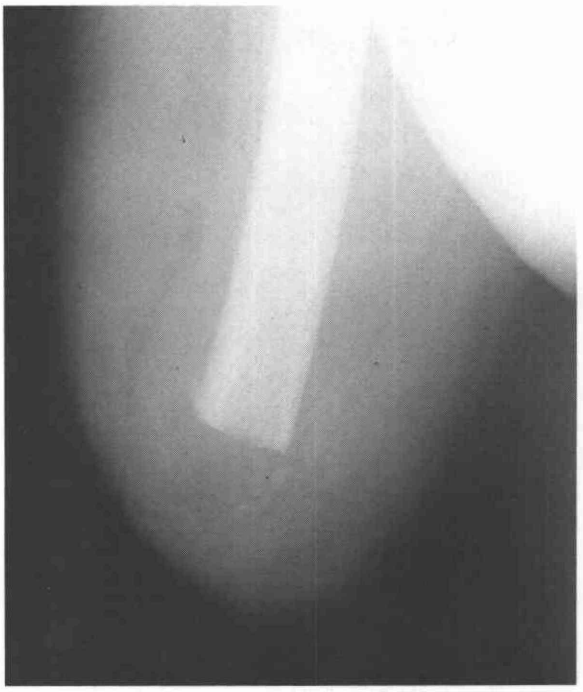

Figure 2.

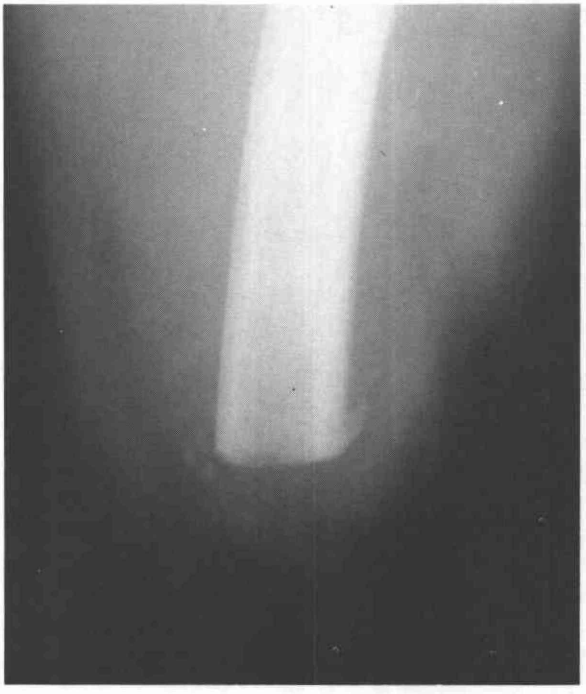

Figure 3.

down in the left peroneal area, and an erythematous area on the distal stump. The patient was not allowed to wear his prosthesis for 2½ weeks. During this time, a repeat stump x-ray showed a large spur in the posterior lateral side of the distal stump and more soft tissue calcifications on the anterior surface of the stump (Figure 3). Consequently, a new socket was designed to give relief over the distal anterior and posterior stump in order to decrease the pain and improve ambulation.

This socket consisted of a vacuum-molded inomer (Surlyn™) flexible socket contained in plastic laminated socket. There were fenestrations put into the anterior (Figure 4) and posterior walls (Figure 5) of the rigid outer

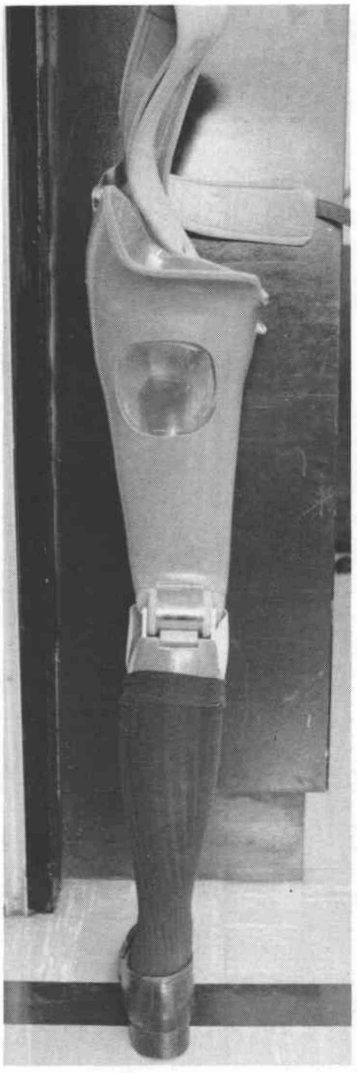

Figure 4.

Figure 5.

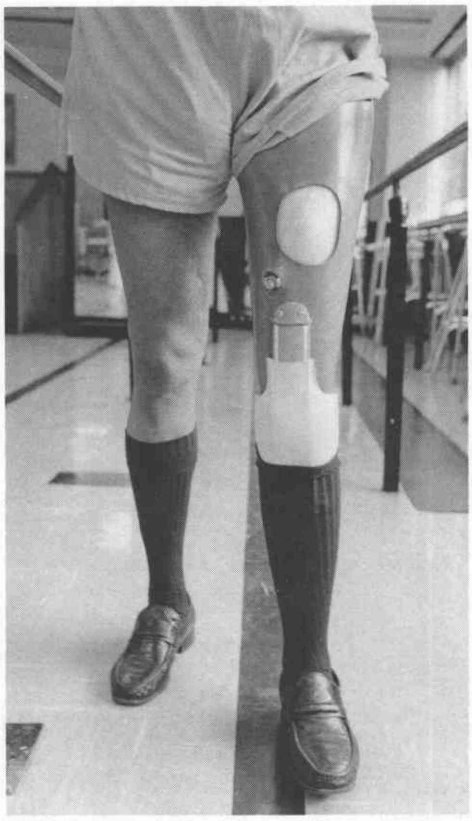

Figure 6.

socket, which afforded relief to the area of spur formation and soft tissue calcification.

The flexible inner socket was chosen for several reasons:

1. Flexibility of the socket results in a more comfortable fit and reduces pressure concentration.
2. Its transparency allows direct visualization of the stump, if skin breakdown is a problem, and to monitor pressure areas.
3. It permits quicker heat dissipation because of reduction in socket wall thickness.
4. The socket allows improved sensory feedback, especially while sitting, due to flexibility in fenestrated areas.

The patient tolerated the prosthesis well, however, he still had pain over the anterior distal stump. Thus, new x-rays of the patient were taken while he was wearing the prosthesis to determine if the fenestrations were, in fact, over the spur and the soft tissue calcifcations. Because of the design of this socket, it was easy to determine that the fenestrations needed correction.

The anterior cut out was then enlarged to better accommodate the soft tissue calcification (Figure 6). This afforded the patient the relief needed. He is presently ambulating independently with a straight cane and the above-knee prosthesis without any pain.

In summary, this flexible socket technique allows improved accuracy in fitting not only routine cases, but is especially suited for problem cases as illustrated here.

Meetings and Events

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

1984

January 25–29, Academy Annual Meeting and Seminar, Dutch Resort Hotel, Lake Buena Vista, Orlando, Florida. Contact: Academy National Headquarters, 703-836-7118.

January 29–February 2, AOPA Business Procedures and Data Committee seminar, Rose Hall Beach and Country Club, Montego, Jamaica. Contact: AOPA National Headquarters, 703-836-7116.

April 6–7, New England Academy Chapter Annual Meeting, Worcester Marriott, Worcester, Massachusetts.

April 11–15, The Pacific Rim Orthotics and Prosthetics Conference, Hotel International, Maui, Hawaii. Endorsed by the Academy and INTERBOR.

April 12–15, AOPA Region IV Annual Meeting, Waverly Hotel at the Galleria, Atlanta, Georgia.

May 3–5, AOPA Regions I, II, and III Combined Annual Meetings, Concord Hotel, Kiamesha Lake, New York.

May 24–26, AOPA Region V Annual Meeting, Amway Grand Plaza Hotel, Grand Rapids, Michigan.

June 1–3, AOPA Region IX, COPA and the California Chapters of the Academy Combined Annual Meeting, Lake Arrowhead, California.

June 21–24, AOPA Region VI and the Academy Midwest Chapter Annual Combined Meeting, Holiday Inn, Merriville, Indiana.

June 28–30, AOPA Regions VII, VIII, X, and XI Combined Meeting, North Shore Convention Center, Lake Coeur d'Alene, Idaho.

1985

January 30–February 3, Academy Annual Meeting and Seminar, Cathedral Hill Hotel, San Francisco, California. Contact: Academy National Headquarters, 703-836-7116.

June 7–9, AOPA Region IX, COPA, and the California Chapters of the Academy Combined Annual Meeting.

October 15–20, AOPA Annual National Assembly, Town and Country Hotel, San Diego, California. Contact: AOPA National Headquarters, 703-836-7116.

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