VICTRE 1.0+: Improved Tools for In Silico Imaging Clinical Trials in Breast Imaging

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Introduction

- Expensive and lengthy imaging clinical trials delay the regulatory evaluation of innovative technologies, affecting early access to high-quality imaging systems.
- Recently, the VICTRE project (Virtual Imaging Clinical Trial for Regulatory Evaluation) replicated a previously conducted breast imaging clinical trial using computational models [1].
- The question VICTRE addressed was whether in silico imaging trials can play a significant role in the regulatory evaluation of medical imaging systems.
- The VICTRE components allow for the simulation of realistic breast models and their corresponding projection images acquired with Digital Mammography (DM) and Digital Breast Tomosynthesis (DBT).
- In this work, we describe the latest advances in VICTRE tools including:
  1. Lesion growing
  2. Breast density distribution
  3. Automatic pipeline for breast imaging simulation

Density distribution

- VICTRE 1.0 used four breast densities ranging from dense to fatty, and each density corresponded to a particular breast shape. In the real world, however, the density range is more continuous and breast shaped varies.
- In VICTRE 1.0+, we have modified the earlier code to now include a continuous range of breast densities.
- We can now also model a variety of random shapes and sizes.

Figure 1. Examples of breasts generated with the updated code with glandular densities ranging from high to low (L to R).

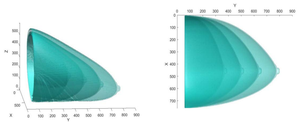

Figure 2. Sample breast shapes obtainable with the updated breast generation code.

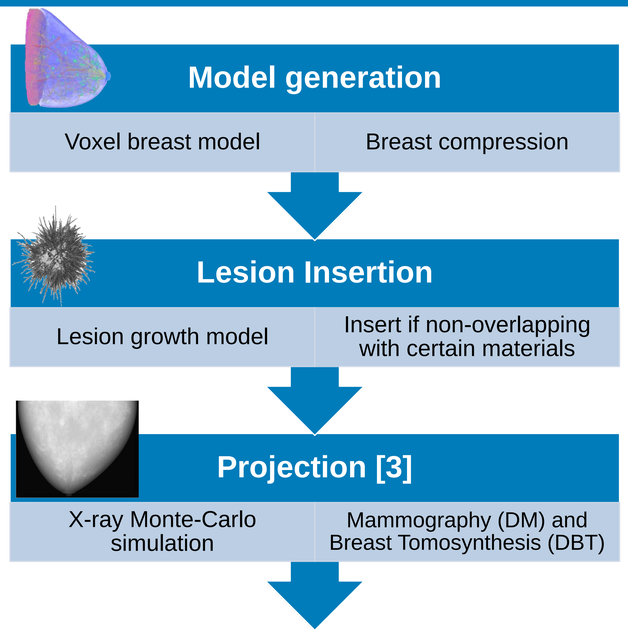

Figure 5. Outline of the VICTRE 1.0+ pipeline with the six steps included in the new Python class.

Lesion growth

- One addition to the VICTRE toolbox is a lesion growth model, inspired by Turing's reaction-diffusion equations, for replicating tumor progression [2].
- The model inhibits tumor growth when it encounters stiff ligaments and promotes proliferation in the more elastic fatty and glandular regions of the breast.

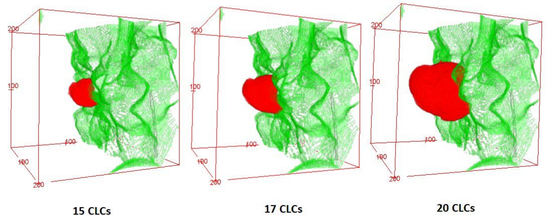

Figure 3. Illustration of the stages of growth for a lesion grown in situ. The lesion and ligaments are represented in red and green, respectively. The simulation time scale for tumor growth is recorded in cell life cycles (CLCs).

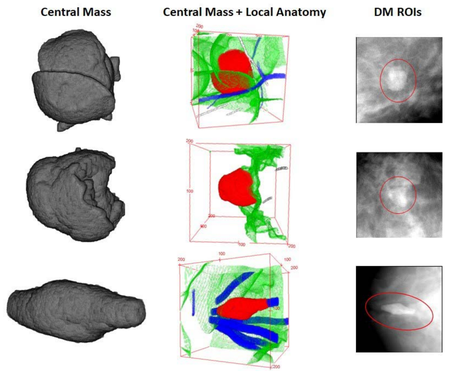

Figure 4. By varying the local environments, a range of lesion morphology has been realized unique to local anatomy (columns 1 and 2). Lesion, ligaments and ducts are indicated in red, green, and blue, respectively. The third column are Digital Mammography ROIs containing the lesions in the first column.

Automatic pipeline

- Finally, all pipeline components were integrated in a Python class that allows for:
  1. Model generation
  2. Lesion insertion
  3. Projection (Digital Mammography and Digital Breast Tomosynthesis)
  4. DBT reconstruction
  5. Region of Interest (ROI) extraction
  6. Reader model
- This pipeline was also parallelized on the CDRH's Betsy HPC cluster.
- The parallelization of the automatic pipeline allowed us to speed up the imaging process up to 33 times compared with a sequential execution: we were able to generate up to 11907 virtual patient's images in 127 hours (averaging 0.64 minutes/patient)

Conclusion

- The new tools described in this work will allow for more efficient and realistic models in imaging trial pipelines. They are available as open source [4], [5]
- Higher efficiency will lead to more utilization of the tools to explore various questions relevant to the regulatory evaluation of novel technology and new technological iterations of marketed products (e.g., reconstruction algorithms and acquisition geometry in digital breast tomosynthesis).

References

[1] Badano et al. 2018, JAMA
[2] Sengupta et al. 2021, Proc. SPIE Med. Imag.
[3] Badal et al. 2020, Comput. Phys. Commun.
[4] https://github.com/DIDSR/VICTRE
[5] https://github.com/DIDSR/VICTRE_PIPELINE

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