

GENERAL CHARACTERISTICS OF DFT[®] COMPOSITE WIRE

BY:

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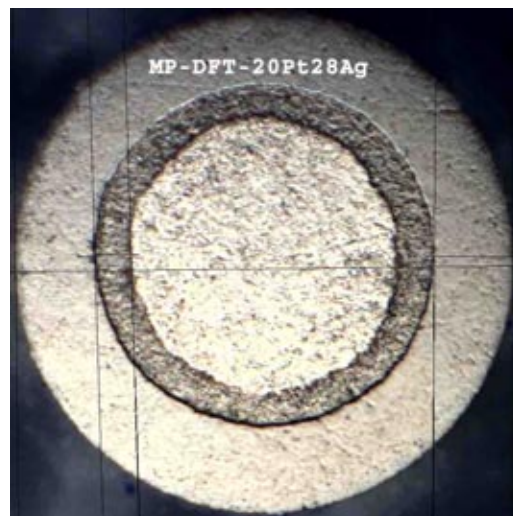


Figure 1

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CHARACTERISTICS OF DFT

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1.0 ABSTRACT

Composites have long been a part of today's engineering community and have found use in nearly every facet of industry. Relatively recent advancements in material processing technology have allowed some key benefits of composite materials to enter the realm of medical wire. DFT® composite wire was first introduced in 1985 and has since been refined continually. This document provides information relating to general characteristics and properties that can be obtained utilizing DFT technology. Some topics include ultimate strength properties, electrical properties, fatigue performance, flexural properties, and some general considerations regarding corrosion performance and material selection.

2.0 INTRODUCTION TO DFT

DFT® is an acronym that stands for **Drawn Filled Tube**. This term does not necessarily relate to materials used, size, mechanical strength or other specifics of the material; DFT simply refers to a material configuration. Any composite material that involves the filling and drawing of a tube is designated a DFT product.

A simple example of a DFT product widely used in today's device market is MP-DFT-28%Ag. Largely because of its excellent fatigue properties, high mechanical strength, and its low resistance to the flow of electric current, this material is currently used in pacing leads and other high strength, low resistance applications. Likely evident by the material name, MP-DFT-28%Ag contains a high purity Silver core which constitutes 28% of the cross-sectional area. The remaining material is type MP35N® and makes up the balance of the material's cross-section.

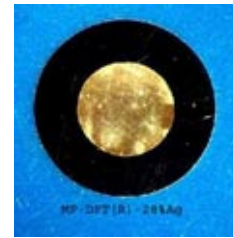


Figure 2

In recent years the medical device community has been introduced to many new and exciting variations of the DFT line. The materials used and configurations attempted have provided many challenges and introduced manufacturers to many learning experiences in materials processing. Ranging from the seemingly impossible to the extravagantly exotic, recent material selections have truly revolutionized the menu of available, medical device worthy materials.

3.0 DFT MECHANICAL STRENGTH

One primary advantage of using DFT over a single material is the ability to provide unique strength properties or to bolster the strength of another material. There are many nonferrous materials that are capable of providing great benefit to medical practice, but offer little in the way of strength, and are sometimes toxic to the human biological system. DFT potentially offers shielding from many of these hindrances and typically adds much needed strength to these types of materials. These materials include but are not limited to: Silver, Gold, Platinum, Zirconium, Tantalum, Palladium, and others.

3.1 TORSIONAL RIGIDITY

In general, pure nonferrous materials do not offer much in the way of torsional rigidity. The equation for angular displacement due to a purely torsional load can be expressed as follows:

$$\text{equation 1: } \theta = (T \cdot L) / (G \cdot J)$$

T = torque; L = work piece length; G = modulus of rigidity; J = polar second moment of cross section. From this equation it is clear that a low modulus of rigidity will result in increased angular displacement. Another note of interest is the fact that it is possible to remove substantial amounts of core area from a rigid material without sacrificing much torsional rigidity. When subjected to torsional loading, the outer fibers of a circular cross-section succumb to the majority of the shear deformation. As long as the modulus of rigidity of the outer material is sufficiently greater than that of the core, it will correspondingly support the majority of the torsional (shearing) load. As expressed in table 1, substantial amounts of core material can be removed while sacrificing little in the way of torsional rigidity.

Table 1

| % Core Removed | ID / OD fraction | % Loss of Torsional Rigidity |
|----------------|------------------|------------------------------|
| 10% | 0.316 | 1.01% |
| 20% | 0.447 | 4.17% |
| 30% | 0.548 | 9.9% |
| 40% | 0.632 | 19.0% |
| 50% | 0.707 | 33.3% |

**assumes homogeneous material properties*

It is also possible to configure a composite in such a way that the core actually bears much of the shear load. In this case the outer material must be able to withstand shear strain without fracture, and the core material must possess a shear modulus that significantly exceeds that of the outer layers. This arrangement can be particularly useful when other properties are needed of the outer material, but resistance to torsional strain is still necessary.

3.2 FLEXURAL RIGIDITY

There are some very noteworthy modifications of flexural properties that can be had by utilizing DFT technology. Flexural rigidity is a property that is intrinsically important to any of a great number of medical devices. Whether it be navigating the tortuous path from the radial artery to the heart, or providing guidance to a well-placed stent, flexural rigidity plays an import role in surgical dynamics.

There are times when low rigidity in combination with high pull strength can provide substantial benefit. While these two properties do not typically work together in this manner, DFT provides a possible solution. Certain low modulus materials can be combined with high strength core materials in a manner that provides very unique properties.

Analogous to torsional rigidity, flexural rigidity is not substantially affected by moderate amounts of core removal. For example, a sample of MP-DFT-28%Ag is only 8.5% less stiff in flexure than its solid MP35N™ counterpart. Similarly, due to a lack of core strain, a sample of Nickel Titanium shape memory alloy retains most of its ability to recover in flexure when filled with low strength materials and or low core area ratios. Figure 3 at the right presents one such material. Shown is NiTi-DFT-36%316LVM, the material was photographed at 0.0050” in order to verify interface quality, material dimensions, and concentricity at finish diameter.

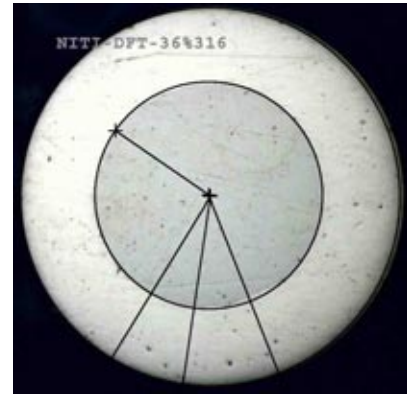


Figure 3. 0.005” NiTi-DFT-36%316LVM

Table 2 provides example data relating to elastic flexural strain in a typical Nitinol application. This data was derived using simple equations of flexion that assume a center-line neutral axis and regard only compressive and tensile stresses as significant to plastic distortion. All values are for reference only. Example: 2nd line, a .0010” NiTi-DFT-10%Pt could be wrapped around a .0158” mandrel without plastically deforming either material.

Table 2

| Example Calculations: Elastic Flexure | | | | | |
|---------------------------------------|------------|------------------------|-----------------------|------------------|--------------------------|
| DFT@ O.D. | Fill Ratio | Max Outer Axial Strain | Max Core Axial Strain | Min Bend Radius* | Outer Strain at Min Rad. |
| .0010 | 5% | 8.0% | 1.0% | .0112 | 4.5% |
| .0010 | 10% | 8.0% | 1.0% | .0158 | 3.2% |
| .0010 | 25% | 8.0% | 1.0% | .0250 | 2.0% |
| .0080 | 5% | 8.0% | 1.0% | .0894 | 4.5% |
| .0080 | 10% | 8.0% | 1.0% | .1265 | 3.2% |
| .0080 | 25% | 8.0% | 1.0% | .2000 | 2.0% |
| .0150 | 5% | 8.0% | 1.0% | .1677 | 4.5% |
| .0150 | 10% | 8.0% | 1.0% | .2372 | 3.2% |
| .0150 | 25% | 8.0% | 1.0% | .3750 | 2.0% |

*Max bend radius refers to the maximum radius of bending along the centerline of the composite that can be withstood without plastic deformation of either the core or the outer material. All measurements given in INCHES.

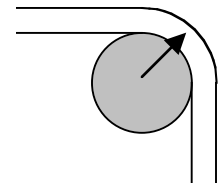


Figure 4: Bend

3.3 TENSILE STRENGTH

In general, materials that offer exceptional conductivity typically lack good strength characteristics. There are some materials that offer excellent radiopacity, but are usually lacking in the ability to withstand mechanical fatigue. It is however, possible to obtain all three of these properties in a single composite material. Pictured to the left (Fig. 5) is a representation of a specialized composite made to satisfy the three previously mentioned tasks. The outer sheath of MP35N provides substantial strength and fatigue performance. The central layer makes up around 20% of the matrix and represents high purity Platinum, thus providing excellent visualization under radiography. For increased conductivity, a silver core has been introduced at approximately 28% of the cross-sectional fraction. This type of composite could conceivably produce ultimate tensile strengths in excess of 200ksi combined with excellent electrical and radiographic properties. Selections such as these can be used to tailor DFT composites to meet specific electrical, mechanical, and radiographic requirements.

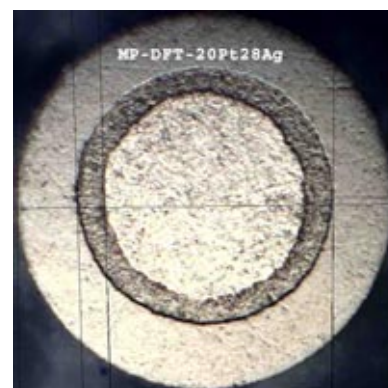


Figure 5

4.0 CORROSION CONSIDERATIONS

4.1 GENERAL CORROSION

It is well known that the human body is chemically one of the harshest environments in which engineering materials are used. There are a number of materials that are capable of providing useful properties but considered a danger to humans if exposed directly to bodily fluids and membranes. Implant quality materials can be used as a protective cladding in order to eliminate concerns of bodily toxicity. Materials such as Conichrome[®], MP35N, 316LVM, and Nitinol are a few that are capable of providing excellent resistance to biocorrosion.

4.2 GALVANIC CORROSION & MATERIAL SELECTION

Anytime dissimilar metals are placed in electrical contact with one another there is a chance that one of the materials could be subject to increased corrosion. In order for this type of corrosion to take place there needs to be a common electrolyte, that is, one in contact with both species. In this type of accelerated corrosion, one material undergoes an increased rate of attack. The other material typically undergoes decreased corrosion, and will generally be the nobler of the various species present. The relatively noble material that sees a decrease in the rate of corrosion is considered the cathode in a galvanic cell, the less noble being the anode.

There are a number of ways to avoid galvanic corrosion. First of all, if there is not a common electrolyte between the materials, the galvanic circuit cannot be complete, thus eliminating the chance of accelerated corrosion. The procedure of termination can be very helpful in preventing galvanic corrosion of DFT product. Care must be taken when sealing the ends to be sure that there are no crevices into which electrolyte may flow to the anodic material, as this could potentially yield disastrous effects.

Another method that may be employed to ensure proper corrosion performance is the selection of materials that are near one another in a particular galvanic series. Materials that are near one another in this series will set up little if any electrical potential between them, thus disallowing the undesirable flow of electrons between materials. An important note is that all galvanic series are not equal. Each material has a tendency to behave differently in different electrolytes. One such galvanic series is pictured in table 3 shown to the right. This series qualitatively lists the corrosion potentials of various metals in flowing seawater at set electrolyte conditions.

Table 3

| Galvanic Series of some commercial metals and alloys in seawater | |
|--|-----------------------------------|
| Noble or Cathodic | Platinum |
| | Gold |
| | Graphite |
| | Ni-Cr-Mo alloy C |
| | Titanium |
| | Ni-Cr-Mo-Cu-Si alloy B |
| | Ni-Fe-Cr alloy 825 |
| | Alloy 20 stainless steels |
| | Chlorimet 3 |
| | Hastelloy C |
| | Types 316, 317, passive |
| | Types 302, 304, 321, 347, passive |
| | Silver |
| | Chromium steel >11% Cr, passive |
| | Inconel, passive |
| | Nickel, passive |
| | Nickel 200 |
| | Silver Braze Alloys |
| | Ni-Cr alloy 600 passive |
| | Monel |
| | Bronzes |
| | Copper |
| | Brasses |
| | Chlorimet 2 |
| | Hastelloy B |
| | Inconel, active |
| | Nickel, active |
| | Tin |
| | Lead |
| | Lead-tin solders |
| | Types 316, 317, active |
| Types 302, 304, 321, 347, active | |
| Ni-resist | |
| Chromium steel >11% Cr, active | |
| Cast iron | |
| Steel or iron | |
| 2024 Aluminum | |
| Cadmium | |
| Aluminum | |
| Active or Anodic | Beryllium |
| | Zinc |
| | Magnesium and its alloys |

*Chart adapted from Roberge, 343 and ASTM G82, Fig. 1

5.0 DFT INTERFACE STRENGTH

There is no quantitative evidence supporting strong interfacial bond strength. However, upon examining deformed DFT materials, metallographic analysis has provided evidence of a bond that is sufficient to virtually eliminate interface slippage. This bond is believed to be a result of the significant amount of co-processing that is involved in the production of DFT. This includes the

extreme compressive forces associated with typical wire drawing, and the thermal processes needed to impart ductility to the highly cold-worked materials prior to further deformation.



5.1 INTERFACIAL EFFECTS

There are other factors contributing to the integrity of the composite. Sufficiently large artifacts that enter the tubing prior to reduction can embed themselves in the tubing wall and provides initiation sites that can lead to premature failure. Manufacturers must take careful precaution to ensure that these types of failure do not occur. All raw materials must be cleaned prior to shipment by the vendor. In addition, supplementary cleaning of all ID surfaces and of every fill material must be performed prior to construction of a DFT composite. Materials that may form a detrimental oxide layer prior to construction require extra care to ensure a clean composite interface. In addition to mechanical anomalies, a contaminated interface can contribute chemically to the interaction between core and sheath. Material adjacent to certain constituents can, in extreme cases, become denude of chromium and other corrosion inhibiting elements as pictured in figure 8.

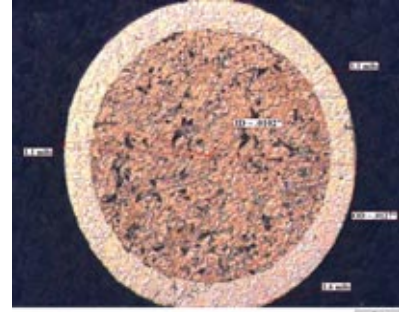


Figure 7: Clean Interface
Note: 65% fill

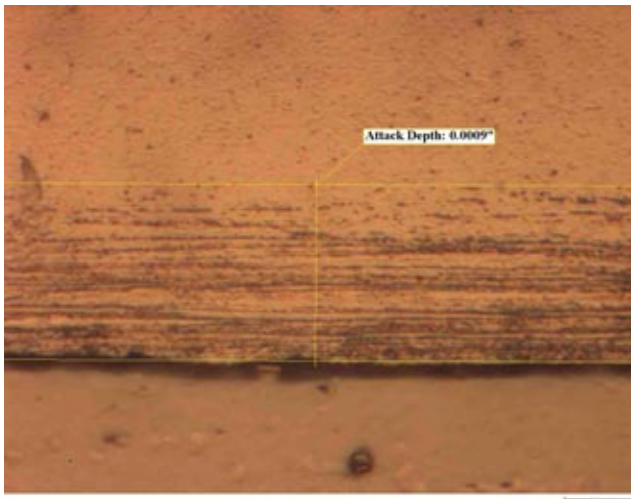


Figure 8: Attack due to interfacial interaction
Note: 65% fill



Figure 9: Flat DFT; Note: No interfacial separation after roll forming.

6.0 MODES OF FAILURE

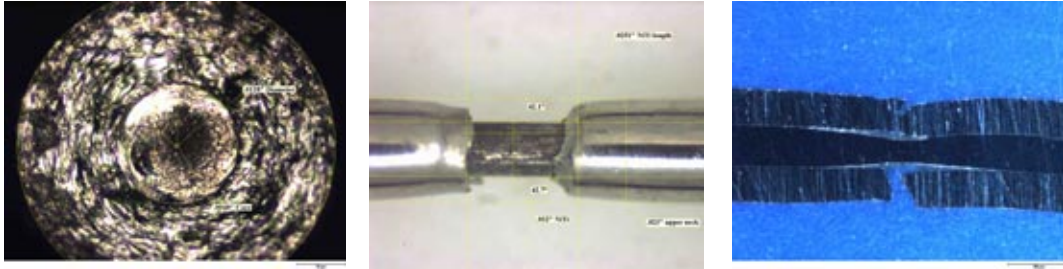


Figure 10: Left to right. Typical DFT composite torsional failure (note: core material hard relative to outer). Partial tensile rupture of high strength outer w/high ductility core. Partial flexural failure of DFT.

In general, failure modes of DFT closely resemble that of their single material counterparts. Some of the most notable exceptions occur when one species fails, leaving behind a single mode of support. This type of failure is usually seen only when there are significant differences in the ductility of core and sheath material. The second photograph in figure 10 shows a 316LVM outer material that has reached tensile rupture, leaving behind the mildly deformed Nickel-Titanium core. Possible bulk mechanical property measurements of this material, and a similarly processed monofilament 316LVM series wire can be found in table 4 below. Note: these values are for reference only and do not necessarily represent actual production parameters, nor do they specify material dimensions.

Table 4: Comparison of varying bulk properties due to super elastic core.

| HARD | | 316-Niti | 316LVM | SOFT | | 316-Niti | 316LVM |
|----------------------------|--|----------|--------|----------------------------|--|----------|--------|
| Ultimate Tensile Strength: | | 252 | 255 | Ultimate Tensile Strength: | | 135 | 102 |
| Yield Strength: | | 185 | 227 | Yield Strength: | | 75 | 54 |
| Elongation: | | 6.7% | 3.1% | Elongation: | | 59.0% | 43.0% |

6.1 THERMAL CONSIDERATIONS

When selecting materials to use in a DFT configuration it is important to consider their relative coefficients of thermal expansion. In processing, this becomes especially important, as the matrix is repeatedly subject to large temperature gradients on the order of several hundred degrees Celsius. A core that expands rapidly can readily cause rupture of the outer material if there is insufficient support. A composite that readily survives production is unlikely to suffer temperature related failure in the field; it is however a consideration that needs to be made. Hoop stresses due to expansion and contraction of the core material could conceivably work together with a number of other variables to cause failure. To date, this type of interaction has never been shown to cause failure in a DFT material.

7.0 FINAL REMARKS

The role of DFT is growing at a rapid pace. Present uses range from handheld, electronic cardio resuscitation devices, to implantable defibrillators, neuro-stimulators and radiopaque stents, as well as many others. The ability to combine multiple materials (and properties) into a fully integrated, encapsulated, and biocompatible system is just beginning to yield fruition in the marketplace. It is likely that there are many uses for such a product that have yet to be discovered. Fort Wayne Metals, the leading producer of DFT, is fully willing to attempt combination of virtually any malleable/ductile metallic material that may provide economic and/or medical benefit. This paper has briefly explored a topic that could easily constitute an expansive publication. Additional questions and concerns related to DFT product and/or this document should be forwarded to Fort Wayne Metals.

8.0 REFERENCES

ASTM Specification G-82 -98. "Standard Guide for Development and Use of a Galvanic Series for Predicting Galvanic Corrosion Performance." ASTM 3.02 (1998): 356-361.

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