Creation of a prototype simulator object for quality control of bone segmentation algorithms for use in tomographic post-processing software

Criação de um protótipo objeto simulador para o controle de qualidade de algoritmos de segmentação óssea para o uso em softwares de pós processamento tomográfico

Creación de un objeto simulador prototipo para el control de calidad de algoritmos de segmentación ósea para su uso en software de posprocesamiento tomográfico

DOI: 10.46919/archv5n5-003

Originals received: 06/14/2024
Acceptance for publication: 07/05/2024

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ABSTRACT
Considering the growing influence of Artificial Intelligence (AI) in medicine, especially in radiology, and the advances in computational power and theoretical understanding of AI algorithms (MESKÓ; GÖRÖG, 2020), concerns about the reliability of these methods arise. This study developed a prototype simulator object for quality control of bone segmentation algorithms in computed tomography. To achieve this objective, a 3D simulator object was created using advanced printing techniques, with materials that faithfully replicate the density and hardness of human bones, such as RadioMatrix. The results indicated that bone segmentation in post-processing software is strongly influenced by tissue density and that currently available AI models lack explainability (EXAI). The analysis revealed the need for algorithms that consider not only density but also the specific shapes and characteristics of bones. It is concluded that the developed prototype is effective in the evaluation and quality control of bone segmentation algorithms, promoting greater safety in clinical application and better explainability of bone segmentation algorithms in post-processing software for computed tomography.

Keywords: computed tomography, artificial intelligence, quality control, simulator object, bone segmentation.

RESUMO
Considerando a crescente influência da Inteligência Artificial (IA) na medicina, especialmente na radiologia, e os avanços no poder de computação e na compreensão teórica dos algoritmos de IA (MESKÓ; GÖRÖG, 2020), surgem preocupações sobre a confiabilidade desses métodos. Este estudo desenvolveu um protótipo de objeto simulador para o controle de qualidade de algoritmos de segmentação óssea em tomografia computadorizada. Para atingir esse objetivo, foi criado um objeto simulador 3D utilizando técnicas de impressão avançadas, com materiais que replicam fielmente a densidade e a dureza dos ossos humanos, como o material RadioMatrix. Os resultados indicaram que a segmentação óssea nos softwares de pós-processamento é fortemente influenciada pela densidade dos tecidos e que os modelos de IA atualmente disponíveis carecem de explicabilidade (EXAI). A análise revelou a necessidade de algoritmos que considerem não apenas a densidade, mas também as formas e características específicas dos ossos. Conclui-se que o protótipo desenvolvido se mostra eficaz na avaliação e controle de qualidade de algoritmos de segmentação óssea, promovendo maior segurança na aplicação clínica e melhor explicabilidade dos algoritmos de segmentação óssea nos softwares de pós-processamento em tomografia computadorizada.

Palavras-chave: tomografia computadorizada, inteligência artificial, controle de qualidade, objeto simulador, segmentação óssea.

RESUMEN
Considerando la creciente influencia de la Inteligencia Artificial (IA) en la medicina, especialmente en la radiología, y los avances en el poder de computación y en la comprensión teórica de los algoritmos de IA (MESKÓ; GÖRÖG, 2020), surgen preocupaciones sobre la fiabilidad de estos métodos. Este estudio desarrolló un prototipo de objeto simulador para el control de calidad de algoritmos de segmentación ósea en tomografía computarizada. Para lograr este objetivo, se creó un objeto simulador 3D utilizando técnicas avanzadas de impresión, con materiales que replican fielmente la densidad y la dureza de los huesos humanos, como el material RadioMatrix. Los resultados indicaron que la segmentación ósea en los softwares de posprocesamiento está fuertemente influenciada por la densidad de los tejidos y que los modelos de IA actualmente disponibles carecen de explicabilidad (EXAI). El análisis reveló la necesidad de algoritmos que consideren no solo la densidad, sino también las formas y características específicas de los huesos. Se concluye que el prototipo desarrollado es eficaz en la evaluación y control de calidad de algoritmos de segmentación ósea, promoviendo una mayor seguridad en la aplicación clínica y una mejor explicabilidad de los algoritmos de segmentación ósea en los softwares de posprocesamiento en tomografía computarizada.

Palabras clave: tomografía computarizada, inteligencia artificial, control de calidad, objeto simulador, segmentación ósea.

1 INTRODUTION

Artificial Intelligence (AI) has become pivotal in medical practice, with studies rising from 203 in 2005 to 12,563 in 2019 (Meskó & Görög, 2020). AI's multidisciplinary nature necessitates healthcare professionals to understand its basics, evaluate studies, validate clinically, and recognize AI's limitations and opportunities.

AI, exhibiting human-like intelligence in machines or software, originated post-World War II (Allen

& Chan, 2017). It includes subfields from learning and perception to specific tasks like chess, theorem proving, poetry creation, and disease diagnosis.

Radiology, historically innovative, has embraced AI early. The adoption of CT and MRI has revolutionized image interpretation. Future decades will witness AI's profound impact on radiology, streamlining workflows and reducing workloads but also posing challenges (Brink & Hricak, 2023).

Turing's (1950) query, "Can machines think?" and McCarthy's (1989) emphasis on defining intelligence, underscore AI's foundational questions. McCarthy coined "artificial intelligence" in 1956, defining it as creating adaptive, learning programs (Rich & Knight, 1991).

New technologies, especially in healthcare, demand rigorous evaluation and quality control. The FDA (2019) notes a shift from hardware to software, predicting an exponential increase in algorithm regulation. Simulators, as defined by the International Commission on Radiation Units and Measurements (ICRU), help perform quality control tests for AI-based post-processing systems in computed tomography (White *et al*., 1992).

2 THEORETICAL REFERENCE

2.1 RADIOLOGY - A FASCINATING JOURNEY

The history of radiology is a narrative filled with pioneering discoveries and visionary advancements that have radically transformed medical practice. It all began in 1895 when Wilhelm Conrad Röentgen, fascinated by the behavior of electrons, accidentally triggered a scientific revolution upon noticing a greenish light emanating from cardboard coated with barium platinocyanide in his laboratory. This pivotal moment gave birth to X-rays, ushering in a new era in 20th-century medicine.

Röentgen soon realized the revolutionary potential of his discovery when he captured the first X-ray image of his wife's hand, revealing bones and muscles in unprecedented detail (Hounsfield, 1980). Since then, radiology has been propelled by continuous innovations, from the development of the first X-ray tubes to the modern advancements in computed tomography.

The evolution of equipment, such as Coolidge tubes and state-of-the-art multidetector tomographs, has revolutionized doctors' ability to diagnose a variety of medical conditions with unprecedented accuracy (Hofmann, 2010). Three-dimensional images of high resolution, obtained almost in real-time, represent the pinnacle of this technological journey.

Furthermore, photon-counting computed tomography represents the next step in the evolution of radiology, offering drastic improvements in resolution and reduction of radiation dose (Rajendran *et al*., 2022). These innovations not only expand the horizons of medical diagnosis but also have the potential to revolutionize the treatment and management of complex diseases.

In times of pandemic, radiology departments play a crucial role in combating COVID-19, providing accurate diagnoses and assisting in patient management (Li, 2015; Chan *et al*., 2020). Thus, radiology continues to be a cornerstone of modern medicine, driving the pursuit of clinical excellence and patient well-being.

2.2 POST-PROCESSING SOFTWARE (WORKSTATION): ADVANCES AND FUTURE PERSPECTIVES

With the increasing digitization in radiology, computed tomography (CT) has become immersed in computational technological advancements. Inherent to the method, arose tools for image formation and customization, yet the exclusive use of post-processing software on acquisition equipment was limiting. This instigated the need to add additional workstations, known as Workstations, dedicated to advanced reconstruction of radiological images.

In the global market of medical imaging workstations, there is fierce competition among key players, including Siemens Healthineers, GE Healthcare, Hologic, Philips, Fujifilm, and Carestream Health. They focus on technological advancement and regional expansion. These platforms offer a variety of functionalities, with a particular focus on bone segmentation and Hounsfield Unit (HU) density measurements. Image segmentation, essential for accurate diagnostics, is performed through techniques such as Measurement Space and Spatial Domain, with algorithms based on discontinuity and similarity of grayscale values.

However, segmentation accuracy remains a challenge. The use of traditional methods based on HU values can result in inaccurate segmentations (Liu *et al*., 2022, p. 4). A promising alternative is the use of deep learning-based methods, as proposed by Liu *et al*. (2022), which significantly overcome limitations of manual bone segmentation.

Furthermore, choosing the appropriate framework for the project is essential, considering efficiency and applicability in specific areas. TensorFlow, Keras, PyTorch, OpenCV, and ITK are examples of frameworks that offer a variety of algorithms for medical image segmentation, each with their specific advantages.

While technological advancements promise to improve the accuracy and efficiency of segmentations, transparency and disclosure of the technologies used remain challenges (Liu *et al*., 2022, p.

8). Manufacturers and users require a better understanding of available tools and their applications to further drive progress in this area.

2.3 UTILIZATION OF SIMULATOR OBJECTS FOR QUALITY CONTROL IN THE MEDICAL FIELD AND 3D PRINT

The term "quality" is ubiquitous in daily life conversations, yet its definition remains elusive due to its relative nature. Juran (1992) defines quality as the absence of defects, while Deming (2003) views it as anything that enhances the product from the customer's perspective. Deming (2003) asserts that effective management is pivotal to achieving quality, emphasizing planning, goal setting, resource allocation, and performance monitoring. The formal definition of quality according to ISO-9001 is "the degree to which a set of inherent characteristics meets requirements", where requirements represent established needs or expectations. These concepts underpin the understanding of quality and its assessment in various domains.

In the medical field, image quality control is paramount for accurate diagnostics and patient safety. Simulator objects, such as phantoms, play a crucial role in quality assurance programs. Phantoms mimic human tissue density and aid in evaluating imaging systems' performance.

Medical imaging encompasses anatomical and functional modalities, each serving distinct diagnostic purposes. From X-rays to MRI, these modalities rely on accurate image acquisition and processing, often facilitated by specialized hardware and software.

Quality assessment parameters for diagnostic images remain under development, necessitating the use of simulator objects for comprehensive evaluation. These objects enable the measurement of image characteristics such as spatial resolution and gray-scale transfer function, essential for clinical diagnosis.

Research demonstrates the efficacy of simulator objects in various imaging modalities, including CT, MRI, and radiography. By simulating tissue properties and imaging conditions, these objects ensure consistency and accuracy in image quality assessment. Moreover, the development of novel simulator objects, such as those incorporating gold nanoparticles, promises enhanced image contrast and diagnostic accuracy. This underscores the evolving nature of quality control practices in medical imaging.

Simulator objects represent indispensable tools in ensuring the quality and reliability of diagnostic imaging. Continued research and innovation in this field hold the potential to further enhance patient care and diagnostic accuracy.

The creation of simulator objects can be accomplished through 3D printing, which can contain materials that mimic human organs or tissues. These simulator objects, widely employed as training tools for doctors and healthcare professionals, as well as for testing and validating medical equipment, have been one of the many applications of this technology.

The journey of 3D printing dates to the 1980s when its first seeds were planted in the fields of aerospace and automotive industries. Chuck Hull, a visionary of the time, kickstarted it with the invention of "SLA" (Stereolithography Apparatus), a printer that used lasers to solidify liquids into three-dimensional shapes. This historic milestone opened doors to a world of possibilities, catalyzing a series of technological innovations that shaped the future of 3D printing (Saroia *et al*., 2020).

In 1999, Scott Crump and his team introduced Fused Deposition Modeling (FDM), a technique that utilizes plastic filaments to build objects. FDM quickly became one of the darlings of the 3D printing world, offering an accessible and efficient approach to manufacturing a variety of products (Saroia *et al*., 2020).

Since then, 3D printing has evolved by leaps and bounds. New technologies and materials are constantly emerging, pushing the boundaries of what is possible to create. Photopolymerizable resins, metals, ceramics - the array of materials available for printing continues to grow, driving innovation in fields like medicine, architecture, and fashion. In the realm of healthcare, 3D printing has been a powerful ally. The production of custom prosthetics for amputee patients is just one of the many applications of this technology. These tailor-made prosthetics offer superior functionality and comfort while drastically reducing both the time and cost involved in manufacturing (Kumar Banga *et al*., 2021).

Moreover, 3D printing has proven to be an essential tool for creating training models for surgeons and producing spare parts for medical equipment. These advancements not only improve the effectiveness and safety of medical procedures but also pave the way for a new era of personalized and accessible healthcare (Meyer-Szary *et al*., 2022).

But it's not just in medicine that 3D printing shines. It's also widely used in creating simulator objects, which play a crucial role in training healthcare professionals and developing new medical equipment. With its ability to simulate a wide range of human tissues, 3D printing is raising the standard of excellence in medical practice (Filippou and Tsoumpas, 2018). Of course, challenges persist. The quest for more affordable and reliable materials, along with the constant pursuit of perfection in the quality of printed objects, continues to drive the evolution of 3D printing technology. But despite the obstacles, the transformative potential of this technology is undeniable.

2.4 REGULATORY AND ETHICAL CHALLENGES IN THE INCORPORATION OF ARTIFICIAL INTELLIGENCE IN MEDICAL PRACTICE: A CRITICAL ANALYSIS OF BRAZILIAN AND INTERNATIONAL PERSPECTIVES

In recent years, technological evolution has been pivotal, with intelligent systems emerging as one of the most impactful disciplines. These virtual systems enable the prediction of healthy and pathological dynamics in individuals. According to the European Commission on Artificial Intelligence (2018), Artificial Intelligence (AI) demonstrates intelligent behavior by analyzing its surroundings and autonomously performing actions to achieve specific goals. These systems, whether software-based or interacting through hardware devices, contribute significantly to various fields, including medical practice.

The impact of AI development on human rights, democracy, and the Rule of Law was analyzed during the Monothematic Conference of the Council of Europe in Helsinki (Rodríguez *et al.*, 2019). This scrutiny emphasized the importance of considering human rights principles while advancing new software tools for medical purposes. Regulatory frameworks in this domain remain scarce, necessitating comprehensive regulations.

Before delving into the primary theme, it's crucial to define "Regulation" and "Regulatory" within the Brazilian legal context (Di Pietro, 2004). Regulation refers to establishing rules, irrespective of the authority—be it Legislative or Executive—although, in Brazilian law, regulatory power falls exclusively under the Executive branch.

The evolving landscape of AI encompasses various diagnostic and prognostic technologies, posing regulatory challenges, including algorithm transparency and bias mitigation (Vokinger & Gasser, 2021). While promising, AI presents legal and ethical challenges. The Healthcare Information and Management Systems Society Conference 2022 (HIMSS 22) highlighted the imperative of achieving health equity and eliminating implicit biases, a challenge mirrored in AI solutions.

Regulatory efforts are underway globally, with the FDA and other health agencies developing guidelines to navigate AI's integration into medical practice. Despite these efforts, challenges persist in ensuring transparency, equity, and safety in AI-driven medical applications.

The Brazilian discussion on AI regulation commenced in April 2022, focusing on Bill No. 5,051/2019 and related legislation. Public hearings addressed various themes, including AI concepts, impacts, rights, governance, and accountability. Initial discussions indicate a preference for self-regulation models, emphasizing flexibility and minimal governmental intervention (CASTRO *et al*., 2022).

Recent legislative initiatives in Brazil, such as Provisional Measure No. 1124 of June 14, 2022, underscore the ongoing debate surrounding AI regulation. This legislative action reflects the acknowledgment of AI's transformative potential in healthcare, necessitating a delicate balance between innovation and regulatory oversight.

AI represents a transformative opportunity to enhance medical outcomes, yet it necessitates robust regulatory frameworks to ensure public health and ethical standards. As regulatory policies evolve, legislative action may be required to address regulatory ambiguities and foster innovation responsibly.

3 METODOLOGY

The experimental methodology proposed in this research was established in 3 phases:

- phase 1 - Definition of biological reference values in the literature
- phase 2 - Definition of mimetic material for bone tissue
- phase 3 - Creation of the simulator object using 3D printing technique

Phase 1 - Definition of biological reference values in the literature

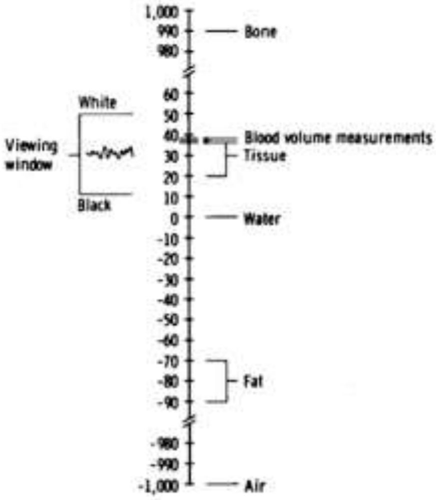
The history of radiology begins with Wilhelm Conrad Röentgen's discovery of X-rays in 1895, which revolutionized medical diagnosis and therapy, earning him the Nobel Prize in Physics in 1901. This discovery gave rise to a separate medical discipline, ushering medicine into the X-ray era and initiating a process of medical and technical development (Hounsfield, 1980).

In 1971, Oxford mathematicians Godfrey Hounsfield and Allan Cormack devised a solution capable of detecting conditions unseen in conventional X-ray systems, such as brain structures, including tumors; blood clots; enlarged ventricles; nerve or muscle abnormalities; abdominal masses; and bone fractures (Carvalho, 2007). Thus, computed tomography (CT) emerged, also utilizing X-rays to create images. The term comes from the Greek words "tomos," meaning "slice" or "section," and "graphia," meaning "describe." Creating sets of X-ray image data as slices overcomes the overlap of human anatomy in images (Francisco *et al*., 2005).

Different densities of various structures and organs absorb X-rays to varying degrees, a process known as differential absorption, creating images displayed on computer screens for interpretation. Often, these images can be displayed in three-dimensional (3D) images. In 1979, Hounsfield and Cormack were awarded the Nobel Prize in Physiology or Medicine for their contributions to health and research (Hounsfield, 1980).

This contribution is mainly due to the so-called Hounsfield scale, also known as Hounsfield Units (HU), which is a quantitative measure used by radiologists in the interpretation of computed tomography images, obtained from a linear transformation of attenuation coefficients. This scale is fundamental to the field of radiology, given its application in different clinical areas, significantly aiding in the diagnostic process (Morar, *et al*., 2022).

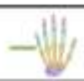
Image 1. Demonstration of the precision with which absorption values can be verified in the computed tomography image



Source: Hounsfield, P. 283. 1980.

The Hounsfield unit remains with the same parameters defined at the origin of the tomography. The thickness characterized for each type of bone was proposed in the publication of Acta Ortopédica Brasileira by the authors Mandarano-filho *et al*, in 2012. Therefore, for this project, the following densities and structures were defined (Table 1).

Table 1: Relationship between thicknesses, human anatomical structures and mean HU values.

Thickness	Relationship with part of the human body	Image	Hounsfield Unit (HU) average value
1 mm	Proximal phalanx of fingers		≅300 HU
2 mm	Metacarpal bones		≅500 HU
3 mm	Proximal region of the radius bone		≅600 HU
8 mm	Femur diaphysis		≅980 HU

Source: Produced by the authors.

Phase 2 - Definition of the mimetic material for bone tissue

In initial tests, an analysis of 23 materials, whether promising in terms of similarity to human bone, was proposed; then an image acquisition was performed by tomography with the materials described in Table 2.

Table 2: Material image and material description

Number	Material
1	Chicken breast
2	Chicken neck
3	Chicken liver
4	Eggshell
5	Multi Density Materials company Stratasys
6	Polylactic Acid Filament (PLA)
7	Polylactic Acid Filament (PLA)
8	Egg
9	Acrylonitrile Butadiene Styrene (ABS)
10	Acrylonitrile Butadiene Styrene (ABS)
11	Acrylonitrile Butadiene Styrene (ABS)
12	Multimaterial PLA+ABS
13,14,15,16	Polylactic Acid Filament (PLA)
17, 18, 19, 20,21,22, 23	Acrylonitrile Butadiene Styrene (ABS)

Source: Produced by the authors.

At this stage of the 23 materials tested, it was identified that materials such as PLA and ABS had low density detected with the HU for bone tissue, the other materials did not present adequate radiodensity for the expected quality control and for the development of the simulator object, with low similarity to bone tissue by HU density. A search for materials with a radiodensity similar to bone on the global market was necessary, and the new PolyJet material from the company Stratasys launched in June 2022, called RadioMatrix, was selected, as it allows 3D printing and has values between -30 HU to 1000 HU. This material is available for research only; commercial sale has not yet been released.

Phase 3 - Creation of the simulator object with 3d printing technique

The creation of a simulator object using 3D printing techniques was defined, allowing to produce three-dimensional objects from a digital model. The 3D printer operates by adding successive layers of material, typically plastic or metal, until the object is complete. This process is controlled by software that translates the digital model into instructions for the printer. In a systematic review published in 2017 in "The International Journal of Medical Research and Practice," it became evident that 3D printing has proven to be a valuable tool for creating accurate and high-quality simulator objects (FILIPPOU & TSOUMPAS, 2018). The authors concluded that 3D printing can be used to simulate a wide variety of human tissues, including bone tissue, adipose tissue, muscle, and hepatic tissue. The 2022 publication of the "Journal of Biomedical Physics and Engineering" presented the finding that 3D printing is a valuable tool for creating breast tissue simulator objects for breast cancer screening tests. The authors found that simulator objects created with 3D printing were accurate and convincingly resembled human breast tissue (ENDARKO *et al.*, 2022). Based on the reference literature, the shapes constituting the simulator object were established: circle, star, and ray. These different shapes were conceptualized because different axes such as star and ray are better for the proof of concept of geometric accuracy testing, and the circle is an excellent option for validating densities and whether the neural networks used in the development of bone segmentation models are of the spatial measurement or discontinuity type.

Table 3: Presentation of the shapes, size, thickness, and relationship with the part of the human body of the internal structures of the phantom that mimic bone tissue.

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	Círculo	[illegible]	[illegible]
		[illegible]	[illegible]
		[illegible]	[illegible]
		[illegible]	[illegible]
[illegible]	Estrela	[illegible]	[illegible]
		[illegible]	[illegible]
		[illegible]	[illegible]
		[illegible]	[illegible]
[illegible]	Raio	[illegible]	[illegible]
		[illegible]	[illegible]
		[illegible]	[illegible]
		[illegible]	[illegible]

Source: Prepared by the authors

Below (Image 2) is the image with the printer used and the parts that make up the model of the simulator developed, capable of evaluating bone segmentation algorithms in tomographic image post-processing systems.

Image 2. The images represent the moment of printing of the defined materials.

*Images generated by the Ricoh USA, Inc team, led by production director Patrick Gannon in Parma, Ohio.
Source: Produced by the authors.

As a component to wrap the twelve 3D printed parts, the agar-agar material that imitates muscle tissue was used, as indicated in the European Radiology publication by the authors Amiras, *et al* (2021). In image 3 are images of how the agar-agar material is used as a simulation for abdominal tissue.

Image 3. Visualization of the HoloLens application was performed, including a 3D model of a torso and a needle with a ChArUco marker attached, including a simulated CT image of a needle for interventional radiology.

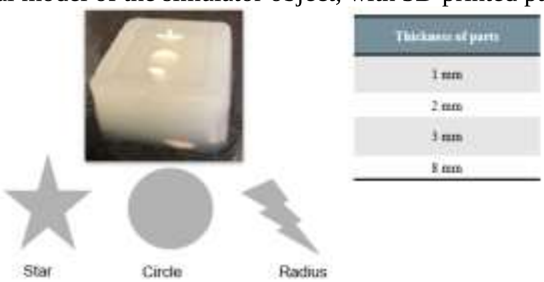
Source: Amiras, *et al* (2021).

Image 4. 22 shows the infographic with the execution of the agar-agar gelatin and the insertion of materials printed with the RadioMatrix material

Source: Produced by the authors.

Each container contained pieces with the same thickness, that is, the three shapes (star, circle and radius) of 1 mm, 2 mm, 3 mm and 8 mm, totaling 4 containers with a total of 12 pieces (Image 5).

Image 5. Final model of the simulator object, with 3D printed parts included.



Source: Produced by the authors.

As an option for comparing materials, a 3D printed simulator object was created with the resin material (Image 6).

Image 6. Simulator object with resin comparison material, 3D printing was used for this development. Source: Images generated by the 3D Applications team, led by Paulo Farias, Guarulhos, São Paulo.

Source: Produced by the authors.

4 RESULTS AND DISCUSSIONS

Medical image processing involves several stages, including quality control during acquisition and post-processing. A phantom, or simulation object, is often used in this process. Phantoms are structures containing one or more regions of tissue substitutes, collectively referred to as propagation material, and may include coupling material when necessary (Collins, 1999). These tissue substitutes, simulation objects, and computational modeling are widely used across diagnostic and therapeutic techniques. They are essential throughout the medical product lifecycle, from development to routine clinical use, serving purposes ranging from qualitative image evaluation to precise energy calibration for thermal dosimetry and safety (Collins, 1999).

According to Amendoeira *et al*. (2013), quality control is crucial for a comprehensive system assessment, image quality evaluation, and the identification of degradation due to equipment or software malfunction. Simulation objects are recommended for this process because exposure to different types of radiation should be minimized, and quality control cannot be performed directly on patients. Additionally, malfunctioning devices pose various risks to patients.

The lack of quality control testing for AI in the global context extends beyond legal and academic issues, raising significant ethical concerns about the responsibility of technology providers. In advanced post-processing software and AI models, this gap presents a substantial risk to clinical practice.

The results were organized into two phases:

1. acquisition of tomographic images of the simulation objects;
2. analysis using post-processing software (Workstation).

4.1 ACQUISITION OF TOMOGRAPHIC IMAGES OF THE SIMULATION OBJECTS

In phase 3 of our methodology, we created a 3D-printed simulation object using RadioMatrix to mimic human bone density. Additionally, we fabricated a resin-based simulation object for density comparison. We conducted computed tomography (CT) scans of these simulation objects using the CT Aquilion One Canon with 360 channels (Image 7).

Image 7: Photo of the computed tomography execution of the simulators developed.

Source: Produced by the authors.

4.2 ANALYSIS USING POST-PROCESSING SOFTWARE (WORKSTATION)

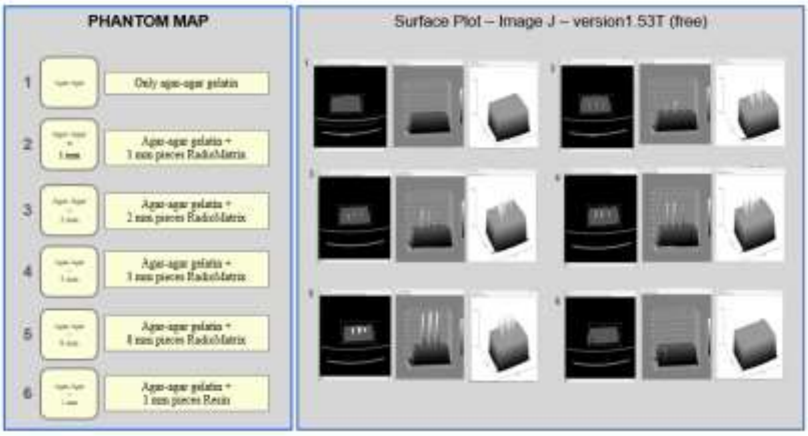
With the advent of digital radiology, computed tomography (CT) emerged, integrating advanced computational technologies. Initially, post-processing software was restricted to image acquisition devices, leading to the development of workstations for advanced volumetric image reconstructions. The global market for medical imaging workstations is competitive, with key players like Siemens Healthineers, GE Healthcare, Hologic, Philips, Fujifilm, and Carestream Health focusing on technological advancements and regional expansion.

For density and HU values, spatial resolution, and geometric accuracy analysis, we used widely available, FDA-approved post-processing software. Each analysis detailed the software version used.

4.2.1 Surface plot analysis

Surface plot analysis was conducted using Image J version 1.53 T. This analysis confirmed the shape of the simulation objects and their density histograms. Phantom 1, which contained only agar-agar gelatin, exhibited a histogram without any peaks, indicating the presence of a single material with a density similar to water. In contrast, Phantoms 2, 3, 4, and 5 displayed distinct peaks in their histograms at the locations of the materials mimicking bone tissue, confirming the presence of two types of materials. The resin-based Phantom 6 showed a low density, resembling that of water. The corresponding histograms for each phantom clearly illustrate these findings.

Image 8: Surface Plot analysis performed in Image J software



Source: Produced by the authors.

4.2.2 Hounsfield scale analysis

Using tools like Radiant, Onis Viewer, and Philips DICOM Viewer, we analyzed the Hounsfield scale values of each phantom. Phantom 1 and 6, made of agar-agar and resin, respectively, showed low HU values similar to water. Phantoms 2, 3, 4, and 5 demonstrated increasing HU values with thicker RadioMatrix layers, making them suitable models for mimicking human bone. Phantom 4 was ideal for proximal phalanges, and Phantom 5 for femur diaphysis, confirming our initial hypothesis. Observe the values found in the table 4 below.

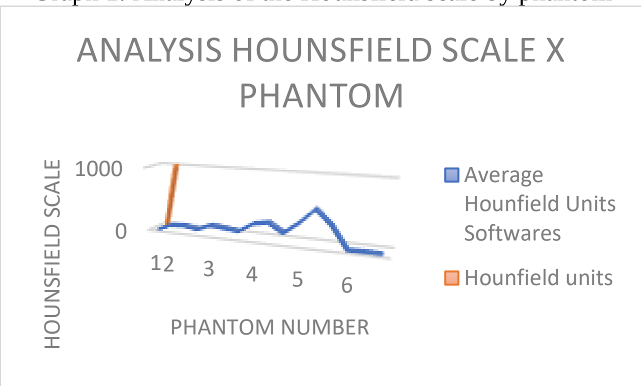
Table 4: Values obtained with the ROI tool available in medical image visualization software, related to the Hounsfield scale values and parts of the human body.

Número do Phantom	Formato da peça	Espessura	Relação do phantom com parte do corpo humano	Hounfield Units Radiant	Hounfield Units Onis Viewer	Hounfield Units Philips DICOM Viewer	Média Hounfield Units Softwares	Correspondência Hounsfield Unit e parte do corpo
1	Gelatina Ágar-Ágar	67,5 mm	Tecido abdominal	4,81	2,39	-2,78	1	0=água
2	Raio	1 mm	Falange proximal dos dedos	63,67	82,98	115,88	90	100 to 1000= Osso
	Círculo			86,71	101,309	123,29	104	
	Estrela			54,12	74,038	85,94	71	
3	Raio	2 mm	Ossos dos metacarpo	128,61	182,45	156,77	156	
	Círculo			116,8	156,12	134,34	136	
	Estrela			99,58	120,3	114,95	112	
4	Raio	3 mm	Região proximal do osso rádio	174,39	234,77	348,23	252	
	Círculo			247,73	279,98	351,79	293	
	Estrela			107,75	140,59	239,34	163	
5	Raio	8 mm	Diáfise do fêmur	347,11	283,99	370,03	334	
	Círculo			564,04	606,22	503,31	558	
	Estrela			237,14	516,62	283,57	346	
6	Raio	8 mm	Resina	0,53	10,65	9,88	7	0 = água
	Círculo			5,76	20,05	22,38	16	
	Estrela			4,18	12,92	14,82	11	

Source: Produced by the authors.

After conducting these analyses, it became evident that bone values described on the Hounsfield scale can be detected using commercially available DICOM Viewer software. Simulation object 1, containing only agar-agar gelatin, exhibited a low HU value close to zero, comparable to water. Simulation object 6, composed of resin pieces, also showed low values similar to water, indicating that these models are not suitable for bone recognition tests using AI-based post-processing software. As the thickness of the pieces increased (1 mm, 2 mm, 3 mm, and 8 mm), higher bone values on the Hounsfield scale were observed. Therefore, simulation objects 2, 3, 4, and 5 proved to be excellent models for mimicking human bone. Simulation object 4 mimics the proximal phalanges, while simulation object 5 simulates the femur diaphysis, thus confirming the initial research hypothesis. In the image below, observe the graph depicting the Hounsfield units and the phantom.

Graph 1: Analysis of the Hounsfield scale by phantom

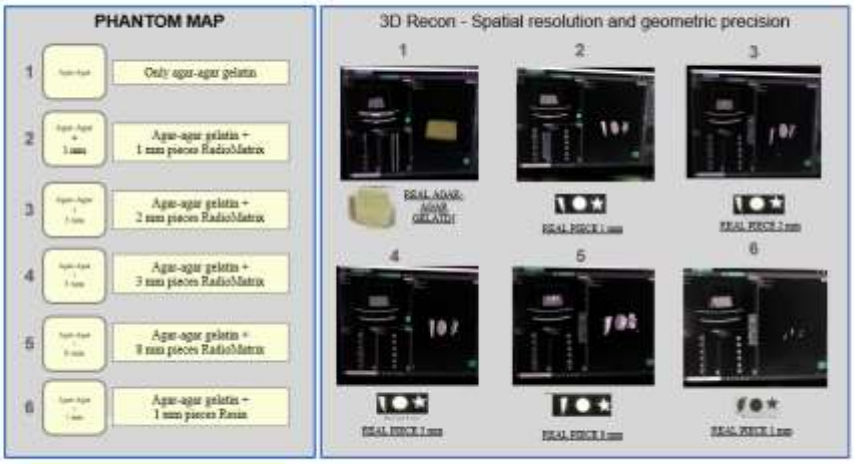


Source: Produced by the authors.

4.2.3 Spatial resolution and geometric accuracy analysis

Using Synapse 3D version 6.4.0017 EU from Fujifilm, we created 3D volumes and detected the actual size and internal structures of each phantom. The resin-based phantom proved ineffective as a bone simulator.

Image 9: 3D Recon - Spatial resolution and geometric precision



Source: Produced by the authors.

4.2.4 Bone segmentation algorithms analysis

We evaluated various AI-based segmentation algorithms, focusing on bone segmentation and density measures (HU). Segmentation techniques include Measure Space and Spatial Domain, based on gray-level values' discontinuity and similarity. Using tools like 3D Slicer, Horos, and Synapse, we confirmed that our phantoms successfully tested these techniques. Interestingly, a phantom with a non-anatomical shape was segmented correctly, showing AI's reliance on density and similarity despite the unusual form. This highlights the need for AI models to alert users when segmenting non-standard shapes. Overall, our study demonstrated that the developed phantoms are effective in testing various imaging and segmentation techniques, with phantoms 2, 3, 4, and 5 being particularly suitable for simulating human bone.

Image 10: Automatic bone segmentation using AI model

Source: Produced by the authors.

5 CONCLUSION

In the next two decades, healthcare will undergo unprecedented changes driven by AI. Radiologists must add value beyond image interpretation, such as anticipating AI-related risks in clinical applications.

This study developed a bone tissue simulator using materials matching the Hounsfield scale's radiodensity, enabling quality control for post-processing tomography software. Key findings include surface analysis, Hounsfield scale accuracy, spatial resolution, geometric precision, and bone segmentation using Threshold, Measurement Space, and Automatic Bone techniques.

The promising simulator, made from RadioMatrix, highlighted the need for Explainable AI (EXAI). Current AI models lack transparency, as demonstrated by the segmentation of non-existent shapes like rays as bone. This underscores the necessity for human-understandable AI results.

This research successfully developed a methodology to validate bone segmentation AI models on CT scans without the need for subjective human validation. Embracing technological advances benefits patients and optimizes healthcare professionals' time, but proper regulation and quality control are essential to mitigate risks from improper AI use and development.

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