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Reduction in Stent Rejection during Manufacturing in Process

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ABSTRACT :

The study on rejection reduction in stent manufacturing during the electropolishing process focuses on enhancing surface quality and functional performance while minimizing production defects. Inefficiencies in the electropolishing process can lead to elevated rejection rates due to irregularities such as surface roughness, dimensional deviations, and incomplete polishing. This research aims to analyze and optimize critical parameters within the electropolishing process, including current density, electrolyte composition, and process duration. Electropolishing, an electrochemical method, effectively removes oxide layers from the stent, resulting in a smoother metal surface. By employing a data-driven approach and utilizing real-time monitoring tools, the study identifies process inconsistencies and formulates corrective strategies to reduce defect rates. The results indicate a significant improvement in surface finish, a reduction in material rejection, and an enhancement in overall yield. These findings contribute to more cost-effective and reliable stent manufacturing, ultimately ensuring the production of higher-quality medical devices for patient care.

Key words: Stent manufacturing, Electropolishing process, Rough Surface, Rejection reduction, Dimensional accuracy, Process parameter and stent surface quality.

Introduction :

Different kinds of rejections occur in stent manufacturing during the manufacturing process. This study investigates strategies for reducing rejection rates in the electropolishing process of stent manufacturing. The importance of rejection reduction in stent manufacturing in the electropolishing process is ensuring the success and competitiveness of the industry. Stent manufacturing represents a critical sector within the medical device industry, providing life-saving solutions for patients with cardiovascular diseases. Electropolishing is an important step in enhancing the surface properties and biocompatibility of these complex devices. Electropolishing is an anodic dissolution process currently used in industry to reduce metal surface roughness in order to obtain a bright and smooth aspect (1). The electropolishing process often encounters challenges that result in shows high rejection rate that causes operational hurdles for the manufacturers with little to no increase in manufacturing time and has enabled the production of parts with optimized topology or complex internal design, which would not be feasible through traditional manufacturing (2).

The rejection of stents during electropolishing can stem from various factors, including material inconsistencies, insufficient process control, and ideal parameter configurations. Each rejected stent not only acquires a financial loss but also presents a setback in fulfilling the requirements for timely delivery and upholding product quality standards. Therefore, addressing rejection rates in the electropolishing process is crucial to improving manufacturing efficiency, reducing costs, and ensuring consistent product quality.

Disorders of the heart or blood vessels are referred to as cardiovascular disorder, and they are thought to be the primary cause of health problem and death around the world. Ever since the balloon dilation procedures were performed, cardiovascular angioplasty has been the main treatment for coronary heart disease. Cardiovascular diseases are disorders that involve the heart or blood vessels and are considered to be the leading cause of morbidity and mortality worldwide (3). The sign of coronary artery disease (CAD) is arterial stenosis caused by plaque that occurs in the endothelium and because of the restricted blood flow and oxygen in the heart muscle, cells, calcium, and other substances may build in these deposits. This can eventually cause transient cerebral ischemic attacks and stroke. CAD is characterized by the narrowing of the artery due to plaque deposits beneath the endothelium. Cells, fats, calcium, cellular debris, and other substances may accumulate in these deposits, starting a cascade of events—diminished blood vessel artery lumen, restricted blood flow, and inadequate nutrients and oxygen supply to the cardiac muscle—that can eventually cause myocardial infarction or transient cerebral ischemic attacks and stroke (4).

This paper explores the issue of rejection reduction in stent manufacturing, focusing specifically on the electropolishing phase. By examining current practices, analyzing potential causes of rejection, and exploring innovative solutions, this research seeks to provide insights and strategies to reduce rejection rates effectively. Furthermore, understanding the underlying mechanisms of rejection in the Electropolishing process can pave the way for the development of robust quality control measures and optimization techniques.

Ultimately, the successful reduction of rejection rates in Electropolishing holds immense promise for stent manufacturers, offering not only financial benefits but also the opportunity to bolster their competitive edge in a demanding health care landscape. This study endeavors to contribute to the ongoing advancement of stent manufacturing processes, fostering greater efficiency, reliability, and ultimately, improved patient outcomes. Reducing rejection rates in stent manufacturing during the electropolishing process requires careful attention to detail and the implementation of specific methodologies.

Materials and Method :

Material of Cobalt-Chromium (Co-Cr) and preparation of electrolyte solution and its measuring instrument

Cobalt-chromium (CoCr) alloys are extensively utilized in medical, aerospace, and various other industries owing to their exceptional mechanical properties, corrosion resistance, and biocompatibility. These advantageous characteristics render CoCr alloys particularly suitable for applications in orthopedic implants, dental prosthetics, and other medical devices.

Cobalt (Co): Provides strength, hardness, and wear resistance.

Chromium (Cr): Contributes to corrosion resistance by forming a protective oxide layer.

1. **Stent Material:**
- Cobalt-Chromium (Co-Cr) stent is used in manufacturing due to their high bio compatibility, corrosion resistance, and mechanical strength.

2. **Electrolyte Solution*:***
- An electrolyte solution for the electropolishing process made from a combination of appropriate ingredients for the stent. The concentration and purity of the acids are maintained when making an electrolyte solution. Electropolishing is normally carried out in concentrated acid media such as phosphoric acid, sulfuric acid and their mixtures or in perchloric acid-acetic acid solutions (5).

3. **Electropolishing Setup*:***
- *Power supply unit:* The power supply unit can deliver a controlled current in the range of 0.1 to 5 amps, controlled voltage in the range of 1 to 30 volts, controlled temperature in the range of 20 to 80 ◦c and process time in the range of 10 to 999 sec. Voltage is also determined by the number of amperes needed to electropolish the part. Generally, 600-3,000 A requires an 18-V DC output, and 3,500-10,000 requires a 24-V rectifier. Optimum running voltage is 9-13 V for stainless steel (6).
- *Electropolishing tank:* The electropolishing tank is made of corrosion-resistant material (polypropylene) with electrodes (anode and cathode) submerged in the electrolyte solution. *The material of the cathode is* stainless steel or titanium.

4. **Measuring Instruments*:***
- *Optical microscope***:** Before and after the electropolishing to visually inspect the stent surface, stent thickness, stent dimension and ensure uniformity of polishing.
- *Scanning Electron Microscope (SEM)***:** For high-resolution surface characterization.
- *Vernier calipers***:** For dimensional accuracy checks.

5. **Monitoring and Control Equipment:**
- *Real-time monitoring system to track current density, voltage, time and temperature throughout the process of these variables, time, bath temperature, composition of electrolyte, and current density and voltage relationships are most important to the in-situ electro polisher. (7)*
- *Thermometers are used* to maintain and monitor temperature levels within the electrolyte solution, typically kept at 40-60°C.

Methods for stent preparation and electropolishing setup preparation :

1. **Sample Preparation:**
- Stents are cleaned in the ultrasonic machine. To make a descaling solution with the mixture of (Water, Nitric acid, and Hydrofluoric acid) to remove the existing oxide in the stents. This ensures that surface impurities do not affect the electropolishing process.
- After the descaling process is done the stents are washed with purified *water.*

2. **Electropolishing Process:**
- The prepared stents are mounted with the help of electrodes in the electropolishing tank. Electrode is made by ss wire ensuring proper connection to the power supply and that the stents serve as the anode. An electro-polishing fixture for polishing stents which incorporates multiple anodes in contact with the stent and a center cathode disposed coaxially within the interior of the stent and a curved exterior cathode disposed about the perimeter of the stent. (8)
- *A controlled current density* (between 0.1 to 0.6 A) was applied, and the voltage was adjusted based on optimization to achieve a uniform removal rate.
- The process time was varied (between 3 to 10 minutes) depending on the desired surface finish, with real-time adjustments made based on voltage temperature and current density.
- Temperature control was crucial, as excessive heat could cause surface or uneven polishing. The temperature is kept between the range of 40°C to 60°C.
- After electropolishing, the stents are washed with purified water to remove any residual acids and then passivated by a mixture of water and nitric acid solution to enhance corrosion resistance.
- After finishing the electropolishing process the stents are dried using compressed air.

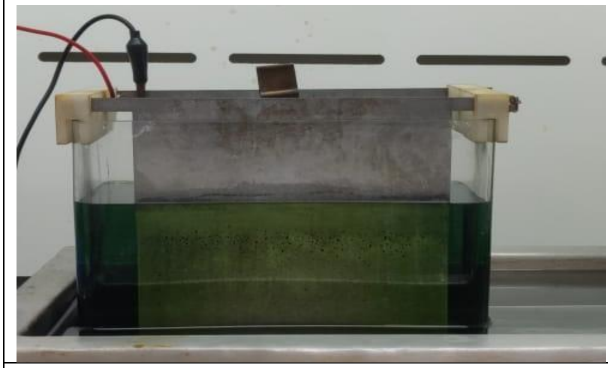

Fig: 1 Electrolyte solution

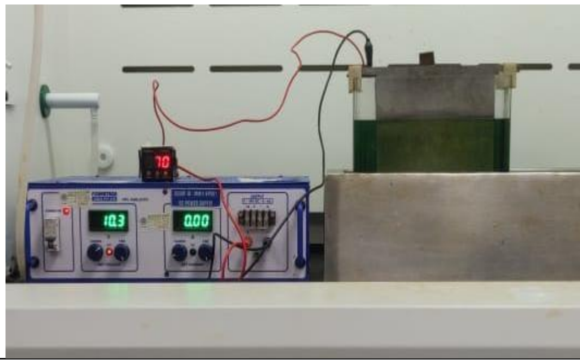

Fig: 2 Power supply connected with the polishing tank

3. Inspection and Measurement:

- *Surface Roughness*: Microscope is used to check the rough surface before and after electropolishing to quantify the reduction in micro-burrs and surface imperfections.
- *Microscopic Analysis*: Both optical and scanning electron microscopy were used to visually inspect the surface and ensure that polishing was uniform without introducing irregularities. To solve this problem is a stent polishing fixture that is able to maintain a uniform current density in the electrolyte solution within the interior of a stent as well as a uniform current density in the electrolyte solution about the exterior of a stent (8).
- *Dimensional Accuracy*: The stents dimensions were checked and visualized in the microscope and this dimension required for medical standards.

4. Rejection reduction:

- Rejections associated with laser cutting, such as cracking, improper cuts, and welding issues, can be mitigated through several key practices. These include regular laser maintenance and calibration, optimization of laser parameters, real-time monitoring, and the implementation of advanced laser systems. By consistently maintaining and calibrating the laser equipment to operate within optimal parameters, we can significantly reduce deviations that may lead to product rejection.

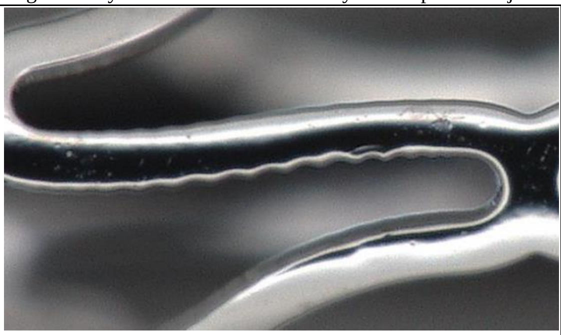

Fig: 3 Before Process (Cutting problem occure due to when the laser parameters not proper or due to calibration)

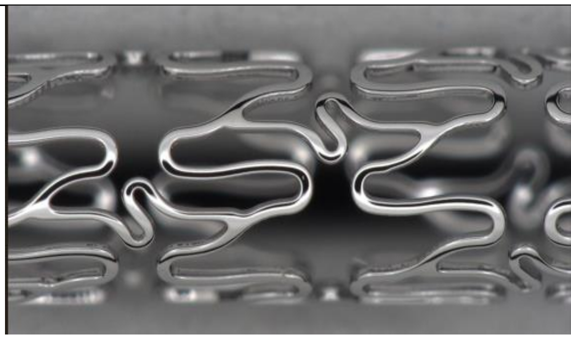

Fig: 4 After Process (If do a regular maintenance and calibration for the laser machine that kind of rejections are reduced)

Fig: 5 Before Process (This is a laser side welding it's occur when the stent materials are not removed properly)

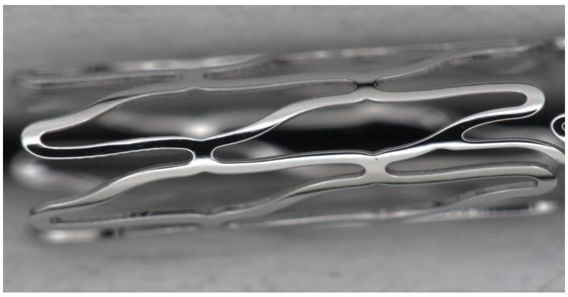

Fig: 6 After Process (Operator check that stent on microscope properly then it's reduced)

- The laser cut procedure is when this type of rejection happens. So continuous observation in an ideal microscope, this type of rejection is decreased.
- Ensure the descaling solution concentration, temperature, and exposure time are optimized to remove contaminants without damaging the stent material. In appropriate chemicals can lead to surface etching or pitting, increasing rejection rates. Ensure the use of appropriate chemicals suitable for Co-Cr material. Additionally, check that the ultrasonic machine operates at the correct vibration level, as excessively high vibrations can lead to cracked stents and cause inner and outer scratches. Regularly maintain the ultrasonic machine, including cleaning the tank and properly adjusting the nozzles

Fig: 7 Before Process (This is an inner outer scratch type rejection this type of rejection has occurred during descaling process when more samples are put in the beaker)

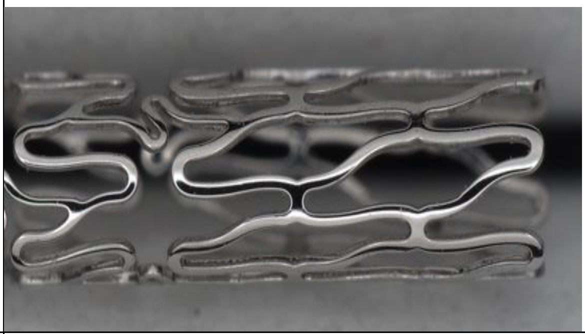

Fig: 8 After Process (When put the less samples in the beaker so got an effective result)

- That kind of rejection mostly occurs during the descaling process when stents are collided with each other, so its outer surface are damage during the process, so we do an experiment and put a less sample during the descaling process that's why we get a better result.
- Many rejections occur specially done in electropolishing process like material polish, welding, surface issue, dimension variation and over polishing. So that kind of rejection is reduced to do Proper post-polishing cleaning removes polishing residues. Ensure that operators are trained in the latest techniques, equipment maintenance, and quality standards to avoid preventable errors. Implement automated inspection tools such as *optical or scanning electron microscopy (SEM)* to detect surface irregularities early in the process, allowing for timely corrective actions. Use SPC tools to continuously monitor quality throughout the production line. This allows for early detection of potential defects and helps in identifying trends that may lead to rejections.

Fig: 9 Before Process (This type of rejection occurs when the particle get occurs the stent)

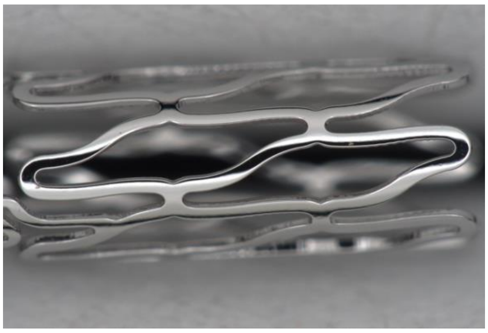

Fig: 10 After Process (proper washing during the process)

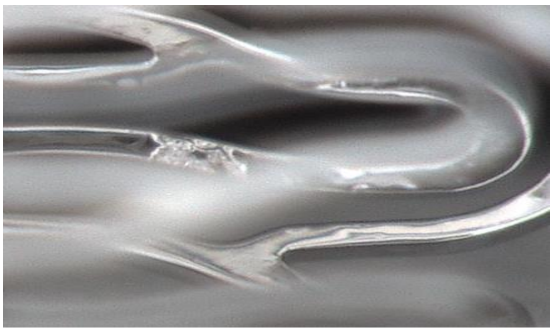

Fig: 11 Before Process (This type of rejection occurs when the particle get occurs the stent)

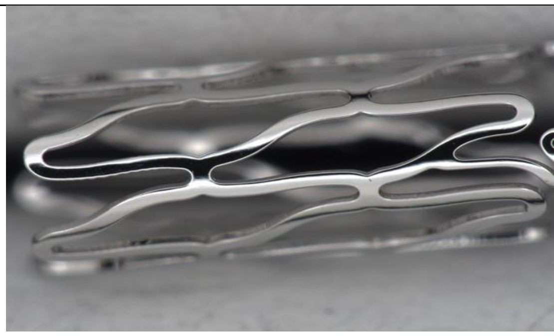

Fig: 12 After Process (proper washing during the process)

- These are the main reduced rejections during the electropolishing process. This is a material polish and welding during the polishing process so post proper washing the polishing process as well as during the process that kind of rejection are reduced.

5. **Optimization and Feedback:**

- Based on the results from the measurements and inspection, the process parameters (current density, electrolyte composition, temperature, and time) were fine-tuned to reduce defects and rejections.
- A statistical process control (SPC) method was employed to track defect rates and continuously improve the process.

Result :

The rejection rate was significantly reduced from 25% to 13% in this study, demonstrating substantial progress in stent manufacturing. This 70% reduction represents a remarkable improvement in manufacturing efficiency, contributing to a more sustainable and profitable process by enhancing operational productivity and substantially reducing waste and associated costs. Unlike earlier studies, which primarily emphasized specific elements of the manufacturing process—such as automation, material selection, or surface evaluation—this research adopts a comprehensive approach. Previous studies have similarly reported improvements in rejection rates, often attributed to advancements in laser cutting precision, electropolishing techniques, or surface treatment optimization. While these innovations have undeniably contributed to the field's advancements, the findings of this study underscore the benefits of broader process modifications.

The significant reduction observed here reflects the efficacy of interventions such as enhanced quality control throughout the production cycle, advancements in machining technology, and improved material handling procedures. These measures not only improve the consistency and reliability of stent manufacturing but also enable production scaling while maintaining stringent quality standards. Additionally, the results suggest the potential for further enhancements in manufacturing methodologies. Emerging technologies, such as advanced robotics for precision handling, machine learning for predictive quality control, and environmentally sustainable materials, could achieve even greater reductions in rejection rates. These findings underscore the importance of integrated manufacturing techniques and sustained innovation to drive long-term growth in the medical device industry.

In conclusion, this study provides compelling evidence that process optimization can revolutionize stent manufacturing, setting a benchmark for improving production efficiency, reducing waste, and enhancing the quality of medical devices.

Conclusion:

A systematic investigation of critical process parameters, combined with real-time monitoring and post-process analysis, was employed to optimize the electropolishing process and ensure superior surface quality and dimensional precision. Continuous feedback from these evaluations facilitated process refinements, thereby minimizing defects and improving overall yield. Effectively reducing stent rejection rates during manufacturing requires a multifaceted approach integrating advanced materials, precision manufacturing technologies, and enhanced quality control methods. The application of AI-driven quality systems and improved surface treatments demonstrates significant potential to further lower defect rates.

The implications of reduced rejection rates are profound, contributing to enhanced product reliability and improved patient outcomes. Higher-quality stents, meeting stringent design specifications, are associated with decreased risks of complications such as restenosis and thrombosis, directly benefiting patient safety. Additionally, reduced rejection rates lower production costs by minimizing material waste and reducing labor associated with rework, particularly advantageous in stent manufacturing, where raw materials such as cobalt chromium or nitinol are expensive.

However, challenges persist due to the stringent precision requirements of complex stent designs, the multi-step manufacturing process, and the capital-intensive nature of advanced technologies. Future research should prioritize innovations in surface coatings, manufacturing technologies, artificial intelligence, machine learning, and smart manufacturing platforms, alongside strategies for improving material consistency and supply chain management, to address these limitations effectively.

REFERENCES:

1. D. Landolt: 'Fundamental aspects of electropolishing', Electrochim. Acta, 1987, 32, 1–11.
2. K. B. Hensel: 'Electropolishing', Metal Finishing, 1999, 97, 440–448.
3. T. Hahn and A. Marder: 'Effect of electropolishing variables on the current density-voltage relationship', Metallography, 1988, 21, 365–375.
4. D. Landolt, P.-F. Chauvy and O. Zinger: 'Electrochemical micromachining, polishing and surface structuring of metals: fundamental aspects and new developments', Electrochim. Acta, 2003, 48, 3185–3201.
5. D. Landolt, P.-F. Chauvy and O. Zinger: 'Electrochemical micromachining, polishing and surface structuring of metals: fundamental aspects and new developments', Electrochim. Acta, 2003, 48, 3185–3201.
6. J. Wang, C. J. Tarapata and M. J. Fitz: 'Electro-polishing fixture and electrolyte solution for polishing stents and method,' U.S. Patent No. 6,375,826; 2002
7. M. Datta and L. T. Romankiw: 'Electrochemical tool for uniform metal removal during electropolishing,' U.S. Patent No. 5,217,586; 1993.
8. D. Gabe: 'Toward a universal electropolishing solution', Metallography, 1972, 5, 415–421
9. . J. Toušek: 'Electropolishing of metals in alcoholic solution of sulphuric acid', Electrochim. Acta, 1977, 22, 47–50
10. H. Hocheng and P. Pa: 'The application of a turning tool as the electrode in electropolishing', J. Mater. Process. Tech., 2002, 120, 6–12.
11. C. Wagner: 'Contribution to the theory of electropolishing', J. Electrochem. Soc., 1954, 101, 225–228