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"INSTANT" ON-LINE QC WITH NEW FLUOROESCING UV/VISIBLE LIGHT CURING ADHESIVES

Peter Swanson, MA (Cantab)
INTERTRONICS
Kidlington, Oxfordshire, England

Abstract
Design engineers of disposable medical devices are continually required to develop products of superior quality and reliability.

The use of fluorescent materials to provide a non-destructive method for on-line inspection has been an area of increased importance for the medical products industry. Significant improvements in productivity have been realised by employing ultraviolet (UV/visible) curing methods to assemble medical devices.

However, the fluorescing agents used for inspection of the final assembly absorb UV light in the same region of the spectrum which is required to cure the adhesive. This filtering or blocking phenomenon limits the quantity of the fluorescing agent which can be incorporated. When the levels of the fluorescent materials are increased in an attempt to improve the brightness (as measured when exposed to long wavelength UV "black light"), the adhesive may not cure properly.

This paper describes the use of the new type of UV/visible adhesives which are not adversely affected by the fluorescing agents. Therefore, UV/visible adhesives with this enhanced fluorescent response can be readily observed by the human eye using "black light" or by an in-line electro-optical device for quality control analysis of each assembly.

Introduction
Disposal medical devices, many of which are manufactured from plastics, have been assembled with a variety of methods, including heat sealing, welding, solvent-bonding, mechanical interlocks and adhesives.

In the 1990's, the drivers for the use of adhesives in the medical device industry were strong. There were concerns over the use of solvents or solvent containing adhesives; health and safety for operators and cleanroom compatibility, for example. Designers required higher performance from the joining method, and wanted to bond multiple substrate types with low stress and gap filling capability. Manufacturing engineers searched for process speed. The new century will not diminish the validity nor the power of these drivers; quite the opposite. In addition, the industry faces increasing complexity of design, regulatory issues and costs.

Adhesives which cure with UV light became a very popular choice amongst engineers, for a variety of well documented reasons[1]. In particular, these include:

1) USP Class VI and ISO 10993 approved formulations.
2) Able to be sterilised with common methods.

3) Structural integrity – adherence to most plastics used in medical device manufacture, with bonds exceeding substrate strength. Also bond glass, metal and ceramic.
4) Bond dissimilar substrates.
5) Resilient grades available from rigid to flexible.
6) Optically clear.
7) Single part – no mixing and minimal wastage.
8) Process speed – cure in seconds.
9) "On Demand" cure, which allows adjustment, fixturing and automation.
10) Use safe, longwave UV light.
11) Worker/environmentally friendly – 100% solids, 100% solvent free.
12) Low cost.

Figure 1 shows some of the types of medical devices which have been assembled using medical grade UV curing adhesives.

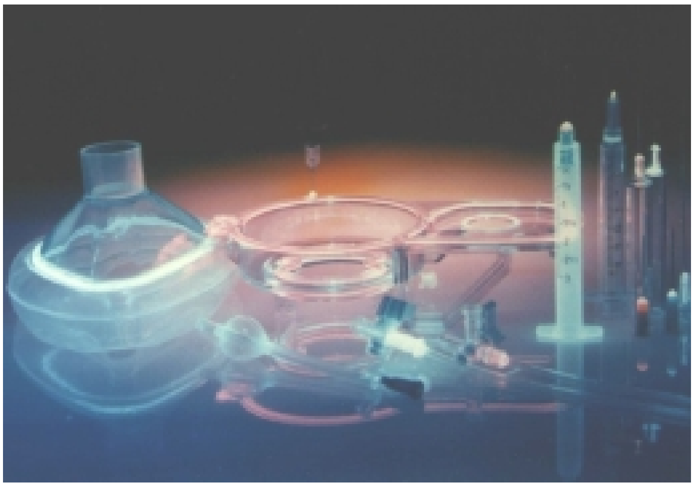

Figure 1

Some Limitations

Common UV curing adhesives which are based on a free radical curing acrylic chemistry are not a universal panacea for bonding medical devices. The adhesive needs to be exposed to UV light whilst in the bondline, so assemblies fabricated with fully opaque parts are usually not suitable. Bond strength is very poor to silicone and other rubbers. Similarly, satisfactory adhesion to polyolefins and other low surface energy polymers may be difficult to achieve - although increasingly, a combination of joint design, surface preparation and clever new adhesive formulations can make applications using these plastics (i.e. polypropylene) very possible.

Ultraviolet stabilisers are added to plastics to protect against weathering and inhibit embrittlement and yellowing. Inconveniently for the medical device manufacturer, they may also prevent or hinder the cure of a UV adhesive through the plastic. Therefore, the addition of visible light curing capability to medical device adhesives (in addition to ultraviolet curing) has been an important enabling technology[2].

UV and Visible Light Cure

The enhancement of medical grade UV curing adhesives with visible light cure allows the device designer to choose from a wider range of materials, including 100% UV blocked transparent or translucent plastics. In addition, the polymerisation speed of a light curing adhesive, already only seconds in duration, is increased significantly when a combination of UV and visible (blue) cure capability is employed. By extending the range of useful light wavelengths, we can increase the available energy to be used for cure. This, combined with the synergistic nature of the UV/visible cure combination, results in the fastest cure speed. Depth of cure is also enhanced, as the visible light penetrates deeper (it is less well absorbed by the plastic), allowing deep section potting or cure through thicker plastic substrates.

Figure 2 details the optical region of the electromagnetic spectrum with which we are concerned.

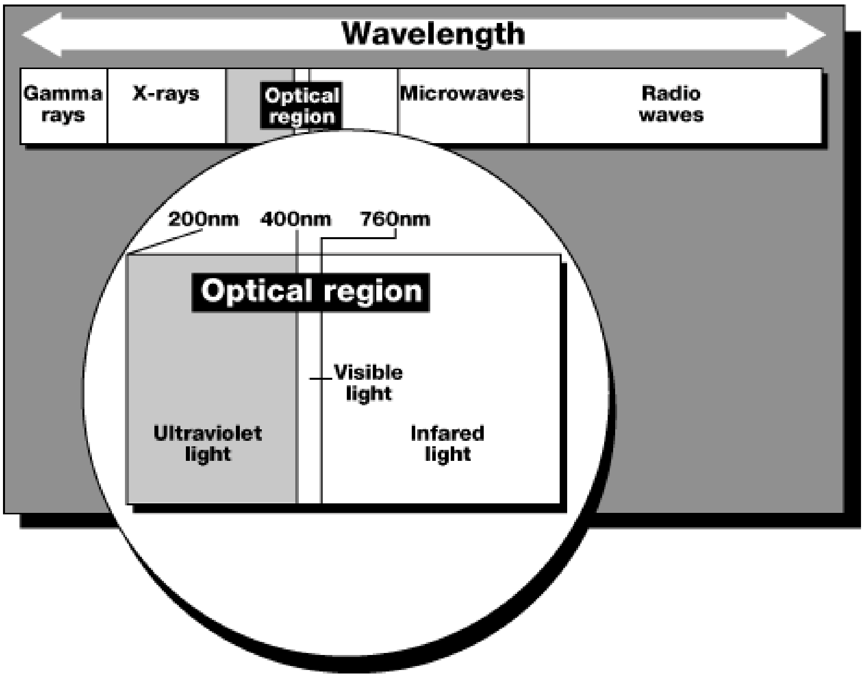

Figure 2 – The Optical Region of the Electromagnetic Spectrum

Providentially, most curing lamps which are designed to be used with UV curing adhesives emit appreciable visible light; users can take advantage of this technology without having to invest in new equipment. Figure 3 illustrates UV curing lamps which are equally suitable for UV/visible light curing adhesives.

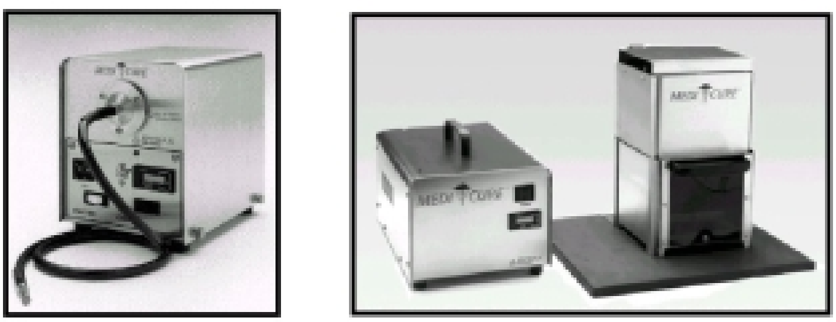

Figure 3 – Curing Lamps for Medical Device Adhesives

Productivity and Inspection

UV/visible light curing adhesives with their very fast, on demand cure and ease of handling lend themselves to automated assembly. Productivity gains and cost savings are easily demonstrated[3,4]. Full and complete cure occurs within the confines of the assembly equipment, and so quality control testing may be integrated into the machine itself. For example, one could place simple go/no-go tests, based on pull or pressure, in-line on the production unit. This would not be possible with, for example, solvent bonding where full bond strength is only developed up to 24 hours after application.

Fluorescence

The detection of fluorescence is often used in quality control, both automatically by machine and also as a manual aid to inspection by eye. For example, it is mandated by a military specification[5] that all conformal coatings used to protect germane printed circuit board assemblies contain a fluorescing agent. For manual inspection, a “black light” inspection lamp which emits relatively low intensity light in the long wavelength UV (near visible) band is directed at the part, and the resulting “glow” of the fluorescence can provide qualitative and some quantitative information about the coating or adhesive. Fluorescence offers an ideal machine-vision inspection capability.

However, fluorescing agents typically absorb UV light in the same region of the spectrum which is required to cure the adhesive. In the past, this filtering or blocking phenomenon limited the quantity of the fluorescing agent which could be incorporated in the adhesive formulation. Generally levels of 0.02% to 0.04% of the fluorescing agent can be incorporated without significant detrimental effect on the depth of cure. When the levels of the fluorescent materials are increased in an attempt to improve the adhesive’s brightness or “glow” when exposed to "black light", the adhesive may not cure properly. Even adhesive layers as thin as 0.25mm to 0.75mm may display a soft undercoat of wet, uncured material. This problem has impeded the acceptance of the UV technology for systems which demand bright fluorescent response for their inspection.

“Ultra-fluorescence”

A new type of UV/visible light cured medical device grade adhesive is now available, which is not adversely affected by the fluorescing agents, so that increased quantities of the fluorescing agents can be employed without retarding the depth of cure. They have been termed “Ultra-fluorescent”, and have recently been awarded a patent[6].

Ultra-fluorescence of a light curing medical device adhesive is facilitated by advent of UV/visible light cure technology and the use of a special photoinitiator (a photoinitiator (PI) is the chemical ingredient which reacts upon exposure to light and initiates polymerisation of a light curing adhesive). Experimental results are shown in Table 1.

	1	2	3	4	5	6
Fluorescing agent	0.02%	0.02%	0.10%	0.10%	0.45%	0.45%
Special PI?	N	Y	N	Y	N	Y
Depth of cure (mm)	7	35	1*	21	1*	15
Response to "black light"	Faded & dull	Faded & dull	Very bright	Very bright	Very bright	Very bright

* Only surface cure, wet and soft below the surface.

Table 1

In column 1, a nominal amount of fluorescing agent restricts the cure depth to 7mm, and does not result in a very good "glow" when a "black light" is shone on the sample. Increasing the percentage of fluorescing agent will increase the fluorescent response, but impedes the light curing capability of the adhesive to a non-functional level (columns 3 and 5). In column 2, the use of the special photoinitiator (PI) allows very deep cure (35mm), although the fluorescent response is still dull with such a small amount of fluorescing agent. In column 4, an increased amount of fluorescing agent in conjunction with the special photoinitiator allows an efficacious and optimal result in terms of cure depth and "glow". Adding extra fluorescing agent to this (column 6) impedes cure depth with no useful addition to inspection capability.

UV/visible light cured adhesives with this enhanced "Ultra-fluorescent" response can be observed more readily and reliably by the human eye using "black light" or by an on-line electro-optical device for quality control analysis of each medical assembly.

On-Line Electro-Optical Devices

It can be most difficult to measure adhesive thickness accurately and detect voids by a mechanical method especially when the adhesive thickness is quite thin in relation to the device. However, inspection is readily accomplished by utilising the fluorescence associated with the adhesive. An optical scanner "tuned" to respond to this phenomenon can provide an extremely accurate measurement of the film thickness and record any voids in adhesive application. A schematic representation of such an instrument and its operation to measure the adhesive thickness is shown in Figure 4.

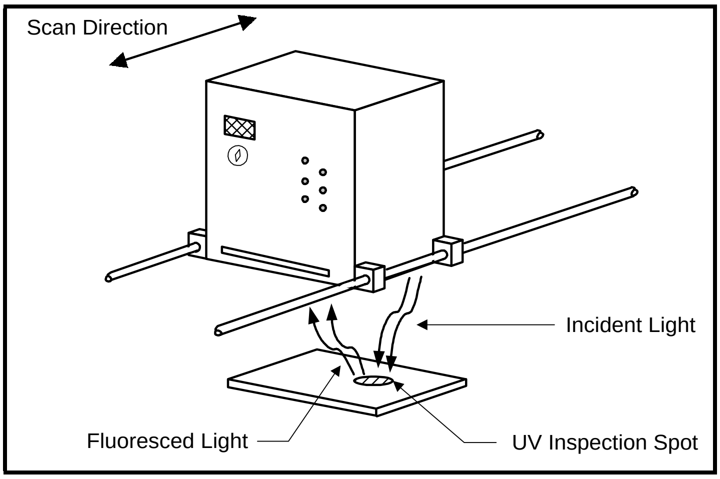

Figure 4 - On-Line Optical Inspection Scanner

The quantity of fluoresced light generated by the adhesive is proportional to three factors:

1) Intensity of the incident UV light
2) Size of UV spot
3) Thickness of adhesive or coating

As the first two, the intensity and area of the UV light, are effectively set, the adhesive thickness can be determined by measuring the amount of light fluoresced by the adhesive. The relationship is linear for a thin film. The output is read in an analogue manner and the data expressed in millivolts. A computer can be incorporated into the system so that the data can be recorded. Then, selected data can be converted to represent the device which is being measured.

Productivity and quality are both enhanced when automatic visual inspection devices are combined with “Ultra-fluorescence”.

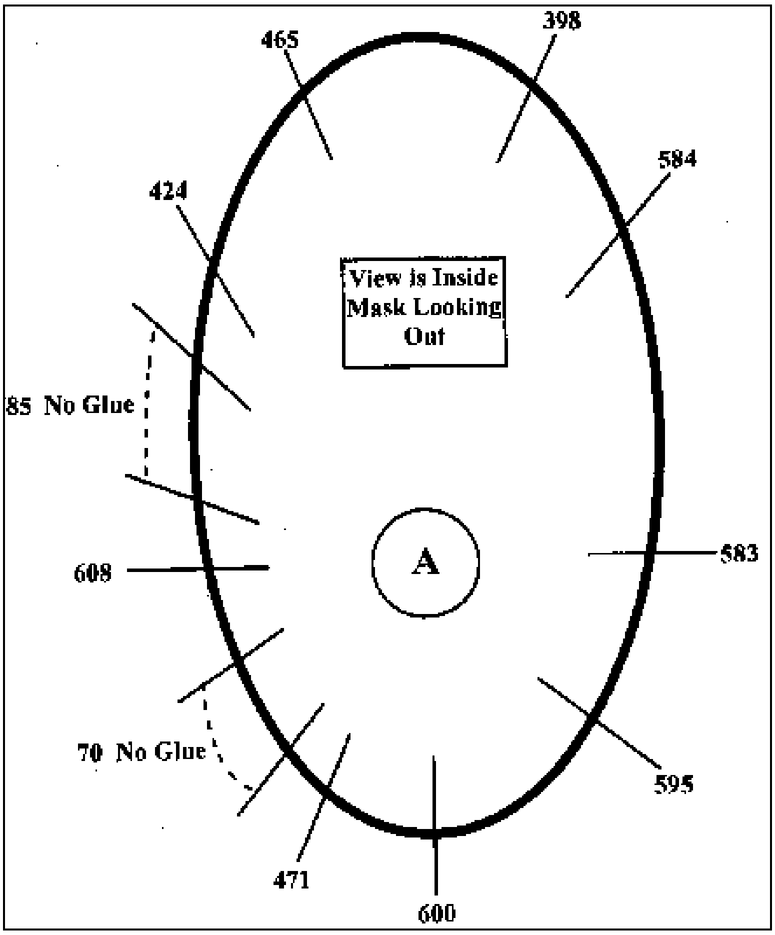

Figure 5 – Face Mask Scanner Results

Figure 5 represents an anaesthesia face mask like those shown in figure 6. The fluorescing adhesive application was measured by an optical scanner. Adhesive was intentionally misapplied to test the optical scanner’s capabilities. The areas shown as “no glue” represent voids the optical scanner picked up in the adhesive application.

Figure 6 – Face Mask Bonded with Light Cure Adhesive

Conclusion

"Ultra-fluorescing" adhesives have enabled many types of medical devices to be optically scanned on-line for voids in adhesive application and adhesive thickness in a short amount of time. This capability, along with the increased speed of cure and productivity provided by UV/visible light curing adhesives, provides design engineers with the ability to design products that are superior in quality and reliability while lowering their costs to produce them.

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