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Application of AHP and TOPSIS Approaches in Evaluating Pacemaker Manufacturing Methods Using Multi-Criteria Decision Making

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Abstract
Pacemakers are vital biomedical devices used in the treatment of cardiovascular diseases. The selection of the most appropriate manufacturing technique for these devices is crucial in terms of biocompatibility, precision, and production quality. In this study, eight different manufacturing techniques were evaluated using Analytic Hierarchy Process (AHP) and the Technique for Order Preference by Similarity to Ideal Solution (TOPSIS). The criteria weights determined by AHP were machining precision (0.4369), surface roughness (0.2942), defect rate (0.1947), and processing time (0.0742). According to the TOPSIS analysis, the most suitable manufacturing method was determined as EDM (C_i = 0.9621). This analysis provides a systematic and objective approach for decision-makers in the pacemaker production field.

Keywords: *Pacemaker, AHP, TOPSIS, Manufacturing Methods, Multi-Criteria Decision Making*

1. Introduction

A pacemaker is a vital medical device that generates appropriate electrical impulses to maintain the heart's regular rhythm when the heart's natural electrical impulse system fails. It is widely used, particularly in cases of bradycardia, complete atrioventricular block, and some cases of congestive heart failure. These devices not only support heart function but also significantly improve patients' quality and duration of life [1].

Pacemaker systems generally consist of the housing (pulse generator), electrodes, and battery components. Because these components are implanted inside the body, they must be long-lasting, biocompatible, and reliable. Therefore, the production of these devices should consider not only engineering accuracy but also factors such as biomedical requirements, tissue compatibility, and surface characteristics to prevent infection [2].

With the development of modern manufacturing technologies, methods such as CNC machining, laser cutting, electropolishing, and electrical discharge machining (EDM) have become the preferred advanced manufacturing techniques for pacemaker production. These methods directly impact many important technical parameters, such as surface roughness, process precision, processing time, and defect rate [3]. Therefore, optimizing the manufacturing process is a strategic factor that directly impacts the overall performance of the device and patient safety.

However, studies systematically comparing pacemaker manufacturing methods using a holistic, multi-criteria approach are quite limited in the literature. This study aims to evaluate manufacturing methods from both biomedical and manufacturing engineering perspectives using multi-criteria decision-making techniques, namely the Analytical Hierarchy Process (AHP) and TOPSIS. Thus, the aim is to select the most appropriate method for the pacemaker manufacturing process.

2. Literature Review

Pacemaker production is a multidisciplinary engineering process that intersects biomedical engineering and advanced manufacturing technologies. The literature addresses this process under various headings, including the types of materials used, surface treatments applied, ensuring biocompatibility, and the reliability of assembly methods [4].

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2.1. Materials and Surface Treatments Used in Pacemaker Manufacturing

The most commonly preferred metal among the materials used in pacemaker manufacturing is titanium and its alloy, Ti-6Al-4V. This alloy's high biocompatibility, low density, and excellent corrosion resistance to body fluids make it an ideal choice for implant applications [5]. Titanium is also prominent in medical devices due to its compatibility with MRI (magnetic resonance imaging) [4].

Surface roughness (Ra) has a direct impact on an implant's cellular adhesion, infection risk, and tissue interaction. Electrochemical polishing, in particular, can reduce surface roughness, reducing the Ra value to the 0.01–0.1 μm range. This both enhances cell adhesion and provides protection against corrosion [6].

Mechanical surface preparation processes, such as sandblasting and sanding, can be applied before electropolishing to increase surface homogeneity. However, these procedures should be applied in a controlled manner as micro-roughnesses that may occur after these procedures may cause problems in bacterial adhesion and tissue integration [7].

2.2. Advanced Manufacturing Methods and Assembly Techniques

CNC machining is a widely used method for precisely creating the complex geometric structures of pacemaker bodies. CNC turning, in particular, can achieve accuracy levels of ±5 μm. Laser cutting, on the other hand, is preferred for machining titanium alloys, offering fast cutting within tight tolerances [8].

Electrical Discharge Machining (EDM) is ideal for precise surface finishing and the creation of complex geometries because it shapes the workpiece without physical contact. However, its relatively long processing time can create time constraints in mass production processes [9].

In the assembly process, laser welding and ultrasonic welding techniques are prominent. Laser welding enables the joining of biocompatible metals such as titanium with low heat input, while ultrasonic welding is particularly used for joining plastic and composite parts. Technical parameters of these welds, such as joint strength, surface stability, and error rates, directly determine production reliability [10].

2.3. Gaps in the Literature

Existing academic studies on pacemaker production generally examine the impact of a specific production or assembly method on a technical or biological property. For example, topics such as the effect of laser welding on joint strength or the contribution of electropolishing to corrosion resistance are addressed separately [11]. However, in vital implant devices like pacemakers, not just a single parameter but multiple criteria such as precision, biocompatibility, surface quality, processing time, production cost, and error rate are simultaneously important.

Despite this, studies that systematically and holistically evaluate all of these criteria are quite limited. Selecting a manufacturing method using multi-criteria decision-making (MCDM) methods, such as AHP (Analytical Hierarchy Process) and TOPSIS (Technique for Order Preference by Similarity to Ideal Solution), has been largely overlooked in the literature [12]. However, these methods enable objective and scientific decisions to be made by considering the importance of different criteria.

This study presents a multi-criteria analysis that combines both biomedical engineering and manufacturing technology perspectives to address existing shortcomings. This aims to ensure that engineering decisions regarding manufacturing processes are based not only on technical expertise but also on analytical methods.

3. Pacemaker Manufacturing Methods

Pacemaker manufacturing is a complex process that combines high-precision mechanical processes with surface treatment methods that enhance biocompatibility. This section presents the primary mechanical and surface treatment methods used in pacemaker body manufacturing, based on scientific data.

3.1. Mechanical Manufacturing Methods

Table 1 summarizes the main manufacturing and post-processing methods used in pacemaker production, along with their specific application areas and functional purposes. The listed methods cover primary shaping processes, precision machining operations, surface finishing techniques, and post-processing treatments applied to titanium and stainless steel pacemaker housings. Each method contributes to critical requirements such as dimensional accuracy, surface quality, biocompatibility, and mechanical reliability, which are essential for the long-term performance and safety of implantable cardiac devices.

Table 1. Manufacturing and Post-Processing Methods Used in Pacemaker Production

	USAGE AREA ON PACEMAKER	PURPOSE OF USE
CNC Turning	Forming the external shape of titanium and stainless steel cases. Manufacturing of precision cylindrical parts (e.g. screw housings).	Creating cylindrical and symmetrical parts with high precision. Ensuring flawless surface quality and desired dimensional tolerances.
CNC Drilling	Machining the connection holes required for assembly into the titanium case. Preparing the mounting slots for electronic components	Drilling holes and creating connection points with precise tolerances. Ensuring correct placement of electronic components.
Sandblasting	Removing roughness from the case's exterior. Preparing the surface for biocompatibility and subsequent processing (e.g., electropolishing).	Creating a smooth and aesthetic surface. Preparing the surface for processes such as painting, coating and polishing.
Sanding	Removing roughness from the case's exterior. Preparing the surface for biocompatibility and subsequent processing (e.g., electropolishing).	Creating a finer surface finish. Increasing the effectiveness of finishing processes such as electropolishing or coating.
EDM (Electrical Discharge Machining)	Drilling complex geometries and fine holes. Detailed operations on hard materials (e.g., titanium).	Creating precise shapes and holes with minimal thermal damage. Machining areas inaccessible with traditional methods.
Electropolishing	Polishing of titanium and stainless steel surfaces. Removal of microscopic surface irregularities.	Increasing the biocompatibility of the surface. Improving corrosion resistance and aesthetic appearance..
Laser Cutting	Precisely cutting the required shapes for the case. Preparing the mounting points and holes.	Creating shapes and joints with high precision. Processing with minimal material waste and deformation.
Heat Treatment	Increasing the durability of the titanium case. Reducing internal stresses and ensuring the longevity of the device.	Increasing the mechanical strength of the case. Ensuring the device's longevity and reliability.

3.2. Numerical Performance Data for the Evaluated Production Methods

Technical performance data for the production methods to be used in the multi-criteria analysis are summarized in the table below. These data were compiled based on a literature review and international standards. Critical metrics such as average machining accuracy, surface roughness (Ra), processing time, and defect rate for each method were determined, and numerical comparisons were conducted for use in the TOPSIS analysis.

Table 2. Numerical Performance Data of the Evaluated Manufacturing Methods

Method	Average Machining Precision (µm)	Average Surface Roughness (µm)	Processing Time (min/piece)	Defective Part Rate (%)	Resources
CNC Turning	±10	0.8	6	0.4	[13], [14], [ISO 2859-1]
CNC Drilling	±7	0.6	2	0.3	[13], [14], [ISO 2859-1]
Sandblasting	±15	1.5	3	0.5	[15], [16], [ASTM F86]
Sanding	±12	0.25	4	0.4	[15], [16], [ASTM F86]
EDM	±2	0.2	20	0.5	[17],[18], [ASTM E29]
Electropolishing	±5	0.05	4.5	0.2	[19], [20], [ASTM B912]
Laser Cutting	±5	0.3	3	0.3	[21], [22], [ISO 9013]
Heat Treatment	±10	1.6	200	0.3	[23], [24], [ASTM E8]

Table 2 presents the numerical performance data of the manufacturing and post-processing methods evaluated in this study. The methods are quantitatively compared based on four critical technical criteria: average machining precision, average surface roughness, processing time per part, and defective part rate. The values reported in the table were compiled from the relevant literature, international standards, and experimental studies, providing a consistent and objective data set for subsequent AHP and TOPSIS analyses. These parameters directly reflect the dimensional accuracy, surface quality, production efficiency, and reliability requirements of pacemaker manufacturing.

Table 3 presents the pairwise comparison matrix used in the Analytical Hierarchy Process (AHP) to determine the relative importance of the evaluation criteria. The criteria were compared using Saaty's 1–9 scale based on their impact on pacemaker manufacturing performance. The matrix reflects the decision makers' judgments regarding the relative importance of machining accuracy (sensibility), surface quality, processing duration, and defective part rate, forming the basis for the calculation of criterion weights and subsequent consistency analysis.

Table 4 outlines the rationale behind the pairwise comparisons of the evaluation criteria used in the AHP analysis. Each comparison reflects the relative importance of the criteria in the context of pacemaker manufacturing, where dimensional accuracy, surface characteristics, and reliability are critical for implant safety and performance. The assigned preference rates are based on clinical relevance, manufacturing constraints, and international standards, emphasizing that precision and surface quality outweigh processing time in implantable medical device production.

Table 3. Pairwise Comparison Matrix.

	Sensibility	**Surface Quality**	**Duration**	**Faulty Part**
Sensibility	1	2	2	5
Surface Quality	0.5	1	2	4
Duration	0.5	0.5	1	3
Faulty Part	0.2	0.25	0.333	1

Table 4. Reasons for choosing the criteria used in the study.

To compare	Preferred Criterion	Preference Rate	Reason
Machining Accuracy and Surface Roughness	Processing Accuracy	2	Submicron dimensional precision is vital in pacemaker manufacturing, and if the part is out of tolerance, it will lead to assembly mismatch or implant failure.
Processing Accuracy vs. Processing Time	Processing Accuracy	4	Dimensional accuracy, not time, is critical for intracardiac implants. Time is secondary to production optimization..
Machining Accuracy vs. Defective Part Rate	Processing Accuracy	3	A large portion of defective parts is already caused by precision deviations. Improving precision indirectly reduces the error rate.
Surface Roughness vs. Processing Time	Surface Roughness	3	Surface roughness is critical for protein adsorption, inflammation, and tissue response on body-contact surfaces.
Surface Roughness vs. Defective Part Rate	Surface Roughness	2	Roughness values directly affect biocompatibility according to ISO 10993-1.
Processing Time vs. Defective Part Rate	Defective Part Rate	3	While optimizing time is important, an increase in defective parts is unacceptable in medical device manufacturing.

Basic Formulas Used in AHP Calculation:
Each element in the pairwise comparison matrix is normalized by dividing it by the sum of its column. Thus, the sum of each column of the resulting normalized matrix is 1.

Calculating the row average of the normalized matrix (criterion weights):

$$a_{ij}^{*} = \frac{a_{ij}}{\sum_{i=1}^{n} a_{ij}}, \quad i,j = 1,2,\ldots,n$$

Calculating the Priority (Weight) Vector:
The values in each row of the normalized matrix are summed and averaged by dividing by the number of rows (n). The resulting values form the priority vector, which represents the relative weights of each criterion.

$$w_i = \frac{1}{n}\sum_{j=1}^{n} a'_{ij}, \quad i = 1,2,\ldots,n$$

Calculating the Consistency Ratio:
In AHP, the consistency of the matrix is tested to ensure the reliability of pairwise comparisons. To do this, the maximum eigenvalue (λ_max) is first calculated:

$$\lambda_{\max} = \frac{1}{n}\sum_{i=1}^{n} \frac{(Aw)_i}{w_i}$$

From here, the Consistency Index (CI) is obtained: The Consistency Ratio (CR) is calculated by comparing the CI value with the Random Consistency Index (RI).

$$CR = \frac{CI}{RI}$$

For the decision matrix to be considered consistent, CR<0.1CR < 0.1CR<0.1.

Dielectric barrier discharges are usually induced by Weights are configured based on priorities found in the literature. Therefore, AHP outputs are generated in line with multi-criteria decision-making logic. When these formulas are substituted, the results are obtained.

Comparison of Mathematical Results of Calculations and Results Found via MATLAB. When you substitute the mathematical calculation results into the formulas, you get the following results:

Table 5. Weights

Criterion	Weight
Machining Accuracy	**0.**4369
Surface Roughness	**0.**2942
Defect Part Rate	**0.**1947
Processing Time	**0.**0742

Table 5 presents the final criterion weights obtained from the AHP analysis. The results indicate that machining accuracy is the most influential criterion, followed by surface roughness and defective part rate, while processing time has the lowest relative importance. This weighting structure highlights the dominance of precision- and quality-related factors

over time efficiency in the manufacturing of implantable medical devices such as pacemakers.
It was found in the form of.

The maximum eigenvalue of the decision matrix (λ_{max}) is calculated

$$\lambda\_max = 4.0564$$

This value should be equal to the number of criteria in an ideal consistency situation. The resulting λ_{max} = 4.0564 is very close to the theoretical value of 4.000 in the four-criteria system. This indicates that the decisions were largely consistent. The Consistency Index (CI) was then found as follows:
CI (Consistency Index) = 0.0188
The CI obtained here was compared with the Random Consistency Index (RI = 0.90) to obtain the Consistency Ratio (CR):
CR (Consistency Ratio) = 0.0209 , the matrix is consistent.
Since CR < 0.1, the decision matrix is consistent and AHP calculations were performed reliably.

Matlab Code Output
AHP RESULTS ---
Criteria Weights (w):
0.4369
0.2942
0.1947
0.0742

λ_max: 4.0564
CI: 0.0188
CR: 0.0209
The matrix is consistent (CR < 0.10).
Graphs Obtained as a Result of Calculations with MATLAB.

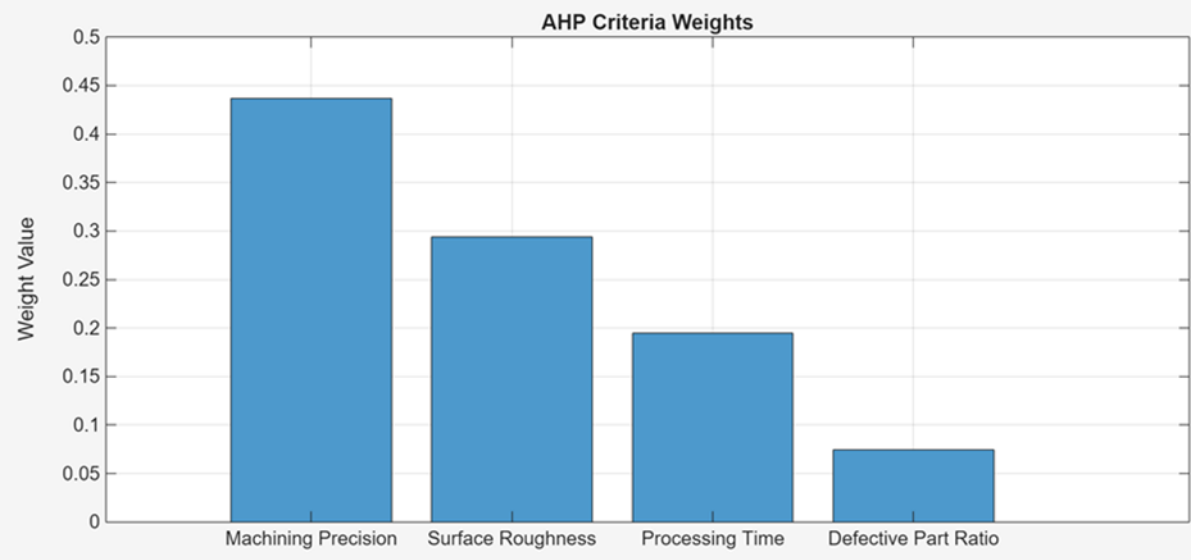

Figure 1. AHP Criteria Weights Graph

Figure 1 illustrates the relative weights of the evaluation criteria obtained using the Analytical Hierarchy Process (AHP). The results indicate that machining precision has the highest importance, followed by surface roughness and defective part ratio, while processing time has the lowest weight. This distribution reflects the prioritization of dimensional accuracy and surface quality over production speed in the manufacturing of implantable medical devices such as pacemakers.

The reliability of the criterion weights obtained using the AHP method was verified using Saaty's consistency test. This verification process aims to understand the degree of consistency between decision makers in pairwise comparisons. First, the maximum eigenvalue of the decision matrix (λ_{max}) is calculated. This value should ideally equal the number of criteria for consistency. The resulting λ_{max} = 4.0564 is very close to the theoretical value of 4.000 in the four-criteria system. This indicates that the decisions were largely consistent.

The Consistency Index (CI) was then calculated using the following formula:

$$CI = \frac{\lambda_{max} - n}{n - 1} = \frac{4.0564 - 4}{3} = 0.0188$$

The CI obtained here was compared with the Random Consistency Index (RI = 0.90)** to obtain the Consistency Ratio (CR):

$$CR = \frac{CI}{RI} = \frac{0.0188}{0.90} = 0.0209$$

According to Saaty, a decision matrix is considered consistent when CR < 0.10. Since the CR = 0.0209 obtained in this study is well below this threshold, it is concluded that there is significant consistency among the decision-makers' preferences.

This result demonstrates that decision-makers' assessments are scientifically based and that the resulting weights can be used confidently in the AHP process. Thus, the relative importance of the criteria has both logical and methodological validity.

4. Ranking Methods with TOPSIS

The TOPSIS (Technique for Order Preference by Similarity to Ideal Solution) method is a multi-criteria decision-making technique that minimizes the distance of each alternative from the positive ideal solution and maximizes its distance from the negative ideal solution.

In this method, a weighted normalized decision matrix is created by applying criterion weights to the normalized decision matrix, and the C_i score for each alternative is calculated. The C_i score represents the relative proximity of each alternative to the ideal solution; the closer the score is to 1, the more suitable the alternative is.Normalized matrix:

$$r_{ij} = \frac{x_{ij}}{\sqrt{\sum_{i=1}^{m} x_{ij}^2}}$$

[27]

Weighted normalized matrix:

$$v_{ij} = w_j \cdot r_{ij}$$

[25]

Positive (ideal) and negative (anti-ideal) solution:

$$A^+ = \{\max_i v_{ij}\}, \quad A^- = \{\min_i v_{ij}\}$$

[28]

Distance measurement using each alternative:

$$S_i^+ = \sqrt{\sum_{j=1}^{n}(v_{ij} - A_j^+)^2}, \quad S_i^- = \sqrt{\sum_{j=1}^{n}(v_{ij} - A_j^-)^2}$$

[29]

Calculating the relative proximity score:

$$C_i = \frac{S_i^-}{S_i^+ + S_i^-}, \quad 0 \le C_i \le 1$$

[30]

When comparing the mathematical results of the calculations with the results obtained via MATLAB:
$0 \le C_i \le 1$, $C_i \approx 1 \rightarrow$ The best alternative,
$C_i \approx 0 \rightarrow$ The worst alternative

TOPSIS scores each method based on multiple criteria, allowing us to select the one that is closest to the best and farthest from the worst. Weights from AHP are integrated into TOPSIS.
When we apply the formulas, the C_i Score values are obtained as follows;

Table 6. Results

Method	C_i Score	Ranking
EDM	0.9621	1
Electropolishing	0.8606	2
Laser Cutting	0.6841	3
Sanding	0.4433	4
CNC Turning	≈0.4076	5
CNC Drilling	≈0.3730	6
Sandblasting	≈0.1585	7
Heat Treatment	≈0.0233	8

Table 6 presents the ranking results of the evaluated manufacturing methods based on their relative closeness coefficients (C_i) obtained from the TOPSIS analysis. The results indicate that Electrical Discharge Machining (EDM) achieved the highest C_i score, demonstrating the most balanced performance across all evaluation criteria. Electropolishing and laser cutting follow as the second and third most suitable methods, respectively, while heat treatment exhibits the lowest score, indicating limited suitability as a standalone manufacturing method for pacemaker production.

In this study, the highest C_i score, 0.9621, belongs to the EDM (Electrical Discharge Machining) method. This demonstrates that EDM exhibits a more balanced and superior performance compared to other methods

across all technical criteria (machining accuracy, surface quality, processing time, and defect rate). Submicron precision and the ability to process complex geometries, in particular, make EDM a prominent choice for implant devices such as pacemakers.

The consistency of the criterion weights obtained with the AHP method with CR < 0.10 confirms that the TOPSIS analysis is built on a solid foundation. Thus, the EDM method stands out as the most suitable method not only in terms of technical parameters but also in terms of the reliability of the decision model.

Matlab Code Output
--- TOPSIS RESULTS ---
CNC Turning Ci: 0.4991 -> Rank: 4
CNC Drilling Ci: 0.3730 -> Rank: 6

Sandblasting Ci: 0.1585 -> Rank: 7
Polishing Ci: 0.4433 -> Rank: 5
EDM Ci: 0.9621 -> Rank: 1
Electropolishing Ci: 0.8606 -> Rank: 2
Laser Cutting Ci: 0.6841 -> Rank: 3
Heat Treatment Ci: 0.0233 -> Rank: 8

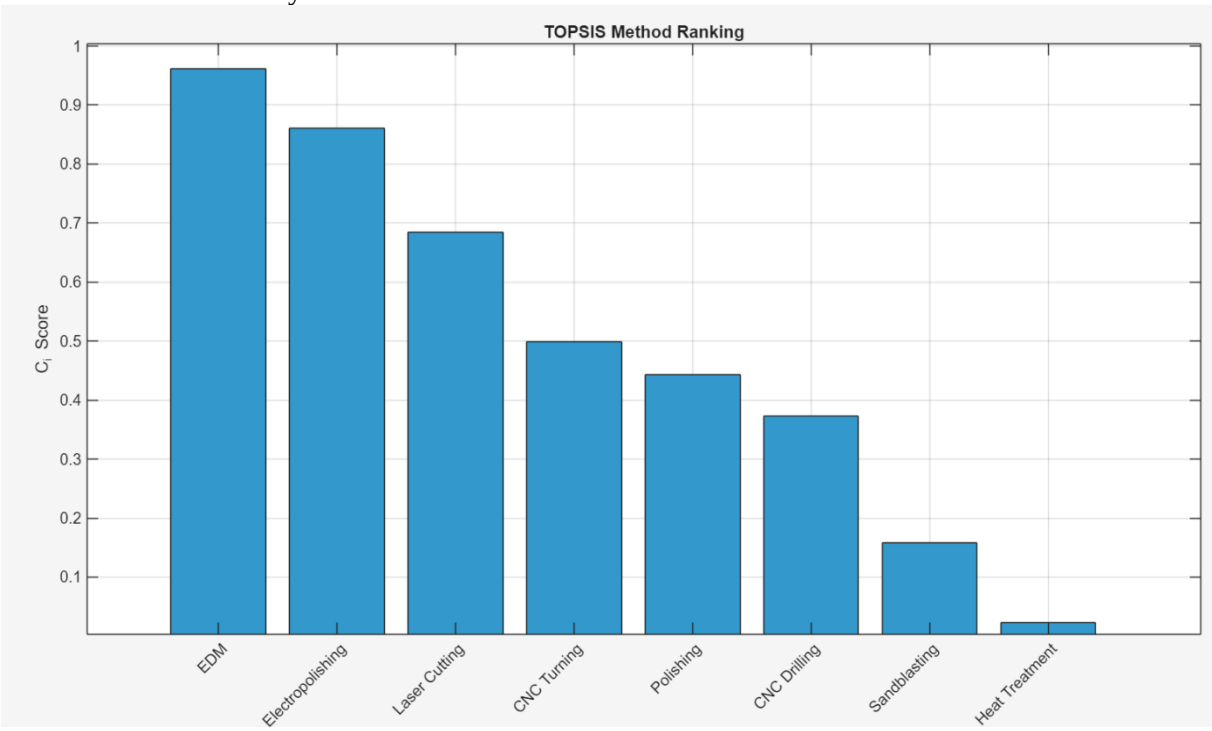

Figure 2. TOPSIS Method Ranking

Figure 2 illustrates the ranking of the evaluated manufacturing and post-processing methods based on their relative closeness coefficients (C_i) obtained from the TOPSIS analysis. The results show that EDM achieved the highest C_i value, indicating the closest proximity to the ideal solution, followed by electropolishing and laser cutting. Methods such as sandblasting and heat treatment exhibit significantly lower scores, reflecting their limited suitability as standalone processes in pacemaker manufacturing.

5. Conclusions

In this study, eight different manufacturing methods used in pacemaker production were analyzed using multi-criteria methods using the AHP (Analytical Hierarchy Process) and TOPSIS. The relative importance of the criteria was determined as follows: machining accuracy (0.4369), surface roughness (0.2942), defect rate (0.1947), and processing time (0.0742). This distribution demonstrates that precision and surface quality are the primary criteria in the production of vital medical devices such as pacemakers.

A consistency analysis conducted to test the reliability of the AHP results yielded values of $\lambda\_max = 4.0564$, CI = 0.0188, and CR = 0.0209. Since CR < 0.10, the decision matrix was confirmed to be consistent. The mathematical calculations performed here were repeated in MATLAB, yielding the same results. This demonstrated that the calculation steps were validated both theoretically and software-based. This verification demonstrates that the criterion weights can be used reliably in the analysis.

When the alternatives were ranked using the TOPSIS method, EDM (Electrical Discharge Machining) was

determined to be the most suitable manufacturing method, receiving the highest C_i score (0.9621). EDM was followed by electropolishing (0.8606) and laser cutting (0.6841), respectively. Heat treatment (0.0233) was also evaluated as the least suitable method, with the lowest score. This ranking supports the superior performance of EDM, particularly in dimensional accuracy and surface quality.

In conclusion, the results obtained from the AHP and TOPSIS methods support each other and demonstrate the methodological soundness of the analysis process. The full compatibility between the mathematical steps and the MATLAB application demonstrated both the accuracy of the calculations and the reliability of the method used. Thus, EDM emerged as the most suitable option for pacemaker production from both technical and biomedical perspectives.

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