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REVIEW ARTICLE

Innovations in Advanced Wound Care from India

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ABSTRACT

India is undergoing significant development in medical device manufacturing, driven by strong government support throughout the conceptualization, inception, and development stages. This growth has been fuelled by initiatives like "Make in India" and the vision of an "AtmaNirbhar Bharat" (self-reliant India), which have provided impetus to the industry. With the integration of AI and machine learning technologies, India has made remarkable progress in the development of domestically manufactured robotic surgery systems. These advanced systems have revolutionized surgical procedures by enhancing precision, efficiency, and accessibility. By leveraging 3D printing technology, India has also made significant strides in producing customized medical devices, prosthetics, and anatomical models. These innovations have facilitated surgical planning and training and contributed to the overall advancement of healthcare in the country. The growth of the medical device industry in India is particularly evident in the class I devices segment. Numerous Indian companies have experienced rapid expansion and have even ventured into foreign markets. This trend is exemplified by the success of hemostatic dressings and wound care devices, where Indian manufacturers have developed high-quality products that have gained recognition globally. While India was traditionally known as the "global pharmacy" for its production of generic pharmaceuticals, it is now making its mark in the medical devices industry by offering innovative and reliable devices on the global stage. The government's unwavering support and the emphasis on self-reliance have fostered a favorable environment for the growth of India's medical device manufacturing sector.

Keywords: India, Wound care, Wounds, Wound dressings

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INTRODUCTION

The breach in the integrity of biological tissues, such as the skin, mucous membranes, and other internal organs, is commonly referred to as a wound.[1] During procedures, wounds can be unintentionally or purposefully produced. Although wounds can occur anywhere on the body, as mentioned, the skin is the organ most frequently affected by wounds because it is exposed to the outside world. When categorized by surface area, it is the biggest organ in the human body. It keeps the body temperature constant and shields the interior tissues from harmful exterior factors like physical harm, microbial infection, and UV radiation.[2] The majority of the literature discusses the skin's role in the healing of wounds, which highlights how common skin wounds are. Given the ubiquity of wounds on the skin, most of the literature discusses the wound-healing process regarding skin. According to estimates, there are 2.2 wounds per 1000 people worldwide across all wound aetiologies.[3] As a result, the expense of treating wounds is also rising.[4] By 2024, the market for advanced wound care is anticipated to surpass $22 billion.[5] The wound care market has expanded recently due to recent technological advancements and an increase in the prevalence of chronic wounds. The introduction of new products and the rise in interest in wound care are further significant factors. India is keeping up with the developments in this direction by developing advanced wound care dressings to cater the needs of the world. It is proven that the subcontinent is the pharmacy of the world in providing affordable pharmaceuticals and now its gaining pace in the development of advanced wound care dressings. Before delving deep into the wound care devices, we discuss what are wounds and areas where advanced wound care is needed and then we discuss how India is developing advanced wound care dressings.

Wounds on the skin and their healing capabilities

Skin is the largest organ, playing key roles in preventing the body from microbial attacks and maintaining the body

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temperature. However, it can't regenerate thus, it gives scars on the wounds that have healed.[6] After the wound occurrence, the skin acts to restore its barrier function and closes the wound eventually. However, the maximum tensile strength of the healed skin would only reach 70% of the unwounded skin. The wound is delivered by myriad substances by the surrounding skin tissue, including various inflammatory cells, chemokines, cytokines, matrix molecules and nutrients for efficient wound healing. Wound healing gets tougher as we age. The elderly are the highest risk groups for non-healing wounds as the healing process is hindered in these populations. The fetal healing occurs at an accelerated rate and results in complete skin restoration without scarring. However, this is not possible in the case of adults as the fibroproliferative response results in the deposition of poorly organized collagen. This results in loss of hair follicles and sebaceous glands and results in decreased tensile strength.[7] This phenomenon is age-dependent. The wounds created on the skin of fetuses heal without any scars. The adult skin gives scars on the wounds that are healed. It is a huge market in cosmetics that heal wounds without leaving any scars.

Naturally, wounds heal on their own.[1] The wound healing process is categorized into five main stages: hemostasis, inflammation, proliferation, re-epithelialization and remodeling.[7] Some researchers adjust these into four stages.[1] If unattended, The hemostasis stage lasts for a few minutes to hours. The arterial rupture would lead to excess blood loss and can be life-threatening in cases where the bleeding does not stop within the time period. In fact, during traumatic injuries, the deaths were caused due to uncontrolled bleeding. However, in minor injuries, the bleeding stops as the natural hemostasis process takes place after the injury. The next phase is the inflammatory phase, and it starts after the hemostasis is achieved. The inflammation takes place at the wound site primarily to clear the pathogens and any foreign material from the wound. Vascular permeability increases with vasodilation, increasing the neutrophils and monocyte localization to the wound site. Cytokines play a key role during this phase. Monocytes are converted to macrophages, which phagocytose debris and secrete growth factors and cytokines to facilitate proliferation and cell migration. In 3 days, collagen is provided to the wound area to act as a tissue scaffold and to build the extracellular matrix. Endothelial cells enter the growth phase and angiogenesis takes place within the newly formed granulation tissue. These newly formed blood vessels supply the required cells and nutrients to the healing area. In 2 to 3 weeks, the wound transitions into a remodeling phase. During this phase, wound tissue matures, crosslinks, and restores the skin's normal structure. However, it cannot reach the normal strength of the skin. Non-healing wounds or chronic wounds rest in the inflammatory phase and generally do not proceed to the proliferative stage. These are the wounds that need to be managed for discomfort, pain, and healing.

While assessing the wound, pH, temperature, oxygen, and moisture play a key role. About 80% of the wounds with elevated pH are infected wounds.[8] Skin's pH is naturally between 4-6, which means it is acidic. This acidic environment is needed for the proliferation of fibroblasts, promoting angiogenesis and epithelialization, and helping in releasing oxygen from oxyhemoglobin. Chronic wounds will have a higher pH value than the normal skin pH and even go up to 10, which is even higher than the normal physiological pH which is 7.4. Measuring wound temperature can provide information about local blood flow, lymphocyte extravasation, chronicity, and wound infection. Optimum temperatures are required for wound healing; extreme hypothermia or elevated temperatures are not favorable for wound healing.[3]

Areas of wound care

Wound bed preparation

The wound environment plays a key role in the healing process.[9] There are many approaches that modify the wound environment for optimal or brisker wound healing. It is especially important in case of chronic wound healing. However, even minor outpatient surgeries need to be treated with care. Otherwise, they might be infected and lead to serious complications. As discussed in the previous section, the wound-healing process is a complex interplay of various cells at the wound site. The stages are overlapping and simultaneously, many processes are working. Thus, providing a better environment for the wounds to heal is important. Other than prevention of infection, temperature, pressure, pH, gases and moisture seem to play an important role in wound healing. All these are discussed in the following sections. There are 4 general steps in the wound bed preparation, which are debridement, inflammation and infection management, moisture control & environmental and epithelial assessment, termed as DIME.[10]

The necrotic tissue needs to be removed continuously from the wounds or else it might lead to increased bioburden and other complications, leading to amputations in some cases. Sharp, mechanical, chemical enzymatic and autolytic debridement options exist for proper wound healing.[11] Sharp debridement is using sharp instruments like a scalpel or scissors to remove the necrotic tissue.[12] It is considered the fastest debridement method, and a chronic wound can be converted to an acute one immediately. Mechanical debridement is achieved by scrubbing, hydrotherapy, wet to dry gauze dressings and is nonselective and may remove viable as well as necrotic tissue.[13] Chemical debridement is an option for mist wounds as in the dry state, enzymes are inactive but can be used on dry wounds after moistening them.[14,15] Autolytic debridement is utilizing the body's cells and fluids. The use of hydrogel, hydrocolloid, and transparent adhesive dressings can accomplish this.[16] Biological debridement using larvae of *Lucilia sericata* green bottle fly is another option for painless debridement of the necrotic tissue.[17] Erbium-doped yttrium aluminum garnet (Er:YAG) laser is an emerging technology in wound debridement without pain.[18]

George Winter was the first to demonstrate that wounds heal faster in a moist environment.[19,20] A Moist environment is also essential for chemical and autolytic debridement. However, excess fluids or exudates on the wounds are

not preferred because of the risk of infection and other complications. Thus, having a moist environment but not excess wound exudates is important. Oxygen supply and oxygen tension in the wound bed plays an important role in wound healing. Oxygen interacts with various cytokines and cells that are migrating to the injured area need the continuous supply of this gas. Wound requires oxygen tension of at least 20 mmHg to heal and non-healing wounds have lower values than this.[21] Lower oxygen tensions create more necrotic debris, facilitating bacterial growth. Hypoxia is known to be a causative factor for many of the diseases and is not an exception for wound healing.[22] Hyperbaric oxygen therapy uses 100% oxygen at pressures ranging from 1-3 atm. Supplying oxygen at these high pressures increases the plasma concentrations and supplies it to the oxygen deprived tissues in a higher quantity than would be achieved with the normal pressures. It promotes neovascularization and decreases inflammation.[23] Topical negative pressure (TNP) therapy or negative pressure wound therapy (NPWT) has gained popularity in recent years. The proposed mechanism by which the NPWT reduces the risk of infection is by the removal of exudate from the wounds that might act as the microbial growth medium. It can be helpful in wounds on complex fractures.[24] However, high level evidence for its efficacy and economy in usage were sparse.[25]

Wound care and dressings

Wound care has been known to humans since olden days. However, the importance of wound care has been established from the past decade or so.[4] With the increased burden of chronic wounds due to lifestyle and diseases, greater importance has been given to wound care nowadays. Few researchers even termed the wounds the 'silent epidemic'.[26] wound management has evolved from simple herbal formulations or cotton gauze to novel wound debridement techniques and advanced wound healing strategies. Still wound care dressings play an important role in wound management. These dressings have also evolved to manage various types of wounds and are generally termed as advanced wound care dressings.[27]

If the wounds are deeper and if there is arterial puncture, there is a chance of excess blood loss. To avoid this condition, hemostatic agents are generally used. Hemostats come in a variety of forms. They can be in powder,[28] liquid,[29] spray[30] or in a sponge form.[31] After hemostasis has been achieved, the wounds are and applied medication if required and dressed with a wound care dressing. In some instances, a hemostatic device can act as a wound care dressing and can be kept until the wound is healed or replaced every now and then for efficient wound care.[32] There may be primary and secondary dressings depending on the wound type, where primary dressing is in contact with the wound and the secondary dressing is on top of the primary dressing. After the hemostasis, the wound is closed by suturing or by applying temporary wound care dressings further to heal the wound.

The purpose of wound care dressings is to prevent or protect from infection and to promote wound healing. Traditional gauze wound dressings might not be able to provide a moist environment for the wounds. Low adherent dressings and semipermeable films represent basic types of wound dressings that allow air and water vapor through them and prevent the entry of bacteria. Hydrocolloids and hydrogels help absorb the excess exudates and keep the environment moist. Next, there are foams, alginate dressings and collagen dressings. Some of the wound care dressings are loaded with antimicrobial drugs like silver, polyhexamethylene biguanide etc. Recently, chitosan-based dressings are gained popularity as they are highly absorptive, have antimicrobial properties, and pain reducing abilities. Chitosan-based wound dressings and their mechanisms are explained in detail in the following section.

Advanced wound care device development – Indian scenario

Initiatives such as streamlined regulations, tax incentives, and research and development grants have further incentivized companies to invest in this field. Additionally, the availability of a skilled workforce and cost-effective manufacturing capabilities have contributed to India's competitive advantage in the global medical devices market. The rise of India as a significant player in the medical device industry has not only bolstered the country's economy but has also positively impacted healthcare outcomes. By encouraging indigenous manufacturing, India has improved access to high-quality medical devices and has reduced dependence on imports. This, in turn, has made healthcare more affordable and accessible to the masses, both domestically and globally. Looking ahead, India's medical device manufacturing revolution is expected to continue its upward trajectory. With ongoing advancements in AI, machine learning, and 3D printing technologies, coupled with robust government support, the country is poised to become a leading hub for medical device innovation. As India strengthens its position in the global market, it will contribute to the improvement of healthcare outcomes worldwide while reaffirming its status as a center for excellence in medical device manufacturing.

In the field of wound care, Axio Biosolutions has emerged as a notable player with several patents for their innovative products. Axiostat, one of their key developments, is a hemostatic device based on protonated bioadhesive technology (PBT). This groundbreaking product has been widely recognized for its ability to control severe bleeding and prevent excessive blood loss. Maxiocel, another product by Axio Biosolutions, is based on bioactive microfiber gelling technology. It has proven to be highly effective in treating chronically non-healing wounds, including venous leg ulcers, pressure ulcers, and diabetic foot ulcers. What makes Axio Biosolutions unique is their utilization of shellfish waste to extract chitosan, the primary ingredient used in their wound care products. This eco-friendly approach not only reduces waste but also ensures the availability of sustainable resources.

The success of Axiostat and Maxiocel has transcended national boundaries, as these products are manufactured in India and distributed worldwide. Their efficacy has been

acknowledged by military personnel and civilians alike, making them indispensable components of first-aid kits such as the Axio Suraksha Kavach (ASK) kit. Axiostat's ability to prevent severe blood loss in pre-hospital settings has been particularly vital in saving lives during emergencies, while Maxiocel has demonstrated remarkable healing properties in various types of chronic wounds. These innovative technologies and products have not only improved patient outcomes but also enhanced the overall accessibility and affordability of healthcare services. With continued research, development, and investment in such transformative initiatives, India is poised to become a global leader in healthcare innovation, ultimately benefiting millions of people around the world.

The advanced wound care device development field in India has been steadily growing in recent years. With an increasing focus on healthcare innovation and the rising prevalence of chronic wounds, there is a growing demand for advanced wound care products in the Indian market. Here we discussed some key aspects of the Indian scenario in advanced wound care device development.

The India wound care management market is expected to register a CAGR of 6.2% from 2018 to 2028. The COVID-19 pandemic causing serious disruptions to the entire health care services of India, including the care of wounded patients. Due to the need, the key objective for wound management has changed. The main objectives of wound care nowadays are to accelerate the wound healing process and prevent major wound complications to reduce hospitalization time, nursing cost, improve the quality of patient life, and prevent surgery-related complications. Since last few decades, the percentage of non-healing chronic wounds has continuously increased in India, which acts as a key driving factor for the wound care market. In India, patients with co-morbid medical diseases suffer lot due to chronic wounds. The diseases include diabetes, leprosy, tuberculosis, heart disease or, peripheral vascular disease and malignancy.[33] According to recent evidence, diabetic foot ulcers, venous ulcers, pressure ulcers and burn wounds are the major segments in the wound care market. India is a developing country, and the wound care domain continuously plays an important role in improving the patient's quality of life.

India has witnessed significant growth in the healthcare sector over the years, including the development of wound care companies (Table 1). These companies specialize in producing and distributing various wound care products, aiming to

Table 1: Indian-origin wound care companies

Company Name	*Key Product Segments*
Advanced MedTech Solutions	Absorbable and non-absorbable sutures, hernia solutions, surgical kits
Aegis Lifesciences	Hemostatic dressing based on absorbable gelatin, oxidized regenerated cellulose (ORC) and medical grade PVA sponges.
Axio Biosolutions Private Limited	Chitosan-based advanced hemostat, gelling fiber dressing for wound care, wound irrigation solution and wound healing gel
Bipson Surgical Pvt. Ltd	Paraffin gauze, eye pad, gauze swab, x-ray detectable abdominal pad
Cologenesis Healthcare Pvt Ltd	Collagen-based sheets, particles, gels, dental products and surgical products for wound management and bleeding control
Datt Medi Products Private Limited	Velseal patch and disc for bleeding control, Velvert antimicrobial dressing, Velnext negative pressure wound therapy, Velsoft compression and adhesive bandage, Velfix IV dressing, Velpore surgical tape
Fibroheal Woundcare Pvt. Ltd	Fibromoist gel and spray for tissue debridement, fibroheal ag for infection and inflammation control, fibroheal powder and particles for wound re epithelization
Jajoo Surgical	Cotton wool, gamgee rolls, dental cotton rolls, surgical tape, gauze dressing, abdominal sponges
Lotus Surgicals Pvt Ltd	Absorbable, non-absorbable, braided, and monofilament sutures for cardiovascular and plastic surgery, surgical mesh, clips and appliers, surgical staplers, surgical kits, pledgets, bone wax, umbilical cotton tape, and temporary cardiac placing wire
Medicare Hygiene Limited	Medical bandage, gauze swab & x-ray detectable abdominal gauze pad
Medilivescare Manufacturing Pvt. Ltd	Medicated and non-medicated adhesive and elastic bandage, orthopedic cast padding bandage, plaster of Paris bandage, iv cannula fixator, capsicum bandage, paraffine, and chlorohexidine gauze dressing, gamgee roll
Meril	Synthetic and natural absorbable sutures, non-absorbable sutures, ophthalmic and plastic surgery sutures, topical absorbable hemostats, and skin adhesive
Mil Laboratories	Film dressings, island dressing, hydrocolloid dressing, alginates dressing, hyaluronic acid based product, antimicrobial dressing
Orion Sutures (India) Pvt Ltd.	Synthetic absorbable & non-absorbable surgical sutures
Sundaram Surgical	Surgical gauze dressing, gamgee roll gauze, non-woven gauze sponges, surgical cotton gauze, sterile mopping pad
Triage Meditech	NPWT dressing & accessories, surgical disposables & consumables, medical tapes & dressing, IV cannula & wound dressings
Unisur Lifecare Pvt. Ltd.	Absorbable and non-absorbable sutures based on catgut, polyglycolic acid, polypropylene, polyamide, polyester, silk etc.

improve the management and treatment of wounds. These companies offer a wide range of wound management products, including surgical gauze dressings, hemostatic dressings, Absorbable and non-absorbable sutures, wound healing creams, gels, adhesive and elastic bandages etc. Most of these companies manufacture the products in good manufacturing practices (GMP) facilities and also have international Organization for Standardization (ISO) 13485 certification to maintain the best quality of their products. Indian wound care companies invest in research and development to develop advanced technologies. These companies are collaborating with medical institutions and research organizations to enhance their product portfolio and address specific wound care challenges. Continued innovation enables Indian companies to stay competitive in the global wound care market. Indian wound care companies are known for their ability to provide cost-effective wound care solutions without compromising on quality. With their expertise in frugal innovation, these companies can cater to both the domestic and international markets, especially in resource-constrained settings. Indian originated wound care companies are increasingly exploring international markets. They are exporting their products to various countries and forging partnerships with global distributors. This expansion allows Indian companies to gain exposure to diverse markets, learn from global best practices, and further enhance their product offerings. Companies including Axio Biosolutions, Datt Medi Products Private Limited, Meril, Aegis Lifesciences, Fibroheal Woundcare Pvt. Ltd etc. has the CE mark for their key products to access the European market. Moreover, Axiostat dressing has become the first Indian wound care product to get 510(K) FDA clearance in the US for its pioneering hemostasis application. This is also encouraging the global market players to make their presence felt in India. The key global market players operating in the Indian wound care management market are Smith & Nephew, Coloplast, B Braun, Medtronic, 3M, Convatech Group and Johnson and Johnson. Overall, the Indian wound care companies are catering the needs of India as well as the world.

DECLARATION

The authors are Axio Biosolutions Private Limited employees, Ahmedabad, Gujarat, India.

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