Machinability and Biocompatibility Studies on Human Implant Material

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Abstract

In the present day and age, human implant materials are making significant strides in their application towards the biomedical sector. Human implants have piqued the interest of material and metallurgy researchers due to their unique properties. Stainless steel based human implant is widely used in orthopedic implantology, although biological complications may result from its insufficient mechanical and tribological properties. There are multiple forms of stainless steel starting with the introduction of type 302 for its application in orthopedic surgery. Type 316L stainless steel is commonly used in surgical procedures to replace biological tissue or to help stabilize a biological structure. To contribute further in the same area, the purpose of the current research work is to investigate the machinability of -SS-L107.12 (a stainless steel based human implant) using a non-traditional method called wire electrical discharge machining (WEDM). The machinability of the machining process has been evaluated based on the material removal rate, using a roughness meter and the atomic force microscope. The further impact of the machining parameters on the output responses was analyzed based on the statistical analysis.

Keywords: Human Implant Material, Titanium, Roughness, material removal rate (MRR), Machinability and Biocompatibility.

1. **Introduction**
2. The use of biocompatible metals in medical implants at the time of the Industrial Revolution in the 19th century led to a period that saw the beginning aspects of the process of the metal industry. The key element that spurred the rise of the metal implant business was the growing need for surgical treatments to repair broken bones. These operations often include the internal healing of long bone fractures. However, until the aseptic method of Lister's surgery was used in the 1860s, there were so few successes in attempts to implant metal appliances like bone pins & spinal wires composed of gold, silver, or iron. These attempts were met with extremely limited levels of success. Up until recently, there were relatively few obstacles that needed to be overcome in order to implant metal appliances. After that, biocompatible metals led to the development of orthopedic applications that currently play an important role in orthopedic appliances. These orthopedic appliances include both temporary appliances like bone plates & pins and screws, & permanent implants such as overall joint replacement. In the meanwhile, biocompatible metals can also be found in orthodontic and dental applications, like dental roots & fillings. This is because these metals can be used without causing any adverse reactions. This is due to the fact that there is no chance of an allergic response

while using these metals. Applications such as vascular stents make use of shape-memory alloys made of nitinol, while magnesium-based improvements on more contemporary alloys are employed for tissue engineering & bone regeneration. Recently, increased research of biocompatible metals has been progressed for the non-conventional reconstructive surgery of organs & hard tissue application. This study is being done in preparation for the use of these metals. These metals include magnesium-based alloys that increase current alloys' performance, which may be used for tissue engineering and bone regeneration. Only a tiny percentage of the alloys and metals that are produced during the manufacturing process are biocompatible and have the potential to be realized in a permanent form as implant materials. This is despite the fact that the manufacturing process may create a large range of alloys and metals..

2.1 Implant Materials

Medical industry's use of biocompatible materials has grown dramatically during the previous two decades. Gold, silver, & iron are some of the metals that are used most often in the production of long bone fracture pins & spinal cables. Joint/replacement fractured/damaged bone is the primary use of biocompatible materials in orthopedics. Through examination, these materials are put to use as long-term implants It is anticipated that alternative biomaterials will have an effect on major areas of burden, including spinal components, tumor bones, orthopedic joints, and dental components. Hence, It is essential to take into consideration both the mechanical strength and also the performance. Because the bone is so sensitive to changes in its mechanical properties, even at the microscopic level, implants have the potential to influence cellular responses such as

differentiation and mineralization. During the course of bone repair, the mechanical characteristics of the implant materials played a major role and had a significant effect. Combining a material's mechanical strength with its ability to withstand fractures is ideal for transplant materials. In comparison to the other types of materials, the tensile strength of metals is the greatest, followed by polymers & ceramics (except for zirconia). In comparison to ceramics, tensile strength, ductility, & resistance to corrosion are all areas in which metals excel. The metallic biomaterial has a number of deficiencies that need to be addressed. The most important one is the release of toxic elements from metals during the process of metallic corrosion. Among the most common kinds of examples are cobalt alloys, stainless steel alloys, titanium alloys, and several other kinds of metallic biomaterials. Since the 1930s, austenitic stainless steel was used in around ninety percent of osteosynthesis devices. Both the biocompatibility and the mechanical strength of the material were outstanding attributes. As a result of the outstanding strength-to-weight ratio that CO-based alloys possess, they are often used in the study of human anatomy. The inclusion of chromium at a concentration of more over 18 percent contributes significantly to both the inherent strength and the wear resistance of these material.

Implants made of vacuum-melted 316L stainless steel are available on the commercial market. Afterward Biomedical industries began employing titanium implants in the 1930s, and the titanium alloy has been employed as a technology in alloying and thermo mechanical beneficial to greatly strengthened and also low-density

(4.5g/cm3) titanium alloy implants. Vacuum processing necessitated a high temperature to avoid the formation of a reaction with oxygen. Pure titanium (Cp–Ti) is the only commercially available form of the four grades.

The present work has been focuses on stainless steel human implant materials for testing and evaluating their Machinability and Biocompatibility being a implant material using WEDM approach.

2.2 WEDM Technique

Machine tools, control systems, power supply units, and dielectric supply units are all included in the WEDM. In addition to the primary work table, the tool control section includes an auxiliary work table, a wire feed mechanism, and a wire cutter. There is a large work table on which the pieces of work are placed. One micron increments are used in servo motor control of axial movement. The U and V axes of the table are parallel to the X and Y axes, resulting in a flat configuration. Continuous feed is ensured by two guides on either side of the wire feed system (In and Out). Guides aid to maintain the wire's tension. Due to the U-V axis and lower guide being inactive, there is a transverse displacement of the top wire guide. To remove material from a work piece, an electrical spark is generated by the pulse generator unit. As a dielectric liquid, deionized water was used to keep the top and bottom work pieces hydrated. The low viscosity and rapid cooling speeds of deionized water are its primary advantages. The controller stores the route of the work item and shifts it transversely. Tilting the tapper as the X-Y table moves along a specified route and the U-V table remains stationary is required for a straight cut. To carry out the operations, the route information is completely controlled by the CNC(Wedm, 2015).

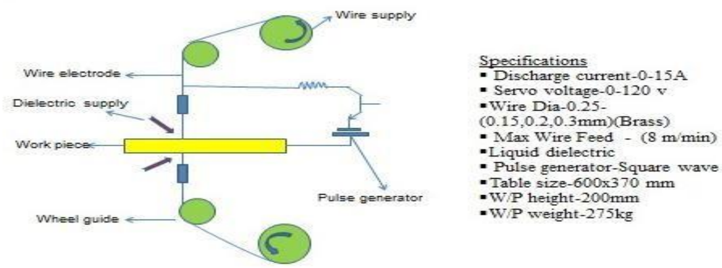

Figure 1: Schematic Diagram of the Basic Principle of the WEDM Process

2.2.1 Surface roughness

Over a given length, it may be summed up as a deviation from the nominal surface in the vertical axis. The micro-level profile of a machined surface's key nomenclature is,

(1) Roughness Distance from the nominal surface to the peak of the waviness.
(2) The Roughness Width is the distance between the peaks.
(3) The maximum spacing of irregularities included in the measurement is represented by the cut-off distance/width.
(4) In machining parlance, the term "lay" refers to the direction in which a surface pattern is generated as a

reflection of the machining process.

The roughness average (Ra), sometimes referred as the arithmetic mean of the precise quantity of each height slightly above nominal surface, is a metric which may be used to highlight the surface imperfections that are present. Ra is frequently referred to be the arithmetic mean of each height slightly above nominal surface. Roughness may also be addressed in terms of Roughness maximal (Rz), which is the distance between the highest point as well as the lowest point on the surface. This distance is measured from one point on the surface to the next. Similar to how this may be stated in terms of Roughness,

2.2.2 Material Removal Rate

Material removal rate, sometimes referred to as MRR, is the amount of material which is removed in a certain amount of time, with the objective of achieving higher levels of productivity overall. It is recommended that the MRR machining process continue its upward trajectory toward increased productivity without compromising surface quality (i.e., decrease in surface quality). High MRR combined with a high-quality surface finish should lead to increased productivity in the component production process.

3. Material and Method

For the purpose of this examination, orthopedic human implant materials that are available for purchase on the market were acquired for the research project. The technical grade of implants that were acquired from Catalogue, who served as the primary supplier of the implant material, L107.12 (Hole Diameter: 4.9 mm–12 Holes) material were used.

Tables 3.1 detail the material's nominal chemical composition, which may be obtained by looking at those tables.

The nominal composition of titanium-based human implant material of grade SS-L107.12 implant

Alloying elements in SS-L107.12	C	Mn	Cr	Ni	Mo	Si	S	P	Fe
Weight %	0.08	2	18	1.1	2	0.75	0.03	0.04	Balance

Wire Electrical Discharge Machining

The WEDM machine, which is computer aided and numerically controlled, is used in the performance of the experimental research (Model: ELEKTRA). The WEDM machines are made up of the power supply unit, the flushing unit, and the industrial machinery process speed.

The definition of the method makes use of deionized water as the dielectric medium, and the electrodes wire material is a half-hard EDM brass wire with a diameter of 0.25 millimetres.

Figure 2. ELEKTRA wire EDM machine

3.1 Specifications of the Equipment

The Machine, the Control cabinet, and the Work table are the three primary elements that comprise the ELEKTRA wire EDM. In the following table, Table 3.1, representation of the machine's specifications has been given.

Table 3.2 ELEKTRA wire EDM - technical specification

Parameters	**Value**
Main table traverse (X, Y)	300 mm x 400 mm
Aux. table traverse (u, v)	80mm x 80 mm
Table size	440 mm x 650 mm
Maximum taper angle	±30 degree/50 mm
Maximum workpiece height	200 mm
Maximum workpiece weight	300 kg
Resolution	0.0005 mm
Max. JOG speed	900 mm/min
Maximum wire spool capacity	5 kg
Wire electrode diameter	0.25 mm (std.) 0.15, 0.20 mm (opt.)
Least input increment	0.001 mm
Interpolation	Linear and circular

Table 3.2 provides an overview of the input process parameters that may be modified for implant machining. A problem has been constructed using the input variables and the MINITAB program to design twenty-one sets of input parameters combinations for experiments. This problem was built using the input variables.

Experiment design for machining implant material

Table 3.3: Experiment design for machining implant material

Run	Pulse on time	Pulse off time	Voltage
I	5	8	65
2	5	3	65
3	5	8	65
4	6	5	80
5	6	10	50
6	3	10	80
7	3	5	80
8	3	10	50
9	5	8	65
10	5	8	40
11	5	8	65
12	2	8	65
13	5	8	90
14	6	5	50
15	3	5	50

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3.2 SURFACE ROUGHNESS:

The values of the surface's two-dimensional roughness may be assessed using probe-style tester with an MITUTOYO roughness metre (model number: Surface test SJ 410; manufactured in Japan).which is configured in the manner seen in Figure 3. The Ra values show where the peaks

and troughs are located in a certain direction parallel to the path taken by the probe. The measures of the surface roughness are as follows:

Manufactured with a cut off value of 0.8mm and thus are manufactured in the opposite direction from that in which the wire traverses, which ultimately results in increased values for the surface's roughness. Vertical moments were able to measure motions to an accuracy of 0.01 millimetres.

Figure 3. Surf test SJ 410 surface roughness tester

4. Results and Discussion

Surface roughness of the WEDM machined implants

Experiments were done using a statistical model that had already been set up, and the measured surface roughness is shown in table

Table 4.1 Surface roughness with reference to individual process parameters involved in machining titanium-based implant material

Run	T_{on}(µs)	T_{off}(µs)	Volt (V)	Ra (µm)
1	6	7	65	3.284
2	6	4	65	2.883
3	6	7	65	2.524
4	5	6	80	2.274
5	5	9	50	3.613
6	4	9	80	2.103
7	4	6	80	2.131
8	4	9	50	2.608
9	6	7	65	2.781
10	6	7	50	3.385
11	6	7	65	2.385
12	3	7	65	1.739

When it comes to surface roughness, the lowest voltage combined with either a pulse on (T on) or a pulse off (T off) has the most impact. The linearity goodness of fit (R 2 value) for the experimental data is 84.61 percent, confirming all of this. A linear regression equation for such a suggested model is created utilising the applied voltage (v) and the pulse on (T on) as the most essential parameters to analyse the theoretical difference in Ra. The regression line's equation is as follows.Surface roughness (Ra) = 8.6487 v (0.052418) Ton(-0.30245) You may compute the theoretical changes in surface roughness by adjusting the applied voltage and pulse on time.Surface roughness has a higher order response to diverse applied voltages as compared to pulse on time.

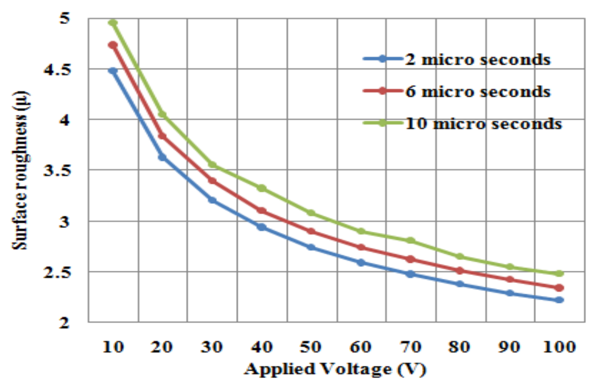


Figure 4. Theoretical variations in surface roughness with reference to applied voltage (*v*) at three different pulse on time (*Ton*)

Materials removal rate (MRR) = 0.01164 v (0.236211) Ton(-1.0997)(5)

Table 4.2 Surface roughness with reference to individual process parameters involved in machining stainless steel-based implant material

Run	***Ton*** **(μs)**	***Toff*****(μs)**	**Volt (V)**	***Ra (μm)***
1	6	8	65	3.173
2	4	3	65	2.192
3	4	8	65	2.912
4	5	5	80	2.190
5	6	10	50	3.504
6	3	10	80	2.403
7	4	8	50	3.475
8	5	8	65	2.675
9	2	8	65	1.529
10	5	8	90	1.994
11	6	5	50	3.269
12	3	5	50	3.126

The empirical calculations of the theoretical changes in surface roughness and the rate of material removal are accomplished by adjusting the applied voltage and the pulse on time.

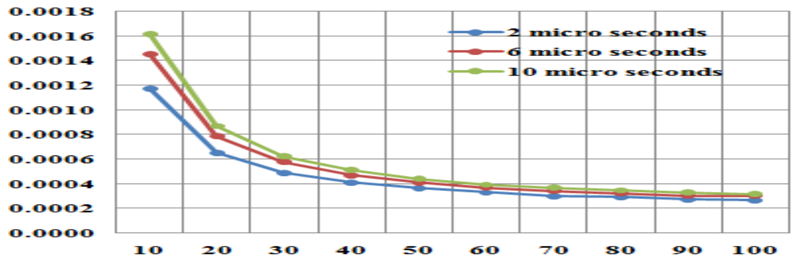


Figure 5. Theoretical variations in MRR with reference to applied voltage (*v*) at three different pulse on time (*Ton*)

Convergences are seen in the material removal rate when the voltage is increased to its maximum for a variety of pulse on times.

4.2. SS-L107.12 WEDM machined implants

Experiments that were conducted using a preset statistical model are submitted to a thorough examination. Following the conclusion of the inquiry, the experimental data are statistically analyzed to establish the contribution of each individual process parameter & their effect on machining. Figure 4.5 depicts the findings of this investigation.

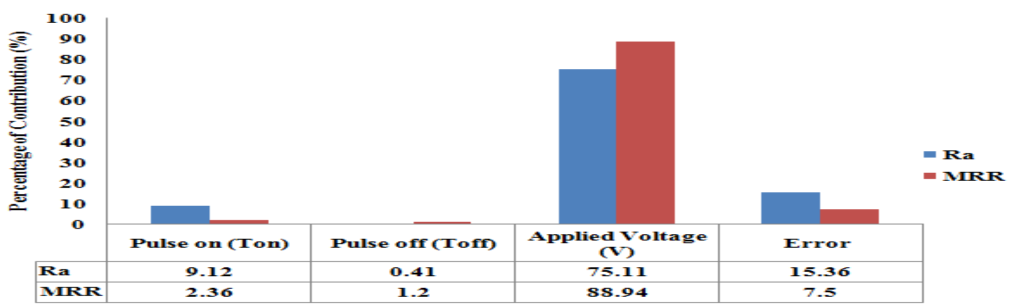
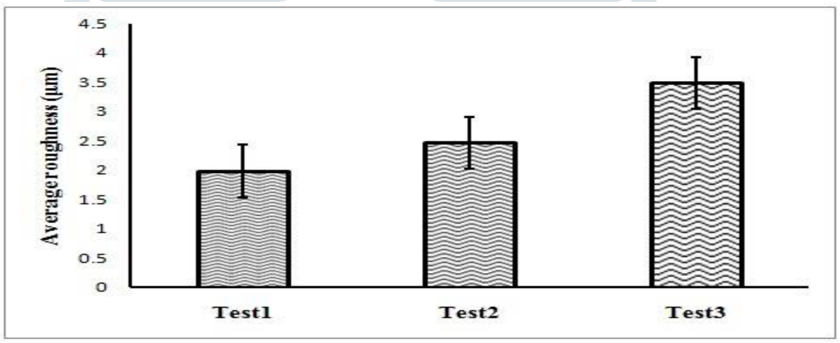


Figure 6. Level of process parameters contribution towards surface roughness (Ra) and material removal rate (MRR)

Calculating the contributions of the process parameters based on the results of an analysis of variance is an empirical approach (ANOVA). The three critical machining parameters for processing titanium-based human implant materials throughout the machining process are applied voltage (v), pulse on time (also known as T on), & pulse off time (also known as Toff). T on is another name for pulse on time. Toff stands for "pulse off time." Given this data, it is clear that the applied voltage is the most important variable in the operation, as it has a significant impact on both the surface polish (75.11%) and the rate of material removal (88.9 percent).

A wire-EDM machining process very similar to the one described above was carried out, & statistical analysis revealed that the voltage that was provided had a substantial influence on the surface finish produced. When machining is being done, the voltage that is being applied will, in the majority of instances, be directly involved in the formation of resistance as well as plasma arcs (between the wire and the contact zone) between the dielectric medium and the wire. The other two parameters are the management of the pulse on time for plasma spark creation and the surface finish and material removal contributions of the pulse on time (T on), respectively. The surface finish contribution of the pulse on time (T on) is 9 percent, and the material removal contribution is 2.3 percent. An related parameter is the pulse off time, which is also often referred to as T off Ra. MRR Pulse on (Ton) Take the plunge and do it (Toff) Applied Voltage (v) Error in the stated problem of creating trials, the importance of the factor Ra 9.12 (0.41 75.11 15.36 MRR 2.36 1.2 88.94 7.5) was found to be negligible. The variation in inaccuracy for Ra and MRR is due to the fact that the surface polish does not remain constant in relation to the quantity of material that has been removed.

Conclusion



In the figure above, the Ra value is measured in micrometer over the machined surface which was treated with WEDM. When the largest pulse on setting is utilized and the lowest applied voltage is chosen, it is fair to anticipate that the intensity of electro spark needed to machine the material will be reduced. With an increase with in high intensity of electro spark generated, the roughness of machined surface was revealed to be greater, while quality is discovered to be lower. In addition to the roughness assessment, the same surface is then investigated further using electron imaging and 3D profile surface analysis.

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