ADVANTAGES OF ULTRASONIC SPRAY COATINGS OF BIOMATERIALS ONTO DEVICES AND IMPLANTABLES

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Presented at the 15th International Coating Science and Technology Symposium,
September 13-15, 2010, St. Paul, MN (1)

1. Basic Nozzle Theory

a. Pressure Nozzles cause atomization by shearing liquid in all directions after forcing it through an orifice. The three characteristics of spray droplets cannot be independently manipulated, if you change one, you change them all: Kinetic Energy of the droplets, Volume of liquid being sprayed, and Droplet size. This leads to disadvantages such as overspray, bounceback etc… Ultrasonic Nozzles atomize by harmonic vibrations and allow superior spray and coating results.

b. Sound waves exist in the air as a result of a substrate vibrating at a certain frequency. Those same waves can exist in materials and liquids.

c. Piezoelectric effect (piezo being the Greek word meaning “to press”) is defined as creating a potential in a material when squeezing it. Conversely, when these same transducers are stimulated with electrical potential, they expand. By rapidly alternating the electrical potential, the transducer rapidly contracts and expands and thus creates a mechanical vibration. Keeping these transducers very tightly captured in a material can cause a tight enough “coupling” such that a shock wave is transferred into the material.

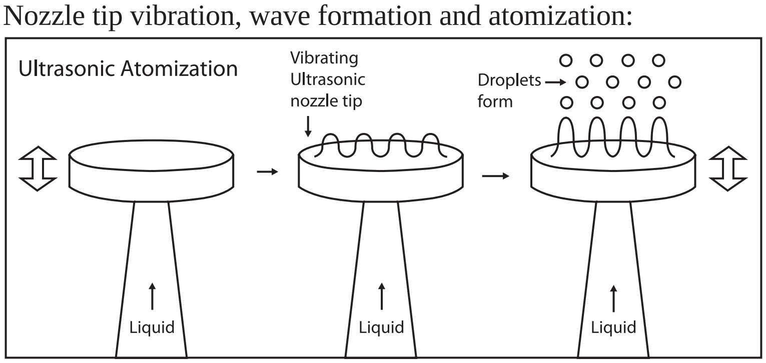
d. A given piece of material or compound structure has its own resonant frequency. A frequency is defined by its length and materials of construction. If the AC frequency being used to excite the transducers matches that natural frequency in the compound structure, an efficient standing wave is created in the material, with the highest amplitude of motion existing, by definition, at the two ends.

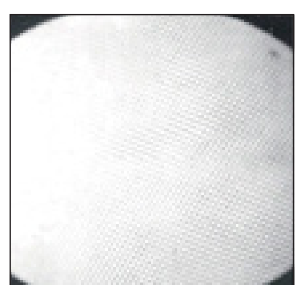
e. Thus, without the use of motors, electrical energy can be converted into mechanical vibration. Ultrasonics applies this physical property by creating high frequency mechanical vibrations by stimulating transducers with high frequency oscillating electrical energy.

f. When liquid is added to a resonating nozzle, waves are formed on the atomizing surface perpendicular to the axis of vibration underneath.(2)

g. Increasing the power causes the wave peaks to get so high that droplets fall off the tips of the wave. These droplets have a mathematically definable size.(3)

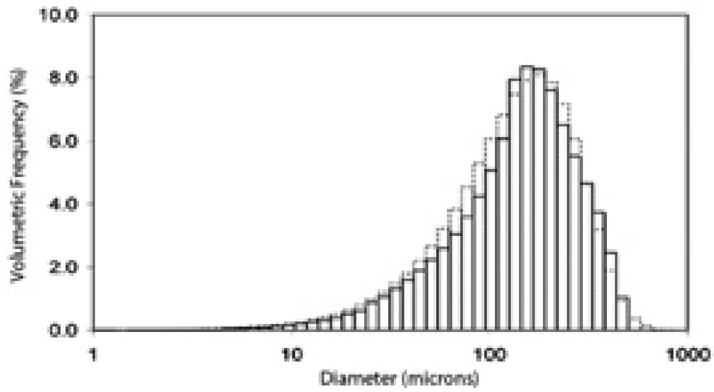
h. Nozzle tip vibration, wave formation and atomization:



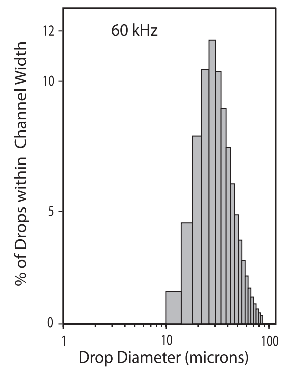


Droplets forming on nozzle tip

i. The results can be shown by comparing the two graphs below:



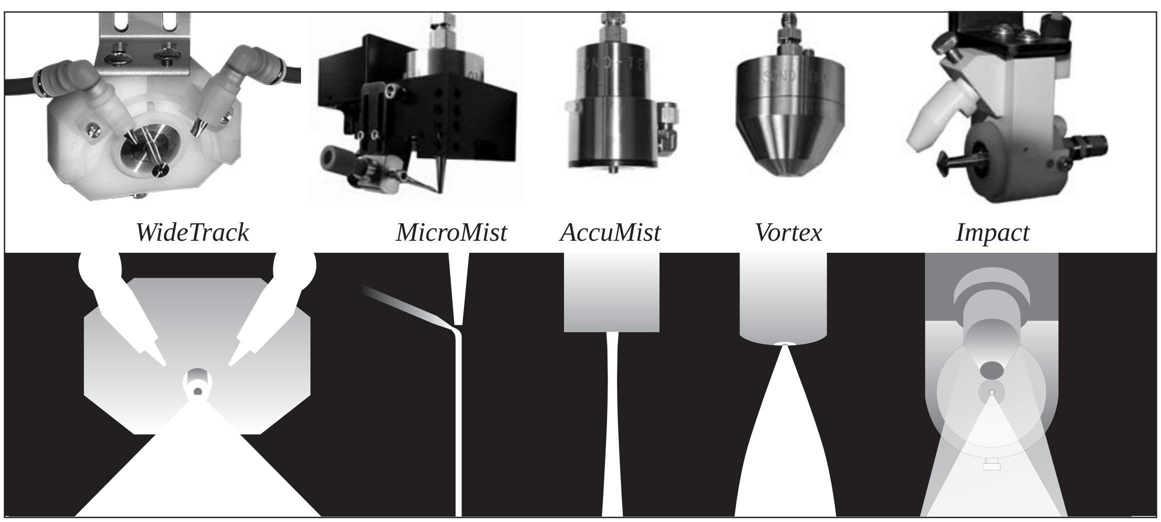
DN, 0.5 of a Pressure Nozzle



DN, 0.5 of a 60 KHz Nozzle

j. Sono-Tek Ultrasonic nozzles produce a soft, low velocity spray resulting in a minimum of overspray. The soft spray is easily shaped into a uniform pattern with controllable air. We do not rely on pressure to produce atomization, resulting in the capability to deliver liquids over a wide range of flow rates. This also allows for less required maintenance. The large orifice and ultrasonics make it possible to atomize high solids materials without any concern for clogging. The nozzle's titanium construction makes it impervious to chemical attacks resulting in high reliability and long life.

k. The technology is also ideally suited for suspended solids as agglomerations are naturally broken up by the same energy causing atomization. And micro-encapsulations are more easily achievable as high shear forces are not acting on the liquids.



Air shaping technologies employ low velocity air to entrain the atomized drops into defined, precisely controlled spray patterns.

2. Medical/Biomaterial Processes in which Sono-Tek has Demonstrated Success

a. Stents: Coronary, Peripheral, Biliary
b. Implants: Rods, Pins and Screws, Surgical Mesh, Bandages and Wound Care, Nasal Implants, Prosthetic and Orthopedic Implants

3. The Advantages of Biomaterial Coatings with Ultrasonic Nozzles versus Pressure Nozzles or Dual Fluid (Air Atomizer) Nozzles

a. Ultrasonic nozzles provide better control of variables.

i. **The following are the direct variables in spray coating process: coating speed (i.e. conveyor or nozzle motion), flow rate, droplet size, droplet energy, effective concentration**

ii. **The main indirect variable is coating efficiency (effective chemistry on substrate/effective chemistry sprayed)**

iii. **The main results: coating thickness or coating weight (or chemical dose), coating uniformity, coating repeatability**

iv. **Alternative technologies achieve spray by using pressure or force to tear the liquid apart. The result is that the droplet sizes being atomized, the kinetic energy of the droplets and the volume of material being added to the process are interconnected and cannot be easily separated.**

v. **Since an ultrasonic nozzle provides the atomization without pressure (which would be otherwise tied to flow rate) the following process variables are at the control of process engineer:**

1. Droplet sizes are determined by frequency and chemistry

   In accordance with the governing math equation:

   $$\mathbf{D_{N,\,0.5} = .34 * \lambda_L} \quad (2)$$

   And

   $$\mathbf{\lambda_L = ((8 * \pi * \theta)/(\rho * f^2))^{1/3}} \quad (3)$$

   Where:
   π = pi
   θ = Surface Tension
   ρ =Density
   f = Frequency of Nozzle
   $D_{N,\,0.5}$ = Number Median Diameter of Droplet size
   λ_L = Wavelength in the liquid

2. Volume in the sample is determined by a metering pump. The process engineering can turn up or down the flow rate without significantly affecting droplet size or the kinetic energy.

3. Droplet kinetic energy and velocity are controlled separately via a plume shaping device. The velocity can be optimized to layout efficiently (softly) with minimal overspray or bounce-back. Or if necessary gas input can be increased to effect penetration or to overcome interfacial surface tension challenges. These changes result in little to no changes to the droplet sizes and have zero effect on the flow rate. But the efficiency of the coating process can be highly dependant on optimization of the gas-powered plume shaping.

vi. Ultrasonic nozzles provide more stable process, therefore higher yields.

1. Clogging: When alternative spray technologies are used, it is common for the process engineer to have high maintenance frequencies because pressure nozzles and air atomizers are highly susceptible to clogging. But the "clog" is not a binary function. The nozzles are not "fully open" and then "fully clogged." As they function, they are in the process of clogging. This process changes the coating evolution continuously. For instance, in an EtoP controlled device, the process of clogging tends to close the spray orifice. As it does, the regulator will turn down its output to maintain pressure in the fluid system, and as a result, the volumetric flow rate will be reduced, the droplet size will be increased, and the kinetic energy of said droplet will be changing.
2. Wear: Pressure devices (sometimes called LPHV nozzles for Low Pressure, High Velocity), the constant erosion of the atomization orifice means that the device will never spray the same way twice.
3. Processes that are more stable will generate a higher yield.

b. The dangers of losing process parameters on a biomaterial coating result in changes in localized efficacy and possible coating separation.

Medical GMP's (or GxP's) are often based around an easily measurable result such as weight gain. The danger of an unstable process is that all of the weight gain on a Biomaterial may be concentrated in certain areas. The lighter or fully uncoated areas will fail to deliver a uniform dose or expose the surrounding tissue to uncoated or undercoated surfaces.

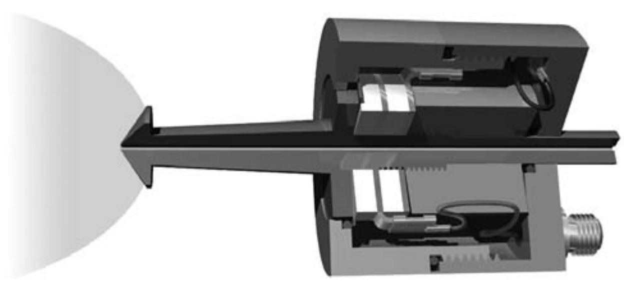
The opposite of the same scenario may be true where over-concentrated areas exist, particularly with drug dosages.

Finally, in the cases of biodegradable polymers both conditions above would result in "polymer islands" on the surface of the biomaterial as opposed to a continuous film. These polymer islands would be much more prone to separation.

This can result in the following losses of efficacy:

i. Localized restinosis
ii. Lack of fully exposing super bacteria to antibiotic
iii. Dispersed areas of rejection (cyto-toxicity or apoptosis)
iv. Weakened bone ingrowth into prosthetic implants

c. Reduced bounce-back and higher efficiency result in reduction of expensive drug amounts and reductions in consumption of dangerous solvents.



Cross section view of the inside of an ultrasonic nozzle showing piezoelectric transducers and electrical connections

Notes

(1) Unpublished. ISCST shall not be responsible for statements or opinions contained in papers or printed in its publications.

(2) Rayleigh, "Theory of Sound", 1898

(3) Lang, 1962