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GPP04: Presentation Time: 10:57 AM: In-House Development of Novel Brachytherapy Applicators: Navigating Regulatory Frameworks

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and 3D LAVA-FLEX are appropriate pulse sequences for MR-only BT planning, and their corresponding advantages can thus be exploited.

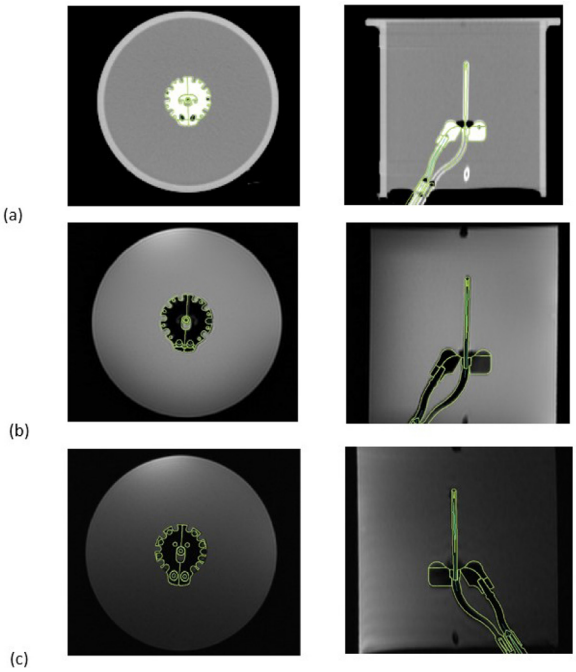

Figure 1. Axial (left) and reconstructed sagittal (right) MRI images for the phantom using (a) PROPELLER, (b) 3D LAVA FLEX, and (c) CT. The reconstructed applicator is shown.

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In-House Development of Novel Brachytherapy Applicators: Navigating Regulatory Frameworks

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Purpose: The clinical introduction of novel medical devices (MDs) requires conformity to the Medical Device Regulation (MDR) 2017/745 in Europe, or the Food and Drug Administration (FDA) in the USA. Compliance is also required for hardware or software developed or modified in-house for investigational purposes, custom treatment, or hospital-specific procedures. This entails a significant workload for hospitals. For investigational MDs this includes documentation of, among others, device description, design controls, manufacturing procedures, risk analyses, and evaluations of device safety and effectiveness. This work describes our efforts from a regulatory perspective in the context of in-house development and evaluation of a novel 3D-printed brachytherapy (BT) applicator.
Materials and Methods: Figure 1 shows an overview of the implemented regulatory workflow. The patient-tailored ARCHITECT applicator contains optimised needle channels and is intended for locally advanced cervical cancer (LACC) patients. To establish a programme of design requirements, a process tree was constructed (IEC 62366-1:2015), and function and risk analyses (ISO 14971:2019) were performed with stakeholders. Several design iterations were created, 3D-printed, and evaluated by users in a phantom. A manufacturer was selected based on their QMS certification (ISO 13485:2016) and experience with selective laser sintering of PA-12. For this material, a biological evaluation plan (ISO 10993-1:2020) was created to demonstrate biocompatibility. Several pre-clinical evaluations were performed: (1) dose attenuation (TG-43:2004), (2) applicator channel temperature during steam sterilisation at 134°C and 3.04 bar, (3) virtual dose planning for 22 patients previously treated with a clinically used commercial applicator, and (4) needle deflection with varying insertion angles in a phantom.
Results: The final concept embodiment design of the ARCHITECT applicator consists of two 3D-printed halves connecting to a commercially available tandem. Evaluations showed that: (1) PA-12 had a water-equivalent response with dose attenuation differences $<1\%$ between dose depth curves for PA-12 and water, (2) in-channel temperatures of 134°C were maintained for the required 3 minutes, (3) virtual dose planning for all patients resulted in clinically acceptable plans that had similar or improved dose conformity in comparison with the clinically used configuration, and (4) maximum deviations from straight line needle paths amounted to 0.7-4.7 mm at 40 mm depth, depending on the insertion angle.
Conclusions: Regulatory aspects associated with the introduction of novel brachytherapy devices to the clinic have only been scarcely documented. In this work we provide a case example for the ARCHITECT applicator. A series of pre-clinical validations were performed to demonstrate safety and performance of the device. Researchers are encouraged to document similar tests and share best practices to provide guidance for the development of novel brachytherapy devices.

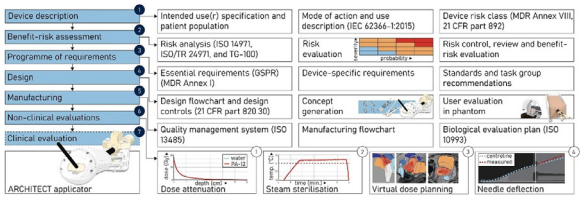

Figure 1. Schematic showing major steps in the regulatory workflow for the ARCHITECT applicator up to clinical evaluation.

GPP05 Presentation Time: 11:06 AM

Visualize the Target, Adjust Your Crosshairs: EM-Tracked MR-US Live Fusion and Needle Location in Gyn Brachytherapy

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Purpose: The disease control and toxicity benefits of adding interstitial needles to cervix intracavitary implants are well established, as are the advantages of MRI for tumor visualization. Yet widespread adoption of these advanced techniques remains elusive, limited by access to frequent MR imaging and the technical challenges of precisely placing needles into the tumor. Ultrasound (US) remains the most accessible form of live imaging but the poorer image quality limits clear visualization of the tumor area and the inserted interstitial needles. We describe a novel system which combines a freehand, stepper-less transrectal ultrasound probe with an electro-magnetic (EM) tracker to continuously fuse a pre-acquired MR, offering a reconstructed MR image to the corresponding live ultrasound image. Inserted needles can be easily visualized using an EM tracked stylet/mandrin, placing a solid circle on the live ultrasound image where the needle is located.
Materials and Methods: The clinical ultrasound system, the BK Spekto with a biplanar side-fire 9048 US probe, was instrumented with a Northern Digital Inc. EM tracker, part of the 3D Guidance Trakstar system. Software was developed using the 3D Slicer toolkit to enable live and continuous fusion of a pre-acquired MR. Contours generated on the MR can be imported and displayed on the live US image. An additional EM tracker can be placed inside a needle to visualize its location on the live US image and removed for treatment.