

CRP E31006

Safety and Optimisation of Radiation Sterilization in Tissue Banking: Studies on Functional Properties of Irradiated Tissue Grafts

Scientific Secretary: Oleg Belyakov (o.belyakov@iaea.org)

Summary:

To assure safety of patients receiving tissue allografts during surgical treatment, several decontamination or sterilization procedures are implemented during the processing. Irradiation of tissue allografts is one of the developed and widely used methods for sterilization in the world. Gamma rays, X-rays, and electron beams have been used with doses ranging from 15 to 80 kGy. Controversies exist regarding the “optimal dose” for sterilisation since radiation can evoke numerous changes in tissues structure resulting in its change in functionality. The major aim in the project is to facilitate research to find the optimal radiation dose and processing methods for several tissues and disseminate the results in IAEA Member States. Therefore, radiation-induced effects on tissue grafts processed and preserved by different methods will be studied. The newly acquired knowledge established from harmonized research methodologies will be useful in providing high quality tissue allografts.

Overall Objective:

Three major aims of the project are (1) to find the optimal radiation dose and processing methods for several tissues providing allograft sterility (SAL 10^{-6}) without compromising tissue biological or structural function for clinical use; (2) to facilitate research and disseminate research results in IAEA Member States to study radiation-induced effects on tissue grafts processed and preserved by different methods and; (3) to initiate collaboration between relevant laboratories, establishing of exchange programmes and joint applications for future additional funding will be stimulated.

Specific Research Objectives:

There are limited studies that have been published, however, they have not been standardized and thus comparability is difficult and, in some cases, not possible. As a result, controversies exist regarding the optimal dose for sterilisation since radiation can evoke numerous changes in tissue structure resulting in its change in functionality. Therefore, this research programme is to validate the optimal sterilization dose and processing methods for several tissues providing allograft sterility (SAL 10^{-6}) without compromising tissue biological or structural function for clinical use. Important tissue allografts to be investigated are: bone, tendon, cartilage, skin, amniotic membrane, vascular grafts, and heart valves.

For successful distribution of safe and good quality tissue allografts, it is important to understand:

- Interaction between processing methods and irradiation process,
- Dose response relationship and validation of relevant physical, chemical, biological and clinical end-points,
- Effect of irradiation conditions (temperature, oxygen, water content, dose rate, radio-protectants, etc.) on biological properties of tissue allografts.

In order to improve tissue banking processing and preservation protocols the following questions need to be answered:

- What type of testing methods should be applied for tissue allografts?
- What is the optimum processing and preservation method to preserve functionality of tissue grafts?
- What is the maximum tolerated irradiation dose for different levels of damage in different tissue allografts (type of tissue, method of processing)?
- Which processing combinations have the highest potential reducing the radiation-induced tissue toxicity in specific tissues?
- Which processing combinations have the highest potential preserving functionality of irradiated tissues?

Is there any relation of dose-rate on physical, chemical, biological properties of tissue allografts?

Expected Research Outputs:

- New data on efficacy of irradiated tissue allografts. Tissues of interest are: bone, tendon, cartilage, skin and amniotic membrane, vascular grafts and heart valves.
- Development of methodology for quality control testing of different types of (irradiated) tissues
- Research progress in radiation sterilization and tissue banking

Expected Research Outcomes:

- To provide technical expertise in processing procedures of tissues subsequently radiation-sterilized;
- To improve knowledge and expertise in tissue allograft irradiation;
- To provide the improved quality tissue grafts;
- Advancement in tissue banking activities.

Participating institutions:

<i>Country</i>	<i>City</i>	<i>Institution</i>
ARGENTINA	EZEIZA	Comisión Nacional de Energía Atómica; Centro Atómico Ezeiza
BRAZIL	SAO PAULO	Comissão Nacional de Energia Nuclear (CNEN); Instituto de Pesquisas Energeticas e Nucleares (IPEN)
INDIA	MUMBAI	Tata Memorial Centre
UNITED KINGDOM	CLWYD	North East Wales Institute of Higher Education (NEWI); Clwyd and Oswestry Research Tissue Bank

SINGAPORE	SINGAPORE	National University of Singapore; National University Hospital; Department of Orthopaedic Surgery; Tissue Bank
MALAYSIA	KOTA BHARU	Universiti Sains Malaysia; School of Medical Sciences; Department of Nuclear Medicine, Radiotherapy and Oncology
PERU	LIMA	Instituto Peruano de Energía Nuclear (IPEN)
GERMANY	BERLIN	Universitätsklinikum Charite
URUGUAY	MONTEVIDEO	Universidad de la República; Facultad de Medicina; Hospital de Clínicas; Banco Nacional de Órganos y Tejidos; Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos
POLAND	WARSAW	Medical University of Warsaw; Center of Biostructure Research; Department of Transplantology and Central Tissue Bank
SLOVAKIA	BRATISLAVA	Ruzinov General Hospital; Central Tissue Bank
AUSTRALIA	BRISBANE	Griffith University; School of Medical Science; Gold Coast Campus
AUSTRALIA	MELBOURNE	Victorian Institute of Forensic Medicine
COLOMBIA	BOGOTA	Secretaria Distrital de Salud
CUBA	MIRAMAR	Ministerio de Ciencia, Tecnología y Medio Ambiente (CITMA); Agencia de Energía Nuclear y Tecnologías de Avanzada (AENTA); Centro de Aplicaciones Tecnológicas y Desarrollo Nuclear
CHILE	SANTIAGO	Comisión Chilena de Energía Nuclear (CCHEN)