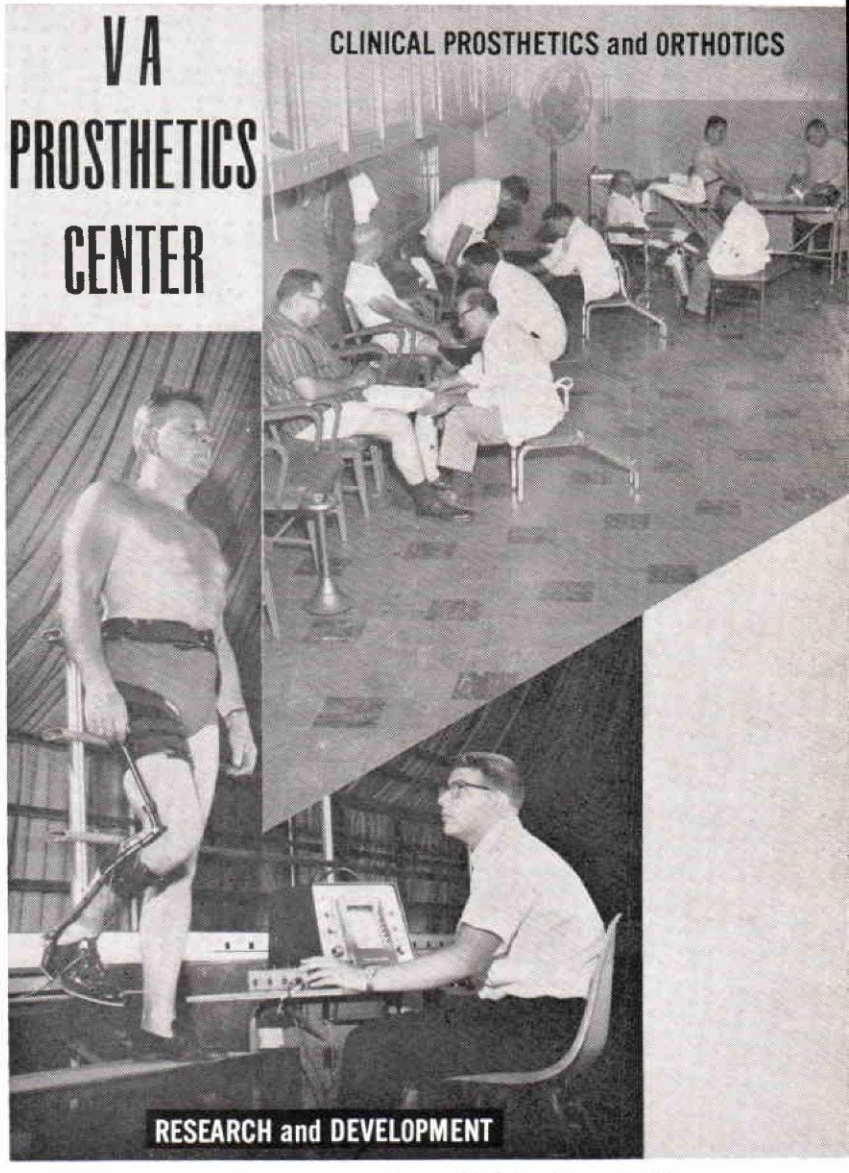
SEPTEMBER, 1963

ORTHOPEDIC & PROSTHETIC APPLIANCE JOURNAL

The Journal of the Limb and Brace Profession

VA PROSTHETICS CENTER



"In Tribute to the VA Prosthetics Center" (See Page 240)

publisher: American Orthotics and Prosthetics Association

OFFICIAL NOTICE

The 1963 National Assembly of the

American Orthotics and Prosthetics Association

will be held November 2 - 6, 1963

at the Jung Hotel, New Orleans

The Assembly is open to all who are interested in the

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Assembly Registration forms are available from:

AOPA

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Orthopedic and Prosthetic Appliance Journal

(Title registered U. S. Patent Office)

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Publication does not constitute official endorsement of opinions presented in articles. The *Journal* is the official organ of its publisher, The American Orthotics and Prosthetics Association (formerly Orthopedic Appliance and Limb Mfrs. Assn.) and of the American Board for Certification. All correspondence should be addressed to the Editor of the *Orthopedic and Prosthetic Appliance Journal*, 919 18th St., N.W., Washington, D. C. 20006. Telephone, Area Code 202, 296-4160.

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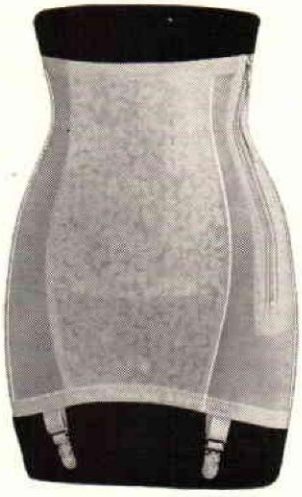

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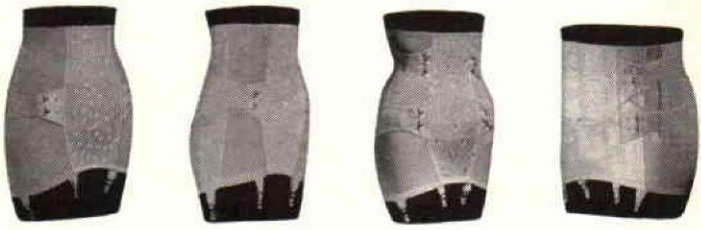

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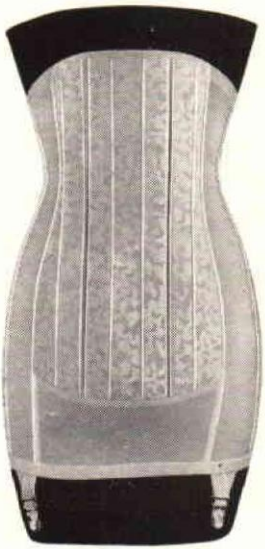

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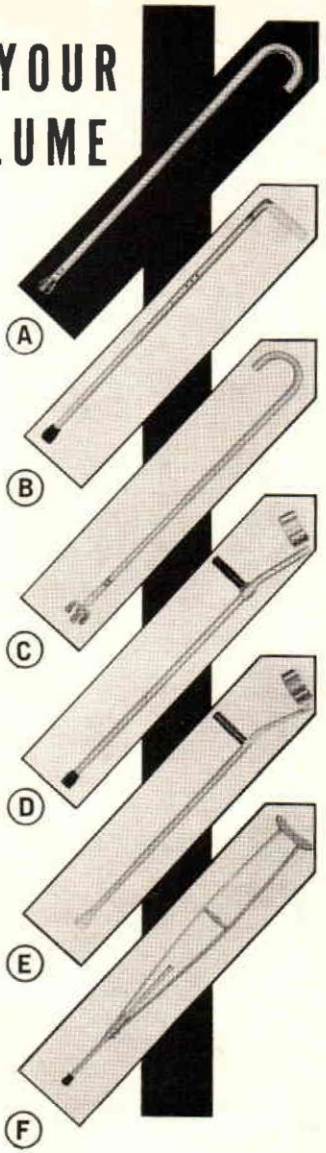

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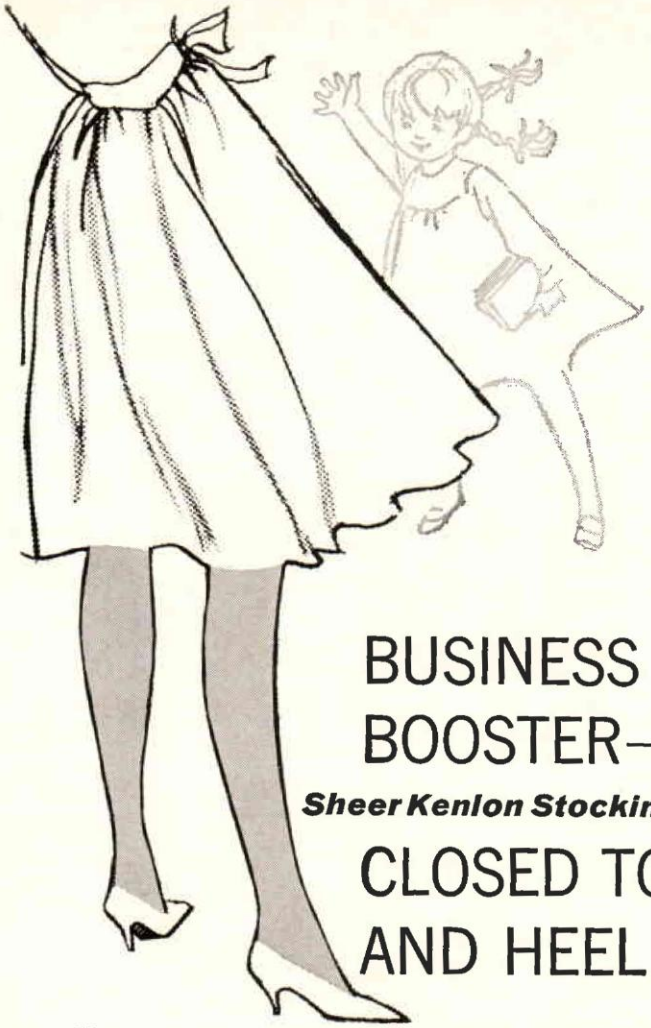

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In Tribute to

The Prosthetics Center of the United States Veterans Administration

It is with pleasure and satisfaction that we dedicate this September 1963 issue to the VA Prosthetics Center, located at 252 Seventh Avenue, New York 1, New York. The contents of this issue have been prepared by the staff of the Center.

For the past seven years, the work of the Center has been a significant factor in the development of improved appliances and services to the disabled veterans and indeed the handicapped throughout the world.

The orthotists and prosthetists of America, perhaps more than any other group, are aware of this contribution. Through these seven years, they have come to value the officers and staff of the Center for their technical skill, their efficiency and their devotion to duty.

The staff of the Center have worked long hours to assist all who genuinely want to improve the lot of the handicapped. By their publications, their demonstrations and the technical programs they have presented at our Regional and National Meetings, they have made an outstanding contribution.

The orthotists and prosthetists of America have come to think of them as friends and colleagues. We look forward to the continuation of this cooperation which has been so fruitful in terms of progress in prosthetics and orthotics.

CARLTON FILLAUER, *President,*
American Orthotics and Prosthetics Association

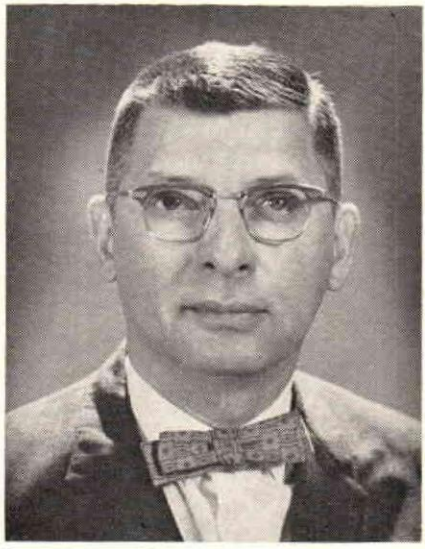
RICHARD G. BIDWELL, *President,*
American Board for Certification in Orthotics and Prosthetics, Inc.

Contributors to this issue:

MEMBERS OF THE STAFF OF THE VA PROSTHETICS CENTER

ANTHONY STAROS

Anthony Staros, Chief of the VA Prosthetics Center, was born and raised on Long Island's South Shore. Educated at the Massachusetts Institute of Technology, Cornell University, Stanford University, and Hofstra University, Mr. Staros has a Master's Degree in Mechanical Engineering and is a Registered Professional Engineer. After discharge from the U. S. Marine Corps in 1946, he worked in ordnance design before joining the Veterans Administration in 1949 as Chief of the Prosthetic Testing and Development Laboratory. When the VA Prosthetics Center was formed in 1956, Mr. Staros was made its Chief. He is a past member of the Committee on Prosthetics Research and Development of the NAS-NRC and is still active on its subcommittees. Mr. Staros is also a member of the International Committee on Prostheses, Braces, and Technical Aids of the ISRD and chairman of its U. S. subcommittee.

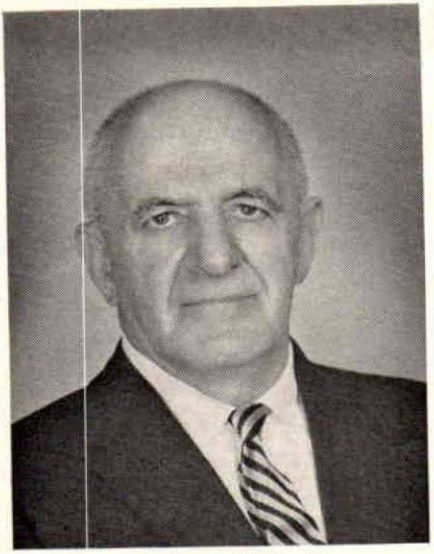


FRANK A. WITTECK

Frank A. Witteck, Assistant Chief of the VA Prosthetics Center, is a native New Yorker. Educated at the Polytechnic Institute of Brooklyn and New York University, Mr. Witteck is a Registered Professional Engineer. He was discharged from the U. S. Army in 1946. In 1950 he joined the Veterans Administration in the Testing and Development Laboratory. He was Chief of the Testing and Development Laboratory and the Limb and Brace Section before assuming his present position.

GABRIEL ROSENKRANZ, M.D.

Dr. Rosenkranz, full-time medical consultant to the VA Prosthetics Center, was raised and educated in Vienna, Austria, receiving his Medical Diploma from the University of Vienna. His post-graduate studies include six years of internship and residencies in Vienna hospitals and were followed by ten years of medical practice, specializing in sports medicine



GABRIEL ROSENKRANZ

and traumatology (he was club physician of the Polo Club, the Jockey Club, Chief Medical Advisor of Accident Insurance "Zurich," Workmen's Insurance and others).

He arrived in the United States in 1938 and passed state board examinations in New York and Massachusetts. After a one-year residency here, World War II started. Dr. Rosenkranz was commissioned a Captain in the U. S. Army M.C. and served for about two years at Station Hospital 81 (Orthopedic Dept.) in New York. Since 1946 he has been associated with the New York offices of the Prosthetic and Sensory Aids Service. In 1947 he participated in the Suction Socket Instructor's Course at the University of California — Berkeley. For several years thereafter he conducted numerous VA Suction Socket Training Courses throughout the country.

In 1949 he took part in the European Research Trip (with Professor H. Eberhart and Dr. V. Inman of the University of California), sponsored by the National Academy of Sciences.

In 1951 he was assigned consultant to a group of German prosthetics experts on a U. S. A. tour sponsored by the State Department. Between 1951 and 1957 he served several times as a guest lecturer at national conventions and regional meetings of the AOPA.

Recently he started year-round courses in functional anatomy for prosthetists and orthotists in the VA Prosthetics Center. Other regular duties include studies of domestic and foreign medical and associated publications for the information of clinicians and research and development personnel. His translations from the German literature, typically accompanied by his perceptive analyses and suggestions, have been extremely helpful. He has written several articles relative to prosthetics (on "Creatinuria as a Stress Phenomenon in Major Amputations," on the patellar tendon bearing socket and other topics).

In 1961 he also assumed the duties as a member of the regular weekly and "Instant" or daily prosthetics and orthotics clinic teams of the VA Prosthetics Center.

He is a member of several professional societies. His exuberance and enthusiasm for the problems of the amputee keep him perennially young. A prolific reader, he still finds time for hobbies: dabbling in technical innovations ("circometer," "prosthetoscope" and, more successfully, chess).

He has just recently participated in the Triennial Congress of the International College of Surgeons and Traumatologists in Vienna (Sept. 1-7, 1963) where he spoke on "Modern Prosthetics in USA." During a 7-week stay in Europe at the time of the Congress, he visited numerous research and rehabilitation centers.

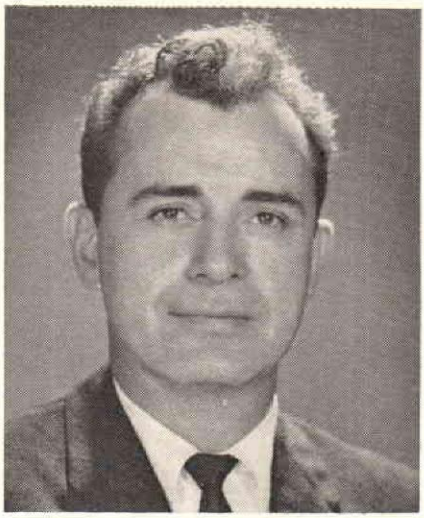
ANASTASIA S. KEANE

Mrs. Anastasia S. Keane, a native of Massachusetts, began her Government service at the Springfield Armory in 1935. As secretary and assistant to the Procurement Officer during the war years she was especially

ANASTASIA KEANE

active in following up shipments of steel, gun stocks, and all the parts and materials that went into the making of the Garand rifles.

Mrs. Keane came to New York in late 1945 as administrative assistant to the Chief of the newly organized Medical Rehabilitation Clinic in the New York Regional Office of the Veterans Administration. Here she began her close association with all the projects which the Prosthetic and Sensory Aids Service has encompassed through the years. With the exception of one year as chief supervisor of administrative personnel in the NYRO Medical Division, she has been actively interested and involved in VA's varied prosthetics programs. In July, 1948, she was appointed administrative assistant to Dr. Augustus Thorndike, then Acting Director of VA's Prosthetic and Sensory Aids Service. When the VA Prosthetics Center was established in February 1956, she was appointed as its Administrative Officer and has functioned since then in this capacity. Budgets and finances, procurement, personnel—so vital in VAPC's active, diversified programs—are her primary concerns.

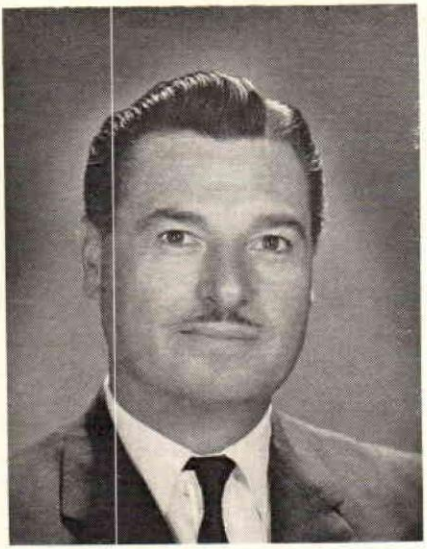


WILLIAM J. McILMURRAY, C. P. O.

William McIlmurray, Chief of the Center's Limb and Brace Section, is a native of Brooklyn, New York where he received his schooling. He started working in prosthetics for Amsterdam Brothers in New York City. Shortly after his discharge from the U. S. Navy in 1946, he was employed by the New York Veterans Administration Regional Office as an Orthotist. He started working for the VA Prosthetics Center in 1956, as an Orthopedic Technologist and since that time he served as the Acting Chief, Testing and Development Laboratory and as a Research Staff Prosthetist-Orthotist, both prior to his present position.

HENRY F. GARDNER, C.P.O.

Henry Gardner, Chief of the VA Prosthetics Center's Special Projects Staff, was reared on Michigan's upper peninsula where he attended Houghton Tech. At the outbreak of World War II he joined the Maritime Service and was trained at the U. S. Army Academy of Marine Engineering at St. Petersburg, Florida. He graduated in 1943 and served as an engineering officer on board several ships in both the Pacific and the Atlantic theaters.



HENRY GARDNER

EDWARD PEIZER

He worked as a limb fitter's helper during his early school days and later worked as a fitter for the C. A. Frees Company of New York City. In 1947 he joined the Veterans Administration where he concentrated upon research and development. He has assisted several of the prosthetics schools and has recently been extensively involved in educational seminars for VA clinicians. He has been quite active on subcommittees of the Committee on Prosthetics Research and Development and has participated in several international prosthetics projects, notably in Argentina and Yugoslavia.

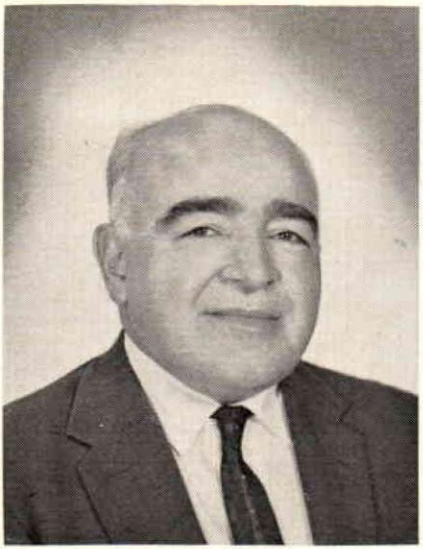
EDWARD PEIZER, Ph.D.

Edward Peizer, Chief of the Bioengineering Laboratory, was born and raised in New York City. After his release from active duty with the U. S. Army in 1945, he continued his education at New York University where he earned his Ph.D. As a faculty member of the New York University School of Education, he divided his time between teaching and laboratory work in the Performance Physiology Laboratory until recalled to active duty for service in Korea. Returning in 1954, he joined the staff of the College of Engineering at New York University where he held various positions including Field Study Supervisor, Associate Project Director for Child Prosthetic Studies and Orthotic Studies until 1962 when he joined the Veterans Administration. He is a member and current Vice President of the New York Metropolitan Chapter of the Human Factors Society and has served on several *ad hoc* panels of the NAS-NRC's Committee on Prosthetics Research and Development.

FRANK SCHENCK

Frank Schenck, Chief of the Orthopedic Shoe Section, was born in Germany where he received his basic education consisting of eight years of public school and two years of trade school. At the age of fourteen, he began his apprenticeship as an orthopedic shoemaker which lasted for 3½ years. Upon completion of his apprenticeship he received a certification as a journeyman.

At the age of 19, he emigrated to the U.S.A. (in October, 1929) taking up residence on Long Island. He was employed by the J. H. Block Orthopedic Shoe Company, then located at 146 E. 53rd Street, where



FRANK SCHENCK

OTTO ROTHMAN

he specialized in orthopedic shoe prescription, foot measurement, and the making of orthopedic shoe lasts.

In October, 1945, after his discharge from the U. S. Army for which he served as an orthopedic technician at the Orthopedic Shop, Valley-Forge General Hospital, Phoenixville, Pa., he returned to the J. H. Block Company. He joined the Veterans Administration's Orthopedic Shop at 252 Seventh Avenue, New York in October, 1946.

Mr. Schenck was put in charge of the nationwide orthopedic shoe program in 1951. Later, he was made Chief of Orthopedic Shoe Section of the VA Prosthetics Center.

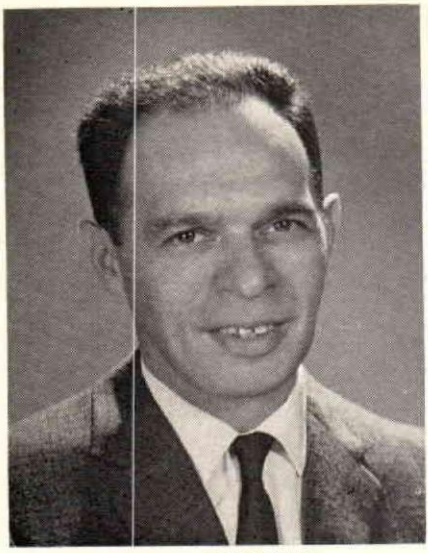
OTTO ROTHMAN

Otto Rothman has been Chief of the Testing and Development Laboratory since 1959. He has had wide experience in design and specifications work—valuable background for the mission of the Laboratory. The broadening of the scope and the strengthening of prosthetics specifications are his primary responsibilities. In addition, Mr. Rothman supervises the physical testing and evaluation programs and specification compliance checks. He designs new test equipment and also improves on designs of new prosthetic devices. Previous to coming to the VAPC, he worked on noise-control at the U. S. Navy Material Laboratory. Since the beginning of World War II and for some years after, Mr. Rothman worked in various research laboratories on such unrelated projects as radar instruments, sound recording machines, anti-aircraft guns, bombing computers, bomb bay mechanisms, and others.

Mr. Rothman graduated from elementary and technical high school in Vienna, Austria. He got his M.E. degree at the City College of New York, then took post-graduate courses at the Polytechnic Institute of Brooklyn. He is a Registered Professional Engineer in the State of New York.

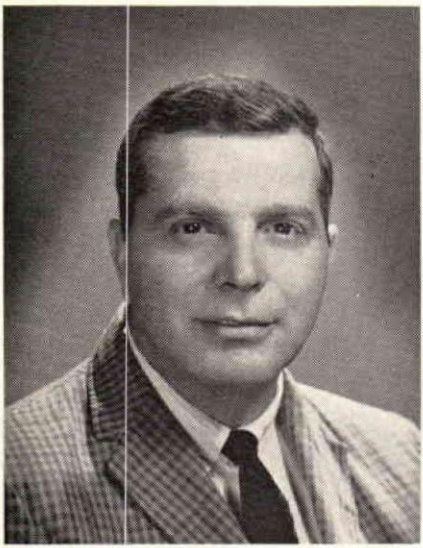
WERNER GREENBAUM, C.P.O.

Werner Greenbaum, Supervisor of the Orthotics Unit of the Limb and Brace Section, started his career in orthotics in 1939 as an apprentice in the brace shop of the Hospital for Joint Diseases in New York. Upon completion of his apprenticeship he transferred to the brace shop of the Lenox Hill Hospital. After his discharge from the U. S. Army in 1946,



WERNER GREENBAUM

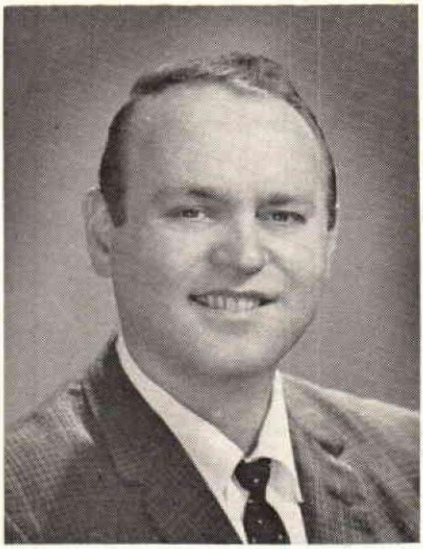
he joined the Veterans Administration as an orthotist. Shortly after the establishment of the Prosthetics Center in 1956, he became Supervisor of the Orthotics Unit.



THOMAS PIRRELLO, JR., C.P.O.

Thomas Pirrello, Jr., a member of the Special Projects Staff of the VA Prosthetics Center, is a native New Yorker and at present resides on Long Island. While serving in the U. S. Navy during World War II, he received his introduction to prosthetics. After discharge from the service in 1947 and with his interest still in the field, he joined the Veterans Administration prosthetics activities at the New York Regional Office. He has attended various courses in prosthetics and has lectured at numerous seminars and AOPA regional meetings.

For the past several years, he has primarily participated in research and development in prosthetics and orthotics.



ANTON J. REICHENBERGER

Anton J. Reichenberger, Supervisor of the Testing Unit, Testing and Development Laboratory, VAPC, was born and reared in Europe. Educated in both Europe and the United States, Mr. Reichenberger has an A.A.S. degree in Mechanical Technology and is a certified Engineering Technician. After discharge from the U. S. Army in 1953, he worked in the machine industry before joining the Veterans Administration in 1954. Mr. Reichenberger has been with the Testing and Development Laboratory, VAPC, since 1957. He is a member of the Institute for Certification of Engineering Technicians and the American Society for Metals.

An Introduction

In this issue of the *Orthopedic and Prosthetic Appliance Journal,* we present the VA Prosthetics Center, an organization "to serve him who served"—and also in helping the disabled veteran, to provide indirect benefits to all disabled. How can the Veterans Administration best provide such service—with due regard to the diverse needs of the disabled?

First of all, it must assemble dedicated and knowledgeable people to work, nay to *serve,* for it is truly service that is sought. Next, the managerial environment for these people needs to be enlightening, guiding, and never too restricting. Team effort among diverse disciplines and creativity must be fostered. Above all, close contact and technical and even social exchanges with colleagues throughout the nation and world are mandatory.

Each member of the organization should be made to feel the deep satisfaction and gratitude that come from his contributions in behalf of the disabled; true, these are intangible benefits but ones that motivate many humans more than financial profit. And management must encourage contribution from all, no matter their role in the organization. Care for patients brings to one a direct awareness of the joys of service. Whether the results of patient care are immediately observable or whether they are known to take place in a distant setting is of little moment. The important thing is the realization that one's participation in the prosthetics restoration process has aided another human being.

But satisfaction with the present—with the conventional—can be stagnating. We need to study human capability and human disability to find new avenues for service and new devices and techniques. We must also review the conventional—clinical practice as it exists—to improve and progress through development. Particularly in this latter area, there is need for extremely close contact between clinical and research activities. Preferably, research and development personnel should have daily contact with patients so that not only will generalized improvements be made on sound clinical bases but special problem cases can benefit from the innovations of the development-oriented practitioner.

Of course, "evaluation" is ever-present. But it need not restrict nor delay. It should guide development; it should not police it. Certainly some items require longer programs of testing and evaluation than others— but generally, evaluation should be simplified, perhaps standardized to take a secondary role to development—to improvement—to constant and continuous change for the better.

Similarily, when we specify or standardize, we should leave the door open for change. Specify we must because of practical production and procurement problems. Testing against specifications assures quality and quality assures service. But specifications, more than anything else, fully define the present, the take-off point for the change for which we plead. For truly, "if it works, it's obsolete."

And always, the change yielded needs to be reported and demonstrated. Clinicians throughout the world should be continually informed about those items which can be used now and those which might be used in the near and distant future.

So to the American Orthotics and Prosthetics Association we extend our gratitude for this opportunity to "show and tell." We want your membership and others to know about the VA Prosthetics Center—to know who we are, how we are organized, what we are doing, and what we will do. Our purpose is service, and improvement is our product. Both need to be applied through the private practitioner in orthotics and prosthetics. Only thusly might we achieve the gains, the satisfactions we seek.

ANTHONY STAROS

A Broad Spectrum Structure for Prosthetics and Orthotics Restoration

Since its inception in early 1956, the Veterans Administration Prosthetics Center has had two basic missions: one, research and development in the fields of prosthetics and orthotics and; two, the furnishing of prosthetic and orthotic services to veteran beneficiaries. These missions were not to be separate, but rather were conceived to be complementary. An additional function, ever-increasing in importance, is the cooperation with the Research and Development Division, Prosthetic and Sensory Aids Service, in the carrying out of their educational mission, especially as related to intra-VA training in various aspects of prosthetics and orthotics. Thus, the Center's programs range from basic research through development and evaluation, hence through specifications and compliance testing to procurement, distribution, clinical treatment and education and dissemination of information.

To carry out these manifold and overlapping responsibilities, the Prosthetics Center is organized into a number of Sections or Laboratories each with its own unique responsibilities. The form of the organization is shown in Fig. 1. Administration of the Center is carried out by the Office of the Chief, a group concerned with direction and coordination of all of the Center's activities as well as budgets and other fiscal matters. A part-time orthopedic consultant who is Chief of the Center's Orthopedic and Prosthetic Appliance Clinic Team and a full-time medical advisor are also part of this group. The Special Projects Staff, a small group of research prosthetists and orthotists, handles those projects which are not directly the responsibility of any one Section or those projects which may involve the services of several Sections.

The five Sections of the Center are the Bioengineering Laboratory, the Limb and Brace Section, the Orthopedic Shoe Section, the Prefabricated Appliances Section, and the Testing and Development Laboratory. The major functions of the two Laboratories and the Limb and Brace Section are quite adequately covered in the articles which follow in this *Journal*. But the orthopedic shoe and prefabricated appliance programs, which are alike in many respects, constitute a unique but major part of the Cen-

Figure 1. VAPC Organization Chart.

ter's overall clinical mission; therefore some description of these programs is needed. Brief overviews of the function of the Center's clinic teams and the evaluation and educational programs are also presented here.

The physician prescribing for an eligible beneficiary with a foot disability or deformity has several courses of action open to him. If the disability does not require an orthopedic shoe, he may prescribe modification or correction of stock shoes furnished by the beneficiary. If the veteran's condition warrants, the physician may prescribe orthopedic shoes to be furnished by one of three sources: a local custom orthopedic shoemaker, the nearest VA Last Clinic, or the VAPC Orthopedic Shoe Section. These orthopedic shoes are made over individual lasts based on the physician's prescription and measurements. The overwhelming majority of shoes furnished by the Orthopedic Shoe Section are fabricated by firms under contract with the VA. The same is true of those orthopedic shoes returned to the Orthopedic Shoe Section for repair. In particularly difficult cases, orthopedic shoes are fabricated over lasts by an orthotist (shoes) in one of the Last Clinics or in the Orthopedic Shoe Section. Procedures for procuring new shoes, repeat orders, or repairs are illustrated in Fgures 2, 3, and 4.

In a similar fashion, physicians may prescribe fluid-controlled mechanisms, elastic hosiery, or orthopedic corsets and belts. Elastic hosiery and orthopedic corsets or belts may be procured through local facilities or the Prefabricated Appliances Section of the VAPC. Fluid-controlled mechanisms for above-knee prostheses are issued by prescription through the Pre-

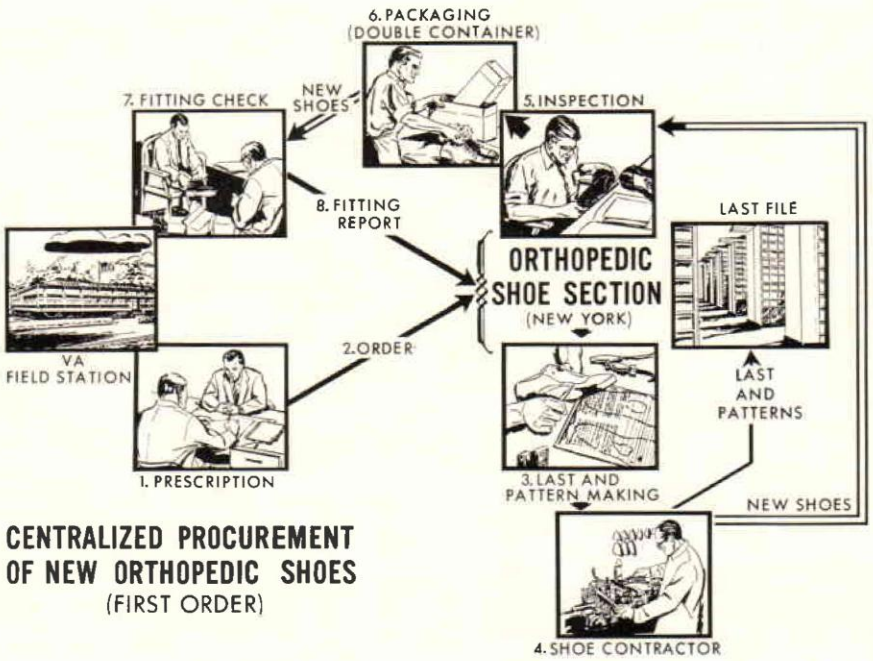


Figure 2. Centralized procurement of new orthopedic shoes—first order.

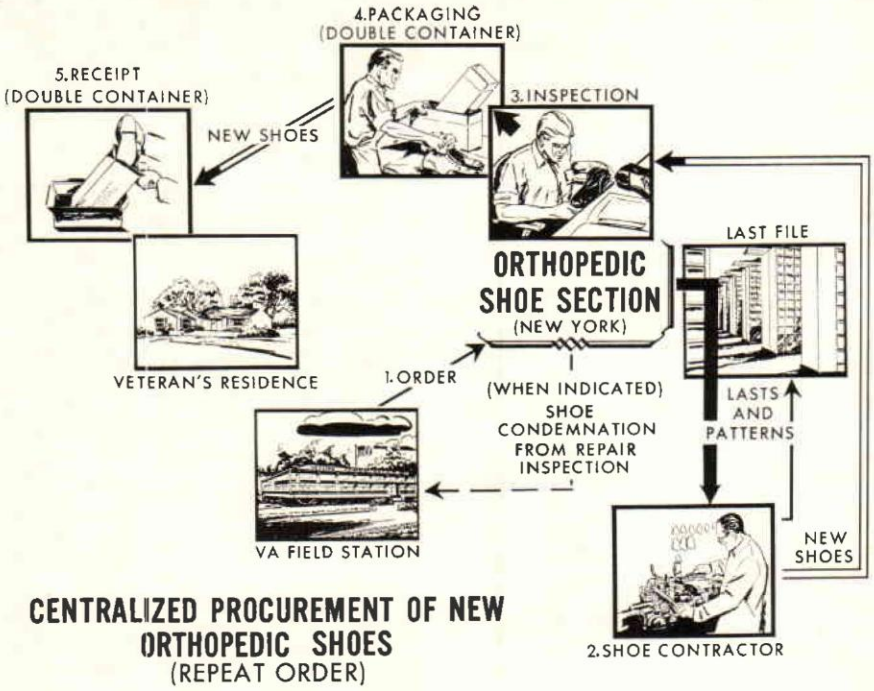


Figure 3. Centralized procurement of new orthopedic shoes—repeat order.

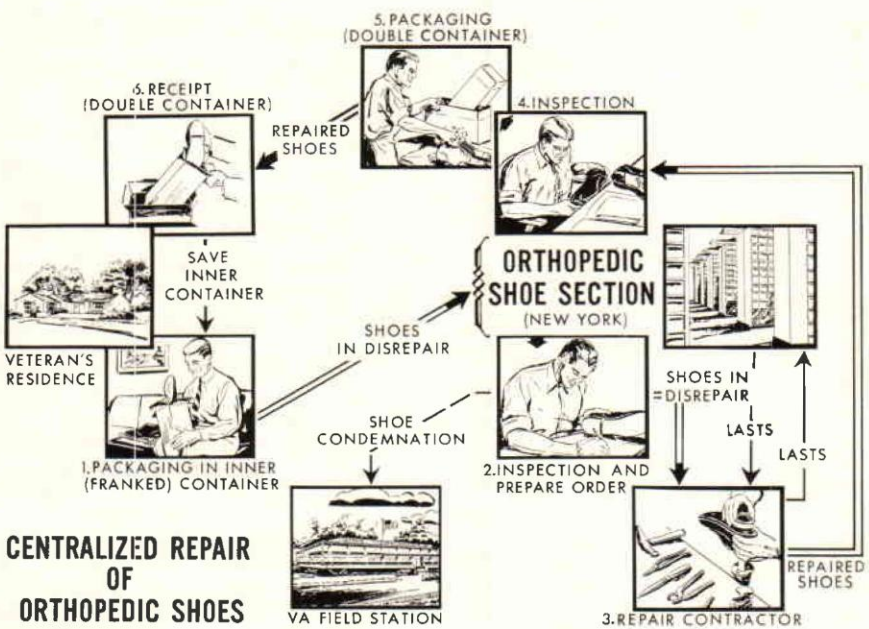


Figure 4. Centralized repair of orthopedic shoes.

fabricated Appliances Section. The unit is shipped directly to a limb facility for inclusion in a veteran's prosthesis. This procedure permits better quality control as all units are inspected upon receipt and before shipment. Feedback received through clinical experience enables the VA to make the manufacturer aware of shortcomings which can be corrected by design changes or improved production techniques.

An important adjunct of VAPC operations is the Orthopedic and Prosthetic Appliance Clinic Team. The team meets weekly to see veterans whose prosthetic or orthotic problems are out of the ordinary. These beneficiaries usually are referred to the Center from other VA offices or hospitals. Often it is necessary to house these patients locally while devices that are sometimes unique in nature are fabricated. Such cases require much time, study, and experimentation. Of course, universal success cannot be claimed, but by a concerted effort of all involved, including the patient, it is usually possible to come close to the desired goal. In many cases, patients are referred for consultation only. In these instances, opinions and recommendations of the Clinic Team are forwarded to the requesting station. Arrangements are then made by the station for local procurement of the desired appliances. The work of this VAPC Clinic Team is supplemented by an informal team that is prepared to handle unscheduled patients and emergent situations on a moment's notice. This "instant" clinic team is headed by the Center's medical advisor who has at his immediate call any or all of the resource people of the Center.

The Clinic Team also plays an important role in those clinical evaluations or application studies conducted in the Center. New devices or techniques often require simple quick evaluations to determine such factors as practicality, effectiveness, and patient acceptance. The Clinic Teams participated by performing such functions as screening, medical examination, prescription, follow-up examinations, etc. The case histories including diagnoses, X-rays, photographs, and the like furnish the basis for publication in various media and the dissemination of information to those in the fields of prosthetics and orthotics.

The education and training functions of the Prosthetics Center discussed in some additional detail in another article in this issue, manifest themselves in several ways. Intra-VA training courses are conducted by the Research and Development Division, Prosthetic and Sensory Aids Service. Participants include physicians, therapists, prosthetic specialists or representatives, and orthopedic shop personnel, all coming from VA installations in various parts of the United States. Many lectures and/or demonstrations are given by staff members of the Center to these diverse groups. Teams are often sent out to various parts of the country to conduct specialized seminars for both VA personnel and industry groups. A trainee program has been instituted in the Limb and Brace Section of the Center. Several young men are being trained in prosthetics and orthotics with the aim of their sitting for certification in several years. It is

expected that this program will not only continue but be expanded in the near future. The Bioengineering Laboratory has a summer employment program for graduate and undergraduate students. These men are not only making a worthwhile contribution to the operation of the Laboratory but are receiving an exposure to a facet of human factors engineering quite different from any other.

Assignments or projects come to the VA Prosthetics Center in many ways. Some are the result of instructions received directly from the Prosthetic and Sensory Aids Service in Central Office, Washington, D. C. Others come about from ideas generated within the Center by its own personnel. Of course, there are those assignments by the Committee on Prosthetic Research and Development of the National Academy of Sciences—National Research Council. Lastly, there are projects which are international in scope and derive from contacts with the U. S. State Department, Vocational Rehabilitation Administration (formerly Office of Vocational Rehabilitation), and the Committee on Prostheses, Braces, and Technical Aids of the International Society for Rehabilitation of the Disabled.

Tables of organization and missions are fine in themselves but mean nothing without dedicated people to make them come alive. Many arts and skills are represented in the VA Prosthetics Center: machinist, illustrator, engineer, orthotist, prosthetist, physiologist, secretary, physician, engineering technician, photographer, and others. The efforts of these men and women are devoted to a common goal: to serve the disabled.

Man, Mechanism, and Mobility: Bioengineering

Ἐν ἀρχῇ ἦν ὁ Λόγος : "In the beginning was the word . . ." according to St. John, and perhaps it would be a proper beginning to offer a formal definition of the term Bioengineering. We shall refrain, however, since much of the meaning we intend to convey is obvious from the mere juxtaposition of bio and engineering. To define it further would impose limits on our appreciation of the scope and potentiality of the issue to be expected from a union of physics and biology, engineering and medicine.

The trend to consider research and development simultaneously from both human and mechanical standpoints can be noted in many recent and current research programs. Space exploration, for example, must proceed in terms of the limitations and capabilities of both primary factors: the man as well as the machine. Appreciation of the human factor in the man-machine equation has become increasingly vital in military research. On the other hand, medicine and physiology primarily concerned with biological processes are increasingly dependent upon the development of improved instrumentation. But this is an old story in prosthetics and orthotics where, as perhaps nowhere else, the limitations of engineering science and the complexities of human disability combine to impede advancement. Most promising in this respect is a systems analysis approach in which physiological and engineering concepts, intimately related in a common frame of reference, are focused on problems of human disability.

The Veterans Administration has long recognized the value of systematic research and began to organize such efforts in prosthetics and orthotics 15 years ago. Other agencies of course have since contributed to the same objectives. The results in this field have kept pace with scientific development everywhere and it is generally conceded that more has been achieved in the last 15 years than in the previous 1500 years. But goals in this respect have not remained static; although progress has improved the lot of the handicapped, increasingly higher achievements are demanded and sought.

Future advancement requires both the improvement of present concepts and the evolution of new ones. Improvement can be achieved by the refinement of present techniques; innovation calls for the introduction of new ideas to provide a breakthrough in design. Both avenues of progress must be based upon adequate research and evaluation systems.

In keeping with its tradition of leadership and its responsibility to offer the best service possible to veterans, VA has taken steps to meet these challenges. It has very recently organized the Bioengineering Laboratory, a major division of the VAPC, in an effort to consolidate its resources and increase its capacity for research and development.

Facilities

The section of the Bioengineering Laboratory specializing in human factors research occupies an area 76 ft. x 66 ft. providing 5,016 square feet of floor space.

It is located on the street-level main floor of the building providing easy access for wheelchair and crutch-using patients. Completely girdling the main floor is a mezzanine with 2000 square feet of additional space.

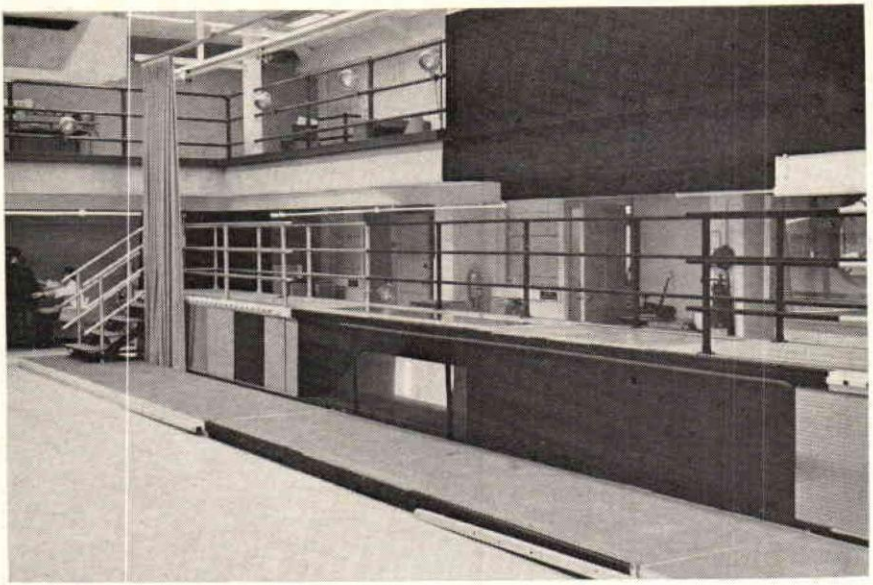


Figure 1. The main floor of the Bioengineering Laboratory showing several walkways used in laboratory studies.

On the main floor are several specially designed walkways which are used in studies of locomotion. The lower walkway, 50 feet long, has been equipped with a metal conductor tread for use in studies of the temporal factors of gait. Metal electrodes, attached to the subject's shoes, close a circuit when they make contact with the metal walkway permitting such primary gait characteristics as stance time, swing time, and velocity to be recorded. Other significant variables such as ratio of swing to stance time and ratio of step times are derived from these basic data.

The center section of the lower walkway, 18 feet long, can be raised or lowered from either end by means of an electrically powered jack installed through the flooring beneath. It provides inclinations of up to 14 degrees and it is used to study the effects of various prosthetic and orthotic devices on the ability of a subject to walk up and down hills.

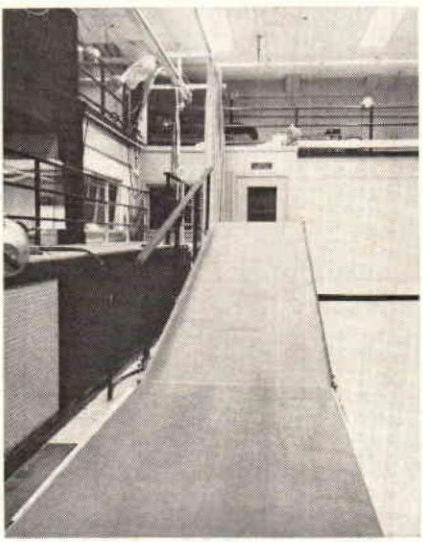


Figure 2. Electrically powered ramp permits the evaluation of patient performance in ascending and descending hills with varying slopes.

The center section of the lower walkway, 18 feet long, can be raised or lowered from either end by means of an electrically powered jack installed through the flooring beneath. It provides inclinations of up to 14 degrees and it is used to study the effects of various prosthetic and orthotic devices on the ability of a subject to walk up and down hills.

The upper walkway is equipped with an eight foot long gridded glass

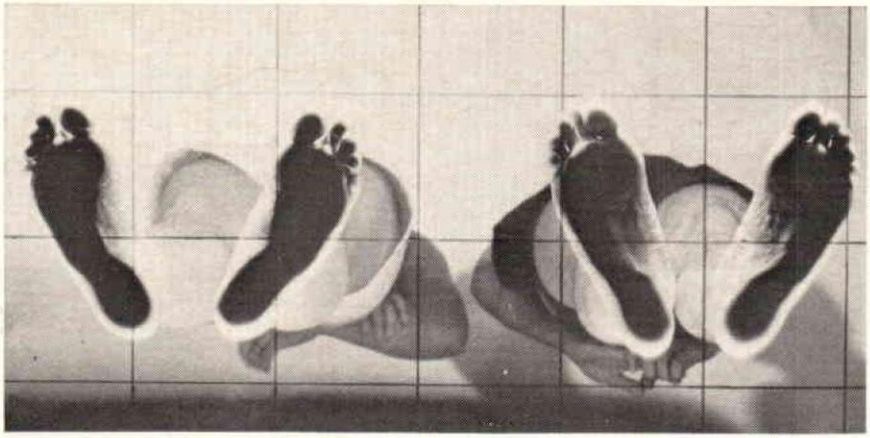


Figure 3. Glass Walkway: Density differences in the photographs obtained through the glass walkway indicate pressure patterns between the foot (or shoe) and the floor.

section and a mirror mounted beneath it at an angle of 45 degrees to the vertical. With this arrangement it is possible to photograph the interface between the foot or shoe and the floor in order to study the weight transition during the stance phase of gait.

Also installed in the upper walkway is a pair of force plates, which are used to measure the several kinds of forces interacting between the foot and the ground during stance: vertical, shear, and torque forces.

Many of the studies conducted in the Bioengineering Laboratory require the simultaneous recording of several rapidly changing variables, a task which depends upon the use of complex electronic instrumentation. All the electronic outputs are fed into appropriate amplification and recording apparatus housed in the instrument room, a glass enclosed area permitting observation of the entire Laboratory testing area. Equipment for

Figure 4. Instrumentation Room: Nerve center of the laboratory where all electrical outputs are monitored and recorded and where multiple data collecting devices are synchronized.

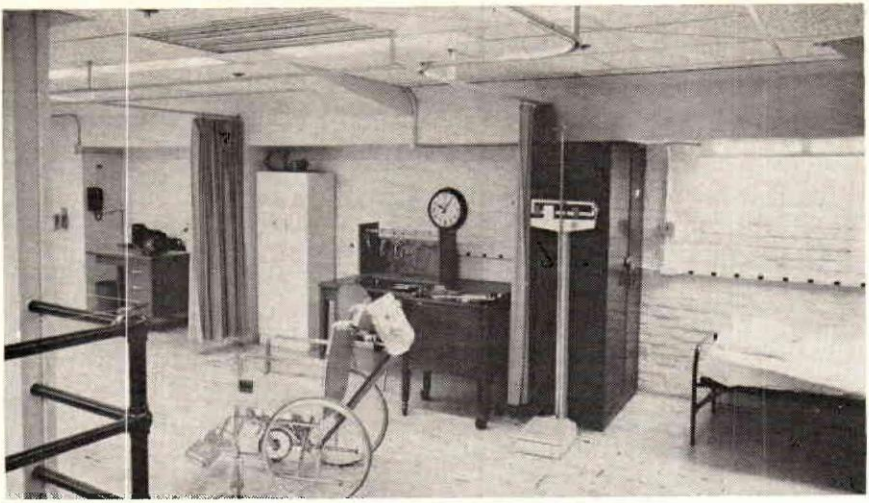


Figure 5. Part of the metabolic laboratory located on the mezzanine where space is also furnished for graduate engineering students assigned to special individual projects.

maintaining a relatively stable atmospheric environment has been installed here.

Above the main level of the Bioengineering Laboratory is a mezzanine which features a 172 foot long rectangular track. The track has been designed primarily for metabolic studies of the energy cost of using artificial limbs, braces, wheelchairs or other devices under more natural conditions than are possible on the walkways alone. A device has been installed to aid in controlling cadence and velocity during these studies. It consists of a light cable which is drawn through pulleys along the outside rail of the track by means of a variable speed motor. The subject adjusts his speed to keep up with a signal on the cable. Access to this area is provided by a flight of stairs from the main floor and by a separate entrance at the level of the mezzanine.

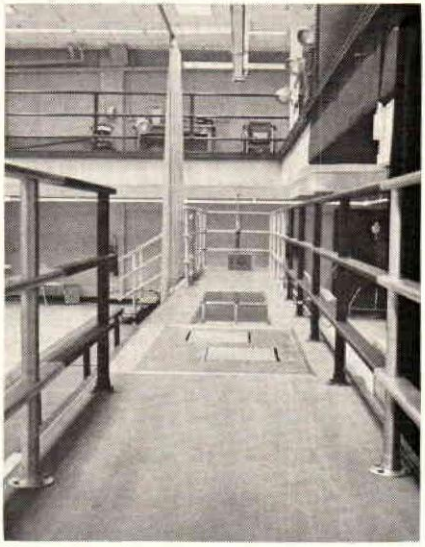


Figure 6A. Force Plates: Rigidly constructed of heavy gage aluminum and mounted on concrete and cork base they respond with extremely small deflections to floor reaction forces.

EQUIPMENT

The Bioengineering Laboratory is equipped with a variety of devices for recording and analyzing the major parameters of locomotion and other physical activities. The primary instrumentation consists of a pair of force plates and a cyclograph. The force plates are 15x20 inch aluminum platforms set flush with the walkway surface. Each plate is supported on four columns which are instrumented with strain gages. When a subject steps on a plate, forces of varying magnitudes and directions are applied to the plate during the entire period from heel contact to the instant of

toe-off. These forces are transmitted to the supporting columns and the strain gages which are part of a Wheatstone bridge circuit. The gage outputs, calibrated in pounds of force, are amplified and recorded. The gages are arranged in a geometric pattern to respond to vertical forces, fore and aft shears, medio-lateral shears, torques and by analysis, instantaneous centers of pressure are determined.

Used in conjunction with the force plates is the tachograph, a device for measuring the linear velocity of the subject's center of gravity as he walks. It consists of a light webbing waist belt to which is attached a light cable. It is adjusted on the subject at the level of his Center of Gravity

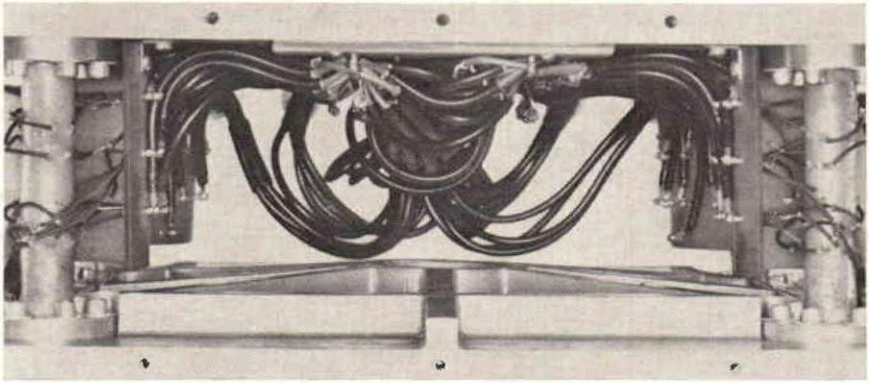


Figure 6B. Geometry of strain gage arrays mounted on supporting columns resolves component forces applied to plates.

Figure 7. Twelve force plate channels record forces in three planes for each leg during the stance phase of gait. The measures obtained include curves of vertical, horizontal, fore and aft shear, medio-lateral shear and torque forces as well as instantaneous center of pressures on x and y axes.

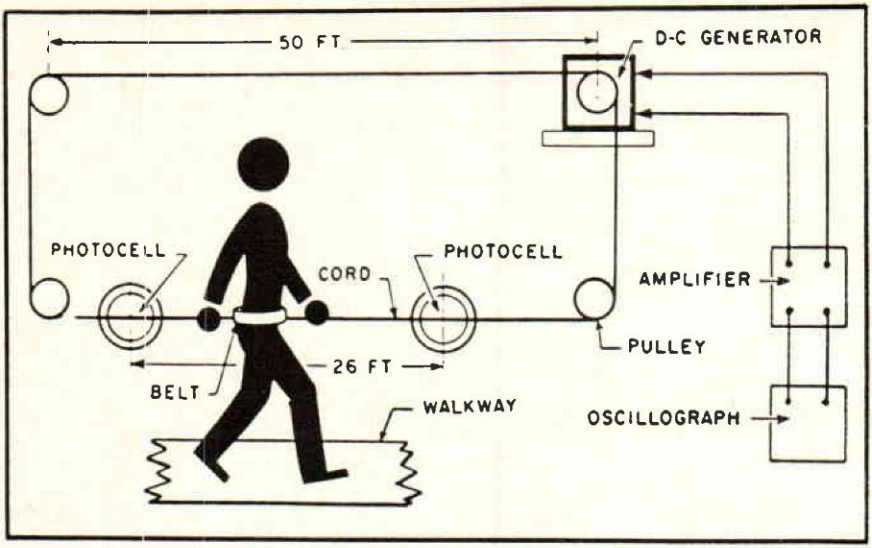


Figure 8. Tachograph: Instantaneous velocities of the CG are recorded during locomotion as a subject drives a DC generator.

(CG) as determined by weighing him while he is lying down on a large board, one end of which is placed on a scale and the other on a block of equal height; the total body weight, the weight recorded on the scale, and the length of the board are combined in a formula from which vertical height of the CG can be calculated. As the subject walks, he pulls the cable attached to the belt through a Direct-Current (DC) generator whose output, proportionate to the velocity, is recorded.

The cyclograph is essentially two cameras whose films are exposed by means of a slitted disc which rotates in front of the camera lenses at a constant speed of 12.5 rps. One camera is a static cyclograph consisting of a specially modified 8x10 view camera. With the shutter open, the film plate is exposed each time one of the four equally spaced slits on the rotating disc passes the lens, providing up to 50 exposures per second. As the film remains static, the product is a so-called "stick picture" with multiple exposures of the subject, appropriately targeted with reflective tape, as he passes through the camera field. The second camera, mounted 12 inches away in the same horizontal plane, is a gliding cyclograph, a modification of the type developed by Dr. Rudolfs Drillis of NYU. This device is similar in function to the static cyclograph, the important difference being that it transports the film in the same direction as the subject walks. The obtained photo-

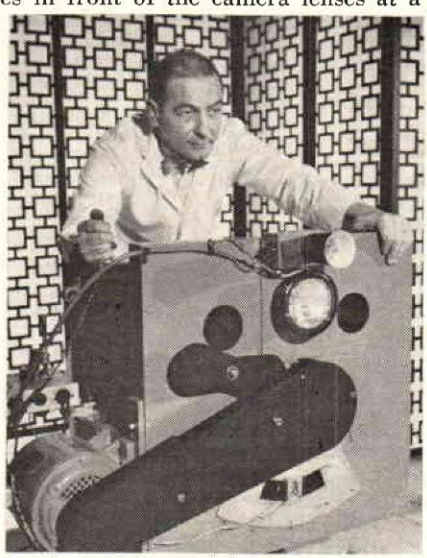


Figure 9. Cyclograph: Provides multiple synchronous exposures at 25 or 50 FPS of targeted subjects on the level walkway and on the ramp.

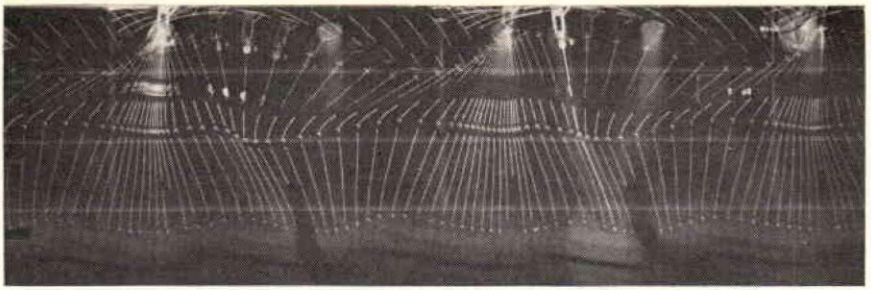


Figure 10. Static Cyclogram: Displacement of body segments in space are indicated by sequent "sticks" which are 1/50 second apart permitting calculation of velocities.

graph does much to simplify the analysis of the "stick picture" in areas such as the ankle joint where the sticks fall too closely together in the static cyclograph to permit accurate measurement.

Because a large part of modern bioengineering techniques depends upon photometric analysis, high quality photographic laboratory facilities are essential. The photographic laboratory, located on the main floor, is extensively equipped to provide these services. "Stick pictures" are processed within minutes after exposure to assure adequacy while the subject is still available for retakes if necessary. Advanced development procedures are employed to simplify analysis.

Supporting Facilities

The Bioengineering Laboratory enjoys an unusual advantage in the availability of other facilities in the VAPC. Supporting the Bioengineering Laboratory is a well equipped machine shop, an integral part of the Testing and Development Laboratory. Models, jigs, tools and components can be

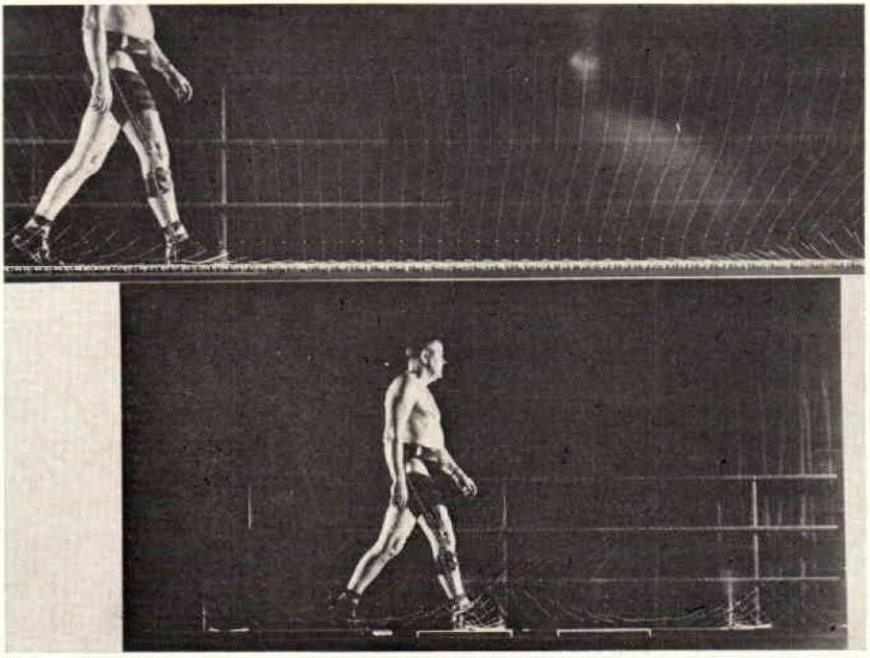


Figure 11. Gliding Cyclogram: Prevents overlapping of "sticks" particularly during stance phase.

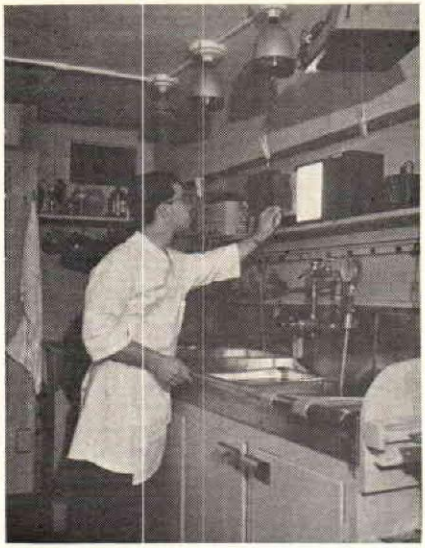


Figure 12. Photographic Laboratory: Equipped for processing stills, movies, and cyclograms.

fabricated quickly, economically and efficiently in this section of the VA Prosthetics Center.

The technique of applying experimental limbs and braces is an important aspect of many studies conducted in the Bioengineering Laboratory. As the fitting procedure is often a key factor in the research design, precision and reproducibility are fundamental requirements and it is absolutely essential that the best technological skills be available. For this reason, the Laboratory facilities include a Prosthetic/Orthotic Shop and the services of the personnel of the Limb and Brace Section of the Center.

Research and evaluation on braces also require expert technical advice on the fabrication and fitting of orthopedic shoes. The Orthopedic Shoe Section of VAPC provides assistance and support in these matters by making available highly experienced technicians and extensive facilities. This Section is also actively participating with the Bioengineering Laboratory in recently undertaken studies of the effectiveness of shoe corrections, a relatively unexplored area.

PERSONNEL

It is obvious that facilities and equipment are not the most essential ingredients of a productive laboratory; the key factor is the staff which operates the facility. As presently constituted, the full-time staff of the

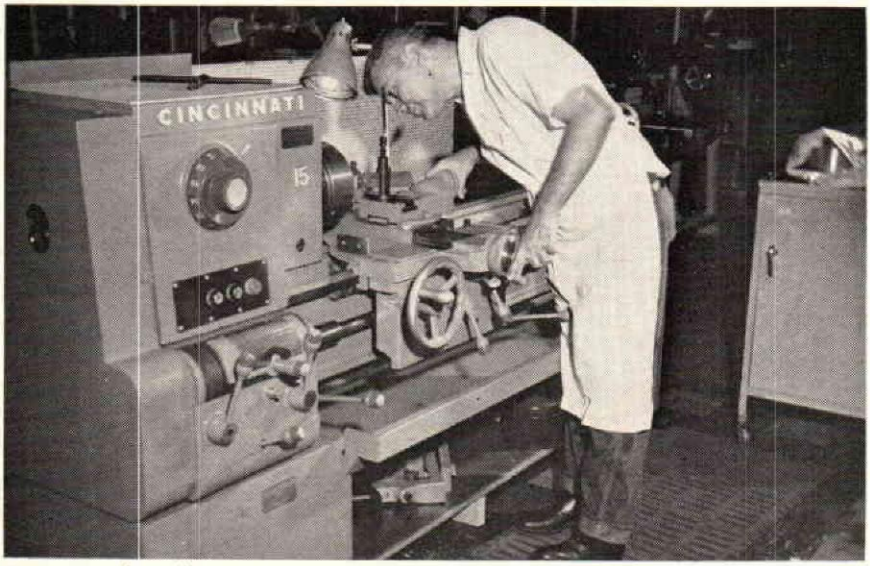


Figure 13. A small part of the machine shop: Modern equipment makes for versatility, high quality work, safety and economy.

Figure 14. Limb & Brace Section: Designed to provide the most advanced service to veterans and to improve prosthetic and orthotic devices.

Bioengineering Laboratory includes people whose primary training is in physiology, electronics, photometry and engineering. Not on a full-time basis, but available as consultants or participants in specific studies are physicians, physical therapists, engineering specialists and a physicist. This wide range of backgrounds and specialties provides versatility in research design and strong support for a variety of studies.

Activities and Plans

The Bioengineering Laboratory was conceived and organized as a center for bioengineering study; to furnish an efficient environment and modern means for research and development in this field. This intention

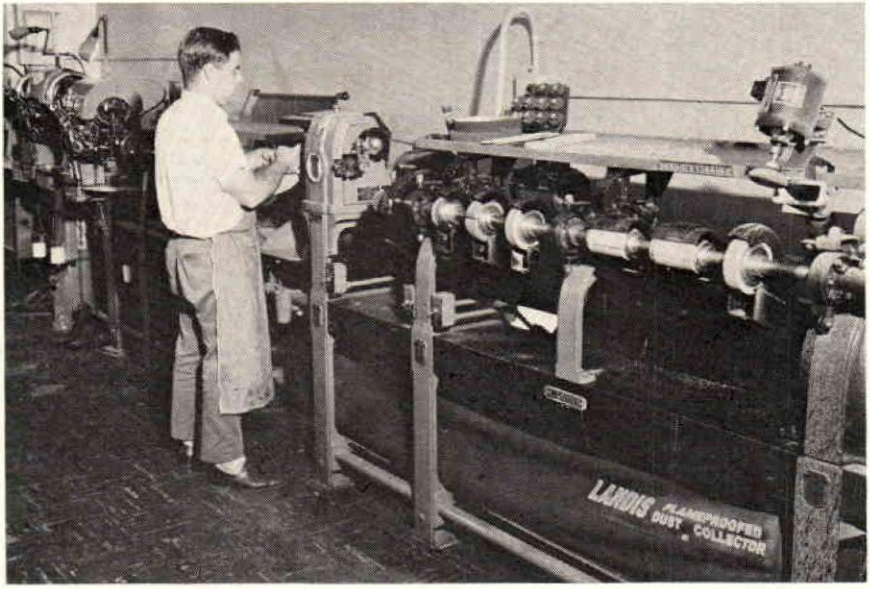


Figure 15. Part of the shop of the Orthopedic Shoe Section: Modern facility serving 12,000 veterans all over the country also provides support for research and development.

is being translated into appropriate action in accordance with a long term plan. It was devised on the basis of current needs, an appreciation of strong trends in the field, avoiding duplication of effort, and the economic exploitation of our own and others' capabilities and efforts. It calls for the development of four distinct, though closely correlated programs:

VAPC Intramural Research and Development
Cooperation with VA Contractors
Service to Other Governmental Agencies
Student Work-Study Project

1. VAPC Intramural Research and Development

VAPC is necessarily interested in an extremely broad range of problems relating to prosthetic and orthotic devices, orthopedic shoes and other appliances for the handicapped. Each of the several organic sections as well as other VA units require research and development services. These needs can be substantially met by the Bioengineering Laboratory and accordingly, the following series of studies reflecting their interests are now being undertaken:

a. Evaluation of the Effect of Several Shoe Correction Procedures on Stability, Comfort and Gait.

Mild deformities of the foot are usually stabilized or corrected by the prescription of orthopedic or modified conventional shoes. While this practice may be entirely adequate, too little is known about the actual outcome of the applications. We plan, therefore, to study the influence of conventional shoe correction practices on patient function and comfort. Conventional shoe corrections will be systematically introduced into shoes worn by normal and handicapped subjects, and the effects on their performance will be objectively described.

b. Evaluation of Externally Powered Devices for Upper Extremity Amputees.

Increasing emphasis on auxiliary sources of power for prosthetic and orthotic devices for the upper extremity creates a need for clearer understanding and a rational selection of the areas of utilization. The specific functions of the shoulder, elbow and wrist for which externally powered devices are most applicable should be clarified. Accordingly, we plan to study the forces and ranges of motion required for a variety of useful activities and to identify those areas in which external power is most needed.

c. Studies on the effect of Transverse Rotations in Normal Human Locomotion.

The purpose of the study is to fill out our present concepts of normal locomotion as regards the role of the relative rotations occurring in the tibia, femur, pelvis and spine during ambulation. Of particular interest are the relationships between the floor reaction torque forces and the displacement/acceleration of the contralateral hip joint. As an extension of this study, an objective description of several pathologic gait patterns and the accompanying muscular substitution techniques may be obtained.

d. Evaluation of Current Leg-Thigh Brace Designs.

Conventional non-weight bearing leg-thigh braces are usually constructed of two lateral uprights and fitted with knee locks. A critical analysis is required to determine areas of overdesign in strength and restraint and to improve function.

The results of this study will be applied to further development and optimization of a device offering adequate support, stability in stance phase and perhaps, some degree of flexion in swing phase.

e. Evaluating the Physical Capacities of Geriatrics.

In this field a complete program is required to determine decrements

in performance with age. The work tolerance, endurance and physical educability of the aged are not completely understood. To be sought is a valid system of subject evaluation and physical conditioning to provide a rational basis for the prescription of aids.

f. Pressure Distribution Within Lower Extremity Sockets.

Several commercially available pressure transducers are being evaluated and modified where necessary, for use in this study which is of fundamental importance in evaluating the effectiveness of several currently used socket fitting methods. Of particular interest for example, is the determination of pressures on the ischium in above knee sockets, and those on the patellar tendon in weight-bearing below knee sockets.

g. Evaluation of Knee and Ankle Mechanism for AK Amputees

A definitive, long-term study is indicated in which the performance of a carefully selected sample of subjects, fitted under highly controlled conditions, will be evaluated. This study is designed to apply an objective measurement technique to the evaluation of the several hydraulic, pneumatic and mechanical knee mechanisms which are now available or in various stages of development. The ultimate goal is to improve prescription indications.

Knee and ankle mechanisms are being evaluated on the basis of several sets of comparisons. First, knee and ankle function data obtained in mechanical tests on gait simulating machines are compared to similar data obtained when used by an amputee. Then the function of the new device is compared to others with respect to its effect on the gait pattern.

h. Analysis of the Energy and Motion Requirements of a Lightweight Wheelchair.

A new lightweight wheelchair was recently submitted for evaluation. The primary purpose of the study is to compare the comfort, maneuverability, durability and energy cost requirements of the new device with conventional models currently in use. Four subjects presently using conventional wheelchairs are participating. Their subjective reactions to use

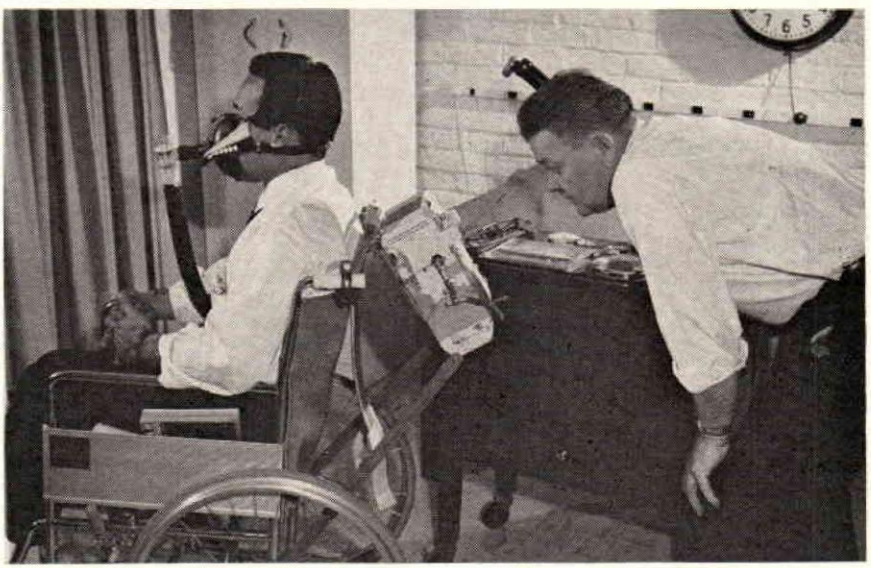


Figure 16. Wheelchair and subject instrumented with device to meter and sample expired air in energy consumption studies.

of the chair have been recorded and an analysis was made of the relative maneuverability of both items in turning corners, climbing curbs and avoiding obstacles. The metabolic costs of using each chair were determined. In addition, destructive tests to measure durability of axles, wheel bushings and framework are being undertaken.

i. Evaluation of the Single Bar Leg-Thigh (Long Leg) Brace With Limited Knee Flexion.

A leg-thigh brace featuring a single lateral sidebar and limited knee flexion has been designed by VAPC. A program is in progress to evaluate its effect on the gait patterns of several subjects. The performance of each participant in this study will be compared while using his conventional brace and the experimental brace.

j. Evaluation of the "Stand-Alone"

A mobile unit has been developed to enable wheelchair patients—paraplegics in particular—to wheel themselves about in an upright position. This device is currently being evaluated in a program to: (1) determine the ease of entering and exiting the unit; (2) analyze the design with respect to materials and mechanical adequacy; (3) determine the mechanical forces required to operate; (4) measure the metabolic energy cost required to operate; and (5) evaluate maneuverability and durability.

2. Research and Development Program in Cooperation with VA Contractors

It is at times more convenient or more efficient for the VA to assign specific programs or studies to responsible private contracting agencies or universities. Innovation and development in this field do not occur in an orderly, well-spaced progression. Rather, there are lean years and fat years in which many more devices and techniques appear than can be studied or evaluated in a reasonable time. In certain instances, other agencies have highly specialized skills which are more easily obtainable under contract than by attempting to develop them within the Bioengineering Laboratory. For these reasons, study areas involving extensive engineering services, for example, are investigated by contractors who, operating in some instances under the general supervision of the Bioengineering Laboratory, are given access to laboratory space and facilities.

An example of this arrangement is the current study by New York University to evaluate the mechanical and functional utility of the Henschke-Mauch Model A Swing and Stance Phase Control Unit. The mechanical analysis of the hydraulic unit is conducted by NYU engineers in the Bioengineering Laboratory. The biomechanical analysis of performance is also conducted in the Bioengineering Laboratory using the facilities and the equipment described above and with the assistance of Bioengineering Laboratory personnel.

3. Service to Other Governmental Agencies

Other departments of the government, notably the Vocational Rehabilitation Administration (VRA), support extensive research programs through a system of grants awarded to universities and other agencies. The recipients of such awards frequently require facilities and special services which already exist in the Bioengineering Laboratory. In order to improve economy and prevent needless duplication, the Bioengineering Laboratory cooperates in these projects. Several VRA projects, awarded to NYU, are currently being carried out with this assistance.

One example of such aid is a study dealing with the analysis of several bracing parameters. Dr. F. Rae Finley, Associate Research Scientist at NYU is evaluating the effect of ankle joint placement on the stability and gait

patterns of leg brace wearers. In addition, an attempt is being made to evaluate currently used leg-thigh brace weight bearing designs.

Another example is the study of Body Parameters conducted by Mr. M. Bluestein, Associate Research Scientist at NYU. Three methods are being used in this study to measure the volumes of limb segments. In the first, castings of body parts are made in alignment and their volumes are determined by water immersion. Volumes are also determined by photogrammetry, a technique in which colored tapes are projected onto a lateral view of the casting and the areas enclosed by each grid line on the frontal surface are measured. These values are converted to volumes by Wild's contour Method. ("Surveying and Mapping," Vol. 12, April-June 1954). The third method employs a modification of Sheldon's somatotyping technique in which photos of subjects are obtained in three views and the body segments are measured. Mass moments of inertia are being determined by means of a torsion table which vibrates with a subject lying upon it, the period of vibration being proportional to the mass moment of inertia.

In certain special instances technical assistance is given another government agency for a project only peripherally related to prosthetics and orthotics. In this connection, APRL has been instrumental in developing and evaluating a protective footgear (termed SABOT) designed to reduce the incidence of limb loss due to mine explosions among military personnel. The facilities of the Bioengineering Laboratory are being employed to evaluate the effects of wearing the device (which features an "ankle joint" mechanism) on gait patterns, stability and endurance.

In a similar category was a recently completed study of an experimental exoskeletal leg harness called a Pedipulator. It was designed by the Human Factors Section of an Army research contractor as a prototype of a servolocomotion apparatus for possible military and space applications. An investigation was conducted in the Bioengineering Laboratory to determine the effects of the device on the normal motion and force pattern of ambulation and the energy requirements for the operator.

Several other governmental agencies, in particular National Aeronautics

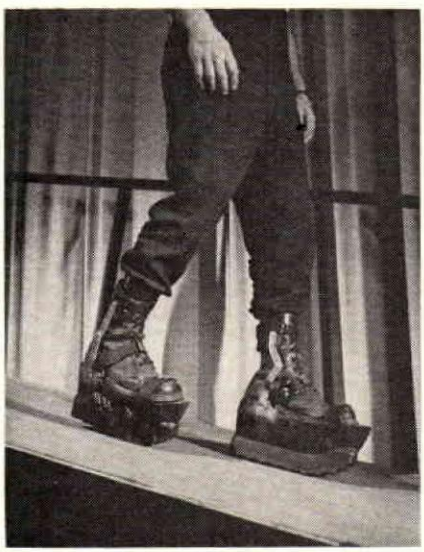


Figure 17. Sabot: Energy cost studies on injury reducing device for military use.

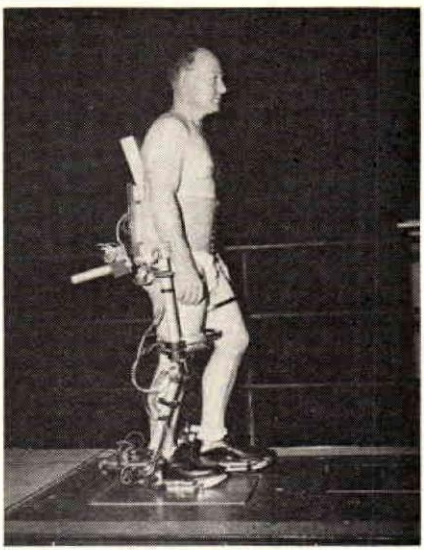


Figure 18. Pedipulator: Kinematic analysis of gait pattern using exoskeletal leg harness.

and Space Administration and U.S. Army Quartermaster Corps, maintain substantial programs of research and development. As a significant portion of these programs deal with the evaluation of human performance under varying conditions of environment, physical stress, implement use and clothing, the VA's Bioengineering Laboratory facilities may be of important service.

4. Student Work/Study Project

Currently in operation is a program in which students from several universities work in the Bioengineering Laboratory. This group includes graduate students who are matriculated in a doctoral program in which bioengineering techniques are employed. On the recommendations of their faculty advisor, they are assigned to work in the Bioengineering Laboratory on an independent study program. They gain experience by participation in data collection and reduction activities and develop the technical skills needed in their own work.

At the present time, two graduate students are participating in a joint VA/NYU Study on tibial torsion. They are obtaining data on a large sample of normal subjects to determine the ranges of normal tibial torsion and other anthropometric data relating to the ankle and shank.

During the academic year, undergraduate students also participate in the work of the Bioengineering Laboratory. Each semester several (4 to 8) undergraduate students, recommended by their professors, spend from four to ten hours per week in the laboratory, in fulfillment of a course project requiring familiarity with bioengineering methods. They learn the fundamentals of biomechanics and gain experience in laboratory methods. In the process, they perform a useful service by assisting in the preliminary steps of data handling.

The students working in the Bioengineering Laboratory during the academic year are not salaried. However, in the summer vacation period, up to six students are hired as part-time employees. These students, primarily in engineering or the medical sciences, are carefully selected on the basis of their professors' recommendations, interviews and an interest in human factors work. They become temporary employees for periods of up to 90 days at hourly rates commensurate with their background. They are directly assigned to ongoing projects under the immediate supervision of professional personnel.

The advantages of this program to both graduate and undergraduate students are obvious; they receive access to facilities, equipment, subjects and professional consultation in return for services as members of a research team in the Bioengineering Laboratory. On the other hand, they provide useful service to the Laboratory and represent a potential source of "new blood" for the field.

In the preceding sections, we have discussed the rationale underlying the organization of the Bioengineering Laboratory and we have described the equipment and facilities it contains, the people who operate the laboratory and some of the current work. In the process, we may have come a little closer than we did at the beginning of this article to a definition of bioengineering in prosthetics and orthotics, a task we avoided then as now because its full compass cannot be foreseen. We can see, however, that it is intimately involved in the restoration or improvement of volitional mobility, a fundamental process of human life. No less a task is undertaken than that of designing mechanisms to augment or substitute for human muscles and joints. While our immediate preoccupation is man, his mobility and the mechanisms to enhance it, service to the medical profession and above all to the disabled is our purpose.

Improvement and Innovation: Development

Everyone has at one time or another contemplated and perhaps experienced the joy of free thinking unshackled by scientific law. If our indefinite fancies and dreams of progress were to materialize, prosthetics and orthotics methods and devices would be advanced far beyond now practical limits.

Unfortunately, developments of new devices and techniques do not spring spontaneously from a fertile imagination alone. New methods and devices must certainly be based on new concepts exposed as a result of extensive fundamental research or on problems revealed by study of all available literature and practices, particularly clinical experiences. Before a new item may be developed, there is a need to determine design criteria on the basis of a clear and accurate definition of the new concept or the problem.

Although improvement in prosthetics and orthotics is intended primarily for the patient, many advantages may accrue to the manufacturer of components and the fabricator of appliances. The goals of development groups include improved function and comfort for the disabled, as well as convenience in terms of simplicity and durability of devices. Also, the developer tries to aid the manufacturer and fitter not only by providing new products but by making their jobs perhaps a little easier and more profitable.

All new items are generally tested by various means during transition in development, with each item presenting differing requirements for the development programs depending on the problems which it confronts or the new concept it manifests. Basically, there are two groups of items: the first group representing *techniques* including methods, systems, and materials; the second group covers the *devices*. To further define the often subtle variances which exist within these two groups, the following classification is offered:

Group I—Development of Techniques

All efforts are directed toward the ultimate improvement of prostheses and orthotic devices through a continuous investigation of materials, seeking those which meet, as the main criterion, the physical requirements of an appliance. In addition, development is required to integrate such requirements with adaptability, in a simple workable technique, to advanced concepts of fitting, alignment, and function. Technique development, most of which is materials-oriented, may be given the following sub-classification:

A. The development of techniques reflecting new fitting concepts and better fabrication methods but with existing materials.

B. The development of applications of new or different materials and methods.

C. The development of new appliance designs based primarily on the proper application of existing materials and methods.

D. Refinements in applications of existing materials and techniques.

Group II—Development of Devices

As we continue to encourage the development of new components to provide better functional mechanisms and controls for prostheses and orthotic appliances, we need not limit the functions to the precise sites in which normal functions occur in the anatomical members. Our *only* restrictions in providing function are those limitations imposed by the physical shape, size and weight of the appliance.

Device development may be given the following sub-classification:

A. The development of devices (prosthetic or orthotic components) providing a new function in an appliance.

B. The development of devices used as instruments or tools in the preparation or fabrication of an appliance but primarily based on existing principles.

C. The development of devices necessary for a new technique, method, or concept.

EXAMPLES OF TECHNIQUE AND DEVICE DEVELOPMENTS

TECHNIQUE DEVELOPMENTS

A. The development of techniques reflecting new fitting concepts and better fabrication methods but with existing materials.

EXAMPLE: Below-knee weight-bearing brace with PTB type socket (Fig. 1).

Typically, the leg-thigh (or "long-leg") brace has been used for all cases involving the unweighting of the lower extremity. Although such bracing appears to be excessive in certain cases, research has not fully defined the problems which such over-bracing may present. As a step in seeking such information, the below-knee weight-bearing brace using the technique of PTB socket fitting was designed to obviate unweighting the entire extremity for bracing below-knee involvements.

The ischial weight-bearing brace is needlessly heavy, cumbersome, and certainly uncomfortable. Seemingly undue restrictions are imposed upon the normal function of the knee, thigh, and hip muscles when bracing only for an arthritic ankle or foot or malunion of the tibia, fibula or portions of the foot. While improved gait, mobility, and conservation of energy appear evidenced with the use of the below-knee type weight-bearing brace, studies

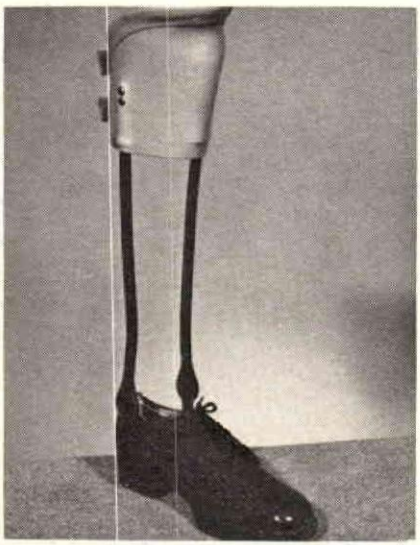


Figure 1. Below-knee weight-bearing brace showing PTB type socket.

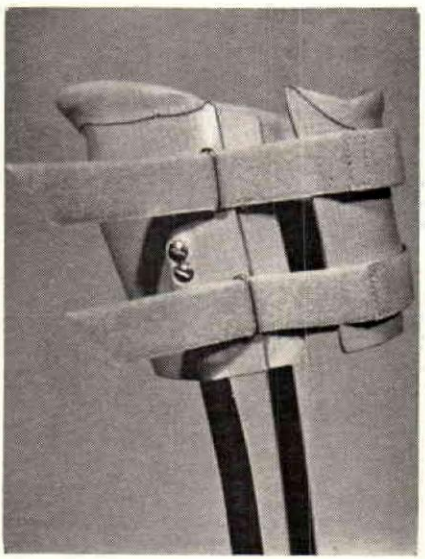


Figure 2. Below-knee weight-bearing brace with adjustable socket secured by "Velcro".

are continuing, to provide more objective information regarding the possible effects of active muscular knee control upon malunions and nonunion of the tibia when braced in the manner described below.

The below-knee weight-bearing brace consists of three basic component groups: the socket, brace bars, and shoe. The socket is the typical plastic-laminate PTB design, hinged in the posterolateral aspect to provide entrance of the limb (Fig. 2). The methods of casting the leg and subsequent mold modifications are typical of those used in the PTB below-knee fabrication techniques. The socket is sectioned in the posterolateral aspect and joined with a hinge.

The socket hinge assembly is constructed from a metal frame tailored to size and containing a hinge and two brackets (to receive the brace bar uprights). The frame is sandwiched in the lamination lay-up and held in position by a string during lamination. The plastic lamination incorporates the frame (with hinge) into the socket body. The most recent below-knee sockets for this type of brace are fabricated without the sponge and leather liner shown in the illustration.

The weight-bearing cast about the knee and upper shank is achieved by use of the casting stand illustrated later in this article: the method of casting used is similar to the technique for casting the below-knee stump. During casting, the patient wears a shoe modified to accommodate the brace stirrup. Alignment of the brace uprights is established on the patient as he stands in the casting stand. Careful reference marks made upon the cast are used to locate the final brace bar positions. Adjustment holes in the upper portion of the brace bar uprights also aid in making more precise dynamic adjustments.

The shoe is modified externally to incorporate a metatarsal rocker bar and a compressible SACH type heel insert. Since limited motion in the brace ankle joint is essential to achieve best unweighting characteristics, these modifications are used to provide "roll-over" function in the shoe, allowing full limitation on ankle joint motion.

The trophic changes which would normally develop in the thigh with the use of the weight-bearing leg-thigh brace and knee lock should be eliminated by use of the below-knee PTB brace.

B. The development of applications of new or different materials and methods.

EXAMPLE: The dip method for plastic finishing of prostheses, a technique using an ethyl cellulose plastic which permits the dipping of components to achieve a reinforced plastic finish (Fig. 3).

The value of this technique will be appreciated most when there is a large production volume. With fabrication techniques using pre-fabricated components, shop time and cost in making a prosthesis up to the point

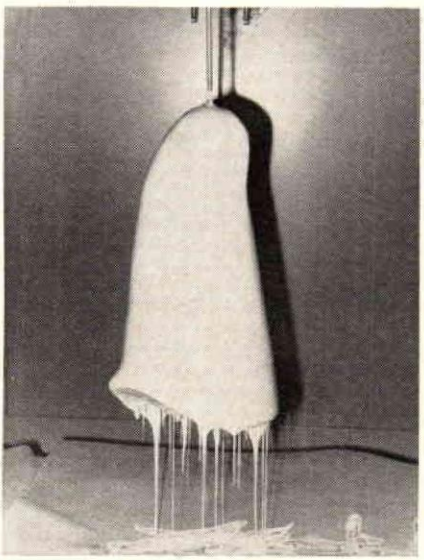


Figure 3. Above-knee socket dipped in ethyl cellulose.

of lamination are considerably reduced. However, the typical plastic-laminate finishing process required to reinforce a prosthesis and provide an acceptable cosmetic appearance still requires the time and skill of an artisan.

Experiments have been conducted using an ethyl cellulose material into which the prosthetic components are dipped and left to drip-dry providing either a clear or pigmented coating of approximately 50 to 60 mils thickness. The technique requires the use of metal or plastic containers (cans) large enough to accommodate an increase in contained volume caused by the introduction of a component which has to be completely submerged in the liquid. A drying rack is needed to hold components between dips.

A total of approximately five (5) dips is necessary to provide adequate strength and a smooth finish in the present experimental method. The first dip is a "tie-coat" sealer, for wood sockets only. The second dip is into the ethyl cellulose, clear or pigmented. The third dip is made over one stockinet (Helanca nylon) stretched over the component for reinforcement. Two more dips are added to finish the process. If a clear dip is used, the last dip should be into a pigmented lacquer.

The only problem in this process is the drying time required between dips. One (1) to two (2) hours time is recommended between dips. However, if a large number of components needed finishing routinely there would be a minimum of delay time and the operations could be assigned to a rather unskilled person to accrue production savings.

The dip operation must be accomplished slowly and methodically to minimize introducing air bubbles into the dip tank. The recommended rate of immersion and withdrawal of a component from the dip tank is 5 to 9 inches per minute. Perhaps a large plant could mechanize this process.

The following table indicates the approximate cost of materials for dip finishing:

		COST OF MATERIAL	
Foot:	Approx. 60 square inches	* .30	** .35
Shank:	Approx. 200 square inches	* 1.00	** 1.15
Socket:	Approx. 340 square inches	* 1.70	** 1.95
		$3.00	$3.45

* Cost computed at $.005 per square inch.
** 15% waste included.

Results of recent tests suggest that the strengths of the dip-coated (ethyl cellulose) specimens (1) without reinforcement and (2) "reinforced" with one layer of Helanca stockinet are at least equal and perhaps greater than those with the typical nylon stockinet laminate finishes using polyester resin. Tests were made applying a vertical load through a tapered mandrel inserted into the specimens, mating tapered wood "cylinders" finished in various manners. A most significant reduction of weight in the test specimens was also noted, as shown in the table on page 271.

C. The development of new appliance designs based primarily on the proper application of existing materials and methods.

EXAMPLE: The medial-opening Syme prosthesis.

Syme's amputation allegedly prepares the patient for ambulation with a stump which can carry, through the stump end, full body-weight at all times. Although the properly performed Syme's operation enables the patient to tolerate weight-bearing upon the end of his stump for short periods of time, most Syme prostheses wearers examined in our Center admitted that they were unable to use their prostheses for long periods of time unless the stump was always securely stabilized in the socket. Our early assump-

TABLE I

WEIGHT CHANGES AND STRENGTHS PROVIDED BY VARIOUS FINISHES ON WOOD CYLINDRICAL SPECIMENS

Specimen Number	Type of Finish	Average Weight of Specimen Before Finishing (ozs.)	Average Weight of Specimen After Finishing (ozs.)	Increase in Weight %	Vertical Breaking Load (lbs.)
1, 2, 3	Ethyl Cellulose dip w/o Helanca Stockinet	4.73	5.86	23.8	3650
4, 5, 6	Ethyl Cellulose dip w/1 layer Helanca Stockinet	4.74	6.04	27.4	3889
7, 8, 9	Ethyl Cellulose dip w/2 layers Helanca Stockinet	4.74	6.38	34.6	3500
10, 11, 12	Ethyl Cellulose dip w/3 layers Helanca Stockinet	4.73	6.87	45.2	3199
13, 14, 15	Polyester Laminate w/2 layers Nylon Stockinet	4.27	6.13	39.3	3189
16, 17	Ethyl Cellulose w/2 layers Nylon Stockinet	4.72	6.87	45.5	2489

tion that better suspension was needed was probably erroneous since above-knee strap suspension did not seem to help. It seemed that the lacer of the older type socket provided a much needed additional weight-bearing, however inadequate otherwise.

It was increasingly apparent that most Syme's amputation stumps responded most successfully to use of an artificial leg when all available areas of weight-bearing and support were provided. However, interference with the normal function of the knee must not be permitted. In order to design a Syme prosthesis which would provide maximum body weight support, it was necessary to employ below-knee weight-bearing concepts. Such a socket design enables the amputee to adjust the weight load distribution between the typical below-knee weight-bearing areas proximally and end-bearing by controlling the thickness of "pads" in the bottom of the socket. The proximal portion of the Syme cast (about the knee) may be formed by using the below-knee casting equipment described later in this article.

The proximal portion of this prosthesis is contoured and fitted like a below-knee socket thus providing proximal as well as distal weight-bearing. An oblong opening is cut into the medial side of the socket shank to allow entrance of the bulbous Syme stump end into the socket. The rounded bottom of the Syme socket is recessed into the top of a special type of SACH foot having a heavy keel with a narrow heel wedge. The socket and foot are united by a heavy steel bolt which passes through the keel and engages a concave washer set into the bottom of the socket flush with its inner surface.

By use of this design (Fig. 4), the completely intact anterior and posterior socket walls will provide a greater resistance to the high parasagittal stresses created during walking, thus increasing the structural strength of

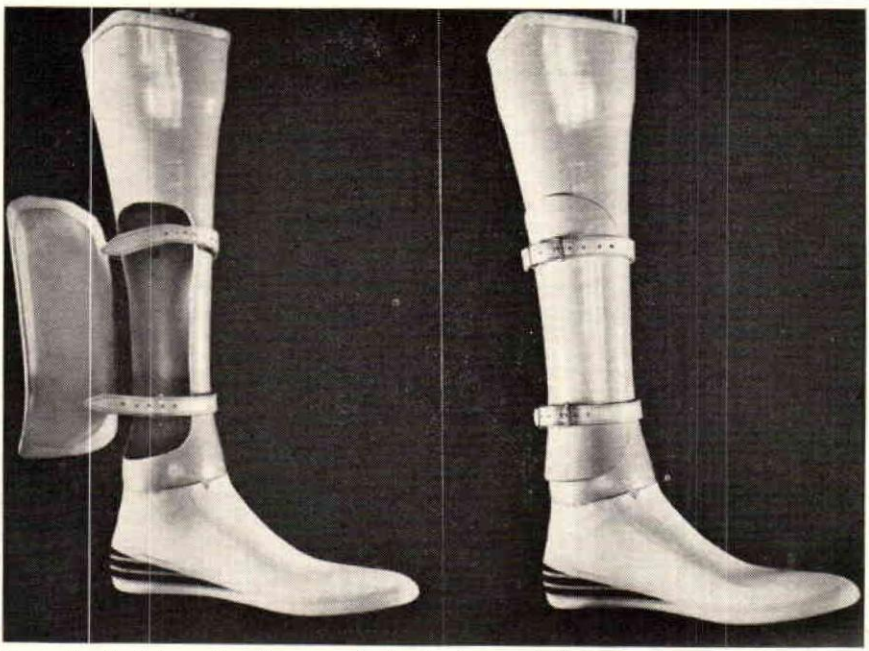


Figure 4. Medial-opening Syme prosthesis showing method of attaching "window" cover. Normally "Velcro" straps will be used to secure the cover.

the Syme prosthesis. There is no need for adding special reinforcements such as Fiberglas; only nylon stockinet and Dacron felt are used in the lamination.

D. Refinements in applications of existing materials and techniques.

EXAMPLE: A vacuum technique for porous lamination using long accepted lamination procedures and resins except that Helanca stretch nylon stockinet is used.

The nonpermeable plastic laminate sockets now generally used certainly have limitations in terms of providing a proper environment for the body. In a way, wood and leather sockets are superior in that moisture from perspiration might readily be transmitted or absorbed. But all realize the hygenic problems and the poor durability resulting from the use of either wood or leather; thus, The Army Prosthetics Research Laboratory devoted a considerable effort to the development of porous laminates, to provide diffusion of water vapor and improved comfort. That Laboratory reported: "Within the limits of strength requirements, maximum porosity should be the goal."

Based on the previous work of the Army Prosthetics Research Laboratory on porous epoxy laminates and most recently on porous polyester laminates using a Banlon knit stockinet, a somewhat different technique was developed by the VAPC for the construction of porous sockets. Both upper extremity sockets and below-knee sockets have been fabricated using a technique not too far different from present laminating procedure and using materials quite familiar to the limb industry.

The interior and exterior surfaces of the socket laminations are made smooth by using tubular Helanca nylon stockinet, of size large enough to cover the mold without stretching to minimize the "ribbing" effect caused by opening the stockinet weave. Approximately thirteen additional Helanca stockinet layers are used to form the bulk of the socket. But with these stockinet layers, between the inner and outer socket surfaces, a reduction in porosity will result because of the large number. These layers therefore must be stretched over the mold sufficiently to open the stockinet weave spaces. This is achieved by selecting a stockinet size requiring a stretch of twice its diameter to cover the mold.

Since, within the limits of strength requirements, maximum porosity is desired, a vacuum system is used to remove all excess resin from the interspaces of the stockinet weave leaving only the stockinet fibers saturated (Fig. 5). In this process, the vacuum also pulls air through the resin.

The mold is first covered with a PVA sleeve. The air space between the PVA and the mold is evacuated to provide an intimate mold separator. The first tubular Helanca nylon stockinet is pulled over the mold. The next thirteen layers of tubular Helanca stockinet are then *stretched* over

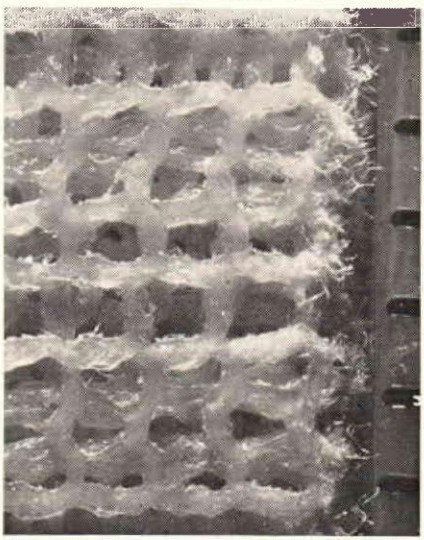


Figure 5. Photomicrograph of Helanca nylon stockinet showing the effects of vacuum lamination over stretched stockinet. Note: Absence of resin in interspaces but the saturation of the stockinet fibers.

the mold. The final layer of tubular Helanca stockinet should be large enough to be pulled on without stretching. A PVA sleeve is pulled over the lay-up to form the resin container. But the top of the sleeve is left open.

The resin is introduced to saturate the stockinet fully. After the stockinet is saturated, the inner PVA sleeve is perforated. The hole punched in the inner PVA sleeve now allows the vacuum, still applied to the inside of the inner PVA sleeve, to be also applied *between sleeves* or directly to the resin and will cause an air flow *through* the resin, producing porosity.

Although difficulties still exist in achieving uniform porosity in undercut socket surfaces, deviations from the present method are being investigated to overcome this problem.

DEVICE DEVELOPMENTS

A. The development of devices (prosthetic and orthotic components) providing a new function in an appliance.

EXAMPLE: The lower-extremity prosthesis torque absorber, a device designed to provide a controlled axial rotation in above-knee and below-knee prostheses.

Axial rotation of the leg segments is indeed an essential part of the dynamics of walking. Studies on amputees reveal a less than desirable gait and show an increase in shear stresses between the stump and socket if some axial rotation is not permitted.

A great portion of axial rotation normally takes place during the non-weight bearing phases of gait; a rather complex powered device would probably be required to duplicate this function. As a simplification and as a contribution at least to control of rotation during the stance phase, a unit which functions only against the torques occurring during weight-bearing was designed. The present experimental device is a simple two-piece design providing a controlled resistance to rotation. It can be used in either an above-knee or below-knee prosthesis.

The "rotator" (Fig. 6), a wafer type design, is 1 1/16" thick by 2¾" in diameter; thus, it can fit into nearly any adult prosthesis beneath the socket. The weight of the unit is approximately six (6) oz.

It consists of two aluminum plates joined by four set screws which hold a standard bearing, the main rotation element. The top plate carries a vane which rotates against four (4) gum rubber bumpers set into the bottom plate (Fig. 7). The material used as

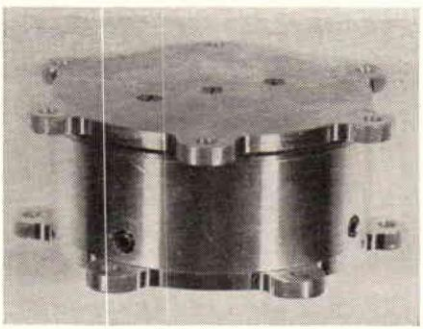


Figure 6. Torque absorber for above- and below-knee prostheses.

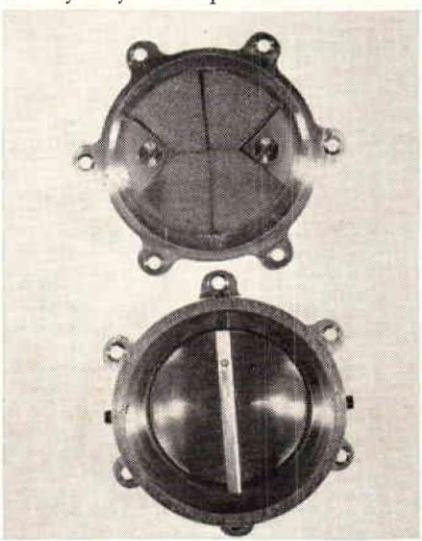


Figure 7. Internal view of torque absorber showing the elastomer inserts in the top section and the vane attachment in the bottom section.

well as the size and shape of the bumpers control the amount of resistance to rotation. The resistance of the present unit is 40 inch lbs./15° deflection each side of center.

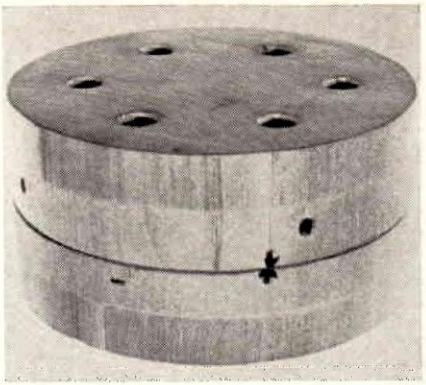


Figure 8. The torque absorber "sandwiched" between two pieces of wood to facilitate attachment to the prosthesis and for external shaping.

It is intended that the rotator element will be sandwiched between two pieces of wood when produced commercially (Fig. 8). Each inner surface of the wood plates is attached to the aluminum "rotator" by epoxy resin and machine screws. The top and bottom surfaces of the wood "sandwich" in turn, can be glued to the standard wood prosthetic shank providing a uniform base material for easy shaping and finishing. Current evaluation studies are concentrating on the following:

(1) The different resistance characteristics, if any, required in the above-knee and the below-knee prosthesis.
(2) The effect on the gait of an above-knee wearer of above-knee and below-knee locations for the "rotator."
(3) The different resistances that may be required in control of internal and external rotatory motions.

B. The development of devices used as instruments and tools in the preparation or fabrication of an appliance.

EXAMPLE: The alignment coupling, a device designed to facilitate the proper dynamic alignment between the various components of a lower extremity prosthesis (above-knee socket to thigh or knee and below-knee socket to shank or foot).

During the last few years prosthetic knee units containing varied and more highly refined functions have been developed for routine amputee use. The standard alignment device used (the adjustable leg) is a single axis mechanical friction device of pylon construction. Transfer of alignments obtained upon such devices will probably be inadequate when a knee-shank unit having entirely different functional characteristics is substituted. Ideally, the proper alignment of a prosthesis can best be achieved with the various *permanent components* adjusted under dynamic conditions, thus incorporating in the determination of alignment the integrated influence of the functions offered by all the components used.

Similarly, it must be understood that an existing alignment cannot be imposed upon a new socket in instances where the remaining components of a long-worn prosthesis will not be changed. The new socket fitting will influence the nature of the stump weight-bearing and control; the influences change with each new socket fitting as do the forces acting about the stump. For instance, maintaining a pre-set alignment of a prosthesis upon which a suction socket replaces a "plug-fit" will certainly cause problems. Such problems and alignment difficulties encountered during the early fittings of fluid-controlled knee mechanisms stimulated the development of the coupling.

The VAPC alignment coupling (Fig. 9) can be used to determine the best alignment of above-knee or below-knee prostheses using any prescribed combination of components (Fig. 10). The coupling has the rotary, angular

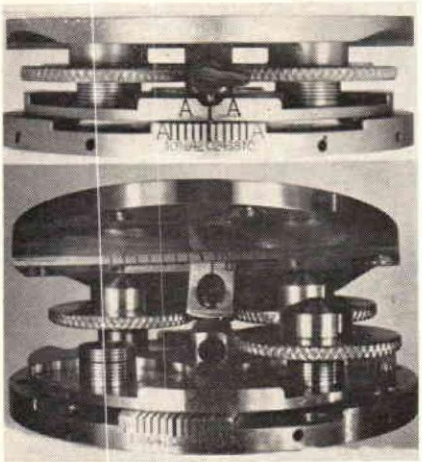


Figure 9. Alignment coupling.

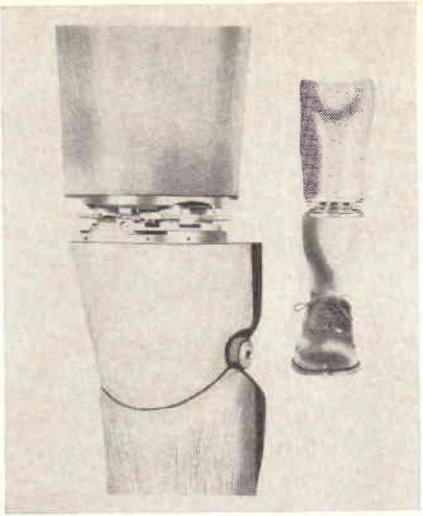


Figure 10. Alignment coupling in above- and below-knee prostheses.

and linear adjustments of both the above-knee and below-knee adjustable legs.

The coupling measures 3¾" in diameter, is 1⅛" thick (measured along the vertical centerline) and weighs slightly under 1 lb. It consists of two aluminum plates (top and bottom) joined centrally by a 1⅛" long stainless steel toggle-type column, having a circular slide on each end. The two plates contain countersunk holes to provide screw or bolt attachment to wood or metal prosthetic components above and below the coupling.

Each plate has a channel of rectangular cross-section (to contain the slides) for horizontal linear adjustments; the two channels are oriented at right angles to one another permitting full horizontal plane adjustment of one plate with respect to the other.

A third and intermediate aluminum plate rests upon the bottom plate and contains four threaded bushings fitted with four mushroom-shaped cap screws with knurled rims. The simultaneous adjustment of any two opposing screws (or screw-pairs) allows control of the angular relationship of the top plate with respect to the bottom (tilt). These adjustment screws, when firmly tightened, also serve to prevent any relative motion of all three plates. With the cap screws loose, rotation of the top plate with respect to the bottom one can be made.

The alignment coupling is designed as a simple device for economical production. Except for the central toggle, it was originally made of 7075 aluminum, but in production, aluminum-magnesium alloy castings have been employed. All components are of relatively simple design.

The unit provides combinations of the following adjustments in the ranges listed (the adjustment calibrations are primarily used to provide reference for readjustments):

Tilt, 10° in any direction between upper and lower plates.

Linear, Anterior-Posterior Positioning, 1½" both directions from center.

Linear, Medial-Lateral Positioning, 1¼" both directions from center.

Rotation, 10° both directions from center.

The coupling is used in the thigh section of above-knee prostheses. In the below-knee, as well as in the above-knee, the coupling should be inserted into the set-up as close as possible to the end of the stump. Placing

the coupling near the bottom of the socket will reduce the projected effects of angular adjustments which ordinarily necessitate linear (A-P and M-L) readjustments as compensation.

Alignment duplication is achieved by use of the alignment duplication jig or the transfer compass. The procedure of transfer using the alignment duplication jig requires one saw cut above and parallel to the coupling base. The location of the cut can be made to coincide with the thickness of a pre-cut wood block. The procedure of transfer using the transfer compass also involves a saw-cut 2 inches above and parallel to the coupling base to match a pre-cut wood block made two inches thick. Use of the transfer compass enables the prosthetist to locate the level and orientation of the saw cut which can be made on a band saw.

In addition to the functions previously mentioned, the coupling may be used in temporary prostheses to provide a continuing means of adjustment during the prosthetics training of a patient. It has also been found valuable in research to determine the mutual effects that the functional characteristics of various combinations of prosthetic components and alignment have on each other.

C. The development of devices necessary for a new technique, method, or concept.

EXAMPLE: VAPC Casting Stand (Figure 11), a device using three separate and adjustable components to form the cast of a thigh stump under weight-bearing or with two other adjustable components, to form the cast of a below-knee stump under weight-bearing.

Use of the quadrilateral above-knee suction socket has certainly contributed to the reduction of problems in fitting the above-knee stump. Although problems in body-weight support and prosthesis control were appreciably diminished by the rationale underlying quadrilateral socket shape, the high contrast in the forces acting about the thigh stump (1) in the upper areas (positive forces at ischial level) and (2) in the distal areas (negative forces at stump end) still created a serious problem in further restricting an already disturbed circulatory mechanism. To overcome this difficulty particularly, a new socket-fitting concept (total contact) has been introduced. Now the entire stump is made to have contact with the socket wall but still with control of the distribution of weight and other forces acting on the various stump tissues according to the individual capability of the tissues. Of great significance is the control of the force magnitudes as functions of levels within the socket but particularly the forces created about the stump end. Since suddenly changing force distributions can be as detrimental, if not more so, than an overall high force distribution, techniques such as the "tension analysis" system of UCLA have proven very advantageous for controlling the gradient of forces within the socket. The success of this technique indicates that primary socket fitting should be based on circumferential measurements along the length of the stump.

Casting the Above-Knee Stump

A pressure gradient must be planned into the socket beginning with a very low pressure (contact) at the bottom and increasing gradually to the forces required to provide the main control and weight-bearing at the top. To make a socket that will provide a stabilization of the stump under conditions of high force concentrations, it is first necessary to plan the socket shape so as to accommodate the stump changes which occur during periods of high force (in the stance or weight-bearing phase). Full control of the fit is probably most nearly achieved with a socket fabricated over a stump replica

formed from a weight-bearing cast. Unfortunately, we must deliberately deform the upper thigh stump to place a nearly vertical component of support under the ischium and gluteofemoral areas.

In addition, when using a weight-bearing method of casting in which the entire stump is wrapped, the overall forces are distributed about the entire periphery of the stump minimizing distortion of tissue. Although the tissue mass of the thigh stump appears to accommodate distortion in any direction, each muscle compartment is confined within the fascial bulkheads formed by the connecting tissues, aponneuroses and fascia, etc., restricting the deformation to the limits imposed by these structures. Often during surgery, however, the muscle packs at the site of amputation are severed and may retract somewhat. Slight stump elongation which occurs during casting takes place within these muscle groups thus helping to restore them to a safe anatomical attitude.

Hence, a device (Figure 11) was designed to form the cast of a thigh stump under conditions of weight-bearing. The device consists of (1) a stand assembly, (2) cross member assembly, (3) posterior socket form, (4) anterior socket form and (5) lateral socket form (Figure 12).

The stand assembly includes a vertical upright, a base plate, and a vertical traversing head. The cross member provides adjustable attachments for the socket form brackets and for positioning the lateral form. This assembly is attached to the stand assembly and is pivoted around an axis at right angles to the upright to provide flexion and extension adjustment of the forms (as a unit).

The posterior socket form consists of the major weight support surface and part of the vertical posterior wall with a section representing part of the medial wall. The contour of the posterior form is based upon concepts of socket shape developed from successful quadrilateral fittings and anthropometric measurements. The medial section of the posterior socket form helps to establish the medial-to-lateral width of the socket and the proper position (medial-lateral) of the ischium upon the posterior socket support. The pos-

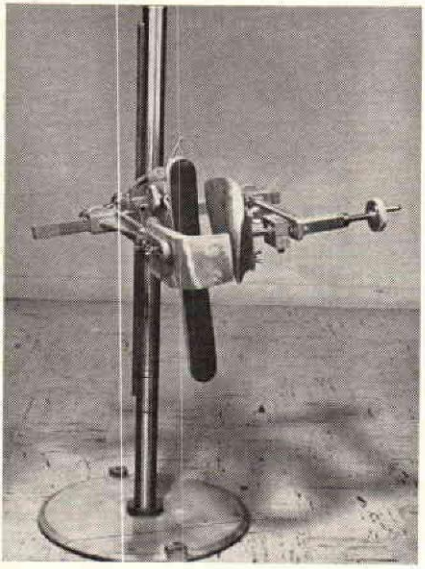


Figure 11. Casting stand with above-knee forms.

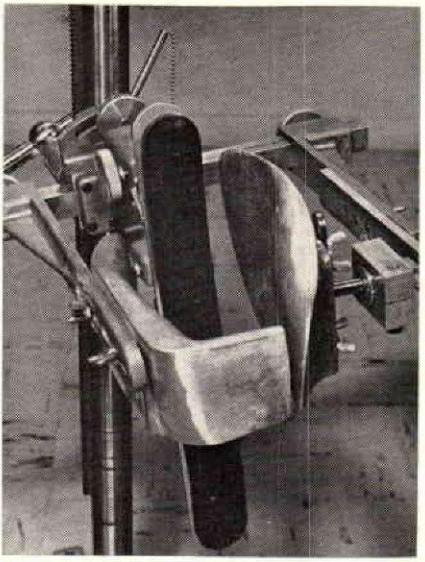


Figure 12. Close-up of above-knee casting forms showing contours and apparatus for adjustments.

terior socket form is adjustable with respect to the stump in a medial-lateral plane. This medial-lateral adjustment is used to orient the adductor longus tendon in its proper position relative to the anterior socket form.

The anterior socket form contains a proximal anteromedial flare and a rectus femoris channel. The form is pivoted so that a reasonably even distribution of the posteriorly directed forces will result within the guides provided by this form's shape. A locking mechanism is provided locking the pivot of the anterior form once the proper attitude has been achieved. The resistive characteristics of the stump tissues and the individual contours of the stump tissues and the stump position in relation to the contours of the forms determine the orientation of this form when it is pressed against the anterior of the stump. The anterior section is also adjustable in position proximally and distally, a control used depending upon the length of stump. Usually a low position is used for long stumps and a higher one for short stumps.

The lateral socket form consists of a flat surface adjustable for varying degrees of adduction or abduction. Adjustments are also provided for medial or lateral positioning of this form as well as for a limited range of flexion-extension. The normally flat surface of the form can be readily given rather sharp curves to provide the contouring necessary for the best lateral support.

Before casting the stump, the patient must be carefully examined and all pertinent prosthetic information recorded on an information form. This information will be used to define the most nearly exact contours and size of the socket.

An estimate is obtained by a socket plan based on stump dimensions. The following rules for the initial plan have proved successful:

a. 1/3 of the most proximal circumferential stump measurement is used for the initial setting of the M-L socket dimension.
b. 1/5 of the most proximal circumferential stump measurement is used for the initial setting of the A-P socket dimension.

Further refinement of the contour provided by the socket forms is achieved by trial adjustments of the various segments of the stand about the unwrapped stump. Once the correct settings are achieved the forms may be lowered away from the stump.

The patient's stump is then wrapped with elastic plaster-of-Paris bandage and then after the positions of the forms have been adjusted to compensate for the thickness of the wrap, the fixture is elevated about the stump restoring the original position of weight-bearing.

The elastic plaster-of-Paris wrap provides the tension required to maintain the stump volume during the shaping process in the casting fixture. The forms shape the cast to provide the socket contours which stabilize the stump at a prescribed attitude under weight-bearing conditions.

Previous methods of mold modification have required a careful analysis of stump musculature to classify its resiliency (soft, medium or firm). Based upon these criteria a pre-determined amount of material was removed from the mold to provide a desired tension within the socket. We have found that stumps cannot be so simply classified but range in degrees of softness and firmness. The varied reductions in stump volume caused by casting are proportionate to the muscular resistance to compression and distortion. Hence, the most dependable method for classification of stump musculature is based upon the amount of stump distortion (circumferential reduction) which occurs during casting—as compared to the circumferential stump measurements originally recorded.

In this present method, classification of stump resiliency for mold modification is no longer required. The casting pressures will cause the magnitude

of volume change (circumferential reduction) to be greater on soft stumps and less on firm stumps. Hence, further reductions to the cast circumferential measurements are made using the reduction factors indicated on the work sheet shown as Figure 13.

WORK SHEET FOR TOTAL-CONTACT SUCTION SOCKET

	ORIGINAL STUMP MEASUREMENTS COLUMN A	MOLD MEASUREMENTS COLUMN B	MOLD MEASUREMENT REDUCTION SCALE COLUMN C	MODIFIED MOLD MEASUREMENTS COLUMN D
CIRCUMFERENCE 0" (ISCHIAL LEVEL)			MOLD MEASUREMENT Less 1/2" to 5/8"	
CIRCUMFERENCE 2" BELOW			MOLD MEASUREMENT Less 1/4" to 3/8"	
CIRCUMFERENCE 4" BELOW			MOLD MEASUREMENT Less 1/8" to 1/4"	
CIRCUMFERENCE 6" BELOW			MAINTAIN ORIGINAL STUMP MEASUREMENT	
CIRCUMFERENCE 8" BELOW			MAINTAIN ORIGINAL STUMP MEASUREMENT	
CIRCUMFERENCE 10" BELOW			MAINTAIN ORIGINAL STUMP MEASUREMENT	
CALCULATE A-P & M-L from CIRCUMFERENCE at ISCHIAL LEVEL A-P = 1/5 of the CIRCUMFERENCE M-L = 1/3 of the CIRCUMFERENCE				
CALCULATED ORIGINAL A-P →			RE-CALCULATED A-P BASED ON MOLD CIRCUMFERENCE IN COLUMN B ←	
CALCULATED ORIGINAL M-L →			RE-CALCULATED M-L BASED ON MOLD CIRCUMFERENCE IN COLUMN B ←	

Figure 13.

Although initial A-P and M-L dimensions have been established for casting the stump, these dimensions were computed from the original *stump* circumferential dimensions. Once the proximal *mold* dimensions have been established, it is necessary to recompute the A-P and M-L dimensions based upon the smaller mold measurements (the new, compression-dependent proximal circumference) resulting from the tension of the elastic plaster wrap and the casting process itself. The work sheet illustrates the mold modifications required after casting to control the forces acting upon the entire stump particularly the proximal-distal gradient of these forces.

Casting the Below-Knee Stump

Fitting of the below-knee socket requires considered technical skill and experience. The more successful prosthetist will understand the weight-bearing capabilities and the physiological functions of the anatomical knee structure. Although the major weight-bearing areas of the below-knee stump have been clearly defined and have been recognized in practice for many years, the development of standard, reliable fitting methods exploiting the full weight-bearing capacity of these areas has not yet been achieved. Primary are those problem areas over the various bony prominences which still create fitting difficulties due to improper socket size and contouring.

Carving of a well-fitted wood socket is extremely difficult since the socket must first be made large enough for stump entrance which is used to determine fitting contours. Any socket reliefs necessary for intimate contouring will reduce the effectiveness of the weight-bearing surfaces since such subsequent carving in the socket for purposes of "relief" results in an additional

increase in socket volume. The resulting error is usually of sufficient magnitude to permit the stump to drop further into the socket, off the intended weight-bearing areas. Each time the procedure is repeated the effectiveness of the intended weight-bearing areas is further reduced.

Stump casting methods which require cast modifications by removal of material over weight-bearing areas and build-up of material over bony prominences similarly cause problems in socket fitting. Modifications usually adversely affect the transverse dimensions of the stump replica which has been taken from a non-weight-bearing cast by finger and hand deformations. These methods do not provide reliably the accuracy in socket size and contouring necessary for proper weight-bearing.

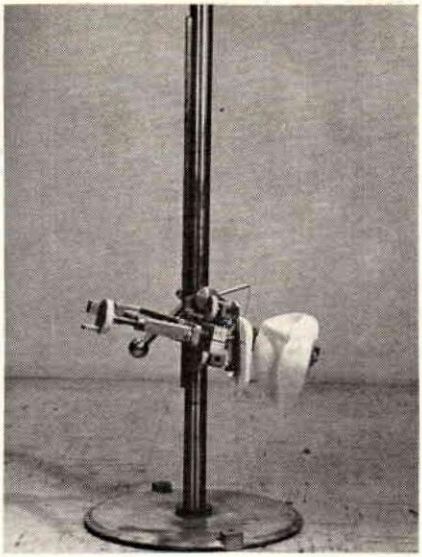


Figure 14. Casting stand with below-knee casting forms.

Recently, a stump casting method was developed limiting body weight support to the designated weight-tolerant areas of the below-knee stump as a cast impression was made. Subsequently, below-knee casting forms were made adaptable for use with the VAPC above-knee casting stand (Figure 14).

The casting forms consist of two sections:

(1) An anterior section internally shaped to provide stump contact anteriorly in the known weight-tolerant areas.

(2) A posterior section designed to provide the necessary counter-forces against the posterior of the stump.

During casting the pre-positioned forms (Figure 15) provide stump support only in the intended weight-bearing areas. The non-weight-bearing contours of the stump are formed by the elastic plaster-of-Paris wrap.

The proximal portion of the anterior socket form is contoured to provide patellar tendon support. The anteromedial and anterolateral oblique walls are contoured to establish firm stump contact on both sides of the tibia. In this manner, contact along the anterior crest of the tibia is prevented. The form contour immediately below the patellar tendon protuberance creates a concavity of sufficient size to prevent contact of all the bony anterior tibial protuberances: the tibial tubercule, the anteromedial tibial condyle, the anterolateral tibial condyle, and the crest of the tibia.

The anterior below-knee socket form is mounted upon a plate having attachment screws which mate in the slots of the form-holding bracket. These slots provide medial and lateral position adjustments of the form. Angular adjustments of the below-knee forms are provided by means of a pivot in the center of the plate.

The proximal portion of the posterior form is contoured to provide the upper posterior socket flare, to shape a relief for the hamstring tendons. The form is tapered distally to encompass the gastrocnemius bulge preventing the formation of steps in the cast.

The posterior below-knee form contains two bolts for its attachment to the form-holding bracket. The bracket is slotted providing a vertical sliding

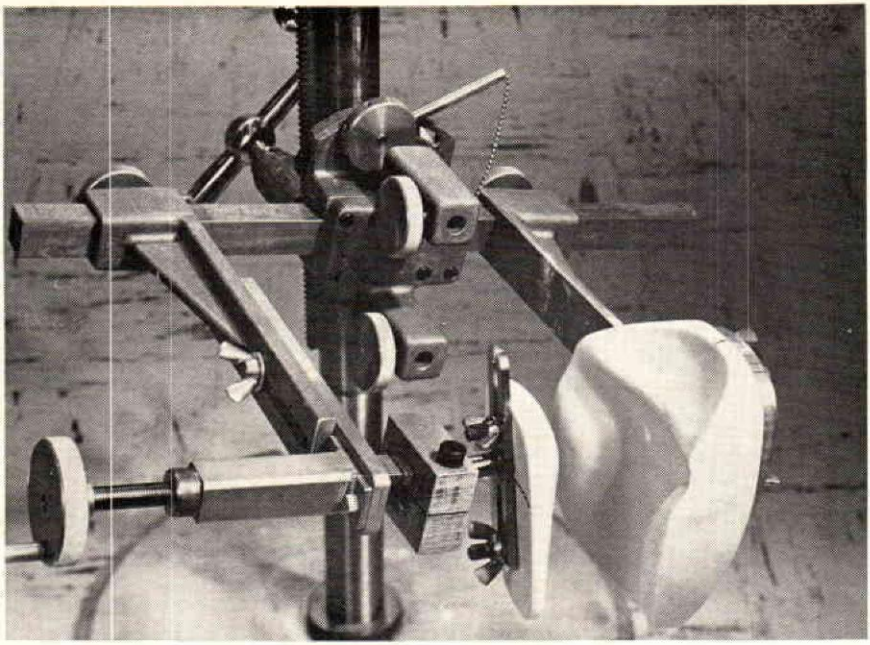


Figure 15. Close-up of below-knee forms showing contours and apparatus for adjustments.

adjustment. The bracket provides a pivot with a locking mechanism to secure the posterior form in any position.

The below-knee casting procedure is similar to that used in above-knee stump casting. The casting stand is adjusted to the proper height and the angular orientations of the forms are established. Pre-fitting adjustments of the various segments of the stand are based on prosthetic information data. During the trial fitting the patient stands with his stump held between the casting forms (with the patella on the form's tendon protuberance). The posterior form is moved against the back of the stump to provide contact. Using the small wheel adjustment on the bracket, the A-P distance is reduced until the patient's weight is *partially* supported. The proper distance between the two forms is established when the patient no longer feels the tendency to slip "through" the "socket" and is still able to pull his stump up between the forms. The bracket positions are marked to serve as references for proper repositioning when shaping the cast subsequently. Also an outline of the sound foot is traced on a paper secured to the floor; this defines a reasonably exact alignment reference for restoration of the patient's original position.

The elastic plaster-of-Paris wrap then placed on the stump provides the tension required to maintain the volume of the stump during the shaping process in the casting fixture. The fixture forms shape the cast to provide the socket contours which stabilize the stump in the prescribed attitude and under weight-bearing conditions.

The stump replica resulting from a cast taken in this manner represents the shape, size and contour of the below-knee stump under weight-bearing conditions. The PTB hard socket with closed-end and the PTB conventional socket may be fabricated over the cast *normally without* further modification. NOTE: This model requires the addition of an extension to the mold for the open-end socket, the socket with foam-end, below-knee weight-bearing brace sockets, and Syme sockets.

Improvement and Innovation:
Some Case Studies in Orthotics

Much has been published in this and other Journals on prosthetics and artificial limb design and on cases using prostheses. Therefore, it was thought desirable to use this opportunity to provide some experiences had by the VA Prosthetics Center in orthotics, an area which deserves much more attention generally.

The cases described here represent orthotic disabilities commonly referred to the VA Prosthetics Center. All of the orthopedic shoe cases were never seen in the Center; all assistance and the appliances themselves were provided on the basis of detailed correspondence from VA field stations.

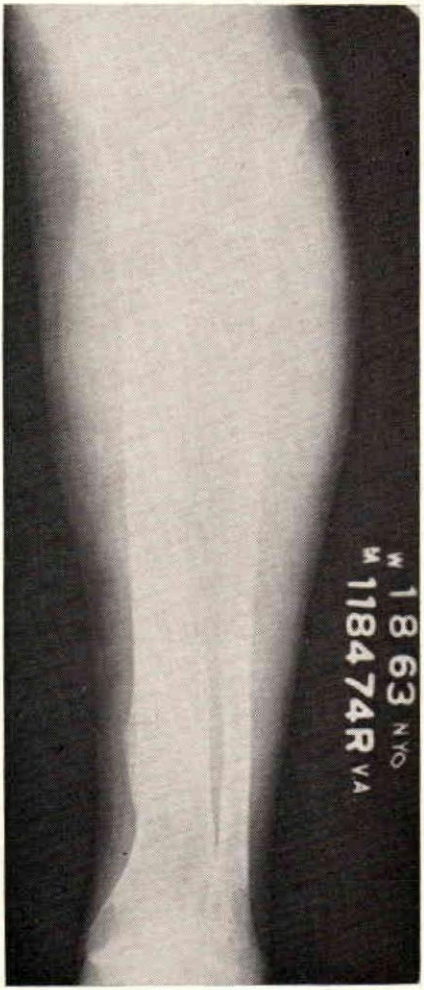


Figure 1. Case #1: Incompletely united fracture of distal third of tibia.

Some of the appliances used in bracing represent new developments, of devices and techniques not covered in the previous article.

Case #1. This 46-year-old baker fractured his right tibia in the distal third as a result of a fall in May 1962. After 17 weeks in a plaster cast, he was discharged and returned to work. Ten days afterward he fell and fractured the tibia at the old fracture site.

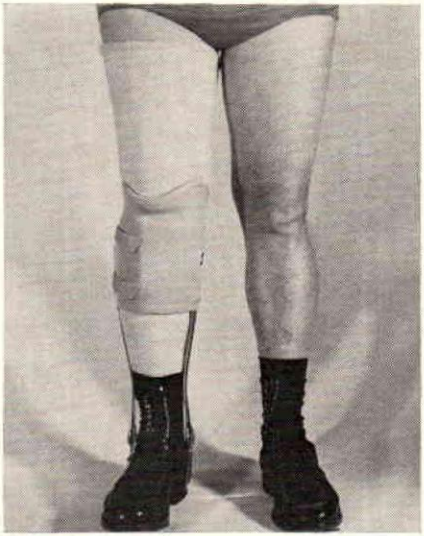


Figure 2. Case #1: Anterior view of brace showing the patellar tendon bearing socket.

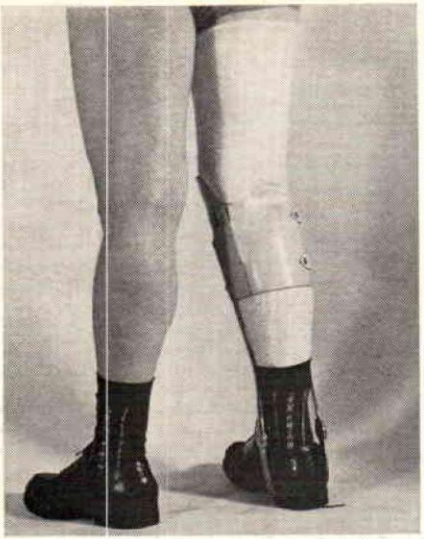


Figure 3. Case #1: Medial posterior view showing hinge for posterior opening.

Figure 4. Case #1: Lateral view illustrating Velcro closures.

He was referred to the VAPC in January 1963 for brace prescription. X-rays taken at that time (Fig. 1) showed an old incompletely united fracture of the distal third of the tibia with the fracture line still visible. There was no impairment of the knee-joint.

Brace prescription was as follows: below-knee weight-bearing brace with patellar-tendon-bearing type plastic socket (Fig. 2) with medial hinge (Fig. 3) and Velcro closures (Fig. 4); stainless steel uprights and a stirrup with ankle motion limited to 0° in dorsiflexion and about 10° in plantar flexion; a Sach-type heel and a rocker bar to partially compensate for the limitation of ankle motion.

Patient was fitted with an open-end stump sock and after a short amount of gait training did exceedingly well. The cast was discarded and he was discharged.

He was seen again on a 30-day follow-up. He reported that he was back at work, and the brace socket felt comfortable. Examination of the leg showed weight-bearing to be similar to that of a patellar tendon-bearing prosthesis. His gait was good, with the restriction of ankle motion hardly noticeable.

Case #2. This 43-year-old farmer's case was submitted by the VA Hospital, Wichita, Kansas.

The physician's diagnosis was as follows: patient suffered a compound, comminuted fracture of the left lower extremity from gunshot wounds. Chronic osteomyelitis and deformity

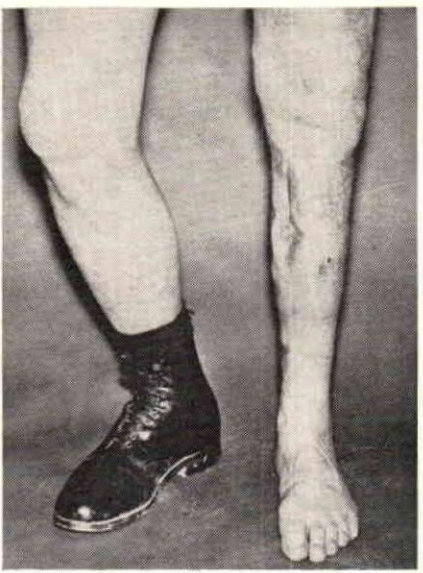


Figure 5. Case #2: Residual fracture C.C. with osteomyelitis and marked shortening.

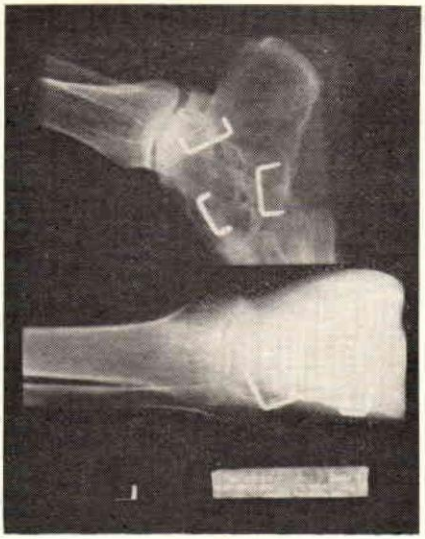


Figure 6. Case #2: Ankylosis, subastragalar: staples in situ.

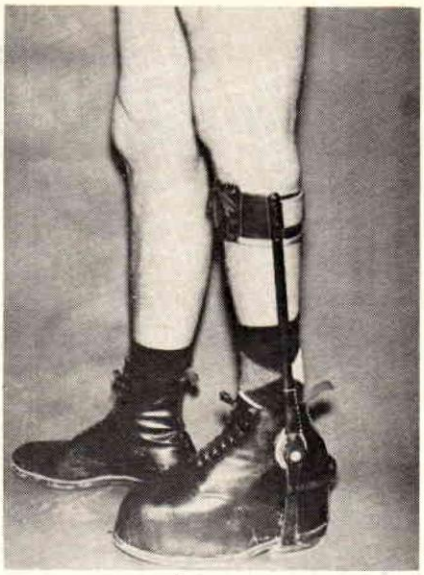


Figure 7. Case #2: High quarter custom orthopedic shoes with inside cork extension left shoe—attached to leg brace.

of the foot with a $3\frac{1}{2}''$ shortening of the extremity resulted. (Figs. 5 and 6).

Prescription called for high quarter, custom orthopedic shoes with left inside cork extension $3\frac{1}{2}''$ at the heel, $2\frac{5}{8}''$ at the ball and $1\frac{1}{2}''$ at the toe, with leg brace. (Figure 7). Results were gratifying and lasting inasmuch as the patient returned to his farming duties without interruption.

Case #3. This 38-year-old patient fractured his right patella and tibia in a fall from a telephone pole during World War II. In 1949 he developed a popliteal cyst, and an arthrotomy for chrondromalacia was performed. In 1957, he injured his right knee. A debridement was performed which was followed by aseptic arthritis of the knee. He was fitted with an ischial-bearing brace, and the knee became ankylosed. In 1960 he again injured his knee and developed severe pain with a high fever. He had an incision and drainage of an abscess and two decortations of the tibia with packing of the wound.

In 1962 he was referred to the VAPC with a prescription for a weight-bearing leg-thigh brace with a diagnosis of chronic osteomylitis of the right leg. There was a deep wound just below the knee with a scar extending about 10° down the leg (Fig. 8). There had not been any drainage for almost a year with ambulation aided by cast and crutches. He was fitted with a leg-thigh brace with a free motion stirrup at the ankle, stiff knee, plastic quadrilateral socket with medial hinge and Velcro closures (Figs. 9, 10, 11).

During the cast-taking on the casting stand, it was found that the patient could not tolerate complete ischial bearing. And his dissatisfaction with his old ischial ring made it necessary to include an extensive amount of gluteal bearing into the socket. The major portion of his weight is now being borne by the socket, and his gait is satisfactory despite the stiff knee.

There has been no flare-up of the osteomylitis nor any other complications.

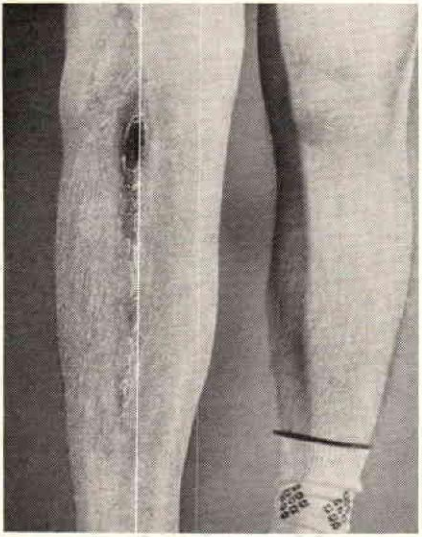


Figure 8. Case #3: Chronic osteomyelitis, post-operative.

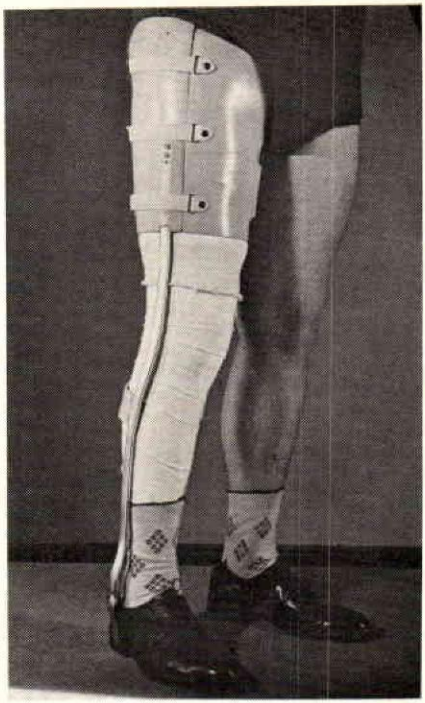


Figure 9. Case #3: Weight-bearing leg-thigh brace with free motion stirrup, stiff knee and plastic quadrilateral socket.

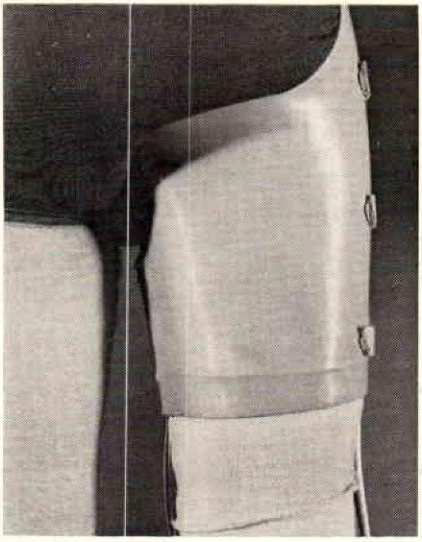


Figure 10. Case #3: Posterior view of socket showing gluteal as well as ischial bearing.

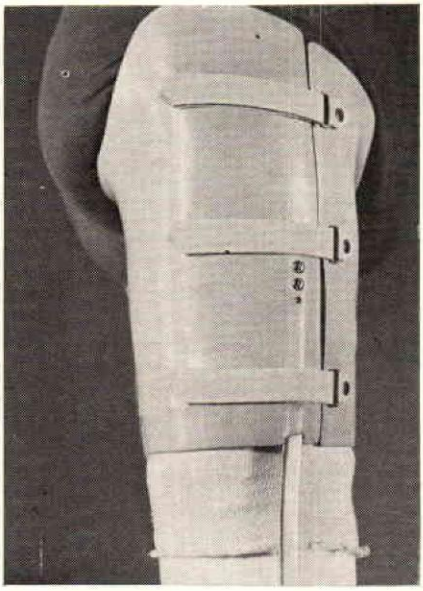


Figure 11. Case #3: Lateral view of socket illustrating anterior opening as well as Velcro closures.

Case #4. This 36-year-old clerk's case was submitted by the VA Center, San Juan, Puerto Rico.

The physician's diagnosis was: Patient suffered a gunshot wound through the mid-portion of the right femur in Korea, 1951. After hospitalization for several years, because of multiple severe complications (osteomyelitis, insertion and removal of endothesis and a subsequent Kuencher intramedullary nail), he was left with a 5" shortening of the right extremity and an ankylosed knee. (Figs. 12 and 13).

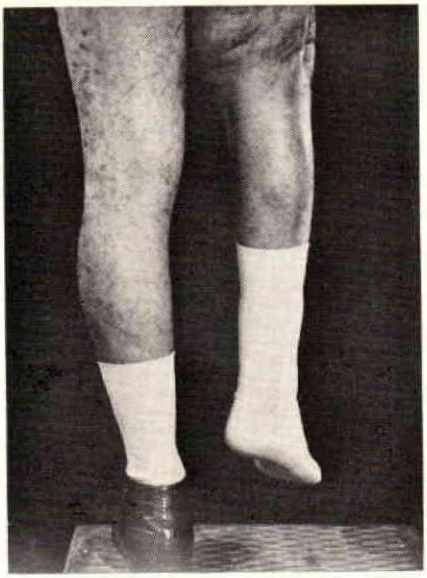


Figure 12. Case #4: Marked shortening of lower extremity and ankylosed knee.

The prescription called for ¾ Chukka, custom orthopedic shoes with a right outside cork extension of 4¾" heel, 3¼" ball, 1¼" toe, with caliper attachment to leg-thigh brace having a molded lacer. Results have been satisfactory with subsequent issues of shoes and brace parts of identical prescription. (Figs. 12, 13, 14).

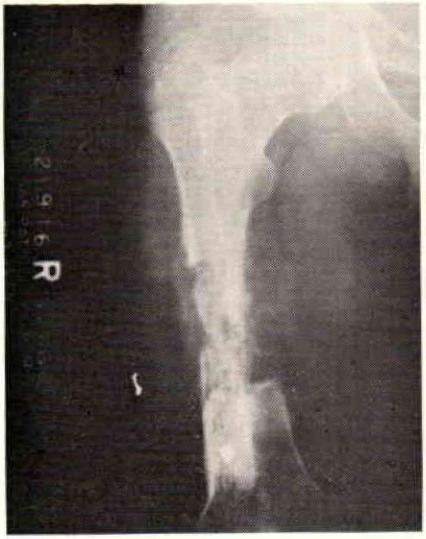


Figure 13. Case #4: Old fracture, C.C., mid portion of the right femur: residual osteomyelitis, large bone defect.

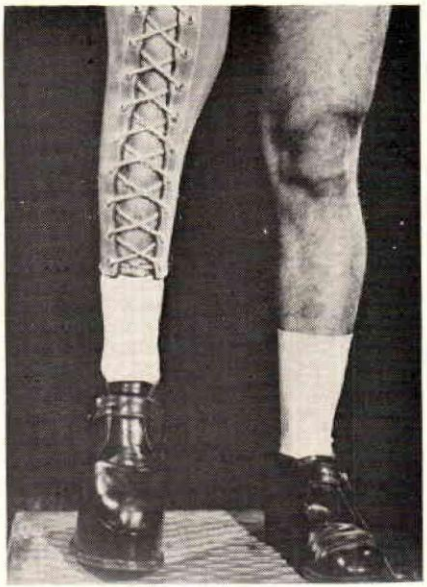


Figure 14. Case #4: ¾ Chukka custom orthopedic shoes with outside cork extension, attached to molded leather leg-thigh brace.

Case #5. A surprisingly large number of patients have been referred to the Orthotic Shop of the VAPC for bracing of ununited fractures of the humerus. While most of these non-unions are the results of World War I injuries, there were some cases of recent origin where surgery for one reason or another did not seem feasible and bracing was prescribed. Since muscle power is usually good in these cases, all that is required for good function of the extremity is a firm support about the area of the non-union. If the non-union is in the middle part of the humerus only a well-fitting upper arm cuff is required, and the shoulder and elbow can be free from bracing. If the injury is close to the shoulder or elbow, bracing will have to include the contiguous joint.

Figure 15 presents a patient with a good portion of the distal humerus missing, and bracing consisted of part rigid, part flexible polyester arm and forearm cuffs with a polycentric elbow joint on the lateral side. The extension of the forearm cuff covering the posterior part of the elbow was requested by the patient, since this area was quite sensitive and readily subjected to injuries by knocking against objects. Since the patient was quite fleshy, a polycentric joint was used to reduce bunching during elbow flexion (Figs. 16 and 17).

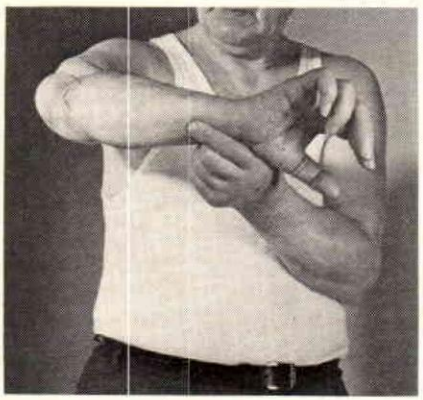


Figure 15. Case #5: Patient rotating forearm demonstrating non-union at elbow.

With this device the patient could perform most tasks required in his daily routine.

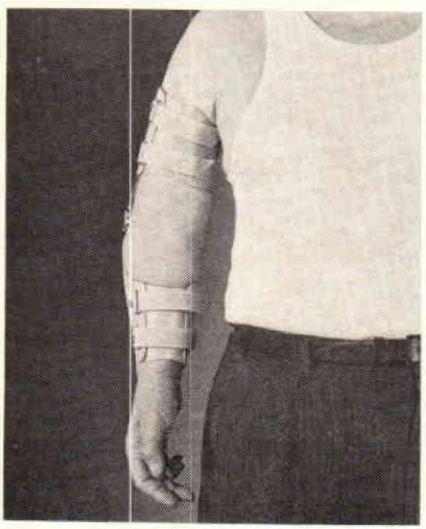


Figure 16. Case #5: Extremity in extension with brace applied.

Figure 17. Case #5: Elbow in flexion showing polycentric brace joint and protective elbow shield.

Case #6. This 46-year-old retired veteran's case was submitted by the VA Regional Office, St. Petersburg, Florida.

The physician's diagnosis was: Residuals of compound comminuted fracture of left tibia and fibula with malunion and synostosis; residuals of compound comminuted fracture of right tibia and fibula with malunion and synostosis; residuals of a fracture of right os calcis; ankylosis, mid-tarsal and subastragalar joints, right foot; residual osteomyelitis right heel and right leg, lower third; residual osteomyelitis lower third, left leg; pes planus, acquired, right foot, symptomatic with traumatic arthritis; residual osteomyelitis, left foot; varus deformity, left foot and ankle, with lateral displacement of left ankle and inward rotation; 1" shortening of right extremity. (Fig. 18 and 19).

Prescription called for custom orthopedic shoes with modifications for deformities and 1/8" sponge rubber insoles for cushioning plus inside cork extension of 3/4" heel, 1/2" ball tapered to the toe on the right shoe. Satisfactory results were reported.

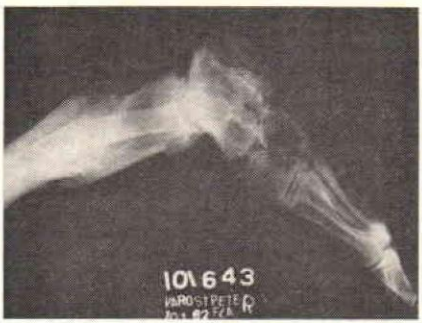


Figure 18. Case #6: Old fracture, C.C. tibia and fibula: malunion: old fracture, OS calcis: ankylosis, subastragalar and mid-tarsal joints: residual osteo-myelitis, leg, lower third, and OS calcis: pes planus.

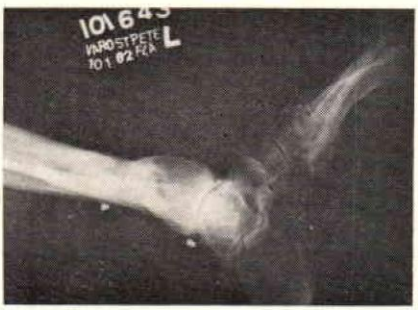


Figure 19. Case #6: Old healed fracture, C.C. of distal tibia and fibula—multiple metallic fragments.

Case #7. The patient (Fig. 20 and 21), a 26-year-old Korean War veteran, had a pneumonectomy performed in 1956 due to advanced pulmonary tuberculosis. He was referred to the VAPC for a protective shield for the heart, the pulsation of which was clearly visible underneath the skin. The apparency of the heart pulsation and distorted thoracic shape were of major concern to the patient.

The appliance (Fig. 22) was fabricated with a rigid center area, which was not in contact with the body, and flexible in all other parts. The center area had perforations for ventilation. A simple chest strap with Velcro fastener served as suspension. The patient wore this appliance continuously for four (4) years; then, the chest strap was replaced and a spare appliance was fabricated for alternate use. The patient, a former truck driver, was retrained as a draftsman and is now gainfully employed.

As this case illustrates, the orthotist may be frequently called upon to fit protective shields for vital organs of the body which have been exposed due to major surgery. These shields have also a cosmetic function since they help to restore as normal an appearance as possible.

Polyester laminates were found to be an excellent material in these cases. A material which allows the orthotist to make an appliance with some parts rigid and others flexible, all in one lamination, has advantages.

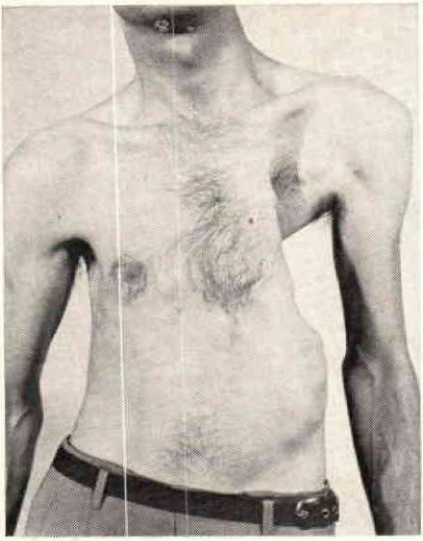


Figure 20. Case #7: Anterior view of chest.

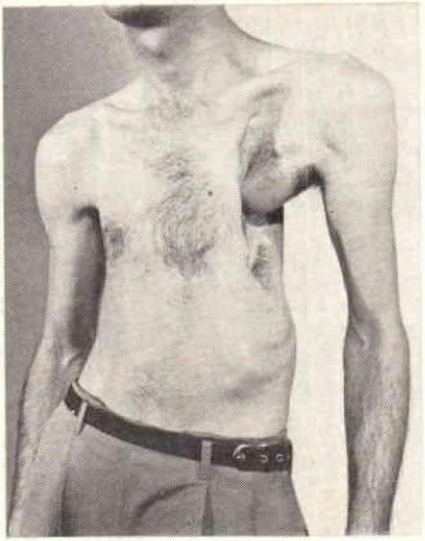


Figure 21. Case #7: Anterior-lateral view.

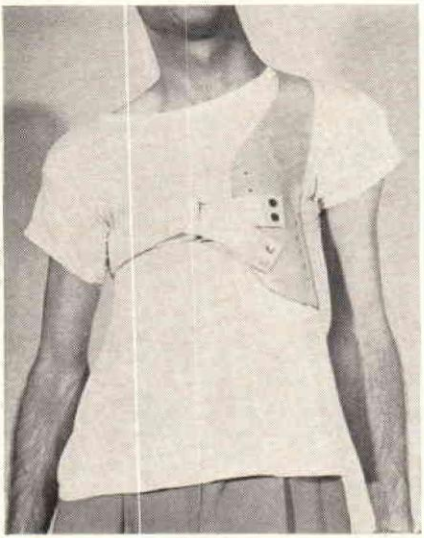


Figure 22. Case #7: Patient wearing protective shield.

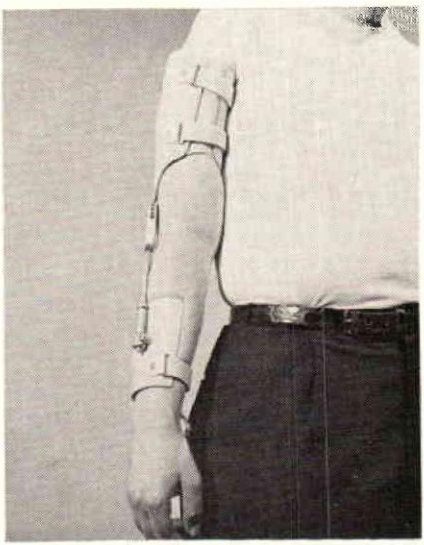


Figure 23. Case #8: Arm in extension with plastic arm cuffs and lateral elbow joint.

Also the neat appearance and ease of cleaning make the resin laminates superior to previously used materials such as metal, leather, celastic, etc.

Case #8. This 28-year-old dentist had polio while in service in 1961. Recovery in the lower extremities was good, but there remained some loss of muscle power in the upper extremities. Muscle tests showed the elbow flexors and pronators on the right to be poor, while on the left, the finger extensors, and abductors and adductors were poor. The patient could feed himself and take care of his toilet needs by using the hand on the right and reaching over with his left hand to flex the right elbow and shoulder.

The patient intended to continue his studies in oral pathology hoping eventually to teach in this field, but he felt some device was needed to

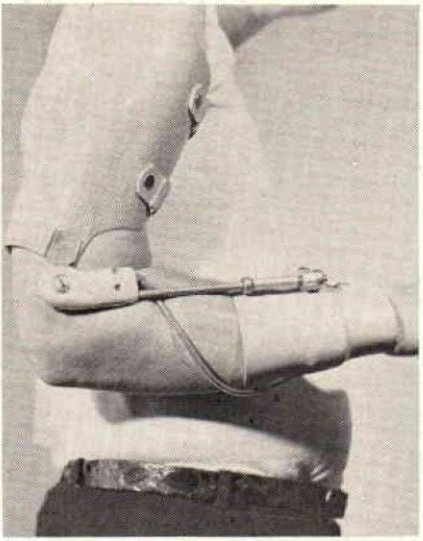


Figure 24. Case #8: Elbow locked in desired working position (about 90°) with the forearm in pronation.

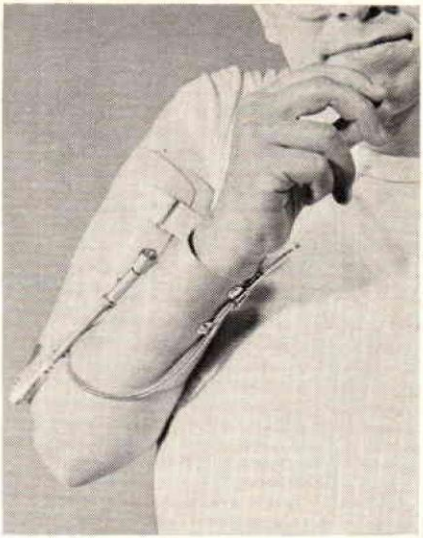


Figure 25. Case #8: Maximum elbow flexion possible with the appliance.

improve the functions of his upper extremities, so he could work on a microscope and at least examine patients.

It was decided to confine bracing to the right side and prescription was as follows: porous plastic upper arm and forearm cuffs with ratchet type elbow lock and pronator assist. Control for the elbow joint was fastened at the volar aspect of the wrist so that the ring finger could be used for operation (Fig. 23, 24, 25). The patient's initial reaction to the device was favorable. The remaining muscle power in the shoulder enabled him to swing the forearm into a maximum flexion of about 110° at which time the ratchet would lock the elbow. His supinators were strong enough to balance out the spring on the pronator assist. This device simplified his eating problems, and the patient was confident it would enable him to pursue his studies as planned.

Case #9. There has long been dissatisfaction by patient as well as orthotists with the conventional brace designs for neuro-muscular disabilities of the lower extremity. The conventional brace with the lock at the knee forces the patient to walk stiff-legged with a circumducted or vaulting gait and requires an excessive amount of energy for ambulation. This dissatisfaction with the conventional brace encouraged experimentation with so-called functional leg-thigh braces, especially in Europe. Ideally these braces would lock the knee during stance phase and allow knee flexion during the swing phase. While success has been claimed with a number of designs, it seems that only a few patients have been fitted. Certainly such braces have not been adopted for general use, probably because of their complex designs which made them heavy, bulky, and expensive. Other negative factors probably were the need for extensive gait training and the frequency of readjustments and repairs.

In experiments with functional knee joints here, some early disappointments were encountered due to complexity of design. Attempts to provide simple devices evolved into the design shown in Fig. 26 in which, instead of a positive lock, the stick control idea of above-knee prosthetics is employed. A piece of tubing containing a spring telescopes on a section of

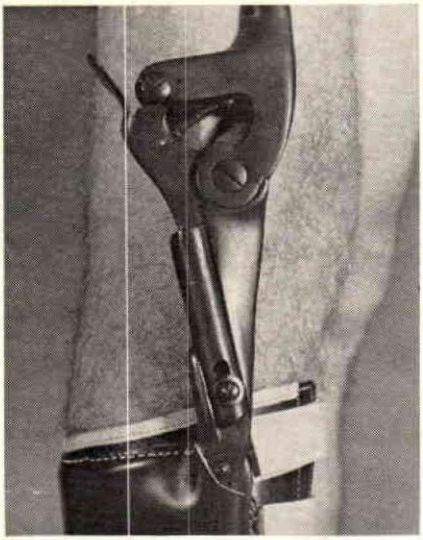


Figure 26. Case #9: Close-up of functional knee joint in full extension.

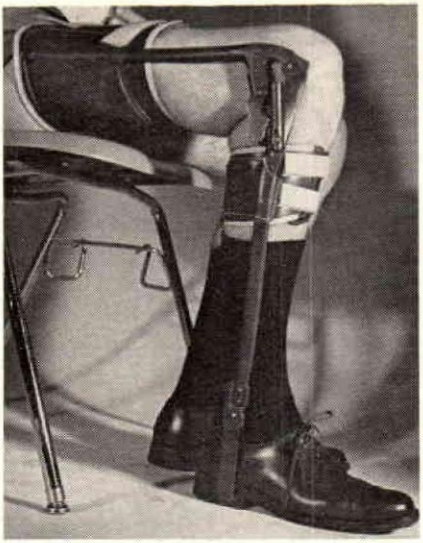


Figure 27. Case #9: Lock has been disengaged for sitting. Plunger will automatically return to "locked" position, when patient rises.

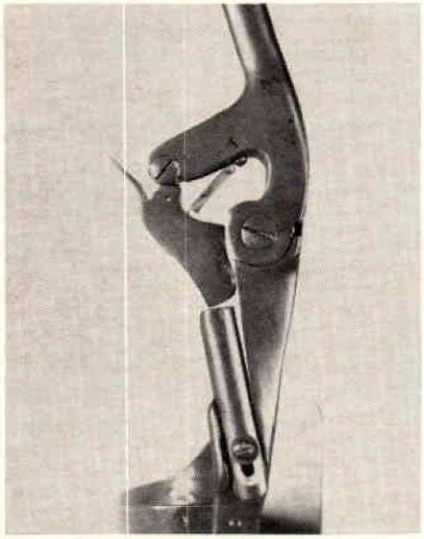


Figure 28. Case #9: Joint in about 20° of flexion. Length of slot in tubing determines the amount of flexion allowed.

Figure 29. Case #9: Anterior view of brace illustrating the single bar construction.

the lower bar. A plunger connected to the upper bar rests on this tubing and as the knee is flexed the spring within this tubing is compressed. This compressed energy in the spring acts as an aid or substitute for the quadriceps in extending the knee. The more the knee is flexed during swing, the greater the force of the extension aid provided by the spring. The length of the slot in the lower part of the tubing determines the maximum amount of flexion allowed, and the slot end serves as a safety stop. The plunger can be pivoted out of position permitting the patient to sit with a flexed

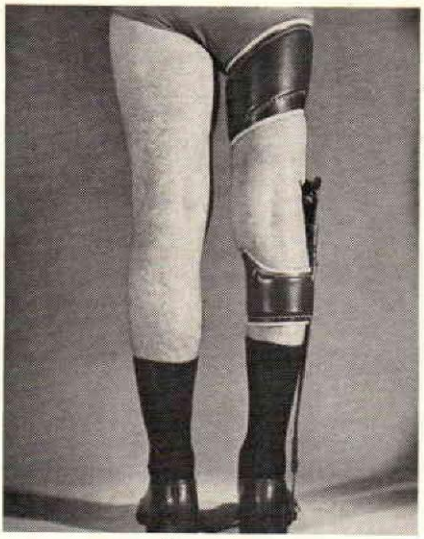


Figure 30. Case #9: Posterior view of brace. Note the fitting of the calf band supporting the medial condyle of the tibia.

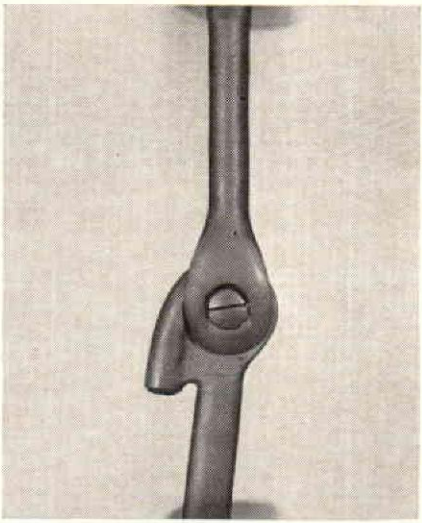


Figure 31. The second version of the function knee joint illustrating its simplicity.

knee (Fig. 27). The spring-loaded plunger will automatically return to the "locked" position as the patient rises.

The first patient fitted with this device is a 33-year-old accountant who contracted polio in Korea in 1951. His recovery was good with the exception of the right lower extremity, which was then described as poor. Although issued a conventional leg-thigh brace, he attempted to get along without a brace. While he was able to walk for short distances, he frequently fell due to knee buckling. One of these falls resulted in a fracture of the patella; he then decided to wear his brace.

When seen by the VAPC clinic team in January 1963, he was wearing the conventional double-bar leg-thigh brace with the ring lock at the knee, a knee cap, and a spring-loaded equinus-control stirrup. He was interested in reducing the amount of bracing and in improvement of his gait. The results of muscle test taken at this time were:

Hip: Flexors—poor; Extensors—fair
Knee: Flexors—fair to good; Extensors—trace
Ankle: Plantar flexors—good; Dorsiflexors—poor

Prescription by the clinic team was: functional knee lock with 20° of maximum flexion initially, unilateral bar, and spring-loaded equinus-control stirrup. During fitting several spring rates were tried, and the design found most suitable for this particular patient had a resistance moment of approximately 154 in. lbs. at 20° of flexion (Fig. 28).

Initial reaction to the brace was quite favorable. The patient did very well and after a short period of gait training; the amount of maximum flexion was increased to about 30°. A follow-up visit found the patient very pleased with the device. His gait was improved, and he stated he could walk with less effort and for greater distances (Figs. 29 and 30).

An improved version of this type of knee lock has been designed. It consists of a commercially available plunger type knee lock with tubular steel uprights modified in the following way: the flexion stop in the lower bar is replaced by a curved tubing, which houses a ball bearing, spring, and

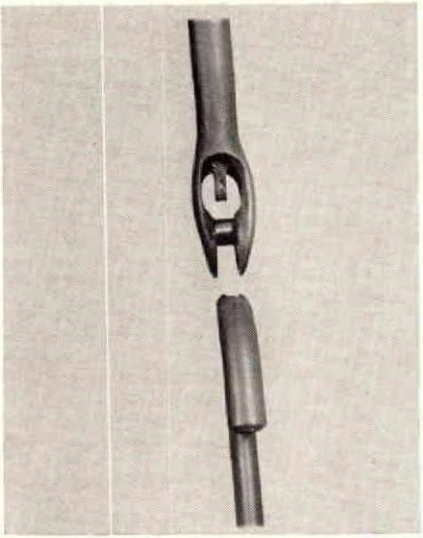


Figure 32. Posterior view (exploded) of joint showing plunger and clearance in upper bar for the tubing of the lower bar.

Figure 33. Lateral view of brace with simplified functional knee joint: lock is released to allow patient to sit.

adjustment screw. When the plunger is in the "locked" position, it can travel in a slot in the tubing against spring pressure allowing knee flexion. The length of the slot determines the maximum amount of knee flexion during walking (Fig. 31 and 32). The upper bar was modified to permit clearance for the tubing when the "lock" is released for sitting (Fig. 33). The advantages of this design over the first model are compactness and spring load adjustability.

The reaction of a second user, who had a flail right lower extremity due to polio and complained of back pains, was quite favorable at the time of initial fitting. He was highly pleased with the ability to flex his knee after having walked "stiff-legged" for about 18 years. The extension assist appeared to be essential since he could not walk with the device once the tension on the spring was released. It is hoped that after a period of gait training he will be able to manage the device fully. A reduction in the effort necessary for walking may reduce the back pains most likely due to the strain of the vaulting gait forced upon him by the conventional knee-lock.

Case #10. This 34-year-old clerk is a paraplegic (D-11) due to injuries received in service in 1945. He had the usual training for ambulation with braces and crutches, but soon after discharge discarded these devices and used a wheelchair exclusively. In recent years, repeated hospitalization was required for bladder and kidney problems. When seen by the VAPC clinic team in January 1963, he expressed the desire to use braces again with the hope of minimizing his bladder and kidney problems. He felt, if the bulk of the braces could be reduced, he could sit comfortably in his wheelchair wearing his braces the full day. And it would be possible for him to stand up either at the desk in his office or at the kitchen counter at home.

Muscle tests taken at this time rated both lower extremities as zero with a moderate amount of spasticity. Brace prescription called for single-

bar leg-thigh braces of steel, ring locks at the knee, and equinus-stop stirrups.

With the aid of these braces, the patient noticed better balance (than with his old braces), less effort in ambulating between parallel bars, and greater comfort when sitting in the wheelchair (Fig. 34, 35, and 36).

A 30-day follow-up showed no undue wear on the braces, and the patient was satisfied.

While the single-bar principle has been used occasionally in the past, it has never been very popular until Russell V. Fuldner, M.D. and Mr. Joseph Rosenberger (P. & O.) started using it on the "Newington Cerebral Palsy Brace." Encouraged by their success, VAPC started investigation of single-bar bracing in other disabilities such as polio, paraplegia, hemiplegia, and multiple sclerosis.

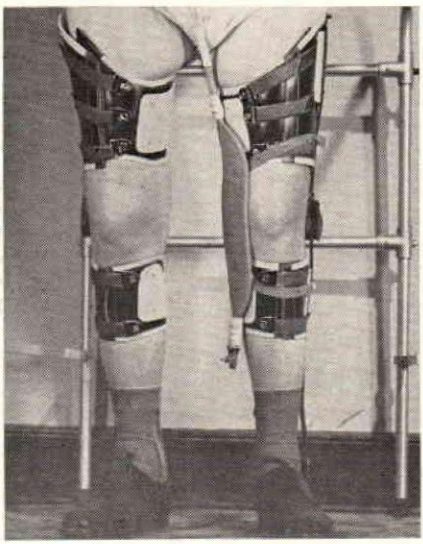


Figure 34. Case #10: Anterior view of patient standing with single bar braces. Note the absence of knee caps.

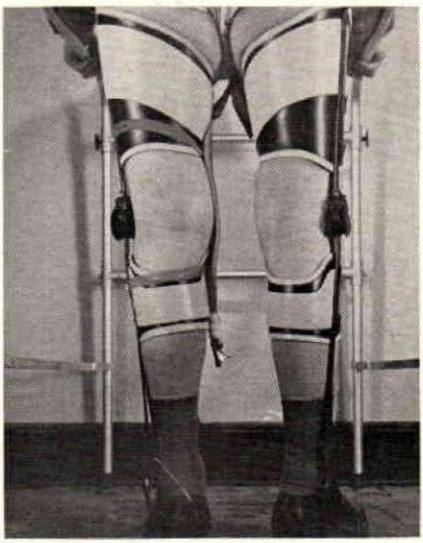


Figure 35. Case #10: Posterior view illustrating the absence of medial bracing.

The advantages of single bar bracing accrue to both patient and orthotist. The elimination of the medial bar reduces the bulk of the brace and makes it a much more comfortable device especially for a bilateral brace wearer who might need to wear other apparatus such as the urinary appliance worn by the case illustrated here. The reduction in the weight of the device is, of course, greatly appreciated by the patient, whose muscle power is far below normal. From the orthotist's point of view, precise brace joint location in relation to the joint being braced can be accomplished much more readily with a single bar.

Accommodation of tibial torsion, to which the ankle joint location studies being conducted by the University of California (San Francisco) has called attention recently, can more readily be built into the single upright construction than into a double-bar brace. Varus and valgus corrections at the ankle as well as "toe-out" can be adjusted rather easily on the single bar even at the final fitting, while attempted changes of this nature in the double bar brace will only result in stressing the joints and band rivets.

It has been quite frequently claimed that it is difficult to achieve

stability and to prevent undue rotation of the extremity within this type of a brace. But rotation of the extremity within the brace is not prevented by the uprights alone. This function is mainly performed by the shoe, the calf band and cuff, and the thigh bands and cuff in assembly with the uprights. If the bands and cuffs of a brace are fitted loosely, the brace uprights will not provide any kind of stabilization no matter how strong or stiff.

Nevertheless, it is necessary, in a single bar brace, to design the upright and its joints with sufficient strength and stiffness to support the extremity and to absorb the loads transmitted by the bands and cuffs.

On a patient with a flail lower extremity, it has been found that by supporting the following areas with bands and cuffs, better stabilization accrues with the single bar brace:

1. The lateral-posterior part of the thigh just below the greater trochanter along the gluteal fold.
2. The medial-anterior portion of the thigh as close to the knee as possible.
3. The medial flare of the tibia.

In addition, the foot must be supported by a properly fitted shoe.

The cuffs and bands have been used in the following way: one thigh band fitted high just below the greater trochanter and along the gluteal fold laterally and posteriorly, but then curving down rather sharply on the medial side so that the lower edge of the band is about 4" above knee-center in the anterior medial area. This design frees the medial upper portion of the thigh from bracing and is greatly appreciated by the patient, especially the bilateral brace wearer. A medial "roll" will not develop from this design since the thigh cuff is simply supportive and not weight-bearing. The calf band is located at mid-calf, but the medial portion is extended to fit into the medial flare of the tibia. This extension of the calf band has made it possible to eliminate the knee cap in this design, even for those patients accustomed to knee caps for a great number of years.

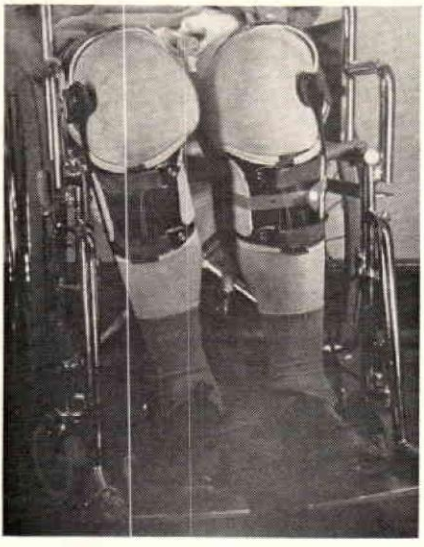


Figure 36. Case #10: Patient in wheelchair wearing braces.

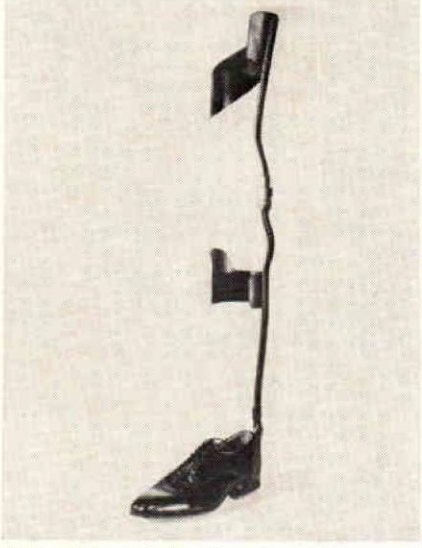


Figure 37. Anterior view of metal frame of single bar brace. Note the shape of the calf band for support of the medial tibial condyle.

Both bands are made to encircle about 2/3 of the extremity, leaving only enough anterior opening for easy entry of the patient (Fig. 37). This is a variation from the conventional half-bands.

For uprights and joints commercially available parts were at first used even though it was recognized that they were not ideally suited for the purpose. There were no suitable stirrups available, so these had to be custom-made.

Experience, had with about 10 patients, suggests that the lower-extremity can be properly supported with this type of appliance. But most brace parts commercially available today are not designed for use in single bar braces; there have been prosthetic knee joints with ball bearings available for many years, but brace joints, with the exception of cerebral palsy brace components, have not been produced with bearings. One manufacturer recently started producing a brace joint with thrust bearings in aluminum uprights. Such a joint will help because it appears that ball-bearing joints will be needed at the hip, knee and ankle of a single bar brace.

The commonly used rectangular bar is probably not the best shape for this design. The commercially available oval steel tubing upright, from a structural point-of-view, is quite adequate and was used on a number of patients. The great difficulty in changing the shape of the tubing after the brace has been assembled has prevented it from being universally adopted for double bar braces. This problem is greatly reduced in the single bar brace since there is much less shaping required on a lateral bar than on the medial bar for a lower extremity brace.

Fitting of patients with single bar braces will be continued, using presently available parts. But tests of different shapes such as round, oval, square, etc., and different types of metal, such as steel, aluminum, titanium, will be performed.

Experiences with single bar bracing indicate that the design as described above is adequate. The advantages for the patient and the orthotist are significant. Presently available brace uprights and joints, while suitable for some cases, especially in flail polios, need some redesign however for best application of the single bar brace to all cases with neuro-muscular disabilities including spastics.

Specifications Development And Compliance Testing

"Let us raise a standard to which the wise and honest can repair. The event is in the hand of GOD."

—GEORGE WASHINGTON

The Testing and Development Laboratory is organized and has the facilities to perform a number of activities for the Veterans Administration. The most important two are the development of specifications covering VA approved products, and the compliance testing of these items. This article will deal with these two functions. Some of the *other* activities of the Section can be briefly summarized as follows:

a. *Evaluations*—It conducts physical evaluations on various devices, inventions, new and modified products, new materials, etc., all submitted by interested parties with the aim of improving the lot of the disabled.

b. *Development*—Either on its own initiative or in cooperation with other sections of the Center, it develops and fabricates new devices, special test equipment, cycling machines, special jigs for new prosthetic techniques, experimental prostheses and braces, and other aids for the handicapped.

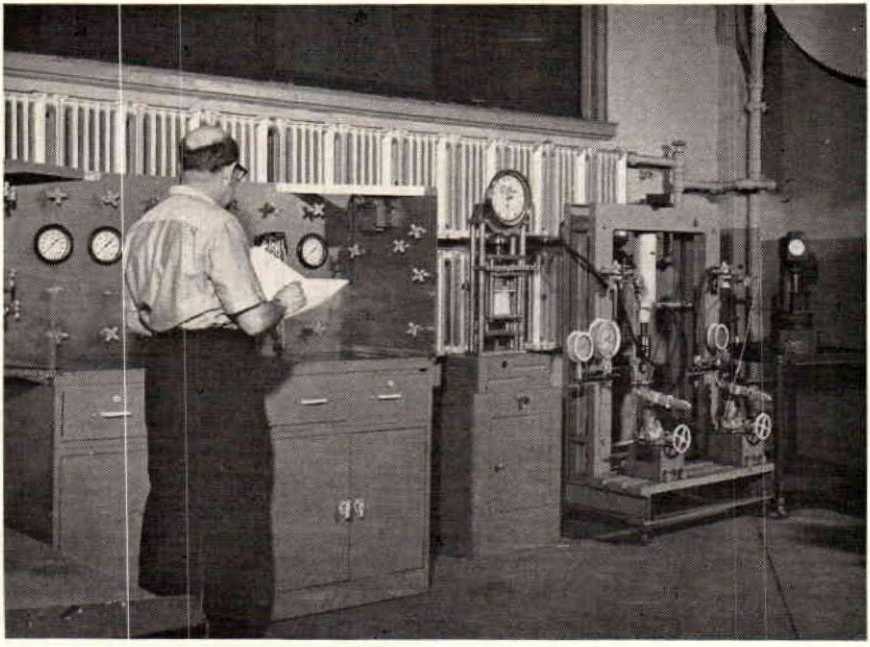


Figure 1. Physical test room. Left to right: Hydraulic test stand, Universal testing machine, another hydraulic tester, Rockwell hardness tester.

c. *Illustrations*—The Illustrations Unit of the Section serves the VA Prosthetics Center and the Prosthetics and Sensory Aids Service by supplying photographs and art illustrations for various publications and projects, such as technical reports, manuals, or special published articles (of which the illustrations appearing in this journal are an example). Charts, visual displays for exhibits, and slides for lectures are other services furnished.

Figure 2. Illustrator.

FACILITIES

The facilities of the Section consist of a well-equipped experimental Machine Shop which has been shown in a previous article, a welding, plating, and heat-treating room; a testing unit which contains accelerated testing machines and specialized equipment for testing of structures and materials (Fig. 1); and offices equipped for the engineering draftsmen and scientific illustrators (Fig. 2)

THE PHILOSOPHY AND BENEFITS OF SPECIFICATIONS

Specifications and standards have become fundamental requirements in all industrial and governmental activities. Standards have been used throughout history in isolated instances, but modern life would be almost impossible without them. What is the difference between a "Standard" and a "Specification"? Here are *some* definitions:

A *Standard* is that which is set up and established by authority as a rule for the measure of quality, weight, extent, value or quality (Webster).

A *Specification* is always the document that "specifies" the essential attributes of the subject matter. For differentiation, a standard is the item itself when it conforms fully to the specification.

These definitions should suffice. However, to confuse matters a bit, a specification that deals with a very *basic* item, such as screwthreads, is often called a "standard," and a *complex* product which is made according to a specification is not necessarily a standard. To be more specific, a specification (or, if you will, a standard) "defines a product, process, or procedure with reference to one or more of the following: nomenclature, composition, construction, dimensions, tolerances, safety, characteristics, rating, certification, testing and the service for which intended" (American Standards Association).

The most basic standards are standards of measurement: the meter, the pound, the volt, etc. They are the tools we build with. We cannot specify anything that we cannot measure. Neither can we reproduce it. So we see that basic standards are the building blocks which are used in specifications to construct more elaborate standards.

There are by now thousands of standards for such basic things as screws and nuts, gages, all kinds of materials, codes, symbols, etc. The use of approved standards in most cases is not mandatory, yet conditions in a highly civilized society like ours would be chaotic without them. Just

imagine things reverting to the "good old days": when you asked for an ell of cloth, you could get anything from 27 to 45 inches, depending on the locality. This example points up an important requisite of standards: the standards used must be well-defined and their accuracy suitable for the end result, otherwise the purpose of the specification is defeated. More precise standards are necessary, for instance, in pharmaceutical process specifications, where it may be necessary to measure to a few parts per million. Many examples could be given to show why our advancing technology needs ever more refined primary standards.

Specification is essential in procurement for several reasons. For one, the government's principles of purchase, which are based on obtaining a satisfactory material or item for the intended use at minimum cost, normally requires competitive bids. Secondly, specification is necessary so that prospective bidders will know the properties and quality of the material or items they must deliver, and thus enable them to make a reasonably close estimate of cost. Thus a good specification represents the lowest cost item that will do the job.

Thirdly, a specification describes the test method necessary to determine the properties and characteristics that are required. It is necessary to test each unit with the same method and apparatus so as to have a basis for ready comparison.

Fourth, a specification reduces waste by eliminating unnecessary sizes and types, costly manufacturing procedures, excessively expensive materials, or materials which may be inferior and cause premature failures thus increasing costs. Before specification, each manufacturer may have produced his own assortment of sizes and types, in variation with his competitors. This is not only confusing to the users, but also a nuisance and a bigger expense to distributors and retailers, because they have to carry much larger stocks, and parts of one manufacturer are usually not interchangeable with other makes. After agreement is reached through specification, the manufacturers' production lines can move faster and smoother, with longer runs and fewer changes, because there are fewer and simpler types to make. His set-up time, tooling, inspection, training of workers and raw materials requirements are all simplified. He is able to keep the factory busy in slack times by making standard parts for stock.

Finally, a specification establishes the limits and tolerances within which the product or process is acceptable. The concept of tolerance is based on the fact that variations *do* exist in all natural and manufactured materials. For the product to be economically feasible, the specification requirements must make allowance for some variation in the physical and chemical characteristics of raw materials and in the processing of these materials to the finished item. It then becomes necessary to decide how much variation can be permitted without lowering the standard. It usually resolves itself to the question of how much the buyer is willing to pay for quality, if no other determining factors are involved such as safety or reliability.

The ultimate benefits of standards have already been implied. Both industry and user achieve economies from well worked-out specifications, resulting in conservation of time, materials, labor and money. As in other industries, much waste results in the prosthetics business due to the great variety of manufactured products. Many types and sizes can not be justified from a sound economic standpoint. A majority of the varieties constitutes an unnecessary waste of materials, production facilities, and operating capital, needlessly increasing the cost to the consumer. Obvious ad-

vantages are to be gained by concentrating production on the varieties and sizes in greatest demand. One of the objectives of specification is "simplified practice" in accord with the foregoing.

Specification helps the manufacturer in other ways: (1) The standards tests enable a ready comparison between competitors' products. Thus, one finds out in what way his product is deficient compared to somebody else's and tries to improve it. This was the case with SACH Feet, for instance. (2) Specifications provide the necessary means of communication for the establishment of understanding between workers in the field of prosthetics. This helps to open to the research worker a knowledge of the work being done elsewhere, and so leaves their creative faculties free for the problems that are still unsolved. (3) Standards help designers to develop new products in such a way that they function better, and are attractive from the standpoint of cost and maintenance.

From the standpoint of the Veterans Administration, a major buyer of prosthetic items, specifications are of benefit to the taxpayer and to the disabled veteran, who is the ultimate user. Some of these benefits can be listed as follows:

a. The specifications and the tests performed in accordance with them, ensure the user of products made by proper techniques and from acceptable materials with known properties.

b. Product performance is uniform and predictable, and a number of manufacturers' products can be used interchangeably, from the standpoint of sizes and tolerances.

c. The availability of the product is increased, minimizing the need for the VA or one of its contractors to maintain large stocks.

d. When the Government buys in quantity under a bidding system, the product supplier with the lowest bid gets the contract for the specified product, thus saving the taxpayer money.

To sum up, the user of a specified product can look forward to a better product, better reliability, and better service, and the producer who complies with specifications will find himself in a more advantageous position with respect to a competitor who does not abide by the standard.

Perhaps a few words about general standards activities throughout the country are indicated. All nations have organizations for the development and preservation of standards. The primary source of standards in the United States is the National Bureau of Standards in Washington. Its works would fill many volumes, and its contributions to science and engineering are almost uncountable. They continue and increase with each passing month. In addition to the National Bureau of Standards, each major government agency develops and issues its own specification according to its needs. The Department of Defense to date has issued approximately 24,000 military specifications and standards. While their primary purpose is in the defense of the United States of America, these specifications and standards are of equal value to the daily pursuits and well-being of our people. The General Services Administration (GSA) promulgates the Federal Specifications and Standards which concern mainly commodities, supplies, materials and equipment which are purchased and used by all branches of the Federal Government. There are many other Government agencies whose daily pursuits involve standardization, but their work is more highly specialized, and directed to a narrower audience. One of these is the Veterans Administration which, of course, works for the benefit of all veterans, including the disabled.

Outside the Government, American industries and professional societies are continually developing standards to increase their abilities to specify. There are hundreds of these organizations. A few of them are:

American Society of Mechanical Engineers
American Institute of Electrical Engineers
American Society of Testing and Materials
American Standards Association
American Petroleum Institute
American Society for Metals
Society of Automotive Engineers
United States Pharmacopoeial Convention

A quite complete list can be found in reference (2).

The Development of a Specification

There are five major steps in establishing a VA specification on an orthotic or prosthetic item. Salient features of each are as follows:

a. *Request*—The request usually comes from the Prosthetics and Sensory Aid Service (PSAS) in Washington, D. C. to the VA Prosthetics Center. PSAS, which is a Service under the VA's Department of Medicine and Surgery, is usually contacted when a vendor wants to sell a new prosthetic or orthotic product to the VA. The Government's principle of purchase requires that, with some exceptions, competing vendors bid for a contract through a procurement document which has a specification attached. If a specification already exists on this commodity, (perhaps issued by a different Government agency), the Veterans Administration may adopt it for its own use. This was the case, for instance, with the specification for crutches, which was originally a Federal Specification. If it is a new product, or unique for veterans' use, and is acceptable, a specification has to be written. It is then that the request is sent on to the VA Prosthetics Center (VAPC) for development.

b. *Evaluation*—The item is first evaluated. Physical and physiological testing are performed by the Bioengineering Laboratory and clinical tests by the Orthopedic Shoe Section or Limb and Brace Section of the Center. In addition, the Research and Development Division of PSAS may possibly be involved with a national VA Field test. Sometimes comments are elicited from other interested sources. Or the job may be handled entirely by a VA contractor such as New York University. Depending on the complexity of the item, this investigation may consume a considerable amount of time. (In the case of the Hydra-Cadence hydraulic unit, VA field testing took about a year to complete.) When all the data are in, an evaluation report is written giving recommendations regarding possible future utility. Weighing all the factors involved, VA Central Office then decides whether the product has sufficient merit to be issued. If the decision is favorable, VAPC is asked to prepare a specification, which in large part employs methods and findings of the evaluation.

c. *Draft*—The vendor or manufacturer in the field of prosthetics usually has the skill and technique to make an acceptable product, but rarely has he the technical know-how to write the specification for it. As the writing of a specification is a cooperative venture between the vendor or a group of vendors and the government, a *draft* is usually written by experienced men in the Government. Requirements must be stated clearly and accurately; words and phrases should be simple and easily understood; Tables and graphs must be presented in an easily understandable form.

The structure of a Government Specification is usually composed of a heading and six numbered sections. The heading consists of the specification symbol, revision (if any), effective date, title, and preamble. The sections are titled as follows:

1. Scope
2. Applicable Documents
3. Requirements
4. Quality Assurance Provisions
5. Preparation for Delivery
6. Notes

Example

1. Scope

1.1 Description. This specification establishes the requirements for a prosthetic knee-ankle system with coordinated hydraulic swing control. The complete assembly (or system) consists of (a) the hydraulic mechanism, including the knee cap, fairing and foot attachments, hereafter referred to as the "unit," (b) the foot, and (c) the cosmetic cover with attachments.

1.2 Sizes. Ranges of sizes as specified in 3.5 and 3.12.

In section 2, all documents are listed which form part of the specification. These may be governmental or non-governmental specifications and standards, drawings, and other publications.

Section 3 states all essential requirements and descriptions applying to the design, material, or construction which the commodity must meet to be acceptable. The requirements should be worded so as to provide a definite basis of rejection in those cases where the quality and workmanship are such that the item is unsuitable for the purpose intended.

Example

3. Requirements

3.1 Materials

3.1.1 Materials shall be as specified on the detail drawings for each component.

3.1.2 Castings shall have no cracks or flaws, and shall be inspected for such before anodizing, by using a penetrating dye or by using black-light techniques.

3.2 Plating and Finishing. Those component parts or sub-assemblies formed from other than corrosion resistant materials and located externally shall be finished or plated to resist corrosion. For such parts, there shall be no rough spots, porosity, thin spots, or peeling evident in either the finishing or the plating.

3.3 Fastenings. The unit shall be assembled and fastened so that no fixed part or sub-assembly shall become loose, and no movable part or control be shifted in setting, position, or adjustment under extreme service conditions.

3.4 Effectiveness of Seals. There shall be no fluid leakage perceptible on the hydraulic assembly after any phase of testing under these specifications. (The normal film of fluid found on the piston rod is not to be considered as leakage).

3.5 Sizes

3.5.1 Units shall be furnished, or be adjustable, in the following lengths: When measured from the prosthetic knee axis to the bottom

of the attached, unshod foot, these sizes shall range from 16½ inches to 21½ inches in a maximum of 1 inch steps.

3.5.2 The foot shall be furnished, as specified, in left or right, and for any shoe size ranging from 6 to 13 inclusive. The foot shall be constructed so that when assembled to a unit, that the foot will be in a neutral position of valgus-varus.

3.6 Noise. There shall be no objectionable noise when the unit is tested or when it is being worn.

3.7 Swing Characteristics. The swing characteristic acquired by the unit is a function of the hydraulic resistance of the mechanism. This resistance shall range from a specified minimum to a maximum and shall be manually adjustable by setting the resistance range control. The hydraulic resistance shall be measured by the time it takes for a specified weight to drop through a certain height, when the weight is attached to the unit in the manner described in test 4.7. Using the apparatus specified in this test, the unit shall receive a drop-test at the minimum and at the maximum resistance settings, both in flexion and in extension (4 tests). The four drop-times shall be recorded as an average of at least 3 drops at each setting. There shall be no erratic reading when a drop is repeated within a setting. The weight shall be such as to produce a constant torque on the knee joint of 51.5 inch-pounds ± 0.1 inch-pounds (e.g. 10 lbs. 13.6 oz. for a pulley diameter of 9.5 inches). The height of the drop shall be adjusted so as to produce a knee flexion or extension of 65° ± 2°. Flexion shall be started from the initial position given in 3.9.2. Extension is a return to this initial position. The drop times shall be as follows:

1. Max. setting, flexion 0.7 to 1.2 sec.
2. Min. setting, flexion 0.35 sec. or less
3. Max. setting, extension 0.7 to 1.2 sec.
4. Min. setting, extension 0.35 sec. or greater

The time values shall be recorded on all units.

3.8 Workmanship—The assembly delivered shall be clean, well made, and free from any defects (such as flaws, burrs and rough edges) which may affect its appearance, impair its serviceability, or require preventive maintenance for the duration of the guarantee period stated in the contract. Workmanship and design shall be such that an unconditional guarantee for the stipulated period can be supplied, provided the hydraulic mechanism is not tampered with by the prosthetist or customer.

3.9 Interchangeability—Major component sub-assemblies, which may be considered to be expendable during the life of the unit, shall be manufactured with tolerances to permit easy replacement, as required in the maintenance of the unit, either in a local shop facility or at the manufacturing plant.

3.10 Identification Marking—Each unit shall be permanently marked on a main component with a serial number for identification. Such serial numbers need not be in sequence. The component selected for such marking should be one which will probably not require replacement during the life of the unit.

3.11 Storage Reliability—The units shall be shelf-stored in a horizontal position for at least one month and then reinspected for leakage.

In section 4.2 "Quality Assurance Provisions," procedures concerning sampling and inspection are given, test methods are described, and tests are differentiated (as between qualification tests and acceptance tests). Sam-

pling is an important factor in determining compliance with requirements. Sampling should be made on a rational basis so as to attain the greatest economy consistent with the required assurance of quality. Details of sampling will vary with the commodity. In complex mechanisms each unit is usually examined. Simple items, like stump socks, are sampled in random lots drawn from each shipment.

Descriptions of tests and methods of analyses shall appear in this section to insure that they will be properly conducted. Other information, such as description of testing apparatus shall also appear.

Example

4. Quality Assurance Provisions

4.1 Unless otherwise specified herein, the supplier is responsible for the performance of all inspection requirements prior to submission for Government inspection and acceptance. Except as otherwise specified, the supplier may utilize his own facilities or any commercial laboratory acceptable to the Government. Inspection records of the examinations and test shall be kept complete and available to the Government as specified in the contract or order.

4.2 Mechanical Inspection—Preliminary to performing the subsequent tests, each system shall be given a thorough visual and mechanical inspection to determine conformity with:

(1) the drawings listed under 2.1

(2) requirements 3.1, 3.2, 3.3, 3.5, 3.6, 3.8 and 3.10

4.3 Tests—Before performing the following tests, a) check hydraulic fluid level as per 5.1, b) hand cycle the unit through full extension and compression for a minimum of ten (10) cycles.

4.4 Alignment Check—Extend the knee fully. Invert the unit and set it with the knee casting resting on a horizontal plate. With a level and a plumb line check the requirements of 3.9.2. If not in the initial position as defined, make necessary adjustments until the requirements are met.

4.5 Manual Foot Flexion Control—With the unit in the initial position, check the requirement of 3.9.3 with the manual control knob, using a protractor to measure the angles.

4.6 Coordinated Knee-Ankle Flexion Ratio Test—Set the unit to the initial position. Flex the knee to 60 degrees and measure the dorsiflexion of the ankle with a protractor. Check conformity with the requirement 3.8.2.

4.7 Hydraulic Resistance Test—The hydraulic resistance of the mechanism shall be tested on the apparatus shown in Fig. 7. The unit shall be mounted as shown, and the weight specified in 3.7 shall be attached to the cable around the pulley. The procedure of 3.7 shall be followed.

4.8 Leakage and Flaws—Check for fluid leakage, adequacy of welds, existence of cracks and flaws in frame and all castings by using one of the techniques listed in 3.1.2. Requirements 3.1.2 and 3.4 to hold. This check shall be repeated after one month's storage for requirement 3.11.

4.9 Reports of Test—Tabulated results of the test data shall be recorded for each unit, showing quantitative results for all tests required by this specification.

The section "Preparation for Delivery" covers the applicable requirements for preservation, packaging, packing, and marking of packages and containers.

Example

5. Preparation for Delivery

5.1 Fluid Level—When delivered to the standards Laboratory or to the ultimate user, the unit shall be filled with the correct amount of hydraulic fluid as required for operation. When checked with a calibrated dip-stick, the level shall fall within the band marked thereon.

5.2 Alignment—The unit shall be delivered aligned to the initial position as defined in 3.9.2.

5.3 Wrapping—Units shall be wrapped in a dust-proof bag.

5.4 Shipping Container—Each unit shall be packaged and shipped in a carton secured to prevent accidental opening. Packing shall be accomplished in such a manner as to prevent marking or scratching of the unit. The carton shall contain sufficient cushioning material, corrugated liners, die cut pads, air cells, or other suitable material to prevent shifting or breakage of the unit.

Under "Notes," information of a general or explanatory nature is given. No requirements appear herein. This section contains information designed to assist in determining the applicability of the specification and in the selection of the appropriate type, grade, or class of commodity. Included are the following:

Intended use
Ordering data
Standard samples
Qualification (where required)
Suggested features to be included in the contract.
Miscellaneous notes

Example

6. Notes

6.1 Intended Use—These hydraulic units are intended for use by above-knee amputees to replace, to a limited extent, the functions of the knee and the ankle.

6.2 Ordering Data—Procurement documents should specify:

(a) Title, number and date of this specification

(b) Size of the unit and accessories and whether right or left.

6.3 Procedure before contract—Initially, and for any subsequent modification of the unit, the manufacturer shall supply two units that he wishes qualified. These units shall be submitted to the Standards Laboratory for qualification under these specifications. With the units submitted, there shall be included (1) a set of any special tools required for installation and maintenance of the units, (2) a general assembly drawing showing major sub-assemblies and the dimensions critical to installation in a prosthesis, (3) a schematic drawing showing principles of function with (a) a detailed description of the operational (functional) sequence of designed-in characteristics for one complete cycle, and (b) the accepted variation or tolerance range for the functional characteristics in one complete cycle, and (4) necessary instruction manuals for installation, maintenance, and use. The initial units and associated materials described in this paragraph when approved by the Standards Laboratory and agreed on by the manufacturer, will constitute Standards to be used for future compliance testing under these specifications.

6.4 Approval of Model—If and when approved under these specifications, the initial units shall be appropriately labeled. One unit will be retained by the Standards Laboratory as a Standard and the other re-

turned to the manufacturer to be used by him as a manufacturing reference.

6.5 Approval of units. Approval or disapproval shall be determined by the Standards Laboratory according to the maximum defect score allowable.

d. *Modification*—When the draft has been polished and edited, copies are sent to the interested manufacturers or vendors, and to others concerned, for their views and criticisms. Their comments are reviewed to determine the most satisfactory method of revision. If need be, a conference of manufacturers is called by VAPC, and the draft is revised and resubmitted for further consideration, the cycle being repeated until all problems have been resolved. It must be stressed that liaison between VAPC and the manufacturers is important to "iron out" all possible defects to develop a meaningful specification. The most effective form of cooperation exists where communications are kept straightforward and open between the Government and suppliers. VAPC must also be alert to feedback from VA clinics and other users because the most carefully worked-out specification is useless if the product does not satisfy the wearer.

e. *Acceptance*—The draft is finally adjusted to secure widest concurrence, and a tentative specification is issued, effective as of a certain date.

Why tentative? Although the draft has been worked out as carefully as possible, there is still no assurance that all the requirements are realistic, or even that all the requirements have been incorporated. After the first shipments have come in and the items have been gradually distributed, feedback is constantly coming back from the field. After a trial period of about 1 year, some changes will probably have to be made to the specification. The revised specification may be still tentative, or, if proven satisfactory, will be hopefully issued as the final version. New technologies, new concepts, changes in other ways may warrant the revision or amendment of a specification. Periodic review is, therefore, necessary to keep a specification from becoming obsolete. Of course, revisions are not made without a thorough investigation and the consent of all concerned.

Compliance Testing

After the specification of an item is put into effect, each manufacturer who wishes to be considered as a supplier to the VA or to the industry which serves VA beneficiaries, must submit production samples of his product for qualification testing to ascertain that the product complies with all requirements. Qualification tests are more severe and exhaustive than acceptance tests, which consist mostly of routine inspections and non-destructive tests. Qualification tests include all the acceptance tests, and in addition, the samples are subjected to endurance tests on accelerated testing machines, wear tests, strength tests, etc.; the samples may be tested for shrinkage, corrosion resistance, fungus resistance, water absorption, or whatever is stated as required. If a failure occurs, or a requirement is not met, the manufacturer is so notified. If he still wishes to qualify, he must submit improved samples, usually before a given deadline.

VAPC also uses sampling plans which depend on the kind of item, the quantities involved, and the character of the tests. Uusally a certain percentage is selected at random from each lot. If the item is complex, each unit may have to be checked. The samples are then submitted to the Testing and Development Laboratory for compliance testing, another term for specification checks or acceptance tests.

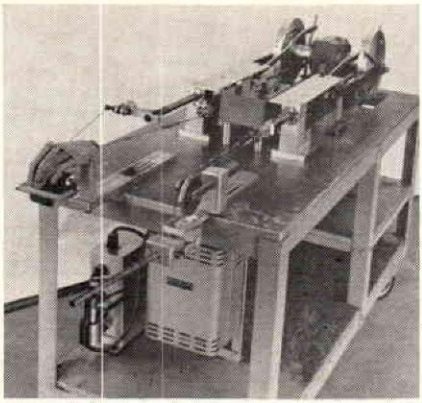


Figure 3. Two-station cycling machine originally designed by APRL.

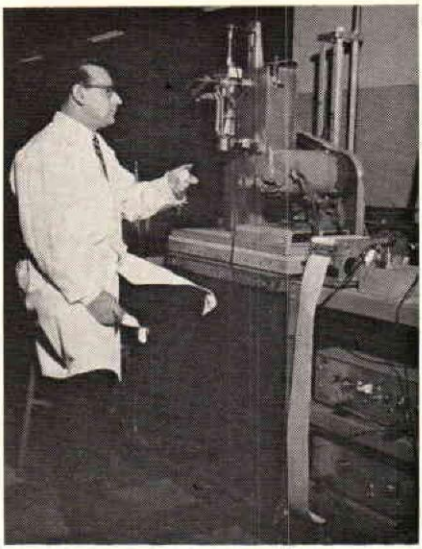


Figure 5. University of California knee testing machine

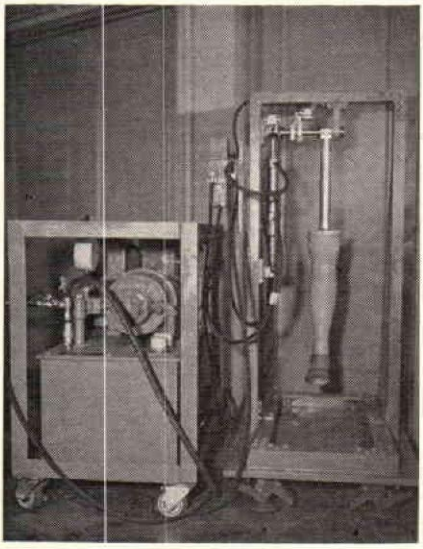


Figure 4. Dynamic knee tester.

As pointed out before, section 4 of the specifications explains all the test procedures and any *special* test apparatus needed. Most test and measuring equipment are standard and can be bought from many sources. Such equipment would include precision gages, precision weighing scales, force gages, all kinds of transducers, such as strain gages and accelerometers, universal testing machines for tension and compression testing (one is shown in Fig. 1), hardness testers, abrasion testers, and many others. Most transducers require electronic gear to amplify their signals and to record the results, usually on tape.

But often special apparatus is needed which cannot be purchased. It must then be designed and built. The Laboratory has a number of special purpose test machines. Fig. 3 shows a two-station cycling machine which is electronically controlled for variable speed. Shown mounted on this machine, originally designed by the Army Prosthetics Research Laboratory, is a prosthetic hand and an internal elbow, both being cycled simultaneously. The hydraulic test stand shown in Fig. 1 was built to check the static pressure of hydraulic knee units. It can accommodate 6 units at one time. The stand can also be used as a hydraulic power source for dynamic applications.

Fig. 4 shows a dynamic knee tester. The unit on the left is a hydraulic motor-pump. On the frame to the right, a knee system is set up for dynamic testing. With a programmed input to the stump, represented by the vertical tube, the prosthesis will be tested for swing reactions such as the angular acceleration of the shank. The electronic gear is not shown. The recorded result will be compared to an accepted standard knee characteristic curve.

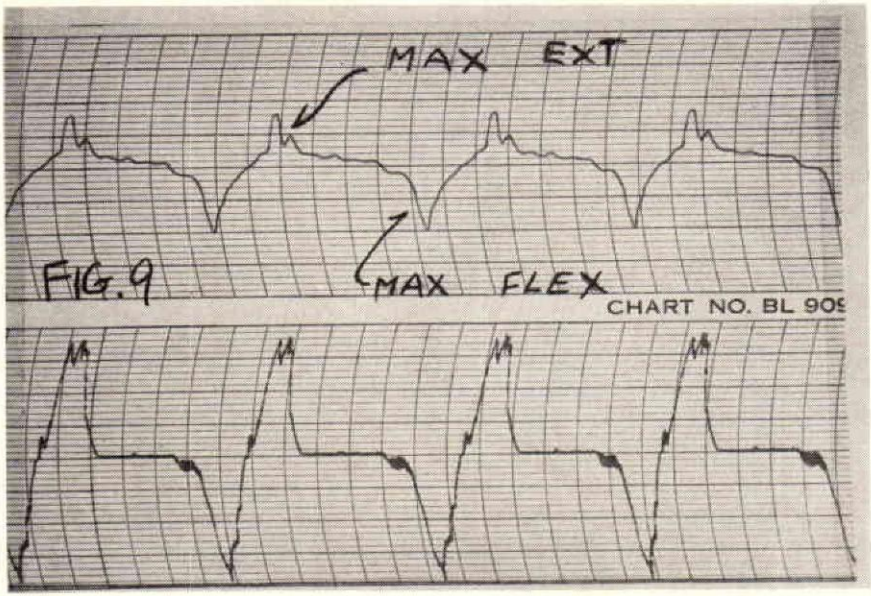


Figure 6. Force and velocity recordings from University of California knee testing machine.

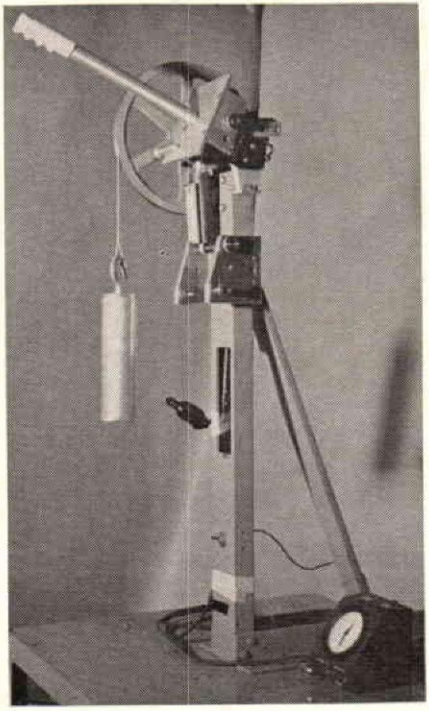


Figure 7. Drop tester.

Another dynamic cycling machine is shown in Fig. 5. This is an oscillating cycler for flexing and extending knee units with a forced input. Built by the University of California Biomechanics Laboratory, it has a strain gage element which measures the resistance of the unit to the flexing and extending forces. The amplifiers are in the lower compartments, and the oscillograph (with the paper tape output) is on top of the table. As most knee units have resistance adjustability, this machine is useful for checking resistance ranges particularly at different speeds and also for comparing the characteristics of different systems. Sample curves are shown in Fig. 6. The lower curve is that of input velocity and the upper curve is the corresponding resistance force measured in the rod producing flexion and extension.

A constant torque resistance test apparatus or drop tester used quite commonly for acceptance tests of hydraulic units is shown in Fig. 7. This unit was mentioned in the specification example given above.

Quality Control

Competition has been the way of life in our country ever since its inception—we seem to thrive by it. The system rewards that enterprise which can make its product a little better or market the same thing at a little lower price than its competitors. The secret of success can usually be summed up in two words: "quality control."

Quality control is a modern industrial concept which requires that every product be checked against established standards to make sure that nothing defective reaches the consumer. This concept also applies to the artificial limb industry as well as to other businesses. With a new product, where competition is absent, the VA sees to it that a standard of quality is established. The VAPC then acts like a quality observer to see that products abide by standards and prevents a shoddy product from reaching any disabled person.

Any supplier or manufacturer who neglects to practice quality control will eventually fall by the wayside. The things which will cause him to lose out may at first seem inconsequential to him—skimping on the thread count in stump socks . . . knee joints that are poorly assembled . . . a leak that develops in a hydraulic system . . . inferior workmanship in a SACH Foot . . . sloppy fits in a device . . . limb shop fitters who do their second best . . . substituting an inferior material because it is cheaper.

American orthotists and prosthetists and their suppliers have potentially the experience, competence, and ingenuity to do any job a little better than it is done now. This is a time when quality matters more than ever before, world conditions being as they are. The function of the Veterans Administration is to help the American industry along this path and to see to it that the words "Approved by the Veterans Administration" will always be a symbol of excellence and worth.

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1. "Industrial Specifications."—E. H. Mac Niece, John Wiley & Sons, N.Y.
2. "Standardization Activities in the United States"—A Descriptive Directory.—U. S. Department of Commerce, National Bureau of Standards.

Education and Training

The Research and Development Division of the Prosthetic and Sensory Aids Service, also physically located in New York, has the primary responsibility for VA education and training in prosthetics and orthotics. The VA Prosthetics Center, however, supports these activities by guidance in curriculum development, by visual aid design and production, by technical reports, manuals, and articles, and by providing lecturers and instructors for seminars and courses. Also, the Center conducts on-the-job training for several kinds of students.

It seems reasonable that a center active in a broad spectrum program for prosthetics and orthotics restoration would indeed also be involved in education and training; particularly as the products of research and development become available, there is need for dissemination of information on the new devices and techniques. A government limb and brace activity attempting to practice the best and latest techniques developed by itself and others also provides an excellent facility for on-the-job training of orthotists and prosthetists.

Nevertheless, we know full well that only those who are willing and able to learn can teach. Indeed, the reservoir of prosthetic knowledge grows steadily, and especially he who might choose to teach must keep his knowledge in constant repair. Consequently, the leading journals and all publications, domestic and foreign, are made available to the Center's staff and are reviewed and group-discussed. In addition, intensive communication is maintained with American and foreign research and clinical centers. Members of the teaching group are often sent out to get first-hand insight, to keep abreast of "prosthetics on the move," home and abroad.

Only so, can cross-fertilization of knowledge and a sufficient transfer of new ideas be achieved. Only so, can the teachers be well-taught.

It has been generally recognized that the nationwide establishment of orthotics and prosthetics clinic teams was a major step forward, not only in clinical practice but in education of the team members. Sometimes, for quite understandable reasons, these teams do not always function at the summit of efficiency, but all seem to be rising to the challenge and are constantly improving. The VAPC has an Orthopedic and Prosthetic Appliance Clinic Team meeting weekly under the leadership of a consultant, but it is also fortunate in having available, full-time and under one roof, a surgeon, prosthetists and orthotists, and therapists with whom it organized what may be called the "Instant Team" to be assembled with "push button" speed anytime a case of "Clinic Team" substance comes in. This arrangement has proven so strikingly valuable in many respects, particularly in educating our educators, that its adoption by other institutions wherever possible is highly recommended.

A four-year program of full-time and salaried apprentice-training has been organized in the VA Prosthetics Center to prepare carefully selected high school graduates as orthotists or prosthetists with certification as a goal. The education, although including all necessary craft activities, focuses on the professional responsibilities of the discipline. For example, year-round courses in functional anatomy are given to the trainees as well as to regular staff members. Special lectures on mechanics, materials, and

principles underlying limbfitting and bracing are presented at appropriate times during a trainee's four-year tenure. All trainees are also given a brief, yet comprehensive research and development experience so that they may become familiar with the rationale underlying the methods used.

The four-year training program is primarily intended for United States citizens. Nevertheless, many foreign technicians supported by various international organizations are assigned to the Center, after appropriate clearance, for varying periods of time to learn about modern American methods and devices. Most of this unsalaried training is craft-oriented but discussion of the fundamental principles underlying any new technique or device is always provided. The VA assumes no financial responsibility for expenses incurred by such trainees.

On a number of occasions, American and foreign physicians have spent varying periods observing activities involved in the production of artificial limbs, braces, and orthopedic shoes or the research activities associated with these programs. In several instances, physicians were given job-training in the fabrication of prostheses, braces, or shoes.

Regular one-week courses in prosthetics and orthotics are held in New York periodically with VAPC personnel providing most of the faculty services. The Research and Development Division of PSAS sponsors two such training programs per year for physicians, therapists, prosthetics specialists, and orthotists from Veterans Administration installations all over the country. Lectures on prosthetics and orthotics, with particular emphasis on the newest devices and techniques, are supplemented by demonstrations and practical work sessions. Occasionally, a course of this type will be organized in another city with instructional personnel from the New York activities.

Periodically, special training courses are given to certain VA employees. For example, the use of the casting stand in the fabrication of above-knee and below-knee brace supports and for sockets to be used in temporary prostheses were taught to VA orthotists to assist them in their regular VA brace shop responsibilities.

Upon invitation, VAPC personnel have conducted lecture and demonstration programs at local VA stations or Area Medical Offices. These are usually one or two-day sessions to which commercial prosthetists and orthotists and private practitioners from the region of the VA station may be invited.

Special seminars are occasionally conducted at AOPA meetings or at least in collaboration with AOPA. A typical example was the recent series of seminars on fluid-controlled mechanisms, a PSAS program involving VAPC, Research and Development, and some university personnel.

In addition to these programs of education and training, the VAPC also prepares for the PSAS manuals, brochures, and pamphlets. Its staff has made significant contributions to the literature. Prosthetics and orthotics information dissemination responsibilities also include replies to daily inquiries on problems confronting VA and other clinicians and practitioners. Many such inquiries come from overseas.

The Center and the R&D Division have a huge photographic file including color slides, as well as motion pictures, microfilm and patents, which facilitate information dissemination. Visual aids, models, samples and other training aids useful in educational programs are produced routinely, both for lecture-demonstrations and the permanent exhibit associated with the offices of the Research and Development Division in New York.

From time-to-time, Center personnel are involved in international conferences and seminars or courses. Most particularly, the international prosthetics courses, sponsored by the Committee on Prostheses, Braces and Technical Aids of the International Society for Rehabilitation of the Disabled, have been supported by faculty participation. Also, regional seminars in several parts of the world have been organized by Center personnel in cooperation with several international organizations and with the support of the governments involved.

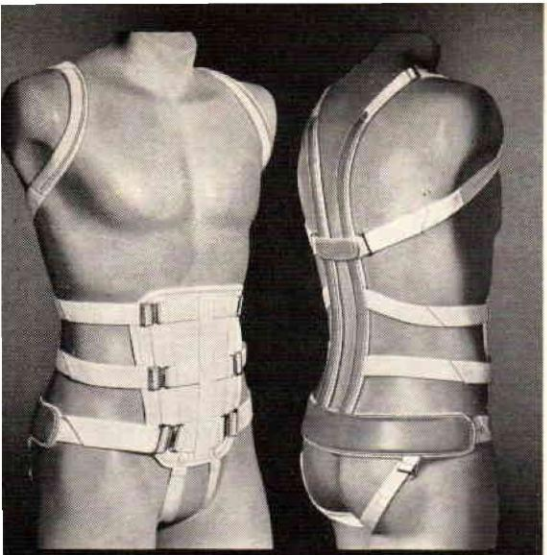
We of the VA Prosthetics Center hope that what we have done and what we aspire to do may have some impact on national and international progress in prosthetics and orthotics, especially in constantly raising the level of practice by technical improvements and through education and training. We believe that every contribution is needed since after all, the field of orthotics/prosthetics is now and will always be pretty much unfinished business.

Dr. Rosenkranz's Prosthetic Splinters III.

1. STABILITY itself is nothing else but instability in slow motion.
2. ANATOMY OF THE HUMAN BODY: If one knew how the body is made, he would not dare move; Physiology: If one knew how it works, he would rejoice in making it work.
3. To the prosthetist who frowns upon alignment devices: INTUITION is that strange instinct that tells the limbfitter he does right, whether he does or not.
4. Prosthetics should be planned on physiological lines, not by mere carpentry.
5. Some prosthetists I have met were still young enough to know everything.
6. When the stump turns blue, it is the limbfitter's turn to blush.
7. The prosthesis is to the stump what a house is to the individual: A machine to live in. (after Frank Lloyd Wright).
8. How many COMING IMPROVEMENTS has one known! Where on earth do they all go to?
9. Nothing will ever be attempted if all possible objections must first be overcome. (after Samuel Johnson).
10. If you think of STANDARDIZATION as the best that you know today, but which is to be improved tomorrow—you get somewhere. (Henry Ford).
11. The LARGEST ROOM in the world is the room for improvement.
12. RESULTS! Why, man, I have gotten a lot of results. I know several thousands that won't work. (Thomas Edison).

13. Prosthetic care must begin before amputation starts.
14. Prosthetics means harnessing the greatest force in the Universe, the force of gravity.
15. Friendship between surgeon and prosthetist is often only a suspension of hostilities.
16. Recent Books:

    The Prosthetic Team—A Conspiracy
    On Alignment: A mystery story
    Amputation and Prosthesis: A sad story with a happy ending
    The Electric Hand: Science-Fiction
    The Suction Socket: A German best seller
17. The first principle in Prosthetics is getting the job.
18. An orthotist's dream: A centipede's order for arch supports.
19. Some contemporary legs are the deplorable results of an omitted wood burning.
20. Only a mediocre prosthetist is always at his best.
21. God may forgive you your sin; the stump won't.
22. Don't expect the socket to say "when."
23. The ISCHIAL SEAT is the signature of the prosthetist.
24. All modern appliances are descended from obsolete creations, but it shows more on some.
25. All men are created equal, but no two stumps are alike.
26. Honor FITTING and ALIGNMENT, and the days of your staying in business will be long.
27. The ideal leg. There does not exist a "best" leg for all cases. The "best" limb is always that which the wearer through energy and skill renders "the best for him."



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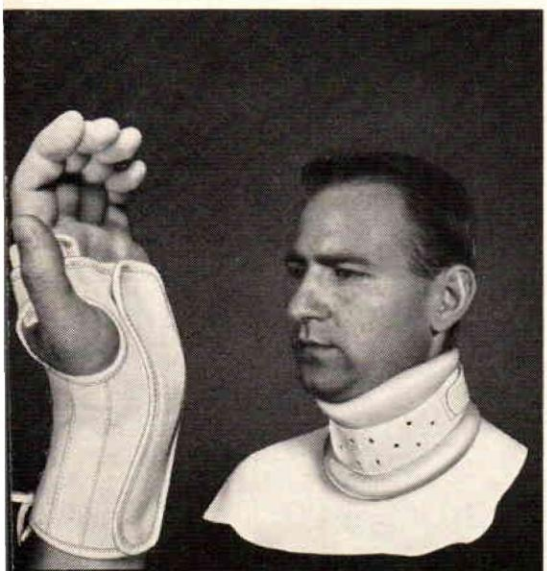

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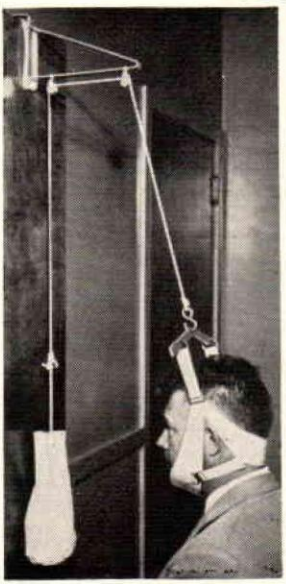

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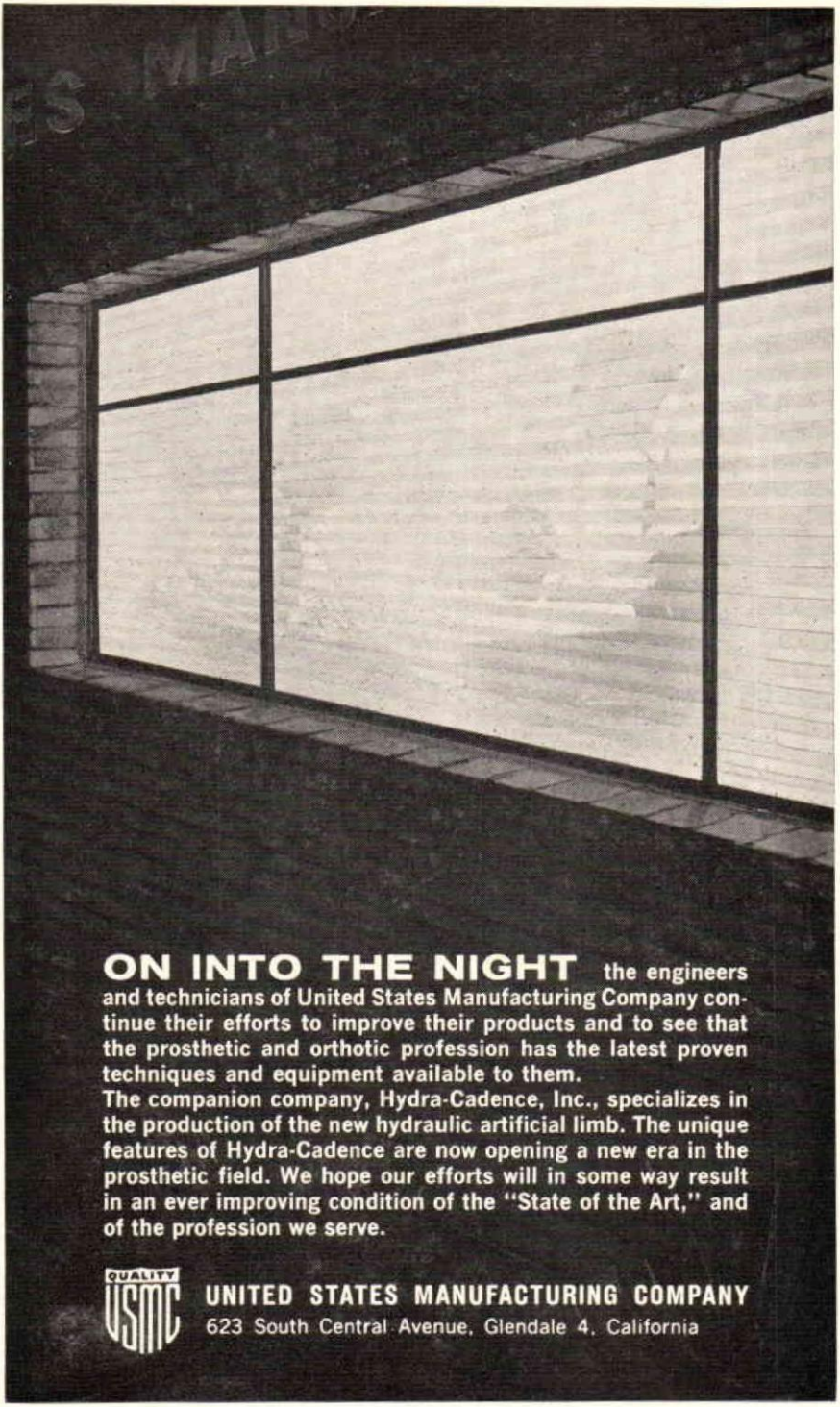
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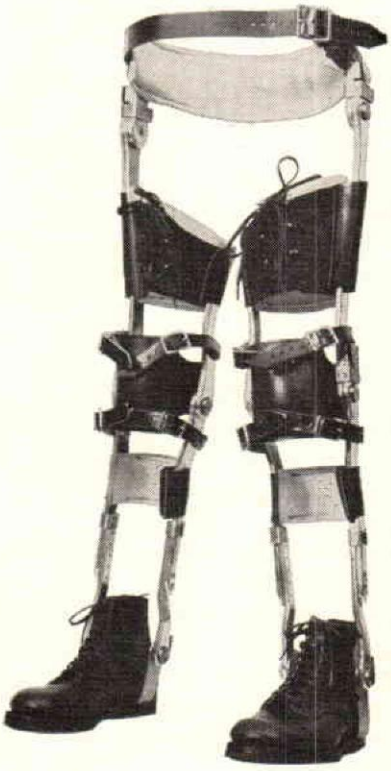

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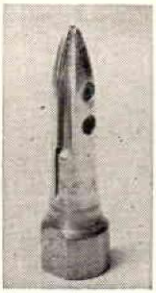

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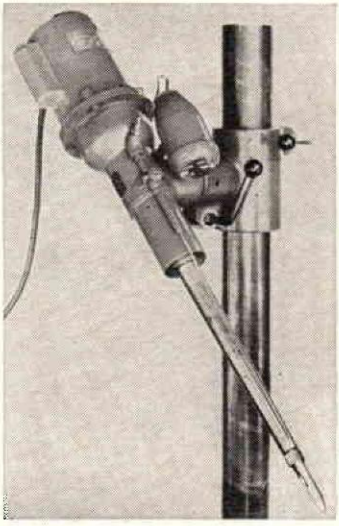

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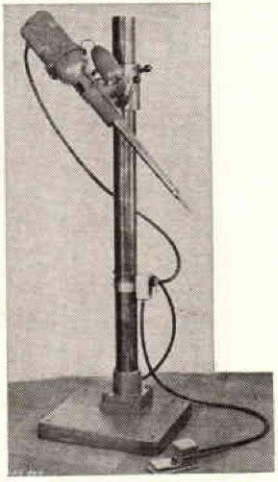

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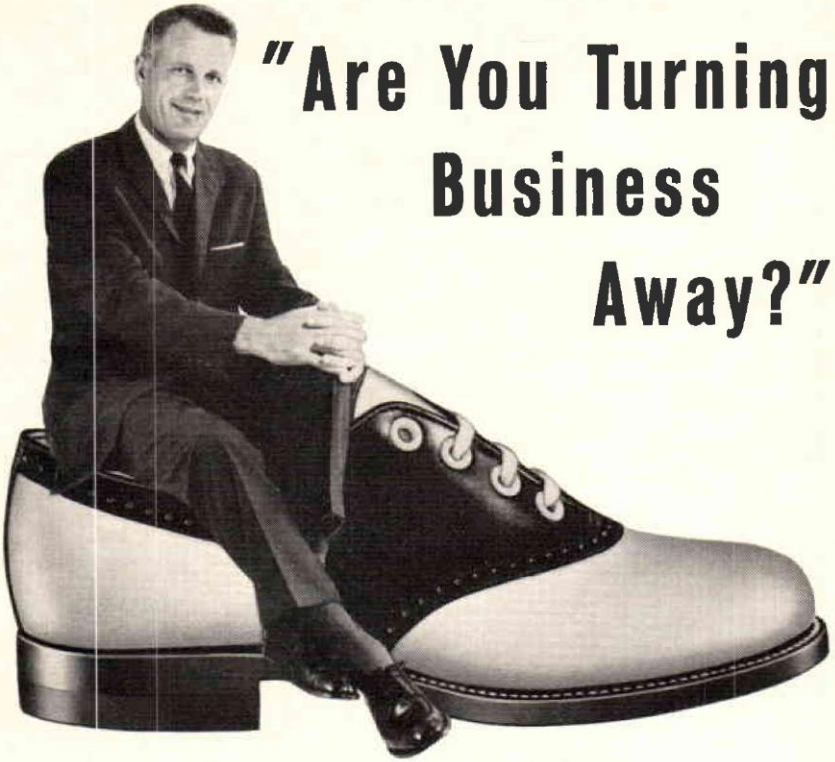

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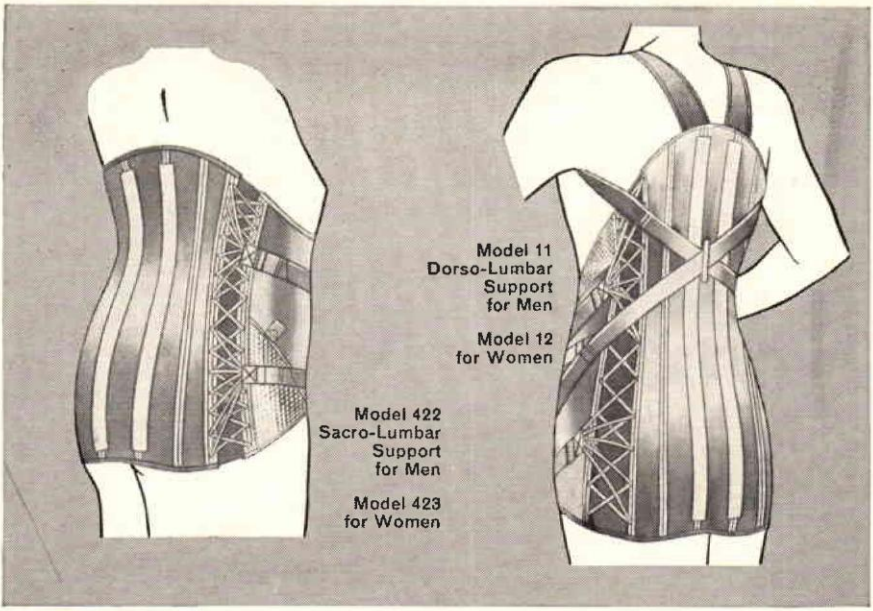

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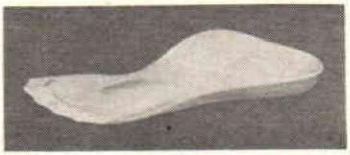

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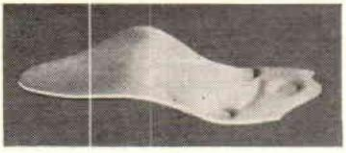

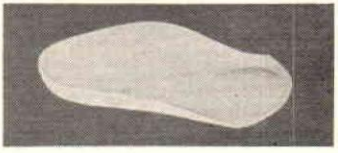

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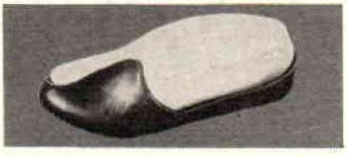

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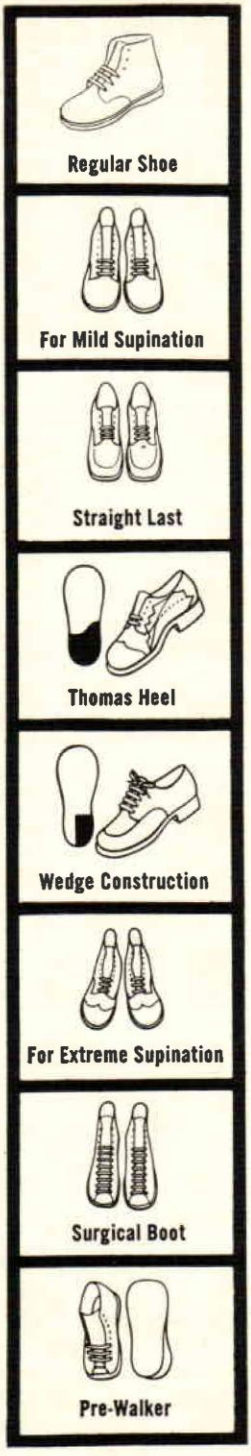

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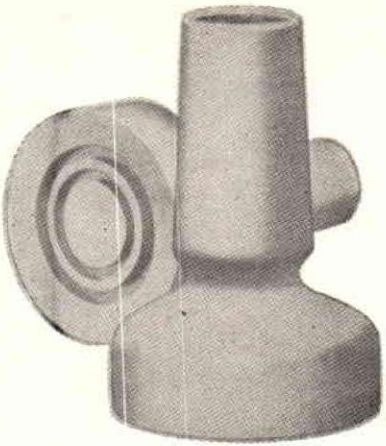

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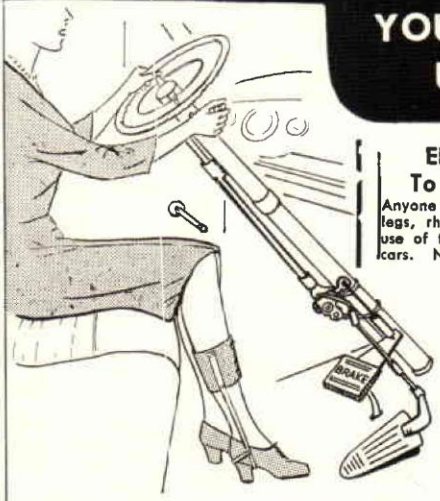

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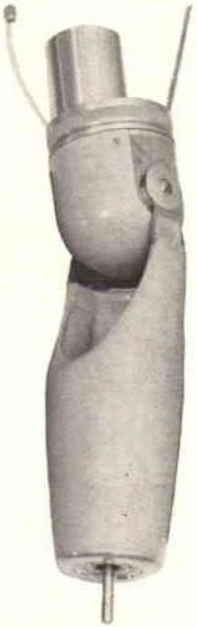

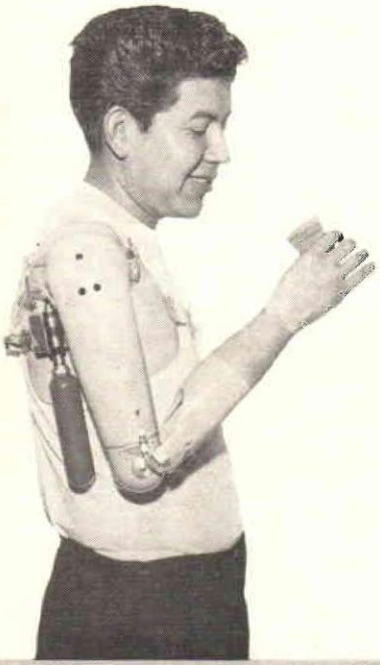

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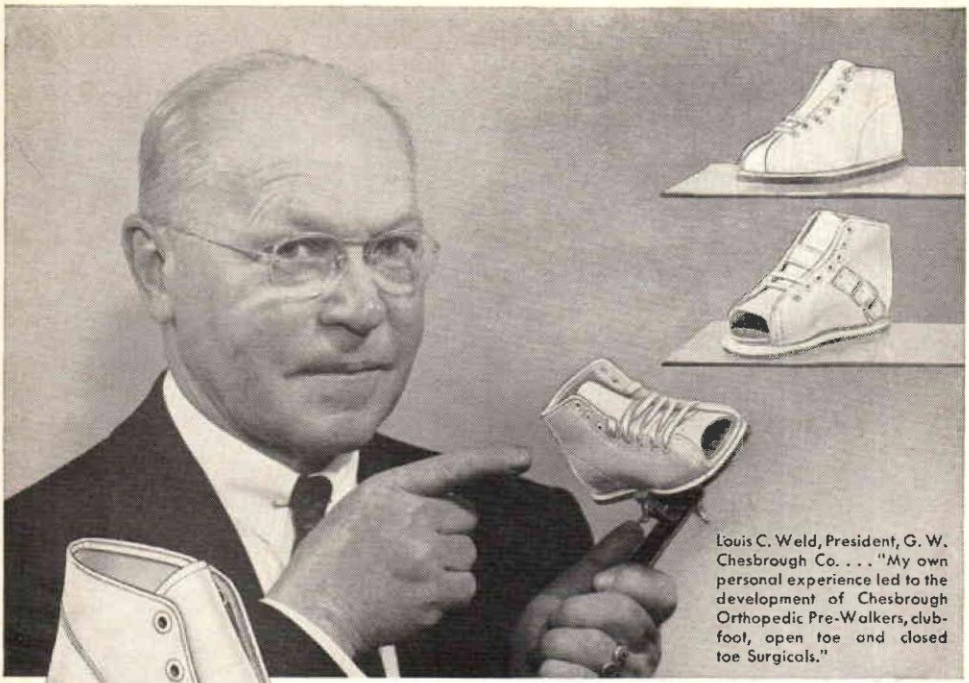

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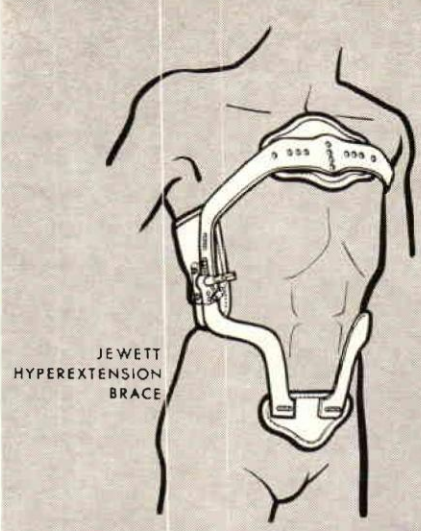

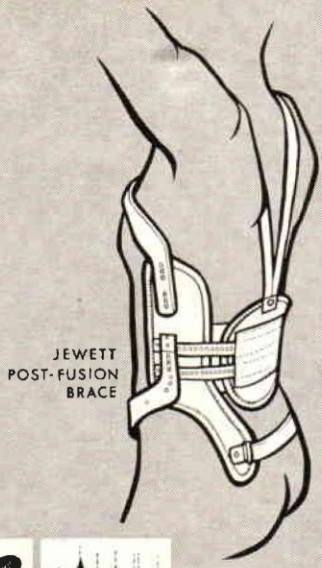

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