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Original Article
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Morphological and Chemical Analysis of Various Disposable Acupuncture Needles Used in South Korea

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Objectives: The Korean Industrial Standard (KS) for sterile acupuncture needles was established in 2009 based on research on the quality control of acupuncture needles. We aimed to determine the quality of acupuncture needles available in South Korea in 2021 by examining their surface condition and chemical composition using field-emission scanning electron microscopy (FE-SEM) and energy-dispersive X-ray spectroscopy (EDS).
Methods: In South Korea, there are 23 brands of acupuncture needles, and we examined 10-15 needles from each brand, resulting in a total of 285 needles. The microstructures of the needles were assessed by SEM. Using SEM images, we evaluated the acupuncture needle tips for the following defects/aspects: scratches, lumps, detached coating, bent tip, and tip sharpness. EDS was used to determine the chemical composition of the selected acupuncture needles.
Results: Overall, 88.4% of 285 needles were found to have at least one type of abnormality. The most frequently observed abnormalities were scratches and dents on the surface (68.1%), followed by detached coating (63.2%), and lumps (61.8%); blunt tips were observed in about 24% of them. Of 252 needles with at least one defect, 86.9% had two or more types of defects. The ratio of the number of needles with any defect to that of needles without any defect varied among brands, ranging from 50% to 100%. Regarding foreign materials, higher proportions of Si and O were observed on the needles, indicating incomplete or detached silicone coating.
Conclusion: The quality of acupuncture needles varied among brands, suggesting that further improvements can be made through various inspection methods.

Keywords: acupuncture, acupuncture needle tip, field-emission scanning electron microscopy (fe-sem), energy-dispersive x-ray spectroscopy (eds), quality of acupuncture needle

INTRODUCTION

Acupuncture is a treatment method in which needles are inserted into specific areas of the body [1, 2] and is one of the most widely accepted evidence-based forms of alternative medicine [3]. This has been used in traditional Asian medicine for thousands of years and is currently being implemented worldwide [1, 2]. In South Korea, about 69% of the population has visited Korean medical institutions, and 91% received acupuncture treatment [4]. As the use of acupuncture is increasing in the USA [5] and many other countries [6], increased attention is being paid to the safety of acupuncture treatment.

Acupuncture needles were initially designed for multiple use, requiring sterilization after use [7]. Disposable needles were introduced in 1977 because of the hepatitis B epidemic in the UK, which raised concerns about the reuse of needles [8]. According to a recent report on the acupuncture market, the global acupuncture market was valued at $114.8 million in 2020 and is expected to expand at a compound annual growth rate (CAGR) of 5% from 2021 to 2031. The disposable acupuncture

needles segment accounted for 75% of the market in 2020, and Asia Pacific was found to lead the acupuncture needles market [9]. Acupuncture needles are the top oriental medical devices produced in South Korea, and the revenue from acupuncture products in 2020 was approximately 23 billion won [10]. To our knowledge, no cases of diseases transmitted through needles have been reported since the start of use of disposable acupuncture needles decades ago [11]. However, there are concerns about the condition of acupuncture needles that contribute to adverse events such as bleeding, hematoma, and pain persist [11, 12].

Previous research on acupuncture has mainly focused on the therapeutic efficacy or underlying mechanisms of acupuncture using in vivo or in vitro experimental methods and clinical trial research methods [13]. There is little scientific research on the needles themselves, which are the most important components of acupuncture [7, 14, 15]. A previous study on needles published in 2002 [7] focused on the tip of disposable needles using scanning electron microscopy (SEM), and a report published in 2014 [11] focused on the surface condition and other properties of needles of Chinese and Japanese brands [11]. Reports [16, 17] on the defective condition of acupuncture needles used in South Korea were published in the early 2000s. To control the quality of acupuncture needles, the standard for sterile filiform acupuncture needles for single use, KS P 3007:2009, was established in 2009 and revised several times thereafter; this standard is used for the qualitative and quantitative evaluation of needle tips [18]. Standards for the manufacture of acupuncture needles have also been suggested by the International Organization for Standardization (ISO) 17218. These standards focused on basics such as the material, strength, sharpness, and sterilization of needles, and there is no standard for the microstructure. In this study, we aimed at determining the quality of acupuncture needles, examining the surface condition and chemical composition of acupuncture needles produced in 2021 in South Korea, and comparing our results with those of previous studies published before the establishment of the standards.

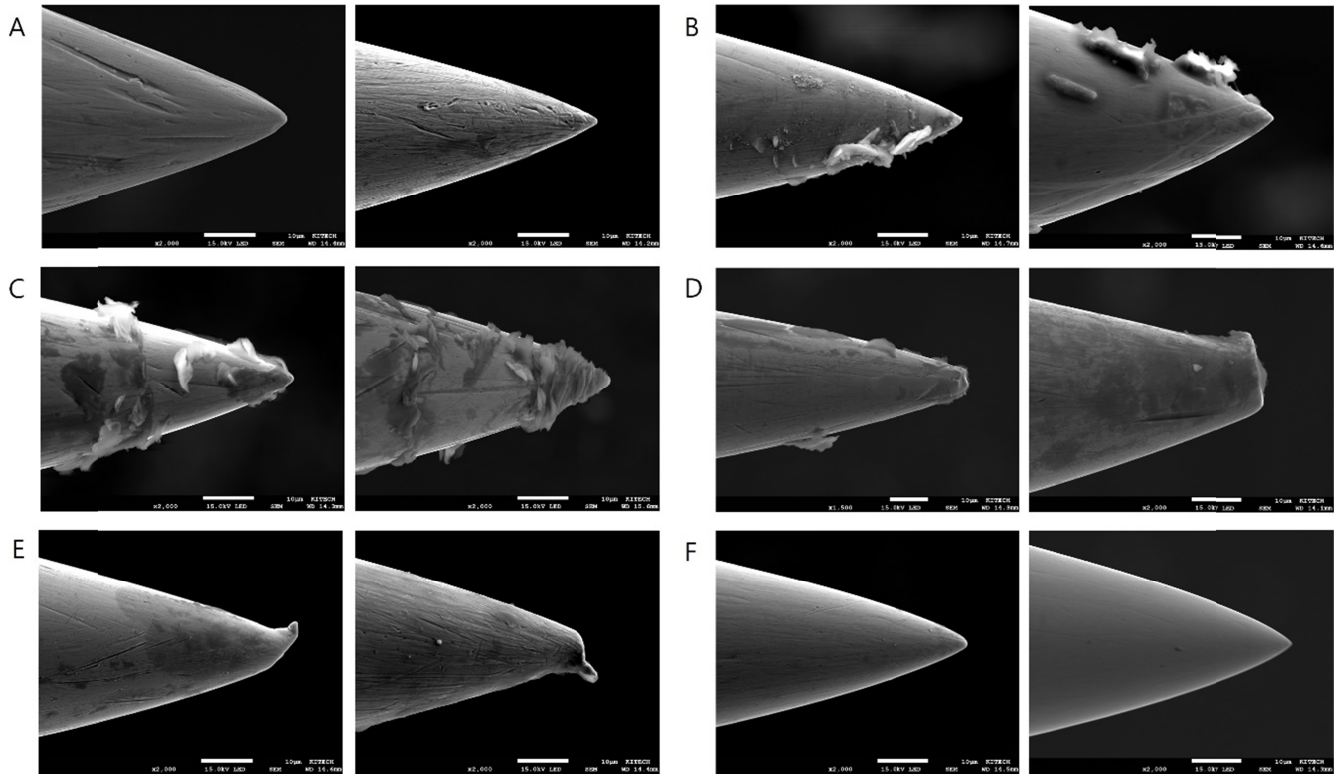

Figure 1. SEM images of acupuncture needle tips with each type of defect including (A) scratches or dents, (B) lumps, (C) detached coating on the surface, (D) blunt, (E) bent tip, and (F) normal tip (magnification 2,000×). SEM, scanning electron microscopy.

MATERIALS AND METHODS

1. Acupuncture needles used for examination

We selected 23 brands of acupuncture needles from 11 different manufacturers in South Korea in 2021 and assessed the condition of 10-15 needles from each brand. Of the 23 brands included in this study, 18 were produced in South Korea and the rest in China. The diameter of the needles varied from 0.12 to 0.25 mm and the length from 15 mm to 50 mm (Supplementary Table S1); these variations were not expected to significantly affect the evaluations of the surface and tip. All manufacturers and products were masked throughout the study.

2. Visual assessment of acupuncture needle tips using SEM images

Using FE-SEM (JSM-7200F, JEOL), the microstructure of each acupuncture needle was measured at 500, 1,000, 1,500, and 2,000× magnification. We used an aluminum jig plate designed to eliminate noise in the background. The microstructures including the shape, surface conditions including roughness, and attached foreign materials were evaluated.

To evaluate the condition of acupuncture needle tips, we used SEM images with 500× magnification, considering that inspection can be performed well at 400× (10). Each image was assessed by three Korean medicine doctors. A needle was considered to have defects when at least two evaluators agreed on a condition. All SEM images were masked so that the evaluators could not recognize the name of manufacturers and products.

Based on previous research data [4, 6], we categorized the defects into five types: scratches or dents (Fig. 1A), lumps (Fig. 1B), detached coating on the surface (Fig. 1C), blunt tip (Fig. 1D), and bent needle tips (Fig. 1E).

3. Chemical composition of foreign materials on acupuncture needle tips using energy-dispersive X-ray spectroscopy

Energy-dispersive X-ray spectroscopy (EDS) analysis was used to determine the chemical composition of foreign materials found on the surface of the needle tip.

RESULTS

1. Defects observed on SEM

Of the 285 acupuncture needles included in this study, 88.4% had at least one defect. Scratches or dents on the surface were the most frequently observed defect followed by lumps on the surface (n = 176) and detached coating (n = 180). Of the 252 acupuncture needles with any defect, blunt and bent tips were observed in 71 and 51, respectively (Table 1).

Most acupuncture needles had multiple types of defects. Among 252 needles with any defect, 86.9% had two or more types of defects; there were two defects in 79 (31.3%), three in 87 (34.5%), four in 42 (16.7%), and five in 11 (4.4%) acupuncture needles (Table 2).

2. Defects observed on SEM by brand

To compare the quality of acupuncture needles by brand, we grouped them according to the manufacturer and brand. No acupuncture needle without defect was found among the samples of the eight brands (B-1, B-2, D-1, E-1, E-6, F-3, G-1, and J-2). Acupuncture needles of C-2 and F-4 were of better quality than those of the others (percentages of acupuncture needles

Table 1. Percentages of acupuncture needles with different types of defects on SEM image evaluation (n = 285)

Description	Acupuncture needles (n = 285)
Acupuncture needles with any defect	252 (88.4%)
Type of defects	
Scratches or dents on the surface	194
Lumps on the surface	176
Detached coating	180
Blunt tip	71
Bent tip	54

Each acupuncture needle may have multiple types of defects.

Table 2. Number of defect types in acupuncture needles with any defect (n = 252)

Number of defect types	Number of needles with any defect (n = 252)
1	33 (13.1%)
2	79 (31.3%)
3	87 (34.5%)
4	42 (16.7%)
5	11 (4.4%)

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without any defect: 46.7% and 50%, respectively).

The quality of acupuncture needles differed according to the manufacturer. There were also inconsistencies in the quality of acupuncture needles of different brands of the same manufacturers, for example, among the brands of manufacturer F, the ratios of normal-to-defective needles ranged from 50% to 100% (Table 3).

3. Chemical composition of foreign materials attached to acupuncture needle tips

EDS mapping of the surface at 2,000× magnification showed that needle tips without defect mainly consisted of Fe (63.2%), Cr (18.7%), and Ni (7.2%) as the main elements of SUS304 stainless steel, which is the raw material used to fabricate acupuncture needles (Fig. 2).

Compared with normal needle tips, defective needle tips contained high proportions of C (31.3-44.7%), Si (14.8-18.8%), and O (18.4-25.4%), which are the main elements of silicone used to coat acupuncture needles (Fig. 3).

DISCUSSION

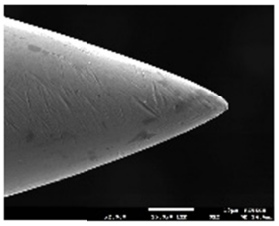
While the most common acupuncture-related adverse events prior to the use of single-use disposable needles were infections, including hepatitis, due to a lack of stringent sterilization [19], infections are no longer a major concern with the use of disposable needles [11]. A large European survey on the safety of

Table 3. Conditions of acupuncture needles of 23 brands from 11 manufacturers

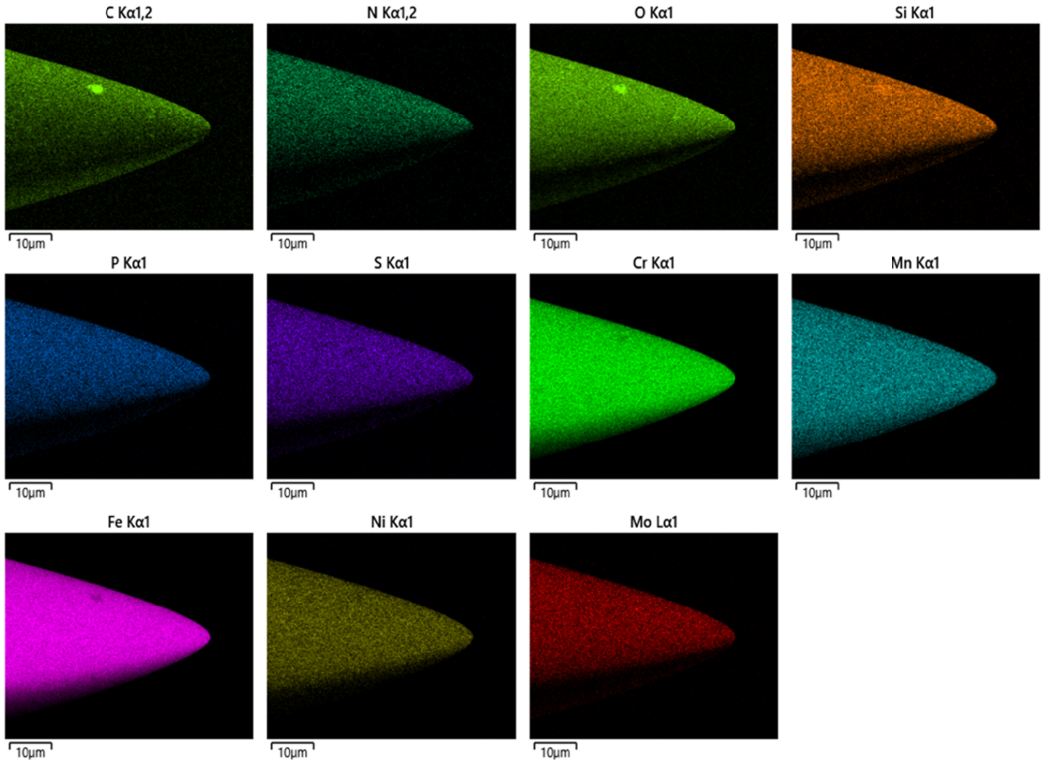
Manufacturer-product	Number of needles examined	Number of needles with any imperfection on tip (%)	Type of defect				
			Scratches or dents on the surface	Lumps on the surface	Detached coating	Blunt tip	Bent tip
A-1	15	14 (93.3)	13	9	8	4	3
B-1	15	15 (100)	15	9	11	0	3
B-2	15	15 (100)	11	11	4	2	3
C-1	15	14 (93.3)	11	11	14	5	1
C-2	15	8 (53.3)	7	4	2	5	4
D-1	15	15 (100)	15	9	7	3	0
E-1	10	10 (100)	10	5	7	7	3
E-2	15	12 (80)	5	10	11	1	0
E-3	15	11 (73.3)	8	9	7	2	1
E-4	15	14 (93.3)	8	13	12	1	2
E-5	15	14 (93.3)	13	7	11	3	1
E-6	15	15 (100)	11	15	11	3	0
F-1	10	9 (90)	9	4	3	2	1
F-2	10	9 (90)	6	4	9	1	3
F-3	10	10 (100)	4	8	10	3	3
F-4	10	5 (50)	2	3	4	1	1
F-5	10	8 (80)	5	7	7	1	0
G-1	10	10 (100)	9	6	4	6	3
H-1	10	9 (90)	4	5	9	4	3
I-1	10	9 (90)	7	8	7	3	7
J-1	10	8 (80)	8	6	8	3	2
J-2	10	10 (100)	10	5	8	5	7
K-1	10	8 (80)	3	8	6	6	3

Each acupuncture needle may have multiple types of imperfections.
Information on the manufacturers and products was masked. For example, B-1 indicates one of the brands manufactured by company B with two different brands (B-1 and B-2) included in this study.

A



B



C

Element	Weight, %
Fe	63.2
Cr	18.7
C	7.4
Ni	7.2
Mn	1.7
Si	0.8
O	0.8
N	0.1
Mo	0.0
P	0.0
S	0.0

Figure 2. EDS analysis of the surface of normal acupuncture needle tip: (A) SEM image, (B) EDS elemental mapping images of the acupuncture needle tip with normal condition at 2,000×, (C) quantitative results of weight ratio of selected elements. SEM, scanning electron microscopy; EDS, energy-dispersive X-ray spectroscopy.

acupuncture reported a low risk of side effects from acupuncture. Bleeding, hematoma, and bruising causing intense pain were the most common event in some surveys [12, 20-22]. The quality of acupuncture needles can be determined in relation to the side effects of acupuncture, but there are few studies on this aspect. Two reports on acupuncture in China and Japan [7, 11] and two reports on domestic acupuncture brands in South Korea were published in 2002 [16, 17].

Our study examined the microstructure of the needle tip of various types of acupuncture needles from 23 brands of needles used in South Korea at 2,000× magnification, and investigated their chemical composition using EDS to determine their quality. The morphological defects of needles were divided into five types using SEM images: scratches or dents on the surface, lumps on the surface, detached coating, blunt tip, and bent tip. A normal needle was one with normal sharpness, smoothness, and uniformity of the surface as well as a balanced overall shape. In our observation, the shapes of needle tips were diverse, 88.4% had one or more defects, and of 252 needles with at least one defect, 86.9% had two or more types of defects. Compared with the results of previous studies [16, 17] conducted in the 2000s, our results showed improvements in the morphology of acupuncture needles with low ratios of defects that could lead to significant adverse effects. However, most acupuncture needles still had minor defects on the surface and tips and high proportions of Si and O, indicating incomplete or detached silicone coating.

According to a consensus from the National Institutes of Health in 2007, an advantage of acupuncture is that it has far fewer side effects than many drugs or other acceptable procedures for some conditions [20]. Nevertheless, people hesitate to undergo acupuncture for fear of pain caused by the needles [21, 23, 24]. A needle that is not smooth or stained with impurities may cause pain during needle insertion, bleeding, hematoma, or bruising [11, 12, 21, 22]. A malformed tip may be associated with unexplained intense pain at the acupuncture site [7]. If the quality is improved by enhancing quality control techniques such as grinding, cleaning, and removal of impurities in the

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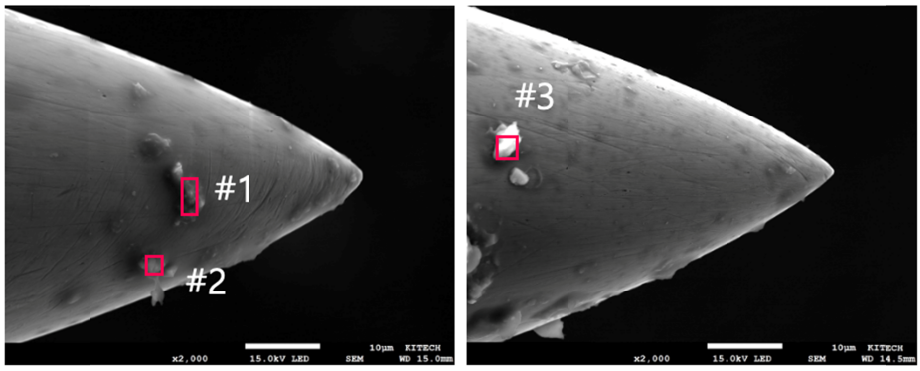
A



B

#1		#2		#3	
Element	Weight, %	Element	Weight, %	Element	Weight, %
C	31.3	C	42.4	C	44.7
Fe	23.9	O	22.7	O	25.4
O	18.4	Si	18.8	Si	15.6
Si	14.8	Fe	7.1	Fe	7.2
Cr	7.1	N	4.6	N	2.6
N	2.1	Cr	2.9	Cr	2.5
Ni	1.6	Mo	0.9	Mo	0.8
Mn	0.4	S	0.4	Ni	0.7
Mo	0.3	P	0.2	S	0.2
S	0.1	Mn	0.1	Mn	0.2
P	0.1	Ni	0.0	P	0.0

Figure 3. EDS analysis of foreign materials of acupuncture needle tips: (A) selected points on SEM images, (B) weight ratio of selected elements at each point. SEM, scanning electron microscopy; EDS, energy-dispersive X-ray spectroscopy.

needle manufacturing process, the number of acupuncture-related side effects will be reduced, and acupuncture treatment will gain popularity.

Considering that disposable acupuncture needles were introduced in the late 1970s and regulatory standards and manufacturing technology have been developing for more than 40 years, it is natural for Korean medicine doctors and patients to expect high-quality acupuncture needles. Therefore, these results are of concern to both patients and Korean medicine doctors. Since the establishment of KS and ISO standards for sterile acupuncture needles, the quality of manufactured sterile acupuncture needles has been assured to a moderate extent. However, the defects observed in this study would not be captured using the KS standard. KS suggests visual inspection and/or microscopic evaluation at 10× magnification; however, this magnification is insufficient for the thorough inspection of the condition of acupuncture needles. Meanwhile, SEM and EDS [7, 11] are methods that can achieve high resolution, allowing evaluators to check the chemical composition of impurities. Therefore, existing regulations need to be supplemented by developing appropriate manufacturing quality control methods for disposable acupuncture needles. It will be necessary to check the microstructure of the present needle tip and problems such as foreign materials at a magnification much higher than 10× using methods such as SEM and EDS. In addition, this study provides factors to establish international standards for quality control of sterile acupuncture needles, including the establishment of standards for chemical remnants.

Although there is no established association between needle defects observed using high-resolution microscopy and the clinical significance of the treatment, efforts for improving the quality of acupuncture are needed as the quality of needles could have a substantial impact [25] on acupuncture treatment. Roughness and bluntness of acupuncture needles can cause lo-

cal reactions such as pain, subcutaneous hematoma, and minor hemorrhage at the site of needling [26, 27]. In addition, detached silicone coating on the acupuncture needle surface can be deposited on the skin after manipulation, which may lead to skin reactions [11]. Further animal studies and clinical studies are needed to determine whether the use of acupuncture needles with defects is associated with adverse events during or after acupuncture treatment.

To the best of our knowledge, this is the first study to examine various acupuncture needles commonly used in South Korea since the establishment of KS for sterile acupuncture needles, but there are some limitations. First, we used acupuncture needles with different shaft diameters ranging from 0.12 to 0.25 mm. However, we compared only the shape and condition of acupuncture needle tips using SEM, and the differences in shaft diameter may not have affected the results. Second, although needles were randomly selected, the number of acupuncture needle samples might not have been sufficient to represent their quality. In order to be used as the basis for the standard of acupuncture needles, further systematic research should be conducted with an appropriate number of samples and better research methods.

The quality of acupuncture needles can be improved through various inspection methods for observing the microstructure of the acupuncture needle surface to ensure patient safety and enhance physicians' performance during acupuncture treatment. We hope our results will help improve the quality control procedures for acupuncture needles and expand the use of acupuncture treatment.

CONCLUSION

Most needles that we examined had defects and the quality of the needles differed depending on the brand. The quality of acupuncture needles can be improved through various inspection methods that check the microstructure of the needle surface.

SUPPLEMENTARY MATERIALS

Supplementary data is available at https://doi.org/10.3831/KPI.2022.25.4.382.

Supplementary Table S1. Information on the acupuncture needles used in this study including diameter and country of origin.

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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