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TITLE

Utilization of ionizing radiation for the sterilization of membranous connective tissue allografts, (part of a coordinated programme on radiation sterilization of medical products and biological tissues)

FINAL REPORT FOR THE PERIOD

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AUTHOR(S)

N.Triantafyllou

INSTITUTE

Nuclear Research Center "Demokritos"
Department of Reactors
Aghia Paraskevi - Attiki
Greece

INTERNATIONAL ATOMIC ENERGY AGENCY

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GREEK ATOMIC ENERGY COMMISSION
NUCLEAR RESEARCH CENTER "DEMOKRITOS,"
AGHIA PARASKEVI - ATTIKI - GREECE
TEL.: 65.13.111 - TELEX: (21) 6199 CABLE: GREEKATOM

DEPARTMENT OF: REACTORS

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HUMAN TISSUE BANK

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FINAL REPORT (Summary)

THE UTILIZATION OF RADIATIONS FOR THE STERILIZATION OF
MEMBRANEOUS TISSUE ALLOGRAFTS

The work carried out, covered several aspects of radiation sterilization of membraneous allografts. The conclusions reached are the following.

- 1 - The use of ultraviolet radiation(254nm and lower) did not give the results expected, although those obtained are considered preliminary and the subject needs further investigation.
- 2.- The use of gamma irradiation at dose levels of 2.5 to 3 Mrads, is satisfactory for the sterilization of membraneous allografts. The biological properties of the sterilized material are excellent, although the antigenicity is still an open question.
- 3.- Sterilization with gamma radiations, definitely affects the mechanical properties of the sterilized material, as well as permeability. The tensile strength is lowered while permeability is increased.
- 4.- The use of detergents binding to macromolecules was studied, in order to develop a method for protecting the tissue from radiation damage. Cetylpyridinium chloride monohydrate (CPC) and dodecylbenzyltrimethylammonium chloride (DBTAC), bind to anionic sites of mucopolysaccharides and act as energy scavengers during gamma irradiation. These compounds are successful energy absorbers. They protect the membranes from radiation damage. This method of protection could have practical application.

5.- Experiments were carried out to investigate morphological changes occurring to a variety of tissues, because of irradiation. The first tissue to be investigated was peripheral nerve. Doses up to 4 Mrads were given and the alterations observed were, rearrangement of the epineural connective tissue, condensation of the endoneural connective tissue and dilatation of the intratrabecular spaces containing the fibres.

6.-In general the findings show that the sterilization of biological membranes with gamma irradiation using doses of up to 3 Mrads is a very satisfactory method for the sterilization of the material, since it does not seriously alter the biological properties of allografts. As for the changes of the mechanical properties, this is not considered to be a serious draw back, because the membraneous allografts cover surgical needs where the mechanical strength is not of paramount importance.

7.- Finally a more extensive study of the antigenic properties of irradiated membraneous allografts should be undertaken, and this is considered to be only a part of the overall view of the problem of transplantation of gamma rays sterilized tissues. The group will continue the work along these lines.



N. TRIANTAFYLLOU

