Limb Prosthetics Services and Devices

Critical Unmet Need: Market Analysis

White Paper

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Introduction

When a person becomes a limb amputee, he or she is faced with staggering emotional and financial lifestyle changes. The amputee requires a prosthetic device(s) and services which become a life-long event. A prosthesis is an artificial extension that replaces a missing body part such as an upper or lower body extremity. It is part of the field of biomechatronics, the science of fusing mechanical devices with human muscle, skeleton, and nervous systems to assist or enhance motor control lost by trauma, disease, or defect. An artificial limb is a type of prosthesis that replaces a missing extremity, such as arms or legs. The type of artificial limb used is determined largely by the extent of an amputation or loss and location of the missing extremity. Artificial limbs may be needed for a variety of reasons, including disease, accidents, and congenital defects.

There are four main types of artificial limbs. These include the transtibial, transfemoral, transradial, and transhumeral prostheses:

Transradial Prosthesis
A transradial prosthesis is an artificial limb that replaces an arm missing below the elbow. Two main types of prosthetics are available. Cable operated limbs work by attaching a harness and cable around the opposite shoulder of the damaged arm. The other form of prosthetics available are myoelectric arms. These work by sensing, via electrodes, when the muscles in the upper arm moves, causing an artificial hand to open or close.

Transhumeral Prosthesis
A transhumeral prosthesis is an artificial limb that replaces an arm missing above the elbow. Transhumeral amputees experience some of the same problems as transfemoral amputees, due to the similar complexities associated with the movement of the elbow. This makes mimicking the correct motion with an artificial limb very difficult.

Transtibial Prosthesis
A transtibial prosthesis is an artificial limb that replaces a leg missing below the knee. Transtibial amputees are usually able to regain normal movement more readily than

someone with a transfemoral amputation, due in large part to retaining the knee, which allows for easier movement.

Transfemoral Prosthesis

A transfemoral prosthesis is an artificial limb that replaces a leg missing above the knee. Transfemoral amputees can have a very difficult time regaining normal movement. In general, a transfemoral amputee must use approximately 80% more energy to walk than a person with two whole legs. This is due to the complexities in movement associated with the knee. In newer and more improved designs, after employing hydraulics, carbon fibre, mechanical linkages, motors, computer microprocessors, and innovative combinations of these technologies to give more control to the user.

The type of prosthesis depends on what part of the limb is missing.

Major technological advancements drive the limb prosthetics market. Outstanding innovative advancements in technology have catalyzed the modernization of prosthetics, spurring a significant growth in the prosthetics market. Thanks to these developments, today's prosthetic devices cater to the specific needs of patients. Products ranging from conventional knees to energy-storing feet help amputees lead more normal and productive lives. The prosthetics market is impacted by the occurrence of disease, war, and accidents. Diabetes and peripheral vascular diseases rank as the number one cause of amputation in the United States, where an average 185,000 amputations are performed annually, thus increasing the consumer base and presenting opportunities for service providers. While diseases such as diabetes and peripheral vascular disease are the leading causes of amputation, accidents and war continue to play a major role in driving the limb prosthetics market.

The demand for restoring mobility and independence from amputees including a growing number of amputee soldiers impacts the market positively, urges manufacturers to address amputee issues and the market. The impact of technology on this market is tremendous and it is likely to continue for the next several years in response to novel innovations such as bionic technology, sensor technology, artificial intelligence, and micromechatronics. The growing consumer base of amputees drives the market with demands for improvement in quality of life and innovation will address quality of life needs.

Technological growth and an increasing consumer base of amputees are bolstering the prosthetics market growth, according to an analysis from the business and research consulting firm Frost & Sullivan. The overall prosthetics market in the United States

earned revenues of $1.45 billion in 2006 and estimates that number to reach $1.85 billion by 2013. The global dental prosthetics market is estimated to exceed $5 billion. Hip and knee replacements are big drivers of the orthopedic prosthetic market. Over 100,000 cochlea implants are currently in place globally. The limb future prosthetics devices and the accompanying services market are estimated to exceed $5 billion (of which an estimated $3 billion alone is in amputee patient services) in the U.S.

"Every component--whether the socket, knee, or foot--involved in the prosthesis has undergone immense research and development," says Frost & Sullivan Research Analyst Archana Swathy. "Furthermore, the use of novel materials has further redefined the potential of prosthetic devices."

The limb prosthetics market is fragmented in the U.S. No single company or small group of companies dominate the limb prosthetic device or service market. The device market is national and the service market is regional. There are scores of small/boutique companies that are providing services, selling devices and innovating new technologies for the market.

However, market growth is dampened by the high price of prosthetics and reimbursement issues. The high price of prosthetics and unfavorable reimbursement issues compel amputee consumers to opt for lower priced products that are less effective, thus restricting market growth. The high cost of innovative prostheses coupled with third party payer restrictions create a dearth in the market, which cannot be overcome by out-of-pocket payments. Currently, this restraint has a significant impact on growing the limb prosthetics market and this unlikely to change unless there are major and systemic changes in federal policies.

Scope of Market Analysis

The scope of this market analysis focuses on limb prosthetics in the United States. Accessible data on individual limb prosthetics market segments are limited and in some instances non-existing. Some projections are based on the global markets for all prostheses and orthopedic services. Available data describes national amputee incidents, reimbursement issues, etc. but not by regional or state. Such data can only be extracted and extrapolate through a significant and labor intensive effort.

The lack of common standards, a common lexicon and common data collections negatively impact on the ability to assemble precise market data on limb prosthetics. A National Institutes of Health study concluded, *"For example, documented rates of prosthesis use vary from 27 to 56 percent for upper-limb amputation (ULA) and from 49 to 95 percent for lower-limb amputation (LLA). A number of studies have attempted to identify variables that explain inconsistent use rates and identify persons less likely to wear and benefit from a prosthesis. Unfortunately, the existing literature is equivocal and limited by a number of factors."*

U.S. Limb Amputation Incidents

There are an estimated 1.9 million amputees in the United States and approximately 185,000 amputations surgeries performed each year. Of those amputations performed, 82% are due to Peripheral Vascular Disease and Diabetes. However, there are other causes of amputation. Approximately 8,900 children receive amputations each year due to lawn mower accidents. Birth defects result in a life long need for prosthetic devices. About 6,000 of these are upper extremity amputees in a given year. Walter Reed Army Medical Center is treating about 1,000 military amputees. The Veterans Administration has 40,000 amputees currently receiving services in the VA healthcare system. In western developed countries the rate of amputations of lower limbs is 17.1 amputations per 100,000 inhabitants – in Spain alone 5,000 such amputations are carried out each year.

The overall annual numbers of amputees in the U.S. as well in the Veterans Administration healthcare system are accelerating because of diabetes related limb amputations. The growth rate of the over-65 age group is nearly triple that of the under-65 age group. More than 65 percent of amputations are performed on people age 50 and older. There is a direct correlation between age and the onset of diabetes and vascular disease, which are the leading causes of amputations. Limb loss does not affect just the aged. Every day in the United States, children are born with missing limbs, and teenagers

suffer amputations as a result of accidents or cancer. Today there are approximately 200 amputee-clinic teams in operation throughout the United States. (see Appendix A)

Market Trends

The last decade of the 20th century and the first years of the new millennium have been a period of rapid technological advances in lower limb prostheses. Paradoxically, this has occurred concurrently with an estimated reduction in funding for amputee care of 20% compared to prior decades. Despite these technological improvements in components and materials, aggregating studies from Europe and the United States suggest that overall amputee satisfaction with the prosthesis has remained relatively constant, varying between 70-75% of those polled.

Pending decreases in academic research in prosthetics have forced commercial component manufacturer to divert profits into increased product research and development to fill the void in academic research. The accuracy of that prediction was borne out during the 1990s when published research from universities and government research organization dropped dramatically. In the past fifteen years, virtually all applied research has come from the commercial sector, e.g. new suspension options, innovative socket configurations, advances in knee mechanisms, and guidelines for prescription and reimbursement of prostheses.

The recent global economic down-turn has exasperated the rate of commercial R&D for limb prosthetics innovation. All markets have been hit hard. Third party payers are more restrictive. Money for start-up prosthetic device companies has all but dried up. However, because of the Iraq and Afghanistan, U.S. Department of Defense budgets have been increased by tens of millions of dollars to finance limb prosthetic innovation.

Increased understanding of the biomechanics of locomotion combined with clinical experimentation has led to a steady evolution in lower limb prosthetics, especially in the area of socket design. In general, today's sockets emphasize diffuse rather than localized weight bearing, to reduce peak pressures and hopefully increase amputee comfort.

Advances in material technology have led to the use of novel polymers for the manufacture of socket liners, and to the creation of ever thinner, lighter, and stiffer sockets for transmission of weight bearing loads. R&D on direct skeletal attachment via osseointegration and limb transplantation are being explored as alternatives to the use of external prostheses. Research at the Bioengineering Institute of Worcester Polytechnic Institution, University of Utah, University of Washington and the University of Illinois at Chicago are current leaders in osseointegration and limb transplantation research.

In the final decade of the 20th century, the combination of amputees' expectations and industrial competition resulted in many new lower limb component developments. American companies combined advance prosthetic feet with various shock absorbing systems. European firms took the lead in developing novel components such as a rotary hydraulic knee and microprocessor-controlled knee mechanisms. This was also a period of rapid growth and consolidation of prosthetic component manufacturers worldwide, often through the purchase of young and innovative companies by established and better funded multinational firms. The result is the creation of several major multinational competitors with sufficient sales to privately fund ongoing research activities. However, private company R&D continues to be pressured by economic down-turn and reimbursement issues.

The market for limb prosthetics is anything but linear. There are a variety of forces, some measurable and some not so measurable, that determine the market trends of limb prosthetics. Among the most important of these determining forces are:

Aging U.S. Population. The growth rate of the over-65 age group is nearly triple that of the under-65 age group. There is a direct correlation between age and the onset of diabetes and vascular disease, which are the leading causes of amputations. With broader medical insurance coverage, increasing disposable income, longer life expectancy, greater mobility expectations and improved technology of limb prosthetic devices, the elderly will increasingly seek orthopedic rehabilitation services and products.

Growing Physical Health Consciousness. The emphasis on physical fitness, leisure sports and conditioning, such as running and aerobics, is growing, which has led to increased injuries requiring orthopedic rehabilitative services and products. These trends are evidenced by the increasing demand for new prosthetic devices that enable amputees to

actively participate in fitness and leisure sports. Some military amputees have returned to active duty in war zones such as Iraq.

Increased Efforts to Reduce Healthcare Costs. Prosthetic services and devices have enabled patients to become ambulatory more quickly after receiving medical treatment in the hospital. Significant cost savings can be achieved through the early use of prosthetic services and products. The provision of prosthetic services and products in many cases reduces the need for more expensive treatments, thus representing a cost savings to third party payers. However, reimbursement trends by third party payers for restricting and/or denying coverage for limb prostheses services and devices in fact have increased healthcare costs.

Advancing Technology. The range and effectiveness of treatment options for patients requiring prosthetic services have increased in connection with the technological sophistication of prosthetic devices. Advances in design technology and lighter, stronger and more cosmetically acceptable materials have enabled amputees to replace older prosthetic devices with new prosthetic products that provide greater comfort, protection and patient acceptability. As a result, treatment can be more effective or of shorter duration, giving the amputee greater mobility and a more active lifestyle. Advancing technology has also increased the prevalence and visibility of prosthetic devices in many sports, including skiing, running and tennis.

Market Fragmentation. One of the most distinguishing factors about the limb prosthetics market is fragmentation. There is no single or small group of companies that dominate the market. In fact, the opposite is true. No company has over 2% of the overall orthopedics and prosthetics market. Extrapolated, no company or small group of companies dominate or control the limb prosthetic market. There is a huge number of small/boutique companies in the U.S and Europe that are providing limb prosthetics services, developing and marketing limb prosthetics and innovating new technologies improving limb prosthetics.

Third Party Reimbursement

Third party reimbursements for limb prosthetic services and devices may have the biggest influence on limb prosthetics market trends. The principal reimbursement sources for prosthetic services and devices are:

Private payer/third-party insurer sources, which consist of individuals, private insurance companies, HMOs, PPOs, hospitals, vocational rehabilitation, workers' compensation programs and similar sources.

Medicare, a federally funded health insurance program providing health insurance coverage for persons aged 65 or older and certain disabled persons, which provides

reimbursement for limb prosthetics products and services based on prices set forth in fee schedules for 10 regional service areas;

Medicaid, a health insurance program jointly funded by federal and state governments providing health insurance coverage for certain persons in financial need, regardless of age, which may supplement Medicare benefits for financially needy persons aged 65 or older.

Department of Defense and Department of Veterans Affairs, DOD cares for active duty military with its military healthcare systems. Inpatient care is superb, but outpatient follow-up is sometimes lacking. VA healthcare systems are stressed by the lack resources and increasing numbers of aging veterans using the VA system.

It is estimated that government reimbursements, comprised of Medicare, Medicaid and the U.S. Department of Veterans Affairs, in the aggregate, accounted for approximately 40 to 50% of reimbursements for limb prosthetics services and devices. These percentages will grow. These payers have set maximum reimbursement levels for prosthetic services and products. Medicare prices are adjusted each year based on the Consumer Price Index-Urban (‘‘CPIU’’) unless Congress acts to change or eliminate the adjustment. Medicare price increases for 2008 and 2007 were 2.7% and 4.3%, respectively. Effective January 1, 2009, the Medicare price increase was 5.0%. There can be no assurance that future changes will not reduce reimbursements for limb prosthetic services and products from these sources.

Though components of limb prosthetic devices can be mass produced, each individual device must be customized. Costs for limb prosthetic devices vary widely:

For $5,000 to $7,000, a patient can get a serviceable below-the-knee prosthesis that allows the user to stand and walk on level ground. By contrast, a $10,000 device will allow the person to become a "community walker," able to go up and down stairs and to traverse uneven terrain.

A prosthetic leg in the $12,000 to $15,000 price range will facilitate running and functioning at a level nearly indistinguishable from someone with two legs.

Devices priced at $15,000 or more may contain polycentric mechanical knees, swing-phase control, stance control and other advanced mechanical or hydraulic systems.

Computer-assisted devices start in the $20,000 to $30,000 range. These take readings in milliseconds, adjusting for degree and speed of swing. Above-the-knee amputees can walk with a C-Leg without having to think about every step they take.

Upper-extremity amputees can buy a nonfunctional cosmetic hand for $3,000 to $5,000 that "just fills a sleeve". It allows getting by in public without being noticed.

$10,000 will buy a transradial upper-extremity prosthesis that is a functional "split hook" device for below-the-elbow amputees.

Cosmetically realistic myoelectric hands that open and close may cost $20,000 to $30,000 or more. These contain processors that tell how much pressure the amputee putting on a held object and whether it is hot or cold.

A neuroprosthetic arm (i-Limb, DEKA, Utah Arm3) may cost as much as $100,000.

Yearly third party health insurance caps on prosthetic services range from $500 to $ 3000 and lifetime restrictions range from $10,000 to one prosthetic device during a person's lifetime (from birth to death). In a recent survey of the 20 major insurance insurers, the number of insurers with financial caps, exclusions or unusually high deductibles rose 100% during a six-year period from 2000 to 2006. All 20 insurers surveyed had implemented financial caps to prosthetic coverage.

Private insurers say not everyone needs the most expensive devices and they try to match each patient with cost-effective equipment prescribed by his or her doctor that meets the criteria of medical necessity. "In today's world, there are probably dozens of new treatments, services and devices employers are struggling to incorporate into benefits," said Susan Pisano, spokeswoman for America's Health Insurance Plans in Washington, D.C., which represents the nation's insurers. "Generally, what employers, policymakers, doctors and others will find most compelling and be willing to pay for is evidence that something is not only new but that it works better and more cost-effectively than an existing drug, service or device," Pisano said.

A recent poll of 468 Amputee Coalition of America members revealed ongoing insurance reimbursement problems: 24 percent of responders reported that their private prosthetics coverage had been reduced during the past three years and 4 percent said it had been

eliminated entirely. For 48 percent, there had been no change, and 24 percent said they have no private insurance.

"These are very telling numbers," said Meredith Goins, the Amputee Coalition of America's marketing and outreach coordinator. "It helps to show the percentages of people out there still not getting care."

Prices remain high because prostheses cannot be mass-produced. If one device could serve everyone, then prosthetics could be mass produced and costs reduced. But limb prosthetics are produced in relatively small numbers and made of custom materials, with a variety of componentry. Sizes are different so each model may have six or eight variations depending on the needs of each patient.

Amputee advocates contend that medical need should remain the overriding approval criteria and all medically necessary limb prostheses should be covered. An amputee should qualify for a cosmetically appealing device no more easily than someone who seeks elective cosmetic surgery or who wants a brand name -- rather than a generic -- prescription. Some advocates argue that the third party reimbursement system should allow case-by-case exceptions that distinguish between medical necessity and functional necessity.

Amputee advocates insist that access to limb prosthetic devices and services are a medical right and not a privilege. Advocates define "access" as qualifying not only for a first prosthesis after losing a limb but also for a lifestyle-enhancing upgrade as well as the ability to visit a prosthetist of their choice for fittings and maintenance. Neither meets most insurers' criteria for reimbursement based on sheer medical necessity.

Frequent Replacement and Reimbursement Limits

Several factors account for why prostheses require replacement every several years. Technology continually improves, with lighter, more durable materials such as graphite becoming available. Very active amputees, especially athletes, put a lot of wear on the devices. And children need more frequent replacements to keep pace with their growth.

A child of twelve may grow four inches and gain twenty pounds in a year. A new limb prosthesis is needed.

Because many insurers impose such low annual caps on coverage, active or athletic amputees cannot afford anything but basic artificial limbs with restrictions as low as $2,500 or less a year becoming the standard. Some insurers also will readily reimburse for an amputation and secondary complications (including further amputation) stemming from inactivity, but they will limit or refuse to cover a prostheses replacement for an active amputee or a growing child.

"Access is getting worse every year," said Guy Savidan, a certified prosthetist/orthotist and president of Inland Limb and Brace Co. "As baby boomers retire, many who remain physically active could really benefit from state-of-the-art prostheses. But what do they get? Cheaper, run-of-the-mill versions that just get them by."

The coverage that employers now provide is much more likely to include cost sharing by the employees such as 20 percent to 50 percent co-insurance or deductibles for many prosthetic devices and services, as opposed to the small co-payments more typical of managed-care plans in the 1990s, according to the America's Health Insurance Plans spokeswoman. Kaiser Permanente, for one, requires patients who use prostheses to cover 20 percent of the cost. "We purchase in large volume and pass discounts on to our members," said Jennifer Resch-Silvestri, spokeswoman at Kaiser Permanente Medical Center, Fontana.

A plan with minimal loss-of-limb coverage will cost much less than one with full coverage. Few people figure at the time they sign up that a catastrophic amputation will ever happen to them.

Neuroprosthetics

Current prosthetic limbs are far less than optimal. All prosthetics must deal with the issues of function, control and fit. In other words – How does the current prosthesis function? Can the prostheses be controlled? How does it fit? Each of these issues present

significant hurdles that can only be addressed by a completely new paradigm of neuro-implantable prostheses. Neuroprosthetics (also called neural prosthetics) is a discipline related to neuroscience and bioengineering concerned with developing artificial prosthetic devices to replace or improve the function of an impaired nervous system. Neural prostheses are a series of devices that can substitute a motor, sensory or cognitive modality that might have been damaged as a result of an injury or a disease. The goal of the neuroprosthetic limb is to restore an optimal degree of natural function for the missing or damaged limb.

Neuroprosthetic limbs are just now moving from beta devices to commercially available prosthetics. The integration and application of emerging technologies is moving laboratory research into commercial applications for the limb amputee. The limb amputee is beginning to see the dream become a reality. However, at this point in time, a true neuroprosthetic limb may cost up to nearly $100,000.

Here are three examples of neuroprosthetic limbs that are on the market or close to being commercialized:

i-LIMB Hand Touch Bionics

Touch Bionics is a leading developer of advanced upper-limb prosthetics to become the worlds first fully articulating and commercially available bionic hand.. One of the Touch Bionics products now commercially available from the company, the i-LIMB Hand, is a first-to-market prosthetic device with five individually powered digits. This replacement hand looks and acts like a real human hand and represents a generational advance in bionics and patient care. The Touch Bionics i-LIMB Hand was developed using leading-edge mechanical engineering techniques and is manufactured using high-strength plastics. The result is a next-generation prosthetic device that is lightweight, robust and highly appealing to both patients and healthcare professionals.

The i-LIMB Hand is controlled by a unique, highly intuitive control system that uses a traditional two-input myoelectric (muscle signal) to open and close the hand's life-like fingers. Myoelectric controls utilize the electrical signal generated by the muscles in the remaining portion of the patient's limb. This signal is picked up by electrodes that sit on the surface of the skin. Existing users of basic myoelectric prosthetic hands are able to quickly adapt to the system and can master the device's new functionality within minutes. For new patients, the i-LIMB Hand offers a prosthetic solution that has never before been available.

The modular construction of the i-LIMB Hand means that each individually powered finger can be quickly removed by simply removing one screw. This means that a prosthetist can easily swap out fingers that require servicing and patients can return to their everyday lives after a short clinic visit. Traditional devices would have to be returned to the manufacturer, often leaving the patient without a hand for many weeks.

The Utah Arm 3 – Motion Control

Since 1981, the Utah Arm has been the premier myoelectric arm for above elbow amputees. It was originally developed at the University of Utah by the Center for Engineering Design, led by Dr. Steve Jacobsen. In 1987, Motion Control released the Utah Arm 2, with entirely re-engineered electronics that made the Utah Arm the most durable and dependable myoelectric arm available.

In 2004, Motion Control introduced microprocessor technology into the Utah Arm 3 (U3), with a Computer Interface that allows the prosthetist or wearer to fine-tune the adjustments to achieve maximum performance. A variety of inputs may be used, so more options are available to more wearers. Meanwhile, the U3 still delivers the same sensitive, proportional control of elbow, hand and wrist (optional), letting the wearer move the arm and hand slowly or quickly in any position. This provides a more natural response with less effort than the traditional on/off movement.

DEKA

A neuroprosthetic type arm grew out of DARPA's Revolutionizing Prosthetics program, which was created in 2005 to fund the development of two arms. The first initiative, the four-year, US $30.4 million Revolutionizing Prosthetics contract, to be completed in 2009, led by Johns Hopkins Applied Physics Laboratory in Laurel, Md., seeking a fully functioning, neuro-controlled prosthetic arm using technology that is still experimental. The latter, awarded to DEKA Research and Development Corp., was a two-year $18.1 million 2007 effort to give amputees an advanced prosthesis that could be available immediately ”for people who want to literally strap it on and go.” DEKA's team designed the DEKA arm to be controlled with noninvasive measures, using an interface a bit like a joystick.

The DEKA arm is modular, usable by anyone with any level of amputation. The arm works as though it had a very complicated set of vacuum cleaner attachments; the hand contains separate electronics, as does the forearm. The elbow is powered, and the electronics that power it are contained in the upper arm. The shoulder is also powered and can accomplish the never-before-seen feat of reaching up as if to pick an apple off a tree.

DEKA worked closely with the Rehabilitation Institute of Chicago, where neuroscientist Todd Kuiken has had recent successes in surgically rerouting amputees' residual nerves—which connect the upper spinal cord to the 70 000 nerve fibers in the arm—to impart the ability to ”feel” the stimulation of a phantom limb. Normally, the nerves travel

from the upper spinal cord across the shoulder, down into the armpit, and into the arm. Kuiken pulled them away from the armpit and under the clavicle to connect to the pectoral muscles. The patient thinks about moving the arm, and signals travel down nerves that were formerly connected to the native arm but are now connected to the chest. The chest muscles then contract in response to the nerve signals. The contractions are sensed by electrodes on the chest, the electrodes send signals to the motors of the prosthetic arm—and the arm moves. With Kuiken's surgery, a user can control the DEKA arm with his or her own muscles, as if the arm were an extension of the person's flesh. However, the DEKA arm also provides feedback to the user *without* surgery. Instead, the feedback is given by a tactor. A tactor is a small vibrating motor—about the size of a bite-size candy bar—secured against the user's skin. A sensor on the DEKA hand, connected to a microprocessor, sends a signal to the tactor, and that signal changes with grip strength. When a user grips something lightly, the tactor vibrates slightly. As the user's grip tightens, the frequency of the vibration increases.

Conclusion

There are 1.5 million amputees in the U.S. who are customers of limb prosthetics services and products. This number increases by 185,000 per year. 6,000 are upper-extremity (arm, hand, fingers) amputees. 40,000 amputees are currently served by the Veterans Administration. The overall number of amputees will accelerate because of diabetes related amputation

Third party insurance reimbursement (private insurers, Medicare, Medicaid, Veterans Administration, and Department of Defense) have the largest impact on the growth of the limb prosthetic markets. Restrictions and caps on insurance reimbursement dominate the selection and utilization of prosthetics used by amputees. Restrictions and caps often have the result of increasing long-term healthcare costs.

New technologies and innovations in limb prosthetics create more market demand and market pressures. Academic funded research of limb prosthetics has decreased, but defense related research of prosthetics has dramatically increased.

Neuroprosthetics have the promise of turning dreams into realities for limb amputees. Because of costs and current reimbursement structures, it is unlikely in

the near-term that limb neuroprosthetics will have much of a market beyond the military and self-payers. As technologies advance, federal policies (may) change and quality of life demands are vocalized, the market for limb neuroprosthetics will grow. This market may take a path similar to biological/large molecule pharmaceuticals in its product acceptance, demand trajectory and third party reimbursement.

Sources

Among the sources for this market analysis are:

Walter Reed Army Medical Center
Henry Jackson Foundation
Amputee Coalition of America
O&P Edge
The Press-Enterprise
Frost & Sullivan
Securities and Exchange Commission
Boston Globe
Aetna Insurance
Atlas of Prosthetics
National Institutes of Health
Disabled-World.com
One Source
ArmDynamics.com

Appendix A

Incidents of Limb Loss in the U.S.

Limb loss affects a variety of people in the United States and around the world and includes people of every race, ethnicity and background without regard to geographic location, occupation or economic level. In 2007, there are approximately 1.7 million persons living with limb loss in the U.S. * Datasource: Unpublished paper from Johns Hopkins.

The main cause of acquired limb loss is poor circulation in a limb due to arterial disease, with more than half of all amputations occurring among people with diabetes mellitus. Amputation of a limb may also occur after a traumatic event or for the treatment of a bone cancer. Congenital limb difference is the complete or partial absence of a limb at birth.

Table 1.0 Persons Living with Limb Loss, 1996*	
Age Group	Frequency
< 18 years	70,000
18 - 44 years	293,000
45 - 64 years	305,000
65 - 74 years	395,000
75+ years	223,000
Gender	
Male	893,000
Female	392,000
Race	
White	1,188,000
Black	98,000

*Absence of extremity, excluding fingers and toes.
DATA SOURCE: National Health Interview Survey, Vital Statistics Report, Series 10, No. 200.

INCIDENCE

There are approximately 185,000 amputation related hospital discharges each year in the U.S. The number of new cases of limb loss is greatest among persons with diabetes, with 1 out of every 185 persons diagnosed undergoing amputation of a limb. (See **table 2.0**)

Limb difference occurs in 1 in 3,846 live births in the U.S., or at a rate of 2.6 per 10,000 live births. Congenital upper limb difference occurs 1.6 times more often than lower limb difference.

Table 2.0 New Cases of Limb Loss, 1996	
	Incidence per 10,000 persons
Dysvascular Disease*	4.6
Diabetes Mellitus**	54.0
Trauma	0.6
Bone and Joint Cancer	0.04
	Incidence per 10,000 live births
Limb Difference	2.6
*Not including persons with diabetes mellitus. **Among persons diagnosed with diabetes mellitus.	
DATA SOURCE: Health Care Utilization Project National Inpatient Sample (HCUP-NIS), 1996.	

SECONDARY CONDITIONS

Most individuals experiencing the loss of a limb have the potential to attain a high degree of function and a satisfying quality of life. However, disability may result in persons with

limb loss as a result of secondary conditions, such as back pain and phantom pain in the amputated limb as well as vascular and orthopedic complications.

PROSTHETIC USE

Use of prosthesis or artificial limb among amputees can assist with ambulation and participation in activities of daily living. It is estimated that approximately 199,000 persons in the U.S. were using an artificial limb in 1994, with the majority using an artificial leg or foot (173,000). * Datasource: National Center for Health Statistics, Disability Report. Table 1

RISK FACTORS

The risk of limb loss increases with age, with persons aged 65 years or older having the greatest risk of amputation. As with diabetes and heart disease, smoking, lack of exercise and improper nutrition may also increase the risk of limb loss. Certain racial and ethnic groups are at increased risk of amputation (e.g. African-Americans, Native Americans and Hispanic Americans).

Appendix B

Types of Amputation

Amputations are generally classified according to the level at which they are performed. Some amputation levels are referred to by the name of the surgeon credited with developing the amputation technique used.

Lower-Extremity Amputations

Syme's Amputation

Developed about 1842 by James Syme, a leading Scottish surgeon, the Syme amputation leaves the long bones of the shank (the tibia and fibula) virtually intact, only a small portion at the very end being removed. The tissues of the heel, which are ideally suited to withstand high pressures, are preserved, and this, in combination with the long bones, usually permits the patient to bear the full weight of his body on the end of the stump. Because the amputation stump is nearly as long as the unaffected limb, a person with Syme's amputation can usually get about the house without a prosthesis even though normal foot and ankle action has been lost. Atrophy of the severed muscles that were formerly attached to bones in the foot to provide ankle action results in a stump with a bulbous end which, though not of the most pleasing appearance, is quite an advantage in holding the prosthesis in place. Since its introduction, Syme's operation has been looked upon with both favor and disfavor among surgeons. It seems to be the consensus now that "the Syme" should be performed in preference to amputation at a higher level if possible. In the case of most women, though, "the Syme" is undesirable because of the difficulty of providing a prosthesis that matches the shape of the other leg.

Below-Knee Amputations

Any amputation above the Syme level and below the knee joint is known as a below-knee amputation. Because circulatory troubles have often developed in long below-knee stumps, and because the muscles that activate the shank are attached at a level close to the knee joint, the below-knee amputation is usually performed at the junction of the

upper and middle third sections. Thus nearly full use of the knee is retained- an important factor in obtaining a gait of nearly normal appearance. However, it is rare for a below-knee amputee to bear a significant amount of weight on the end of the stump; thus the design of prostheses must provide for weight-bearing through other areas. Several types of surgical procedures have been employed to obtain weight-bearing through the end of the below-knee stump, but none has found widespread use.

Knee-Bearing Amputations

Complete removal of the lower leg, or shank, is known as a knee disarticulation. When the operation is performed properly, the result is an efficient, though bulbous, stump capable of carrying the weight-bearing forces through the end. Unfortunately, the length causes some problems in providing an efficient prosthesis because the space used normally to house the mechanism needed to control the artificial shank properly is occupied by the end of the stump. Nevertheless, prostheses have been highly beneficial in knee-disarticulation cases. Development of adequate devices for obtaining control of the shank is currently under way, and such devices should be generally available in the near future.

Several amputation techniques have been devised in an attempt to overcome the problems posed by the length and shape of the true knee-disarticulation stump. The Gritti-Stokes procedure entails placing the kneecap, or patella, directly over the end of the femur after it has been cut off about two inches above the end. When the operation is performed properly, excellent results are obtained, but extreme skill and expert postsurgical care are required. Variations of the Gritti-Stokes amputation have been introduced from time to time but have never been used widely.

Above-Knee Amputations

Amputations through the thigh are among the most common. Total body weight cannot be taken through the end of the stump but can be accommodated through the ischium, that part of the pelvis upon which a person normally sits.

Hip Disarticulation and Hemipelvectomy

A true hip disarticulation involves removal of the entire femur, but whenever feasible the surgeon leaves as much of the upper portion of the femur as possible in order to provide additional stabilization between the prosthesis and the wearer, even though no additional function can be expected over the true hip disarticulation. Both types of stump are provided with the same type of prosthesis. With slight modification the same type of prosthesis can be used by the hemipelvectomy patient, that is, when half of the pelvis has been removed. It is surprising how well hip-disarticulation and hemipelvectomy patients have been able to function when fitted with the newer type of prosthesis.

Upper-Extremity Amputations

Partial-Hand Amputations

If sensation is present the surgeon will save any functional part of the hand in lieu of disarticulation at the wrist. Any method of obtaining some form of grasp, or prehension, is preferable to the best prosthesis. If the result is unsightly, the stump can be covered with a plastic glove, lifelike in appearance, for those occasions when the wearer is willing to sacrifice function for appearance. Many prosthetists have developed special appliances for partial-hand amputations that permit more function than any of the artificial hands and hooks yet devised and, at the same time, permit the patient to make full use of the sensation remaining in the stump. Such devices are usually individually designed and fitted.

Wrist Disarticulation

Removal of the hand at the wrist joint was once condemned because it was thought to be too difficult to fit so as to yield more function than a shorter forearm stump. However, with plastic sockets based on anatomical and physiological principles, the wrist-disarticulation case can now be fitted so that most of the pronation-supination of the forearm-an important function of the upper extremity-can be used. In the case of the wrist disarticulation, nearly all the normal forearm pronation-supination is present. Range of pronation-supination decreases rapidly as length of stump decreases; when 60 per cent of the forearm is lost, no pronation-supination is possible.

Amputations Through the Forearm

Amputations through the forearm are commonly referred to as below-elbow amputations and are classified as long, short, and very short, depending upon the length of stump. Stumps longer than 55 per cent of total forearm length are considered long, between 35 and 55 per cent as short, and less than 35 per cent as very short.

Long stumps retain the rotation function in proportion to length; long and short stumps without complications possess full range of elbow motion and full power about the elbow, but often very short stumps are limited in both power and motion about the elbow. Devices and techniques have been developed to make full use of all functions remaining in the stump.

Disarticulation at the Elbow

Disarticulation at the elbow consists of removal of the forearm, resulting in a slightly bulbous stump but usually one with good end-weight-bearing characteristics. The long bulbous end, while presenting some fitting problems, permits good stability between socket and stump, and thus allows use of nearly all the rotation normally present in the upper arm-a function much appreciated by the amputee.

Above-Elbow Amputation

Any amputation through the upper arm is generally referred to as an above-elbow amputation. In practice, stumps in which less than 30 per cent of the humerus remains are treated as shoulder-disarticulation cases; those with more than 90 per cent of the humerus remaining are fitted as elbow-disarticu-lation cases.

Shoulder Disarticulation and Forequarter Amputation

Removal of the entire arm is known as shoulder disarticulation but, whenever feasible, the surgeon will leave intact as much of the humerus as possible to provide stability between the stump and the socket. When it becomes necessary to remove the clavicle and scapula, the operation is known as a forequarter, or interscapulothoracic, amputation. The very short above-elbow, the shoulder-disarticulation, and the forequarter cases are all provided with essentially the same type of prosthesis.

The Postsurgical Period

The period between the time of surgery and time of fitting the prosthesis is an important one if a good functional stump, and thus the most efficient use of a prosthesis, is to be obtained. The surgeon and others on his hospital staff will do everything possible to ensure the best results, but ideal results require the wholehearted cooperation of the patient.

It is not unnatural for the patient to feel extremely depressed during the first few days after surgery, but after he becomes aware of the possibilities of recovery, the outlook becomes brighter, and he generally enters cooperatively into the rehabilitation phase.

As soon as the stump has healed sufficiently, exercise of the stump is started in order to keep the muscles healthy and reduce the possibility of muscle contractures. Contractures can be prevented easily, but it is most difficult and sometimes impossible to correct them. At first exercises are administered by a therapist or nurse; later the patient is instructed concerning the type and amount of exercise that should be undertaken. The patient is also instructed in methods and amount of massage that should be given the stump to aid in the reduction of the stump size. Further, to aid shrinkage, cotton-elastic bandages are wrapped around the stump and worn continuously until a prosthesis is fitted. The bandage is removed and reapplied at regular intervals- four times during the day, and at bedtime. It is most important that a clean bandage is available for use each day.

The amputee is taught to apply the bandage unless it is physically impossible for him to do so, in which case some member of his family must be taught the proper method for use at home.

To reduce the possibility of contractures, the lower-extremity stump must not be propped upon pillows. Wheel chairs should be used as little as possible; crutch walking is preferred, but the above-knee stump must not be allowed to rest on the crutch handle.

Appendix C

Prostheses for Various Types of Amputation

Much time and attention have been devoted to the development of mechanical components, such as knee and ankle units, for artificial limbs, yet by far the most important factors affecting the successful use of a prosthesis are the fit of the socket to the stump and the alignment of the various parts of the limb in relation to the stump and other parts of the body.

Thus, though many parts of a prosthesis may be mass-produced, it is necessary for each limb to be assembled in correct alignment and fitted to the stump to meet the individual requirements of the intended user. To make and fit artificial limbs properly requires a complete understanding of anatomical and physiological principles and of mechanics; craftsmanship and artistic ability are also required.

In general, an artificial limb should be as light as possible and still withstand the loads imposed upon it. In the United States willow and woods of similar characteristics have formed the basis of construction for more limbs than any other material, though aluminum, leather-and-steel combinations, and fibre have been used widely. Wood construction is still the type most used in the United States for above-knee prostheses, but plastic laminates similar to those so popular in small-boat construction are the materials of choice for virtually all other types of prostheses. Plastic laminates are light in weight, easy to keep clean, and do not absorb perspiration. They may be molded easily and rapidly over contours such as those found on a plaster model of a stump. Plastic laminates can be made extremely rigid or with any degree of flexibility required in artificial-limb construction. In some instances, especially in upper-extremity sockets, the fact that most plastic laminates do not permit water vapor to pass to the atmosphere has caused discomfort, but recently a porous type has been developed by the Army Medical Biomechanical Research Laboratory (formerly the Army Prosthetics Research Laboratory). Except experimentally, its use thus far has been restricted to artificial arms. Of course, most of the mechanical parts are made of steel or aluminum, depending upon their function.

As in the case of the tailor making a suit, the first step in fabrication of a prosthesis is to take the necessary measurements for a good fit. If the socket is to be fabricated of a

plastic laminate, an impression of the stump is made. Most often this is accomplished by wrapping the stump with a wet plaster-of-Paris bandage and allowing it to dry, as a physician does in applying a cast when a bone is broken.

The cast, or wrap, is removed from the stump and filled with a plaster-of-Paris solution to form an exact model of the stump which-after being modified to provide relief for any tender spots, to ensure that weight will be taken in the proper places, and to take full advantage of the remaining musculature- can be used for molding a plastic-laminate socket. Often a "check" socket of cloth impregnated with beeswax is made over the model and tried on the stump to determine the correctness of the modifications.

For upper-extremity cases the socket is attached to the rest of the prosthesis and a harness is fabricated and installed for operation of the various parts of the artificial arm. For the lower-extremity case the socket is fastened temporarily to an adjustable, or temporary, leg for walking trials. With this device, the prosthetist can easily adjust the alignment until both he and the amputee are satisfied that the optimum arrangement has been reached. A prosthesis can now be made incorporating the same alignment achieved with the adjustable leg.

There are many kinds of artificial limbs available for each type of amputation, and much has been written concerning the necessity for prescribing limbs to meet the needs of each individual. This of course is true particularly in the case of persons in special or arduous occupations, or with certain medical problems, but actually limbs for a given type of amputation vary to only a small degree. Following are descriptions of the artificial limbs most commonly used in the United States today.

Lower-Extremity Prostheses

Prostheses for Syme's Amputation

Perhaps the major reason Syme's amputation was held in such disfavor in some quarters was the difficulty in providing a comfortable, sufficiently strong prosthesis with a neat appearance. The short distance between the end of the stump and the floor made it extremely difficult to provide for ankle motion needed. Most Syrae prostheses were of leather reinforced with steel side bars resulting in an ungainly appearance. Research workers at the Prosthetic Services Centre at the Department of Veterans Affairs of Canada were quick to realize that the use of the proper plastic laminate might solve many of the problems long associated with the Syme prosthesis. After a good deal of experimentation, the Canadians developed a model in 1955 which, with a few variations, is used almost universally in both Canada and the United States today.

Necessary ankle action is provided by making the heel of the foot of sponge rubber. The socket is made entirely of a plastic laminate. A full-length cutout in the rear permits entry of the bulbous stump. When the cutout is replaced and held in place by straps, the bulbous stump holds the prosthesis in place. In the American version, a window-type

cutout is used on the side because calculations show that smaller stress concentrations are present with such an arrangement.

In those cases where, for poor surgery or other reasons, full body weight cannot be tolerated on the end of the stump, provisions can be made to transfer all or part of the load to the area just below the kneecap. When this procedure is necessary, it can be accomplished more easily by use of the window-type cutout.

Prostheses for Below-Knee Amputations

Until recently most below-knee amputees were fitted with wooden prostheses carved out by hand. A good portion of the body weight was carried on a leather thigh corset, or lacer, attached to the shank and socket by means of steel hinges. The shape of corset and upper hinges also held the prosthesis to the stump. The distal, or lower, end of the socket was invariably left open. Other versions of this prosthesis used aluminum, fibre or molded leather, as the materials for construction of the shank and socket, but the basic principle was the same. Many thousands of below-knee amputees have gotten along well with this type of prosthesis, but there are many disadvantages. Because the human knee joint is not a simple, single-axis hinge joint, relative motion is bound to occur between the prosthesis and the stump and thigh during knee motion when single-jointed side hinges are used, resulting in some chafing and irritation. To date it has not been possible to devise a hinge to overcome this difficulty. Edema, or accumulation of body fluids, was often present at the lower end of the stump. Most of these prostheses were exceedingly heavy, especially those made of wood.

In an attempt to overcome these difficulties, the Biomechanics Laboratory of the University of California, in 1958, designed what is known as the patellar-tendon-bearing (PTB) below-knee prosthesis. In the PTB prosthesis no lacer and side hinges are used, all of the weight being taken through the stump by making the socket high enough to cover all the tendon below the patella, or kneecap. The patellar tendon is an unusually inelastic tissue which is not unduly affected by pressure. The sides of the socket are also made much higher than has usually been the practice in the past in order to give stability against side loads. The socket is made of molded plastic laminate that provides an intimate fit over the entire area of the socket, and is lined with a thin layer of sponge rubber and leather. Because it is rare for a below-knee stump to bear much pressure on its lower end, care is taken to see that only a very slight amount is present in that area. This feature has been a big factor in eliminating the edema problem in many instances. The PTB prosthesis is generally suspended by means of a simple cuff, or strap, around the thigh just above the kneecap, but sometimes a strap from the prosthesis to a belt around the waist is used.

After the socket has been made, it is installed on a special adjustable leg so that the prosthetist can try various alignment combinations with ease. When both prosthetist and patient are satisfied, the leg is completed uti- lizing the alignment determined with the adjustable unit.

The shank recommended is of plastic laminate and the foot prescribed is usually the SACH (solid-ankle, cushion-heel) design but other types can be used.

It is now general practice in many areas to prescribe the PTB prosthesis in most new cases and in many old ones, and if side hinges and a corset are indicated later, these can be added.

Stumps as short as 2-1/2 in. have been fitted successfully with the PTB prosthesis.

In special cases, such as extreme flexion contracture, the so-called kneeling-knee, or bent-knee, prosthesis may be indicated. The prosthesis used is similar to that used for the knee-disarticulation case.

Prostheses for the Knee-Disarticulation and Other Knee-Bearing Cases

Because of the bulbous shape of the true knee-disarticulation stump, it is not possible to use a wooden socket of the type used on the tapered above-knee stump. To allow entry of the bulbous end, a socket is molded of leather to conform to the stump and is provided with a lengthwise anterior cutout that can be laced to hold the socket in position. Because of the length of the knee-disarticulation and supracondylar stump, it is not possible to install any of the present knee units designed for above-knee prostheses and, therefore, heavy-duty below-knee joints are generally used. Most prosthetists try to provide some control of the shank during the swing phase of walking by inserting nylon washers between the mating surfaces of the joint to provide friction and by using checkstraps. Better devices for control of the knee joint are being developed and should be available in the near future.

Prostheses for Above-Knee Cases

The articulated above-knee leg is in effect a compound pendulum actuated by the thigh stump. If the knee joint is perfectly free to rotate when force is applied, the effects of inertia and gravity tend to make the shank rotate too far backward and slam into extension as it rotates forward, except at a very slow rate of walking. The method most used today to permit an increase in walking speed is the introduction of some restraint in the form of mechanical friction about the knee joint. The limitation imposed by constant mechanical friction is that for each setting there is only one speed that produces a natural-appearing gait. When restraint is provided in the form of hydraulic resistance, a much wider range of cadence can be obtained without introducing into the gait pattern awkward and unnatural motions.

Throughout the past century much time and effort have been spent in providing an automatic brake or lock at the knee in order to provide stability during the stance phase and to reduce the possibility of stumbling. Stability during the stance phase can be obtained by aligning the leg so that the axis of the knee is behind the hip and ankle axes. For most above-knee amputees in good health, such an arrangement has been quite satisfactory, but an automatic knee brake is indicated for the weaker or infirm patients.

The prosthesis prescribed most commonly today for the above-knee amputee consists of a carved wooden socket, a single-axis knee unit with constant but adjustable friction, a wooden shank, and a SACH foot. The shank and socket are reinforced with an outer layer of plastic laminate to reduce the amount of wood required and thus keep weight to an optimum.

When an automatic brake is indicated, the Bock, the "Vari-Gait" 100, and the Mortensen knee units are the ones most generally used. All are actuated upon contact of the heel with the ground. The Bock and "Vari-Gait" units can be used with almost any type of foot, while a foot of special design is necessary when the Mortensen mechanism is used.

The "Hydra-Cadence" above-knee leg was until recently the only unit available that provided hydraulic friction to control the shank during the swing phase of walking. In addition to this feature, incorporated in the Hydra-Cadence design is provision for coordinated motion between the ankle action and the knee action. After the knee has flexed 20 deg., the toe of the foot is lifted as the knee is flexed further, thus giving more clearance between the foot and the ground as the leg swings through. Other hydraulic units recently made available are the Regnell (a Swedish design) and the DuPaCo. Still others are in advanced stages of development.

A number of methods for suspending the above-knee leg are available. For younger, healthy patients, the suction socket is generally the method of choice. In this design the socket is simply fitted tightly enough to retain sufficient negative pressure, or suction, between the stump and the bottom of the socket when the leg is off the ground. Special valves are used to control the amount of negative pressure created so as not to cause discomfort. No stump sock is worn with the suction socket. A major advantage of this type of suspension is the freedom of motion permitted the wearer, thus allowing the use of all the remaining musculature of the stump. Another important advantage is the decreased amount of piston action between stump and socket. Additional comfort is also obtained by elimination of all straps and belts.

In some cases additional suspension is provided by adding a "Silesian Bandage", a light belt attached to the socket in such a way that there is very little restriction to motion of the various parts of the body.

Patients with weak stumps and most of those with very short stumps will require a pelvic belt connected to the socket by means of a "hip" joint. Because the connecting joint cannot be placed to coincide with the normal joint, certain motions are restricted. Pelvic-belt suspension is generally indicated for the older patient because of the problems encountered in donning the suction socket, especially that of bending over to remove the donning sock.

Shoulder straps, at one time the standard method of suspending above-knee prostheses, are still sometimes indicated for the elderly patient.

Prior to the introduction of the suction socket into the United States soon after the close of World War II, virtually all above-knee sockets had a conical-shaped interior and were known as plug fits, most of the weight being borne along the sides of the stump. Such a design does not permit the remaining musculature to perform to its full capabilities. In the development of the suction socket, a design known as the quadrilateral socket evolved, and now is virtually the standard for above-knee sockets regardless of the type of suspension used. When the pelvic belt or suspender straps are used, the socket is fitted somewhat looser than in the case of the suction socket, and the stump sock is generally worn to reduce skin irritation from the pumping action of the loose socket. Most of the body weight is taken on the ischium of the pelvis, that part which assumes the load when an individual is sitting.

The quadrilateral socket, because of the method employed to permit full use of the remaining muscles, does not resemble the shape of the stump but, as the name implies, is more rectangular in shape. Until recently the standard method of fitting a quadrilateral socket called for no contact over the lower end of the stump, a hollow space being left in this area. Although this method was quite successful there remained a sufficient number of cases that persistently developed ulcers or edema over the end of the stump. Experiments involving the use of slight pressure over the stump-end led to the development of what is known as the plastic total-contact socket. As the name implies, the socket is in contact with the entire surface of the stump. The total-contact socket has helped to cure most of the problem cases and is now being used routinely in many areas.

In fitting the above-knee prosthesis, the prosthetist carves the interior of the socket using measurements of the stump as a guide. When a satisfactory fit has been achieved the socket is usually mounted on an adjustable leg for alignment trial, after which the wooden shank and the knee are substituted for the adjustable unit and the leg is finished by applying a thin layer of plastic laminate over the shank and the thigh piece.

In the case of the total-contact socket, the prosthetist obtains a plaster cast of the stump, usually with the aid of a special casting jig, and thus obtains a model of the stump over which the plastic socket can be formed.

Prostheses for Hip-Disarticulation and Hemi-pelveclomy Cases

A prosthesis developed by the Canadian Department of Veterans Affairs in 1954 and modified slightly through the years has become accepted as standard practice. In the Canadian design a plastic-laminate socket is used, and the "hip" joint is placed on the front surface in such a position that, when used with an elastic strap connecting the rear end of the socket to a point on the shank ahead of the femur, stability during standing and walking can be achieved without the use of a lock at the hip joint. The location of the hip joint in the Canadian design also facilitates sitting, a real problem in earlier designs.

A constant-friction knee unit is most often used with the hip-disarticulation prosthesis, but some prosthetists have reported successful use of hydraulic knee units.

The hemipelvectomy patient is provided with the same type of prosthesis but the socket design is altered to allow for the loss of part of the pelvis.

Upper-Extremity Prostheses

The major role of the human arm is to place the hand where it can function and to transport objects held in the hand. The energy for operation of the hand substitute in upper-extremity prostheses is derived from relative motion between two parts of the body. Energy for operation of the elbow joint, when necessary, can be obtained in the same way. The stump, of course, is also a source of energy for control of the prosthesis in all except the shoulder-disarticulation and fore-quarter cases. Force and motion can be obtained through a cable connected between the device to be operated and a harness across the chest or shoulders.

Hand Substitutes-Terminal Devices

All upper-extremity prostheses for amputation at the wrist level and above have, in common, the problem of selection of the terminal device, a term applied to artificial hands and substitute devices such as hooks. In some areas of the world there is a tendency to supply the arm amputee with a number of devices, each designed for a specific task such as eating, shaving, hairgrooming, etc. In the United States such an approach has been considered too clumsy, and opinion has been that the terminal device should be designed so that most upper-extremity amputees can perform the activities of daily living with a single device, or at most with two devices.

The so-called split hooks are much more functional than any artificial hand devised to date. The arm amputee must rely heavily upon visual cues in handling objects and the hook offers more visibility. The hook also offers more prehension facility, and can be more easily introduced into and withdrawn from pockets than a device in the form of a hand. Therefore, the hook is used in manual occupations and those avocations requiring manual dexterity. When extensive contact with the public is necessary and for social occasions, the hand is of course generally preferred. Many amputees have both types of devices, using each as the occasion warrants. Two basic types of mechanism have been developed for terminal-device operation- voluntary-opening and voluntary-closing. In the former, tension on the control cable opens the fingers against an elastic force; in the latter, tension in the control cable closes the fingers against an elastic force. Each type of mechanism has its advantages and disadvantages, neither being superior to the other when used in a wide range of activities. Both hands and hooks are available with either type of mechanism.

The major types of terminal devices are shown in and .

Prostheses for the Wrist-Disarticulation Case

One of the problems in fitting the wrist disarticulation in the past has been to keep the over-all length of the prosthesis commensurate with the normal arm. The development of

very short wrist units, especially for wrist-disarticulation cases, has materially reduced this problem. However, these units are available in only the screw, or thread, type, and cannot be obtained in the bayonet type which lends itself to quick interchange of terminal devices.

The socket for the wrist-disarticulation case need not extend the full length of the forearm and is fitted somewhat loosely at the upper, or proximal, end to permit the wrist to rotate. A simple figure-eight harness and Bowden cable are used to operate the terminal device .

Prostheses for the Long Below-Elbow Case

The prosthesis for the long below-elbow case is essentially the same as that for the wrist-disarticulation patient except that the quick-disconnect wrist unit can be used when desired.

Prostheses for the Short Below-Elbow Case

The socket for the short below-elbow stump, where there is no residual rotation of the forearm, is usually fitted snugly to the entire slump, and often rigid hinges connecting the socket to a cuff about the upper arm are used to provide additional stability. Either the figure-eight harness or the chest-strap harness may be used, the latter being preferred when heavy-duty work is required since it tends to spread the loads involved in lifting over a broader area than is the case with the figure-eight design.

A wrist-flexion unit, which permits the terminal device to be tilted in toward the body for more effective use, can be provided in the short below-elbow prosthesis but is seldom prescribed for unilateral cases.

Prostheses for the Very Short Below-Elbow Case

Often the very short below-elbow case cannot control the prosthesis of the short below-elbow type through the full range of motion, either because of a muscle contracture or because the stump is too short to provide the necessary leverage.

When a contracture is present that limits the range of motion of the stump, a "split-socket" and "step-up" hinge may be used. With this arrangement of levers and gears, movement of the stump through one degree causes the prosthetic forearm to move through two degrees; thus, a stump that has only about half the normal range of motion can drive the forearm through the desired 135 deg. However, when the step-up hinge is used, twice the normal force is required. When the stump is incapable of supplying the force required, it can be assisted by employing the "dual-control" harness wherein force in the terminal-device control cable is diverted to help lift the forearm. When the elbow stump is very short or has a very limited range of motion, an elbow lock operated by stump motion is employed to obtain elbow function.

Recently a number of prosthetists have reported success in fitting very short below-elbow cases with an arm which is bent to give a certain amount of preflexion. This type of fitting, which was developed in Munster, West Germany, eliminates the necessity for using the rather clumsy step-up hinges and split socket, thus providing improved prosthetic control without a disadvantageous force feedback. Furthermore, the harness is not necessary for suspension of the prosthesis. The maximum forearm flexion may be limited to about 100 deg., but this does not appear to be a significant disadvantage to unilateral amputees.

Prostheses for the Elbow-Disarticulation Case

Because of the length of the elbow-dis-articulation stump, the elbow-locking mechanism is installed on the outside of the socket. Otherwise the prosthesis and harnessing methods are identical to those applied to the above-elbow case.

Prostheses for the Above-Elbow Case

For the above-elbow prosthesis to operate efficiently, it is necessary that a lock be provided in the elbow joint, and it is, of course, preferable that the lock is engaged and disengaged without resorting to the use of the other hand or pressing the locking actuator against an external object such as a table or chair.

Several elbow units that can be locked and unlocked alternately by the same motion are available. This action is usually accomplished by the relative motion between the prosthesis and the body when the shoulder is depressed slightly and the arm is extended somewhat. The motion required is so slight that with practice the amputee can accomplish the action without being noticed. These elbow units contain a turntable above the elbow axis that permits the forearm to be positioned with respect to the humerus, supplementing the normal rotation remaining in the upper arm and thus allowing the prosthesis to be used more easily close to the mid-line of the body.

The elbow units described above are available with an adjustable coil spring to assist in flexing the elbow when this is desired. The flexion-assist device may be added or removed without affecting the other operating characteristics.

The plastic socket of the above-elbow prosthesis covers the entire surface of the stump. The most popular harness used is the figure-eight dual-control design wherein the terminal-device control cable is also attached to a lever on the forearm so that, when the elbow is unlocked, tension in the control cable produces elbow flexion, and, when the elbow is locked, the control force is diverted to the terminal device.

The chest-strap harness may also be used in the dual-control configuration.

Prostheses for the Shoulder-Disarticulation and Forequarter Cases

Because of the loss of the upper-arm motion as a source of energy for control and operation of the prosthesis, restoration of the most vital functions in the shoulder-disarticulation case presents a formidable problem; for many years a prosthesis was provided for this type of amputation only for the sake of appearance. In recent years, however, it has been possible to make available prostheses which provide a limited amount of function. To date it has not been possible to devise a shoulder joint that can be activated from a harness, but a number of manually operated joints are available. Various harness designs have been employed but, because of the wide variation in the individual cases and the marginal amount of energy available, no standard pattern has developed, each design being made to take full advantage of the remaining potential of the particular patient.

Prostheses for Bilateral Upper-Extremity Amputees

Except for the bilateral, shoulder-disarticu-lation case, fitting the bilateral case offers few problems not encountered with the unilateral case. The prostheses provided are generally the same as those prescribed for corresponding levels in unilateral cases. Artificial hands are rarely used by bilateral amputees because hooks afford so much more function. Many bilateral cases find that the wrist-flexion unit, at least on one side, is of value. The harness for each prosthesis may be separated, but it is the general practice to combine the two. In addition to being neater, this arrangement makes the harness easier for the patient to don unassisted.

Some prosthetists have claimed success in fitting bilateral shoulder-disarticulation cases with two prostheses. Because of the lack of sufficient sources of energy for control, most cases of this type are provided with a single, functional prosthesis and a plastic cap over the opposite shoulder which provides an anchor for the harness and also fills this area to present a better appearance.