H E A L T H

Technologies for Better Quality of Life

HYDROGEL BURN AND INJURY DRESSING

Hydrogel is a gel like material, capable of holding large amount of water within its structure.

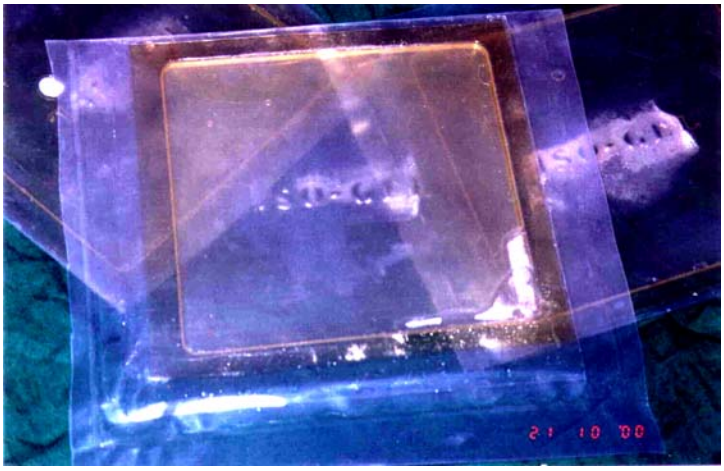
The development of Hydrogel Burn & Injury Dressings is an excellent example of application of radiation for healthcare.

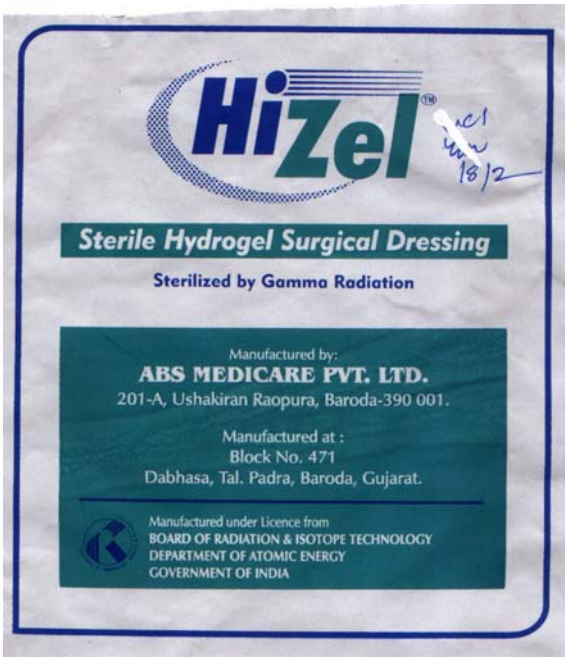
Hydrogels for medicinal purposes are prepared from hydrophilic polymers like Polyvinyl Pyrrolidone (PVP), Polyacrylamide, and Polyvinyl Alcohol (PVA) etc. Molecules of these materials can be cross-linked to form a three dimensional network structure, which can hold large quantities (10-15 times the dry weight) of water. Cross-linking can be achieved by either chemical means or by gamma irradiation. Former method has a major disadvantage of leaving behind some toxic residues of chemical initiators in the product. In addition the gel so produced has to be cleaned and sterilized subsequently. On the other hand, radiation processing is a clean process in which gel formation and sterilization are accomplished simultaneously in one step. This not only results in cost reduction but also gives high quality product. The world over, hydrogels are being used increasingly for treatment of burn injuries as well as in plastic surgery on donor areas. However, high cost of the product and use of a large number of

synthetic additives in some variants has limited its use. Majority of the hydrogels available abroad use PVP as the base material.

The Bhabha Atomic Research Centre (BARC) has developed a process for large-scale production of hydrogels based on cross-linking of PVA by radiation (national and international patent filed). All ingredients used in the process are low cost, biocompatible and are locally available or can be readily imported under OGL.

Hydrogels are used for medicinal purposes particularly for burn and injury dressings. These dressings have water content in excess of 90% and have capacity to absorb wound exudates. They have a cooling effect on the burn wound and thus reduce the severity of the pain. It further provides moist environment, soften any slough, provides sterile cover and regulates the oxygen supply to the wound site to enable faster healing. The hydrogel has the property of adhering firmly yet gently to the healthy surface. It does not adhere to wet wound surface. This results in painless dressing. The narcotic tissues in the wound stick to the inner surface of the hydrogel and come out with the dressing. Being transparent, the progress of the wound healing can be observed without removing the dressing. In many cases, the use of hydrogels has been observed to prevent scar formation as well as to flatten old scars.





Other areas where hydrogel could find use are for application on donor areas for plastic surgery, on various ulcers, as drug delivery systems etc.

The clinical trials on donor and burn affected areas carried out at Sion Hospital, Mumbai have established that the product is safe and effective on humans.

Process, Materials and Equipment

The process basically consists of three steps:

1. Solution preparation
2. Filling the solution in disposable plastic trays, sealing and putting in cardboard cartons
3. Radiation Processing in the sealed and packed cardboard cartons

About 225 pieces of 12 cm x 12 cm x 0.4 cm size of hydrogel can be accommodated in a carton of the size of 34cm x 43cm x 59cm. On coming out of the radiation processing plant, packets are ready as a finished product for dispatch. There can be various sizes for the product, for example, 4x4, 8x8, 12x12, 15x20 (cm x cm). Other required sizes can also be made depending on the market requirement.

The commercial radiation processing services are available at (1) ISOMED, BARC, Mumbai (2) Shri Ram Institute for Industrial Research, Maurice Nagar, New Delhi and (3) RASHMI, Kidwai Memorial Institute of Oncology, Hosur Road, Bangalore.
The material and radiation processing cost per piece of 12 cm x 12 cm x 0.4 cm hydrogel is estimated to be less than Rs.10 only. For production of one million pieces of hydrogels per year, additional infrastructure cost to an existing pharmaceutical company is expected to be very small unless fully automated production facility is aimed at. The only additional equipment required may include dissolution tanks, autoclaves and glass flasks. In addition plastic trays and other packaging materials will be needed. Manpower required for manual production of one million pieces per year is estimated to be 8 including one scientist, two assistants and 5 unskilled workers.

Although radiation processed hydrogels are well established abroad, the product is new in India. As most of the burn victims in India come from the poorer strata of the society, availability of the product at low cost will be a boon. This will not only help in provision of this superior product to poorer sections of the society but can help in earning foreign exchange by export of this product.

Technology for manufacture of plain hydrogels has already been developed by BARC which included successful clinical trials of the product. Large number of hydrogel sample pieces have been produced in-house and used in various hospitals particularly in and around Mumbai. The product has been well received.

The technology for this product has already been transferred to to ABS Medicare Pvt. Ltd., Vadodara by Board of Radiation & Isotope Technology (BRIT) in November 2002. The company launched the product in the market on February 21, 2003.

It is proposed to continue to support the company, which has already taken the technology, by provision of know-how whenever needed as well as by provision of radiation processing services at ISOMED plant. It is also proposed to transfer the technology to more number of interested parties so that patients all over India can get benefited from this technology. Further work is going on to develop technology of medicated hydrogels, which will be very useful for infected burns and wounds. The technology for this also is intended to be transferred to interested private entrepreneurs. Production of medicated hydrogels will help in more wide spread utility of this technology.

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