

Single-Use Acupuncture Needles: Scanning Electron-Microscopy of Needle-Tips

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The photomicrographs in this article were displayed in a poster presentation at the BMAS Autumn Scientific Meeting at Imperial College, London in October 2000

Summary

Unselected, disposable acupuncture needles from various manufacturers and retail suppliers were taken from a pool of donated and bought samples. Three needles of each type were prepared for electron-microscopy. The needle tips were inspected at two magnifications (x39.37 and x612.5): 52 electron-micrographs were taken of 31 individual needles from 11 different types. No needle-tip looked perfect and significant faults were seen in most; some appeared seriously deformed. The faults noted were: scratch marks along or across the needle, metallic scuff, lumps and irregularities in the needle surface, needle-tip stubbed or malformed, and needle point off-centre. An additional test made was to wipe a number of needles firmly on white paper tissue. Some left grey lines, and these were regarded as evidence of metallic or oily residue from the needle surface which could have been deposited in the patient. These unexpected findings, in a variety of popularly used needles from well-respected suppliers, suggest that most manufacturers need to reassess their quality control procedures.

Keywords

Acupuncture, acupuncture needles, electron microscopy, needle manufacture, quality control, silicone coating.

Introduction

The earliest known acupuncture implements were of bone and stone (*Bian Shi*) dating to the Stone Age.^{1,2} Later, needles were made of gold, silver, bronze, and more recently stainless steel. Acupuncture needles were traditionally hand-crafted to perfection, but increased demand meant a mass production method had to be devised: silver and gold handled, stainless steel filiform needles in both coil and spiral format were produced initially. These needles were intended for reuse many times, being sterilised either by autoclave or glass bead heater.

Regrettably, sterilisation standards were not always observed, due to ignorance or laxity, with resulting cases of cross infection, some of which achieved high-profile media coverage.^{3,4} The notorious 1977 UK West Midlands hepatitis B outbreak, caused by reuse of unsterile acupuncture needles, prompted a needle supply firm (*AcuMedic*) to invest in designing the first disposable acupuncture needle in 1978. The initial production batches were rather expensive, as single-use, sterile

packaging had a high set-up cost. Then a new method was tried of packaging the needles in plastic tubes; this allowed reduction of cost by using gamma-ray sterilisation, thus introducing the disposable acupuncture needle as a popular concept. This original type of disposable needle was responsible for the initial change in usage in the West, but the new demand from European countries and North America encouraged manufacturers in Japan and Korea to follow suit, reducing the cost further by designing plastic handled needles suitable for mass production. Chinese manufacturers took up the challenge in reducing the cost of disposable needles by combining automation with low labour costs.

Following a review of possible prion transmission via surgical instruments, the UK Ministry of Health has recommended that single-use, disposable acupuncture needles should be used for all acupuncture practice.⁵ The rationale for this is that variant Creutzfeldt-Jakob Disease (vCJD), popularly known as human-form BSE (Bovine Spongiform Encephalopathy), appears to

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be transmitted by prions that are not destroyed by heat sterilisation and are found particularly in neural and lymphoid tissue. Since needles are quite likely to reach one or both of these tissues, and there is no way of knowing if an acupuncture patient has or carries vCJD, which has an unknown, but long, incubation period, there is a small risk of human to human transmission of this disease if needles are autoclave-sterilised in the normal manner. Those UK acupuncturists who have continued to sterilise reusable needles will thus be looking for a reliable source of cheap, but good quality, disposable needles. Our investigation is likely, therefore, to be of interest.

The current, highly competitive marketing of needles has unfortunately created new problems: some manufacturers may feel under pressure to use low quality steel wire and packaging and omit essential safety and quality assurance processes for the sake of cost.

Method

Unselected, single-use, disposable acupuncture needles were acquired from various sources: either bought by the authors, or kindly donated by members of the British Medical Acupuncture Society (BMAS) or from stock by needle suppliers exhibiting at the BMAS Autumn Scientific Meeting held in London in October 1999. The collection comprised samples of most of the popular ranges of disposable needles used in Great Britain and Germany, many currently available internationally. Some were manufactured in China, some in Japan and some in the United States.

Three of each type of pre-packed, sterile, disposable needle were taken, without conscious selection, and removed from their wrappings. Each needle end was cut off from its handle and shaft, and mounted with the other two of its type in one of the blocks we had specially made to hold three needle-tips. They were secured with Silver DAG suspension to ensure full electric contacts, thereby preventing any charge from building up. The block was then placed in the electron microscope chamber. Care was taken to avoid contamination during preparation, however needle tips were mounted directly with no coating, so that any loose dirt or contamination from the mounting process would have been blasted off the specimen

in the electron beam before photographs were taken. Following standard electron microscopy technique, we used a JEOL JSM 25 S111 scanning electron microscope at 12,500KV and a working



Plate 1 Low (x39.4) and high (x612.5) power magnification of a single needle. The lump on the upper surface of the high power photo can be seen close to the tip on the low power.



Plate 2 Three magnifications of a single needle (x65, x850 and x5000).

distance of 10mm to take photomicrographs of needle tips at both low (x39.37) and high (x612.50) magnification (see plate 1). In the initial trials with the test needle the voltage was varied to find the optimum value, and magnifications of x65, x850, x4500 and x5000 were studied (see plate 2). The two highest magnifications gave too close-up a view of the point, with insufficient length of the rest of the needle tip.

Electron microscopy is expensive, so the scope of our investigation was inevitably limited by cost, although we were able to make detailed inspection of a reasonable variety of needle types.

Results

By the end of the investigation we had taken 52 scanning electron-micrographs of good quality, including 8 showing various views of the test needle at 4 magnifications. They were of 31 individual needles from 11 different types, plus 2 that were duplicate types but of different gauge. Fourteen were at low magnification (x39.37) and 30 at high magnification (x612.50); for the test needle there were two at x65, four at x850, one at x4500 and one at x5000. All photographs taken may be seen on the BMAS website

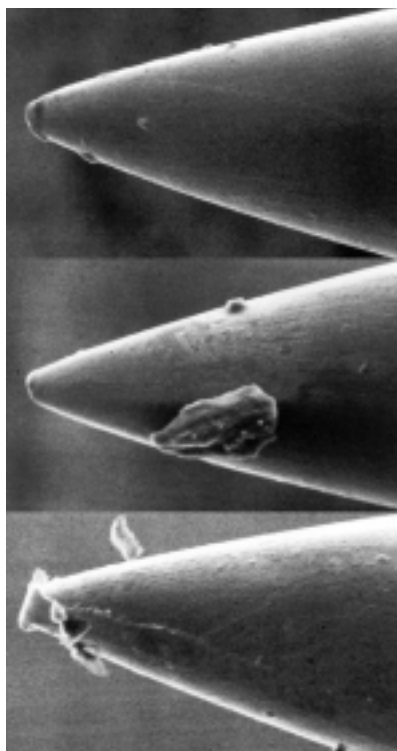


Plate 3 Three needles of a single type to show the range of quality found (x612.5).

www.medical-acupuncture.co.uk except those of poor visual quality and some repeated views of the test needle (leaving 47 in all).

To our surprise, no needle was perfect and most showed significant faults, some apparently serious. Although we did not formally obtain quotations from needle suppliers, relying instead on possibly out of date catalogue prices, we found no apparent correlation between the retail cost (which sometimes varied widely between suppliers of an identical product) and the needle-tip appearance; also several types showed a wide range of needle-tip quality within the three sample needles inspected (see plate 3). Faults noted were:



Plate 4 Scratch marks along a needle (x612.5).

- i. Scratch marks along or across the needle (see plate 4)
- ii. Metallic scuff, lumps and irregularities of the needle surface (see plate 5)
- iii. Needle tip stubbed or malformed (see plate 6)
- iv. Needle point off-centre (see plate 7)

Having obtained these unexpected results, the clinical author (SH) recalled occasionally noticing a fine grey ring on the skin surface around needles while in situ, or a dark discolouration of the exit hole after needle withdrawal. To investigate this further, we took plain, white, paper tissue and unselected needles freshly removed from their packaging. Each needle was gripped firmly in the tissue and wiped through. A number of the needles left clear grey lines on the tissue with the first wipe (see plate 8) reducing to none on subsequent wipes. One type of needle left a clearly visible line with several of the needles tested; a second type (as plate 9) marked with a few, while a third (as plate 10) marked with none. We also tested various silicone-coated, hypodermic needles: none of these left any mark. We regard this as evidence of residue on the surface of some acupuncture needles.

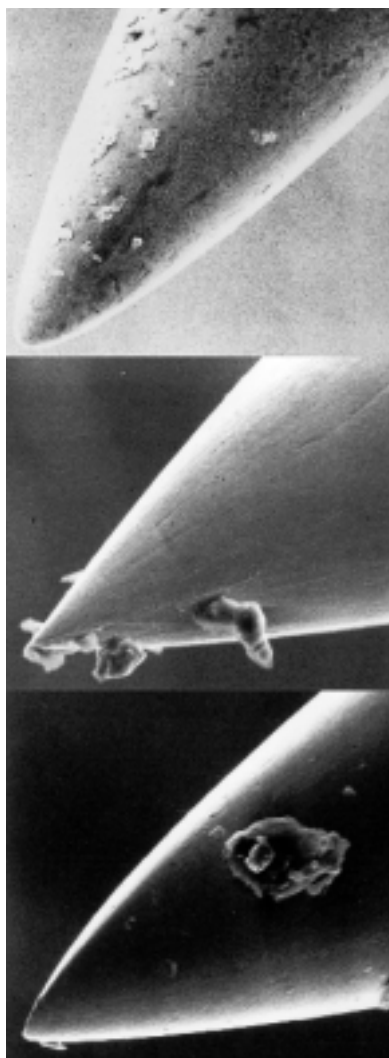


Plate 5 Scuff, lumps and irregularities of the needle surface (x612.5).

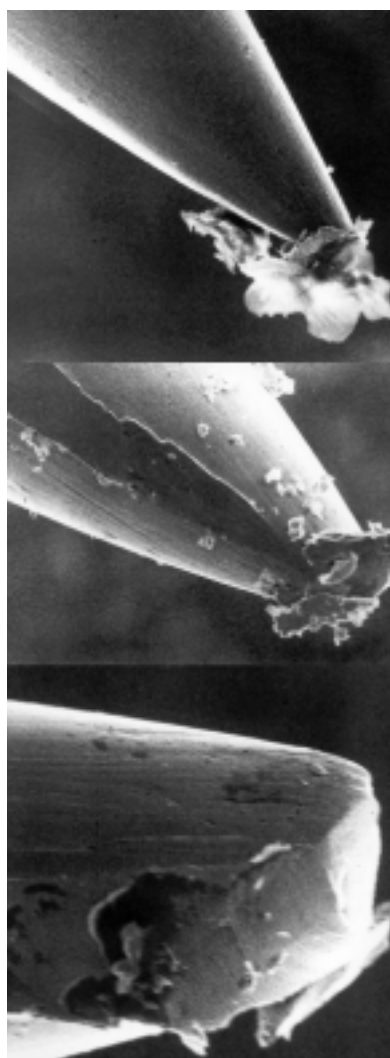


Plate 6 Stubbed and malformed needle tips (x612.5).

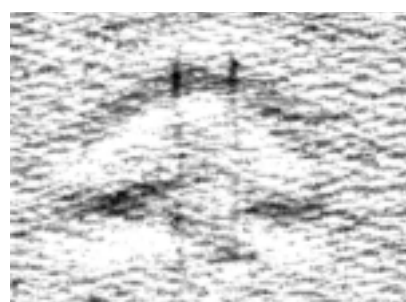


Plate 8 Marks left on a tissue by wiping an unused needle.

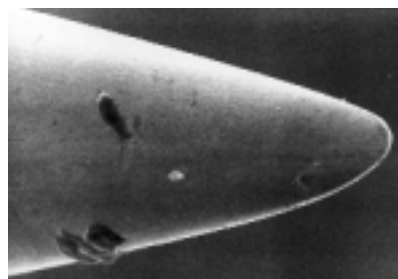


Plate 9 Needle type with surface residue (x612.5).



Plate 10 An almost perfect needle-tip (x612.5).

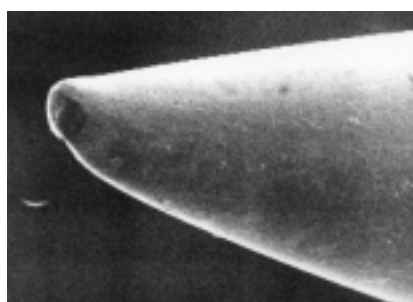


Plate 7 Needle point off-centre (x612.5).

Discussion

Our needle suppliers had been told what we intended doing and had had the chance to refuse us samples if they suspected that any of their needles were not of the best quality (we had included some independently bought needles to control for this - unnecessarily, it seems) so our

findings can be considered an unbiased picture of current needle-tip quality: one which has been as much of a surprise to the suppliers as it was to us.

Our first reaction was one of considerable surprise; but, on reflection, many millions of these *faulty* needles have been used clinically without apparent ill effect, so there seems to be little real danger from using them. Indeed, the needling sensation (*de qi*) is thought to be caused by muscle fibres catching and twisting around the needle-tip,⁶ a process which would occur more surely if the tip were irregular. So it is possible that a perfectly smooth needle might not be as effective clinically. Scratch marks, and minor lumps and irregularities of the surface may therefore be acceptable faults. However, malformations that might predispose to needle fracture, that could adversely influence the handling characteristics of the needle, that are likely to cause excessive pain,

or might leave metallic deposits in the skin or muscle tissue of a patient, are very clearly unacceptable. This means that metallic surface scuff and significant lumps and irregularities in the needle surface due to inadequate smoothing, polishing and wiping, of any part of a needle that might be inserted into a patient, must somehow be eliminated in future. Likewise, quality control during the manufacturing process must aim to prevent distortions and asymmetry of the needle point, and ensure that all faulty needles are removed from the production line before packaging.

Polishing and smoothing ferrous metals can induce magnetic and electrostatic fields, so it is possible that some of the metal filings produced in forming a point become adherent to the needle through these forces, which further polishing might merely increase. This is one possible explanation of the grey residue that can be wiped off some needles with a tissue, and it may be that by preventing the build-up of these fields the needles could be kept relatively free of deposit. On the other hand, it has been suggested that at least some beneficial clinical effects can be due to induced magnetic and electrostatic forces.⁷⁻¹⁰ This is an area that needs further investigation.

Silicone is routinely used as a covering for many surgical and hypodermic needles to reduce friction, aiding smooth and pain-free insertion. Some Japanese-manufactured acupuncture needle types (see plate 11) have been similarly treated, although there is evidence that, while silicone coating increases the durability and sharpness of needles repeatedly used in deep tissues, as measured by the energy required for penetration, it makes little difference to insertion through the skin.¹¹ Additionally, there have been reports of formation of silicone granulomata following the use of coated needles for injection and for acupuncture.^{12,13} The photographic appearance of the needle in Plate 11 is misleading, as the silicone



Plate 11 Silicone coating (damaged during microscopy) (x39.4).

coating has been damaged by the electron beam during microscopy. This made it impossible for us to investigate the surface of these needles in our survey, but if there were any metallic scuff or lumps on a needle, silicone coating might be presumed to smooth these over and anchor them to the surface, preventing them from catching in the skin or muscle and causing pain, or from becoming dislodged in the patient's body.

There have been many reports of needles accidentally broken in the skin or muscle of a patient,¹⁴⁻¹⁷ particularly from Japan, where fine gauge needles are popular and deliberate needle breakage and embedding has been widely practised. These may be due either to microscopic faults allowing a fracture to occur after manual or electrical manipulation or muscular contraction, or to the inappropriate use of a steel manufactured with characteristics that allow a fine wire to snap rather than bend. The unexplained sharp pain at a single needle site, occasionally reported by patients during insertion or extraction, could be due to a malformed needle-tip catching in skin, nerve or muscle tissue. Off-centre points, with a greater curve on one side of the tip than the other, are likely to alter the direction of insertion while being pushed through body tissue: the needle may end up going to a different position to that expected.

The retail cost of a needle is influenced by many factors other than the manufacturing cost of the needle itself. It varies with the number bought (often discounts are given for 1000 or more), the type of packaging and sterilisation, whether any guide tubes are provided, whether needles are ready-packed in individual guide tubes, the length and diameter of needle, the type of handle, the speed and reliability of delivery, and the range of needles and other services offered by the supplier. Also, the overall quality of a needle is related not merely to the microscopic appearance of its tip, but to the characteristics of the wire used for the shaft, and the surface and attachment of the handle. (We incidentally noted one needle with a handle attachment fault: the handle slid along the shaft while the needle was being wiped through a tissue.) Nonetheless, the fact that there is no apparent relationship between the electron-microscopic appearance of a needle and its price suggests that for most manufacturers current

methods of quality control need reassessment. It is not necessarily that corners are being cut to reduce cost: it may be that a completely different approach to quality in the manufacturing process is necessary.

Manufacturing specifications

Like most medical equipment, disposable acupuncture needles are now subject to prescribed, but differing, standards set by authorities such as the European Medical Devices Agency (MDA) and the United States Federal Drugs Agency (US FDA). For instance, the Australian Therapeutic Goods Administration (TGA) requires a sterilisation dose of 25kgy of ethylene oxide (EO) gas, but other countries accept lower specifications. As true sterilisation is essential, manufacturers must ensure that the disinfection level reaches SAL=10 (sterile) according to European Union (EU) standards EN46002 and EN550. Other EU harmonised standards applied to acupuncture needles are: EN556 and EN1441 together with the international standards ISO 9000/2 in conformance with the European Council Directive Annex V of 93/42/EEC. Different standards are required for US FDA registration.

The first step in the process of manufacture is to choose the stainless steel wire. The composition and manufacturing process of the steel wire should be such that needle characteristics are as near ideal as possible. Wire should be high tensile, flexible, springy, strong, able to withstand corrosion, evenly ductile (constant gauge), able to take and retain a fine point, not over-rigid, and above all not brittle - to minimise the possibility of a needle fracturing while in a patient. Surgical grade stainless steel OCr19Ni9 or OCr18Ni9 is suitable and has been selected for some popular types of needle. The wires of different diameters are cut to appropriate lengths ready for sharpening, polishing, and winding of the handles (see plate 12). Oil is used during the grinding and polishing processes, and this may not always be fully cleaned from the needles. Thus surface oil, possibly mixed with metal filings, could be an alternative cause of the residue that we were able to wipe off some needles during our tests.

The finished products are then classified and put on the production conveyer belt to the test room for tactile testing and quality examination



Plate 12 Sharpening and polishing during manufacture.

(see plate 13). This is a crucial procedure, which is possibly rushed sometimes to cut costs. Needles that have passed these checks are cleansed and the points re-examined according to different manufacturers' technical facilities, but a microscope linked with a computer system would be considered suitable (see plate 14). All this work, including checking and packaging, must be carried out to EU standard EN46001 (as specified for sterile, single use, medical device production) in an isolated, clean room environment containing fewer than 100,000 suspended dust particles of 0.5mm or less in diameter, and not more than



Plate 13 Quality control: tactile testing.



Plate 14 Quality control: computer-linked microscope.

3,500 particles greater than that size, per litre of air (a class 100,000 clean room). This requires an effective air filtration system. Some manufacturers aim for a class 10,000 clean room.

Before packaging, the plastic slice PVC and the dialytic paper are tested with heat-pressure and for resistance to pressure in accordance with the standards for sterile packaging. The final product is sterilised in an EO chamber capable of meeting the bacteria indicator test of ATCC9372 specification. Finally the products are stored in a quarantine area for distribution.

Besides proper labelling and storage, all needles in the chain of sales and distribution must be accountable (ISO 9002). Should clinical accidents happen, or if there are faulty needles, they must be traceable back through the distribution channel and manufacturing process in order to identify the batch and investigate what has gone wrong. Traceability is of great importance considering the billions of needles being produced and the complicated supply chain. The needle packaging (boxes and individual sealed wrappers) should be labelled with the method and date of sterilisation, a use-by date and the manufacturer's code (lot number). Needles that conform to EU standards of production are granted a **CE** mark. All the needles we tested had been granted **CE** mark 0123 or 0124, so it seems that the EU controls the manufacturing process, but not necessarily the quality of the final product.

Clinical usage

The point shape of acupuncture needles varies with the country of manufacture: by tradition, Chinese needles tend to have a pine-sharp point for needle sensation ('de qi') while Japanese needles have a thin pointing; however, there is no consistent difference in shape visible in the photomicrographs of our study. Also, needles are made with various types of handle, of which the most popular are smooth plastic (usually of Japanese manufacture) or metal coil (usually manufactured in China or Taiwan); the latter may be stainless steel, silver, copper or aluminium alloy. A metal handled needle is preferable for electroacupuncture, as plastic handles are not electrically conductive. Needle shafts, being made of steel, are all conductive; however, contacts may

be difficult between fine needles and bulky clips, and some silicone-coated needles make poor contacts. Plastic handles are clearly unsuitable for moxibustion, as they are damaged by heat.¹⁸

Disposable needles are made from wire of various diameters, to some extent dependent upon shaft length. The range available varies between types, but diameters from 0.16mm to 0.35mm can be found, with lengths up to and beyond 75mm. For deep muscle treatment, a thicker needle is more suitable to cope with muscle tension and the possibility of spasm, as there is a greater risk of fine diameter needles being bent or broken by violent muscle movement, while for more sensitive or superficial points, as in ear, facial and finger acupuncture, short, fine needles are commonly used.

Conclusion

The major advance in patient safety and comfort and in practitioner convenience resulting from the introduction of single-use, disposable, acupuncture needles has also introduced a significant cost to treatment. There has thus been pressure on manufacturers to provide low-priced needles, sometimes with a consequent loss of quality that, not being readily visible to the naked eye, has remained unnoticed by practitioners. In our electron-microscopic survey every needle-tip tested showed some physical fault. We regard the commonly-found surface scratches and minor irregularities as acceptable and perhaps even beneficial for inducing needling sensation, but the faults that could result in pain, or metal and oil deposition in patient tissues should, we believe, be eliminated by more rigorous needle-tip inspection during quality control and possibly by a reassessment of production quality in the manufacturing process, although there is no reported evidence linking physical needle-tip faults with clinical ill-effect.

Now that we have identified unsuspected irregularity in the tips of a variety of popular, widely used acupuncture needles, practitioners should aim to look out for, and report, any adverse events that could be due to faulty needles. In particular, events that might be significant include: grey discolouration of the needle-puncture hole or tattooing at the puncture site (due to oily or metallic residue being wiped off the needle surface), unexplained sharp pain at a needle site during

insertion or withdrawal (possibly due to a malformed needle-tip catching in tissue), a needle altering direction during insertion (possibly due to an off-centre needle-point) and, of course, any physical evidence of needle mal-construction such as a loose or jagged handle, visible tip deformity, or needle fracture. Reporting would be greatly aided by a centralised, adverse event recording system for acupuncture to ensure that evidence is not lost through lack of systematic correlation.¹⁹

It would be instructive to repeat this survey after manufacturers have had a chance to address the issue of needle-tip quality. If adequate funding could be made available, it would then be reasonable to perform a blind comparison of different makes and types of needle. As the numbers of needles that we were able to subject to electron-microscopy in this survey were too small to make meaningful comparisons, and no needle type was conspicuously free from defect, we felt it unfair to name the manufacturers of individual needles. However, suppliers may obtain details of their own needles from the corresponding author.

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Competing interest

MFM is Chairman and Chief Executive Officer of Mei Group PLC, parent company of AcuMedic Ltd; the latter company manufactures and distributes acupuncture needles.

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