Lesion Lens

CS 491 Senior Design Project

Specification Report

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1. Introduction

1.1. Description

The neurology department at Hacettepe Hospital (HH) is under significant strain, with too few doctors, too many patients, and not enough hours in the day to meet the growing demand for healthcare. Lesion Lens (LL) aims to save time and reduce the workload on doctors at HH by automating the lesion detection and tracking process on brain and spine MRIs.

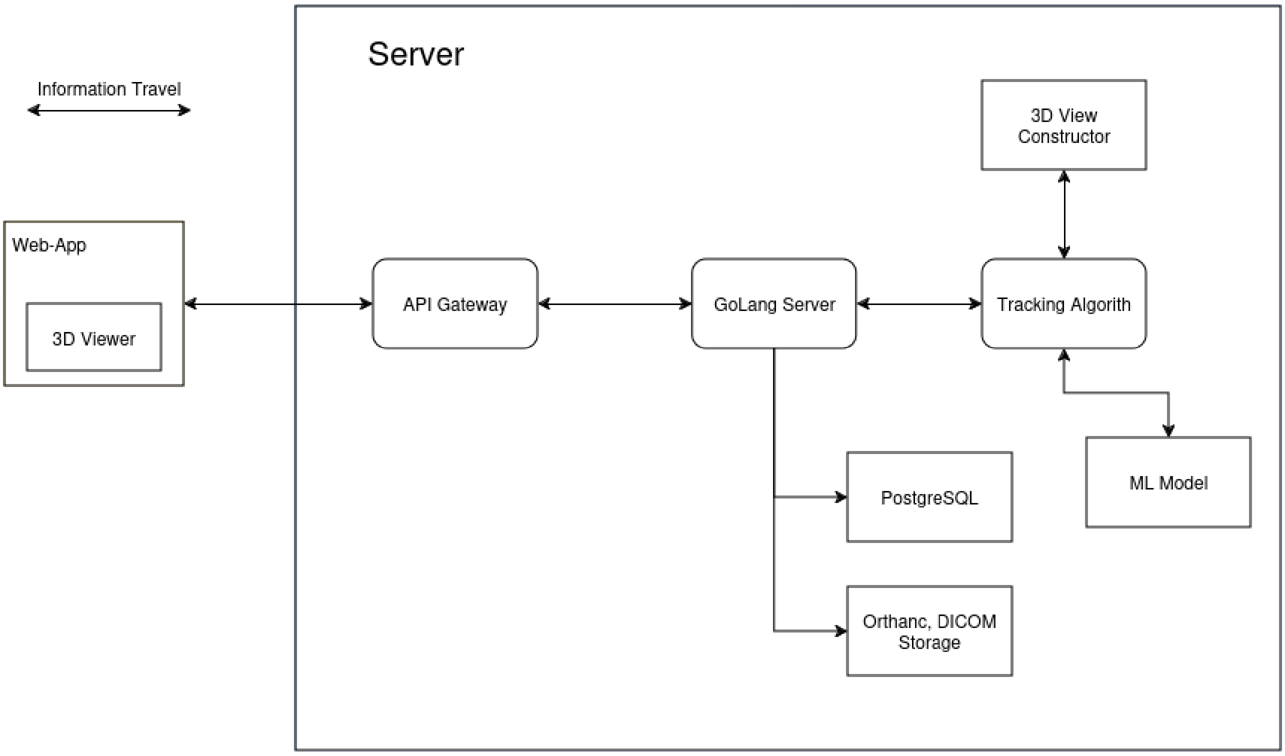
When assessing a patient with lesions, neurologists at HH look for:

- how many lesions have developed
- what type of lesions there are
- how previous lesions have progressed

Currently, doctors scroll through past and present MRIs to find differences and developments in a tediously cumbersome process. Additionally, they use their specialised knowledge to evaluate the type of lesion using information such as location, size, shape, and more. This method is manageable with small quantities of lesions, however, more severe cases tend to be difficult to evaluate accurately and quickly.

Lesion Lens will be a web-application that analyses the progression of lesions using a patient's MRI history. LL will use a machine learning (ML) model to find areas of the brain and spine with lesions and use a sophisticated algorithm to track the differences/progressions of the lesions through time. Using information gathered from the tracking algorithm and ML model, LL will construct a 3D volumetric view of the lesions to help doctors apply their specialist knowledge.

1.2. High Level System Architecture & Components of Proposed Solution



1.3. Constraints

1.3.1. Implementation Constraints

- Use JIRA to track work of team members
- Pydicom will be used to read, process, and write MRI scan data in DICOM format.
- TensorFlow or PyTorch will be used for machine learning model development.
- Three.js will enable interactive 3D visualisation of lesions on reconstructed MRI data.
- Backend development will use GoLang to handle model inferences and API integration.
- A web-based user interface will be built using React.js for scan uploads and result visualisation.
- AWS S3 will be utilised as the primary storage system for MRI scan data, lesion analysis results, and model outputs.

- Google Colab will be used for model training and testing due to its free GPU and TPU support.
- Orthic will be used to store DICOM files.

1.3.2. Economic Constraints

- Open-source libraries like Pydicom, TensorFlow, and Flask will not cost anything.
- Publicly available datasets (e.g., MICCAI) will be used for training and testing.
- Training the lesion detection model using high-performance GPU, especially during development and deployment, will be the biggest cost for us.
- Storage costs for large-scale MRI datasets for deployment will also be a significant cost.
- Purchasing a domain for the web-app will be costly (we will initially consider locally restricted web-app due to safety and privacy concerns).

1.3.3. Ethical Constraints

- Patient data in DICOM files must be anonymized to protect sensitive information.
- The machine learning model will be evaluated to ensure fairness and eliminate biases in lesion detection accuracy across diverse populations.
- During production, users will be informed of data usage, and explicit consent will be obtained for any data processing or storage.
- Final decisions on lesion detection will always involve a medical professional to avoid over-reliance on automated systems.

1.3.4. Privacy and Security Constraints

- All uploaded MRI scans and patient data will be encrypted during transmission and storage.
- Implement role-based access control (RBAC) to restrict system usage to authorised personnel.

- Logs will be maintained of all data access and modifications for accountability and compliance.
- Users will be provided with the ability to request data deletion to comply with necessary legal requirements.

1.3.5. Maintainability Constraints

- While the first stage is restricted to HH, the system will be developed with expansion to other hospitals kept in mind
- The system will be built with a modular architecture to allow future updates and additions, such as new detection models or visualisation features.
- Users will be able to report issues and bugs.

1.4. Professional and Ethical Issues

- Full transparency will be maintained regarding how sensitive data, such as patient information, is collected, processed, and utilised within the application.
- Users will be informed about the types of data being collected and the purposes of its use, and their consent will be obtained before data collection or usage.
- The application will strictly adhere to the KVKK and GDPR guidelines to protect user and patient data, ensuring that all legal and ethical standards are met.
- The machine learning models will be rigorously monitored during development to ensure fairness and impartiality in lesion detection outcomes.
- The training processes for the machine learning model will be conducted transparently, detailing the steps taken to ensure ethical handling and usage of data.
- Both internal and external testing phases will include diverse datasets and user groups to accommodate a wide range of needs and ensure the inclusivity and reliability of the application.

- All patient data used in training and testing the machine learning model will require approval from the Ethical Board of HH, ensuring compliance with ethical standards.

1.5. Standards

- For modelling our software, UML 2.5.1 will be used.
- ISO/IEC 42001 will be used as a standard for building a responsible AI system.
- OFSEP minimal MRI protocol will be used as a standard for MRI scans.
- IEEE 830 will be used for requirements documentation.
- OPM3 will be used as the standard for project management.
- ISO 13485:2016 will be used to ensure that our medical software meets the customer and regulatory demands for safety and efficacy.
- AES 256 will be used as a standard for encryption of user data.
- Unit testing will be used for quality assurance of the software.

2. Design Requirements

2.1. Actors

- Users (doctors)
- ML Model
- Tracking Algorithm
- Server Admins

2.2. Functional Requirements

- Doctors can upload multiple MRI collections to the system.
- Uploaded MRI data is securely stored in the database for further processing and analysis.
- Doctors can view individual MRI slices (2D images) through the web application.
- ML Model detects and outlines lesion-like objects in brain and spine MRIs.

- ML Model counts the number of lesion-like objects.
- ML Model can differentiate between closely clustered lesions.
- Tracking Algorithm generates 3D mappings of lesion-like objects using multi-angle MRI data.
- The system calculates the area and volume of identified lesions.
- Tracking Algorithm compares current and previous MRI scans to identify potential lesion growth or new developments.
- Doctors can view a 3D reconstruction of lesion-like objects through the web application for enhanced analysis.
- Doctors can share their analysis, including 2D and 3D visuals, with other users.
- Analysis results can be exported for offline use or integration into other tools.
- Admin users can perform basic administrative tasks such as user management, system monitoring, and managing MRI collections.

2.3. Non-Functional Requirements

2.3.1. Usability

Even though our application will run on the web, we have a very specific user base and specific desktops to run on–namely neurology doctors at HH and their designated computers. As such, our web-app should be intuitive and easily adoptable to our users. In order to accomplish our goals are usability requirements are:

- Our web-app must allow multiple users to use the same account simultaneously.
- Our web-app must have an intuitive user interface for the target audience (doctors at HH).
- Any login should take at most 4 steps with valid credentials.
- All functionalities of the app should be accessible and easily visible from the main page.
- All undo/back buttons should be placed on the top left corner of the screen.

- All “exit”, “escape,” or “X” buttons should be placed on the top right of the corresponding window.
- All network requests should be asynchronous and allow users to keep interacting with the frontend.
- All in-progress network requests should be clearly visible.

2.3.2. Reliability

Reliability is the most important requirement, as doctors will be making decisions with our application and we will be managing sensitive personal data. As such,

- Lesion-like detection should have a 94% accuracy for both brain and spine.
- A doctor should never be able to access other patient’s data without authorization.
- User data should never be vulnerable in the database or throughout the transfer of said data into the database.
- All user data must be kept encrypted.
- DICOM or NII data of the user must never contain user information or link back to the user in any way. These files should be only accessible via key and path kept in an encrypted user database.

2.3.3. Performance

While performance and usability are separate requirements, they tie into each other significantly—especially in our case. A doctor at HH spends roughly ~15 minutes analysing a patient's MRI scans. Our web application must demonstrate significantly greater speed or accuracy than a doctor, ensuring it provides a compelling reason for adoption. Therefore our performance requirements are:

- When using the machine learning analysis and tracking feature for lesions, the latency, also known as response time, of the server needs to be less than 120 seconds.

- The 3D model should not lag on modern PCs used at Hacettepe Hospital (HH) and should run at at least 30 fps.
- The load time of an MRI scan into the 3D viewer must be less than 10 seconds.
- Our web-app must allow multiple user accounts to use the ML service simultaneously without a loss in performance.
- Any part of the UI should load in under 5 seconds in internet speeds of 9 b/s and above.

2.3.4. Scalability

Our system must be designed to handle increasing demands in terms of data, users, and computational requirements without compromising performance or reliability. It should adapt seamlessly to growing needs of HH, ensuring continued usability and efficiency over time. The scalability requirements include:

- Efficient storage and retrieval of large MRI datasets, supporting up to 100,000 scans.
- Support for at least 100 concurrent users without noticeable performance degradation.
- Ability to process high-resolution MRI data and larger datasets without impacting ML model accuracy or response time.
- Infrastructure capable of handling peak traffic demands and dynamically scaling resources as needed.
- Easy integration of new technologies, improved ML models, or additional imaging modalities.
- Interoperability with external databases or systems for research or regulatory purposes.

2.3.5. Security & Privacy

Our application relies on sensitive data, such as patient information, to deliver accurate lesion detection and ensure reliable results. This data includes training and testing datasets for the machine learning model, making it critical that we handle such information with utmost care and implement stringent security measures. To balance functionality and privacy, we will adhere to established privacy regulations, including the Kişisel Verilerin Korunması Kanunu (KVKK) and the General Data Protection Regulation (GDPR), while seeking necessary approvals and user consent as required. Therefore, we will implement the following measures to safeguard data and ensure system security:

- All datasets used in training and testing the machine learning model must comply with KVKK and GDPR guidelines. Furthermore, any patient data provided by HH for the training and testing processes of the model must be approved by the Ethical Board of HH.
- All passwords will be securely hashed using the SHA-256 algorithm to prevent unauthorised access.
- Session tokens will be issued using secure protocols and must remain valid for a maximum of 8 hours.
- Refresh tokens will be provided to allow users to regenerate session tokens as needed.

3. Market and Competitive Analysis

3.1. Target Users

Lesion Lens is developed in partnership with Hacettepe Hospital to meet their medical professionals' needs on lesion tracking in brain and spine MRIs. Therefore our target users are neurologists and researchers specialising in neurodegenerative diseases like multiple sclerosis (MS). Our primary users will be healthcare providers in hospitals, clinics and medical faculties who rely on MRI imaging for patient care.

Secondary users include medical students, educators, and researchers in neuroscience, who can use LL for training and analysis. As a versatile tool, LL also appeals to pharmaceutical companies developing treatments for neurological conditions, as it enables precise tracking of lesion progression in clinical trials.

3.2. Market Research

The medical imaging software market, valued at $39.8 billion in 2023, is anticipated to grow at a compound annual growth rate (CAGR) of 4.9% through 2030, driven by technological advancements and the integration of artificial intelligence (AI) [1]. A significant trend within this market is the adoption of AI in medical imaging, which enhances diagnostic accuracy and reduces analysis time. Machine learning models capable of detecting patterns and anomalies in imaging data are becoming indispensable in healthcare delivery. Particularly, the utilization of 3D imaging and volumetric analysis in diagnosing neurological conditions stands out, providing healthcare professionals with enhanced visualization of disease progression [2].

Hospitals and diagnostic imaging centers are the largest adopters of AI-driven medical imaging solutions, motivated by the need for precise diagnostics and operational efficiency. Research institutions also play a crucial role in driving demand, focusing on the development and refinement of AI algorithms tailored for healthcare applications. Emerging technologies in AI-driven lesion analysis tools are revolutionizing neurological diagnostics by offering features such as automated detection, volumetric analysis, and temporal tracking of disease progression. These innovations support the growing demand for personalized medicine, enabling healthcare providers to customize treatment plans based on individual patient data [2].

Lesion Lens positions itself strategically within this dynamic market by leveraging AI and machine learning to deliver an advanced lesion analysis tool. Unlike conventional imaging software, LL emphasizes detailed temporal and volumetric insights, facilitating accurate tracking of lesion progression. The integration of 3D imaging and a user-friendly interface aligns with market trends that prioritize precision, efficiency, and accessibility, ensuring that LL meets the evolving needs of healthcare professionals.

3.3. Competitive Analysis

In the realm of medical imaging software, Lesion Lens faces competition from both general imaging platforms and specialized AI-driven solutions. Direct competitors include OsiriX, Aidoc, and other AI-powered imaging tools. OsiriX is a leading platform for advanced DICOM image analysis, focusing on 3D and 4D imaging but lacks integrated AI for automated lesion detection and progression tracking [3]. Aidoc offers AI-powered radiology tools that identify anomalies across various imaging modalities, including brain imaging, with a particular emphasis on emergency use cases [4].

Indirect competitors encompass open-source software like 3D Slicer and specialized platforms such as Brainlab. 3D Slicer provides advanced visualization and analysis capabilities for medical imaging data, offering some lesion analysis features but lacks tailored AI models for longitudinal studies [5]. Brainlab focuses on neurosurgical planning and visualization, delivering robust imaging tools without specializing in automated lesion progression tracking [6].

Lesion Lens distinguishes itself by combining advanced AI-driven lesion detection with sophisticated tracking algorithms that provide both temporal and volumetric insights. This specialized focus on tracking lesion progression over time fills a significant gap in the market, where most competitors concentrate either on initial detection or broader imaging applications without the same depth in longitudinal analysis. Additionally, LL's user-friendly interface and emphasis on spine and brain imaging make it a unique and valuable tool for healthcare professionals dealing with neurological conditions. By offering a comprehensive solution that integrates seamlessly into clinical workflows, Lesion Lens stands out as a preferred choice for precise and efficient lesion management.

3.4. Our Position In The Market

Lesion Lens occupies a unique position in the medical imaging market by offering a specialized tool that combines cutting-edge AI with a focus on lesion progression analysis. Key differentiators include comprehensive lesion tracking, which goes beyond mere detection to provide invaluable insights for patient management. The platform's ability to create detailed 3D volumetric views of lesions enhances diagnostic accuracy and aids in effective treatment planning. Furthermore, the user-centric design ensures that the platform is accessible to professionals with varying levels of technical expertise, promoting widespread adoption.

Cost efficiency is another critical advantage of Lesion Lens. By automating lesion analysis, the platform reduces the time and expense associated with manual MRI reviews, delivering substantial value to healthcare providers. This aligns with broader market trends that prioritize precision, efficiency, and accessibility in medical diagnostics. Given the growing demand for AI-driven precision diagnostics and the increasing prevalence of chronic neurological diseases, Lesion Lens is well-positioned to become a preferred tool for neurological lesion management, effectively addressing the evolving needs of this dynamic market.

3.5. Foreseen Challenges

While we believe this project to be feasible, there still are challenges to overcome. We have identified the challenges of implementing this project to be as follows,

Challenge	**Proposed Solution**
The hardware on HH computers are not state of the art and may struggle with our 3D viewer.	We plan to overcome this challenge by optimising our viewer as much as possible. Additionally, we will utilise the computer's GPU by using WebGL. We will also conduct further research on the hardware specs of the computers.
The web-app needs to send large DICOM files into the database, run the machine learning model, run the tracking algorithm and send a	We plan to overcome this challenge by reducing the file transfer sizes significantly. Also, the machine learning model will need to

3D renderable response to the server. HH's WI-FI may struggle to undertake this task within our requirement specifications (120 seconds).	process the DICOM files quickly as well. Moreover, we will try to optimise the computation times for preprocessing and postprocessing steps.
Unlike other European countries, especially like France, there is no standard for MRI scans. Their size, shape, and frequency vary from machine to machine, making the analysis process difficult.	We plan to overcome this challenge by standardising the incoming DICOM files. This process would include adding padding and adjusting perspectives.
Doctors can access MRI scans of patients from either *e-Nabız* or Hacettepe's own database. Ideally a doctor would be able to directly upload a scan into our web-app from eNabız or Hacettepe's own DB.	We will try to have authorised access to Hacettepe's own database. The best solution would be to access data directly from e-Nabız, however, this is unlikely to happen.

4. Academic Analysis

4.1. Advances in Medical Imaging and Lesion Detection

Medical imaging, particularly MRI, plays a pivotal role in diagnosing neurological conditions such as multiple sclerosis (MS) and brain tumours. However, up to 18% of patients are misdiagnosed due to the inherent complexity of identifying lesions, which often appear as bright spots that can be confused with other structures in MRI scans [7]. Recent advancements in machine learning (ML), particularly deep learning models such as convolutional neural networks (CNNs) and U-Net architectures, have significantly improved lesion detection and segmentation accuracy.

Studies have demonstrated the potential of these models. For example, Goldberg-Zimring's artificial neural networks achieved high specificity and sensitivity in MS lesion detection [9]. Similarly, Lee's patch-based U-Net architecture improved segmentation accuracy by 10% compared to traditional U-Net methods, albeit with higher computational costs [10]. Zeng et al.'s CNN-based approaches consistently outperformed classical segmentation techniques, particularly in MS lesion detection [12].

These advancements enable innovative applications such as lesion counting, monitoring lesion progression over time, and creating 3D volumetric maps for visualisation. By integrating these capabilities, machine learning-driven tools act as assistants to healthcare professionals, enhancing diagnostic speed and accuracy while alleviating the burden of manual analysis.

4.2. Challenges in Machine Learning for Medical Imaging

Despite these promising developments, several challenges hinder the widespread adoption of ML in medical imaging. Dataset limitations remain a significant obstacle, as deep learning models rely heavily on large, labelled datasets. For instance, models such as the Mohsen hybrid FPCNN, while accurate, were constrained by the availability of small datasets [7]. Acquiring extensive labelled datasets continues to be a bottleneck, as noted by Zeng et al. [12].

Another challenge lies in generalizability. Variability in MRI protocols and image qualities can lead to inconsistent model performance. Commowick et al. emphasised the difficulty of replicating human expertise across diverse imaging conditions, highlighting the need for standardised imaging datasets and robust model generalisation [13].

Artefact misclassification is another concern. Methods such as those proposed by Lladó and Goldberg-Zimring demonstrated good sensitivity but struggled with artefact misclassification, affecting their reliability [8], [9]. Additionally, computational costs pose scalability issues. Resource-intensive architectures, like Lee's patch-based U-Net, require significant computational resources, which can limit their practical application [10].

Moreover, automated lesion segmentation algorithms, while capable of approximating human expertise, often fall short in lesion detection tasks, as demonstrated during the MICCAI 2016 challenge [13].

4.3. Ethical and Regulatory Considerations

The implementation of ML in clinical settings must adhere to ethical and regulatory standards to ensure patient safety and privacy. Transparency in model design, training data, and data handling practices is essential for fostering trust and ensuring compliance. Bias mitigation is another critical concern, as addressing potential biases in training data is vital to prevent discriminatory outcomes.

Data privacy is equally important, requiring adherence to regulations like GDPR and KVKK to safeguard sensitive patient information. Ethical Board approvals, while adding procedural complexity, are indispensable for maintaining ethical integrity and ensuring the responsible use of patient data.

4.4. Future Directions and Opportunities

To overcome current limitations and enhance the integration of ML in medical imaging, future research must focus on developing data-efficient models that require fewer labelled datasets while maintaining high accuracy.

Hybrid approaches, such as combining classical methods with deep learning as demonstrated in the Mohsen hybrid FPCNN, can help balance accuracy with dataset limitations [7]. Explainable AI (XAI) techniques should also be incorporated to improve interpretability and foster trust in clinical settings.

Standardisation initiatives like PyRadiomics play a vital role in establishing reproducible workflows and standardised imaging protocols, addressing the variability in MRI practices [11].

By addressing these challenges and leveraging emerging techniques, machine learning can further evolve into an indispensable tool in medical imaging, reducing diagnostic errors and improving patient outcomes. Therefore, the development of robust, scalable, and clinically applicable solutions will become even more instrumental in transforming healthcare practices.

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