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OPTIMIZING MANUFACTURING EFFICIENCY WITH COST-EFFECTIVE AUTOMATION: A FOCUS ON PTCA BALLOON PRODUCTION

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ABSTRACT

Harnessing human beings as an energy source not only proves inefficient but also subjects workers to tedious and monotonous tasks, often coupled with high-risk factors and a lack of skilled engagement. This research suggests a new way of thinking about Low-Cost Automation (LCA) as a better and more efficient approach. LCA incorporates automation solutions that are not only technologically advanced but also economically viable, particularly suitable for small and medium-sized enterprises (SMEs). The LCA methodology involves integrating basic mechanical, electrical, hydraulic, and pneumatic components into existing industrial setups to enhance productivity. Focusing on a case study within the medical industry, this research article highlights the implementation of LCA in the manufacturing of medical balloons, specifically at the Neck Welding Station during the outer lumen cutting process and low cost automation is also implemented on the various PE sheaths process to ease their operation of trislit cutting, peelable stretching etc. Results indicate that LCA reduces manpower requirements by half, significantly boosting productivity within a shorter timeframe. This approach contributes to the development and evolution of products, showcasing its potential impact on various manufacturing sectors. Moreover, the study presents LCA's positive influence on product accuracy and the overall growth of companies by minimizing energy consumption. The findings also extend to the application of similar methodologies in the production of different balloon protective sheaths, such as those used in angioplasty balloon catheters. In summary, LCA emerges as a transformative force in industrial processes, offering a cost-effective and efficient alternative to human-centric energy sources, thereby creating a more sustainable and productive future for manufacturing industries, particularly for SMEs.

KEYWORDS: *Low-Cost Automation (LCA), Small and Medium-sized Enterprises (SMEs), Industrial Productivity, Medical Industry and Sustainable Manufacturing*

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INTRODUCTION

In today's manufacturing world, where we're always trying to make things faster and more precisely, a new way of doing things has become really important. It's called "low cost automation" or LCA. This is a smart way of using new technologies to make more stuff while using fewer resources. LCA uses affordable and easy to handle resources, helping to save money in making things and helping companies grow.

One area where this is making a big impact is in making balloon catheters, which are important for heart surgery. With the way we live nowadays, eating lots of unhealthy carbohydrates and not moving much, we're more at risk for heart problems. When we need surgery for heart issues, balloon catheters are crucial. They help extend arteries, making it easier for doctors to reach and work on implants.

This study looks at using LCA in making balloon catheters, especially at the part of the process where the neck is welded. The result shows that, using LCA here makes things more precise, quicker, and safer for the workers. Automation, which means using machines and computers to do tasks, is a big help. It lets people avoid doing hard tasks and makes better use of resources, making work more efficient. Lots of industries are using automation now because it has many benefits.

The good things about LCA, like saving money, doing more work, being flexible, making better-quality products, and keeping things safe, show how it's changing manufacturing. One best thing about LCA is that it lets us use the same equipment to make different parts for balloon catheters. This article proves that using LCA in making balloon catheters, like protective sheaths, helps improve the quality, safety, and speed of production. It shows that LCA is really useful in making medical devices work better.

MATERIALS AND METHOD

The process of making balloon catheters involves several processes, from the raw material to the packing of the finished product. In which LCA implies in outer lumen cutting process at neck welding station, at which outer lumen binds with balloon proximal by PTCA (Percutaneous Transluminal Coronary Angioplasty) process. Outer lumen is a hollow plastic PA (Poly amide) tube that is used nylon as a raw material specifically based on its end-use application. Following the WI (Work Instruction), the outer lumen is inserted into the balloon proximal end upto a specified distance of 2 to 6mm based on the balloon dia. Subsequently, a Heat Shrink (HS) Tube is applied to the welding area, and the assembly is welded using laser technology, as illustrated in the figure 01.

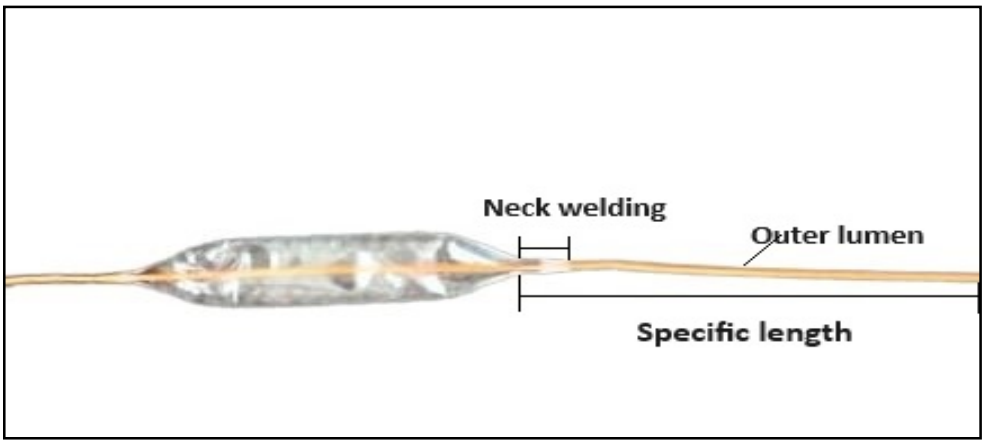

Figure 1: Assembly of Balloon Proximal and Outer Lumen.

This automation device has work by combination of different parts, HMI, Machine Stand, Servo Motor, Gear mechanism, Base Plate etc., which is illustrated in figure 02.

LCA Combination Parts

Human-Machine Interface (HMI)

A Human-Machine Interface (HMI) refers to a user interface or control panel facilitating the connection between an individual and a machine, system, or device. Although the term could be broadly used for any display enabling user-machine interaction, it is predominantly employed within the realm of industrial processes.

Machine Stand

A Machine Stand is the stand on which shaft is fixed and it helps the tube roll to revolve around its circumference.

Servo Motor

A servo motor stands as an autonomous electrical apparatus that efficiently and precisely rotates components of a machine. The output shaft of this motor can be moved to a particular angle, position and velocity that a regular motor does not have.

Gear Transmission System

Gears are mechanical components designed to interlock through teeth, facilitating the transfer of rotary motion from one shaft to another. Gears are characterized by two important components: radius and number of teeth. Typically, they are affixed or linked to other components through a shaft or a base.

Base Plate

A Base Plate is the bottom plate that supports all the units of the machine like Tube Roll, Machine stand, Servo Motor, Gear Transmission system, Guide Rail etc.

Calendering Rolls

These rolls are connected with gears and are rotated with the help of gear mechanism. These rolls pull the tube from the tube roll.

Guide Rail

Guide Rail are the supporting base for the tube during pulling from calendering roll. Guide rail directs the tube into a straight path and helps in the consistent cutting of the tube.

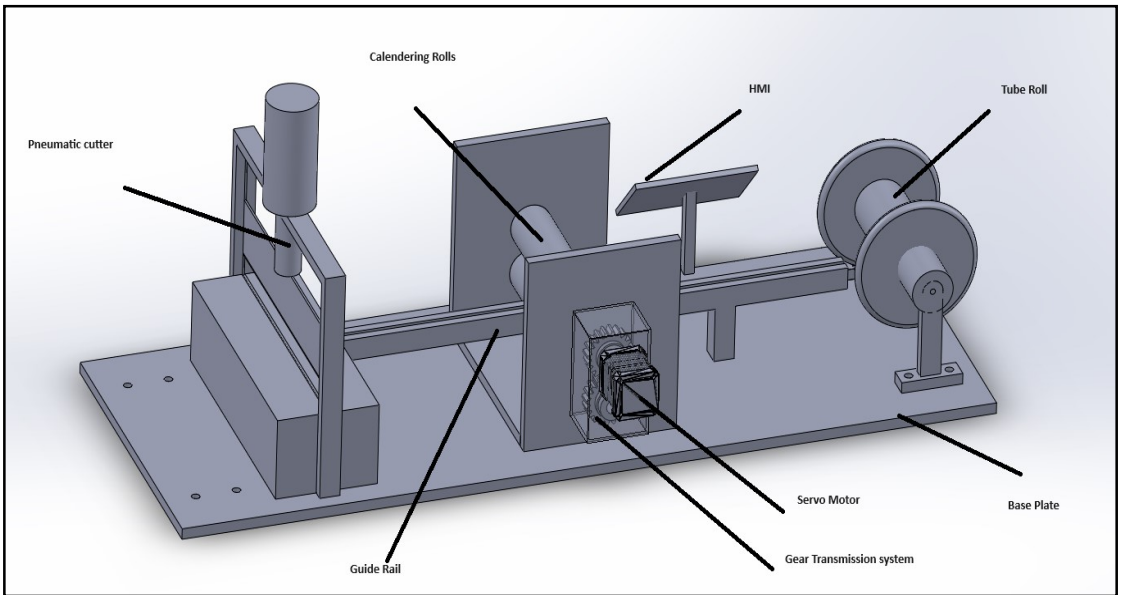

Figure 2: Mechanical Representation of LCA.

Initially, the outer lumen roll is placed on the shaft fixed to the machine stand in this automated mechanism. Following that, the servo motor receives a command from the HMI (Human Machine Interface) and begins to rotate at the predetermined speed. Since the first gear is directly attached to the servo motor shaft and the second gear is attached to the first gear, the power transmission causes the two gears to rotate in opposite directions. Because both gears are attached to calendaring rolls, they are also moving in opposing directions. Thus, the outer lumen tube is extracted from the tube roll by rollers in this manner. The laser displacement sensor senses the required length after pulling the specified length from the tube roll. It then sends a feedback signal to stop the servo motor. The cutting blade then cuts the specified length. This entire cycle repeats itself, resulting in low-cost automation without human interference.

LCA in PE Protective Sheath

From the good benefits of low cost automation in every aspects of the production of balloon, it encourages the use of same kind of methodology in production of PE protective sheath for the protection of balloon. Three different types of protective sheaths were manufactured with same kind of machinery.

LCA in Peelable Protective Sheath

Manufacturing of balloon catheter protection sheaths was done by hand until automation was introduced. The introduction of Low-Cost Automation (LCA) has brought about significant improvements in the production of peelable sheaths, incorporating a semi-automated approach. Through the assistance of this automation, we've formulated a fixture that facilitates the precise cutting of protective sheaths to specific lengths. Additionally, a slit cut is applied to one side of the sheath, as illustrated in Figure 3.

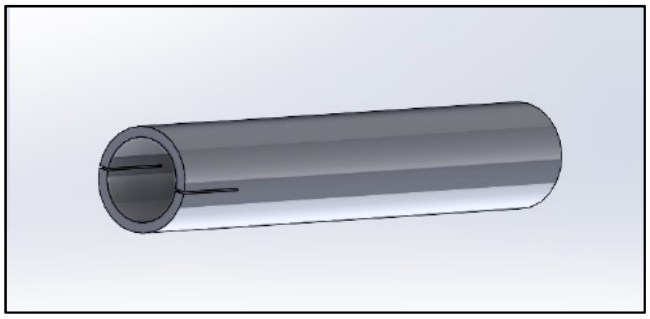

Figure 3: Peelable Protective Sheath.

Tri-slit PE Protective Sheath

The initial approach involved manual labor to produce the Tri-slit PE sheath for stent protection. Because of the unique length and side cuts of the PE protective sheath, older machinery requires manual operators. Recognizing the need for efficiency and cost-effectiveness, they introduced a semi-automated system using low-cost automation. This involves that instead of relying entirely on manual labor, they incorporated machinery to streamline the process. This automation takes into account several auto mechanics with precise dimensions for the particular length and side slits. Final appearance is demonstrated in figure 4.

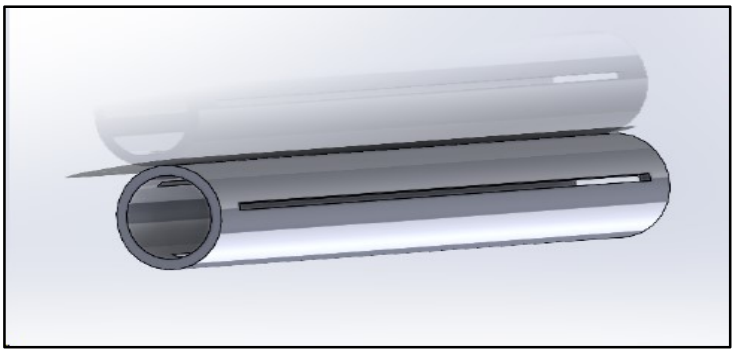

Figure 4: Tri-slit Protective Sheath.

Flaring PE Protective Sheath

To safeguard the PTCA catheter balloon and ensure quick and convenient access, a protective sheath with a flared end is employed. In some cases, operators manually flare the sheath using gray methods. They flare the sheaths with the help of Hot Air weller and manually rotate the sheath with hand in front of weller. Manual processing can occasionally put operators at risk, cause unintentional damage that lowers product quality, and result in batches that don't meet quality standards. This type of danger can be reduced by using low-cost automation and fixtures that cut the protective sheath at a precise length and flare at the right points to eliminate human touch throughout the procedure. Now we make a tool as per final flare dia. covered up with heated element jacket and for cooling external pneumatic air is used, this assembly is connected with simple robotic arm to run the process in a continue sequence. This provides the precise protective sheath dimensions shown in picture 5.

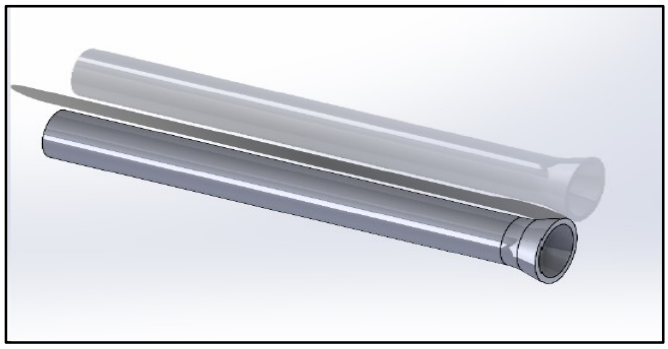

Figure 5: Flaring Protective Sheath.

RESULTS AND DISCUSSION

The integration of low-cost automation (LCA) in the balloon catheter production process has yielded significant improvements in both operational efficiency and product quality. The initial focus was on the outer lumen cutting station, where the implementation of LCA reduced the need for manual intervention. This led to a transition from a two-operator system to a single-operator setup per shift, resulting in a considerable increase in overall efficiency.

At the end of each day, the manpower previously allocated to three shifts in the sleeve cutting machine operation could be reallocated to other product manufacturing areas, demonstrating the maximization of human resources. Notably, the switch to LCA not only addressed the risk associated with manual cutting processes but also substantially decreased the overall cycle time upto 42%, underscoring a significant boost in productivity without compromising precision.

The application of LCA extended to the production of protective PE sheath layers for angioplasty balloon catheters. The methodology, encompassing peelable, tri-slit, and flaring sheath designs, demonstrated enhanced accuracy and reduced production time. Specifically, in peelable sheath production, time decreased by 38% compared to manual production, while tri-slit and flaring sheath production saw reductions of 44%and32% respectively.

This all outcomes ultimately reflect in product quality and company's beneficial growth like:

- **Affordability and Accessibility:** The primary advantage of a low-cost automated machine is its affordability, making advanced process through optimization technology accessible to a wider range of businesses and industries.
- **Cost-Efficiency in Operations:** Implementing a low-cost automated machine allows organizations to streamline operations and reduce overall costs associated with process inefficiencies.
- **Rapid Return on Investment (ROI):** Due to its low initial investment, organizations can expect a quicker return on investment, enabling them to recoup costs and start realizing savings sooner.
- **Versatility in Applications**: Despite being budget-friendly, these low cost automated machines often offer versatility, catering to various industries and applications. This adaptability enhances their appeal for businesses with diverse needs.
- **Integration with Existing Systems:** Many low-cost optimization solutions are designed to seamlessly integrate with existing systems, reducing the disruption during implementation and ensuring a smoother transition.

- **Adaptation to Evolving Technologies:** Despite their cost-effectiveness, these machines often leverage modern technologies allowing organizations to stay competitive and adapt to future advancements.
- **Empowering Innovation:** The availability of affordable optimization tools empowers businesses to innovate in their processes, fostering a culture of continuous improvement and adaptation to market changes.
- **Environmental Impact:** A lower cost often translates to reduced energy consumption and resource usage, contributing to a more sustainable and environmentally friendly approach to optimization.

CONCLUSION

In Conclusion, this research article highlights the utilization and advantages of low-cost automation in high production requirements, where stringent standards and rapid production are essential. The adoption of low-cost automation introduces an innovative and forward-thinking approach in manufacturing industries, providing cost-effective solutions with positive outcomes. The integration of LCA in the manufacturing of balloon catheters signifies a commitment to innovation, facilitating the development of high-standard products at a reduced production cost. This, in turn, directly benefits customers by offering top-quality products at more affordable prices. The enhanced accuracy and product quality, stemming from reduced human contact, contribute to a decrease in the chances of contamination. Moreover, low-cost automation, which requires only half the manpower compared to manual labor, allows for the redirection of human resources towards more skilled and forward-looking tasks. Similarly, this type of automation demonstrates promising results in the production of PE protective sheaths for angioplasty balloon catheters. Additionally, the implementation of LCA mitigates risk factors associated with human contact injuries from equipment such as flames or cutting blades. Hence, LCA shows tremendous results in product outcomes in terms of quality, accuracy, required time and production cost.

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