BUILDING AN ASSURANCE CASE FOR AORTA GEOMETRY RECONSTRUCTION SOFTWARE

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BY

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Medical image processing software is another domain that requires a

Abstract

used to build safe

of

Assurance cases have been ~~proven to be effective developing a~~ real-time system software. ~~Another domain that requires the~~ high standard correctness, completeness, and consistency ~~is medical software~~. Therefore, we have investigated adopting real-time assurance cases techniques to medical image processing software.

Throughout the development of the Aorta Geometry Reconstruction software, we implicitly listed the evidences that are essential to build our confidence in the software for assurance cases, build the artifact and the evidences simultaneously.

Finally, we present this software with the list of the evidences built for assurance cases, to show that the assurance cases can apply well on the medical software

Add a sentence to introduce AGR.

Be specific about your evidence

Your Dedication

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Acknowledgements

I would like to thank all the people who contributed in some way to the work described in this thesis.

First and foremost, I would like to express my sincere thanks and gratitude to my supervisor Dr. Spencer Smith for his motivation, patience, and the continuous support of my master's studies and research. His guidance helped me in all the time of research and writing of this thesis.

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Notation, Definitions, and Abbreviations

Definitions

Aorta The aorta is the largest artery of the body and carries blood from the heart to the circulatory system. It has five ~~several~~ sections: aortic root, ascending aorta, aortic arch, descending aorta and abdominal aorta. the aortic root is the transition point where blood first exits the heart. It functions as the water main of the body, the aortic arch, is the curved segment that gives the aorta its cane-like shape. It bridges the ascending and descending aorta. Throughout this ~~the~~ documentation, aorta means ~~would only include~~ ascending aorta, aortic arch and descending aorta. The Abdominal aorta and aortic root are ~~is~~ outside of the scope of the current work.

Ascending Aorta

The ascending aorta is the first part of the aorta, which is the largest blood vessel in the body. It comes out of the ~~your~~ heart and pumps blood through the aortic arch and into the descending aorta.

I found this exact text online. (Cleveland Clinic) This is a serious academic integrity issue. You cannot use someone else's words (except in a direct quote). Make sure there are no spots in the report that are copied from someone else!!!

Descending Aorta

If you write common knowledge like this in your own words that is fine, although it is never a bad idea to include a citation.

The descending aorta is the longest part of your aorta ~~(the largest artery in your body)~~. It begins after ~~your~~ the left subclavian artery branches from your aortic arch, and it extends ~~down~~ into ~~your~~ the belly. ~~The descending aorta runs from your chest (thoracic aorta) to your abdominal area (abdominal aorta)~~.

Organ Segmentation

The definition of the organ boundary or organ segmentation is helpful for the orientation and identification of the regions of interest inside the organ during the diagnostic or treatment procedure. Further, it allows the volume estimation of the organ, such as the aorta.

DICOM Digital Imaging and Communications in Medicine (DICOM) is the standard for the communication and management of medical imaging information and related data.

Inferior Inferior is the direction away from the head; Inferior means the lower parts of the body (e.g., the foot is part of the inferior extremity).

Superior Superior is the direction toward the head end of the body; superior means the upper parts of the body (e.g., the hand is part of the superior extremity).

Slice Slice is a A 2-dimensional image that is retrieved from a 3-dimensional volume.

Binary Dilation

Binary dilation is a mathematical morphology operation that uses a structuring element (kernel) for expanding the shapes in an image.

Label Map A labeled map or a label image is an image that labels each pixel of a source image.

Euclidean Distance Transform

The ~~e~~Euclidean distance transform is the map labeling each pixel of the image with the distance to the nearest obstacle pixel (black pixel for this project).

Contour Line A contour line (also isoline, isopleth, or isarithm) of a function of two variables is a curve along which the function has a constant value so that the curve joins points of equal value.

Level Sets Level Sets are an important category of modern image segmentation techniques based on partial differential equations (PDE), i.e. progressive evaluation of the differences among neighboring pixels to find object boundaries. The Figure ~~pictures~~ 2.4 demonstrate an example of how Level Sets method work on finding the region of the heart. It starts with a seed contour that is within the region of interest, then by finding the gradient based on the contour line, the segmentation result will propagate towards outside of the region until the maximum difference between the neighboring pixels are reached.

Is this your own words?

Segmented slice

A 2-dimensional image with the relevant ~~interested~~ pixels labeled as 1 and other pixels as 0.

Kernel Size The size of the kernel for binary dilation.

Stop Limit This limit is used to stop the segmentation algorithm. It is used differently in segmentation in the inferior and superior directions ~~and segmentation in superior direction~~.

Threshold Coefficient

This coefficient is used to compute the lower and upper threshold passing through the segmentation filter SITK's ThresholdSegmentationLevelSetImageFilter. The algorithm first uses SITK's LabelStatisticsImageFilter to get the mean and the standard deviation of the intensity values of the pixels that are labeled as the white pixel. Larger values with this coefficient imply a larger range of thresholds when performing the segmentation, which leads to a larger segmented region.

RMS Error Value of RMS change below which the filter should stop. This is a convergence criterion.

Maximum Iteration Maximum

Number of iterations to run

Curvature Scaling

Weight of the curvature contribution to the speed term.

Propagation Scaling

Weight of the propagation contribution to the speed term.

Abbreviations

AC Assurance Case

AGR AortaGeomRecon

AortaGeomRecon

3D Slicer's extension module, Aorta Geometry Reconstruction

CT computerized tomography

DD Design Document

DICOM Digital Imaging and Communications in Medicine

GUI Graphical User Interface

MG Module Guide

NFR Non-Functional Requirement

FR Requirement

Functional

SITK SimpleITK

SRS Software Requirements Specification

UI User Interface

VTK The Visualization Toolkit

Declaration of Academic Achievement

The student will declare his/her research contribution and, as appropriate, those of colleagues or other contributors to the contents of the thesis.

You should complete this

Chapter 1

Introduction

Medical Software is a critical component of patient diagnosis and treatment. Medical software refers to computer programs, applications, or systems specifically designed for use within the healthcare and medical field. These software solutions are developed to assist healthcare professionals, researchers, administrators, and patients in various aspects of medical care, research, management, and education [22]. Our project focuses on medical software that could potentially influence a patients' well-being, particularly software that contributes to diagnosing issues related to the aorta. The aorta, a vital artery responsible for transporting blood from the heart to other bodily organs, holds immense significance. Any malfunction in its blood-carrying function could yield severe and potentially life-threatening consequences for the entire body's physiology. Specifically, we focus on the Aorta Geometry Reconstruction (AortaGeomRecon or AGR) software, which can build a 3-dimensional model of the aorta, to help the health professional disagnosing issues related to the aorta quickly and correctly.

Given the importance of medical software like AGR, we need a means to build confidence in the software. In this report, we explore the use of assurance cases. An assurance case can be thought of as a structured argument. The main purpose of an assurance case is to establish confidence and trust in the reliability and safety of a system by presenting a well-structured argument supported by evidence [23]. Assurance cases have been applied regularly in the medical device for approval in U.S. In Europe, the assurance cases are required in systems as diverse as flight control systems, nuclear reactor shutdown systems, and railroad signaling systems, which are all critical systems [23]. Previous work [20] investigating ~~building~~ assurance cases for scientific computing software such as 3dfim+, a medical imaging software analysing activity in the brain, has demonstrated the value of the technique in ~~a great success in~~ showing the software's correctness and reliability. The motivation of our project is to build on this previous work to more deeply investigate the necessary evidence. Specifically we build an ~~an~~ assurance case for AGR by adding more details on the evidence needed to support our correctness claim~~s~~, thus building our confidence in AGR.

In this chapter, we first explain in details the contexts for the key concepts that will be discussed throughout the document, including what is organ segmentation, what is the aorta, listing the diseases that aorta segmentation could detect, and demonstrating an example of an assurance case by showing a simple example ~~diagram of assurance case~~. Next, we will briefly discuss the methodology, especially how we achieve the objective of design, implementation of the software, and building confidence with the evidences in an assurance case~~s~~. In the final section, we explain our report ~~thesis~~ outline ~~covering the entire report.~~

1.1 Background

In this section, we present the contexts of the key concepts within the scope of our work, including background information on the aorta (section 1.1.1), organ segmentation (section 1.1.2), and assurance cases (section 1.1.3).

1.1.1 Aorta

The aorta is the largest artery in the body. It carries blood from the heart to the circulatory system. It has a cane-liked shape made up of the ascending aorta, aortic arch and descending aorta. Figure 1.1 shows the entire aorta, but the abdominal aorta is outside the scope of the current work. Our work focus on building the 3D geometry from the aortic root to descending aorta.

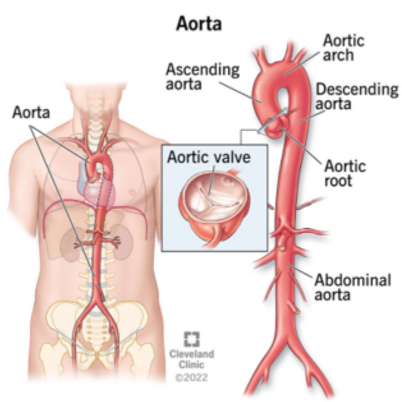

Figure 1.1: Aorta [17]

1.1.2 Organ Segmentation

The definition of the organ boundary or organ segmentation is helpful for the orientation and identification of the regions of interest inside the organ during ~~the~~ diagnostic or treatment procedure. Further, it allows the volume estimation of the organ, such as the aorta. A segmentation takes a medical image as input and outputs the portion of the image that corresponds to the organ of interest. Figure 1.2 demonstrates an example of abdominal organ segmentation.

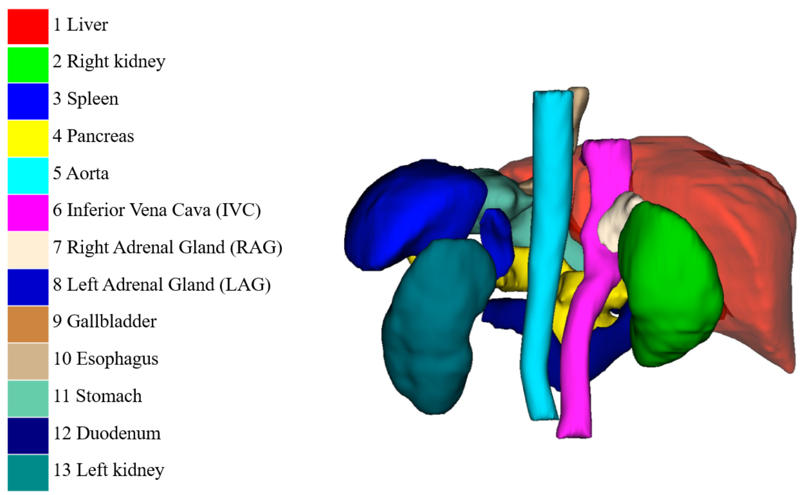

Figure 1.2: Organ Segmentation [16]

diagnosing and treating

Aorta segmentation in CT (computerized tomography) scans is important for:

- Coarctation of the aorta (narrowing of aorta)
- Aortic Aneurysm (bulge in the aorta)
- Aortic calcification quantification
- To guide the segmentation of other central vessels.

1.1.3 Assurance Case

An Assurance Case (AC) can be thought of as a structured argument. When building an AC, you're making a point that specific evidence backs up a particular statement.

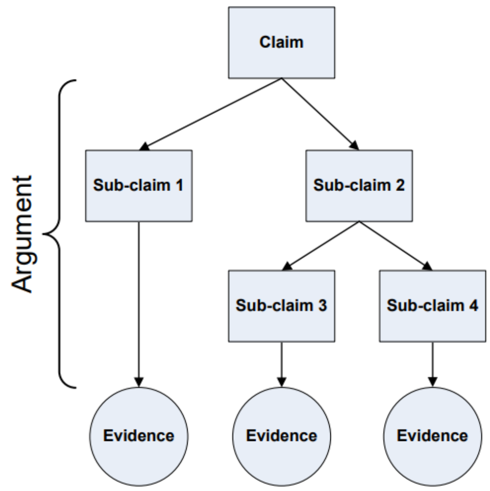

Figure 1.3: Simple Assurance Case Diagram [4]

The fundamental structure is depicted in Figure 1.3. An AC essentially boils down to an organized collection of arguments, backed by a body of evidence, that helps validate the belief in a specific claim [4].

In a practical sense, creating an AC involves beginning with a main claim and then breaking it down into smaller claims through a step-by-step process. These smaller claims, at the most bottom, are supported by concrete evidence.

1.2 Methodology

In this study, we present the outcomes of integrating AC throughout the development of medical software to reinforce the stakeholders' confidence in the software's capabilities. The software, known as AortaGeomRecon (AGR), represents a 3D Slicer [11] extension module designed to semi-automatically construct a 3D model of the aorta using CT scans from a patient's chest. We started by gathering requirements for the AGR from a domain expert, drafted our requirements, and high-level design.

We researched and worked on the implementation of the software, while building the infrastructure for continuous integration, version control, and project managment using GitHub. When we have a functional prototype, we delved into our assurance cases, encompassing chosen arguments and supporting evidence. AC functions as a method to provide assurance for a system by presenting arguments that substantiate s claims about the system. These arguments are based on evidence related to the system's design, development, and tested behavior. By constructing the AC, we were able to follow the best practice including documentation review on the requirements and high-level design. Our goal was to finalize our documentation, and ensure the documentation's completeness and correctness. We have built user documentation to define all operational assumptions, and guide the user to use the valid inputs with a sequence of correct operations. Finally, our assurance case evidence consists of continuous integration tests, code review, and several algorithm reviews ~~reinforced~~. This increased our confidence that ~~in~~ the implementation of the software, ~~which~~ has strickly complied with the requirements ~~that are~~ and is complete and correct.

1.3 Thesis Outline

The thesis is organized into three broad parts. In Chapter 2, we introduce our program AortaGeomRecon by mentioning the existing methods, the AGR's algorithm overview and step-by-step workflow. We explain necessary terms and information to understand how the software functions. We also introduce the 3D Slicer [11] extension module that the user interacts with to get the segmentation result with our algorithm. In Chapter 3, we present our AC, ~~and~~ focusing on the evidence and including some sections of our requirements, high-level design, detailed design, a Algorithm c Review, and a test case we developed for verifying and validating the correctness of AGR. In Chapter 4, future work is proposed and conclusions are drawn based on the developed requirements, segmentation algorithm, 3D Slicer module extension, and AC.