Examination of surface conditions and other physical properties of commonly used stainless steel acupuncture needles

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ABSTRACT

Objectives The present work examined the surface conditions and various other physical properties of sterilised single-use stainless steel acupuncture needles from two of the most popular brands widely used in many countries.
Methods Scanning electron microscope (SEM) images were taken for 10 randomly chosen needles from each brand. Further SEM images were taken after each of these needles underwent a standard manipulation with an acupuncture needling practice gel. A comparison of forces and torques during the needling process was also carried out.
Results The SEM images revealed significant surface irregularities and inconsistencies at the needle tips, especially for needles from one of the two brands. Metallic lumps and small, loosely attached pieces of material were observed on the surfaces of some needles. Some of the lumps and pieces of material seen on the needle surfaces disappeared after the acupuncture manipulation. If these needles had been used on patients, the metallic lumps and small pieces of material could have been deposited in human tissues, which could have caused adverse events such as dermatitis. Malformed needle tips might also cause other adverse effects including bleeding, haematoma/bruising, or strong pain during needling. An off-centre needle tip could result in the needle altering its direction during insertion and consequently failing to reach the intended acupuncture point or damaging adjacent tissues.
Conclusions These findings highlight the need for improved quality control of acupuncture needles, with a view to further enhancing the safety and comfort of acupuncture users.

INTRODUCTION

Acupuncture is a therapeutic modality that involves inserting needles into certain points of the human body. It has been used in clinical practice for thousands of years and is currently being practiced globally.[1 2] In modern China, traditional Chinese medicine including acupuncture accounts for 40% of medical treatment,[3] while in Western countries acupuncture is one of the most frequently used complementary/alternative therapies.[4–8]

The use of acupuncture can perhaps be traced as far back as the Stone Age (around 3 million years ago) in ancient China, using the *Bian Shi* (sharpened stones) to stimulate certain points on a patient's body to achieve therapeutic effects. The use of *Bian Shi* was followed by fine needles made of other materials such as bamboo, ceramic, bones, the thorns of plants, the beaks of birds and metals (including gold, silver, bronze and, more, recently stainless steel).[1 2 9] Modern-style acupuncture related therapies can be applied via a range of equipment including needles, acupressure pellets and electrical or laser stimulation. However, among all these forms of treatment needling acupuncture involving skin penetration is the most frequently used method, in China and in other countries. It is estimated that 1.4 billion acupuncture needles are used each year worldwide.[10]

Acupuncture needles were originally made for reuse multiple times, being sterilised after each usage.[9] An outbreak of hepatitis B in 1977 in the West Midlands, UK[11] raised concerns regarding the reuse of acupuncture needles and consequently single-use disposable acupuncture needles were introduced. The original usage of this type of needle was in Europe, followed by Japan and Korea. Later, Chinese manufacturers took up the challenge of cost reduction by combining automation with low labour costs.[9] Nowadays, China, Japan and Korea are the main suppliers of acupuncture needles, with China providing up to 90% of the world's acupuncture needles.[12]

The increasing use of acupuncture in recent decades has drawn increased attention to the safety and quality of this type of treatment. Although the adoption of single-use disposable needles has reduced the risk of human-to-human transmission of diseases in acupuncture treatment, acupuncture use is not free of adverse events. It was noted in a 2009 study that bleeding or haematoma/bruising at needled points represented 58% of all reported adverse events caused by acupuncture.[13] Recent research on acupuncture has mainly focused on the efficacy or mechanisms by conducting clinical trials or in vivo/in vitro studies.[14] There are very few scientific studies on one of the most critical components of acupuncture: the needle itself.[9 15 16]

A decade ago, Hayhoe *et al* carried out a pioneering study using scanning electron microscopy (SEM) to examine tips of single-use disposable acupuncture needles. He found significant faults in most of the acupuncture needles.[9] Since then, there has been no further research in this important area. The present study is aimed at investigating the surface conditions and other physical properties of the current most commonly used acupuncture needle brands.

MATERIALS AND METHODS

Materials

Prepacked, sterile, single-use, disposable acupuncture needles from two of the most widely used commercial brands, one from China (hereafter called H needles: H1, H2, …, H10) and another from Japan (hereafter called S needles: S1, S2, …, S10), were investigated before and after needling. Due to commercial sensitivity, the identities of the manufactures are not disclosed in this article. Both of these types of needle are made of stainless steel, with the same nominal shaft diameter and lengths of 0.25 and 30 mm, respectively. To examine the surface conditions and the force characteristics, 10 needles from each brand were indiscriminately selected from different batches of the commercial product. The use-by dates of the batches were June 2014 for H needles and May 2014 for S needles, approximately 16 months after the time when all tests were completed (January 2013). To simulate human tissue in acupuncture manipulation, gel pads from a UNICO Needling Practice Kit (Kenshin Trading Corporation, Torrance, California, USA) were used.

Evaluation of force amplitude and frequency in needling

To evaluate the force and torque histories during needling, a needling sensor tool known as an Acusensor was applied.[17] The Acusensor consists of two individual sensors: a needle motion sensor and a needle force sensor. The motion sensor measures the two main components of the needling manipulation: the longitudinal displacement and the rotation. The force sensor measures the axial force in the longitudinal direction and the rotational 'force' (that is, 'torque') acting on the needle.

Acupuncture manipulation tests were conducted at RMIT University, Melbourne, Australia. The Acusensor device was used to record needling profiles produced by a qualified acupuncturist with 20 years of experience in clinical practice in acupuncture. The UNICO gel pad was held between two layers of polymer foam materials. Only the central part of the gel pad was used for needling. To avoid any possible damage to needle tips, the insertion tube of the Acusensor was not used and therefore the displacement and the rotation of the needle were not recorded. In fact, the magnitudes of the needle displacement and rotation are not important in the present study. The time histories of the axial force and rotational torque were recorded using the Acusensor. During the tests, the acupuncturist was not allowed to see the real-time data, in order to avoid any bias of the acupuncture manipulation.

SEM characterisation

To examine the surface conditions of the acupuncture needles before and after needling, a ZEISS Supra 40 VP field emission SEM was used. Prior to the needling tests, SEM images of the randomly selected needles were taken to check the surface conditions of the needle tips and shafts, with a view to identifying defects such as scuffs, scratches, lumps and irregularities. The needles were then used to conduct the needling tests using UNICO gel pads as surrogates for human tissue. Thereafter, further SEM images were taken to investigate whether the imperfections remained on the needles and if any gel materials had been taken out of the pads as a result of the needling. An energy dispersive spectroscopy (EDS) device, which the SEM was equipped with, was used to identify the alloy compositions and alien materials found on the needle surfaces.

For the SEM examination, the as-received needles were unpacked and placed on a thin aluminium plate with their handles fixed by conducting resin. They were then sealed in the vacuum chamber of the SEM device. To assist in identifying the correct angles for observation after needling, the handles were marked with red dots in a certain direction. After the needling tests, these needles were carefully rearranged so as to locate the exact same observation angles to give the same photographing windows.

Further, in order to check the firmness of the lumps or other alien materials attached to the needle surfaces, several other randomly selected needles from each brand were cleaned in an ultrasonic washing machine for 1 min. Then, the needles were examined using the SEM. For H needles, these specimens were designated as H11, H21, …, H101, and for S needles, S11, S21, …, S101.

RESULTS

SEM observation of as-received needles

The SEM images of the randomly selected as-received H and S needles are shown in figures 1 and 2, respectively. A significant difference between the two types of needle was observed. For H needles, only one needle (H8) exhibited a relatively smooth and sharp end, and the best magnification for the SEM observations was 5000×. However, almost all examined S needles had relatively smooth tip shapes. Online supplementary figures S1 and S2 show the SEM images of the shafts of these two types of needle, with a magnification of 400×.

For H needles, typical characteristics of the needle tips included: (i) scratches, (ii) blunt ends, (iii) malformed ends and (iv) lumps and irregularities. Generally, the needle tips had several types of imperfections combined. The shafts of H needles were relatively smooth, particularly that of needle H3. Minute scratches and lumps were observed on the surfaces of the other three needles examined.

In contrast, S needles generally exhibited fairly consistent and smooth tips, where the scratches were patterned, mostly along the longitudinal direction. Few lumps (S3, S8 and S9) or attachments (S5 and S6) could be observed. The shafts of the S needles were almost perfectly smooth, with few scratches on the surfaces. Interestingly, a circle of approximately 0.032 mm in diameter was found on the shaft surface

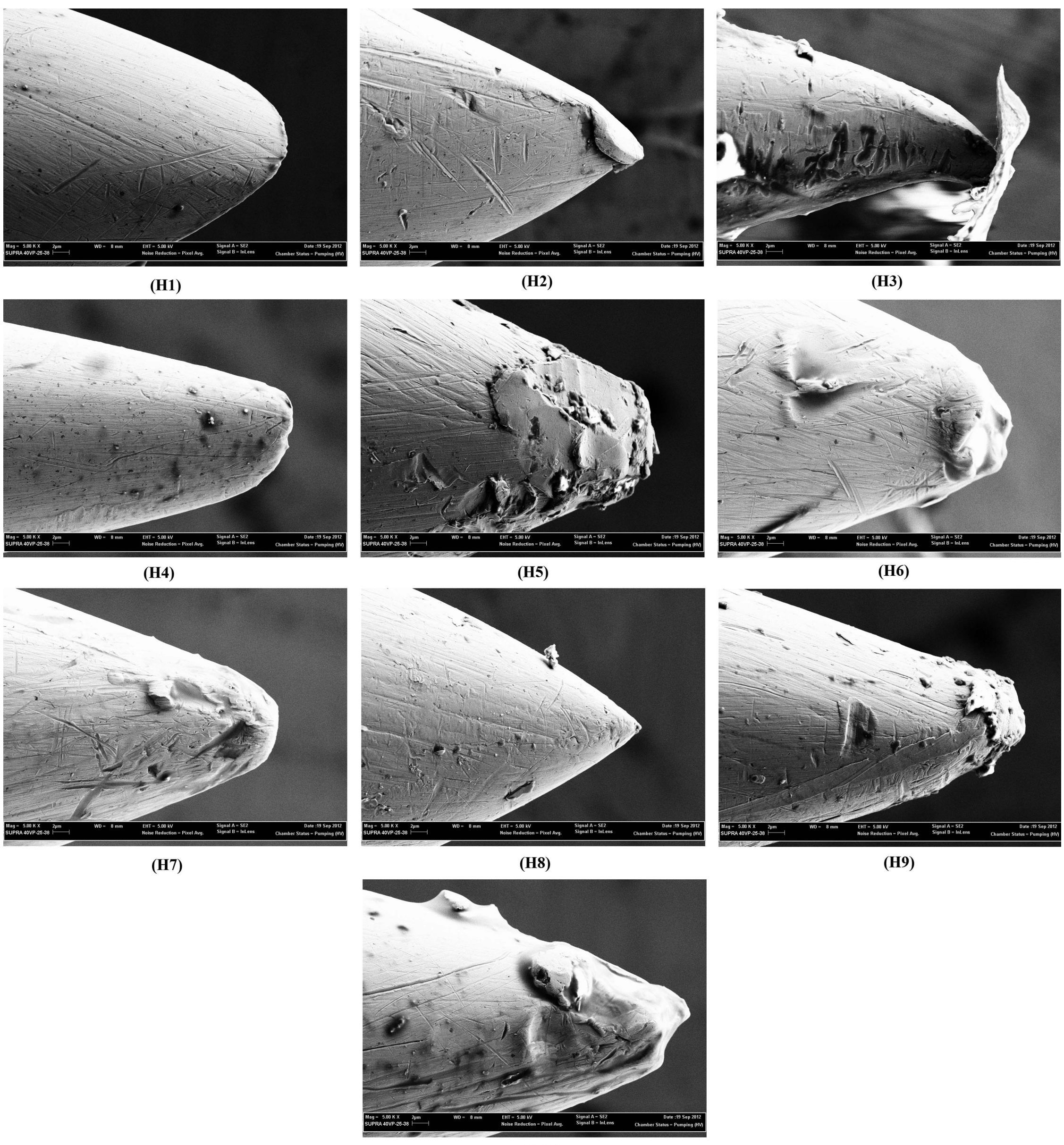

Figure 1 Scanning electron microscope (SEM) images of tips of randomly selected H needles. All images have magnifications of 5000×.

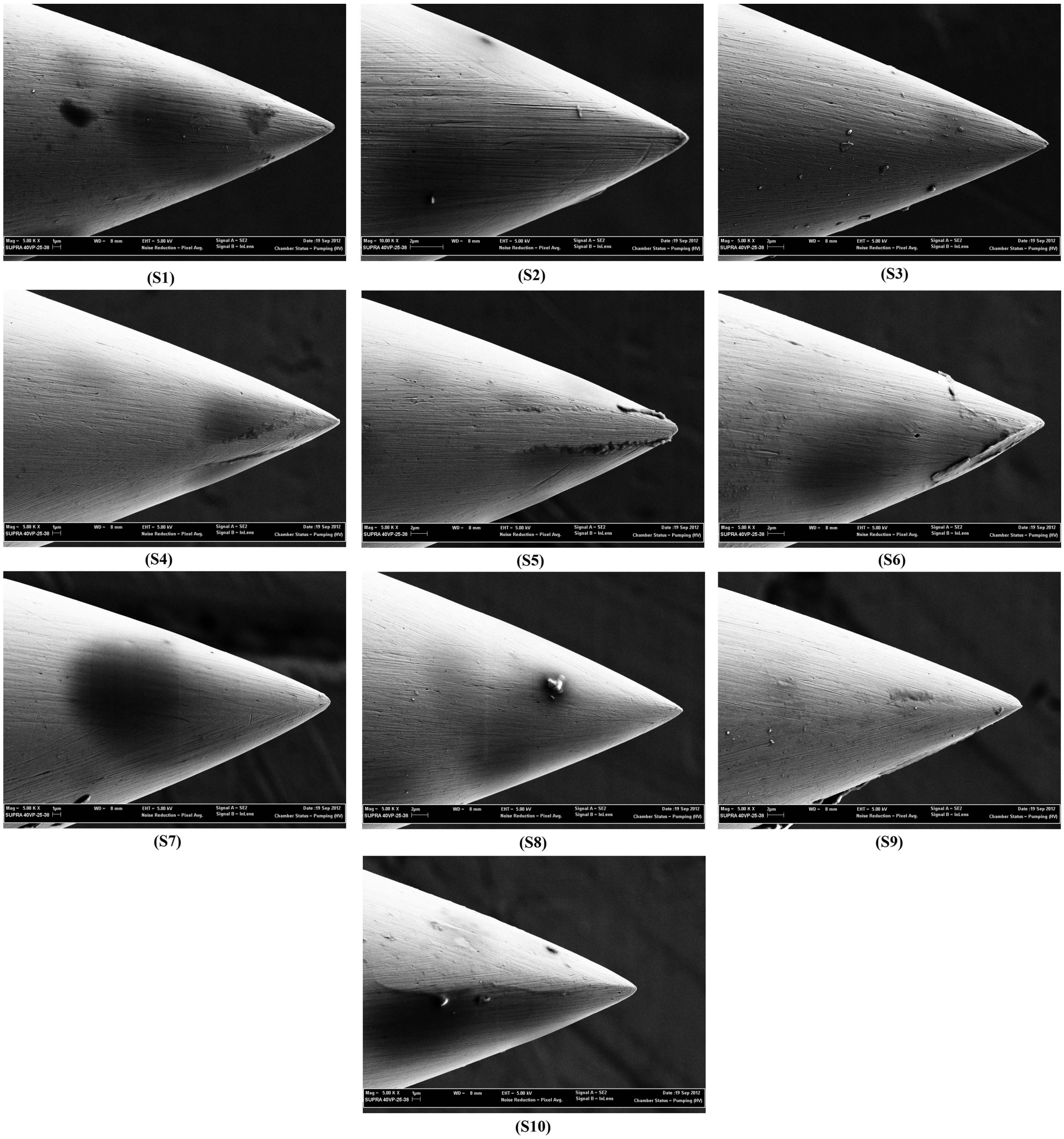

Figure 2 Scanning electron microscope (SEM) images of tips of randomly selected S needles. All images have magnifications of 5000×.

of needle S2 (see online supplementary figure S2), which was possibly due to the detachment of a lump in the polishing process during manufacture.

We also investigated the chemical compositions of the needles and the UNICO gel by scanning selected points on the surfaces using the SEM, which was equipped with an EDS device. For H needles, the representative composition (by weight) was 2.10% C, 0.96% O, 0.41% Si, 17.97% Cr, 66.46% Fe and 12.09% Ni, while for S needles it was 2.73% C, 0.62% Si, 21.34% Cr, 65% Fe and 10.3% Ni. The composition of the gel was 97.92% C, 1.90% O and 0.18% Si. It is of note that the chemical compositions of the two types of needle were quite similar, even though they were manufactured in two different countries.

According to measurements from the SEM images, the actual diameters of the two types of needle were almost identical: the average shaft diameter was 0.256 mm for H needles and 0.254 mm for S needles (against the nominal diameter of 0.25 mm for both types of needle).

Surface conditions of needles after acupuncture manipulation

To investigate changes at the needle tip before and after an acupuncture manipulation, some of the needles were selected to be tested (for example, those with lumps on the surface, or with very unusual ends such as needle H3). When taking SEM images, these needles were carefully positioned in order to obtain the same region for photographing before and after needling, so that changes in surface conditions could be observed clearly.

As shown in the left-hand panels of figures 3 and 4, lumps and irregularities at the needle tips were attached to the surface relatively firmly; most of them were not detached even after ultrasonic cleaning (H91, H101, S31 and S81). It was only found with needle S31 that one of the two major lumps disappeared after ultrasonic cleaning.

As seen in figures 3 and 4, after acupuncture manipulation some of the foreign material previously attached to the needles had been wiped off. At the same time, some gel became attached to the needle surfaces. For H needles, most of the lumps and irregularities disappeared. Specifically, only a small part of the unusual end of needle H3 remained and the rest was torn off during needling. Furthermore, a trace of twist at the slender tip of H3 was observed, which could be caused by the rotational manipulation in needling. For needle H91, after ultrasonic cleaning for 3 min, the attached irregularities still remained. However, some of these irregularities disappeared after needling. For needle H101, the large non-metallic lump, which remained after ultrasonic cleaning, was eliminated with little residue left. Interestingly, no obvious gel material was observed in the SEM images of H needles after needling.

After acupuncture manipulation, the surface conditions of S needles were slightly different from those of H needles. As shown in figure 4, although the tips of S needles were much smoother, gel was found to be attached to the surface of these needles after needling too. The three tested needles, S6, S8 and S31, were all found to have gel on the needle surface. An EDS spectrum showed the chemical compositions of the attachments were 40.36% C, 14.60% O, 4.18% Si, 8.33% Cr, 30.00% Fe and 2.53% Ni, and 23.14% C, 11.15% O, 4.56% Si, 12.39% Cr, 46.34% Fe and 2.42% Ni for needles S6 and S8, respectively, where C, O and Si were

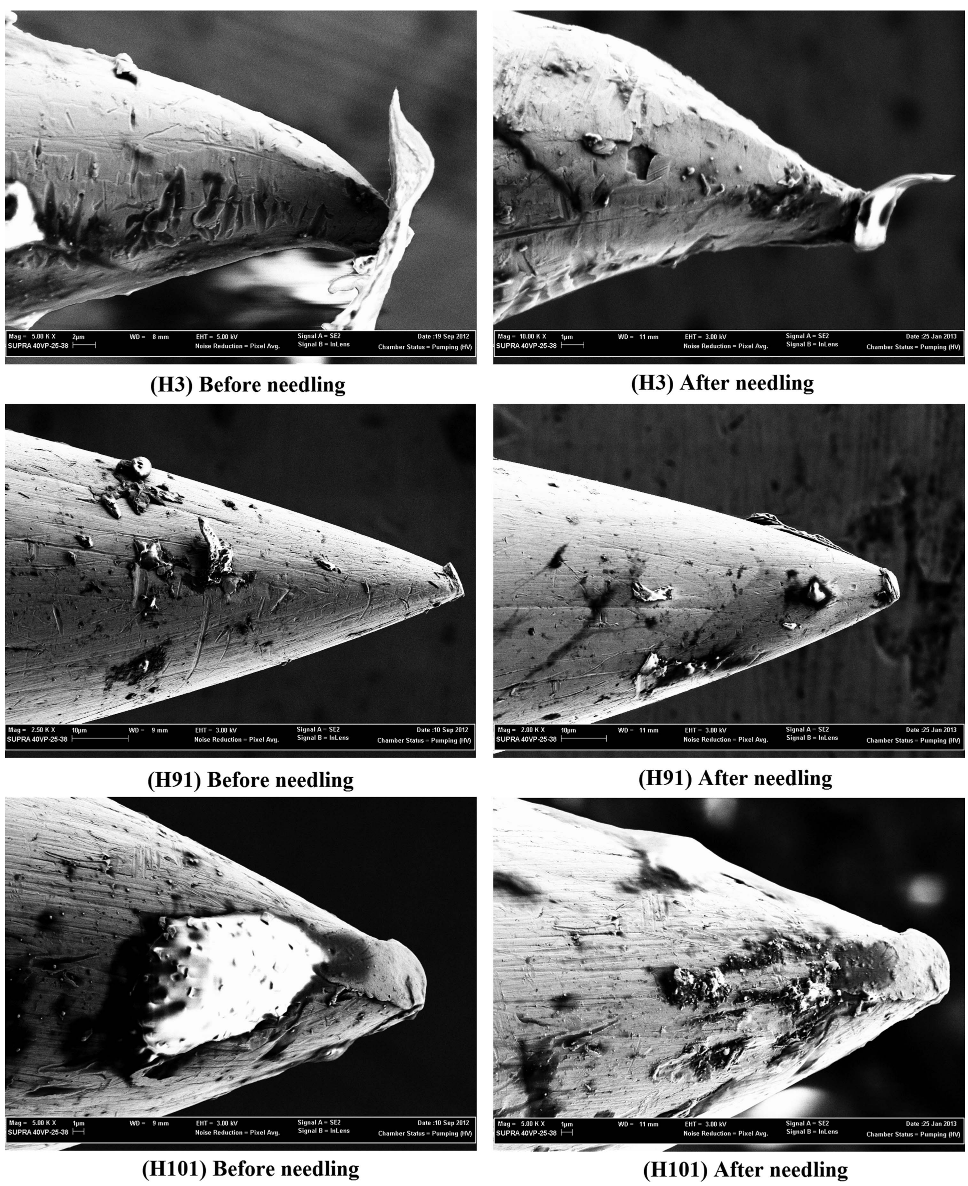

Figure 3 Comparison of surface conditions before and after acupuncture manipulation for three H needles (magnification 5000×).

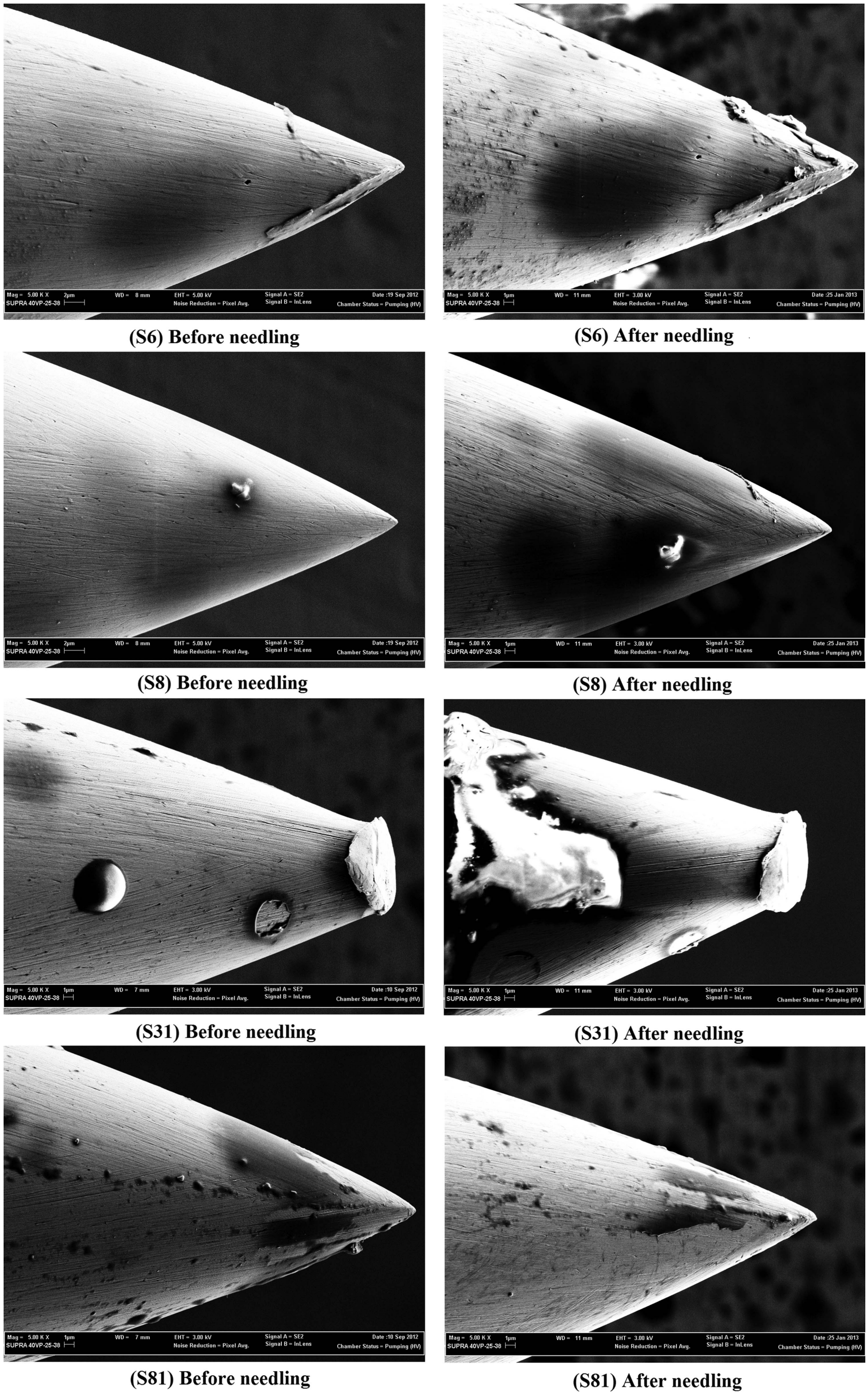

Figure 4 Comparison of surface conditions before and after acupuncture manipulation for four S needles (magnification 5000×).

from the composition of the gel, and Cr, Fe and Ni were from the needle matrix. Additionally, some lumps and irregularities were wiped off the needle during needling (for example, needles S31 and S81), similar to the results seen with the H needles.

Although figure 2 shows that the S needles also had some defects, all 10 randomly selected needles exhibited an identical cone shape at the tip. In stark contrast, each of the 10 randomly selected H needles had its own poorly formed irregular shape (except for H8).

Force and torque histories during needling

The real-time force and torque histories of selected H and S needles during needling are shown in supplementary figures S3 and S4, respectively. It can be seen that the force frequency and the torque frequency were synchronised in every single test for H and S needles. Further, figure 5A demonstrates a perfect linear relation between the torque frequency and the force frequency with the slope being equal to 1. In the manipulation, when the longitudinal (up and down) movement increased in frequency, the rotational movement increased accordingly in a linear relationship. This relationship is, in fact, related to the needing technique of the acupuncturist and independent of the needle type. Figure 5B clearly shows that, overall, H needles had significantly higher force amplitudes than S needles at the same frequency levels. Figure 5C shows that torque amplitudes (for rotational movements) of the two types of needle were scattered in a range from 45 to 120 mN, and no clear trend could be identified.

Although there was an unusually large attachment to needle H3, the force amplitude of this needle was not the highest. Instead, H101, which had the biggest cone at the tip, resulted in the largest force amplitude but, interestingly, the smallest torque amplitude. Needle H91 had a moderate size tip cone and a force amplitude between those of the other two H needles. In contrast, S needles had similar tip sizes and the force amplitudes fluctuated randomly in a relatively small range from 1000 to 1100 mN. Needle S6, with one side of the tip flattened, had a relatively higher force amplitude. Needle S31 had the smallest force amplitude, although its tip was accidentally blunted during the ultrasonic cleaning process.

Another phenomenon was observed regarding the relationship between frequency and force/torque amplitude. For S needles, with increased frequency in longitudinal movement, the longitudinal force generally increases. In contrast, with increased frequency in rotational movement, the rotational torque amplitude generally deceases. However, no clear trends were observed in H needles, possibly due to significant variations of the surface conditions of these needles.

DISCUSSION

The first disposable acupuncture needles were introduced in the late 1970s.[9] After more than three decades of developments in regulatory standards and manufacturing techniques, it would be reasonable for acupuncturists and patients to expect high quality in such a widely used clinical device. The findings from this study were of concern, as acupuncture needles from even most highly regarded manufacturers exhibited significant irregularities and inconsistencies.

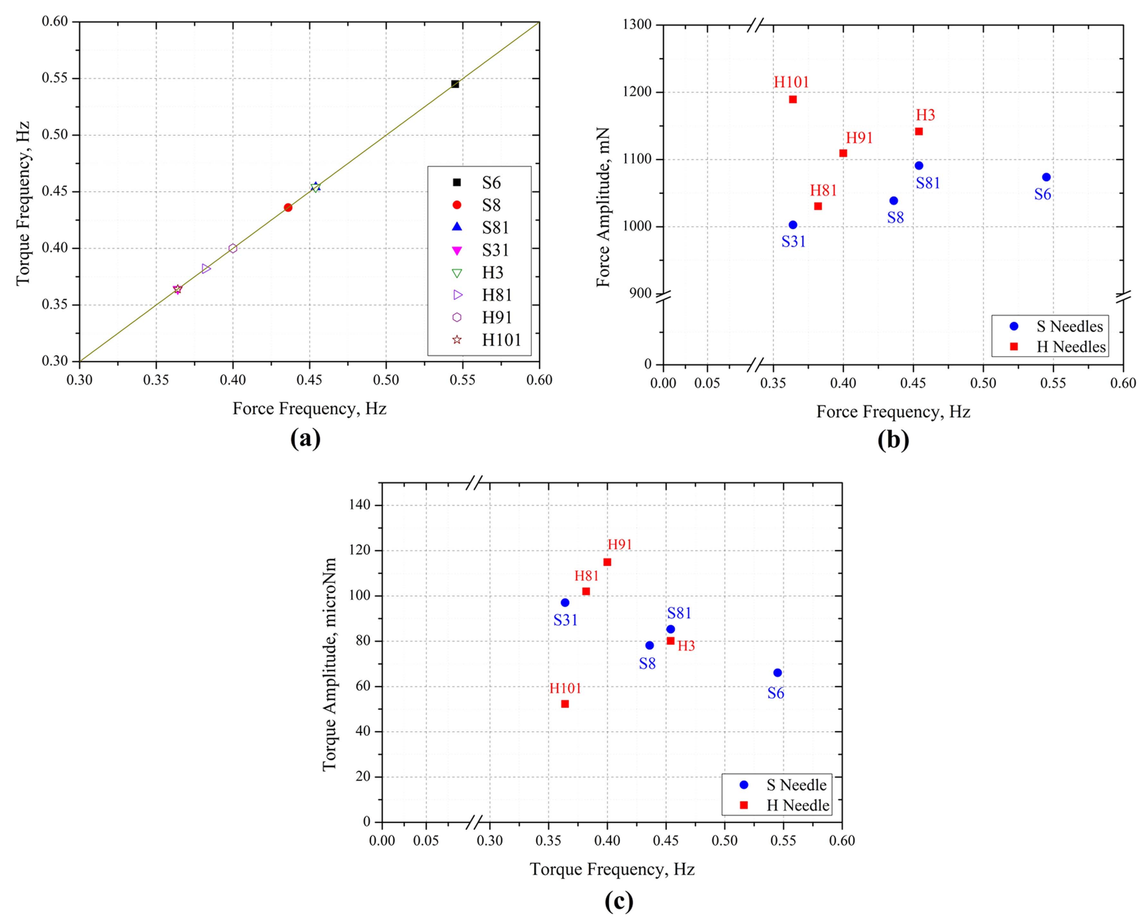

Figure 5 Relations between force and torque: (A) torque frequency versus force frequency; (B) force amplitude versus force frequency; (C) torque amplitude versus torque frequency.

Prior to the adoption of single-use disposal needles, the most commonly reported acupuncture adverse effects were infections, including hepatitis,[18] due to lack of rigorous sterilisation.[9] For example, acupuncture-associated hepatitis B outbreaks were reported in UK,[11 19] Jerusalem[20] and USA[21] between 1970 and 1990. Although there was no such report in China,[22 23] considering the fact that China had a moderate-to-high risk of hepatitis B infection compared to many Western countries,[24] the real situation might be similar in China.[23] Along with the use of single-use disposal needles, infection is no longer the major concern with regard to acupuncture. A number of large surveys on the safety of acupuncture were conducted recently, mainly in Europe. All these surveys reported a low risk of adverse events in acupuncture.[13 25–29] Although the rates of adverse events reported by either practitioners or patients are considered low, it is worth noting that among all reported adverse events, some local reactions such as bleeding or haematoma/bruising were the most common events.[13 26 28] Strong needle pain was also reported in all the above surveys.

In addition, earlier reports of skin reactions to acupuncture due to the presence of chromium or nickel in the needles exist.[30–32] Although the needles used in previous studies were quite different from those used in the present study, the EDS spectra of the H and S needles showed that the needle surfaces contained significant proportions of chromium and nickel (18% Cr and 12% Ni for H needles, and 21% Cr and 10% Ni for S needles). The small metallic pieces loosely attached to the needle surfaces were mainly composed of iron, chromium and nickel. As observed in the present study, some of the metallic lumps and pieces on the needle surfaces disappeared after the acupuncture manipulation. If the needles had been used on patients, these materials could have been deposited in human tissues, which might have caused adverse events such as dermatitis. A more recent review of acupuncture studies published between 1987 and 1999 also revealed that contact dermatitis in needled areas had been reported,[33] indicating that single-use disposal needles might also cause such adverse effects.

The small metallic pieces found on the needle surfaces were mostly likely from the grinding and polishing processes during the manufacture of the needles. The grinding and polishing processes would also generate electrostatic forces that would attract tiny metal filings to the needle surfaces. However, these metallic pieces should have been removed from the needles if adequate cleansing processes were carried out.

The commonly seen bleeding or haematoma/bruising was possibly caused by unsmooth needle tips breaking small blood vessels during needle insertion. Highly malformed tips were found in several H needles. This could be the reason for the occasional unexplained strong pain in the needling area reported by some patients during acupuncture.[9] An off-centre (eg, H10) or an unsymmetrical (eg, H3) needle tip may also cause the needle to alter direction during insertion.[9] If the flaws at the needle tip are eliminated through adequate quality control of the needle manufacturing process, such acupuncture needling associated adverse effects may well be reduced.

It is worth noting that the 2007 National Institutes of Health Consensus Statement stated that 'One of the advantages of acupuncture is that the incidence of adverse effects is substantially lower than that of many drugs or other accepted procedures of the same conditions'.[29] However, fear of needling pain is a major issue preventing people from seeking acupuncture treatment.[34 35] If this fear can be reduced by improving the quality of the needle tip, acupuncture treatment may be accepted more widely in clinical practice.

While it was observed that the force amplitudes of H needles during the needling process were generally higher than those of S needles, no clear correlation was found between the surface roughness/imperfection of individual needles and the corresponding force/torque amplitudes. Further research is needed in order to determine the relationship between the needle surface conditions and the force/torque magnitudes of acupuncture manipulation.

CONCLUSIONS

This research performed a systematic study of surface conditions of acupuncture needles from two of the most popular brands widely used in many countries. Based upon the results, the following conclusions can be drawn:

1. Acupuncture needle manufacturers, including the well established ones, should review and improve their quality control procedures for fabrication of needles. In particular, needle tips should be properly formed, sharpened and cleansed.
2. Significant surface irregularities and inconsistencies at needle tips, especially with the H needles, were found. These defects might cause adverse effects in needled areas, such as bleeding, haematoma/bruising, strong pain or dermatitis.
3. These findings highlight the need to improve the quality control of acupuncture needles, with a view to further enhancing the safety and comfort of acupuncture users.

Summary points

- We examined widely used acupuncture needles with electron microscopy.
- Several had surface irregularities or distorted points.
- These quality issues could produce allergic or painful reactions.

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Competing interests None.

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