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Ensuring the Quality of Surgical Instruments with Artificial Intelligence: A Focus on Sternum Wire

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Abstract
Aim: This study aimed to investigate the Effectiveness of integrating artificial intelligence (AI) into quality assurance processes for surgical instruments, specifically focusing on sternum wire used in cardiac and thoracic surgeries. *Methods*: A total of 200 samples of sterile stainless-steel suture wire were evaluated according to established regulatory standards, including GG-N-211b and ISO 9001. Key quality parameters analyzed included needle strength, sharpness, configuration, penetration force, and labeling. Quality assessments were performed using traditional manual methods as well as automated machine vision systems, which were comprised of vision processing hardware, monochrome cameras, LED lighting, and communication protocols for precise control. *Results:* The study revealed that the automated machine vision systems markedly reduced inspection time while achieving an overall accuracy of 96% in detecting needle quality, compared to 80% accuracy with manual inspections. The new AI-driven visual inspection approach significantly outperformed traditional methods, particularly in identifying nuanced and objective defects. *Conclusion:* The results of our study highlight the potential of AI-powered quality assurance systems to enhance the efficiency and effectiveness of inspections for high-risk medical devices, ultimately promoting patient safety during surgical procedures.

Keywords: Quality Assurance (QA); Surgical Instruments; Artificial Intelligence (AI); Automated Inspection; Quality Control Standards.

Introduction

In the ever-evolving landscape of medical technology, quality assurance (QA) of surgical instruments is paramount to patient safety and surgical success [1, 2]. Poor-quality instruments can lead to unretrieved device fragments (UDFs), causing serious complications such as infections and tissue damage [3]. Among these instruments, surgical needles and stainless-steel sternum wires play pivotal roles in cardiac and thoracic procedures, where precision and reliability are critical [4]. The integration of advanced technologies, such as artificial intelligence (AI), along with structured documentation and quality management systems, enhances the effectiveness of QA processes in the medical field. Effective QA in surgery relies on comprehensive medical documentation, which is essential for generating valid data to inform QA goals [2]. Implementing robust quality management systems (QMS) is vital for ensuring high standards in medical device manufacturing, particularly for high-risk surgical instruments [5].

Artificial intelligence technologies, including machine learning and computer vision, can automate QA processes, identify defects, and predict issues in real time, which enhances productivity and compliance, allowing for proactive interventions that mitigate risks associated with surgical instruments [6]. Artificial intelligence has led to into the health care sector, new methodologies have emerged to evaluate the quality and performance of these essential tools. Intelligent visual inspection systems (IVIS) are related to different subjects, such as pattern recognition, image processing, machine learning, image analysis, signal processing, and software and hardware behind artificial vision systems, as well as AI [7]. Implementing AI inspection reduces the labor costs associated with manual quality assurance, making it a more economically viable option for manufacturers [8]. Artificial intelligence systems can operate continuously without fatigue and maintain consistent performance throughout the inspection process [9]. Automated systems can process images rapidly, significantly reducing inspection time compared with manual methods, which can become bottlenecks in production [10]. Automated systems utilize image-processing techniques to monitor needle wear, allowing timely replacement before critical wear levels are reached [9].

This study aimed to employed software and innovative technology to assess parameters that vary based on the data and relevant product information. It also measures the differences in quality control results between the new inspection method and the traditional approach.

Materials and Methods

Sample Preparation

We utilized a specific model of suture wire, known as Sternum Stainless Steel Non-Absorbable Sutures, for our quality control assessments for its relevance in cardiac and thoracic surgical procedures, where precision and reliability are critical. This model comprises two components: a steel wire and a curved needle, which is classified as a regular reverse cutting-edge needle with a ½ circle radius, commonly employed in cardiovascular surgery. In total, 200 samples were manufactured (Turkey, 2023) and sent to the laboratory for evaluation.

Quality Control Standards

The quality parameters and testing methods conformed to established standards, including the GG-N-211b Federal Specification Needle, Suture, US Pharmacopeia, ASTM F1840 related to surgical suture terminology, and ISO 9001. Specific tests conducted included Needle Strength Testing and Bend Moment Testing (ASTM F1874-98) and Needle Sharpness Testing (ASTM F3014, https://www.instron.com/en/testing-solutions/astm-standards/curved-needle-testing-astm-f3014). Needle Strength Testing involves measuring the force required to break the suture wire. Bend Moment Testing test evaluates how the needle bends under a specific load until failure. Needle Sharpness Testing requires assessing the sharpness of the needle, typically by determining the force needed to penetrate a standardized medium.

Manual Quality Control Evaluation

Quality control assessments were performed manually and with the aid of the laboratory equipment. The following parameters were measured for each sample.

- **Diameter and Length:** Measurements were taken using calipers to ascertain the diameter (target of 0.9 mm) and length (target of 45 mm) of the suture needles, and the results were compared with those from the APKA IRAN HIGH TECH LABORATORY NETWORK.
- **Needle Configuration and Shape:** The configuration was visually inspected to confirm compliance with the specified design characteristics, including the ½ circle regular reverse cutting edge and needle radius.
- **Penetration Testing:** Observational methods were employed for manual testing, whereas objective force measurements were obtained from laboratory tests (target penetration force of 1.60 N).
- **Labelling and Packing:** Confirmation of proper labelling and packaging were visually confirmed.

Automated Machine Vision System

To enhance the quality of inspections, an automated machine vision system was integrated into the manufacturing process. This system comprises several key components:

- **Vision Processing Hardware:** This includes a checkpoint vision processor linked to a network of monochrome cameras and LED lighting configured to optimize the imaging of the suture needles. A multiplexer connects the cameras to the vision processor.
- **3D Imaging Capability:** The system is designed to capture images from multiple angles to facilitate comprehensive inspection of the needle structure. Although three-dimensional (3D) imaging was employed, the focus of this study was to inspect one side of the needle.
- **Communication Protocols:** The vision processing computer communicates with Programmable Logic Controllers (PLC) using Visionlinx software from Cognex and Rslinx from Rockwell Software, enabling precise control of inspection timing and trigger signals.

Penetration Testing Procedure

Sharpness testing of the needle was performed by fixing it in a stable clamp. The clamp apparatus was programmed to move toward the test medium at a constant speed, simulating a realistic penetration scenario:

- **Clamp Movement Specifications:** The arm was designed to rotate at a speed of $4° \pm 2°/s$, with needle curvature specifications allowing a rotational range of 156° to 200° and an approximate rotation angle of 60° to ensure complete passage through the test medium.
- **Data Acquisition:** Penetration forces were monitored using specialized software that recorded the maximum force exerted during the testing process. Graphical representations of the data were displayed on the screen to assist in analyzing the sharpness of the needle.

Image Processing Methodology

For effective image analysis, appropriate image processing software was selected based on the unique requirements of visual inspection. The process involved:

- **Feature Recognition:** The software employed advanced image processing techniques, including PatMax pattern matching, to identify and evaluate the critical geometrical features of the needles in comparison to approved standards.
- **Data Reporting:** The software facilitated the automation of reporting analysis, providing detailed graphical outputs and performance statistics in real time, thereby enhancing the overall accuracy and reliability of quality assurance procedures.

By employing these materials and methods, we aimed to streamline quality control in the manufacturing process of surgical needles by leveraging both manual inspection techniques and advanced machine-learning technologies.

Results

The project aimed at differentiating between true surgical needles (non-defective) and false surgical needles (defective) demonstrated significant improvements when leveraging deep learning methods, specifically utilizing the EfficientNetV2 architecture for convolutional neural networks (CNNs). Traditional manual inspection methods were compared with the new AI-driven visual inspection approach to assess their accuracy and Effectiveness in quality control (

Table **1**). Table 1 presents the overall accuracy, accuracy for nuanced defects, and accuracy for objectively identifiable defects as assessed by manual inspection and the AI-driven visual inspection methodology. The results indicate a marked improvement in detection accuracy achieved through the automated approach.

Table 1. Accuracy percent of results in manual inspection and AI inspection.

Inspection method	Overall accuracy, %	Accuracy for Nuanced Defects, %	Accuracy for Objective Defects, %
Manual inspection	80	60	90
New method visual inspection in Articles	96	85	98

Overall, the deep learning model achieved an impressive overall accuracy of 96% in detecting the needle quality. This represents a marked improvement over manual inspection, with an overall accuracy of 80%.

Detailed analysis of the results revealed:

1- Accuracy for Nuanced Defects: Manual inspection showed a lower accuracy of 60% for nuanced defects, whereas the new CNN approach significantly improved the accuracy to 85%.

2- Accuracy for Objective Defects: For objectively identifiable defects, the new visual inspection system achieved an accuracy of 98%, which exceeded the accuracy of the manual method by 90%.

Additionally, the confusion matrix analysis provided insight into the model's performance (Figure 1).

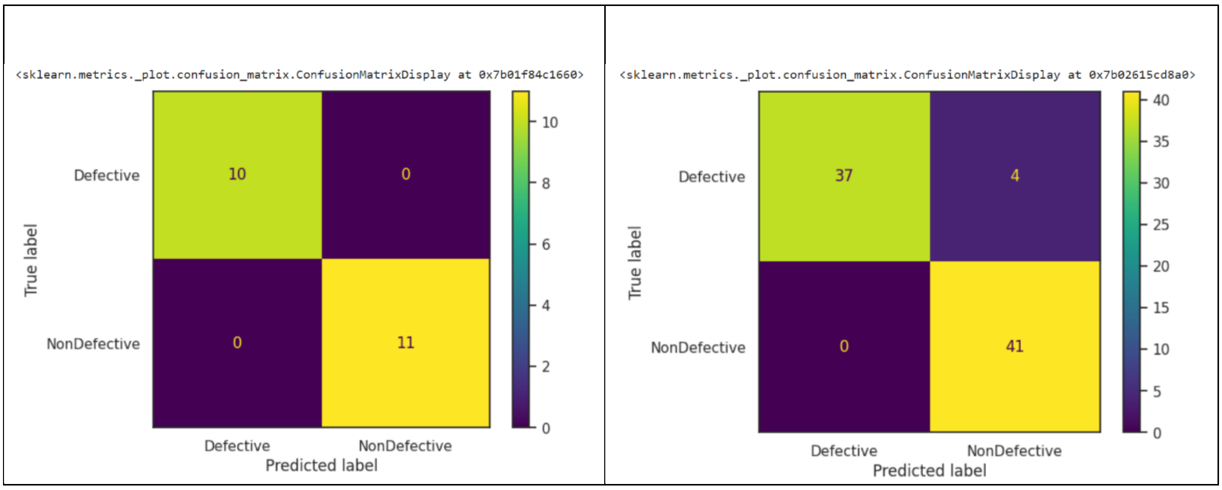

Figure 1. Confusion curve for training data

Out of 82 data points in the training set, all 37 defective needles were correctly identified, reflecting a precision of 1 for the "Defective" class. For the "non-defective" class, 41 of 45 predictions were accurate, resulting in a precision rate of 0.91. The evaluation metrics indicated a satisfactory reduction in loss, stabilizing at approximately 0.1 after 45 epochs of training. The accuracy trends during validation and training displayed no indications of overfitting or underfitting with consistent performance across the evaluation sets (Figure 1).

Discussion

Our results support the integration of deep learning methodologies into quality control processes, balancing efficiency and accuracy while acknowledging the continued need for human oversight in specific contexts.

In the last few years, technological developments in the surgical field have been rapid and are continuously evolving. One of the most revolutionizing breakthroughs was the introduction of the IoT concept within surgical practice [11].

Artificial intelligence and its subtypes, deep learning in particular, tend nowadays to have an expanding role in all fields of medicine, and diagnosing colon cancer is no exception [12, 13].

Artificial intelligence (AI) and image processing are revolutionising the diagnosis and management of liver cancer. Recent advancements showcase AI's ability to analyse medical imaging data, like computed tomography scans and magnetic resonance imaging, accurately detecting and classifying liver cancer lesions for early intervention [14].

The findings of this study highlight a significant advancement in the realm of quality control of surgical needles through the application of deep learning methods, particularly the EfficientNetV2 architecture in CNNs. The marked difference in accuracy between the traditional manual inspection approach and the AI-driven method underscores the potential of machine learning to transform inspection processes in the medical device manufacturing sector. The results of this study are consistent with those of previous studies. Deep learning algorithms can automate the inspection of needle tips and identify geometric defects that human inspectors may miss [15]. Deep learning models can process images rapidly, thereby enhancing the efficiency of quality control processes in medical device manufacturing [6]. Implementing CNNs has been shown to increase the predictive accuracy by over 11% compared to traditional machine learning methods [15].

The overall accuracy of 96% obtained using the AI method represents a substantial leap from the 80% accuracy achieved through manual inspection. This enhancement is particularly notable in the context of nuanced defects, in which human inspectors often struggle. The improvement from 60% to 85% in accuracy for nuanced defects illustrates that the deep learning model can identify subtle imperfections that might be overlooked in manual inspections. Given the critical nature of surgical instruments, this capability is essential to ensure patient safety and device reliability.

Furthermore, for objective defects, the accuracy of the deep learning model increased to 98%, surpassing the 90% accuracy of manual inspection. This demonstrates the strength of AI in scenarios where defects are visually apparent, and helps solidify the argument that automated systems are particularly effective in high-stakes quality assurance tasks. The precision rates calculated using the confusion matrix further reinforce the Effectiveness of the model, particularly the perfect identification of defective needles, which is paramount in healthcare settings. These results are consistent with those of previous studies. AI systems can analyze vast datasets to identify defects that human inspectors might miss, achieving inspection accuracies of up to 99.86%. Traditional manual inspections typically yield approximately 80% accuracy, highlighting the substantial improvement offered by AI [9]. Predictive maintenance and real-time monitoring further enhance operational efficiency, minimize downtime, and ensure consistent product quality [16]. AI systems possess adaptive learning capabilities, which allow them to improve over time based on feedback and changing regulatory requirements [6].

While this study strongly advocates for the integration of AI into quality control workflows, it is crucial to acknowledge the ongoing relevance of manual inspections in certain contexts. There are situations that require a level of nuanced evaluation and human judgment that AI systems may not yet be capable of replicating, especially as product design complexities and variations increase. Manual inspectors provide valuable expertise, particularly in assessing the overall context of products and understanding intricate details that may not be easily quantifiable. These results are consistent with those of previous studies. AI systems, such as those utilizing deep learning, can process vast datasets to detect defects with a higher precision than traditional methods [17]. Artificial intelligence systems continuously improve through feedback, enhancing their performance and compliance with evolving standards [6]. In complex production environments, manual inspections may be necessary to account for the unique human insights and experiences that AI cannot replicate [18]. AI's effectiveness of AI is contingent on the quality of data it is trained on; poor data can lead to inaccurate assessments [19].

The study's use of various related articles to guide AI methodology highlights a collaborative approach that leverages existing knowledge and practices. By analyzing multiple sources, researchers can align their machine vision and deep learning strategies with industry standards, enhancing their applicability and effectiveness. This integrative approach is vital for developing robust quality control systems that are tailored to specific manufacturing needs and can be adapted to different product types.

The findings also shed light on the operational benefits that deep learning methods can provide, such as increased speed and efficiency of the inspection process. With the ability to inspect multiple parameters simultaneously, AI-driven systems allow for faster production rates while ensuring the integrity of the inspection process. This acceleration in quality assurance processes could translate to significant cost savings and more efficient manufacturing workflows, which are critical in today's competitive markets.

Further research is warranted to deepen our understanding of how these AI systems can be optimized for practical deployment in the healthcare industry. This includes addressing potential limitations, such as the need for ongoing training of AI models with diverse datasets to ensure that they continue to perform well in various scenarios. Additionally, the exploration of hybrid systems that integrate AI and human expertise could be a promising avenue for enhancing quality control processes.

The study's limitations include a restricted sample size of 200 sterile stainless-steel suture wire samples, which may not encompass the variability present in different types of surgical instruments, and it primarily evaluates a single model of suture wire, raising concerns about the broader applicability of the findings.

The results may lack generalizability because they are specific to the integration of AI in the QA processes for a singular type of suture wire within a defined regulatory context, which may not translate directly to other surgical instruments or different manufacturing environments.

In summary, although manual inspection methods have served the industry well, the integration of AI presents a compelling opportunity to enhance the accuracy, efficiency, and overall quality assurance processes. As the healthcare sector continues to evolve, embracing such technological advancements is essential for ensuring high standards of safety and Effectiveness in medical devices, ultimately benefiting patient outcomes.

List of Abbreviations: AI- artificial intelligence; QA- quality assurance; UDFs- unretrieved device fragments; QMS- quality management systems; PLC- Programmable Logic Controllers; CNNs- convolutional neural networks.

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