

PROJECT OF PRACTICAL IMPLEMENTATION OF THE SEMI-AUTOMATIC PROTECTIVE SCREEN, NEEDED FOR IMPROVING OF STRUCTURAL PROTECTION AGAINST IONIZING RADIATION, FOR PERSONNEL PARTICIPATING IN FLUOROSCOPY GUIDED INTERVENTIONAL MEDICAL PROCEDURES

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Abstract During fluoroscopy guided medical interventions, at least three people participate in practice, a doctor, a nurse and a radiological technician/professional medical radiologist. The protective screen is still placed manually, everywhere in the world, based on subjective assessment, and not moved during the intervention, according to the changes of the exposure conditions, which we believe is nowadays unacceptable. Because consequences of continuous long-term exposure to radiation are reaching the effective dose limit for occupationally exposed persons, health hazard for the staff, exclusion from clinical work, which also leads to increased labor costs and interventions delays, with incalculable consequences. In this paper is presented an optimal solution, based on automatic repositioning, for the mentioned problem, which has not yet been implemented in practice. In addition to direct protection, evaluation is also ensured in this way. It did not stop at the theoretical solution – a full business plan for implementation was created and mastering the immediate steps was started. his document explains and demonstrates how to prepare your manuscript. Manuscripts should be in the Word format. Use the A4 paper format. Margins: top 2.5 cm, bottom 1.5 cm, left 2 cm, right 2 cm. You can type the text directly into this template. Do not place any text, tables or figures outside the specified area.

Keywords: Fluoroscopy; protective screen; automatic repositioning; practical implementation.

1. INTRODUCTION

The growing demand for high-quality real-time diagnostics, increased awareness among professionals and technical workers, as well as the improvement of ionizing radiation protection measurements, along the increasing number of medical institutions where interventional procedures are performed, are contributing to the expansion of the market for ionizing radiation protection equipment. Less risky than traditional surgery, with shorter hospital stays and faster recovery, minimally invasive fluoroscopy-guided procedures are being used more frequently worldwide. In 2020., the last year for which data is available, 24 million such procedures were performed - six times more than a decade ago, using over 250,000 C-arm X-ray devices - CXD [1]. Lead transparent screens for ionizing radiation protection have been used in medical practice for over 100 years [2]. The shape, dimensions, movement mechanisms, materials and final product processing have been perfected, but currently, the screen is still manually positioned, and its position remains unchanged during the intervention, regardless of potential change in working conditions (as there is no communication between the screen and the CXD). The author has developed a solution for semi-automatic screen control [3], which is still unmatched in the world for mentioned needs.

2. CHALLENGE

Healthcare workers involved in fluoroscopy-guided interventions receive the highest radiation doses compared to all other employees in medical ionizing radiation applications [4]. This is partly due to the proximity to the primary source of ionizing radiation and partly due to changes in exposure pathways during the procedure. While an average patient may be exposed to radiation during fluoroscopy-guided medical interventions a few times at most during lifetime, doctors, medical and radiological technicians, anesthesiologists/anesthetists and others whose job includes performing this type of procedure are exposed daily and are therefore at risk of related serious health problems.

Protective screens play a vital role in protecting against primary and scattered radiation. Proper placement can reduce exposure by up to 99%, but only if they are continuously synchronized with the position of the radiation source [5,6,7]. However, the current situation is that the screen is still manually positioned, based on the subjective assessment, and remains static during whole procedure. This leads to a significant increase in stall exposure and even exclusion from radiation zone, after systematic examinations, with typical exclusion period from 3 months to 1 year. Re-engagement involves waiting for the results of a follow-up medical examination, with procedural delays, so at least an additional month should be added to these deadlines in practice. During all this time, the employee receives a full salary. Therefore, in addition to endangering the health of employees, labor costs for the healthcare institution are increased. Given the general shortage of relevant staff, the exclusion of employees necessary leads to the postponement of interventions, causing incalculable harm to society as a whole.

3. SOLUTION

Through a unique innovation for screen semi-automatic control [8,9], it is continuously positioned to maximize protection against ionizing radiation of the entire medical staff. To confirm this, extensive simulations and calculations were performed. Repositioning can be done, with related screen model [10] used, both clockwise and counterclockwise, as well as curving backward and forward, to adapt the screen's position to different geometric configurations (the current position of the screen in space, the current angulation of the integrated system consisting of X-ray tube and detector relative to the central axis of patient table, the geometric layout corresponding to operator's arrangement and operator heights), based on information about the distribution of scattered radiation for all reference points and angulations.

It is envisaged that operator can not proceed with X-ray exposure until proper repositioning, but it takes seconds. From start to finish, the screen has been assigned status indicator - active, passive, locked. If the indicator status is active or passive, radiation is disabled - exposure is only possible when the screen is locked. A reliable method of screen control is defined as an absolute imperative, with redundancy control and clear priority management, guaranteeing complete mechanical safety during use.

Using data on the position and exposure parameters, saved in the Radiation Dose Structural Report, along with loaded maps of measured scattered radiation, the system systematically assesses the dose received by individual staff members, through relevant software. This is of great importance as it can

be used to change work habits to adjust the proper distribution of dose in essence. It can also serve as an efficient tool if retrospective dose calculations are needed.

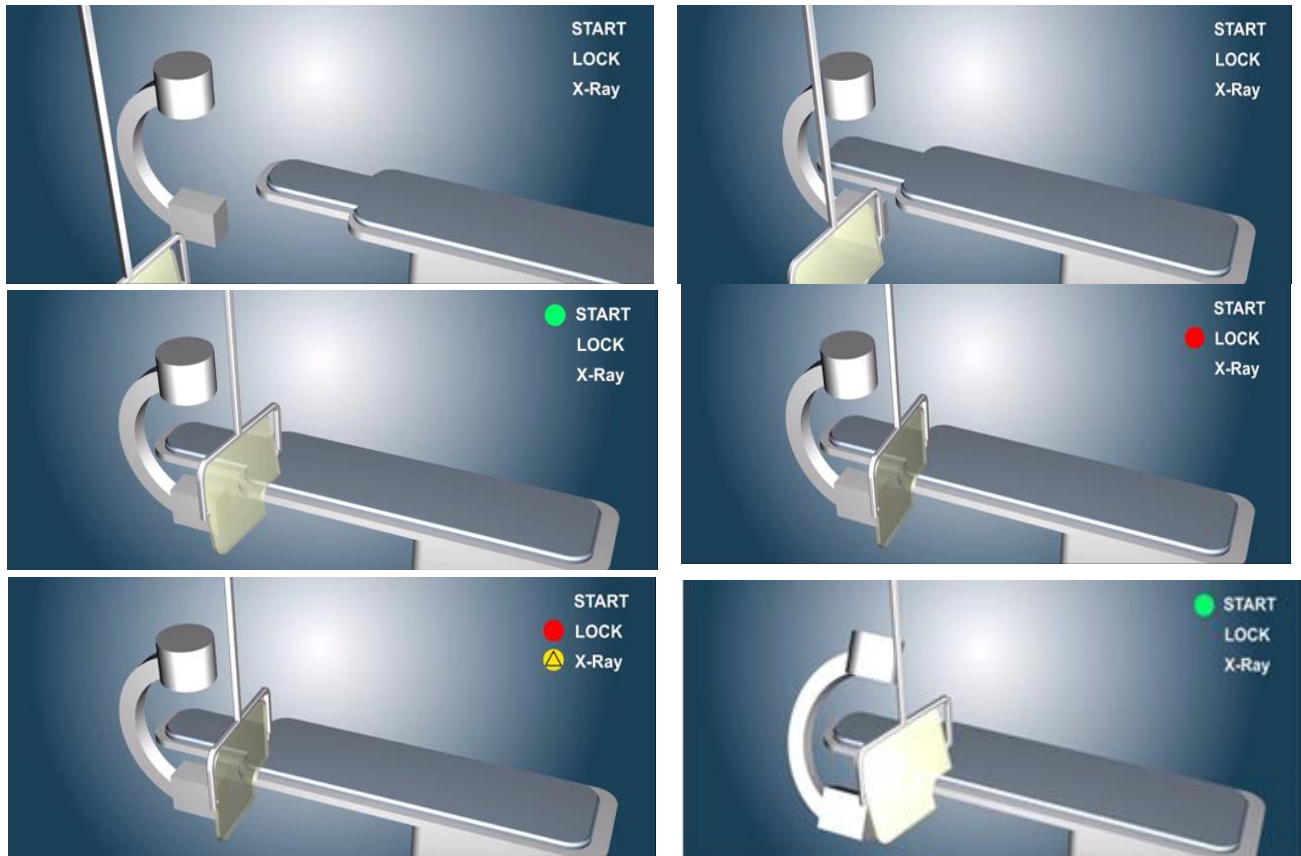


Figure 1. Video excerpts [8,9]. CXD and protective screen merged in one integrated system. After optimal, semi-automatic, initial positioning, it is anticipated that the screen will be repositioned, as the conditions of exposure change. Representation of associated status indicators.

The goal is to create the commercial product. Preliminary results with the prototype show 1.5-8 times lower exposure, compared to passive screen (depending on the position of the medical worker and intervention method). The screen position is adapted, resulting in short-term efficiency (reducing the dose per procedure) and long-term efficiency, ensuring that the annual dose is never exceeded, which allow the staff to work throughout the calendar year. In addition to preserving the health of employees individually, medical centers will also benefit because their staff will be less absent and healthier, enabling continuous work with a significantly lower percentage of employees being off due to occupational illness.

In collaboration with us, X-ray device manufacturers would have a comparative advantage in tenders because they can guarantee better protection for their employees. Protective equipment manufacturers will have opportunity to expand their portfolio through OEM cooperation.

Two types of products have been defined:

1. Radiation Brainscreen Protector - RBP

2. Radiation Brainscreen Interface - RBI

The interface, as the product can be applied to all existing CXDs, and the complete product, initially with newly produced CXDs. The essence of the expected product is, once again, to emphasize the integration of CXD and protective screen into a single system, enabling the repositioning of the screen through automatic control, taking into account the initial positioning and circumstances at the beginning and during the single interventional procedure.

4. CURRENT PROJECT STATUS

After detailed measurement and extensive computer simulations, the mathematical model of repositioning is gradually rounded, covering various types of CXDs. The mechanical study and the prototype have been created. The solution has been published [11] and successfully presented on various specialized scientific meetings and congresses in Serbia, surrounding countries and Europe. All technical and technological aspects for creating the appropriate interface have been considered.

We have approached the International Atomic Energy Agency. They expressed high interest, and principled support. Specifically, they are not allowed to directly support, but aware of the benefits of implementing such a system, they are willing to include a recommendation, in the next edition of International Atomic Energy Agency Basic Safety Standards, that CXDs must have an integrated protective screen, which is currently only solved through the author's patent.

Our clients are hospitals and protective equipments manufacturers. A preliminary cooperation agreement has been signed with Visaris, a leading X-ray device manufacturer in the Balkans, including both laboratory testing and OEM sales issues. We are in negotiations with leading global manufacturers of protective equipment (Mavig, MarShield, Ray-Bar Engineering Corp., Lemerpax), as well as CXDs manufacturers (Siemens, General Electric). The project sustainability is based on three pillars: the need/clients, patented solution and wide recognition/support.

The next steps involve further software and hardware development: component procurement, setting up a testing laboratory, constructing moving systems, implementing microcontroller and induce the software, merged with CXD, to define optimal screen position. Afterwards, clinical testing, mechanical safety checks, corrections/adjustments, and documentation preparation. In addition, prior agreements with CXD manufacturers are necessary. After final testing, full patent protection will be addressed. Continuous work on marketing must be carried out all the way.

For the activities mentioned in the preceding paragraph, we require additional funding. An estimate has been made of the cost of the products, and the product should pay off in 2-3 years. It had been applied to the funds, so far without results.

The innovative concept can also be applied in other situations where workers are exposed to ionizing radiation, so an expert team gathered around the project (colleagues from the Faculty of Electrical Engineering, Belgrade and the Vincha Institute of Nuclear Sciences, plus engineers with practical experience in the production of protective equipment against ionizing radiation) is considering further patent exploitation.

4. CONCLUSION

The aim of this work was to inspire asking questions, finding solutions and, moreover, persevering on the path to practical commercial realization, encouraging to have will and patience to implement knowledge in practice. We firmly believe that this is our duty to life circumstances that have allowed us to be where we are today.

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