The Boston Elbow

November 1984

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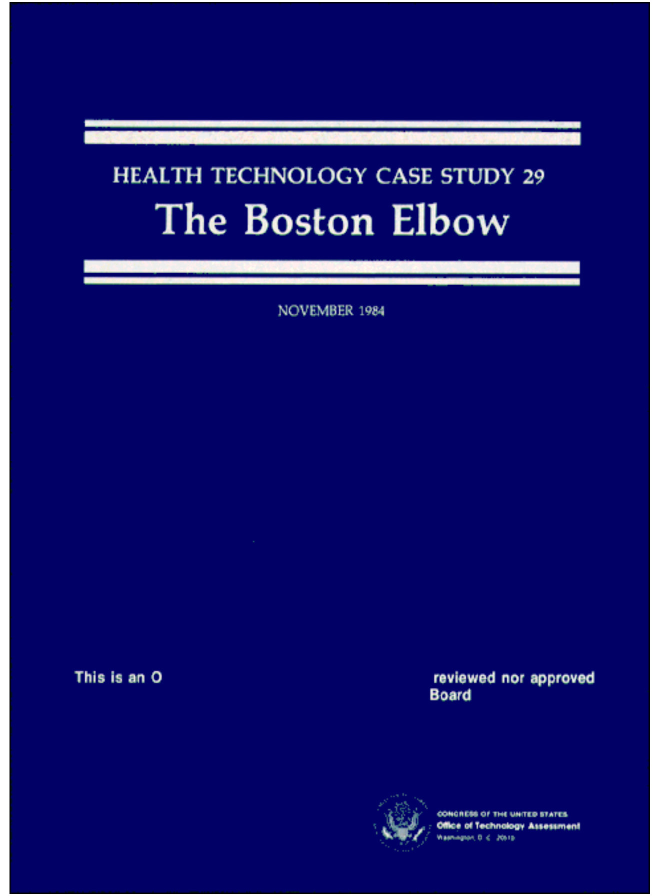

HEALTH TECHNOLOGY CASE STUDY 29

The Boston Elbow

NOVEMBER 1984

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CONGRESS OF THE UNITED STATES
Office of Technology Assessment
Washington, D.C. 20510

HEALTH TECHNOLOGY CASE STUDY 29

The Boston Elbow

NOVEMBER 1984

This case study was performed as part of OTA's Assessment of

Federal Policies and the Medical Devices Industry

Prepared for OTA by:

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OTA Case Studies are documents containing information on a specific medical technology or area of application that supplements formal OTA assessments. The material is not normally of as immediate policy interest as that in an OTA Report, nor does it present options for Congress to consider.

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Preface

The Boston Elbow is Case Study 29 in OTA's Health Technology Case Study Series. This case study has been prepared in connection with OTA's project on *Federal Policies and the Medical Devices Industry,* which was requested by the Senate Committee on Labor and Human Resources and endorsed by the Senate Committee on Veterans' Affairs. A listing of other case studies in the series is included at the end of this preface.

OTA case studies are designed to fulfill two functions. The primary purpose is to provide OTA with specific information that can be used in forming general conclusions regarding broader policy issues. The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall project on *The Implications of Cost-Effectiveness Analysis of Medical Technology.* By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. The design and the funding levels of most of the case studies are such that they should be read primarily in the context of the associated overall OTA projects. Nevertheless, in many instances, the case studies do represent extensive reviews of the literature on the efficacy, safety, and costs of the specific technologies and as such can stand on their own as a useful contribution to the field.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panel to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e. g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies are either prepared by OTA staff, commissioned by OTA and performed under contract by experts (generally in academia), or written by OTA staff on the basis of contractors' papers.

OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated project. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are sent by OTA to numerous experts for review and comment. Each case is seen by at least 30 reviewers, and sometimes by 80 or more outside reviewers. These individuals may be from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists, sociologists, decision analysts, biologists, and so forth, as appropriate, also review the cases.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA's concern with each case study's scientific quality and objectivity. During the various stages of the review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize divergent points of view.

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29	The Boston Elbow; Sandra J. Tanenbaum (OTA-HCS-29)

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[b] Original publication numbers appear in parentheses.

[c] The first 17 cases in the series were 17 separately issued cases in *Background Paper #2:* Case *Studies of Medical Technologies,* prepared in conjunction with OTA's August 1980 report 77re *Implications of Cost-Effectiveness Analysis of Medical Technology.*

[d] Background paper #3 to The *Implications of Cost-Effectiveness Analysis of Medical Technology.*

[e] Background Paper #5 to *The Implications of Cost-Effectiveness Analysis of Medical Technology.*

[f] Background *paper +1* to OTA'S May 1982 report *Technology and Handicapped People.*

[g] Background Paper #2 to *Technology and Handicapped People.*

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Author's Note

The background research on which this case study is based was in large part funded by the Kaiser Family Foundation.

OTA Note

These case studies are authored works commissioned by OTA. Each author is responsible for the conclusions of specific case studies. These cases are not statements of official OTA position. OTA does not make recommendations or endorse particular technologies. During the various stages of review and revision, therefore, OTA encouraged the authors to present balanced information and to recognize divergent points of view.

1
Introduction and Summary

Introduction and Summary

INTRODUCTION

The Boston Elbow is an artificial arm, powered by battery and controlled by signals from an amputees' stump muscles (myoelectric). Electrodes located in the socket of the prosthesis detect the electrical charges that accompany contraction of the stump muscles, A computer in the prosthesis interprets these electromyographic signals and transmits orders to the motor to flex or extend the elbow. The elbow moves at speeds proportional to the intensity of the amputee's muscle contraction. The Boston Elbow thus imitates the flexion and extension of a natural elbow joint.

Despite this technological achievement, the Boston Elbow is worn by only about 100 of the estimated 30,000 to 40,000 above-elbow amputees. In the context of the OTA project entitled *Federal Policies and the Medical Devices Industry,* interest arose in whether this low level of use resulted from characteristics of the device or from policies regarding rehabilitative devices. The case study describes the development and use of the Boston Elbow and compares it to prosthetic and nonprosthetic alternatives. Public policies, such as veterans' benefits, Medicare, and workers' compensation, are examined for their effects on the use of the Boston Elbow and other options. The study concludes that public policies have affected, but have not substantially impeded, the adoption and use of the Boston Elbow. Although the device has certain advantages, it is not clearly superior in price, appearance, and capability to alternatives available to amputees.

It is important to note what this study is not. It is not a discussion of the effects of industrial policy on the "lifecycle" of the Boston Elbow. Nor is it a controlled evaluation of competing above-elbow prostheses. Rather than organizing inquiry around the device, this study focuses on amputees and the social policies that bear on their use of the Boston Elbow. The reason for this approach is the complexity of the Elbow's purpose, i.e., to alleviate disability. Functional impairment due to structural loss, unlike other problems that invite technology's attention, is idiosyncratic, contextual, and, in a technology such as the Boston Elbow, highly conditional and only part of a disabled individual's compensatory strategy.

SUMMARY

The Boston Elbow is technologically distinctive, but it is only one way to compensate for the loss of an arm. The amputee may choose an alternative prosthesis: a body-powered, cable-operated device, an externally powered switch-controlled elbow, or another myoelectric prosthesis. These devices vary in several respects, and each has strengths and weaknesses. The Boston Elbow seems to maximize features that are useful in the workplace; it will lift a relatively heavy object and has the capacity for simultaneous movement of the elbow and terminal device (hook or hand). The Liberty Mutual Insurance Co., a major provider of workers' compensation insurance, financed design of the device and continues to develop and manufacture it.

Other alternatives to the Boston Elbow are nonprosthetic. First, many amputees learn to function without an arm. This does not mean that loss of an arm is trivial, only that humans are immensely adaptable and that prostheses are a poor substitute for the human arm. Second, monetary compensation for functional loss is common, taking the forms of indemnity and income maintenance, Cash benefits help to replace lost earnings and allow amputees to purchase assistance if needed. Adaptation of the environment is a third nonprosthetic option. Vehicles and dwellings can be made more physically accessible to amputees, and legislation can prohibit discrimination against people with disabilities.

Distribution of the Boston Elbow and its alternatives is at least in part a function of public policy, especially the design and implementation of disability benefits. For policy purposes, adults with disabilities seem to fall into three groups—veterans, workers, and citizens—each with eligibility criteria set by law. The group(s) into which an amputee falls determines his or her eligibility for the Boston Elbow and other compensatory options.

The amputee-veteran has many alternatives to the Boston Elbow, including an elbow prosthesis that was originated at the Veterans Administration (VA). As of fall 1983, the Boston Elbow had not yet been approved for VA funding, although an evaluation of all externally powered prostheses was under way.

Amputee-workers face three sets of circumstances. If injured in the workplace, they are eligible for workers' compensation benefits, including monetary compensation and prosthetic devices. They are most likely to be fitted with a Boston Elbow if their employer's insurer is the Liberty Mutual Insurance Co. Workers with long-term disabilities who have paid into the Social Security system receive Disability Insurance benefits in the form of cash payments and Medicare. The latter may provide a Boston Elbow, but program coverage begins 2 years after cash benefits commence. Disabled individuals judged to be potential workers are entitled to enter the Federal/State Vocational Rehabilitation Program and receive services required for their rehabilitation. Potential workers may thus be entitled to a Boston Elbow, but they must compete for limited Vocational Rehabilitation funds.

The amputee-citizen is unlikely to be provided with a Boston Elbow. The Medicaid program in most States provides low-income amputees with prosthetic devices, but these must be "medically necessary" and of reasonable cost. Federal policies do, however, support relevant research by the National Institute of Handicapped Research, regulation by the Food and Drug Administration, and new legislative approaches to disability issues, such as the Rehabilitation Act of 1973.

The Boston Elbow fares differently in different programs. This situation, which is the result of explicit mandates, institutional histories, and ongoing allocation of public resources, can be difficult for the amputee.

The Boston Elbow and other compensatory technologies will almost certainly benefit from the disability rights movement associated with the Rehabilitation Act of 1973. One result of this movement will be more self-aware and assertive consumers of rehabilitation technology.

2.
The Boston Elbow

2.
The Boston Elbow

A DESCRIPTION

The Boston Elbow looks like a whole arm, extending as it does from the wrist (to which various hooks and artificial hands may be attached) to a socket that fits the stump, but only the elbow joint moves.[1] In engineering terms, the arm has one degree of freedom. It reproduces the active movement of the human elbow flexion and extension, but not, of course, other forearm movements such as pronation, supination and flexion or extension at the wrist.

The Boston Elbow is, like some other elbow prostheses (see ch. 3), battery powered. Like a few of them, it is also myoelectrically controlled. This means that electrodes located in the socket of the prosthesis detect, on the surface of the wearer's skin, the electrical charges that accompany contraction of the stump muscles. These electromyographic (EMG) signals are transmitted to and interpreted by a computer housed in the prosthesis, and the battery-powered motor "takes orders" from the computer to flex or extend the elbow. Although any muscle can provide an EMG signal, the Boston Elbow is designed to tap residual biceps and triceps muscles, precisely those that would ordinarily flex and extend the arm. Thus an amputee's control of the prosthesis imitates control of the natural elbow.

The Boston Elbow is both myoelectric and proportional. As such, it moves at speeds directly proportional to the intensity of muscle contraction by the amputee. Proportional control depends on the fact that muscle contraction produces an electrical signal the magnitude of which varies with contraction intensity. This relationship is a continuous one, so by contracting more or less intensely, the wearer of a proportional-control prosthesis produces a full range of signal magnitudes and, after electronic processing, is able to flex or extend the elbow at a full range of speeds.

Fitting a Boston Elbow involves making a cast of the amputee's stump and then a mold to which socket material is shaped. The prosthetist works down from the above-elbow socket with layers of foam and attaches a prosthetic elbow unit that includes a battery-powered motor. The Boston Elbow's forearm houses the batteries and electronics and offers the wearer a choice of terminal devices: a mechanical hook or hand controlled with a roll of the amputee's shoulder, or an electric or myoelectric hook or hand with switch control. The prosthesis is designed so that hook and hand are interchangeable and may be used by the same wearer at different times.

The current Boston Elbow weighs 2.5 pounds. It will lift 5 pounds and hold something over 50 pounds in a locked position. A fully charged battery will power the device for about 8 hours. The prosthesis has a range of 145 degrees, i.e., full flexion is 145 degrees from full extension, and this distance is traveled in a minimum of a second. The Boston Elbow has a 30-degree free swing that lends it a more natural appearance. Even so, the device is not easily mistaken for a human arm, especially because the forearm, which houses batteries and electronics, is noticeably boxy. But neither is the Boston Elbow unpleasant to look at, and its variable speed reduces the robotic aspect. Like many machines, it hums, but the addition of auditory to visual feedback can be advantageous. The prosthesis does not provide tactile feedback, a widely acknowledged (and as yet unrealized) feature of the perfect upper extremity device.

[1] *A Description* was compiled from interviews with Liberty Mutual officials and MIT faculty.

A HISTORY[2]

The Boston Elbow is a cybernetic limb prosthesis, and mathematician Norbert Wiener is considered its "godfather. " Having raised the possibility of cybernetic applications to prostheses in the late 1940s (6), Wiener was moved to reconsider electronic limbs, when, in 1961, he was hospitalized for a broken hip. Wiener's orthopedist at Massachusetts General Hospital was Melvin Glimcher, who also headed the amputee clinic at the Liberty Mutual Insurance Co., a major carrier of workers' compensation policies.

Glimcher had found in his work for Liberty Mutual that below-elbow amputees were using prostheses to recoup much more of their lost functioning than were above-elbow amputees. Even with the most advanced body-powered prosthesis, the above-elbow amputee had to: 1) position and 2) open or close the terminal device sequentially. The single-cable design did not allow for simultaneous execution of these two functions, and the result was unnatural body movements that were unattractive and inefficient. Glimcher visited the Soviet Union where he observed a myoelectric hand prosthesis. When he returned to Boston, he took advantage of Wiener's temporary disability to discuss with him the feasibility of surpassing Soviet technology with a myoelectric elbow. To Glimcher's mind, myoelectric control seemed less necessary for below-elbow amputees, who could function well with conventional devices. As one collaborator on the Boston Elbow project explained, the mission of its creators was and continues to be to make above-elbow counterparts, that is, to allow above-elbow amputees to use a terminal device well.

Weiner encouraged Glimcher's interest in the elbow and put him in touch with two Massachusetts Institute of Technology (MIT) professors, Amar Bose, an electrical engineer, and Robert Mann, a mechanical engineer. By 1965, two graduate theses had been written about the possibility of a myoelectric elbow prosthesis. Both were supported in part by Liberty Mutual, and, in 1966, the company hired two of Mann's former students to develop a real prosthesis from the MIT research. The Boston Elbow Version I was produced in 1968 and made its debut that fall with a press conference at Massachusetts General Hospital. Eighteen Version I Elbows were manufactured. They were by all accounts failures. Every amputee fitted rejected the prosthesis, and a National Academy of Sciences evaluation found the device unsatisfactory (15). The most serious problem was that the first Boston Elbow ran on a battery so large it had to be mounted on the wearer's belt.

At about the same time, another MIT graduate student was modifying the Elbow's design to incorporate a battery into the prosthetic forearm. Liberty Mutual hired this engineer when he finished his training, and he went on to build 25 Boston Elbow prototypes during his l-year tenure with the firm. In 1973, Liberty Mutual added a production engineer to the project, and in 197'4, 25 working prostheses were manufactured. Twelve of these are still being worn. A batch of 100 Boston Elbows followed in 1976; these featured a slimmer forearm and more reliable electronics. One hundred still slimmer and more reliable prostheses are being sold at this time. Liberty Mutual itself manufactures the Boston Elbow. The electronic components are supplied by small firms in the Boston area.

Neville Hogan, a mechanical engineer at MIT, conducts further research on the Boston Elbow. He maintains that the usefulness of the device is limited by the fact that, unlike the natural arm, the Boston Elbow is rigid. It is not, in Hogan's words, "floppy" or "springy" and so does not respond to the press of other objects the way the intact arm does, i.e., with variable force. Hogan proposes to design a Boston Elbow with the same viscosity, stiffness, and inertia as the natural limb. In addition to imitating more exactly the characteristics of the human arm, a floppy Boston Elbow might be positioned more accurately without tactile feedback. Recent research in neurophysiology (4) suggests that animal subjects deprived of all sensory information about a limb are able to return it to its resting position when a human investigator pushes it away. Presumably this occurs because the muscles return the limb to the posi-

[2] *A History* was compiled from interviews with Liberty Mutual officials and MIT faculty.

tion dictated by the balance of normal tension of opposing muscles. Although tactile data are widely thought to be critical to positioning an artificial limb, such feedback continues to elude bioengineers. Hogan believes that floppy arms will enable amputees to function well without it.

AN ASSESSMENT

In 1983, approximately 100 amputees wore Boston Elbows, and, for them, as Glimcher had hoped, elbow flexion and operation of the terminal device were simultaneous. But the Boston Elbow might have been expected to have been more widely diffused by now, and skeptics wonder about the value of the device.

Assessing the diffusion of the Boston Elbow requires knowledge of its clientele. Unfortunately, data specifically about above-elbow amputees are relatively scarce. The number of upper extremity amputees (both below- and above-elbow) in the United States is usually set at 75,000 to 100,000 (19). It has been estimated from data collected in 1967 (9) that 43 percent of the total number of upper extremity amputations (in some cases bilateral) are above-elbow, and the 1977 National Health Interview Survey (43) found the number of arm (as opposed to hand) amputees to be about 53,000, or 58 percent of all upper extremity amputees. More plentiful and timely data are available about limb amputation generally, but lower extremity amputation is far more common—at least three times as common—as upper extremity amputation, making combined statistics unrepresentative of the latter. Loss of an upper extremity usually results from trauma and that of a lower extremity from disease. Thus, above-elbow amputees are likely to be younger than their lower extremity counterparts and to be in better general health.

Amputation denotes loss of an extremity from any cause. It is estimated that 9 percent of the above-elbow amputations in this country are congenital (see table 1). Eight percent result from tumors, 6 percent from disease, and 77 percent from trauma. There were 773 trauma-related, upper extremity amputations identified in a sample drawn from case records provided by 44 prosthetics facilities in 30 States. (Only amputees fitted with prostheses were included.) Industrial, farm, and automobile accidents accounted for almost all amputations in women and 68 percent of amputations in men, who are far more likely than women to lose an arm for any reason (9). The typical above-elbow amputee, then, is a young male who has been injured in some way (see table 2).

Table 1 .—Causes of Upper Extremity Amputation

Congenital	8.9°\0
Tumor	8.2°/0
Disease	5.8°/0
Trauma	77 °/0

SOURCE E. J. Davies, B R. Fnz, and F. W Cl!pplnger, "Amputees and Their Prostheses, " *Artificial Limbs* 14(2) 19-48, 1970

As in all evaluative undertakings, asking the right questions about the Boston Elbow is critical, especially in this case study, because, surprisingly, the objectives of prosthetic technology are not obvious. "It is manifestly unrealistic to think one could write down all the criteria and performance specifications of the normal arm and hope even to begin to be able to reproduce them in a man-made device" (23). Any prosthesis, then, will embody only some subset of the original functions of the human arm; choosing among them is a complex process. Judgments must be reached again and again as new needs materialize, and the

Table 2.—Traumatic Amputation by Cause

	Male	Female	Total
Car	73	12	85
Industrial	253	10	263
War	58	0	58
Farm	164	7	171
Train	18	1	19
Gunshot	46	5	51
Thermal	19	3	22
Lawnmower	5	2	7
Other	87	10	97
Total	723	50	773

SOURCE E J Davies, B R Friz, and F W Cllpplnger, "Amputees and Their Pros. theses, " Artficial Limbs 14(2) 19-48. 1970

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real priorities may be evident only after a provisional device has been fitted (20).

The variety of possible approaches to the design of an arm is startling. First, there is the gross dichotomy between efforts to start from first principles and those directed at improving existing prostheses (12). A more specific list includes simulation of normal arm movement, recreation of command outputs and sensory inputs, and design for specific tasks (23). Goals of functional and cosmetic replacement frequently conflict, and the goal of economy further complicates the choice.

Evaluating the results of the design process means raising these issues again. Should evaluation focus on how well the prosthesis is engineered, how much functioning it restores, how easy it is to use, or simply how satisfied its users are? Even the most comprehensive study entails choosing how to weight the several factors. One engineer notes that because explicit evaluation of prosthetic limbs means attending to so many factors, design decisions are often made intuitively (14). Another anticipates that in the face of all the things a natural arm can do, "each worker will seize on a particular feature he wishes to sustain . . . and a multiplicity of attempted 'solutions' is inevitable" (23). It would be difficult to overstate the divergences of viewpoint expressed by the prosthetics experts interviewed for this study. What was a critical feature for one was a red herring for another, and, although some disagreements rested on data, others concerned ideas about what an artificial arm should be expected to do.

The Boston Elbow is one attempted solution to the problem of amputation. The overriding concern of those who created it seems to have been what Mann calls "innateness" (20) —i.e., the extent to which control of the device imitates control of the natural arm. As described above, the Boston Elbow taps the amputee's residual biceps and triceps muscles—the very muscles that control the human elbow. Innateness is further served by the proportionality of the Boston Elbow, which gives the wearer control of the speed of the elbow movements, and by the independent operation of the elbow and terminal device. Theoretically, innateness makes a prosthesis easier to use. To the extent that it mimics the natural arm, amputees already "know" how to use it. A prosthesis that acts like an arm is also arguably more assimilable into the amputee's body image.

On the other hand, innateness often trades off against "access" (20), the latter meaning accessibility to the user—how easy it is to understand and maintain, how safe and convenient it is to use. The Boston Elbow is less accessible than it is innate. Although it is perfectly safe, the device is technically complex and requires specialized components and personnel for maintenance. An Elbow needs attention on the average once a year, and on these occasions the prosthesis must be returned to Liberty Mutual. Because the Boston Elbow is **a** battery-powered device, it must also be recharged after about 8 hours of use, and complete recharging is a 2-hour process (see table 3).

Anecdotal data seem to confirm this mixed evaluation. All of the several Boston Elbow owners contacted for this study found the device useful, some extremely so, and those who had used other prostheses as well found the Elbow a significant improvement. Users reported that they could do more things more easily with the myoelectric device, although two owners who were not wearing their Boston Elbows had experienced mechanical failure and were unable to return to Boston for repairs. Apart from this, the most common complaints were about the Elbow's noisiness and weight, both of which were said to be greater than those of a conventional prosthesis. Still, neither of these factors deterred any of the owners from using their Boston Elbows, and most owners considered the devices to be helpful to them in doing their jobs. An accountant and lawyer found the Elbow to be of some importance; a benefits examiner, a technician at a utility company, and a machine operator said it was very important; but a janitor gave up wearing his Boston Elbow for heavy work because this activity drained the battery too quickly. It should be noted that almost every owner contacted was a worker's compensation client and therefore did not pay for his prosthesis directly.

The cost of the Boston Elbow is $3,500. When it has been fashioned into an artificial arm and fitted to an amputee, the cost rises to an average

Table 3.—Elbow Prostheses[a]

	Boston Elbow	Cable Elbow	VA Elbow	Utah Arm
Power	battery	body	battery	battery
Control	myoelectric	mechanical	switch	myoelectric
Proportional	yes	yes	no	yes
Number of powered joints	1	o	1	1
Weight	2.5 lb	1.51b	1+ lb	2 lb 1 oz
Lift	51b	very variable	31b	2+ lb
Hold	50 lb	very variable	10lb	50 lb
Speed	1 second	very variable	1.5 seconds	0.5 seconds
Range	145°	165°	135°	135°
Free swing	30°	total	120'	total
Repair cycle	l/yr	Ilyr	1.51yr	2/yr
Repair local	no	yes	some	yes
Time without recharge	8 hours	NA	8 hours	8 hours[b]
Recharge time	2 hours	NA	2 hours	16 hours
costs:				
Elbow	$3,500	$ 400	$ 900	$10,000
Fitting and other costs	$6,000	$1,100	$1,100	$10,000
Total (includes socket, fitting, etc)	$9,500	$1,500	$2,000	$20,000
Annual repair	$ 250	$ 25	$ 100	$ 150
Service Life	5 years	10 years	10 years	6 years

[a]Data for powered arms provided by manufacturers Data for cable arm provided by independent prosthetist Alldataar eapproximate Experts disagree about the importance of these features
[b]But Immediately replaceable so can run 24 hours per day

SOURCE S J Tanenbaum, Brandeis University, 1983

of about $9,500. The cost effectiveness of the Boston Elbow is harder to determine. An engineer at the National Institute of Handicapped Research describes the prosthesisas "essentially overkill,' i.e, an unnecessarily complex technology at a cordespondingly high price. Is the extent to which the Boston Elbow outperforms conventiona! pros thesesso great as to warrant the difference in its cost? He believes not. But proponents of the Boston Elbow and other myoelectrically controlled arms assert that the enhanced innateness of the devices more than justifies their high price.

Whether the marginal benefits are worththe extra costs is ultimately a very personal calculus. Functional loss is idiosyncratic and contextual; loss of an arm means different things to different people and to the same individuals over time. Thus a long and elaborate evaluative study of below-elbow prostheses concludes:

> The mental load, gain in function and acceptance cannot be described with one single scalar quantity. It is therefore not possible to"give a general rule for selection of a prosthesis on the basis of these variables, because of the fact that each individual amputee appreciates and weights the various aspects of these quantities differently. . . (32).

These remarks apply as well to the above-elbow amputee's alternative responses to functional loss.

3.
Alternatives to the Boston Elbow

3.
Alternatives to the Boston Elbow

PROSTHETIC ALTERNATIVES

There are three major prosthetic alternatives to the Boston Elbow. In order of technical sophistication they are: the conventional, body-powered elbow prosthesis; a switch-controlled electric elbow; and another myoelectrically controlled arm, Each can be found in a small prosthetics market, where five firms account for 95 percent of the sales, and sales to prosthetists were an estimated $31 million in 1981. About 55 percent or $17 million was spent on upper extremity prostheses, although (less costly) lower extremity devices were bought in larger numbers. An estimated $5 million was spent on *above elbow* prostheses in 1981 (37).

The largest prosthetics firm by market share is Otto Bock, U. S. A., a division of a West German company. Bock, U.S.A. reported earnings of $11 million in 1981, and this represented about one-third of all U.S. prosthetics industry earnings. The firm does not make elbows, although it does furnish prosthetists with switches to be used in assembling elbows made by other companies. A myoelectric hand prosthesis is one of Bock's most widely used products (37).

The body-powered elbow is the oldest and most frequently worn of the above-elbow prostheses. It is designed so that a steel cable running the length of the arm is under the control of the amputee, who rolls his or her shoulder to flex the elbow and relaxes to allow gravity to extend the prosthesis.

A body-powered prosthesis is not an innate device. It requires unnatural shoulder movements on the part of the user and does not permit the elbow and terminal device to operate at the same time. Because the prosthesis is powered by the amputee, it *is less* powerful than prostheses with batteries and less likely to be good for lifting and holding. On the other hand, the cable-operated arm is lighter than most externally powered devices (see table 3 in ch. 2), and weight is an important consideration for most amputees. A conventional elbow is also virtually noiseless and has a relatively long life of more than 10 years. Its cost is about $400 for the elbow alone and $1,500 fitted to the amputee.

The Hosmer Dorrance Corp. sells the largest number of body-powered elbows. Hosmer is the second largest firm in the prosthetics market, with earnings of $7 million in 1981 (37). In 1983 Hosmer began to market a switch-controlled electric elbow as well.

All commercially available externally powered elbows are electric, that is, they run on batteries. Means of controlling the prostheses differ, however. A control mechanism less sophisticated than the Elbow's is the pull-switch found on the Veterans Administration (VA) Elbow (sometimes called the VA Prosthetics Center or VAPC Elbow). Amputees are able to turn pull-switch prostheses on and off with very slight shoulder movements and, of course, need not power the device themselves. The VA Elbow weighs less than the Boston Elbow (table 3) and has a slimmer forearm. But the VA Elbow is not proportional, so it moves at only one (relatively slow) speed. Nor is it strong enough to lift more than 3 pounds or hold more than 12 pounds. The cost of the VA Elbow is $900 alone and about $2, 000 fitted to the amputee.[2] It was designed at the VA but is manufactured currently by Fidelity Electronics, the third largest manufacturer of upper extremity devices. Fidelity offers an externally powered hand as well as the VA Elbow and earned an estimated $1 million from the manufacture of limbs in 1981 (37).

The Utah Arm is the only commercially available myoelectric alternative to the Boston Elbow.

'Unless otherwise noted, data for *Prosthetic Alternatives* are from interviews with prosthetists and manufacturers, and promotional materials from the latter.

"'Fitted to the amputee" includes such items as socket and training.

It is, in fact, progeny of the latter, having been designed by Stephen Jacobsen, who studied with Mann at MIT. Jacobsen's original idea was to extend the logic of the Boston Elbow to multiple arm functions. He found that myoelectric control was possible not only with biceps and triceps muscles but with muscles around the shoulder as well. These "anticipate" what joints such as the elbow are about to do. The Utah Arm is designed to use this information for as full a set of arm functions as possible. At present, the elbow is still the Arm's only powered joint (excluding a powered terminal device, which may be worn with a Boston Elbow as well). The Utah Arm elbow costs $10,000 alone and an average of $20,000 fitted to the amputee. It is manufactured by a firm called Motion Control, which was founded by Jacobsen in 1974 for the purpose of marketing the Utah Arm.

The Boston Elbow and the Utah Arm are derived from the same idea; as a result, both are myoelectric and proportional. They do, however, diverge at several points, and these differences seem to indicate a divergence of objectives as well. First, the Utah Arm is a more attractive prosthesis than the Boston Elbow. The former has a slimmer forearm and is less noisy, and because it has completely free swing, the Utah Arm is also more natural looking. The Boston Elbow, in contrast, has a boxy forearm and only 30 degrees of free swing. It weighs more than the Utah Arm but will lift more weight. The makers of the Boston Elbow favor a capacity for simultaneous movement of the elbow and terminal device— this having been Glimcher's concern in initiating the Boston Elbow project. When the Utah Arm is worn with a powered terminal device, the 2 degrees of freedom have a single control site and therefore can be operated only sequentially. The Arm thereby loses what, at least according to Glimcher, is an important aspect of functioning. Technically, the Utah Arm and the Boston Elbow both can be wired for simultaneous movement of the elbow and the terminal device or for single-site control. Liberty Mutual has chosen to implement the first and Motion Control, maker of the Utah Arm, the second option.

An additional point of contrast is that the Boston Elbow will run for about 8 hours and then requires 2 hours of recharging, during which time the amputee must do without it. The Utah Arm runs for about the same amount of time (half as long if a powered terminal device is being worn), but the battery pack can be removed for recharging and replaced on the spot with batteries that are fully charged. This means that although recharging the Utah Arm takes 16 hours as opposed to 2 hours for the Boston Elbow, users of the Utah Arm can acquire a sufficient number of batteries and chargers to have a functional prosthesis whenever they wish.

The Boston Elbow emerges from this discussion as a "worker's" arm. If it is to be worn primarily at work, cosmetic strengths may be less important than functional ones, and 8 hours of power are likely to be enough. Liberty Mutual also markets the Boston Elbow as a worker's arm. Promotional materials feature a photograph of a middle-aged man in a tie repairing a television set. The caption reads: "Soldering requires the precise positioning of both the solder and the iron. " Later in the same advertisement, the Boston Elbow battery is described as powering "a full 8-hour workday." The Utah Arm brochure, in contrast, features a young woman in blue jeans who is shown socializing with other young people. In correspondence for this study, a Liberty Mutual official listed Boston Elbow wearers by name, address, and occupation. One retired amputee whose Elbow needed adjustment said he would not return to Liberty Mutual for the repair because younger people deserved the firm's full attention. In conversation about the same man, a Liberty Mutual official indicated that his own interest in making the repair was diminished because the amputee no longer needed the prosthesis for work.

A work orientation is not implicit in above-elbow prosthetics. In a limited number of interviews, Motion Control officials spoke consistently about reproducing the human arm, about building a device that feels real to the amputee. Work is, however, the lens through which Liberty Mutual views its prosthesis—hardly surprising given the firm's interest in the workers' compensation insurance market and the fact that the Boston Elbow's development and refinement themselves took place among workers' compensation clients. These were individuals who had been injured in the workplace, and whose reemployment was at the heart of the rehabilitation process.

Photo credit: Motion Control, Salt Lake City, UT

Photo credit: Liberty Mutual Insurance Co., Boston, MA

Photo credit" Ltberty Mutual Insurance Co , Boston, MA

Left: This woman is wearing a Utah Arm, which has a slim forearm and a completely free swing. Top right: The Boston Elbow, which this man is using, was originally developed to facilitate reemployment of people who had been injured in the workplace. Botton right: A person using a Boston Elbow, shown here, can simultaneously move the elbow and the terminal device

NONPROSTHETIC ALTERNATIVES

Some alternatives to the Boston Elbow are not limb prostheses at all. Many amputees, for instance, learn to function with one arm. Some learn by trial and error. Others work with occupational and physical therapists. It is estimated that approximately half of the above-elbow amputees decline to wear a prosthesis. Although some rehabilitation professionals consider this defeatist and unacceptable, even prosthetists admit that it is possible, with good training, to do most of what is essential with one arm. Loss of the upper extremity differs from that of the lower on just this point. Legs do things in pairs, while a single arm can function independently. Amputees who have lost both arms of course have a greater need for prosthetic devices.

Not wearing a prosthesis can have a psychological as well as physical aspect. Rehabilitation entails psychic accommodation to a new reality, and coming to terms with functional loss can lessen the need for and desirability of an artificial limb. One blind speaker told a recent workshop that the approach of rehabilitation technology to disability was counterproductive and certain to fail. Technology, he argued, serves only to impede adaptation, which he defined as a set of compensatory behaviors and beliefs (17). Some amputees feel that not wearing a prosthesis is more self-affirming. Max Cleland, for example, a triple amputee and former head of the Veterans Administration, related that he was relieved when his physician ordered him off his artificial legs. Wearing them, according to Cleland, was a matter of "machismo," something he had to get over before he could love himself again (7). Other amputees forego a prosthesis to make a political statement—to make able-bodied people come to terms with the physical impairments of others.

That above-elbow amputees sometimes decide against prosthetic devices is in no way an indication that their loss is trivial. One need only tie an arm behind one's back to discover how great a functional loss upper extremity amputation is. Rather, abstention from prostheses testifies to the adaptability of human beings and to how poor a substitute devices are for the human arm.

Money is a second kind of nonprosthetic compensation for the loss of an arm. Private and public programs provide amputees with monetary benefits designed to mitigate impairment; these replace lost earnings and purchase services for amputees should they require help. Money may come in two forms, indemnity and income maintenance. An indemnity is a previously established sum considered fair compensation for a specific anatomical loss. Thus, every individual with the same amputation receives an indemnity payment of the same amount from any one program. Benefits are set to reflect lost wages in a very general way, but an indemnity is not means-tested. An amputee receives the full sum regardless of his or her employment status or assets. As will be discussed further in chapter 4, veteran disability compensation and most worker's compensation programs provide indemnity benefits.

The second form of monetary compensation is income maintenance. This is a program of cash transfers, usually scaled to need and based on the assumption that impairment has a negative effect on labor force participation. Benefit levels are set to provide for basic needs, but because amputees' earnings may make them ineligible for the program, income maintenance is widely thought to be a disincentive to work. Veterans pensions, Social Security Disability Insurance, and Supplemental Security Income pay income maintenance benefits. They will be discussed more fully in chapter 4.

Yet a third alternative to prosthetic arms is to adapt the environment in which the amputee lives and works. Environmental strategies may seem more appropriate for people in wheelchairs than for upper extremity amputees, but the latter can benefit from automobile adaptation, specialized kitchen and bathroom equipment, and assistive devices such as a button hook or an adapted telephone. Moreover, environmental modifications may be social as well as physical, i.e., they may mitigate functional loss by modifying the human relationships in the amputee's environment. Rehabilitation legislation of the last decade, for example, has outlawed discrimination against people with disabilities by some employers and service providers. This makes jobs and services more accessible to amputees, which in turn has monetary and social benefits. Specific environmental programs will be discussed in the next chapter.

To summarize, the above-elbow amputee has both prosthetic and nonprosthetic alternatives to the Boston Elbow. Each replaces some of what was lost with the arm. None provides complete restoration.

4
Public Policy and the Boston Elbow

4. Public Policy and the Boston Elbow

Public policy plays a part in the distribution of the Boston Elbow and its alternatives. The design and implementation of disability policy especially exert considerable influence on the way(s) in which someone who loses a limb may compensate for it. U.S. disability policy is complex, not the least because it is actually many policies addressed to different classes of disabled persons. Adults with disabilities seem to fall, for public policy purposes, into three major groups—veterans, workers, and citizens—each with eligibility criteria set by law. These classes of beneficiaries and the disability benefits to which they are entitled will be discussed more fully below. Suffice it to say here that the group(s) into which an amputee falls determines both his or her eligibility for the Boston Elbow and the availability of alternative measures for coping with the loss of an arm.

THE AMPUTEE= VETERAN

All veterans with honorable or general discharges are eligible for veterans benefits. Although the exact number of above-elbow amputee-veterans is not known, there were about 4,600 receiving service-connected disability compensation for loss of one or both upper extremities in 1980 (45). (A service-connected disability is one that results from an injury or illness suffered while in the armed services.) According to the Veterans Administration (VA), approximately 135 above-elbow amputees are reported to have externally powered prostheses of some kind, but Liberty Mutual reports that only two or three could be Boston Elbows. The Veterans Administration offers its own Elbow and has not yet approved the Boston Elbow for general distribution by the VA.

The veteran-amputee receives prosthetic services through amputee clinics in VA hospitals. Clinic teams of physicians, physical/occupational therapists, prosthetists, and counselors meet with the amputee to decide which if any prosthesis should be prescribed. They choose primarily among devices that have been approved for contract, i.e., for purchase at a specific price, by the Prosthetic and Sensory Aids Service (PSAS) of the VA. The PSAS decides on contract items on the basis of evaluative research conducted by the VA and other investigators. In some cases, amputee-clinic staff may recommend a prosthesis that has not yet been evaluated. VA Central Office (in Washington, DC) is asked to rule on these cases individually and may approve unapproved devices on a case-by-case basis (38).

The PSAS is said to be evaluating the Boston Elbow and other externally powered arms at this time. One VA official suggested that the Boston Elbow was not evaluated sooner because of the VA's commitment to its own Elbow. More than one member of the VA's Prosthetic Technology Evaluation Committee expressed favorable attitudes toward the Boston Elbow and the Utah Arm. They were less positive about the VA Elbow.

Like other amputees, the veteran has nonprosthetic alternatives. First, the VA provides monetary compensation for functional loss and pays both indemnities and income maintenance. The veteran whose amputation is service-connected receives veterans' "compensation," a monthly sum scaled to the amount of disability suffered. As an indemnity, veterans' compensation is received regardless of the beneficiary's financial situation and whether or not he or she wears a prosthesis. Amputee-veterans who have lost a dominant arm above the elbow while in the service are rated 90 percent disabled and as of October 1982 received $729 a month in tax-free compensation (11,44).

On the second track of VA cash benefits, "pensions" are provided to some disabled veterans. Low-income veteran-amputees whose amputations are not service-connected and whose age and functional loss constitute total and permanent disability receive monthly payments that vary inversely with income. Unlike disability compensation described above, pensions are means-tested (and so unlikely to accrue to service-connected disabled veterans, who receive relatively large indemnities); the recipient must file only a simple yearly income report that is generally not subject to investigation by the VA. Although annual pensions are admittedly small, with a maximum for veterans without dependents of about $5,000 (46), they are relatively easy to obtain and keep (27,34). Pensions, like veterans' compensation, do not bear directly on the use of prostheses, but they do represent another way to compensate for the same functional loss.

Disabled veterans are eligible for environmental modifications, as well as monetary benefits. Upper extremity, service-connected amputees are entitled to as much as $4,400 for the purchase of an automobile or other vehicle plus adaptive equipment (46). When the veteran is a unilateral amputee injured on the right side and not using a prosthesis, for example, the VA believes he or she can operate an automobile with an automatic transmission and left-handed steering knob, directional signals, and parking brake (36). The amputee-veteran's social environment, which comprises interactions with people and institutions, is also modified, The Vietnam Era Veterans' Readjustment Assistance Act of 1974 (Public Law 98-77), for example, requires that all Federal agencies establish affirmative action plans to facilitate the disabled veteran's reemployment (46). Section 402 of the act extends to discrimination in the private sector. Employers with Federal contracts of $10,000 or more may not discriminate against disabled veterans and must take affirmative action to employ and advance them. Among the benefits of veteran-amputees, then, are "concessions" regarding their physical and social environments, adaptations that may lessen the necessity or desire for a prosthesis.

The final nonprosthetic alternative to the Boston Elbow is learning to function with one arm. There are incentives that weaken or strengthen the likelihood that the amputee-veteran will choose this course. The veteran is entitled to a prosthesis and encouraged to wear one. If his or her amputation is service-connected, the benefit is two prostheses of the same or different types and their replacements (38). But veteran-amputees are also entitled to long-term physical or occupational therapy and vocational rehabilitation (46), and so have the opportunity to maximize their functioning without a prosthesis.

In either case, the amputee-veteran has a great many alternatives to the Boston Elbow, including an externally powered prosthesis originating at the VA. As things stand now, amputees and their physicians may request approval for Boston Elbows on a case-by-case basis. Once PSAS has completed its evaluation, the Elbow's status in the VA system will be resolved.

THE AMPUTEE-WORKER

The amputee-worker encounters public disability policy under three sets of circumstances. First, almost all workers with work-related injuries or disease are eligible for workers' compensation benefits. Secondly, workers with total long-term disabilities who have paid into the Social Security system receive Disability Insurance benefits including Medicare. Finally, disabled individuals judged to be potential workers are entitled to enter the Federal/State Vocational Rehabilitation Program and receive the services their rehabilitation requires. The Boston Elbow is treated differently in each set of circumstances.

The Workers' Compensation Beneficiary

Workers' compensation is a State program. (Although the U.S. Congress has on several occasions considered setting Federal standards for workers' compensation benefits, legislation to this effect has never been passed.) The program varies greatly from State to State, but in most places, private companies, such as Liberty Mutual, write and handle workers' compensation insurance policies. Employers pay premiums that cover the cost of the program and in turn are represented in all claims by their insurers. Benefits are paid when an individual can show that illness or injury has resulted from his or her work; payment is predicated on the understanding that illness and injury result in functional loss and that this functional loss is compensable (25).

Amputee-workers receiving workers' compensation benefits are almost always eligible for prosthetic devices. (Specific examples below are drawn from Massachusetts workers' compensation law.) It is usually the amputee's physician who decides in favor of one prosthesis or another, and the State in which the injury occurred is relevant to his or her decison. In some States, workers are entitled to a single prosthesis only, even if it fails. In others, such as Massachusetts, prostheses are provided for the rest of a worker's life. Not only is a wornout device replaced, but changes in the amputee's stump are accommodated. The amputee-worker from a one-prosthesis State may not derive much benefit from an externally powered device such as the Boston Elbow, with a service life of only 5 years. Similarly, such a sophisticated arm is more likely to require expert repair. Thus, the Boston Elbow is probably not appropriate for an amputee who has neither a backup prosthesis nor the availability of expert repair (16,21).

Still, workers' compensation is the program for which the Boston Elbow was designed. As detailed in chapter 2, the device was conceived at the Liberty Mutual Insurance Co. when the firm's orthopedist resolved to improve the rehabilitation of above-elbow amputees. Liberty Mutual is the largest writer of workers' compensation insurance in the world. Glimcher treated mostly beneficiaries of this program, who are still more likely than other amputees to wear a Boston Elbow. Liberty Mutual's interest in prosthetics is most clearly viewed through the lens of the workers' compensation benefits and the competitiveness of the insurance market itself.

Cash benefits are the mainstay of workers' compensation. In Massachusetts, they take the two forms previously mentioned: indemnity and income maintenance. First the disabled worker receives payment for his or her specific anatomical loss, which itself is considered in two parts: functional loss and disfigurement. In the case of the amputee-worker, functional loss of the dominant arm means a fixed payment, or indemnity, which in 1983 was $9,000. The maximum disfigurement benefit for an above-elbow amputee was $6,600 in 1983. (Note that Massachusetts workers' compensation benefits acknowledge multiple aspects of the lost arm.) Neither wearing a prosthesis nor returning to work bears on the size of this one-time award (18,21).

The second form of workers' compensation cash benefits is weekly income maintenance, temporary and permanent. Usually the amount received is a percentage of the recipient's former wage up to some cumulative maximum. In Massachusetts, the benefit for temporary total disability is two-thirds of the workers' average weekly wage or about $300 (in 1983), whichever is less. Temporary partial disability is considered to exist when beneficiaries are capable of working, but at lower wages than they were being paid when they became disabled. The benefit in this case is the difference between the old and the new wage. After 250 weeks of temporary income maintenance payments, a worker must be judged permanently and totally disabled or be dropped from the workers' compensation rolls (18,21).

An important difference between the two forms of workers' compensation cash benefits is that income maintenance is paid only as long as the amputee-worker is unable to work. If a prosthesis such as the Boston Elbow can return an amputee to work or mean the difference between partial and total disability, the workers' compensation insurer stands to gain from the availability of the device. Moreover, since workers' compensation premiums are experience-rated—i .e., employers' premiums vary with the amount of benefits paid to their employees—firms are likely to choose an insurer who in whatever way minimizes benefits paid. Income maintenance might serve as a disincentive to wear a Boston Elbow. If the device means a reduced level of benefits, the amputee might choose not to wear it. But according to a member of the Massachusetts Industrial Accidents Board, a workers' compensation beneficiary whose employability is enhanced with a prosthesis is expected to wear one.

The Boston Elbow is good for Liberty Mutual in another way. The company has for many years distinguished itself by conducting research on industrial and automobile safety. Similarly, the firm has its own Rehabilitation Center, located in Boston but open to workers of all Liberty Mutual clients. In this context, the Boston Elbow maybe taken as evidence of the company's commitment to research and restoration. Potential clients are undoubtedly drawn to such an insurer, and Liberty Mutual personnel in several capacities deem the Boston Elbow a successful effort to differentiate Liberty Mutual from other insurers. On the other hand, Liberty Mutual may hesitate to diffuse the device to competing workers' compensation insurers. One Liberty Mutual official describes the situation as "touchy," one that evokes the firm's mixed motives: to diffuse the Elbow and to protect its distinctiveness. Similarly, other insurers have not been willing to buy the Boston Elbow; that would make them customers of a competitor.

The Social Security Disability Insurance Beneficiary

Workers who suffer total, long-term disability are eligible for Social Security Disability Insurance (SSDI) benefits if they have paid into the Social Security system during at least half the 40 quarters preceding their claims. SSDI beneficiaries receive cash payments based on past earnings and after 2 years are also eligible for the Medicare program. Unlike VA and workers' compensation programs described above, SSDI does not recognize partial disability. Claimants are either totally disabled or not disabled at all. If the disability is expected to last at least 12 months or result in death, the claim is paid. An average wage-earner with a nonworking spouse and two children received an annual SSDI benefit of $4,470 in 1978 (5).

Medicare provides the SSDI beneficiary with prostheses and occupational or physical therapy. Outpatient therapy and medical devices are covered at 80 percent of their "reasonable" cost under Medicare Part B, and the beneficiary may choose to wear a prosthesis or learn to function with one arm. Medicare, however, will not pay for every prosthesis. A device must be "medically necessary"—it must provide functional replacement for a lost limb, it must be the most basic replacement strategy, and it must be medically necessary in the case for which it is being prescribed (33).

Is the Boston Elbow a "medically necessary" prosthetic device? It might be, especially for individuals with amputations so high as to preclude the use of a conventional prosthesis. But Medicare's Boston Elbow policy will not be formulated until a claim for the device has been made, and no such claim has been filed, at least in Massachusetts. In that State, requests for items for which there are no policies are referred to Physician Advisory Panels. Medicare decisionmakers at the Federal level consider the reimbursability of devices that, like the CT scanner, will probably be of major significance to the program. Another influence on Medicare prosthetics coverage is the providers' professional association, the American Orthotics and Prosthetics Association (AOPA). In 1983 AOPA was negotiating with Medicare to expand the program's "procedures codes" for prosthetics. One addition to the very limited codes in use at this time would be "externally powered, above-elbow prosthesis, " but this would not guarantee reimbursability. The reimbursement question would be more clearly defined, but even a coded Elbow might not be covered (3,33). And even a covered Elbow is covered for only 80 percent of its cost.

As noted above, Medicare benefits are extended to SSDI recipients only after they have received cash benefits for 2 years. The SSDI beneficiaries are by definition people who have worked; it is likely that they have private medical insurance when they are first disabled. If that insurance does not provide for the Boston Elbow, however, the 2-year Medicare lag may incline the amputee away from the device. It is widely thought that the period immediately following amputation is the best time for a prosthetic fitting. This not only has a strong restorative effect on the amputee, but makes the prosthesis part of his or her body image. Moreover, many amputees whose fittings are delayed find they can function well enough with one arm and therefore never wear a prosthesis.

The new Medicare beneficiary, then, may already have adapted to life without a device or with one less costly than the Boston Elbow. A Medicare-reimbursable Boston Elbow might still be chosen as a replacement device.

The Federal/State Vocational Rehabilitation Client

The Federal/State Vocational Rehabilitation (VR) Program provides work-related training and services to disabled individuals who are potential workers, i.e., who are deemed employable by program staff. Clients come to the program from many situations. Some have long work histories, others do not. Some are receiving cash benefits, others are not. What distinguishes VR clients is that they qualify for vocational rehabilitation on two counts: 1) their disability prevents them from functioning satisfactorily in the workplace, and 2) there is reason to believe that VR services will solve the problem. In other words, the VR client is impaired enough to need help, but not so impaired as to be unemployable (41).

Unlike workers' compensation and SSDI, Vocational Rehabilitation is not an insurance program. Neither the recipients of VR services nor their employers pay into its operation directly. The Federal/State VR Program receives 80 percent of its funds from general Federal revenues allocated to the Rehabilitation Services Administration (RSA), currently in the Department of Education. The remaining 20 percent of the program's funds are raised by the individual State agencies through which VR services are delivered (41).

Vocational rehabilitation services include prosthetic devices when these are expected to facilitate employment. Not infrequently, the State VR agency will contribute to the cost of a desirable prosthesis by paying, for example, the 20 percent Medicare coinsurance. But the VR Program is also mandated to pay for devices other programs do not cover and to buy environmental technologies when these are appropriate. A client's home might be modified to make it easier to go to and come from a job, and a vehicle might be adapted to make transport to and from work possible. These are large, one-time expenditures, expected to enhance the client's earning power enough to pay for their replacement (1,2).

A modified social environment is another feature of the VR Program. Potential workers form relationships with rehabilitation counselors who act in the clients' interests and secure for them access to other professionals, vocational training programs, and the world of work generally. A second kind of social adaptation has been achieved through the Rehabilitation Act of 1973 (Public Law 93-112). This legislation calls for many compensatory measures, among them affirmative action by the Federal Government and its contractors. Federal agencies and all firms holding Federal contracts for $2,500 or more (as of 1983) are required to take affirmative action in hiring and promoting people with disabilities. Employers are expected to make a "reasonable accommodation" to the special needs of disabled employees.

Many clients of the VR Program receive monetary compensation, but the public sources of these moneys are usually SSDI and Supplemental Security Income (SS1) (see below). The real cash benefits of vocational rehabilitation are eventual salary checks, and wages are the unambiguous goal of the VR Program. The term "rehabilitation" is itself defined by the program as employment in the competitive labor market or a sheltered work setting. Of the approximately 370,000 cases closed nationally in fiscal year 1982, 61 percent or about 227,000 were rehabilitations; 39 percent of the clients who finished the program were unable to find jobs they could do and keep (42). The Massachusetts Rehabilitation Commission (MRC) successfully closed more than 4,600 cases in fiscal year 1982. Four hundred and forty of them were public assistance recipients-now able to leave the rolls (22)—and while rehabilitation of these individuals is especially gratifying to public officials and taxpayers, the Vocational Rehabilitation Program in general derives its legitimacy from the number of wage-earners it contributes to the economy. The rehabilitation literature offers many cost-benefit analyses indicating that vocational rehabilitation is a good investment (26). The program confers economic benefits on both worker and society, and this end might justify the cost of a Boston Elbow. Liberty Mutual knows of at least one case in which it did.

On the other hand, the Boston Elbow remains an expensive device, and VR funds are limited. As of 1983, basic State grants had not been cut back under the current Administration, but neither had they been increased. Moreover, the mandate of the program seems to be getting costlier to fulfill. In fiscal year 1981, the percentage of rehabilitations not only fell from the previous year but constituted the lowest success rate since 1946. The RSA cites as a factor in this decline the policy, set by the 1973 Rehabilitation Act, that people with severe disabilities be served first (41). In Massachusetts, severely disabled people were 80 percent of all rehabilitants in 1982 (22), and at least some of these individuals received services more intensive and expensive to provide than those delivered to less disabled clients. A related influence on the use of the Boston Elbow in the VR Program is that hard choices among technologies have to be made. Clients who use wheelchairs, for example, can also benefit from sophisticated devices. Although body-powered and sometimes even electric wheelchairs are provided through such programs as Medicare and Medicaid, what is "medically necessary" may not allow for participation in the work force. Wheelchair users are thus in a position similar to that of the above-elbow amputee. There are many more of the former, however, and their technological alternatives are probably more widely understood and appreciated.

To summarize, amputee-workers may wear Boston Elbows. If injured on the job, they are more likely to be fitted with the device if their employers' insurer is Liberty Mutual. If disabled under other circumstances, they may receive Boston Elbows from Medicare, but only after 2 years on SSDI. And potential workers are entitled to Boston Elbows if the devices will increase their employability, but they must compete for limited VR dollars with other clients who benefit from sophisticated technologies.

THE AMPUTEE= CITIZEN

Every amputee is an amputee-citizen. This status does not thereby entitle a person to a prosthesis (except in some States under the Medicaid program) but there are several Federal policies that bear on his or her securing a prosthesis from some other source. These represent common Federal concerns—research, regulation, and civil rights.

The amputee's experience with prosthetics is shaped by federally funded research in the fields of rehabilitation and rehabilitation technology. Agencies as diverse as the National Aeronautics and Space Administration and the National Institutes of Health have participated in this research, and the VA has long studied questions of importance to veterans. At present, the National Institute of Handicapped Research (NIHR) has primary responsibility for rehabilitation research. The agency was created by the 1978 Amendments (Public Law 95-602) to the Rehabilitation Act of 1973 and sited in the Rehabilitation Services Administration. When in 1980 RSA was moved to the newly created Department of Education, NIHR was separated from RSA and made a sister agency within the department. NIHR"does not have its own research capacity. Rather the institute sets priorities and enters into cooperative agreements with researchers, usually at universities (28). The NIHR budget for fiscal year 1983 exceeded $30 million.

Research conducted for NIHR is largely applied and includes development and evaluation of devices. The institute funds four kinds of projects, but most of its resources are expended on Research and Training Centers (RTCS) and Rehabilitation Engineering Centers (RECS). Each of the former focuses on a single disability or group of disabilities and does research that may not be immediately applicable but from which applications may be drawn. The RECS are more directly concerned with hardware. Center staff design and build prototypical equipment-embodied technologies and improved prostheses, including externally powered above-elbow prostheses, are an explicit objective in NIHR's Long-Range Plan. In fiscal year 1983 the institute did fund research broadly relevant to the Boston Elbow. But NIHR's mission is wide-ranging—to improve the quality of life of all Americans with disabilities—and prosthetics is only one of the agency's 14 areas of "prioritized technology research. " The agency's funding is clearly inadequate to its task and has in fact been decreasing from its 1981 level of $35 million (40,42).

At the other end of the research and development process stands the Food and Drug Administration (FDA), but the agency has had little effect on the development and distribution of the Boston Elbow. The FDA considers prostheses medical devices, and they fall within its mandate to classify and regulate. Prosthetic parts are assigned to Class I, where controls include regulation of manufacturing practices, recall and seizure authority, etc., but not the (as yet unspecified) performance standards found in Class II. Prosthetic limbs are usually fabricated from components by prosthetists and technicians. As long as the prosthetist "customizes" the device in this way, the FDA does not require that the components meet specific performance standards. When a manufacturer sells a fully assembled prosthesis, however, it falls into Class II, and the potential of performance standards does apply. The Boston Elbow has not yet been classified and may be assigned to Class II. In any case, Class I controls apply in Class 11 as well and are unlikely to pose a problem for Liberty Mutual.

The amputee-citizen may actually be provided with a prosthesis if he or she is eligible, on the basis of income, for SSI and the Medicaid benefits that in most States accompany it. SSI pays cash benefits to citizens with low incomes whose disabilities are total and expected to last at least 12 months or result in death. The 1978 annual SSI benefit for a man with a nonworking wife and two children was $3,864 in California and $2,273 in Texas (5). SSI parallels SSDI, although the former is not an insurance program and is financed through general revenues. SSI also offers Medicaid rather than Medicare, and, because Medicaid is a State-administered program, it varies significantly from State to State. Prosthetic and rehabilitation services (e.g., learning to function with one arm) may be among a State's Medicaid benefits but need not be. All prostheses funded through the program must be "medically necessary" (39).

In Massachusetts, the Medicaid program does provide prosthetic devices. Medical necessity is asserted and defended by the physician prescribing the prosthesis and confirmed by the Medicaid officials who review the claim. Unlike durable medical equipment, which may not be "substantially more costly than medically appropriate and feasible alternatives" (8), prostheses are covered if there is an adequate "medical justification" for their expense (13). Medicaid officials are unable to say whether a Boston Elbow has ever been approved or disapproved, and they claim they would seriously consider providing an Elbow if its advantages could be shown to have a medical purpose (13). Still, it seems unlikely that Medicaid, which has been labeled "welfare medicine" (35), would purchase a prosthesis as costly in both absolute and relative terms as the Boston Elbow. An exception might be made in the case of a very high amputation that makes use of a cable-operated device impossible, but according to one Massachusetts physiatrist, Medicaid has a reputation for expending its resources conservatively. He does not prescribe more than basic rehabilitation technology for his patients on Medicaid.

Amputee-citizens have an additional alternative to the Boston Elbow. It is the considerable modification of their environment by the rehabilitation legislation of 1973 and 1978. The Rehabilitation Act of 1973 made significant changes in both the human and manmade environments, creating for people with disabilities points of access to mainstream America. Section 502 established the Architectural and Transportation Barriers Compliance Board to ensure the physical accessibility of Federal buildings and those built with Federal funds since 1968. As noted in The *Amputee-Worker,* section 503 requires Federal contractors to take affirmative action in employing disabled people. And section 504 prohibits discrimination against people with disabilities by organizations receiving Federal aid of any kind.

This mandate to achieve accessibility can be (and is being) interpreted more or less generously. In either case, it represents a break with the traditional vocational orientation of rehabilitation policy. The Federal/State Vocation Rehabilitation Program served many clients between 1920 and 1970, but its success was modest among individuals with severe disabilities. In the early 1970s, some severely disabled people began to challenge the apparent strategy of the VR Program: to place as many clients as possible in jobs by accepting the least severely disabled people as clients. This critique ultimately took the form of the Rehabilitation Act of 1973, which targeted people with severe disabilities for VR services. But the 1970s were also the beginning of the post-Progressive Era (29), when social welfare came to be thought of less as a matter of services and more as a matter of rights. The Rehabilitation Act of 1973—clearly an instance of post-Progressive legislation—not only reallocated services, but broadened "rehabilitation" to mean the integration of people with disabilities into the larger society.

The 1978 Amendments to the 1973 Act further modified the disabled person's environment through title VII, the independent living program. Title VII mandates State rehabilitation agencies to establish independent living centers (ILCS) where severely disabled people without the potential for employment can be assisted to live as independently as possible. The legislation grew out of the independent living movement, which began in the early 1970s among disabled people living in institutions. They believed that even people with very serious impairments could, with training and support, live in a deinstitutionalized setting. The ILC, then, was designed to be the locus of whatever services would prove necessary in attaining maximum independence.

Title VII has never been fully funded. Federal and State moneys have been made available for the establishment and operation of ILCs—including skills training, advocacy, and out-reach—but not the purchase of services per se. As a result, an independent living center is highly unlikely to provide a Boston Elbow, even if the prosthesis promises an amputee more independence. Instead, center staff will assist him or her in finding other sources of funds for the device. ILCS also provide skills training in daily activities, such as homemaking and financial management and help in finding accessible housing, transportation, and social activities (10,24,47).

The rehabilitation legislation of 1973 and 1978 has had an indirect but not inconsequential effect on the Boston Elbow. By redefining services as rights, the Rehabilitation Act envisions disabled people independent of their service-givers and raises expectations about how much independence is possible. By providing support for independent living, the amendments further increased the disabled individual's chances for self-determination. Thus, there has been renewed interest in "technology the enabler' '—compensatory technology that extends independent functioning. Paradoxically, this same affirmation of the disabled person's humanity has led some amputees to give up the prostheses that they felt they were expected to wear.

The amputee-citizen, in summary, is only tenuously connected to the Boston Elbow. But Federal research, regulation, and restatement of old issues do contribute to the fate of the Boston Elbow and other rehabilitation technologies.

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Conclusions

5. Conclusions

This case study has made three points: that the Boston Elbow is technologically distinctive; that it is only one way to compensate for the loss of an arm; and that public policy plays a substantial role in distributing the Boston Elbow and other compensatory measures.

Although this study has not had the benefit of a controlled evaluation of the Boston Elbow and its prosthetic alternatives, it is reasonable to conclude from the data at hand that for some, perhaps for many, above-elbow amputees, the Boston Elbow is an appropriate response to the loss of an arm, The study also indicates that the Boston Elbow is not equally available to every amputee who might want or need it and that the government's role in distributing the device operates on several levels.

First, public policy sometimes works directly on the existence of a prosthetic device. The Boston Elbow is a product of workers' compensation insurance and has been designed to restore abilities valued in the workplace. Second, the government makes explicit decisions about what may be purchased with public funds. The Veterans Administration prosthesis approval process, for example, and Medicare and Medicaid reimbursement practices control the provision of specific prostheses to specific clienteles.

A third government influence is less direct but equally potent. It is the extent to which prostheses are made part of large public programs. In the Vocational Rehabilitation Program, for example, physical restoration is one means to further the objective of increasing the employability of amputees. The Boston Elbow is or is not provided to Vocational Rehabilitation clients depending on whether the device contributes significantly to vocational potential. Finally, the government is influential in making society more accessible to people with disabilities. The Rehabilitation Act of 1973, for example, opened several routes into mainstream America and has made prosthetic compensation simultaneously more of a right and less of a necessity.

It remains to be seen whether the sum of the influences described above constitutes the most appropriate relationship between government and the amputee: What should public policy be with respect to the Boston Elbow? Given that disability is idiosyncratic and contextual, government might favor the match of individual amputees to whatever prostheses they and their physicians choose. Government might also increase the likelihood of such a match by making every device widely available to potential wearers and their agents. This, however, would be a rare show of universalist in a system where health and welfare policies painstakingly distinguish among clienteles.

The programmatic boundaries that shape diffusion of compensatory technologies such as the Boston Elbow are firmly fixed. It is unrealistic to think that a single judgment on the merits of the device can influence the diverse mandates, histories, and resources of the several programs that impinge on it. Rather, the Boston Elbow is more or less appropriate to each of these programs, as it is more or less appropriate to individual amputees.

Public policy is not providing adequate compensation to the extent that individuals' needs diverge from the goals of the program(s) for which they are eligible. Ironically, it is the array of programs available to the amputee-citizen, which do not include provision of the Boston Elbow, that promises to advance the cause of matching amputees to suitable prosthetic technologies and other options. The independent living and disability rights movements encourage people with disabilities to become informed consumers of rehabilitation technologies and to view assistive devices as part of larger compensatory strategies. One result of this movement will be more self-aware and assertive participants in the design and development of compensatory technologies. Another result will be an awareness among disabled people that responses to functional loss derive from political as well as technical intentions.

Appendixes

Appendix A.—Glossary of Terms and Acronyms

Glossary of Terms

degree of freedom: **capacity** for active movement
electrode: conductor through which EMG signals are transmitted from the stump to the prosthesis
EMG signals: electromyographic signals, i.e., electrical charges that accompany muscle contraction
extension: movement of straightening a joint
flexion: movement of bending a joint
hold: amount of weight a prosthesis will support
lift: amount of weight a prosthesis will raise
mental workload: amount of conscious thought required to operate a prosthesis
myoelectric: controlled by EMG signals
proportional speed: speed that varies with the strength of muscle contractions
prosthesis: artificial limb
range: distance a prosthesis travels from full flexion to full extension
repair cycle: how often a prosthesis needs repair
service life: how long **a** prosthesis lasts,, with repairs
socket: hollow part of a prosthesis that holds the amputee's stump
speed: how long it takes for a prosthesis to travel from full flexion to full extension
stump: part of limb left after amputation
terminal device: hook or artificial hand

Glossary of Acronyms

AOPA – American Orthotics and Prosthetics Association
FDA — Food and Drug Administration, Department of Health and Human Services
IAB — (Massachusetts) Industrial Accidents Board
ILC — independent living center
MIT — Massachusetts Institute of Technology
MRC — Massachusetts Rehabilitation Commission
NIHR — National Institute of Handicapped Research, Department of Education
PSAS — Prosthetic and Sensory Aids Service, Veterans Administration
REC — Rehabilitation Engineering Center
RSA — Rehabilitation Services Administration, Department of Education
SSDI — Social Security Disability Insurance
SS1 — Supplemental Security Income
VA — Veterans Administration
VR — Vocational Rehabilitation

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● Until April 1983.
'*Until March 1984.
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•** 'Until August 1983

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