Application of a novel addressable-array X-ray source to medical imaging of extremities

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INTRODUCTION

Field emission and emitter arrays have been subject of intensive study towards application in a variety of devices including microwave and X-ray sources. The requirements on emitter performance for their use as X-ray source in a medical device are challenging in terms of emission current, stability, uniformity, lifetime, and reproducibility. Compared to typical field-emission applications such as electron microscope guns and field-emitter displays, the current demand from emitters in medical devices are orders of magnitude higher, while the lifetime requirements are lower thanks to the intermittent demand on radiology sources, allowing for a different approach. Recent developments in field emitter technology have enabled progress in digital tomosynthesis giving opportunities for lightweight 3D imaging devices [1].

DESCRIPTION OF THE MEDICAL DEVICE

The electron source at the core of the X-ray generation comprises 45 silicon field emitters microfabricated in an array, as shown in figure 1. In the previous version of the electron source, the emitter arrays were typically fabricated on a 4-inch silicon wafer using a wet-etch process and hence exhibited an anisotropic geometry characteristic of the silicon crystal planes. The emitters were highly non-uniform, resulting in non-uniform performance across the array [2-4]. Reactive-ion etching was lately implemented, resulting in a highly improved uniformity in the emitter shape and their improved performance, with a noticeable enhancement of electron current, and therefore X-ray flux, distributed across the array.

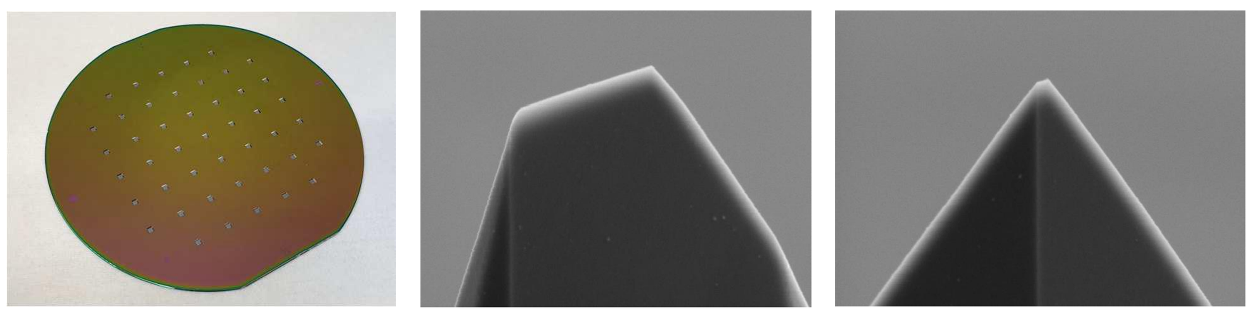

Figure 1: Optical image of a standard field emitters array, the device uses a full wafer (left). Emitters showing strong anisotropic geometry causing non-uniformity after wet-etching (center, right).

Each field emitter operates as a single electron source that generates an X-ray beam from a thin transmission target. The 45 individual projections at different angles, as indicated in figure 2, are acquired in sequence and then converted to a 3D rendering by a meshless reconstruction algorithm for digital tomosynthesis [5].

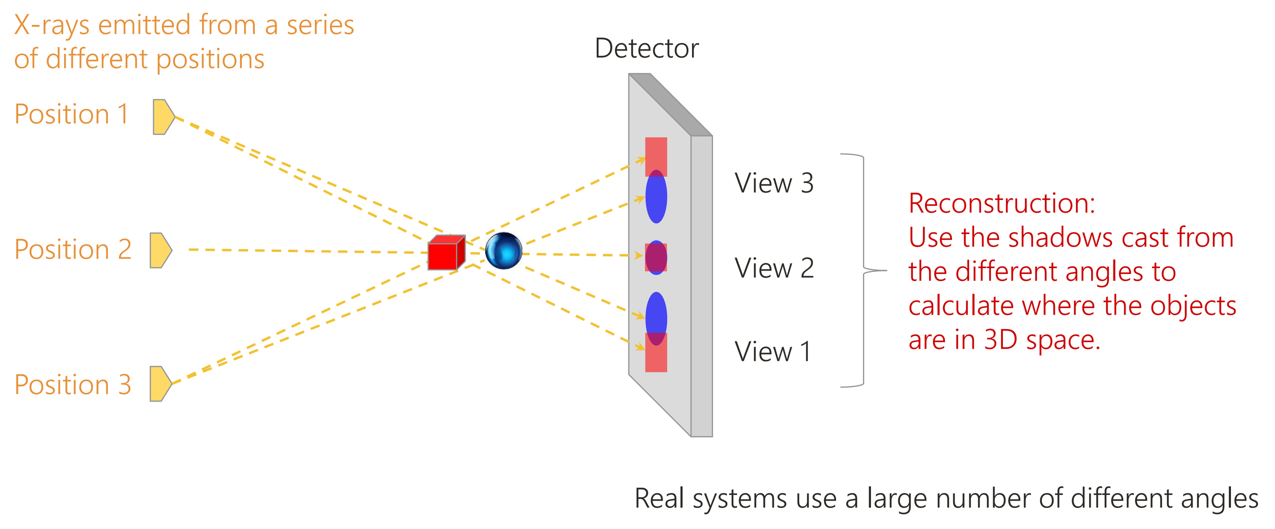

Figure 2: Digital tomosynthesis enables separation of overlapping planes in a 3D object, using X-ray sources in multiple positions, and reconstruction into a 3D image.

A CAD rendering of the miniaturized flat panel X-ray source (FPS) is shown in figure 3. The field emitter array is integrated in an ultra-high vacuum enclosure working in diode configuration and operating at 60 kV for orthopaedic imaging of extremities. The X-ray sources can be individually addressed by electromagnetic switching, enabling the acquisition of data sets for digital tomosynthesis.

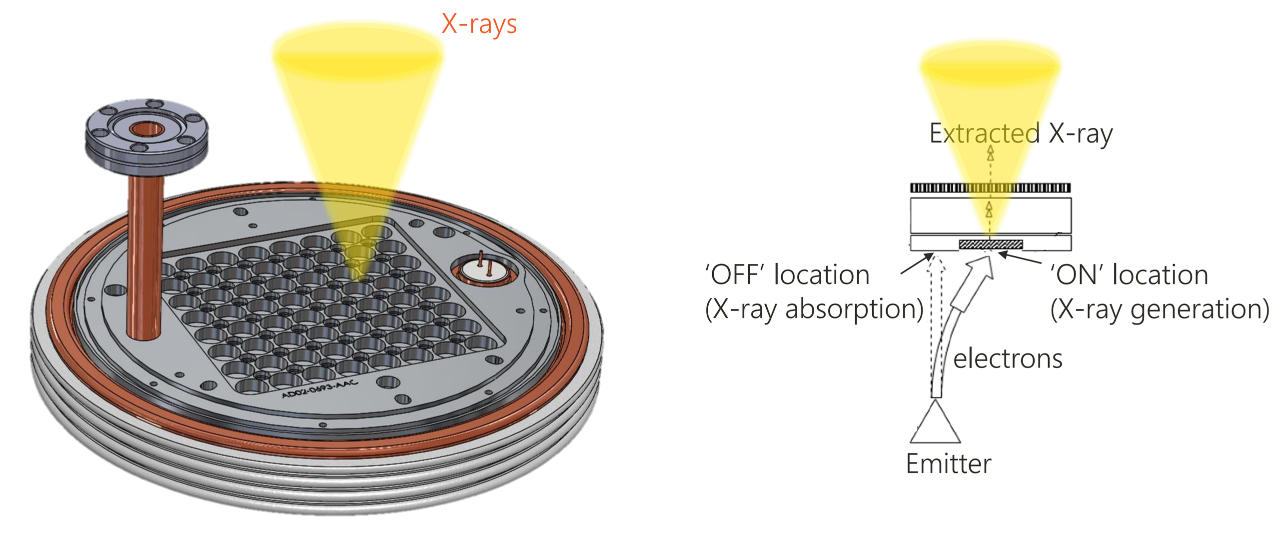

Figure 3: CAD rendering of the FPS (left) and schematic of emitter switching (right).

A picture of the medical device designed for imaging of the limbs is shown in figure 4. The FPS is integrated at the top of the device while a detector sits opposite it, at a source detector distance of about 20 cm. The image acquisition lasts around 7 s, but the total dose is comparable to a conventional 2D Xray system.

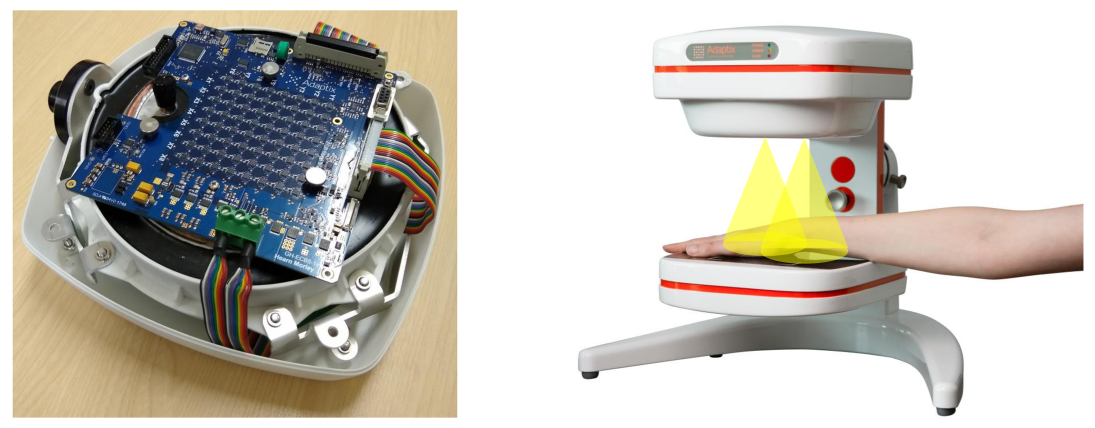

Figure 4: Pictures of the full FPS assembly (left) and a prototype of the Adaptix orthopaedic medical device for imaging of extremities (right).

MEDICAL IMAGING

The quality of the X-ray images acquired by the Adaptix portable medical device for 3D-radiographic diagnostic imaging of human extremity has been proven by a cadaver study conducted at the University of Leeds, Division of Anatomy. Examples of cases from this study, i.e. imaging of wrist, toes and ankle, are discussed and a selection of slices from the Adaptix 3D digital tomosynthesis reconstructions are demonstrated in figures 5, 6 and 7.

Figure 5: Conventional 2D X-ray image of a hand (left) and reconstructed digital tomosynthesis planes through the 3D volume (right). In the 2D image the carpal bones and joints are clearly overlapping, limiting the diagnostic capability of the 2D X-ray imaging. This requires additional 2D views, or if diagnostic uncertainty persists, referral for a follow-up computed tomography or magnetic resonance imaging scan is indicated to obtain additional diagnostic information.

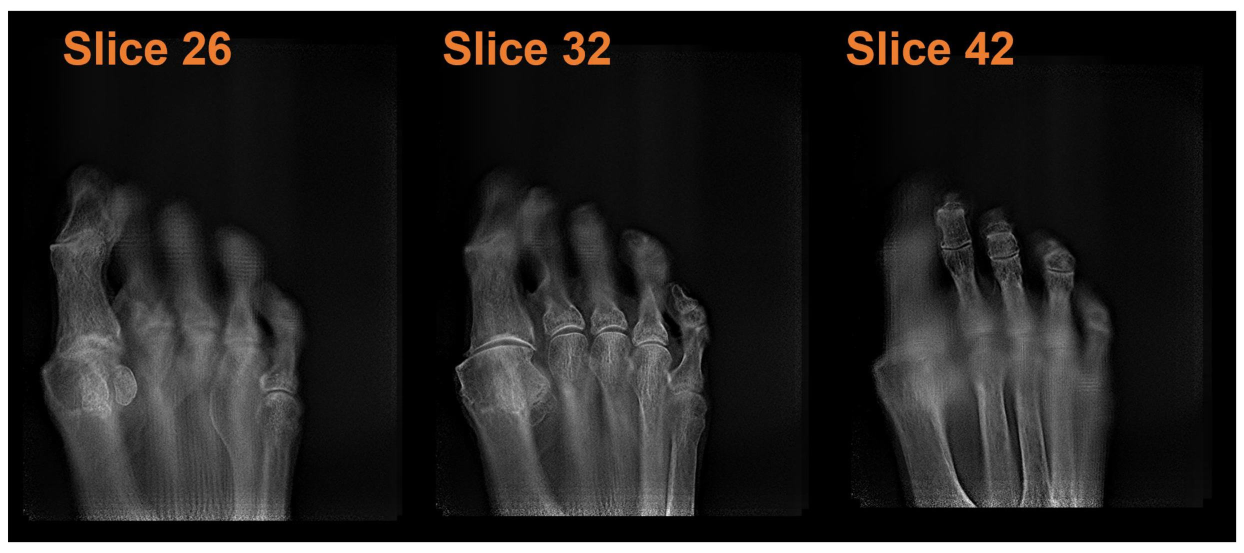

Figure 6: Selection of slices from 3D rendering of an Adaptix digital tomosynthesis reconstruction for toes. The detailed features of the distal metatarsals and phalanges, bones and joints, come into focus at different depths, corresponding to different slices in the rendering, enabling diagnosis in situations for which 2D imaging is of limited diagnostic capability, i.e. fractures at the phalanges and metatarsal joints.

Figure 7: 2D radiography of an ankle is shown alongside two slices from the 3D rendering of an Adaptix digital tomosynthesis reconstruction of a dataset taken on the same ankle. In the 2D image the tarsal bones and joints are overlapping, while their images are decoupled in the digital tomosynthesis slices, enabling diagnosis.

Diagnostic capability is improved by the depth information of digital tomosynthesis reconstructions in the cases for which overlapping bony structures otherwise limit the diagnosis from conventional 2D images. Adaptix received 510(k) clearance from the U.S Food and Drug Administration January 2023 for its first medical device for diagnostic imaging of limbs using digital tomosynthesis.

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