

STATUS OF THE NATIONAL HADRONTHERAPY PROJECT IN FRANCE: ETOILE

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The ETOILE project is a French program for carbon ion beams in cancer treatment. It is now in the final phase. This project also includes the construction of a new facility. Many medical and scientific programs have been initiated around this project. The project has been initially supported by the University of Lyon and extended to the Rhône-Alpes Region and then gained a national visibility with governmental recognition. Many studies have been financed by ETOILE: in beam PET with new solutions, organ motion modelization, tumor cell radio resistance, medico-economical simulation and epidemiological previsions. The facility will be able to produce carbon ion beams and protons. Three treatment rooms are planned, two with horizontal beams and one with an isocentric gantry. The treatment center will be built in Lyon, in partnership with other well-established facilities of the same genre in Europe. The estimated cost of the project is 110 M€. The annual operating cost for the center, for one thousand patients per year, is estimated to be 21 M€.

I. INTRODUCTION

The construction of the French treatment center for carbon ion radiotherapy (CIR) is entering the bidding process, which is expected to end in late 2008 and then give way to the construction of the center from 2009 to 2011 or 2012. It will be built in the town of Lyon the third largest town in France located in the Rhône-Alpes Region.

ETOILE is French for 'STAR'. ETOILE stands for "Oncologic Treatment Space with Light Ions in European network".

ETOILE, as a whole, is a three-fold program including:

- a large scientific & medical project running since 2002, becoming the PNRH (National Program for Hadrontherapy Research);
- a facility project aimed at building a treatment center devoted to carbon ion radiotherapy. The future ETOILE centre will have a capacity of about 1000 treatments per year;
- a network project devoted to organizing the identification and the recruitment of patients on the basis of equity and accessibility according to French standards of care, the OMéRRIC project (Medical

Organization of the Recruitment for the Radiotherapy by Carbon Ions). These three aspects are independent but strongly connected, they will even continue to work together and develop when the treatment center will be in operation.

II. THE SCIENTIFIC & MEDICAL PROJECT

The scientific & medical programs in the ETOILE project were developed first. Instead of only being added values to the project, the success of the scientific and medical portions led to its validation and acceptance by the French health care system. This has been a great success and presently about one hundred researchers are working in collaboration with the project. The main topics are:

- the development of highly rapid and sensitive detectors for PET imaging,
- the modelization of organ deformation during breathing cycle,
- Hadrons radiobiology and pharmacomodulation of the response to hadrontherapy of radioresistant cells,
- the study of carbon ion fragmentation for PET interpretation and its future use as a dosimetry tool,
- the fundamental and theoretical study of the RBE modelization starting from the local effect model of GSI group,
- innovative active beam control...

It is to be noticed that ETOILE enabled the creation of a master of medical physics between Lyon and Grenoble universities and that opened in september 2004.

Moreover, the National Organization of Cancer Care and Research in France has recognized the value of this research program by fully integrating it into the national objectives of cancer research.

The medical contents of the scientific project are developed more independently and have been crucial in obtaining governmental authorization. Its initial objectives were to define as precisely as possible the indications for CIR, to predict the recruitment of the best indications and to demonstrate the feasibility and the medical interest of CIR. It is now focusing on the construction of OMéRRIC, the national recruitment network and policy under the supervision and with the

support of the French National Cancer Institute (INCa). The discussion with health authorities (the High health authority “HAS” and the national health insurance “CNAM”) of a sharing of compliance standards between “consolidated” indications directly afforded by health insurances (about 700 per year in France) and indicators needing further evaluation is pending now. We aim to be in compliance with our European partners. This way we will be able to refer patients from France to Germany, Italy and Japan in the near future. With its design, ETOILE is exclusively a CIR project with no specific equipment for protontherapy. Nevertheless, a strong regional demand for pediatric proton treatment will certainly be considered.

III. SPECIFICATIONS FOR THE MACHINE AND TREATMENT ROOMS

The functional specification has been drawn up by radiotherapist-oncologists in collaboration with medical physicists and accelerator specialists, after consultation with the existing hadrontherapy centers.

Projectiles: $^{12}\text{C}^{+6}$ ions Possibility of other projectiles: protons up to ^{16}O and intermediates Time for changeover between two types of particle: < 1 hour
Machine reliability: annual availability of 97%, average repair time for a first level breakdown: 1 hour.
Depth of penetration of ions (p, C): 2 to 27 cm in water Maximum dimensions of the area of irradiation (perpendicular to the direction of the incident beam): 20 x 20 cm ²
Maximum continuous physical dose rate: 2 Gy per minute and per litre of water
Distribution of the dose in the target volume (max I and E) Distal drop 100% - 30%: less than 3 mm Lateral penumbra 80% - 20%: less than 2 mm Uniformity of the dose in the target volume: $\pm 2.5\%$ Precision of the dose delivered: $\pm 2.5\%$ Lateral precision of the incident beam: 2 mm at the target volume level Spatial resolution of the field of irradiation: ~ 2 mm
Other beam characteristics: - Active irradiation techniques: raster scanning - Diameter of the beam at mid-height: variable from 4 to 10 mm - Angular raster scanning of the beam: yes - Possibility of passive irradiation: yes - Possibility of distributing very low doses: yes - Patient safety: rapid stopping time (≤ 200 μs) - Distance between scanning magnets and isocentre of the tumour: > 3 m
Beam quality control: ionization chambers per beam line: 2 for controlling the position and shape of the beam; 2 for controlling the dose; 1 for redundancy

Beam incidence: - 2 rooms with fixed horizontal beam - 1 room with an isocentric arm (gantry), or else a vertical beam and a fixed horizontal beam
Medical equipment: chair/table One room equipped with a robot-controlled chair and one room equipped with a robot-controlled bed Robot-controlled bed (with six degrees of freedom)
Repositioning control: Marking systems, Lasers Imaging – control (X, PET, etc) X-rays tubes for digital imaging Possibility of online PET in the Gantry room (or with vertical beam) Possibility of X scanner in the treatment rooms
Respiratory synchronisation: yes
Precision of patient positioning in relation to the beam, with appropriate immobilization: head: 1 mm, body: 2 mm

IV. SPECIFICATIONS FOR THE EQUIPMENTS OUTSIDE THE TREATMENT ROOMS

Imaging: dedicated X and MRI scanners. Access to scanner, PET or dedicated apparatus
Treatment planning: dosimetry consoles
Respiratory control system for data acquisition
Preparation rooms for irradiation: pre-positioning, placement of immobilization devices, irradiation control system
Make provision for increased recruitment: possibility of creating 1 or even 2 additional treatment rooms (building architecture)
Associated research (radiobiology, etc): 1 room with horizontal beam dedicated to research
Optimisation of occupancy rate of treatment rooms: 2 pre- and post-positioning rooms per treatment room
Possibility of performing treatments under GA: areas dedicated to anaesthesia

V. TECHNICAL SPECIFICATIONS

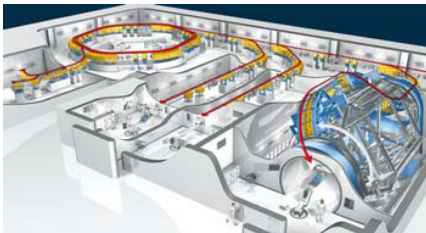
Ions delivered in the rooms: $^{16}\text{O}^{8+}$, $^{12}\text{C}^{6+}$, $^1\text{H}^{1+}$ and intermediate
Final energies for 2 to 27 cm penetration in water: C: 85 – 400 MeV/uma, p: 50 – 200 MeV
Variation of the energy and intensity: around 1 second
Dimensions of the beam (total width at mid-height): 4 to 10 mm spot, diameter adjustable in steps of 2 mm at the patient
Typical intensity of the beam for a physical dose rate of 2 Gy/min per litre: $^{12}\text{C}^{6+}$: $\sim 4 \times 10^8$, protons $\sim 1 \times 10^{10}$
Intensity variations for each energy according to the treatment plan and the shape of the tumour: Imax/Imin = 1000
Raster scanning of the beam in the treatment room: Horizontal and vertical scanning magnets

Variable beam entry angles: Isocentric gantry at the design stage
Reproducibility of the dose delivered (uniformity and contours): beam contamination less than 1%, precise inline monitoring of the beam parameters, inline monitoring of the source ion spectrum
Fast stopping of the beam: rapid deflector, in 200 μ s, associated mechanical stopping of the beam

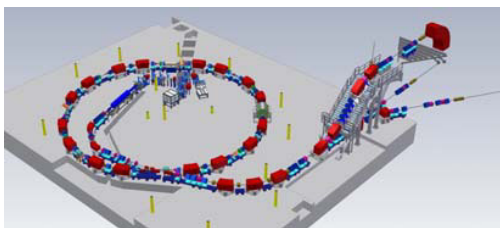
VI. THE CONSTRUCTION OF THE CENTER

The construction project for the ETOILE center is now starting. Through the bidding process the ETOILE center will take advantage of the rising experience of the major industries in the domain. It will be built and run in the frame of a partnership contract. The corporation obtaining the contract for construction will raise the money for the initial investment build and run the facility. The hospital consortium that gathers the medical team will rent the facility for 2 or 3 decades before becoming the owner of the facility. To conduct this type of contract, the French regulation demands different steps that are the “preliminary assessment” of the project, then the contraction for “assistance to the public person” on the juridical, financial and technical points of view, then the competition for the final bid will take place among at least three candidates.

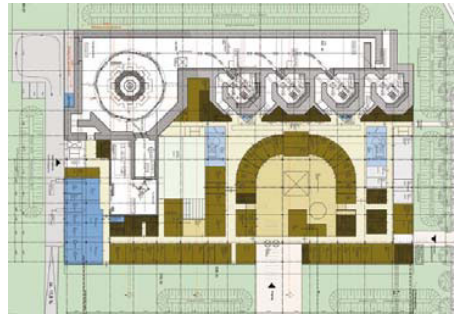
This process will end in December 2008 and the construction will begin in 2009 lasting 4 years. The design will be close to the other projects in construction in Europe. There will be three or four treatment room and a room for research programs (technical and radiobiological).



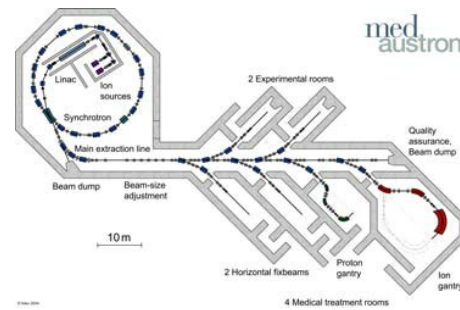
HIT Heidelberg (Germany)



CNAO Pavia (Italy)



Marbourg (Germany)



MedAustron Wiener Neustadt (Austria)

VII. CONCLUSION

ETOILE is a comprehensive hadrontherapy project, which has gained credibility through its sound scientific and medical programs. The inspiration and the scientific support of the other programs, namely the NIRS-HIMAC, the GSI / DKFZ-HIT, the TERA-CNAO and the MedAustron, have particularly been of great assistance for the medical and technical aspects, aspects on which French physicians and scientists worked a lot over the last past years. Therefore, ETOILE will maintain its relationships with all of its scientific and medical partners.

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- * Project director : Jacques BALOSSO
 - Medical committee : Pascal POMMIER
 - Scientific committee : Joseph REMILLIEUX
 - Technical committee : Marcel BAJARD
 - Project internal coordination : Joël ROCHAT.

Reference:

ETOILE, Document for the creation of a national centre for light ion beam hadrontherapy; Lyon, september 2004.

Web site:

www.projet-etoile.fr