Medical Device Surface Finishing by ECM

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Abstract

Faraday Technology, Inc. researches and develops advanced electrochemical technologies for edge and surface finishing of difficult to machine metallic and alloy materials, prominent in the medical industry, such as titanium (Ti), Ti-alloys, stainless steel and Ni-Ti alloys, in the presence of water-based, neutral salt electrolytes (e.g. sodium chloride), unlike other finishing processes that work with highly acidic and toxic fluids. This advanced finishing technology involves alternating non-steady state electric field pulses of reverse polarity between the work piece and tool, instead of the usual direct current, maintaining electrolyte hydrodynamic uniformity in the interelectrode gap to improve metal removal rate and dimensional accuracy by removing heat, gas bubbles, and metal precipitation during the reverse and off-time. Further improvements in surface quality, such as decreasing surface roughness and reducing surface microdefects, are achieved by minimizing oxide film rehealing through a reduction of the oxygen concentration near the workpiece during the reverse period. The theoretical aspects of the advanced Faradayic process technology and results of particular interest to the medical field will be presented in this paper.

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Introduction

Medical devices require extensive finishing in order to satisfy strict design requirements for complete burr removal and excellent surface finishes. Without the proper finishing, devices may not achieve the design function and lifetime that is expected. Often conventional processes are not the best choice due to: (1) the low material removal rates realized for the alloys common to the medical industry, (2) relatively small sized features, and (3) high labor costs associated with manual operations. Advanced techniques are currently being utilized by the industry to address these issues. Examples of techniques currently practiced within the medical industry are electropolishing and glycol-based electrochemical deburring (ECD). In both cases, anodic dissolution occurs via an electrochemical reaction at the surface of the work piece. The advantage of these processes is the non-contact removal mechanism that is equally applicable to large complex surfaces as well as delicate geometries, which can easily be damaged using conventional contact processes.

Electropolishing and glycol-based ECD have proven to be successful in many applications; however, the use of difficult to control chemistries, which are not worker or environmentally safe, demand the development of alternative techniques. The advanced electrochemical process that is introduced in this paper is one such alternative.

Electrically controlled finishing (ECF) is an electrochemical process that is similar to the previous examples in that the metal removal mechanism is anodic dissolution. The main difference between the previous processes and ECF is the control mechanism that is used to limit the pattern of metal dissolution. ECF utilizes a pulsed electric field to drive the dissolution process as well as control the dissolution pattern. By shifting from chemical to electrical control, simple, water based, neutral salt electrolytes are used while realizing an enhancement to process control. For example, a common electrolyte used for the electropolishing of stainless steel is 41% sulfuric acid and 45% phosphoric acid at an elevated temperature of at least 77° C.[1] In ECF, similar results have been achieved at room temperature using a sodium nitrate based electrolyte with no difficult to control additives. Furthermore, ECF provides the capability of machining small cavities and circular, or non-circular, holes and slots in a single pass. When this is coupled with the finishing technology, the manufacturer has a strong set of tools to fabricate a wide range of components in the difficult to machine materials common to the medical device industry.

Electrically Mediated Process Parameters

At the heart of electrically mediated processes is the pulsed electric field. The electric field is obtained via a computer controlled power supply with the asymmetric waveform shape being entirely user defined. The shape of the waveform distinguishes this process from conventional, direct current (DC) electrochemical processes where the only user defined variable in terms of the electric field is a constant current or voltage value. This section identifies the parameters of the waveform that are available to the user.

A typical waveform consists of a forward voltage pulse held for some duration of time (V_{for} and t_{for}) followed by an off period (t_{off}) where no voltage is applied. For enhanced process control, a reverse voltage pulse held for a set period of time (V_{rev} and t_{rev}) may be necessary. The period of the waveform is the summation of the on times and off time. The frequency is the inverse of the period. The duty cycle is defined as the ratio of the on time to the period. Duty cycles are defined for both the forward, γ_{for}, and reverse, γ_{rev}, pulses. The average voltage, V_{avg}, is defined as:

$$V_{avg} = V_{for}\gamma_{for} - V_{rev}\gamma_{rev} \qquad \text{(Eq 1)}$$

where,

$$\gamma_{for} + \gamma_{rev} \leq 1 \qquad \text{(Eq 2)}$$

The average voltage influences the material removal rate, the dimensional accuracy, and the surface quality. Simple examples of pulsed waveforms are shown in Figure 1.

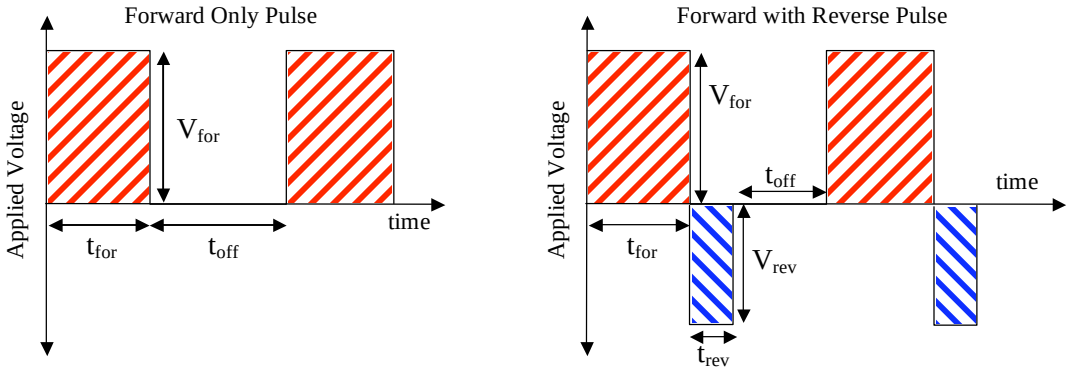

Figure 1. Simple Examples of Pulsed Waveforms

For a given average voltage, traditional DC processes are limited to only one process variable (the steady-state voltage or current). In an electrically mediated process, however, there are nearly an infinite number of process parameter combinations that can provide the desired average voltage. By selecting the appropriate combination of parameters, the mass transport rate, current distribution, and hydrodynamic condition can be strongly influenced during the metal dissolution process. A brief discussion regarding these conditions is given in the following paragraphs.

Mass Transport: When applying a pulsed electric field, mass transport becomes a combination of steady state and non-steady state diffusion processes. The theory of mass transport during non-steady state electrolysis has been discussed previously.[2,3,4] Under constant electric fields, the boundary layer thickness, δ, does not change with time and is defined by the cell geometry and solution hydrodynamic conditions. In pulsed processes, δ varies from 0 at the beginning of the pulse to its steady state value, which is equivalent to that developed under DC conditions. This suggests that the diffusion limiting current density would be infinite at time zero and would eventually reach the DC limiting current density. In pulsed processes, the current is interrupted before δ has a chance to reach its steady-state value. During the off time, the reacting ions diffuse back to the electrode surface. With the proper selection of the on time/off time ratio (defined as the duty cycle), the surface concentration is replenished to its original value. Therefore, the concentration of the reacting species, in the vicinity of the electrode, pulses with the applied waveform. By selecting the appropriate duty cycle, the concentration profile of the reacting species at the beginning of each pulse remains the same, enhancing the uniformity of the process.

To model the effects of applying a pulsed electric field, a "duplex boundary layer" consisting of a pulsating layer, δ_p, and a stationary layer, δ_s, has been proposed (shown schematically in Fig. 2).[5,6] By assuming a linear concentration gradient across the pulsating boundary layer and conducting a mass balance, δ_p is derived using the following equation:

$$\ddot{a}_p = \sqrt{k D t} \qquad (3)$$

where *k* is a constant, *D* is the diffusion coefficient, and t is the pulse length.

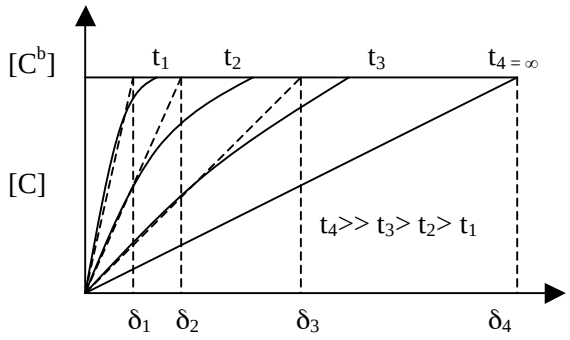

Figure 2. Schematic of the Duplex Boundary Layer Model

The limiting current density, assuming 100% efficiency, in pulsed processes, i_{pl}, and steady state conditions, i_l, are provided by the following expression, respectively:

$$i_{pl} = \frac{nFD(C_s - C_b)}{\delta_p} \qquad (4)$$

$$i_l = \frac{nFD(C_s - C_b)}{\delta} \qquad (5)$$

where n is the number of equivalents exchanged, F is Faraday's constant, D is the diffusion coefficient, C is the concentration of the reacting species at the surface of the workpiece or in the bulk solution, and δ_p is the pulsating boundary layer thickness. The relationship between the limiting current in the steady state condition, i_{lim}, and that in pulsed processes is:

$$i_{pl} = i_{lim}\left[\frac{\delta_p}{\delta}(1 - \gamma_{for}) + \gamma_{for}\right]^{-1} \qquad (6)$$

where γ_{for} is the forward duty cycle, which is defined as the ratio of the forward on time to the period of the waveform.

Because $\delta_p < \delta$, a higher limiting current density can be applied in pulsed processes, as compared to constant current processes. This results in instantaneously higher removal rates.

An additional consideration for mass transport effects is the size of the boundary layer relative to the surface profile. If δ is approximately the same size as the profile height, r, the boundary layer is considered to be conformal (see Fig. 3).

This situation is referred to as a macroprofile. Under mass transport control, a conformal boundary layer yields a uniform current distribution and uniform material removal. If δ is much larger than r, a non-conformal boundary layer exists (see Fig. 4). This is referred to as a microprofile. Under mass transport control, the current distribution and material removal are non-uniform.

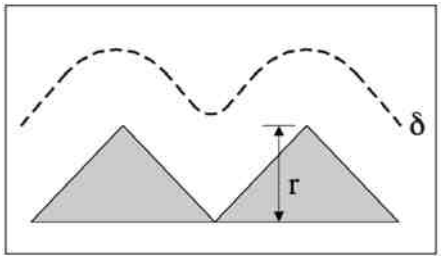

Figure 3. Conformal boundary layer (δ ~ r)

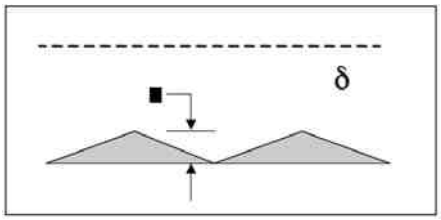

Figure 4. Non-conformal boundary layer (δ > r)

Current Distribution: During pulsed processes, the current distribution consists of primary (geometrical), secondary (kinetic) and tertiary (mass transport) effects, all of which influence the material removal rate, dimensional accuracy, and surface quality. Compared to primary current distribution, the addition of kinetic or tertiary effects tends to make the current distribution more uniform. The application of a pulsed electric field influences the role of kinetic and mass transport effects, thereby significantly altering the current distribution as compared to DC processes. By understanding the influence of pulsed waveforms on current distribution, process parameters can be selected to provide the desired current distribution.

Hydrodynamic Conditions: A properly selected waveform aids in maintaining uniform hydrodynamic conditions in the gap between the tool and workpiece. In conventional electrochemical machining (ECM) which utilizes a constant electric field, heat and undesired products generated by the applied current are removed by high rate, electrolyte flow. In ECF, the addition of a properly selected off time enhances the ability to remove waste products from the gap while reducing the

need for high electrolyte flow velocities. Furthermore, the nascent gas bubbles generated at the surface of the tool during the forward pulse can be anodically consumed during the reverse period. This minimizes the presence of gas bubbles in the electrolyte, which can significantly alter the electrolyte density, thermal conductivity, and flow velocity. In addition, it reduces the local pH at the tool surface to prevent the deposition of metal hydroxides. These reactions are shown in the following expressions:

Forward modulation (i.e., cathodic reaction at the tool):

$$2H_2O + 2e^- \rightarrow H_2 + 2OH^- \qquad (7)$$

Reverse modulation (*i.e.*, anodic reaction at the tool):

$$H_2 + 2OH^- \rightarrow 2H_2O + 2e^- \qquad (8)$$

A detailed discussion on the effects that hydrodynamic non-uniformity has on ECM processes has been provided by Kozak et al.[7]

Dynamic Conditions: As has been discussed, the proper waveform selection for a given application involves a large number of factors. In practice, there is another factor that must be considered, namely the surface profile continues to change as leveling occurs. Therefore, the applied waveform shape must also be dynamic throughout the process. For example, the initial processing conditions dictate that a conformal boundary layer develops such as that shown in Fig. 3. Furthermore, the objective is to provide localized dissolution of the peaks. A high frequency, high amplitude waveform would provide the desired result. As the process proceeds, however, the profile levels out and it transitions away from a conformal boundary scenario into one that is non-conformal as shown in Fig. 4. At this point, if one continues with the initial waveform, uniform metal removal is favored. Therefore, one would not realize a significant improvement in the surface roughness over a period of time. If a different waveform was applied that would resemble a low frequency, low amplitude waveform, the metal dissolution would again favor peak removal and leveling would continue at a relatively high rate. This sequencing of waveforms is a critical tool in providing the best finishing performance in the least amount of time. This type of processing can be programmed to occur automatically with today's power supplies.

In a similar situation, there could be an application where both edge and surface finishing within the same part is desired. One example is two intersecting holes that require burr removal as well as polishing of the interior surface of both holes. Here the concept of sequenced waveforms can be employed to provide complete burr removal and then provide micro leveling of the entire bore. An industrial example of this approach was taken when processing a stainless steel valve for the

semiconductor industry (please see Fig. 5). Burrs and tool lines are shown in the middle photograph. In this case, both the burr removal and surface finishing occurs in a total cycle time of approximately 30 seconds.

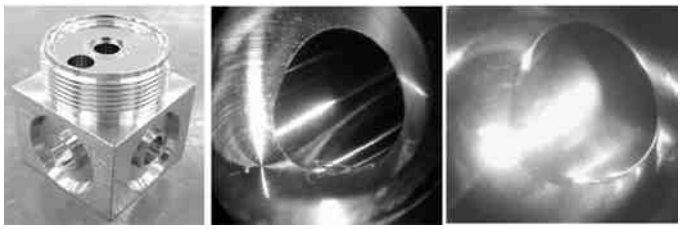

Figure 5. Stainless steel valve (left), intersection prior to finishing (center), intersection after finishing (right).

Summary: The ECF process is a non-contact metal finishing process that relies on anodic dissolution to shape the work piece. Unlike electropolishing and glycol-based ECD, which utilize chemical mechanisms to control the metal dissolution pattern, ECF relies on a pulsed electric field. This allows the ECF process to utilize water based, neutral salt electrolytes, alleviating many worker and environmental safety concerns. Furthermore, the available user-defined process parameters enhance the process control. Finally, the versatility in generating the pulsed electric field allows for an adaptable process that can provide both edge and surface finishing often with the same tooling and electrolyte.

Industrial Applications

The ECF process has been successfully adapted for a wide variety of applications within the automotive, aerospace, and semiconductor industries. Although only a limited development effort has been directed towards the medical device industry at this time, it appears that ECF could have a significant impact on the industry's ability to meet the strict finishing requirements. The materials that have been finished using this technology include: carbon steel, aluminum, nickel (Ni) based alloys, titanium (Ti) based alloys, Ti-Ni alloys, stainless steel, and cobalt-chromium. The latter three being critical materials to the medical device industry. Examples of on-going efforts to adapt this technology to various applications are provided in this section.

Edge Finishing of Surgical Blades: This main goal of this project was to investigate the feasibility of using ECF to deburr surgical blades. Each blade measures 5.6 mm wide and 0.5 mm thick. The feasibility of the process was proven using a very simple fixture. The total processing time required for

complete burr removal was 2 seconds. Figure 6 shows the "as received" knife edge and the edge after processing.

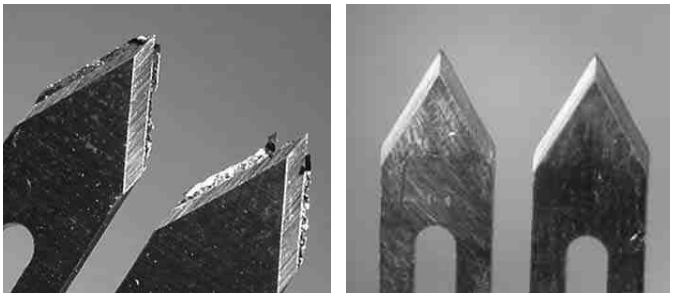

Figure 6. Knife edge "as received" (5.6 mm wide x 0.5 mm thick) (left), after ECF (right).

Edge Finishing of Titanium Medical Clips: Commercially pure titanium medical clips (please see inset in Figure 7) were edge finished using the electrically mediated process in conjunction with a rotating barrel. The setup is shown in Figure 7. The titanium clips are placed in the barrel along with graphite pellets. The anodic lead is allowed to dangle in the barrel making contact with both the titanium clips and the graphite pellets. The purpose of the graphite pellets is to provide a means of passing current without the need for contact between the titanium clips. The cathode is placed approximately 1 cm from the barrel. The entire setup is immersed in electrolyte with a pump providing a stream of fresh electrolyte into the barrel.

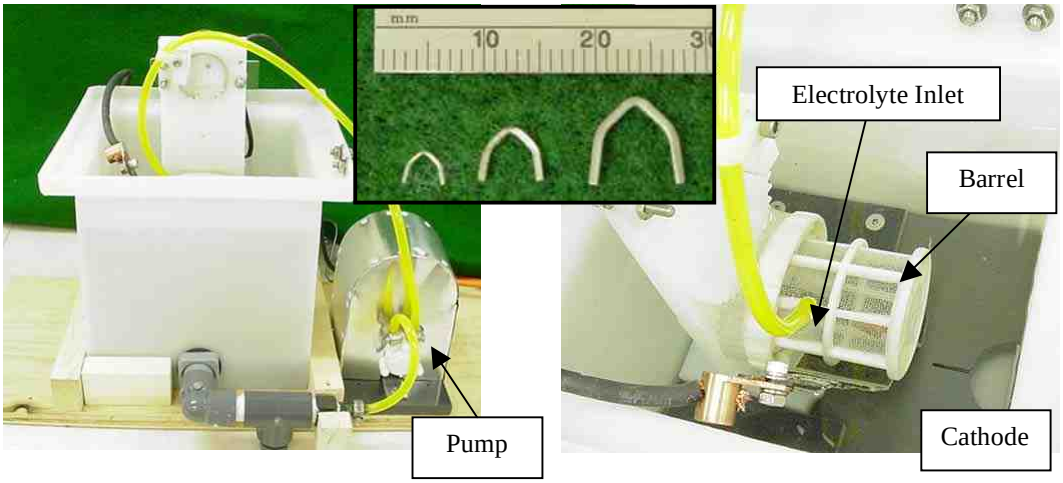

Figure 7. Titanium medical clip samples (inset, above), barrel deburring fixture (left), view of inside of tank (right).

Figure 8 shows the tip view of titanium medical clip samples before and after barrel deburring using ECF. Results have shown that the process is capable of complete burr removal.

a) b)

Figure 8. Tip view of titanium medical clip samples: a) before and b) after barrel deburring using ECF.

Electrochemical finishing of Nitinol stents medical devices: This ongoing project is investigating the feasibility of using ECF to electropolish Nitinol shape memory alloy stents with a recast layer. The outcoming results will be compared to the state-of-the-art process, which utilizes direct current electropolishing in a sulfuric acid/phosphoric electrolyte. Currently, the rejection rate on these devices is high (60-80% yield) as these medical devices must be of the highest quality. Experimental results and discussions will be presented at the conference.

Conclusions

The edge and surface finishing of medical devices is crucial in achieving the design performance and expected lifetime of the component. Combining the complex design of medical devices with the use of advanced materials common to the medical industry makes the finishing requirements difficult to achieve using conventional finishing processes. Electrically controlled finishing (ECF) is a non-contact, electrochemical process that provides enhanced control through the utilization of pulsed electric fields. Unlike other electrochemical processes such as electropolishing and glycol-based electrochemical deburring, ECF does not rely on the aggressive nature of the electrolyte and therefore utilizes water-based, neutral salt solutions.

ECF technology is applicable to a wide range of materials, including titanium, stainless steel, and cobalt-chromium alloys. Through the proper selection of the waveform shape, the process can be tailored to provide either edge or surface finishing. Selected waveforms can also be sequenced together to provide both

edge and surface finishing without the need to adjust the chemical nature of the electrolyte. Furthermore, the process can be automated and is scaleable to large surfaces and very fine details.

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