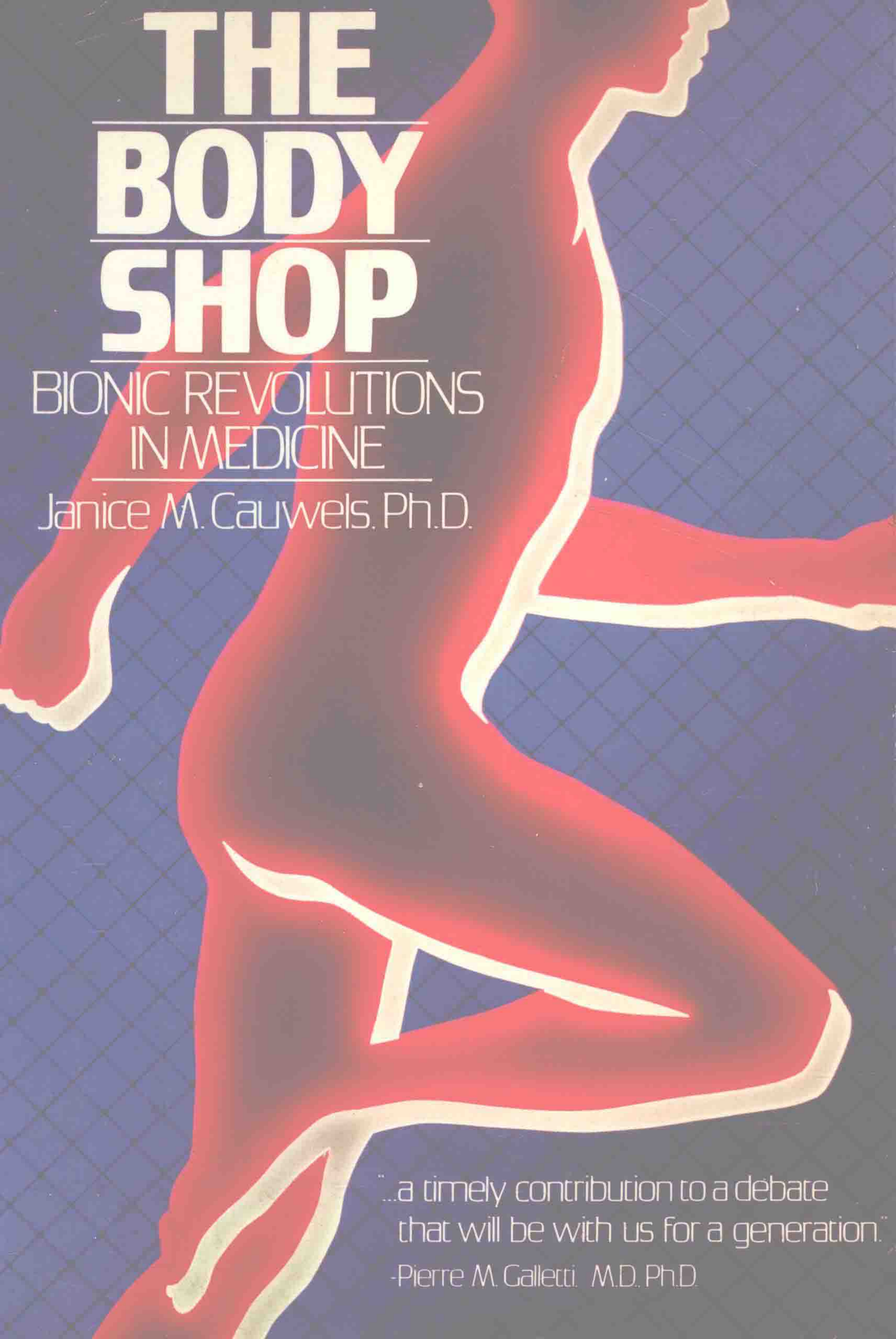
THE BODY SHOP

BIONIC REVOLUTIONS IN MEDICINE

Janice M. Cauwels, Ph.D.



"...a timely contribution to a debate that will be with us for a generation."

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PREFACE

The Body Shop is an optimistic and much-needed book. The concept of spare parts for the human body has surreptitiously entered our consciousness through the practice of specialty medicine and—with more fanfare—the folklore of television, yet until now no serious introduction to this field has been available for the general public. In libraries we can find elementary textbooks of human anatomy and physiology to learn about the structure and functions of the various organs in our bodies. Similar information is not readily found when these organs are replaced by an implant or an electromechanical device. We know intuitively that the replacement parts described in *The Body Shop* are simplistic substitutes for their sophisticated natural counterparts. We instinctively appreciate that our bodies will not necessarily accept the intrusion of man-made spare parts. Perhaps some of us feel guilty about interfering with the order of nature, whether it proceeds from intelligent creation or blind evolution. Above all we have not known where to turn for level-headed information.

Janice Cauwels tells us that even though spare parts medicine may not be as advanced or uniformly successful as popular media suggest, we should not be ill at ease in discussing what it has to offer to medical care. Millions of people have received implants, and their opinions should be heard. Sensational reports about feats of technology should not obscure the fact that less publicized implants such as cardiac pacemakers or middle ear prostheses have entered the standard practice of medicine. Janice Cauwels gives voices to the patients, who are often the true pioneers in the development of medical technology. She tells anecdotes of everyday life with prostheses and writes in terms a candidate for an unorthodox form of treatment can understand and relate to, yet the up-to-date accuracy of her account recommends it to medical professionals as well.

Artificial organ science is still too young to have developed a coherent set of general principles applicable to all medical conditions. Similarities among the various types of implants are often more apparent than real. The prospect of some surgical procedures is loaded with enormous emotion, whether we deal with life-threatening situations such as in the case of the artificial heart, private functional handicaps such as those addressed by penile prostheses or artificial sphincters, or purely aesthetic yearnings such as may justify mammary augmentation prostheses. Janice Cauwels accepted these limitations. She listened carefully to confront the problems of investigators and implant candidates. She recognized the uneasy position of artificial organ research in our medical culture. She identified nonscientific and nonmedical considerations and made a place for them in her account.

I encouraged her to write this book as an outsider looking in. She gives us an upbeat yet balanced report of what she saw and heard. She may not have covered all topics evenly: the field of artificial organs is too wide and disorganized to allow it. More important, she conveys the spirit of research and the mood of pioneer designers and adventurous patients. She has made a timely contribution to a debate that will be with us for a generation.

Pierre M. Galletti, M.D., Ph.D.
Professor of Medical Science
Vice-President (Biology
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Brown University
July 9, 1985

THE BODY SHOP

BIONIC REVOLUTIONS IN MEDICINE

CONTENTS

SECTION

I

A LANDMARK SCIENCE

1

Behind the Bionic Hype

Picture a father seated in a darkened movie theater with his two children. The man, who seems to be in his early forties or thereabouts, is a scientist. Perhaps he has both an M.D. and a Ph.D., for he is intrigued by the engineering and clinical processes involved in making mechanical gadgets perform the functions of the human body. Because of his background, he is amused by the sophisticated technology splashed across the screen during a matinee of *The Empire Strikes Back* (but Darth Vader's mechanical face gives him the subtle creeps).

The climactic fight between Vader and Luke Skywalker finally occurs. Just as the children grow restless, a swish of Vader's laser gun neatly bisects Luke's forearm. A few scenes later, this minor disability has been cured: Luke is seated in a spaceship infirmary, where robot surgeons have attached a perfectly natural-looking artificial hand.

The scientist, who puts in long hours and tends to think about his work in the shower, suddenly feels old. He lowers his chin to one hand and groans softly. First the Six Million Dollar Man. Then the Bionic Woman. Now this.

His son has meanwhile leaned up to his father's ear. "Dad," he whispers, "Isn't that what you do?"

What Dad does is research in *bionics*, a term defined differently among reference sources but generally referring to the application of biological principles to engineering problems. *Biomedical engineering* (or just *bioengineering*), a synonym used in academic circles, likewise varies in definition but generally means the application of engineering principles (or equipment like artificial organs) to biology or medicine. *Bionic* has taken on this meaning in popular usage, confusing the terminology further.

For simplicity, all these terms are used here to mean a science in which knowledge of engineering and physiology is used to produce artificial devices or systems that benefit humans. Some of these devices are implants or prostheses—artificial substitutes for missing body parts. (*Prosthesis* is also used loosely: the Inflatable Penile Prosthesis substitutes not for a penis but rather for a natural erection.) Bionics research has also produced external devices that temporarily attach to the body, implantable pumps that deliver medications, mechanical creatures that substitute for humans in training sessions, and fluids that keep organs alive.

Most of us first encountered artificial human parts when we were children listening to tales of Long John Silver or Captain Hook. Years ago, peg legs or hooks were sure signs that their fictional owners were disreputable or downright villainous. More recently, popular entertainment has shown a reversal in this attitude. The Six Million Dollar Man and the Bionic Woman became superheroes when the creators of their respective television series endowed them with bionic arms, legs, and senses. With our love of superheroes, our fascination with gadgetry, and our faith in technology (recently affirmed by the microcomputer revolution), we welcomed them into our imaginations.

Our scientist is just one of many researchers upset by such goings-on. Most people do not recognize that real bionic persons have existed for over 40 years. Hundreds of thousands of people are alive thanks to artificial kidneys or heart-lung machines; many others are more comfortable and productive because they have artificial joints, heart valves, or pacemakers. Several people who appear in these pages have investigational devices that make disease or disability much easier to bear. Their adventuresome courage and that of their predecessors has helped establish a revolutionary era in medicine. Recipients of the Jarvik-7 artificial heart are corroborating what the Tin Woodman finally learned: one does not need a natural heart to love and be loved. (Given the popularity of film creatures like R2D2, C3PO, E.T., and Gizmo, we might wonder whether we are not rebounding from the natural to a mechanical extreme.)

Today artificial parts—whether external, percutaneous (placed through the skin), or implantable—are a billion dollar worldwide industry. In 1980 one estimate stated that some 2 to 3 million "artificial or prosthetic parts" manufactured by hundreds of companies were implanted in Americans each year. Research on these devices is underway at universities, Veterans' Administration (VA) hospitals, the National Institutes of Health (NIH), and other government organizations. Private companies involved in biomedical engineering range from tiny ones hastily assembled to provide desperately needed funds, to giants of their respective industries like Johnson and Johnson, Pfizer, 3M, Dow Corning, and Revlon. Nobody—not even the Food and Drug Administration (FDA)—has a completely up-to-date list of *all* the manufacturers who are testing artificial body parts.

These days we are bombarded by media hype describing the latest breakthroughs in artificial limbs, joints, organs, nerves, features, and senses. A reader who follows bionic "breakthroughs" in the popular press might naively fantasize, "If I must be crippled or disfigured in an auto accident, let it happen in front of a bionics research center." In the past few years literally hundreds of articles on bionics have appeared in the major newspapers as well as in popular and science magazines. Unfortunately, much of this information is highly sensationalized. "I don't even read press accounts of our work because all of them, even the good ones, are partly incorrect," says William C. DeVries, M.D., a heart surgeon in private practice in Louisville, Kentucky, and the Director of the Artificial Heart Program at Humana Heart Institute. "If I read all that stuff, I get defensive and upset and worry about what the patients' reactions will be if they see it. It's not even worth commenting on."

Bionics researchers write more accurately and even more prolifically than contributors to the popular press. A quick look at EMBASE or other biomedical and technological data bases will reveal that thousands of articles on implants and prostheses are published each year. The *List of Journals Indexed in Index Medicus 1984* has nine entries under "Artificial Organs" and 31 under "Biomedical Engineering." One young bionics researcher has confessed that he had started to write a book on his *specialty* but gave up because he found too much material.

Despite all this enthusiasm, many people—including physicians—do not know what types of implants and prostheses are available or being clinically tested. (Several of the patients we will meet in this book expressed eagerness to inform others about new devices that saved or greatly increased the quality of their lives.) Although the first artificial organ, the kidney dialysis machine, is 40 years old, in the minds of most people the Jarvik-7 artificial heart sprang from a void, so it attracted much attention, analysis, and criticism from a startled public. Artificial hearts, including the Jarvik-7, are far better evaluated within the context of *all* bionic parts.

People who learn about bionics from the media often burden researchers like our scientist with eager and unrealistic expectations of success. Such publicity can be cruelly disappointing to disabled people who investigate further only to find that cures for blindness or paralysis do not yet exist. "What most troubles me about media reports is that they create false hopes," says Woodie C. Flowers, Ph.D., Associate Professor of Mechanical Engineering at the Massachusetts Institute of Technology (MIT). "Many people who are justifiably anxious to have improved devices think that technology is going to make it happen tomorrow. It's a disservice to them, and they deserve more truth."

By encouraging us to await miracles, hype blinds us to the fact that the real science of biomedical engineering is already established as one of the most revolutionary and important advances in modern medicine. Were its status more widely known, people would better understand the significance of the human implantations of the Jarvik-7 artificial heart, for example. "The clinical tests of the Jarvik-7 heart have been public from the beginning, and people have been expecting miracles without recognizing that it will take time for things to go well," says Dr. DeVries. "The press and the public want to know how long a patient would have lived without the artificial heart and whether it will increase his quality of life. If he has complications, they say that the implantation wasn't worth doing. They emphasize the theoretical, therapeutic aspects of the operation rather than its experimental aspects. Many times people submit to experiments without gaining improved quality of life or the therapeutic benefits they hoped for. Meanwhile physicians have learned a tremendous amount that will benefit the patients who come after them. Regardless of outcome, these artificial heart patients have all contributed greatly to the future of humankind—a really important cause."

Bionic parts make such contributions not only in and of themselves, but also because they can spin off other exciting, practical technologies. Even more important, artificial body parts are unique research tools for studying physiology and disease states. Physicians did not know, for instance, that kidney failure victims eventually became anemic until they were able to keep patients alive for long periods on dialysis machines (the kidneys may produce a hormone necessary for red cell renewal). Nor were they aware that left ventricular dysfunction leading to shock could be reversed by prompt, vigorous perfusion until they began testing assist devices in the artificial heart program. The Jarvik-7 artificial heart has enabled tests to be run on its recipients that would not be possible with other patients. Artificial organs have also given researchers new information about atherosclerosis, carcinogenesis, and complex immunological processes.

Traditionally, when surgeons removed damaged organs, scientists learned from the rest of the body what their function had been. From a purely scientific viewpoint, artificial organ technology provides information in just the opposite way: researchers replace a body part with a device they think does the same tasks. By keeping patients alive, they find out that the organ did more than they had originally supposed (and the substitute can be repeatedly improved, the better to approximate its natural counterpart). "This substitutive approach of replacing body parts in a global fashion is philosophically a very important landmark in the thinking about biological science that very few people appreciate," says Pierre M. Galletti, M.D., Ph.D., Professor of Medical Science and Vice-President for Biology and Medicine at Brown University. In this sense artificial organs make a circular contribution to medicine: they teach investigators more about the natural organs and disease conditions, enabling them to return to direct treatment with a better perspective.

Progress in bionics is not nearly as smoothly progressing or as rapidly accelerating as this discussion would suggest. Any bioengineer will point out that we are several million years behind nature in terms of design. Perhaps bionics will eventually change this situation. Obviously our bodies do not evolve to keep pace with modern technology, or we would not be disturbed by the suffocation of air pollution or the scream of jet engines. We may be destined to evolve into closer, more effective interaction with our own technology, with a little help from our friends the scientists. Researchers are now speeding up our movement through the chain of humankind—replacing the lengthy, wasteful, trial-and-error process of natural evolution with more efficient scientific inquiry. They are influencing, even directing, the processes of change and perhaps altering the bases of evolution itself. "There's no *a priori* reason that life should be based on water and carbon just because we evolved that way," says Dr. Galletti. "In the past 50 years, scientists have developed an organic chemistry of silicone that is as refined and unique as organic compounds made of carbon. There are other ways to do things." Rather than implying that we can build bionic superpeople, the possibility of alternative solutions to the same biological problems should remind us how intricate and miraculous our own bodies really are.

The body is superbly equipped to combat invasion; unfortunately, however, it is unable to distinguish friend from foe. As we will see later, the biggest scientific problem confronting bionics researchers is that of finding materials that will not be rejected when they are implanted in the body. Once a material is determined to be biocompatible, the next problem is that of establishing its interface with its living surroundings. "We are entering an era in which the limiting factor of a prosthesis is its interrelation with the environment," says Dr. Galletti. "We don't know how to interface for biological reasons, particularly at the cellular level."

Not only the cells but entire organs and body systems still remain mysteries to medical researchers. The complexity of trying to imitate nature is implied in the example that throughout the world literally hundreds of different artificial knee joints are in use. Many researchers have found that they need not thoroughly understand a particular organ or system to mimic its contribution to human life. Others even design devices unlike their natural models when this makes more sense. "It's a weak argument of tradition to say that designing an organ a certain way is better because that's how nature does it," says Dr. Galletti. "God created the heart, for example, as a pulsatile blood pump—it's made of muscle, which must pulse, and He or She had no other choice." A key criterion for the design of any type of prosthesis is that it be as simple as possible.

Anyone disturbed by this apparent guesswork may be even more dismayed to learn that although some artificial organs like the artificial kidney have been used successfully for decades, *their* functions (like those of many standard medications) are still not completely understood. It is clear what the blood oxygenator does, but that machine performs only one of several functions of the natural lung that are just now being defined.

Some investigators believe that as these mysteries are solved, prostheses can be made superior to their natural counterparts. "In certain areas, we can supersede nature," says Willem J. Kolff, M.D., Ph.D., Director of the Institute for Biomedical Engineering and the Division of Artificial Organs at the University of Utah. "Someday a marathon runner will be disqualified because he has an artificial heart. It's quite feasible that in time we'll produce artificial hearts that are more effective than natural ones, although that doesn't mean that people would prefer them." Most researchers, however, believe that they will never be able to match, much less outdo, the human body. "The first thing people must recognize about bionics is that the devices we make are at best pathetic imitations of the real thing," says Robert Stephen, M.D., Research Associate Professor in the Division of Artificial Organs at the University of Utah. "The cells themselves make millions of judgments every day—that's far more information processing than we could duplicate."

The complexity of natural systems is one reason that implants face competition from transplants, of which kidney transplants are the most widespread. Now and then the media publicize the story of someone who faces death because he or she needs a donor organ that is not available. In June 1984 the U.S. House of Representatives overwhelmingly passed legislation to establish a computerized registry that would match organ donors with potential recipients. While banning the buying and selling of organs, the plan also authorized $30 million over the next 2 years to help transplant patients pay for immunosuppressive drugs and $40 million over the next 4 years for grants to regional organ procurement organizations. The U.S. Senate had already passed a measure to establish a group to study transplants.

This legislation is well meant, but society still has not answered all the legal, ethical, and moral questions surrounding the transplantation of organs removed from humans or animals. Most people do not die in accidents or seem willing to donate their healthy organs to others. Even if they did, physicians would still face the problems of storing the organs and getting them to potential recipients promptly. "With a 1-year survival rate of over 80% and a 5-year rate close to 60%, heart transplantations are absolutely fantastic," says Donald B. Olsen, D.V.M., Research Professor of Surgery and Pharmaceutics at the Institute for Biomedical Engineering at the University of Utah. "But we need ample lead time for evaluation, tissue typing, and location of donor organs." Transplant recipients face the possibility that their bodies will reject the new organs; they must take immunosuppressive drugs, which weaken their immune systems, for the rest of their lives. A transplanted organ can develop any disease that could affect its predecessor. "Transplantation of living organs is a stopgap measure right now," says Emil P. Paganini, M.D., Head of the Section of Dialysis and Extracorporeal Therapy in the Department of Hypertension and Nephrology at the Cleveland Clinic Foundation. "Since we'll never mimic the original organs anyway, it might be better if we could offer artificial implants to patients."

Implants have disadvantages also, however. They must work perfectly without imposing excessive weight, bulk, or toxic materials on the recipients. They must connect with the body's communication lines and energy supplies in a symbiotic interface. Prototypes are expensive and do not regenerate like natural organs. Like transplants, implants can develop the original organ's disease; they also come down with disorders that result uniquely from their artificiality. An artificial lung version of pulmonary edema can occur, along with other implant disorders like thrombosis, aneurysmal dilation or dissection, calcification, and infection. Although the implants themselves may be standardized, not everyone is a candidate for them, often because of complications that would seem to be irrelevant.

Despite these drawbacks, both transplants and implants hold considerable promise. With the use of cyclosporine and other medical advances, transplants are becoming increasingly successful. "We're learning so much about how to control rejection that transplants and implants will be in a race over the next 10 years or so," says Carl F.W. Wolf, M.D., Associate Clinical Professor of Pathology at the Cornell University Medical College. "It may be more pertinent