

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 [18]. Our project focuses on medical software that ^{could potentially} ~~wields a direct and crucial~~ influence on patients' well-being, particularly software that contributes to diagnosing issues related to the aorta. The aorta, a vital ^{artery} ~~organ~~ 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} ~~Our objective centers around~~ the Aorta Geometry Reconstruction (AortaGeomRecon or AGR) software, which can build ^a ~~the~~ 3-dimensional model of the aorta, to help the health professional diagnosing issues related to the aorta quickly and correctly.

Given the importance of medical software like AortaGeomRecon, we need a means

I'm okay with "out" instead of "my".
I've changed my mind on "are" vs "I" you.
I changed it in my head to "I" and "my" in your text and it just doesn't sound right.

I'm not sure the aorta is an organ

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 ~~specific type of argumentation used~~ ^{structured argument} ~~in various cases~~. 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 [19]. 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 [19]. Previous works [17] building assurance cases for scientific computing software such as 3dfim+, a medical imaging software analysing activity in the brain, has demonstrated a great success in showing the software's correctness and reliability. The motivation of our project is to build an assurance case for AortaGeomRecon by adding more details on the evidence needed to support our claim, thus building our confidence in AortaGeomRecon.

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 aorta, listing the diseases that aorta segmentation could detect, and ~~demonstrates~~ ^{demonstrating} an example of assurance case by showing a simple diagram of assurance case. Next, we will briefly discuss ~~on~~ the methodology, especially how we achieved the objective of design, implementation of the software, and building confidence with the evidences in assurance cases. In the final section, we ~~will~~ explain our thesis outline covering the entire report.

↪ For something that is true
but now, use the present
tense

1.1 Background

In this section, we present ^{the} ~~some~~ ^{of} contexts ~~on~~ the key concepts within the scope of our work, ^{including the aorta, organ segmentation and assurance cases.}

1.1.1 Aorta

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

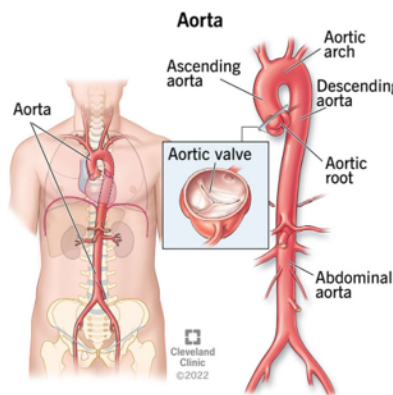


Figure 1.1: Aorta

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

↑ You didn't draw this, so you should provide a citation to the original source. The citation can be in the caption

A segmentation takes a medical image as input and outputs the portion of the image that corresponds to the organ of interest!

as the aorta. Figure 1.2 demonstrates an example of abdominal organ segmentation.

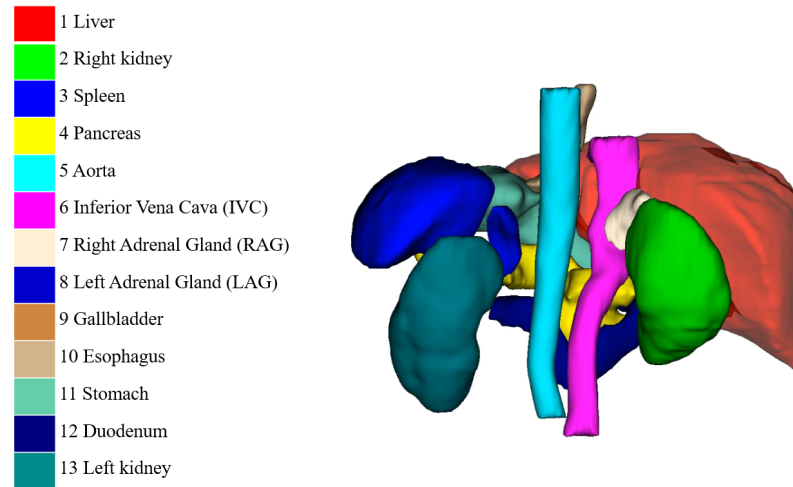


Figure 1.2: Organ Segmentation [15]

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

- Coarctation of the aorta
- Aortic Aneurysm
- 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 ~~specific type of argument used in various cases~~ ^{structured argument}. When building an AC, you're making a point that specific evidence backs up a particular statement. The fundamental structure is depicted in Figure

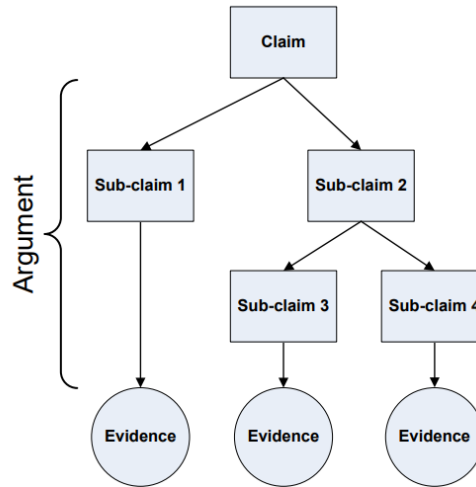


Figure 1.3: Simple Assurance Case Diagram [4]

1.3. ^{So} 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 stakeholders' confidence in the software's capabilities. The software, known as AortaGeomRecon, represents a 3D Slicer [10] 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 AortaGeomRecon from a domain expert, drafted our Software Requirements Specification (SRS), and Module Guide (MG). We researched and worked on the implementation of the

software, while building the infrastructure for continuous integration, version control, and project management 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 claims about the system. These arguments are based on evidence related to the system's design, development, and tested behavior. By constructing AC, we were able to follow the best practice including documentation review on SRS and MG to finalize our documentation, ensure the documentation's completeness and correctness. We have built a user documentation to define all operational assumptions, and guide user to use the valid inputs with a sequence of correct operations. Finally, our continuous integration tests, code review, and several algorithm reviews reinforced our confidence in the implementation of the software, which has strictly complying with the requirements that are 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 AortaGeomRecon's algorithm overview and step by step workflow. We explain necessary terms and information to understand how the software functions, and the 3D Slicer [10] 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, including some sections of our SRS, Design Documents, Module Guide, Algorithm Review, and a test case we developed for verifying and validating the correctness of program AortaGeomRecon. In Chapter 4, future work is proposed and conclusions are drawn

I took out SRS etc. because you haven't yet defined the ac bynoms

based on the developed ^{requirements}~~SRS~~, segmentation algorithm, 3D Slicer module extension, and AC.