Tufnol for Surgical Instrument Handles – Technical Notes & Case Study

These notes have been compiled from researched and many years of experiential information gathered during the day-to-day activities of Bolton Surgical Ltd. They are intended simply to provide explanations of some of the key differences and attributes of Tufnol and other plastics materials commonly used for surgical instrument handles. Although the notes contain some comparisons of materials there is no intention to express any preference or recommend one material in favour of another, this must be done on a case-by-case basis according to the specific application.

What is TUFNOL?

'Tufnol' is the original brand name (of Tufnol Composites Limited) for a broad range of widely used SRBF (Synthetic Resin Bonded Fabric) engineering plastics composite materials that are either, paper, cotton, or glass fibre reinforced, phenolic resin impregnated and bonded laminates.

The material type is available in different forms (sheet, bar etc) and is known under various brand names including Tufnol, Turbax, Resitex, Celoron, Textolit, Cartatextiel, Ferrozell, Harex and Micarta.

The name Tufnol has however, over the years, become a generic name in the UK for these types of SRBF material. This has led to the availability of some inferior performance, lower cost SRBF materials that look the same or very similar to genuine Tufnol but in fact may or may not be manufactured in accordance with the international standards to which Tufnol brands comply.

Cotton/phenolic resin laminated plastic grades of 'Tufnol' have been the material of choice for a number of surgical instrument handles for many years, especially where impact resistance and high strength and general durability are required (eg. chisels, osteotomes, gouges, curettes, mallets, screwdrivers etc.). This is supported by Tufnol SRBF's proven good resistance to repeated exposure to cleaning chemicals and steam sterilising in autoclaves at temperatures up to 137°C in accordance with standard practices. It also has very good wear and shatter resistance, minimising the risk of fragments break off during normal surgical use.

Different Tufnol grades have cotton fabric reinforcements ranging from fine weave to coarse, with varying resin contents. In general, the medium and coarse weave grades are used for larger and more rugged components requiring good all round strength and toughness. The finer weave grades are chosen for their superior finish, higher dimensional stability and improved strength in thin sections.

'Tufnol' has good temperature resistance but, like most plastics materials, has a higher coefficient of thermal expansion than stainless steel and most other metals, the importance of which is explained below.

Tufnol is however a relatively expensive material.

Practical commonly used alternative materials to Tufnol for 'heavy duty' instrument handles are:

- Nylon 6-6 [SEE NOTE 1]
- POM [SEE NOTE 2]
- Propylux [SEE NOTE 3]
- Aluminium (either natural finish or hard anodised)

- Stainless Steel

TUFNOL in Surgical Instruments – Some pro's and con's:

- Tufnol is non-metallic and therefore will not rust.

- Tufnol is a hard thermoset plastic, rigid and strong, relatively light in weight.
  Ie. volume for volume about 80% lighter in weight than steel, 50% lighter than aluminium but about 20% heavier than Nylon 6-6 and about the same weight as POM.

- It is a very good electrical insulator and therefore useful for use on instruments used in association with electro surgery, as is Nylon and POM.

- Resistant to long-term immersion in water with low water absorption. Moisture absorption therefore has less of an effect on the physical properties compared to nylon.

- Tufnol is resistant to a wide range of chemicals.

- As with all plastics, Tufnol will environmentally 'degrade' over time and become prone to environmental stress cracking and decomposition. In this regard, Tufnol does have a tendency to fragment and 'granulate' as it degrades whereas Nylon and POM tends to crack and split. The rate of onset of this natural ageing phenomenon is dependent mainly on the environmental severity and, frequency of use / reprocessing cycles.

- Tufnol has excellent machinability with good dimensional stability and capable of producing an excellent surface finish.

- Approx. 65% higher coefficient of thermal expansion than stainless steel. This is an important factor that can adversely affect long term security of handle to instrument joints.

- Tufnol is a thermosetting plastic and as such will not melt or deform at elevated temperatures whereas thermoplastics (eg Nylon, POM, Polypropylene, Teflon) do soften as the temperature rises.

- Recommended maximum continuous working temperature of Tufnol is between 120 - 130°C (depending on grade).

- Recommended maximum intermittent temperature for Tufnol is between 130 - 150°C (depending on grade). Technically therefore some grades are borderline for long term resistance to steam sterilisation at 137ºC. History however tells us that in practice, Tufnol withstands repeated sterilisation relatively well when compared with other plastics.

- Tufnol can be easily bonded using surgical grade structural adhesives.

- Tufnol is only available in brown or black whereas nylon and POM can be sourced in a variety of colours if required. The natural colour of Tufnol is brown which occasionally leads to the appearance of handles machined from Tufnol being misconstrued as wood!

- Tufnol is a relatively high cost material to use – typically, for the same size of handle it is:

  - Around 9 times higher raw material cost than Nylon plus higher machining cost
  - Around 8 times higher raw material cost than POM-C plus higher machining cost
  - Around 6 times higher raw material cost than Polypropylene plus higher machining cost
  - Around 2 times higher raw material cost than Stainless steel but lower machining cost and is generally a viable alternative in this case, where technical requirements allow.
  - Around 3 times higher raw material cost than Aluminium and lower machining cost but aluminium benefits from anodising resulting in roughly equivalent handle cost.

Durability of Tufnol in comparison to other plastics:
Relative to other plastics referred to in these notes that are used for handles fitted to surgical instruments, the experience of Bolton Surgical Ltd is that Tufnol has a good overall performance record. We have encountered numerous cases of Tufnol handles that have endured >15 years of service before failure. We have also received instruments for handle replacement that had obviously been allowed into theatre for use in a totally unfit condition, confirming that handle failure risk increases with age and frequency of use. The case study below is such an example.

What tends to go wrong and why? (Please also refer to the case study below):

- **Tufnol Handle becomes loose or detached from instrument :**

  This is generally the result of movement and stresses induced during normal use and the effect of differential expansion rates between plastic handle and stainless steel blade that repeatedly induces stresses in the handle to blade jointing compound as the instrument is heat cycled during processing, accelerating the rate of degradation of the materials involved in the joint.

- **Handle Fractures or fragments:**

  This is the result of the natural ageing phenomenon that affects all plastics materials and results in gradual decomposition or de-plasticising of the plastic making it prone to environmental stress cracking.
  The rate at which decomposition takes place in instrument handles is a function of time and the frequency of exposure to severe chemical and physical environmental conditions encountered during normal use and cleaning/sterilising cycles.
  As far as a Thermoset resin such as Tufnol is concerned, this phenomenon tends to result in fragmentation and embrittlement of the material, whereas with most thermo-plastic polymers such as nylon 6-6 and POM, the result tends to be cracking and splitting of the material and is more visibly apparent before a catastrophic failure of the handle occurs.

  Handle failure can often be aggravated (as is illustrated by the case study below) by the bursting load generated by corrosion of the steel shaft (as the iron in the steel corrodes, its volume increases by up to 10 times). The corrosion being the result of water /chemical ingress as is described below.

- **Discoloured fluids leak from handle after processing:**

  This problem is the result of subsequent leaking of fluid or moisture that has ingressed into the handle/instrument joint due to capillary action and/or the 'heat pump' effect caused by temperature changes. The discolouration can be from a number of sources including rust staining from the instrument itself, in-use surgical contamination, cleaning solutions containing dissolved surgical debris.
  What happens is -- once failure of the sealing compound has occurred that would otherwise be securing the handle to the instrument (as described above), air pressure within the handle cavity increases as the air expands during heating cycles causing it to be expelled. As subsequent cooling occurs, the remaining air within the handle contracts. This lowers the pressure causing a suction effect that draws surrounding moist air or fluids into the handle cavity through the instrument joint. Water vapour condenses to liquid and remains within the handle cavity and/or the handle to instrument joint.

Conclusions:

- All metal instruments with plastic handles fitted to them pose similar risk management issues, irrespective of the type of plastic used for the handle. The question is which material best balances handle failure risk minimisation with economics considering handle replacement cost /frequency options versus instrument replacement cost/frequency.

- Tufnol is a very strong and durable material with a generally good service life expectancy compared to other plastics. However, the result of material degradation and decomposition tends to pose a higher level of risk with Tufnol than with the other options discussed above.

- Breakdown of the handle/blade sealing compound is a major factor affecting the rate of deterioration of the joint, making adhesive selection just as critical a success factor as the handle material itself.

- Risks related to failure of Tufnol, or other plastic handles fitted to stainless steel instruments as described above can only be minimised, the only way for the risks to be eliminated would be for the instrument to be formed or fabricated totally from stainless steel. Clearly, this solution poses questions associated with instrument weight, balance and cost.

- Frequent inspection of the handle to blade joint condition between reprocessing cycles is essential, irrespective of the material used for the handle and a planned maintenance programme including periodic submission to a competent surgical instrument repair company for expert inspection and handle maintenance would be highly recommended.

NOTES:

1 - **Nylon 6-6** is a thermoplastic copolymer that has very good physical properties although moisture absorption can affect these properties:

- Good heat resistance
- Excellent chemical resistance
- Excellent impact and shatter resistance
- Excellent wear resistance
- Good electrical and dielectric properties
- Fair to easy machining with very good surface finish
- Available in a variety of colours
- Moderate to low water absorption
- Relatively low price option versus Tufnol but generally slightly higher than POM

2 - **POM** (**P**oly**O**xy**M**ethylene) is a thermoplastic also commonly known as Acetal Copolymer or Polyacetal (POM-C) or Delrin (Acetal Homopolymer, POM-H). POM has very low moisture absorption and good physical properties:

- Good heat resistance
- Good chemical resistance
- Good impact and shatter resistance
- High abrasion resistance
- Low coefficient of friction
- Good electrical and dielectric properties
- Easy machining with very good surface finish
- Available in a variety of colours
- Very low water absorption
- Relatively low price option versus Tufnol and generally slightly lower than Nylon
- POM-C has slightly higher thermal resistance than POM-H and a slightly better resistance to high pH solutions.
- POM-H has generally slightly better mechanical properties than POM-C

3 - **Propylux® HS** (Heat Stabilized polypropylene) is a family of polypropylene resins manufactured by Westlake Plastics. This semi-crystalline thermoplastic offers broad chemical resistance, low moisture absorption, hydrolysis resistance, and toughness.

Medical grade Propylux HS2, a Heat Stabilized Polypropylene, is made from an FDA, USP VI approved polypropylene resin. Through a unique heat-stabilizing process, the compression moulded material can withstand higher temperatures with less water absorption than standard polypropylene.

Propylux HS Properties:

- Good Impact Resistance and Practical Toughness
- Excellent Chemical Resistance
- Low Density
- High Dielectric Strength
- Fatigue Resistance
- Easy machining with very good surface finish
- Available in a variety of colours
- Steam sterilisable
- Low Moisture Absorption
- FDA Approved
- Formable and Weldable
- Relatively low price option versus Tufnol but more costly than POM

CASE STUDY / Example of SRBF Handle failure:

(See photos on next page)

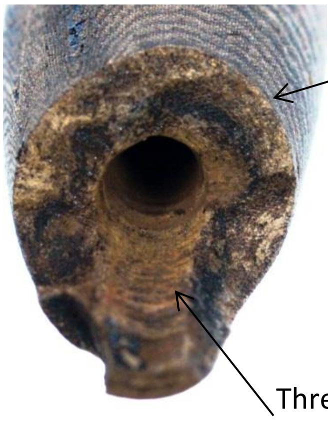
The Capener Gouge featured in this case study was submitted to Bolton Surgical for technical evaluation and comment (It was not returned under complaint) as a result of failure during use. On this occasion no patient harm was incurred but nevertheless, this illustrates a potential risk if the condition of aging instrument handles and their fitments are neglected. The instrument was reported to be over 15 years old. The gouge was not made by Bolton Surgical but that is not to say that a Bolton Surgical equivalent product would not have suffered the same fate under the same circumstances.

1. The handle is manufactured from 'Tufnol' or an alternative Synthetic Resin Bonded Fabric.
2. The general blade passivation was still intact on exposed surfaces but heavy corrosion is present on the threaded end.
3. There is no evidence of any sealing compounds remaining in the threaded blade to handle joint, this could be because the thread was not sealed originally or that the sealing compound has degraded with continual use.
4. Rust in the blade thread is undoubtedly the result of ingress and entrapment of water, saline or maybe RO water that has given rise to chloride or crevice corrosion.

HANDLE FRACTURE:

5. Several failure mechanisms are likely to have contributed the fracture process:
    - 5.1. The fracture surfaces and general granular condition of the resin is typical of decomposition of the resin due to the long term effects of repeated temperature and chemical cycling during reprocessing that has led to environmental stress cracking and fragmentation.
    - 5.2. The thermal expansion of the 'Tufnol' handle is about 65% greater than that of the stainless steel blade resulting in the handle expanding away from the blade during heating causing movement and therefore wear and loosening of the threaded joint over time. This movement also causes sealing adhesives to be repeatedly put under tensile stress and is likely to be a contributing factor (along with high compressive impact stresses induced during normal use) causing gradual loss of any sealing compound originally used to seal the thread.
    - 5.3. Chemical solutions being sucked into the threaded joint due to the expansion and expulsion of air from the joint during heating cycles followed by contraction of the air during cooling, causing a slight vacuum and heat pump effect.
    - 5.4. Solutions ingressed as above become largely trapped between the handle and blade and chemically destroy the passive surface of the stainless steel thread resulting in corrosion. As the iron in the steel corrodes, its volume increases by up to 10 times resulting in significant bursting pressure being applied to the inside of the handle, causing stress cracking of the handle if the rust is not released.
6. It is considered almost certain that cracking of the handle will have occurred over time, starting in the threaded hole or on the end face of the handle adjacent the blade bolster, making it initially difficult for the cracks to be seen during instrument inspection (although it is considered likely that cracks would have been visible prior to failure) with failure occurring as impact stress during use finally exceeded the constantly deteriorating strength of the handle.

Corrosion of thread
caused by trapped fluids



Discoloured, denatured and embrittled
handle fracture surface

Thread in handle almost totally
decomposed and fragmented

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