Engineering Applied to Orthopedic Bracing *

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Introduction

Several hundred thousand people in this country must wear orthopedic braces, many for the rest of their lives. Challenging problems of design and choice of materials confront the engineer, working closely with the doctor and the orthotist, and behind them the brace manufacturer, in the development of the most functional and yet, economical brace.

The systematic study of the loads and conditions to be met by available materials, leading to the most economic designs of rigid structures which are durable and functional yet light in weight, results from the application of engineering to orthopedic bracing. This type of study is necessarily based on fundamental engineering concepts. Other contributions to the handling of orthopedic bracing problems derive from engineering research, including testing, stress analysis, materials evaluations, and time and motion studies.

The engineer, in applying the basic concepts of his field, must be cautious lest false economies greatly decrease the happiness and productivity of the patient. Therefore, use of the essential principles of mechanical and industrial engineering must be tempered with a knowledge of the patient's limitations, desires and motivations as well as an appreciation of the much greater variability encountered in biology than in conventional engineering. Only thus may engineering efforts yield great returns coordinately in cash economies and in human welfare.

Some factors in brace design are common to most conditions. For instance, in braces for children, provision must be made for inexpensive increase in size, poor maintenance, and frequently rough usage.

As in the solution of any engineering problem, the concepts to be used depend to a great extent on the purposes which the appliance or device must serve. Therefore, discussions of the special requirements of orthopedic conditions and of the common problems reported by brace wearers seem warranted. Since so many areas of knowledge are involved, the well-known team approach is needed in design as well as in treatment of the individual patient.

Special Requirements of Orthopedic Conditions

Each of the various conditions requiring braces obviously imposes unique physiological and engineering requirements. As is illustrated in the *Atlas of Orthopaedic Appliances*,[2] a number of full-length leg and thigh braces made for different conditions may appear surprisingly different in design until one understands their separate purposes. Perhaps in the past most braces made by a given

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brace maker tended to bear a great resemblance to each other regardless of the type of patient for whom they were intended. If the individual brace maker happened to specialize in polio, for instance, he tended to make light polio-type braces also for cerebral palsy, fractures, etc. Unfortunately, there was sometimes uniformity in the prescriptions from a busy medical practitioner who specialized in one condition and, under pressure for time, did not think carefully of the special requirements for conditions less frequently encountered.

In a *fracture* leg brace, body weight, in most cases, must be bypassed around the fracture. Stability against bending must also be provided. Adequate support is thus desirable from an ischial seat and probably from long moulded corsets with laces or broad straps. Rigidity of construction, secure attachment to the shoe, and precise alignment of joints (if indeed any are feasible) are obvious requirements. In some cases the brace is needed only for a matter of months so low cost may be more important than durability.

In *polio*, since any combination of muscles may be affected temporarily or permanently in the various individual patients, precise prescription is particularly important. Replacement of lost or damaged muscle function may be provided, with a particular choice at any given stage in the patient's recovery depending upon the function, his special needs, and the degree of activity which is believed possible with his remaining muscles while avoiding contractures due to muscle imbalances. Counterweighting springs might be considered, especially to assist weak muscles which would be sufficient to move the part if gravity were balanced, as in the swimming pool.

The increasing availability of cleverly designed spring mechanisms for other commercial purposes (e.g. "Neg'ator") opens a whole field for

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research and development in the application and development of neat and compact counterbalancing springs whose force may be gradually reduced as the affected muscle improves[8]. Physiological and mathematical analyses were offered in great detail after World War I by von Recklinghausen[14]. To replace a *nonfunctioning quadriceps* muscle group, it is customary to provide a knee lock, which can be manually released for sitting but locked during standing. Occasionally it is possible to use "alignment stability" of a mechanical knee joint which (as in an above-knee artificial leg) is free to flex during the swing phase of walking. Such a joint permits only that limited degree of hyperextension needed, in combination with limitation of dorsiflexion, to attain alignment stability during the stance phase. In this case the patient can walk with a much more normal gait than would be possible with a stiff knee.

Clearing the ground without flexing the knee would require one or more maneuvers: vaulting off the other foot, circumduction of the affected leg, excellent control of toe lift, excessive side sway, excessive lifting of the hip on the paralyzed side, or very short steps. Often most of these feats are precluded by concurrent paralysis of other muscles such as the abductors of the hip, the calf or pretibial groups,

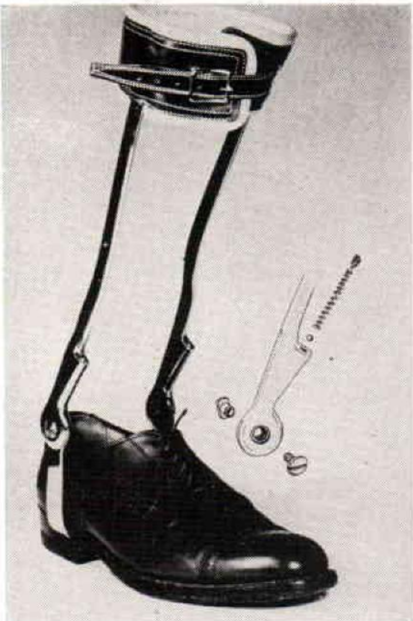


Fig. 1. Spring-Loaded, Equinus Control Leg Brace.

or the lateral muscles of the torso, so a free knee joint would be very welcome if it could be used safely. In contrast to the rubber or felt stops in artificial legs, present brace designs provide only small hyperextension stops of metal which click at every step and rapidly wear or permanently deform. Probably improved designs would greatly increase the use of such braces.

Very commonly, it is desirable to *block some motion* which is regarded as having relatively low priority while attempting to maintain motion on some single axis which is considered particularly important for function. An example is the short leg brace, (Fig. 1) intended to prevent inversion and eversion of the foot (in spite of the loss of muscles controlling these motions) and yet to permit plantar flexion and dorsiflexion of the ankle. If the muscles controlling plantar and dorsiflexion are also weakened or lost completely, stops may be provided to permit only the limited motion needed in walking. As in Fig. 1, springs may be used to permit the necessary limited motion against the spring action as well as resilient return. Reaction forces will result. For example, a stiff spring limiting plantar flexion at the ankle will cause pressure of the calf band against the calf and thus tend to buckle the knee. A certain amount of toe drop and a slapping sound as the toe strikes the ground after heel contact may be preferable to a long leg brace with locked knee joints, so stiffness of the spring limiting joint motion should be adjusted to the best compromise.

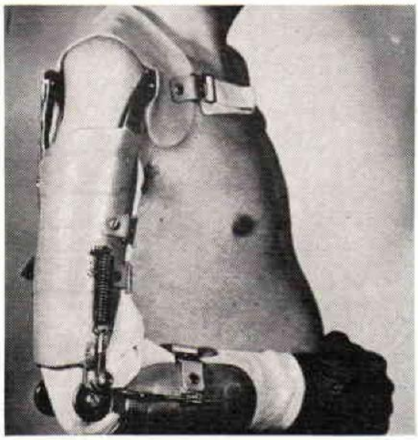


Fig. 2. Arm Brace Having Counterbalancing Springs and Elbow Lock for Control of Forearm Flexion.

Replacement of lost muscle power has been done in a limited way in the application of artificial arm principles to arm bracing through the introduction of force, movements, and control from other parts of the body. In the case of polio affecting the hands, for example, it has been possible to retain the valuable skin and proprioceptive senses by transmitting shoulder motion by a steel Bowden cable to ring-like or plastic splints driving the fingers against muscular or resilient return forces and thus to replace paralyzed finger flexor or extensor muscles. Elbow flexion can be assisted by springs (Fig. 2) or

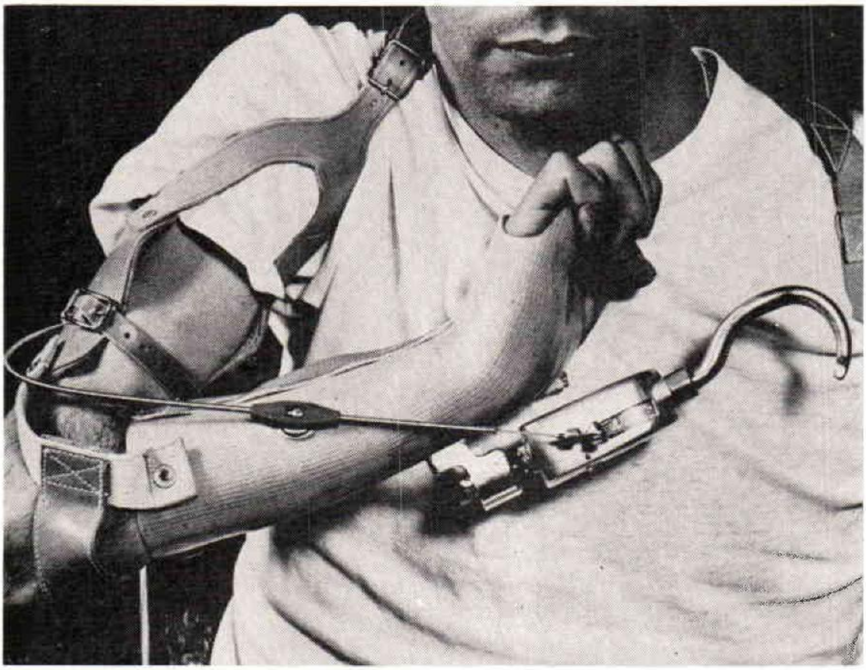


Fig. 3. Cock-up Splint with Prosthetic Hook for Paralyzed and Insensitive Hand.

elastic bands[15] or replaced by energy obtained from shoulder elevation, spreading of the shoulders, or even thigh motion[25]. In the case of a quadriplegic, it has been possible to use the remaining limited shoulder-spreading action to provide motive power for control of a type of hook used on artificial arms. This hook was mounted by a ball and socket joint on the volar aspect of a wrist cock-up splint, (Fig. 3) which kept the insensitive hand out of contact with objects to be held, and thus reduced the risk of burns or other injuries.

In *spastic conditions* due to paraplegia or cerebral palsy, it is generally necessary to prevent unwanted motion while encouraging those which are considered desirable. It is hoped that motion patterns which can thus be developed eventually will permit adequate voluntary function. Great rigidity, it has been pointed out,[12, 13] is thus necessary since springs or even a flexible brace merely serves as a "high resistance exercisor" which stimulates the stretch reflex, causes the muscle to contract involuntarily, and thus by repeated exercising strengthens rather than inhibits the unwanted muscular activity. For example, with spastic calf muscles the right-angle stop preventing plantar flexion must be extremely rigid, the sole of the shoe must be reinforced, and the side bars of the brace must be stiff. A cuff presenting adequate bearing area against the calf is essential to prevent skin damage due to the very high reaction forces.

Due to the difficulty in applying the shoe and brace in such spastic conditions, it is desirable to permit application first of the shoe alone and then addition of the brace, as by *calipers* or *detachable ankle joints.* It has been rightly objected that the ordinary caliper forming the L-shaped part of the side bar fitting into a tube under the heel places the mechanical joint *below* the anatomical ankle axis, which is approximately parallel with the center of the lateral malleolus and the lower edge of the medial malleolus.

A stirrup type of brace with mechanical joint axis opposite the anatomical axis, plus L-shaped pieces fitting into a rectangular slot under the heel, has been used to retain an ankle joint at the anatomical level yet permit easy application, removal, and change of shoes[3]. With a patient having spastic calf muscles, a right angle stop typically is provided to prevent plantar flexion. On the other hand, due to the tightness of the calf muscles, no appreciable dorsiflexion occurs during walking. Since there is so little motion in either direction about the ankle joint, it hardly seems worthwhile to be concerned about the lack of coincidence of the mechanical and anatomical axes, as in a very simple, rugged, and inexpensive plain caliper joint.

In contrast, consider a polio case with a free ankle joint in a brace intended to prevent inversion and eversion, while permitting large amounts of both plantar flexion and dorsiflexsion. Obviously accurate coincidence of the mechanical and anatomical joint axes is essential to prevent chafing between the calf band and the skin.

In *some patients with cerebral palsy*, excessively strong adductor action leads to "scissoring" of the legs, so a pelvic band and hip joints are frequently prescribed. If, however, the pelvic band is relatively flexible and the hip joints are merely simple overlapped joints (which might be quite adequate for stabilization in flaccid conditions), the scissoring tendency will merely tilt the mechanical hip joints so that the upper and lower parts bind rather than permitting free flexion and extension which are so desirable to obtain a semblance of normal walking. Dr. John Young of Mellon Institute designed, for such a case, an extremely rigid thorax cage including both a pelvic band and lateral bars connected to another band about the rib cage.

Extremely sturdy ball bearings permitted free flexion and extension of rigid channel-shaped side bars even if a 100 lb. pull in the adduction direction were applied at the ankle joint. (Although the patient with cerebral palsy retains sensation, careful daily observation may be necessary to avoid pressure sores if there are difficulties in communications. Fortunately, the broad cuffs and the well-muscled, well-nourished limbs distribute even such extreme forces). While this type of rugged construction seldom needs to be carried to such an extent, particularly if the patient has been given proper control appliances while still a small child, the principles of rigidity against unwanted motion plus freedom to encourage desirable motion will apply generally in spastic and athetoid cases.

After a so-called "stroke," the *hemiplegic* patient may require a very light appliance providing only a minimum necessary function such as "toe lift" while causing minimum strain on the rest of the body. Any elderly individual who also has circulatory difficulties should not be burdened with heavy appliances for the same function which might be quite suitable for an adolescent spastic or athetoid individual with all-too-powerful but uncontrolled muscles and a robust heart.

In spinal *paraplegia* and *quadriplegia*, there is a definite pattern of flaccid paralysis and of spasticity depending upon the level of the injury, in marked contrast to the erratic pattern of involvement in polio, for example. Typically, complete spinal paraplegics have symmetrical involvement, somewhat simplifying standardization of components and construction of the appliance. On the other hand, the paraplegic, because of his loss of sensation, offers a special challenge during both fitting and routine use to be sure that pressure sores and chafing do not escape undetected. Atrophy of flaccid muscles will also leave bony prominences and limited bearing area for cuffs, so broader, longer, and more carefully fitted cuffs may be necessary even at the expense of added inconveniences in donning and removing the braces.

Finally, *deformities may be corrected* or at least, increase of the deformity prevented. Quite often the skin cannot tolerate enough permanent counterpressure actually to reduce a deformity like scoliosis, but at least the back can be held in the most favorable position which can be obtained while lying supine, and thus the effect of gravity in constantly increasing the lever arm of the S-shaped curve can be eliminated. Examples are the Milwaukee and other back braces for scoliosis[18]. Tension applied vertically at the upper and lower termini of the curve and pressure applied horizontally to the apex of the curve will counteract the tendency for a progressive increase in the deformity. Increasing knowledge of the effects of pressure on circulation[11], of the pressure between the skin and an appliance[6], and possibly of means for supplying pulsating pressure should lead to better designs.

In the past, some experiments had been made toward the replacement of at least a limited sense of touch for artificial limbs. This area of *sensory feedback* of both pressure and sense of position is recognized as a longtime goal in artificial limb research[24]. It is to be hoped that, in years to come, findings in that field will also be applied to transmit to sensitive areas of the paraplegic's body some elementary information about the position and pressure upon the damaged portions.

Fundamental studies of *locomotion* have been conducted in the last decade at the University of California, Berkeley, primarily in connection with articial limbs but also with support from the National Foundation for Infantile Paralysis[7]. Comparable *motion studies* on the upper extremity have been made at the University of California at Los Angeles[17]. The studies at both Berkeley and Los Angeles greatly increased knowledge of forces and motions involved in common human activities and have led to a rational basis for assigning priority to the various possible motions. For example, in the upper extremity, prehension is most important. Elbow flexion and the possibility of stabilization of the elbow in any of a reasonable number of positions are next in importance, but passive adjustment of pronation and supination would often be adequate when voluntary control is impracticable. Wrist flexion was shown to be of very low priority, and if it is provided at all, a few positions of passive adjustment are entirely adequate.

These principles, and somewhat comparable information on the lower extremity, can guide in the selection of joints for braces and the use of an extremely limited number of auxiliary power sources from other parts of the body. Studies of the energy required and the role of the various joints in walking also provide a basis for long-term analysis of the importance of locks, counterweighing springs, or voluntary control of the various joints. These results of research, as well as humane and economic factors should guide consideration at any given stage of recovery of the relative importance of surgical stabilization, muscle transplant operations, or bracing.

Studies of *muscle activities* at both campuses of the University of California[7, 9, 17] have emphasized electromyographic measurement of muscle activity and have shown the importance of the force-length curve originally described by Blix[5] and its implications in connection with the importance of preventing contractures and of reducing the steepness of the "passive stretch curve" so as to increase the forces which are voluntarily available beyond the resting length of the muscle. These studies also have implications in connection with muscle and tendon transplants and tendon lengthening. A whole field of bioengineering development is available in the application of this type of quantitative information to orthopedic problems.

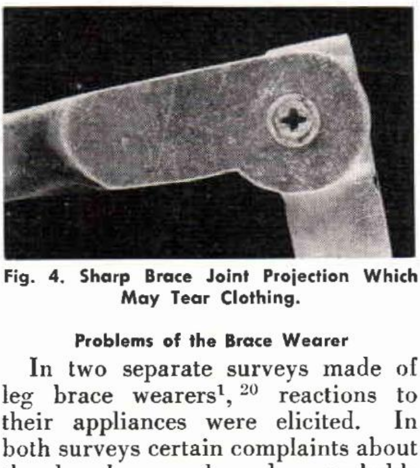


Fig. 4. Sharp Brace Joint Projection Which May Tear Clothing.

Problems of the Brace Wearer

In two separate surveys made of leg brace wearers[1, 20] reactions to their appliances were elicited. In both surveys certain complaints about the leg braces showed remarkable similarity:

1. The wearers would like *lighter, less bulky* appliances.
2. Braces cause excessive *clothing damage*, by lubricant staining and by actual tearing of clothing in the joint regions. (See Fig. 4 for an example of a brace joint having a sharp anterior projection which will tear clothing.)
3. Wear of joints (particularly those requiring lubrication which is avoided by the brace wearer because of clothing staining) causes *noise* and gradual *loss of stability* of the appliance.
4. *Breakage* of the brace is common.
5. Because of joint wear and structural failure, the *inconvenience* and *cost* of *repairs* are objectionable.

As a result of recent developments by many contributors, these complaints can now be very largely overcome. The rest of this paper will describe some possible improvements in materials, design and manufacture.

Elements of Materials and Design

Contrary to the common impression among many individuals practicing in the orthopedic appliance field, there is no single "magic material" which should be used under all conditions. Conditions requiring bracing vary sharply. When considering the appropriate brace for each of these conditions, however, common fundamental concepts about materials and design may be utilized. Each material should be selected based on its special physical, chemical, galvanic, mechanical, and economic properties. The design will be selected for its unique contribution toward remedying the orthopedic condition. Appearance and other factors affecting acceptance by the patient must be considered.

Table I, *Properties and Costs of Selected Metal Alloys*, shows the material characteristics which should be considered when developing brace designs or when prescribing an appliance. Properties may vary somewhat with heat treatment. Besides the properties shown, the design team must evaluate frictional characteristics of joint surfaces and abrasion resistance of all materials. Hardenability, effects of strain or "working" the material, and galvanic compatibility of the metals will be important. Certain plastics tend to creep or change shape slowly under high load even at body temperature. Materials

Table I

Properties and Costs of Selected Metal Alloys

Metal Alloy	T.S.	Y.S.	F.S.	E	D	Relative Notch Sensitivity	Relative Corr. Resistance	Cost per lb., Dollars
Aluminum Alloys:								
AA7075-T Heat treated	82,000	72,000	21,000 (50×10^7)	10.3×10^6	0.10	Fair to Good	Good	1.40
AA2024-T Heat treated	70,000	50,000	18,000 (50×10^7)	10.6×10^6	0.10	Fair to Good	Good	1.25
Carbon Steels:								
SAE 1020 Cold rolled	80,000	66,000	35,000 (10^7)	29.0×10^6	0.28	Good	Fair*	0.05
SAE 1060 Heat treated	120,000	80,000	57,000 (10^7)	28.2×10^6	0.28	Fair	Fair*	0.05
Stainless Steel:								
AISI 316	95,000	45,000	43,000 (10^7)	28.0×10^6	0.28	Good	Excellent	0.70
Alloy Steel:								
SAE 4130 Oil quenched and tempered	140,000	120,000	82,000 (10^7)	28.0×10^6	0.28	Good	Good	0.25
Titanium Alloys:								
TMCA Ti-150A	135,000	120,000	110,000 (10^7)	16.0×10^6	0.16	Good	Excellent	16.00
TMCA Ti-6Al-4V	130,000	120,000	83,000 (10^7)	16.0×10^6	0.16	Good	Excellent	16.00
Magnesium Alloy:								
ASTM AZ31X	37,000	21,000	12,000 (50×10^7)	6.5×10^6	0.06	Poor to Fair	Good**	0.70

T.S. - Ultimate Strength, psi
Y.S. - Yield Strength, psi
F.S. - Endurance Limit, psi; Smooth specimens, Number of cycles is indicated in parentheses.
E. - Modulus of Elasticity in tension, psi
D. - Density, lbs/in^3

* Normally plated, sometimes enamelled in orthopedic braces.
** Must have protective treatment when used in contact with salt water or perspiration.

like synthetic fabrics must not tear easily and must not cause allergic reactions.

Fatigue Properties

Fatigue strength as measured by the endurance limit of materials is especially important in brace applications. Brace parts normally do not fail by reaching the ultimate strength of the material used. The loading applied to a brace by the patient during use is cyclic in nature. Stress variations induced by this pattern of cyclic loading create a condition in which, even though the stress is low, early failure may result. The behavior of materials under these conditions is somewhat predictable from S-N (Stress vs. Number of cycles) curves commonly evolved from tests of the materials in reversed bending[4]. The maximum stress under which a material will safely endure a number of cycles greater than given on the S-N curve of fatigue characteristics can thus be determined for design data.

The effects of *corrosion* and *shape factors* on endurance limit or fatigue life must also be considered. Thus, badly shaped components, surface nicks, notches, and badly located rivet and tapped holes can produce early failure through fatigue. In design, it is necessary that a reasonable radius be allowed at all necessary re-entrant corners such as around the joint heads or at the points where the stirrup is bent to fit the shoe. In fabrication, accidental scratches or gouges should be avoided or at least polished.

Fig. 5. Wear on Surface and in Bore of Brace Joint.

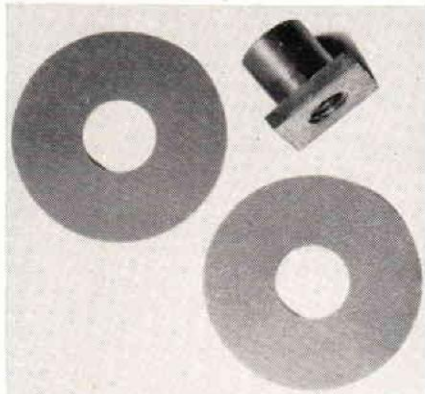


Fig. 6. Plastic Bushing and Liners for Brace Joint.

The tools used to bend the brace should be prepared so that surface defects will not result. The surfaces of all components should be highly finished since even microscopic surface defects cause stress concentration and early failure. If a notch is necessary, the fatigue strength can be increased by reshaping, if possible, to a greater radius.

Metals

Most commonly, *steels* are used in bracing. Many variation in heat treatment and fabrication methods are available depending on alloy. Table I shows that steels have a relatively high density, a high modulus of elasticity, high yield point, and an endurance limit of a high value. They therefore meet most specifications for brace applications. However, carbon steels must be protected against corrosion. Stainless steel, if given a passivation treatment, requires no further processing for protection against corrosion. Because much of the cost of an orthopedic appliance is for labor rather than for the few pounds of materials, the high cost of stainless steel is practically offset by the savings in first cost and in lower maintenance compared to carbon steel with plated finishes. Primarily because of its high modulus of elasticity, either type of steel is particularly desirable for spastic and athetoid conditions where great rigidity is necessary. The high hardenability of the steels with higher carbon content is particularly desirable in the races of ball bearing joints.

Aluminum alloys, as seen from Table I, have lower densities than steel but also have a lower modulus of elasticity. Therefore, they are relatively undesirable for braces to control spastic conditions although quite satisfactory for polio braces. The fatigue strength (endurance limit) of aluminum alloys is less than that of steel. Although some of the many available aluminum alloys have higher ultimate strengths than others, there is much less difference between the endurance limits. Because of greater costs and greater difficulty in forming, it does not seem worthwhile to use in most brace applications an alloy such as 7075-T in preference to 2024-T since fatigue is the usual cause of structural failure.

Aluminum is rather soft, scoring and abrading very easily (Fig. 5). However, recently developed hard oxide coatings help to increase abrasion resistance, and plastic or other bushings and liners (Fig. 6) will prevent serious wear of joints.

Table II

REPRESENTATIVE DATA ON BRACE JOINT WEAR
(All Joints are 2024-T Aluminum Alloy of the Same Design; No Lubrication Used)

	A Shop-Made Joint No Bushing No Liner Machine Tested 1,000,000 cycles	B Prefabricated Joint No Bushing No Liner Worn by Patient 180 Days	C Prefabricated Joint No Bushing No Liner Machine Tested 1,000,000 cycles	D "Mock-Up" Joint No Bushing Plastic Liner Machine Tested 300,000 cycles		E "Mock-Up" Joint Plastic* Bushing No Liner Machine Tested 1,000,000 cycles
				Nylon Liner	Teflon Liner	
Lateral Wear on Aluminum Joint Surfaces	0.090 in.	0.020 in.	0.020 in.	0**	0	-
Wear in Aluminum Joint Bore	0.020 in.	0.004 in.	0.006 in.	-	-	0
Wear on Liner	-	-	-	0**	0.001 in.	-
Wear on Bushing	-	-	-	-	-	0.005 in.

* Bushing was made from Teflon containing molybdenum powder

** Very fine particles of aluminum became embedded in the nylon and started to cause minute scoring of the Aluminum surfaces. The Teflon liner did not show this characteristic. The wear on the aluminum surfaces with both nylon and Teflon and the wear on the nylon liner were less than 0.0005 inches after 300,000 cycles.

Clinical and machine tests have been conducted by the Veterans Administration's Prosthetic Testing and Development Laboratory in which steel and aluminum joints have been analyzed for their *wear characteristics.* In Table II are shown some representative data from tests of aluminum joints. From columns A, B, and C of this tabulation, it can be seen that aluminum rubbing against aluminum can produce appreciable wear on the lateral joint surfaces and in the joint bores. These types of wear are illustrated by the machine-tested ankle joint of Fig. 5. Of special interest in the first three columns of Table II is the correlation of relative magnitudes of lateral and bore wear between clinical use for 180 days and machine tests over 1,000,000 cycles. Lateral wear is consistently from 3 to 5 times as great as wear in the bore. Once substantiated by this type of correlation, the use of controlled and continuous laboratory machine tests is more practical than the more expensive and variable clinical testing procedures.

Magnesium alloys, as seen from Table I, have a lower modulus of elasticity than aluminum alloys as well as a lower density. The special problems in fabricating magnesium, the considerable cross section necessary for adequate strength and stiffness, the relatively high notch sensitivity, and the difficulties in fastening, particularly by screw threads, have all combined with the relatively high cost to limit the use of magnesium in orthopedic appliances. It may, however, be desirable for special cases where a substantial thickness is required for other reasons or where extreme lightness at the expense of stiffness is desirable. Magnesium alloys, particularly those high in copper and nickel, are susceptible to rapid corrosion when immersed in salt water or perspiration. A protective coating must be used to increase the corrosion resistance in such atmospheres.

Titanium has been suggested, and has been used experimentally for a few braces and artificial limb components by the Navy, Army, and Veterans Administration. It is corrosion resistant and intermediate between steel and aluminum in strength, stiffness and weight. The rapidly increasing number of military applications and the research and development both in alloys and in techniques for manufacture and forming may make titanium more widely useful in the next few years as the result of rapid increase in mass production, decrease in cost, and widespread knowledge of fabricating techniques. The Prosthetic Testing and Development Laboratory has fabricated a knee joint using titanium alloy ti-6A1-4V. No difficulty was encountered in machining and working the material with tools ordinarily used by the average orthopedic shop.

Plastics

Methyl methacrylates, such as Lucite or Plexiglas, have a very low modulus of elasticity, but have the advantage of transparency; they are easy to form if uniformly heated. Some of the failures of such appliances in service have undoubtedly been due to the relatively low strength of the material, but others are probably due to an attempt to form the material at too low a temperature or with only the surface sufficiently warmed while material inside still remained cool, leading to concentrated stresses locked in the cooled and completed appliance with consequent possibility of cracking. The considerable thickness of such appliances and the slow rate of heat transfer through the material would be factors in such conditions.

Recently, a Netherlands physician developed simple splints made of *methyl methacrylate* bonded to *polyurethane foam* plastic. The methyl methacrylate is easily heated with an infra-red lamp to a temperature of about 130°C. By using infra-red, to which the material is only partially transparent, it is claimed that absorption of the heat occurs throughout the thickness of the material, leading to rather uniform heating throughout the thickness contrasted to heating of the surface alone in the ordinary oven. The heated plastic can then be moulded directly upon the body of the patient since the foam plastic serves as a heat insulator to protect the patient. The appliance is held in place briefly with a wet plastic bandage, speeding its cooling and fitting in the desired shape. The expense and delays of a plaster cast and plaster model of the body part, necessary for most plastic splints, were thus eliminated.

Polyester laminates have been widely used in both orthopedic and prosthetic appliances, perhaps most effectively in the artificial arm field. Techniques for making plaster models, forming the plastic laminates, and harnessing the completed arms are described in detail in the University of California, Los Angeles, *Manual of Upper Extremity Prosthetics*[19]. It is possible to mix any desired proportions of stiff and flexible polyester resins so as to obtain various combinations of stiffness, strength, and impact resistance of the finished laminate. Strength and stiffness also depend a good deal upon the type of cloth used in the laminate, with glass fiber forming the stiffest and strongest but heaviest assemblage. For many purposes, nylon, Dacron, Fortisan, or cotton stockinette in several layers have been proven entirely satisfactory.

Resins of the *epoxy* type were introduced to the orthopedic field by the Sarah Mellon Scaife Foundation Fellowship on Orthopedic Appliances at the Mellon Institute. These were used with glass fiber fabrics, preferably somewhat loosely woven so that pressure points could be relieved by enough localized reheating to soften the resin, thus permitting deformation of the resin and distortion of the glass fabric. The resins were originally considered to have the advantage of being easy to work but the disadvantage of yielding only a stiff laminate. Recently, flexible varieties have been obtained by mixing flexible polysulphide resins such as Thiokol in the epoxy resin.

A *nylon coating for leather* developed by the Army Prosthetics Research Laboratory has removed the disadvantage of absorption of perspiration by leather[10]. This nylon coating, when properly applied, permits the slow transfusion of water vapor through the leather. Absorption of liquid perspiration with its organic materials by the leather is prohibited by the coating, so there is no longer the problem of breakdown of the organic materials and the consequent development of odor and staining of clothing. In addition, the surface of the leather besides having an increased abrasion resistance remains smooth rather than damp and sticky, reducing the tendency to chafe the skin.

Plastic bushings and liners, as shown in Fig. 6, have been used very effectively in brace parts to meet some of the problems encountered by wearers. The use of these plastic components in joints eliminates wear between metallic surfaces, eliminates the need for lubrication while maintaining a squeak-free and click-free joint, and permits easy and inexpensive replacement of worn bushings and liners with a minimum of mechanical skill. Thus, the expensive metal parts which must be fitted to the individual do not wear, and the inexpensive standard bushings are easily replaced[20]. Standardization of joint design should permit the construction of a relatively inexpensive moulding die to make the bushings at very low cost, a few cents per piece.

In Table II, *Representative Data on Brace Joint Wear,* columns D and E show sample results of wear measurements on a 2024-T aluminum joint (or "mock-up") made especially for checking the effectiveness of plastic liners and bushings. This "mock-up" joint was a duplicate of the shop-made and prefabricated joints of columns A, B and C.

It is apparent from the wear data that plastic liners and bushings such as Teflon or nylon will significantly reduce the wear on the more permanent aluminum surfaces. Even when confined to the relatively soft liners and bushings, the magnitude of wear is not large. The self-lubricating properties of the plastics used probably account for the low values. Throughout 1,000,000 cycles the bushings of Teflon containing molybdenum powder took roughly the same wear which was absorbed by the aluminum joint bore over 180 days of use by a patient (column B). Nylon or Teflon liners, because of the minimal decrease in thickness after 300,000 cycles, would probably contribute significantly to preserving the lateral stability of joints. Other types of bushings and liners of nylon and Teflon with and without additives such as molybdenum powder are still being evaluated in this manner by the Veterans Administration.

Fabrics

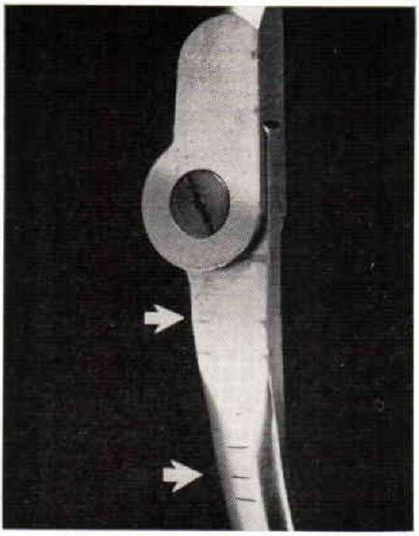
Webbing has usually been made of *cotton,* which was inexpensive and resistant to stretching but which dried so slowly that the patient was not likely to wash the harness frequently. Recently in the artificial arm field, *Vinyon,* "boiled off" *nylon,* and *Dacron* webbings have been used successfully. These synthetic webbings and some of the types of buckles and other hardware which are being introduced for artificial arm harnesses could be adapted to the brace field.

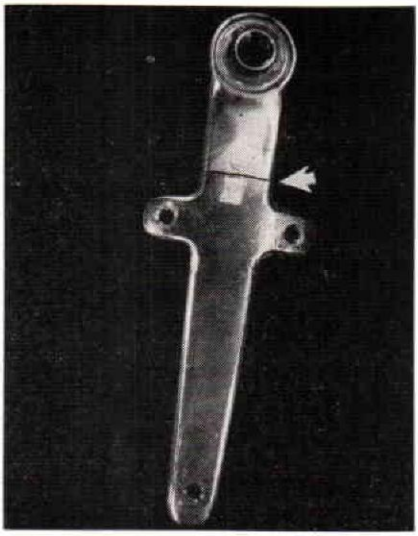
Various synthetic sheeting materials can replace leather for covering bands and cuffs. Some workers have successfully dipped bands in plastisol, to obtain a substitute for padding and covering.

Brace Fabrication and Manufacture

The careful anatomical *fitting* of the brace and the correct alignment of the mechanical axes are extremely important. The orthopedic brace must represent the highest quality of *workmanship.*

Surface nicks such as those caused by bending irons on the component illustrated in Fig. 7, sharp projecting corners, protruding rivet heads or screw heads, poor stitching and upsetting of rivets, defects in plating, malaligned mechanical joints, or excessive length of adjustment straps out of proportion to any reasonable need for future adjustment are indicative of poor or thoughtless workmanship. Fig. 8 illustrates a failure of a prosthetic pelvic joint caused by a name stamp. Another part of the name stamp of the same joint is shown in Fig. 9. Failure by cracking has started in this area also.





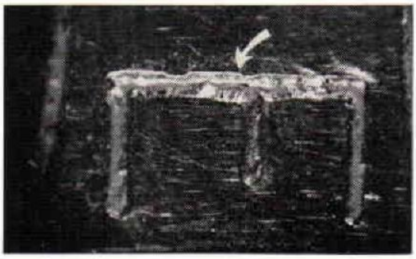


Fig. 7. Bending Iron Marks. Above (left).

Fig. 8. Failure of Structural Component Due to Indentation of only 2% of Thickness by Name Stamp. Above (right).

Fig. 9. Cracking Beginning in Letter "E" of Name Stamp. This Crack would soon have caused failure. At right.

As in any other trade or profession, continuous *education* is essential. Since research and constant change are taking place in the field of brace technology, the brace fitter wishes to become acquainted with newer techniques and improved devices. Publications and formal schooling are media for transferring this information from the research organization to the manufacturer and fitter.

The Veterans Administration has given courses lasting five weeks to the supervisors of practically all the Veterans Administration Orthopedic Shops. These courses, besides offering fundamentals in anatomy, engineering, materials, and the mechanics of materials, provided the means for acquainting the supervisors with new developments in the brace field.

Certification Raises Standards

The American Board for Certification of the Prosthetic and Orthopedic Appliance Industry, Inc., has been an important factor in the constant raising of the professional level of limb and brace fitting. Both individual fitters and the shops or facilities may be certified if found qualified by a unique board composed both of surgeons and of fitters of artificial limbs and braces. The Board has set increasingly high standards for education and has for several years required both written and oral practical examinations for certification. It offers an arbitration system to settle any dispute which may arise.

Studies made by the Veterans Administration's Prosthetic Testing and Development Laboratory have considered the *manufacturing techniques and fabrication methods* in orthopedic bracing[16], [21]. As a result of these studies, use of *prefabricated parts* or parts produced by mass production in one or a very few sizes of standardized subassemblies has been found to yield braces which are more economical yet of superior quality to those made from hand made parts long used in the brace field[22], [23]. Columns A and C of Table II show representative data from machine tests of a shop-made (or hand made) joint and a prefabricated joint of the same design. Because of better tolerance control and smoother machining and finishing, the prefabricated joint showed appreciably less wear over the test period of 1,000,000 cycles.

The central manufacturer of prefabricated parts can afford an excellent design staff, accurate machining and modern equipment, and careful quality control. Provided with prefabricated parts, the orthotist can select and readily assemble a complete brace to meet the requirements of most orthopedic conditions. Finishing of such an assembled brace is, of course, necessary. Fitting the brace to the body contours, polishing (and plating if necessary), and leather work must be performed.

By more widespread use of prefabricated parts certain changes in fabrication techniques and in shop facilities and procedures will result. Eventually, interchangeability of components, even among those of different manufacturers, will result from the use of prefabricated parts. Interchangeability will simplify repairs, especially for itinerant patients. Also, the brace shop will be able to perform repair tasks more quickly and more economically. Since most of the work in producing the brace parts can be done in a factory, a local brace shop will need less space for equipment or may devote some of its space for other necessary services to the patient, such as training. As a result of saving time at the forge or the milling machine, the skilled orthotist or brace fitter will have more time available for self-education, clinic meetings, the more demanding steps of the fitting procedure, training and supervising less skilled workers, and for solving difficult "problem cases."

Following proper fabrication and fitting, *maintenance* of the brace is necessary, essentially to reduce the incidence of repairs and replacements. At home, the patient should periodically check his device and perform any simple repairs. The brace, effectively worn as a structural and functional supplement to his body, should receive similar care. Proper cleaning, even of stainless steel parts, is necessary to prevent material deterioration, both in appearance and in structural adequacy.

Economic Considerations

There has always been pressure to lower the *cost* of orthopedic braces. All too often the patient himself and his family are restricted in paying for braces because of the high costs associated with the prior illness or other condition requiring braces. Many public agencies responsible for supplying braces have tended to secure them from the low bidder, with inadequate specifications because of the difficulties in specifying such intangible factors as comfort for the patient and high skill on the part of the brace fitter. Nevertheless, better braces can be produced at less shop cost, more profit to the brace shop, and yet lower cost for both purchase and maintenance to the ultimate consumer.

The increasing use of *stainless, sanitary and abrasion resistant materials* should help to decrease maintenance. In fact, higher first cost for the small amounts of such materials should prove a very good investment. In general, the cost of materials is only a small fraction of the total cost of the appliance, so the best materials are none too good.

Prefabricated, interchangeable and standardized parts, made in central factories in a limited number of sizes, have already been discussed because of their superiority to most self-produced hand made parts. In addition, however, study at the Prosthetic Testing and Development Laboratory on the cost of fabricating braces by different techniques has clearly shown the superiority of prefabricated parts to self-produced parts in lowering the total cost of the appliance at the shop level[16]. While the cost figures produced in that study do not represent the total cost of the appliance to the consumer since the usual overhead factors as power and light, shop rental, supervisory costs, sales costs, and profit have not been added, the ultimate sale price is usually in proportion to the direct shop cost for materials and labor. Clearly, the necessary unfinished prefabricated brace parts initially cost many times the value of raw materials for the self-produced brace. However, the study showed that because of the great saving in time for the brace maker, an appreciable *saving in total costs* results from the use of prefabricated parts.

The analysis of the present brace fabrication techniques by time study methods also demonstrated the economies of division of labor between a specialized and highly skilled fitter and a less skilled technician to do the more routine operations[21]. This principle is, of course, very widely used throughout all industry, both decreasing costs and increasing the enthusiasm and economically justifiable salary of the highly skilled man who is thus allowed to function at his highest level of capability for a higher fraction of his working day. It is suggested that application of these techniques and principles should help to decrease shop costs for braces as presently made while increasing their quality and the incomes of both fitter and facility. It should thus be possible to meet the problem of constantly rising general price levels and to permit a margin for the introduction of improved mechanisms to give the patient greater function.

Braces, of course, are only a small part of the total cost of care of the patient, and the materials and mechanisms used are even a minor part of the cost of the brace. Perhaps most important to consider is the improvement that can be made in the *comfort and earning power* of the patient, perhaps over many years of productivity by prescription of improvements now available. Elimination of premature and unexpected breakages, reduced wear on joints, more sanitary coating of the leather or replacement by plastics are readily possible. Improvements in the mechanisms so as to replace more nearly the lost functions of the body are steadily being developed. Much can be done with the present knowledge, but constant research and testing towards new designs should be a fine investment paying big dividends in human happiness, in contributions toward a better society, and incidentally in income tax returns.

Conclusions

Economies can be realized by applying engineering principles to orthopedic bracing. Reduction in first cost of the appliance will result from using *prefabricated parts* and a proper *division of labor* in the brace shop. The brace fitter or orthotist will thus be free to handle complex fitting problems and other services which will benefit patients, both economically and functionally. Both he and his facility will justify higher incomes without raising prices.

Careful selection of the proper *brace material* and *brace components* depends on the requirements of the orthopedic condition. A knowledge

TABLE III

Recommended Remedies for Common Problems of Brace Wearers

PROBLEMS	RECOMMENDED REMEDY
1. Desire lighter, less bulky appliances	a. Use of 2024-T aluminum alloy* in non-spastic conditions b. Improved joint design: use of forgings in prefabricated parts made with adequate quality control c. Careful fabrication and fitting
2. Clothing damage by lubricant staining	a. Plastic joint liners and bushings; no lubrication required
3. Clothing damage by joint projections	a. Use of properly designed lever locks whenever possible b. Improved joint design: reduce size of projections in drop-ring knee locks
4. Wear on joint surfaces	a. Use of plastic joint liners and bushings
5. Breakage	a. Use proper material for the orthopedic condition b. Improve workmanship: eliminate tool marks, and give proper consideration to locations of changes in section and holes
6. Inconvenience and cost of repairs	a. Care in machining, fabrication and fitting b. Use of prefabricated, interchangeable components c. Use of plastic joint liners and bushings which can be replaced by the brace wearer at home d. Where bushing is impractical in joint, make joint pivot slightly softer than more permanent component encompassing the joint bore. e. Nylon coating for leather; plastic substitutes for leather; washable straps

* Titanium alloys, as seen from Table I, have physical, chemical, and mechanical properties which will contribute to lighter, less bulky braces. The use of titanium alloys, however, must await a decrease in their cost.

of the properties of the materials and designs should lead to a rational prescription. A correct selection will yield benefits in function for the patient and in reducing the possibilities of structural failures or corrosion.

Workmanship must be of the highest quality both in manufacturing of parts and in fitting of the appliance. Care must be taken to avoid "stress-raisers" in component *design* and in fabrication.

Plastic *liners and bushings* such as nylon or Teflon should be used to eliminate the need for lubrication and to eliminate joint wear. The design of joints should permit the patient to replace worn bushings and liners at home with a simple tool such as a blade-type screwdriver.

Table III, *Recommended Remedies for Common Problems of Brace Wearers*, is a summary of answers for the difficulties commonly encountered by patients, as reported in the two surveys discussed above. Solution of these obvious surface problems, with the help of teams for prescription, check-out, and follow-up, should now permit attack on the basic problems of energy, control, and sensory feed-back, problems so inherent yet apparently insoluble that patients dare not even name them.

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