OPER-ART

Addressing the uncertainty challenges of radiotherapy through personalised 3D molds used in radiotherapy and brachytherapy.

These personalised systems could improve treatment quality, outcomes, and patient comfort, reducing the use of health resources and increasing the well-being of patients and healthcare professionals.

Challenger

The University Hospital of Navarra (HUN) is the public reference centre in the Pamplona Area also being a general hospital for those demands that come from all over Navarra.

The HUN has just over a thousand beds and a total staff of nearly 6,500 professionals grouped into 43 clinical services. It records an annual volume of more than 40,000 admissions, 33,000 surgical interventions and more than 750,000 consultations.

The HUN defines itself as a centre committed to research and the promotion of innovation in healthcare. In the period 2011-2023, the HUN participates actively in research projects with funding from competitive calls and its professionals have published 898 scientific articles (JCR-Journal Citation Reports), with an impact factor of 2581. Likewise, in the last six years, 663 clinical trials have been conducted.

In concrete, Radiotherapy oncology service offers specialized radiation oncology treatments to patients of all ages and types of cancer.

Navarrabiomed-Fundación Miguel Servet will support with all administrative requirements and business support.

Challenge description

Radiotherapy (RT) is a treatment that consists of administering ionizing radiation to the tumour disease while sparing healthy organs. It is a widely used tool in the treatment of cancer: it is received by more than 60% of cancer patients and more than 40% of those who are cured. RT is designed specifically for each patient using medical imaging and planning systems specially tailored for this purpose.
The most common form of RT is External Beam RT (EBRT), which involves linear accelerators that emit radiation in a conformal and disease-targeted manner focused on extremely precise spots. For this, it is essential to use **immobilisation systems** so that patients are positioned in a reproducible way on a daily basis and the treatment is administered with adequate precision.
On the other hand, for the cancer lesions close to the skin where radiation is not adequately deposited, it is common to use **"bolus"**, a flexible accessory with an equivalent density to the human tissue, which is placed on the patient's surface and allows for improved dosimetry. However, commercially available boluses are not always properly adapted to the patient's body surface, which has a negative impact on the quality of treatment.
Another way of delivering RT is by brachytherapy, a procedure often performed in the operating theatre where the radioactive source is delivered close to the disease or inside the tumour itself, using different types of applicators depending on the anatomical location and characteristics of the disease. Nowadays, the **applicators and templates** used in

brachytherapy **are not customised commercial solutions, which can lead to suboptimal** treatment delivery and discomfort for patients.

The development and use of personalised systems for the techniques mentioned before will improve the quality of treatments, which will have an impact on cancer therapy outcomes. In addition, as the devices would be optimally adjusted to the patient's anatomy, the functionality and safety of treatments will be improved and can be performed more easily by professionals. Being tailored ergonomic applicators, this will improve patient comfort and experience. Additionally, it could replace the commercial non-adapted systems that are usually purchased, as new devices will be produced at the hospital on demand, which would mean a saving in expenditure and time together with a reduction in carbon footprint and costs derived from transport.
This project will comply with the Do Not Significant Harm (DNSH) principle by reusing the waste from the molds produced.

Challenge main objectives

The main objective is to co-create **a system for the personalised generation of 3D molds for use in radiotherapy tailored to each patient´s morphology.** This mold generating system would be used in the hospital. In the case of EBRT, this would involve the generation of customised bolus or immobilization elements. In the case of brachytherapy, the aim is to generate customised applicators or guides for interstitial brachytherapy.

The solution should allow bidirectional communication with radiotherapy treatment planning systems. It should allow the design of 3D molds adapted to the patient's anatomy and the dosimetric requirements of the treatment.

Solution functional requirements

Software tool designed to design/print 3D molds adapted to the patient's anatomy. It would be used in both external radiotherapy and brachytherapy.

Compulsory functional requirements

- **In external radiotherapy**: the 3D mold shall be used as a bolus material (tissue equivalent material) customized to the patient's surface. The thickness and shape would be defined in a planning system external to the application according to the dosimetric needs of each treatment.
    - The system would have to be able to use the DICOM[1] and DICOM RT[2] files of the planning system (*Eclipse*[3] and *Oncentra* from Varian and Elekta[4], respectively).
    - It will have visualization tools for the imported structures and specific tools for the manipulation, preparation and editing of the 3D mold corresponding to the bolus

[1] https://www.dicomstandard.org/

[2] https://dicom.nema.org/dicom/geninfo/brochure/rtaapm.htm

[3] https://www.varian.com/es/products/radiotherapy/treatment-planning/eclipse

[4] https://www.elekta.com/products/brachytherapy/oncentra-brachy/

(smoothing, trimming, suitability for the manufacturing process, marks, numbers, letters can be defined on the surface of the mold...).
- The solver must provide the printing material which shall be flexible, have a density equivalent to biological tissue (like water) and be biocompatible and meet legal requirements for contact with patients' skin.

- **In brachytherapy:** 3D molds shall be used as superficial applicators, intracavitary applicators and as needle insertion guides in interstitial implants.
  - The system would have to be able to use the DICOM and DICOM RT files of the planning system as inputs.
  - To have tools for the generation of surface applicators adapted to the external surface of the patient, of configurable thickness and size with the possibility of being displayed together to the patient's images and volumes.
  - Channels must be able to be generated within the applicators of specified diameter to insert the guide catheters of the radioactive source into them. These channels must be able to be generated automatically at a given distance between them and at a given distance from the patient's surface must meet the minimum curvature radius requirements configured by the user.
  - The channels must be able to be edited manually with the computer mouse.
  - Marks, numbers, letters shall be defined on the surface of the mold.
  - The solver must provide the impression material should be biocompatible and meet the legal requirements for contact with the mucosa of patients.

For external radiotherapy and brachytherapy, once the 3D molds are designed, they must be able to be exported manually to the planning system via DICOM RT, for dosimetric validation prior to manufacturing/printing.

The molds should have the minimum accuracy required for use as brachytherapy applicators. They should be made of flexible, rigid, or semi-rigid materials biocompatible with both the patient and the therapy and meet the legal requirements.

Desirable functional requirements

In External Radiotherapy: It would be of interest to be able to generate surface bolus without the need for medical CT (Computed Tomography). For example, through an optical surface reconstruction system.

In Brachitherapy: Auxiliary elements could be designed for commercial intracavitary applicators that facilitate the generation of interior channels for the insertion of needles or catheters, with straight or curved trajectories that can be graphically edited. The molds must be made of sterilizable and biocompatible material for contact with the patient's mucous membranes.

Pilot scope

Type and number of targeted end-users

End-user type	Role	Number
Radiation Oncologists	Recruit patients; provide requirements; validate solutions	4

Medical Physicists	Provide requirements; validate solutions	4
Radiation Therapists	Validate solutions	4
Patients	Better treatment	30

Table 1. Targeted users

Language

Spanish to ensure the co-design and implementation process with the end-users who usually do not speak English.

Other aspects

The best-fit solution may include the hardware and the material needed to accomplish the objectives.

Pilot set up conditions

Ethical, legal or regulatory

The pilot will be conducted with pseudonymized/anonymized data. If the solution incorporates optical reconstruction, patients will be informed of the image capture and will sign an informed consent form. In this case, an Ethics Committee of the Challenger must previously validate the approach of the pilot. The solutions shall be fully GDPR compliant. Once the proposal is made, the risks for data protection will be evaluated jointly with the IT. A data protection plan will be generated in accordance with the procedures.

The project will be evaluated by the *"Sección de Seguridad de la Información y Servicio al Usuario del Servicio Navarro de Salud"* to provide feed-back and approval of a detailed data management plan.

Technological

The system/computer required to run the software during the pilot should be available on the hospital facilities in stand-alone mode. It will exchange information with the radiotherapy planning systems via external storage media (USB flash drives or external hard drives).

Data access

The data will be provided to the Solver through previous data base from Oncology radiotherapist unit to develop, train and validate the solution, and from new patients during the recruitment to improve the accuracy of the solution, improving the treatments. The data

will be obtained from the Aria Network[5], a data management, planning and treatment platform for radiotherapy patients available at the HUN.

Expected impact and KPIs

For **External Radiotherapy:**

- Expected Impact: Better compliance with dosimetric objectives compared to traditional bolus systems. Reduction in millimeters of air between the bolus and the body surface measured in planning CT and treatment CBCT.
    a) Optimal < 1mm
    b) Acceptable: 1-2mm
    c) Could be improved but acceptable: 2-3mm
    d) Not acceptable: > 3mm
    KPI: 90% of cases in groups a,b,c.
- Expected Impact: Satisfaction on the part of radiophysicists in charge of planning and radiotherapy technicians through satisfaction questionnaires.
  KPI: >75% increase in professional satisfaction compared to previous processes measured by questionnaire.
- Expected Impact: workload reduction in mold design.

For **Braquitherapy:**

- Expected Impact: Better compliance with dosimetric objectives compared to traditional systems. Reduction in millimeters of air between the applicator and the body surface measured in planning CT.
    a) Optimal < 1mm
    b) Acceptable: 1-1.5mm
    c) Could be improved but acceptable: 1.5-2mm.
    d) Not acceptable: > 2mm
    KPI: 90% of cases in groups a,b,c.
- Expected Impact: Satisfaction on the part of the radiation oncologists who would handle the product and on the part of the radiation physicists in charge of planning.

KPI: >75% increase in professional satisfaction compared to previous processes measured by questionnaire.

- Expected Impact: reduction in mold manufacturing and design workload.

KPI: 50% reduction in mold development and design time.

- Expected Impact: assessment of toxicity comparatively with traditional brachytherapy systems.

[5] https://www.varian.com/products/software/digital-oncology/oncology-management-systems/aria-oncology-information-system

Business opportunity

Market size

The development and use of personalised systems for the techniques mentioned before will improve the quality of treatments, which will have an impact on cancer therapy outcomes. In addition, as the devices would be optimally adjusted to the patient's anatomy, the functionality and safety of treatments will be improved and can be performed more easily by professionals. Being tailored ergonomic applicators, this will improve patient comfort and experience. Additionally, it could replace the commercial non-adapted systems that are usually purchased, as new devices will be produced at the hospital on demand, which would mean a saving in expenditure and time together with a reduction in carbon footprint and costs derived from transport.
In total, we can estimate that in a first phase, approximately 100 patients per year could benefit from custom-designed personalized systems in HUN, but their potential reach could be much greater and could increase significantly in successive years, being used in other tumours.
On a national scale, this Solution could provide SMEs and the healthcare system with an innovative solution to provide better patient care, reduce upfront work for clinicians and doctors, and a new opportunity for companies to develop and improve new tools in new markets.

Adoption Plans

The solution we expect to achieve will improve radiotherapy treatments in different tumours, having a direct impact on the well-being of the population of Navarra. It will also lead to an improvement in the use of health and economic resources of the region.

If the result of the solution were satisfactory, and after the required feasibility study, we would propose to launch a Public Procurement of Innovative solutions (PPI) including during the process each necessary agent to achieve a successful implementation in the Health System.

The ultimate goal would be to adopt this solution in daily clinical practice.