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3D printing from a biocompatible material for a new design of electron applicators of the intraoperative accelerator

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Abstract

Introduction: A special type of radiotherapy is Intraoperative Electron Radiation Therapy (IOERT). The electron applicator is the element forming the final shape of the electron beam delivered to the postoperative bed. This work presents the new design of an electron applicator made from the biocompatible material MED610. The applicators will form an electron beam in the AQURE intraoperative accelerator.

Material and methods: The main problem to be solved during the construction work was to propose a design solution for the electron applicator that would be light, transparent, and made of a biocompatible material, and at the same time sufficiently shield the patient against radiation scattered outside its walls. Moreover, the applicator used in intraoperative therapy should have the thinnest possible walls.

Results: The calculations and design work performed allowed the lower part of the applicator to be made of a biocompatible, material. This element allows the beam to be formed in accordance with the normative recommendations, it is light and transparent. In this case, PolyJet 3D printing was selected as the most appropriate method.

Conclusions: Thanks to the use of a new solution for the shape of the walls, the applicator limits the leakage radiation by the standard, without the need for thicker outer walls. This material is light, thanks to which the doctor keeps this part of the applicator in the right position until it is fastened with the part on the head that does not require additional, dedicated fastening. The resin MED610 is suitable for 3D printing, it can be easily used to create any shape, and thus the possibilities of forming the lower part of the applicator are not limited. In the future, for individual purposes, the shape of the beam formed by the lower part of the applicator may be dedicated to special applications.

Keywords: 3D printing, intraoperative accelerator, electron applicators

Introduction

Radiotherapy is a method of treating cancer with the use of ionizing radiation. A special type of radiotherapy is Intraoperative Electron Radiation Therapy (IOERT)[1,2]. This therapy consists of combining oncological surgery with radiotherapy with a beam of electrons of high energy (up to 12MeV) and intensity. The device intended for intraoperative therapy with electron beams is the intraoperative accelerator. This accelerator is both an electron accelerator and a mobile manipulator that allows the radiation head to be set in a specific position within a relatively large working area.

The electron applicator is the element forming the final shape of the electron beam delivered to the postoperative bed[3,4].

The task of the electron applicator is to collimate the beam in compliance with the following normative requirements[5]:

- uniform dose distribution over the entire irradiated surface by the IEC60976 standard (Medical electrical equipment – Medical electron accelerators – Functional performance characteristics) and the IAEA TR No.398 dosimetry protocol. Flatness – by IEC60976 – in the Flatness region, i.e. 1 cm in the direction of the beam axis from each of the 90% isodose points. Flatness is calculated as the difference of the

Authors' contribution: A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of the article.

maximum and minimum points at the depth zref (R80/2; R89 – is the depth in water at which the radiation dose drops from 80% of the maximum dose) for each energy <5%.
- minimization of secondary radiation by the PN EN 60601-2-1 standard (Specific requirements for basic safety and basic operation of electron accelerators in the range from 1 MeV to 50 MeV). It is required to attenuate the radiation scattered outside the geometric area of the radiation field by the applicators at the level of 1% of the maximum dose on average in the area of 4 cm from the radiation field boundary to the M10 field boundary.

This work presents the new design of an electron applicator made from the biocompatible material MED610. The applicators will form an electron beam in the AQURE intraoperative accelerator [6]. The aim of this article is to present an experimental path to achieve the proper shape of the electron applicator to meet the design assumptions.

The main problem to be solved during the construction work was to propose a design solution for the electron applicator that would be light, transparent, and made of a biocompatible material, and at the same time sufficiently shield the patient against radiation scattered outside its walls. Moreover, the applicator used in intraoperative therapy should have the thinnest possible walls.

Materials and method

Accelerator overview

The intraoperative accelerator AQURE is intended to treat patients in the so-called Intraoperative Electron Radiotherapy (IOERT). This type of therapy is used in combination with surgery, and the radiation dose is delivered directly to the postoperative bed after the removed tumor[7]. The entire procedure is performed in the operating room. AQURE is a radiotherapeutic device that produces ionizing radiation: beams of electrons with energies ranging from 4 to 12 MeV (**Figure 1**).

Figure 1. AQURE – a mobile accelerator for IOERT.

Due to the targeted nature of the therapy, the radiotherapist must be able to place the applicator over the target as accurately as possible. To properly collimate the beam of electron radiation, applicators limiting/adjusting the radiation field to the field of the target volume should be used[1,4,8]. Accessories used to limit the radiation field and modify the dose (applicators, tissue-like boluses, shield plates) and all elements that have direct contact with the operating field should be made of a biocompatible material that allows sterilization, without changing their physical properties[9].

Applicator overview

The maximum radiation field used in IOERT is 10cm. Applicators intended for the AQURE accelerator should have internal diameters from 3 to 10 cm. It was initially assumed that the applicators would be in the form of pipes made of appropriate material. The applicator consists of two parts: the upper one located at the end of the accelerator head and the lower one intended for use in direct contact with the patient tissue. The applicator is attached using the hard-docking method, after placing the applicator in the patient's body (**Figure 2**).

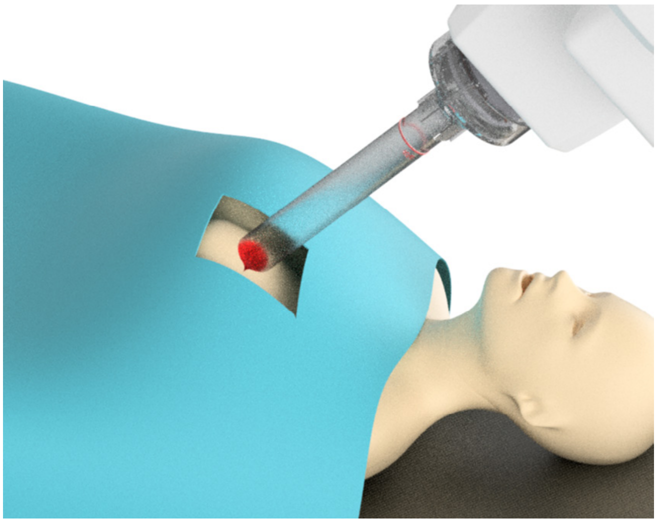

Figure 2. Transparent applicator part – location in the postoperative bed.

The protective properties of materials depend on the so-called stopping power, which depends on the density of the material. Collision-stopping power is defined as the average rate of energy loss per unit path length, due to Coulomb collisions that result in the ionization and excitation of atoms. CSDA (continuous-slowing-down approximation) range is defined as a very close approximation to the average path length traveled by a charged particle as it slows down to rest, calculated in the continuous-slowing-down approximation. In this approximation, the rate of energy loss at every point along the track is assumed to be equal to the total stopping power. Energy-loss fluctuations are neglected. The CSDA range is obtained by integrating the reciprocal of the total stopping power for energy[14].

3D printing method overview

Polyjet technology uses liquid photopolymer resins that harden layer by layer with UV radiation. The 3D printing method was made by the company Objet but after its acquisition by Stratasys – this technology was even better refined. It is a precise and versatile removal technology[10,11,13].

It uses materials from a huge palette of colors and offers resins with a variety of properties and wide applications. PolyJet guarantees unrivaled surface smoothness and precision in mapping shapes, dimensions, and the smallest details. It allows printing with a layer height of up to 14 micrometers and supports soluble support material[11].

The material used to make the applicators is MED610. It is a transparent material, biocompatible by the standards: EN ISO 10993-5; EN ISO 10993-10; EN ISO 10993-10; EN ISO 10993-3; EN ISO 10993-18; USP 34<88> and resistant to ionizing radiation. The material is designed for medical and dental applications and is approved for permanent skin contact (more than 30 days) and limited mucosal membrane contact (up to 24 hours)[12,14]. Low-temperature plasma sterilization equipment will be used for sterilization. Using this method, the applicator can undergo up to 150 sterilization cycles without affecting its service life.

Results

The electron applicator as a beam shaping element must meet the above-mentioned radiation shielding conditions. Initial Monte Carlo simulations (GANT4) showed that the applicator walls meeting the above-mentioned conditions and made of transparent PMMA material would have to be 10 mm wall thick, which was not acceptable from the point of view of usability of the application for an intraoperative accelerator. Therefore, the experiment described below was performed. Its results were then confirmed by simulations and dosimetric measurements, which are described in detail in a separate publication[6].

The first step of the experiment was to compare the capabilities of known materials for shielding and shaping a radiation beam.

During electron beam irradiation, photon radiation is also generated. Therefore, the photon radiation attenuation factor (mass attenuation coefficient) is also included in Table 1. The potential for a material to attenuate photon radiation also depends on its density. The higher is coefficient for the material used to make the applicator, the less it is needed to have for appropriate shielding. Based on data on the density of materials that can be used to produce the applicator and their radiation shielding possibilities for 12 MeV energy, the minimum weight and wall thickness of the applicator can be calculated (**Table 1**).

Table 1. Basic parameters of applicators made of various materials

Material | Parameter	Density [g/ccm]	CSDA range [g/cm^2]	Mass attenuation coefficient [cm^2/g]	Weight [kg]	Wall thickness [mm]
stainless steel	7.86	7.272	2.99x10^{-2}	4.51	1.5
stainless steel	7.86	7.272	2.99x10^{-2}	9.15	3.0
anodized aluminum	2.70	7.152	2.318x10^{-2}	3.14	3.0
PMMA (polymethyl methacrylate)	1.19	5.902	2.1x10^{-2}	4.93	10.0

A stainless steel applicator with a wall thickness of 1.5 mm reduces side radiation to a level consistent with the recommendations of the standard. For practical reasons, such a thin steel wall is not used. This type of element with such a thin wall may pose a risk as it is too sharp for this type of application. There is also a danger that the wall could become deformed during use and sterilization. 3mm is the right thickness, but it also doubles the weight of the applied part. The same applicator made of anodized aluminum, to limit radiation to the same extent, must have a wall thickness of approximately 3.0mm. PMMA already requires the use of a wall of approximately 10mm.

Since the irradiation field is determined by the internal diameter of the applicator, the use of materials other than steel significantly increases its external diameter (for steel and aluminum by 6, and for PMMA by up to 20 mm). This results in the need to make an unnecessarily enlarged surgical incision to place the lower part of the applicator there. If a thinner PMMA wall is used, it is necessary to use additional protective plates covering a field wider than that determined by the applicator, which also involves a larger surgical incision for the patient.

The next stage of construction was to redesign the applicator walls so that, despite being made of a light and transparent material, the wall thickness did not exceed 3 mm.

This was achieved by using the appropriate shape of the internal wall (**Figure 3**).

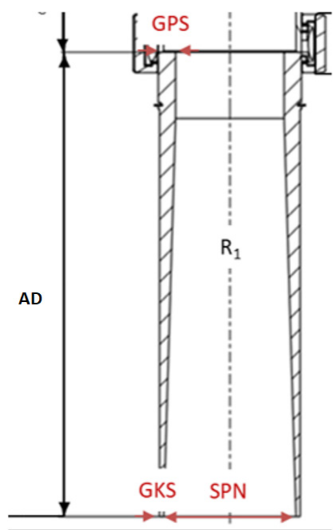

Figure 3. The shape of the internal wall of the applicator GPS – upper wall thickness; GKS – lower wall thickness; AD – total transparent part length; SPN – field diameter; R1 – main axis of the radiation beam.

The relationship between the wall thickness at the top of the transparent part (GPS) of the applicator and its total length (AD); the wall thickness at the bottom (GKS) and the size of the field (SPN) to be formed by the applicator is covered by the patent [13]. From these calculations, we obtain the shape of the transparent part, which first allows for limiting side radiation to an acceptable level and minimizing the external diameter of the applicator.

In this solution, the applicator is made of a material with a density similar to PMMA and an inner diameter (SPN) of 10 cm, weighs 1.87 kg, and the wall at the bottom (GKS) is 3 mm thick.

To experimentally verify the above calculations, comparative measurements were performed for two applicators with an internal diameter of 10 cm – a steel one with a wall thickness of 3 mm, and an applicator made of PMMA with a wall thickness of 10/3 mm. The measurements included leakage radiation outside the M10 area as well as checking the flatness and symmetry of the field determined by both applicators. The measurements results are shown in **Table 2**.

Table 2. The measurement results – leakage radiation outside the M10 area and the flatness and symmetry of the field for two applicators

Applicator | Parameter	PMMA	Stainless steel
Leakage radiation outside M10 field [%]	0.62	0.71
Symetry [%] – *maximum ratio of absorbed doses at points symmetrically displaced from the radiation beam axis in the radiation field*	101.3	101.9
Falttenes [%] – *maximum distance between 90% isodose contours and edge of geometrical field projection*	5.3	6.2

As mentioned above, after experimental confirmation of the correctness of the selected shape, the results were once again simulated and finally the applicators were designed.

However, this shape is not easy to make from a technological point of view. To meet both of the above objectives, the lower part of electron applicators used in the intraoperative accelerator AQURE are made of a transparent biocompatible material MED610, and the 3D printing method was used to make this element.

The hard docking applicator, i.e. a rigid connection between the part placed in the postoperative wound and the radiation head, also requires a fastening element and a system for reading the type of applicator fastened to the head (its diameter, shape, etc.). We used our design of electrical contacts in the cup, so its shape could cause implementation problems (**Figure 4**).

In this case, the use of 3D printing also developed the possibility of shaping this element. However, the use of the PolyJet technique in printing made it possible to precisely fit the screw cap to the contacts.

Thanks to PolyJet 3D printing technology, it is easy to create designed channels for electrical contacts, applicator reading elements, and the possibility of adding descriptions in a different color, which facilitates the identification of the applicator, which is impossible with the traditional method of production. The above method allows for saving material compared to machining, and at the same time allows for making complex shapes such as relief holes, elements that ensure ease of mounting and rotation of the cup, without complicating the technological process (**Figure 5**).

Figure 5. The complete transparent part of the applicator with a cap and a clear description.

Discussion

The density of steel is the highest, the application part of the applicator forms a 10 cm radiation field with a length of 30 cm and a wall thickness of 3 mm weighing 9.15 kg, while the part made of anode aluminum weighs 3.14 kg. Therefore, a special frame attached to the operating table should be used so that the operator/radiologist/doctor does not have to hold the lower part when docking. However, in this case, it is difficult to see through the applicator for correct positioning because the material is not transparent.

The transparent material is PMMA and applicator which meets the requirements for shielding against side radiation while making the walls by the above guidelines bringing its weight closer to the aluminum equivalent – 4.93 kg.

The new design of the applicator required the use of new technological solutions. Applicators for the AQURE accelerator are made of biocompatible material that weighs 1.87 kg

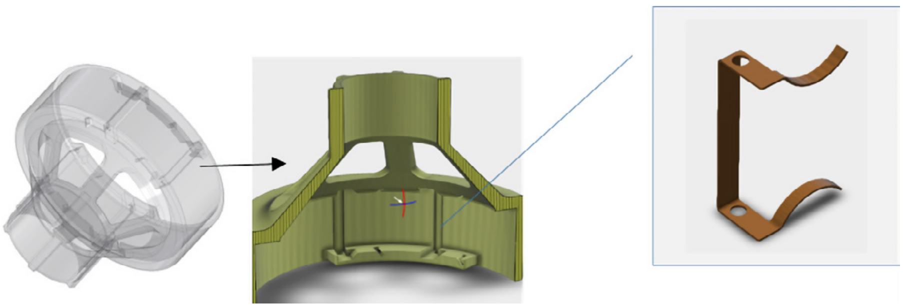

Figure 4. A cap that connects the transparent part of the applicator to the radiation head and the location of the contact for identifying the applicator.

Table 3. The basic mechanical parameters of new 3D printed applicator with the comparison with other materials and shape.

Material | Parameter	MED600	PMMA	Anodized aluminum	Stainless steel	Stainless steel
Biocompatybility	Yes	NO	Yes	Yes	Yes
Transparency	Yes	Yes	NO	NO	NO
Flexibility in choosing the shape	Any shape designed by the designer	Shape and size selected from commercially available pipes and profiles	Shape and size selected from commercially available pipes and profiles	Shape and size selected from commercially available pipes and profiles	Shape and size selected from commercially available pipes and profiles
Wall shape	The thickness at the top is different from the thickness at the bottom	Straight walls (uniform thickness along the entire length)	Straight walls (uniform thickness along the entire length)	Straight walls (uniform thickness along the entire length)	Straight walls (uniform thickness along the entire length)
Weight [kg] – *applicator with the largest internal diameter – 100mm)*	1.87	4.93	3.14	9.15	4.51
Wall thickness [mm] – *applicator with the largest internal diameter – 100mm)*	10/3	10.0	3.0	3.0	1.5

compared to the lightest version made of aluminum, which weighs 3.14 kg. However, it has an advantage over this solution in that it is transparent.

The basic mechanical parameters of new 3D printed applicator with the comparison with other materials and shape are shown in **Table 3**.

The use of 3D printing allows flexible and accurate reproduction of designed shapes and does not impose limitations on the diameter of the applicator to only those available on the market, as is the case with aluminum.

According to the standard regarding biocompatible elements used in medicine, the fact that the material itself is biocompatible is not sufficient. Also, the method used to make the element must be such as not to affect the biocompatibility of the material. In extreme cases, it is required to test a specific element after its production for compliance with the biocompatibility standard, which is time-consuming and costly.

The use of 3D printing solves the above problem for the applicators we designed. Biocompatible material intended for 3D printing does not change its biocompatible properties during the production of elements. While maintaining quality assurance for 3D printing, an element printed from a biocompatible material is also biocompatible.

Conclusion

Thanks to the use of a new solution for the shape of the walls, the applicator limits the leakage radiation by the standard, without the need for thicker outer walls. The developed and patented design of the applicator required the development of a new technology for making this accelerator component. In this case, PolyJet 3D printing was selected as the most appropriate method.

The advantage of using 3D printing is that we can use biocompatible transparent material with a density similar to polymethyl methacrylate (PMMA) (≈1.19 g/cm^3), which ensures its transparency, easy sterilization and correct placement of the applicator part in the postoperative bed.

Thanks to the developed post-print processing technology, the material does not lose its biocompatible properties and is adapted to the upper part of the applicator.

This material is light, thanks to which the doctor keeps this part of the applicator in the right position until it is fastened with the part on the head that does not require additional, dedicated fastening.

Because this resin is suitable for 3D printing, it can be easily used to create any shape, and thus the possibilities of forming the lower part of the applicator are not limited. In the future, for individual purposes, the shape of the beam formed by the lower part of the applicator may be dedicated to special applications.

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