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# Effect of Acupuncture on the Healing of Benign Vocal Fold Lesions

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**Abstract**

Acupuncture treatment has been an active field of research in Western Medicine for many years. This study aims to study the healing effect of acupuncture treatment on vocal fold lesions. Fifty-five subjects that were randomized into three groups, genuine, sham and control group underwent 12-weekly acupuncture treatments, and data from the assessment at pre-treatment, post-treatment and 1 month post-treatment were analyzed. The genuine group received acupuncture treatment on nine acupuncture points. The sham group received the same acupuncture treatment except with blunt needles. Five visual-perceptual judgment of stroboscopic parameters were used to measure the recovery of the vocal folds. Results were inconclusive in terms of whether acupuncture treatment was effective in healing the vocal folds.

## Introduction

Benign vocal fold lesions are often the results of vocal misuse and phonotrauma, and may manifest as nodules, polyps, cysts or contact ulcers (Colton, Casper, & Leonard, 2006). Although there has been no statistics on the prevalence of voice disorders among the general population of Hong Kong, it has been reported that current teachers in Hong Kong self-reported that they had voice problems and that it had a significant negative impact on their quality of life (Yiu, 2002). The general approach of treatment for voice disorders was mainly behavioral voice therapy and vocal hygiene program; surgical treatment and medication treatment will sometimes be used adjunctively (Ramig & Verdolini, 1998). However, the evidence of efficacy of behavioral voice therapy is limited. It was documented that there was only up to 10% of patients with polyp reaching full recovery from conservative treatment (Nakagawa, Miyamoto, Kusuyama, Mori, & Fukuda, et. al., 2011). There were a number of studies that reported an improvement of voice quality or reduction of lesion size after conservative treatment (Speyer, 2008). The number of studies that were of randomized clinical trial was limited and many of the studies used acoustic analysis as outcome measures to evidence the improvement of voice quality (Ziegler, 2010), which were neither valid nor reliable in discriminating normal voice from disordered voices (Ma & Yiu, 2005). Consequently, an exploration in alternative approach to traditional approach of voice treatment is expected.

### Acupuncture – history and modern theories

Traditional Chinese Medicine (TCM) had been documented to be using acupuncture since 1523 in China, where they made the needles out of stone (Sun, 2004). The theory of acupuncture includes the *qi* paradigm (energy), *jing-luo* (channels) system, *xue* (acupoints) and *yin-yang* theory (Birch & Felt, 1999). The traditional concept of *qi* is the idea of energy traveling

throughout the body through the channel system, *jing-luo* (Cheung & Wong, 2001). Such traditional theory was proposed after many years of experience and observations by many practitioners in China (Sun, 2004). However, there was no scientific explanation or experimental evidence to support this theory. Modern researchers have attempted to explain the effects of acupuncture with sympathetic neural activity. The study conducted by Knardahl, Elam, Olausson and Gunnar Wallin (1998), aimed to determine whether acupuncture produces relaxation and calmness in humans by inhibiting sympathetic nerve activity. However, the results showed that acupuncture does not inhibit sympathetic nerve traffic, but rather increased it.

Another study by Shang (2009) attempted to find a scientific theory that could explain acupuncture's therapeutic effects. The method was to identify a model or a theory that was independently evidenced with research data across different independent studies. If such model existed, it would then meet the gold standard of a scientific theory. The result was that there was a model that met the gold standard, and it was called the growth control model (Shang, 2001).

**Growth Control System**

The growth control model suggests that during embryogenesis, a network of organizing centers is developed prior to all the physiological systems. This network regulates and maintains the development of all physiological systems. The organizing centers are under-differentiated and embedded in all physiological systems even after embryogenesis.

**Meridians/boundaries and acupuncture points/organizing centers**

Organizing centers are a small group of cells containing high density of gap junctions, which provide a channel between cells to have electrical and chemical communication. Therefore, organizing centers have high electrical conductance. During embryogenesis, the organizing centers become restricted and create boundaries, leading to development of different

structures of the body. The distribution of these organizing centers is that they are at the extreme points of surface curvature of the body, corresponding to the acupuncture points. The boundaries link up the organizing centers, which correspond to the meridian system.

### *Qi* and *de qi*

The energy that TCM discovered can be explained by bioelectricity (Yang, 2007). Stimulation of the acupuncture points creates a vibrating sensation, which the TCM explains it as *de qi* (Chen, 2000). In electrophysiology, the acupuncture points were discovered to be electrical conductors that had an electrical field surrounding them under stimulation (Becker & Selden, 1998). This corresponds to the organizing centers that they also have high electrical conductance, since they contain high density of gap junctions (Shang, 2009).

### Effects of Acupuncture

The growth control model suggests that acupuncture has a healing effect by activating a self-organizing behavior in the pathological site. Stimulation at the acupuncture points activates the network of organizing centers connected to the pathological site and may adjust the growth process and restore normal function preserved from its function during embryogenesis.

## Acupuncture – voice research in China

In China, researchers began to use scientific method to assess treatment efficacy of acupuncture on vocal fold lesions. One research by Yang, Xie & Jiang (2006) was evaluating the treatment efficacy of the acupoint *Kaiyin 1* on submucosal hemorrhage using randomized-control clinical study design. The treatment outcome included clinician-judge descriptive 4-point rating (cured, very effective, effective, ineffective) and acoustic measurement of maximum phonation time, jitter, shimmer and harmonic/noise ratio. The above research used clinician-judged rating where a double-blind design was not used, thus an experimenter effect would exist and the results would not be valid (Shaungnessy, Zechmeister & Zechmeister, 2000). The outcome

measures used acoustic analysis, which was not reliable or valid to evaluate voice quality (Ma & Yiu, 2005). Two other similar scientific researches aimed to find the treatment efficacy of acupuncture treatment on nodules and pre-nodules, but had also used the same outcome measures (Wang & Tao, 2005; Yang, 2004). Another study by Sun, Zhang, Yan, Ma, & Jiang (2010) investigated the vocal fold rehabilitation post-surgery of polyps using acupuncture on *Sheng's* four points of throat and Chinese medication versus only Chinese medication. The outcome measure was also the same as the above mentioned researches, and the results showed that acupuncture with Chinese medication was superior to only Chinese medication.

Another study was conducted by Yiu, et. al. (2006). It was a multi-dimensional assessment approach with a randomized treatment-placebo group that was used to investigate the efficacy of acupuncture treatment on vocal fold lesions. The study used acoustic measurements, voice activity participation profile, perceptual rating of voice quality and phonetogram as outcome measures. There were 54 female subjects with benign vocal pathologies and randomly assigned to the experimental group or the placebo group. The experimental group received acupuncture on three pairs of acupoints, *Renyin* (Stomach channel 9) on the neck, *Lieque* (Lung channel 7) on the wrist, and *Zhaohai* (Kidney channel 6) on the ankle. The placebo group received placebo acupuncture on two pairs of acupoints, *Houxi* (Small intestine channel 3) on the hands and *Kunlun* (Bladder channel 60) on the ankles. The research reported a significant improvement in the changes of highest fundamental frequency, frequency range, perceptual breathiness and roughness, Total Voice Activity Participation Profile Score, Self-Perceived Severity Score, and Emotion Score.

With the small number of properly designed scientific research in existent, this research, therefore, used randomized treatment-sham-control group design to further investigate the efficacy of acupuncture treatment on the healing of benign vocal fold lesions.

This study investigated the effectiveness of a 12-session long acupuncture therapy for healing benign vocal fold lesions. Since the process of wound healing begins with inflammation, and as healing proceeds, inflammation would cease, epithelialization occurs and tissue remodeling follows (Branski, et. al., 2000). Therefore, as acupuncture treatment proceeds, the area of redness was hypothesized to reduce. As for the resolution of mass lesions, anti-inflammatory process and tissue re-organization had to take place, and acupuncture treatment was hypothesized to facilitate the resolution of the vocal fold pathology and thus reduce the size of mass of lesions. As for the amplitude of vibratory movement, it is directly related to the elasticity and viscosity of the vocal folds. The more elastic the tissue is the bigger movement the tissue can have; the more viscous the tissue is, the better flow of movement it can have. Since elasticity of the lamina propria is controlled by elastin fibers in the extracellular matrix, and viscosity is controlled by the interstitial protein also in the extracellular matrix (Gray, 2000); and fibroblasts are found to be the regulator of the extracellular matrix, where they will replace the old and damaged proteins with new ones (Gray, 2000), and since acupuncture treatment has been documented to induce fibroblasts in non-human research, like electroacupuncture on neuronal ischemic injury in rats (Yang, Huang, Da & Cheng, 1999), and acupuncture on focal cerebral ischemia in rat brain (Ou, Han, Da, Huang & Cheng, 2001), thus, it was hypothesized that acupuncture treatment can result in a significant improvement of amplitude of vibratory movement. As for supraglottic compression, hyperactivity of the ventricular fold is usually a compensatory method of voice patients to force glottal closure (Dworkin & Meleca, 1997).

However, such compensatory method would further stiffen the true vocal folds and reduce their vibratory movement (Dworkin & Meleca, 1997). If such compression continues, it would result in hypertrophy in the false vocal folds (Dworkin & Meleca, 1997). Therefore, if acupuncture treatment has its effect in reducing the lesion, improving the glottal closure and through cell migration to reduce the hypertrophy of the false vocal folds, it was hypothesized that a reduction of the supraglottic compression should be observed after treatment. Lastly, for glottal closure, if the acupuncture treatment can significantly reduce the mass of lesion, it was hypothesized that more subjects would have a positive change than remaining the same over time or having a negative change.

## Outcome Measures

Stroboscopic visual-perceptual ratings will be the outcome measure for this study. Stroboscopy provides a visual inspection of the vocal folds in motion, and by judging it with different parameters, improvement of different aspects of vocal fold functions can be analyzed. A modified version of the Stroboscopic Evaluation Rating Form (SERF), (Poburka, 1999) was used, and there were a total of 9 parameters: mass of lesion (right and left), area of redness (left and right), glottal closure, amplitude of vocal fold movement (left and right) and supraglottic compression (antero-posterior (AP) and medio-lateral (ML)). Mass of lesion reflects the size of nodules or polyps on the vocal folds. Area of redness reflects the area of inflammation in the vocal folds. Amplitude of vocal fold movement reflects the elasticity and viscosity of the vocal folds. Supraglottic compression reflects the tenseness of the supraglottic organs, like the ventricular fold. Glottal closure reflects whether the number of masses of lesions on the vocal folds that prevent the glottis from completing closure.

## Method

The present study was carried out in the Voice Research Laboratory of University of Hong Kong. A randomized treatment-sham-control double-blind group design was employed.

### Participants

A total of 123 Chinese male/female subjects participated in this study. The following selection criteria were used to select subjects:

1. Subjects were between the age of 20 to 55 years old, so as to eliminate voice change due to puberty or presbylarynges.
2. Subjects were diagnosed by otolaryngologist to have hyperfunctional dysphonia associated with pathological tissue changes (ie, nodules, polyps, thickening of vocal folds, and chronic laryngitis) due to vocal misuses or abuses three months prior to the study.
3. Subjects did not have any voice therapy before.
4. Subjects were not receiving any medication and/or other types of treatment which might have an effect on voice.
5. Subjects were not receiving immunosuppressant medication, steroids, photosensitizing drugs, anti-inflammatory drugs, or non-steroids anti-inflammatory drugs.
6. Subjects had no history of tumors (or signs of tumor or pseudotumor), diabetes, heart disease, coagulation disorder or epilepsy.
7. Subjects had no neurological disorders, which might affect the result of acupuncture since acupuncture facilitates neurological transmissions that accelerate recovery (Mann, 1992).
8. Subjects had no history of hearing problem or history of asthma.
9. Subjects did not have respiratory infection during the time of the study.

After eliminating the subjects without complete data or with erroneous data, there were a total of 55 subjects for analysis. Ten (18%) of them were male, and 45 (81%) of them were female. The

mean age of the subjects was 38.75, range was between 20-56, and SD = 10.332. Thirty-four (61.8%) of the subjects were diagnosed with bilateral nodules or unilateral nodules. Eight (14.5%) of the subjects were diagnosed with polyps. Four (7%) of the subjects were diagnosed with chronic laryngitis. Ten (18%) of the subjects had thickened vocal folds. One (1%) subject was diagnosed with granuloma pyogenicum. Some subjects were diagnosed with two pathologies.

**Apparatus – stroboscopy**

The vocal fold examination was conducted with rigid endoscopy (Storz Model Xenon 300 and Storz telecam Model SLII) with its images captured by the Corel Video Studio Pro X2 image processing software (Corel, Corel Video Studio 12) via a DELL PC computer. The vibratory patterns were recorded and analyzed by the Video Studio Editor (Corel Video Studio Pro X2, Corel Video Studio 12), an image processing tool within the image processing software.

**Apparatus – acupuncture needles**

The acupuncture needles used were disposable stainless steel needles that were of 0.25 mm in diameter and 40mm in length for the long ones, and 25mm in length for the short ones. (Fig. 1) The needles had a guide tube, where both were manufactured by Hua Tuo. (Fig. 2) According to Deadman and Al-Khafaji (1998), the acupoints *Hegu* (L14), *Lianquan* (Cv23) and *Zhaohai* (Ki6) require long needles, and *Renying* (St9) and *Lieque* (Lu7) require the short needles. Therefore, the experimental group used both the long and short needle, but the sham group used only the short needles to create the pressure on skin surface without penetrating through the skin to reach *de qi*, a needling vibrating sensation (Chen, 2000).

**Procedures – general**

All the subjects underwent 6 assessment sessions and 12 acupuncture sessions. An assessment was conducted at the 1st session before the first acupuncture treatment (pre-treatment assessment), after the 6th session of acupuncture (mid-assessment), after the 12th session of acupuncture (post-assessment), 14 days after the last acupuncture session (follow up 1), 30 days after the last acupuncture session (follow up 2), and 90 days after the last acupuncture session (follow up 3).

**Procedures – acupuncture**

The acupuncture treatment was conducted by a qualified registered acupuncturist in Hong Kong who had over 4 years of experience in TCM. The session was carried out in a quiet room, and the subjects were told to eat their meals within three hours of the acupuncture session according to the Traditional Chinese Medicine model. This was because the subjects needed to have sufficient energy for recovery to take place from the acupuncture treatment.

The genuine and sham group subjects were needled at 9 acupoints: 2 *Hegu*, 2 *Lieque* both on the wrists; 1 *Lianquan*, 2 *Renying* both on the neck, and 2 *Zhaohai* on the ankle. A foam stand was placed in all acupoints and the needles were inserted to the hole of the stand. The needles were struck and inserted into the acupoints until *de qi*, which was the tingling sensation upon insertion of the needle (Chen, 2000). The needling depth was about 2.54cm, and extra stimulation of moving the needles upward, downward and twirling was done every 5 minutes. The entire acupuncture session lasted for 30 minutes. The difference in the sham group was that the needles used would be short and blunt, and the guide tube would be of 47mm in length. In order for the needles to stay in place and create constant pressure on the skin, the acupuncturist

used a tag that was inserted at the upper end of the guide tube to hold the needle in place (Figure 3). The rest of the procedures remained the same as genuine acupuncture.

Traditionally, needling of *Lieque* required a slanting insertion, however, in this study, with the guiding tube in place, the needle was inserted perpendicularly into the skin surface. Since the needling sensation of *de qi*, where the subject felt the tingling sensation, determined the acupuncture effect (Deadman & Al-Khafaji, 1998), it should not compromise the acupuncture effect with a modified needling method.

## Data Analysis

Out of the six time-assessments (pre, mid, post, fu1, fu2 and fu3), three time-assessments (pre-treatment, post-treatment and follow up 2) with full data set were selected for analysis as the other time-assessments had missing data due to various reasons. There were a total of 186 videos to be rated, with 55 subjects and 7 more sets of repeated data for measuring intra-rater reliability. The videos were randomized across subject and within subject. For across-subject randomization, a random number was generated by Windows Excel, and assigned to each subject. Then the numbers were rearranged from smallest to largest to randomize the order of the subjects. For within-subject randomization, the order of $1^{st}$, $2^{nd}$ and $3^{rd}$ were randomly assigned to the three videos. Next to the experimental video, an anchor was placed for the judges to compare the disordered vocal folds. The anchor was a normal female voice with complete glottal closure. It was suggested by Rosen (2005) to place an anchor because it was useful in auditory perceptual research. Stroboscopic rating being a visual-perceptual judgment, an anchor would be able to help the judges to rate the parameters according to a common reference point. Three experienced judges, each with at least 10 years of experience in laryngoscopic procedure and evaluating laryngoscopic images, rated the 186 videos independently first, then followed by

agreeing on a consensus rating. The diagnosis, type of acupuncture (genuine or sham or control) received or the time of the assessment that the videos were taken, were not given to the judges. The consensus ratings were used in the final analysis.

The modified version of the Stroboscopic Evaluation Rating Form (SERF) (Appendix I) rated on nine parameters. The mass of lesion was measured by counting the number of boxes that the lesion occupies on the two sides of vocal folds individually. The area of redness was also measured by counting the number of boxes that were observed to be inflamed. The amplitude of vocal folds measured the vibratory movement. The rating spanned from small vibratory amplitude (20%), which was only vibrating closely around the midline, to full vibratory movement (100%). A 5 point scale was used for this vibratory rating: 20%, 40%, 60%, 80% and 100%. The supraglottic compression rating was a 6-point scale, with no compression of the supraglottic structures rated as 0, to maximum compression, which the vocal folds were compressed to the midline rated as 5. There were two types of compression being rated separately: antero-posterior (AP) compression and medio-lateral (ML) compression. The glottal closure was classified as either complete closure, anterior gap, posterior gap, hourglass shape, spindle gap shape, irregular or incomplete closure.

## Results

### Reliability

The inter-rater reliability results are shown in appendix table 1.1. If allow within one point difference in visual-perceptual rating, the inter-rater reliability was all above 80%. Since glottal closure was a descriptive rating, only exact match could be allowed. Therefore, the results were reliable.

The intra-rater reliability results are shown in appendix table 1.2. The judges were required to rate seven repeated subjects' videos to measure the intra-rater reliability. If allow within one point difference in visual-perceptual rating, the intra-rater reliability was above 80% for all judges, which was suggested by Rosen (2005) to be the minimum percentage of agreement for intra-rater reliability if to use that judge for research. Therefore, these three judges satisfy the requirement.

**Mass of Lesion**

The right mass of lesion results are shown in appendix table 2.1. Based on the results, the genuine group showed a slight trend of reduction of mass of lesion on the right vocal fold immediately after treatment and reduced even more one month after treatment. For the sham and control group, the mass of lesion increased after treatment. One month after treatment, sham group's mass of lesion maintained its level, whereas the control group subjects had a reduction of mass. However, the difference was not statistically significant.

Table 2.11

*Right mass of lesion ratings between subject and across time (descriptive)*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 1.65 | 1.42 | 1.45 | 1.54 | 1.30 | 1.30 | 0.20 | 0.35 |
| Sham | 1.65 | 0.93 | 1.71 | 0.92 | 1.71 | 1.05 | -0.06 | -0.06 |
| Control | 1.67 | 1.28 | 1.83 | 1.46 | 1.56 | 1.38 | -0.16 | 0.11 |

Table 2.12

*Kruskal Wallis across 3 groups analysis of right mass of lesion ratings*

| Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|
| Chi-square | df | p | Chi-square | df | p |
| 1.54 | 2.00 | 0.46 | 1.46 | 2.00 | 0.48 |

p value must be < 0.05 (2-tailed)

Table 2.13

*Friedman within group analysis of right mass of lesion ratings*

| Group | Chi-square | df | p |
|---|---|---|---|
| Genuine (N = 20) | 2.18 | 2.00 | 0.34 |
| Sham(N = 17) | 0.26 | 2.00 | 0.89 |
| Control (N= 18) | 1.65 | 2.00 | 0.44 |

# p value must be < 0.05 (2-tailed)

The complete statistical analysis of left side mass of lesion results is shown in table 2.2. Based on the results shown, the genuine group had some slight reduction of mass throughout time. Not much change was observed for sham and control group.

The complete statistical analysis of total mass of lesion results is shown in table 2.3. Based on the results shown, in the within subject comparison, genuine group and control group showed a reduction of mass of lesion, but was not supported by statistics. Such reduction was mostly contributed by the reduction in size of the mass of lesion on the right side. However, there was very little change on the left side; therefore the difference was not significant. The sham group showed no difference. The difference between groups was not significantly different.

**Area of Redness**

The complete statistical analysis of right area of redness results is shown in table 3.1. The genuine group had a decrease in area of inflammation after treatment, but did not maintain but instead had gotten worse one month after treatment. The subjects in the sham group had a

consistent decrease in area of redness throughout time, and control group had the opposite results.

The complete statistical analysis of left area of redness results is shown in table 3.2. The genuine group had an increase in area of inflammation after treatment, and the increased inflammation did not completely resolve one month later. The subjects in sham group had a consistent trend of increase of area of redness, and the control group had no change at first, but later had gotten worse.

The complete statistical analysis of total area of redness results is shown in table 3.3. There was a significant difference between the sham and control group for both time-assessments. It was apparent that sham group had a consistent trend of reduction of area of redness on the right side, while control group had an increase of area of redness for both sides. The overall trend of genuine group was also an increase in area of redness, but the trend was not supported by statistics.

Table 3.31

*Total area of redness ratings between subject and across time (descriptive)*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 2.35 | 2.18 | 2.40 | 2.11 | 2.75 | 1.92 | -0.05 | -0.40 |
| Sham | 1.76 | 2.22 | 1.41 | 1.94 | 1.35 | 2.18 | 0.35 | 0.41 |
| Control | 3.28 | 3.54 | 3.72 | 4.85 | 4.61 | 6.85 | -0.44 | -1.33 |

Table 3.32

*Kruskal Wallis across 3 groups analysis and Mann Whitney U of total area of redness*

| | Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|---|
| | Chi-square | df | #p | Chi-square | df | #p |
| Between 3 groups | 8.01 | 2 | 0.02 | 9.21 | 2 | 0.01 |
| | U | Z | *Asymp sig | U | Z | *Asymp sig |
| Genuine – Sham | 149.500 | -0.670 | 0.510 | 120.000 | -1.640 | 0.100 |
| Genuine – Control | 114.000 | -2.050 | 0.041 | 140.500 | -1.240 | 0.216 |
| Sham – Control | 76.000 | -2.820 | 0.005 | 65.500 | -3.210 | 0.001 |

# p value must be < 0.05 (2-tailed)
*Asymp sig must be < 0.016 (2-tailed)

Table 3.33

*Friedman within group analysis of total area of redness*

| Group | Chi-square | df | p |
|---|---|---|---|
| Genuine (N = 20) | 1.67 | 2.00 | 0.43 |
| Sham(N = 17) | 0.80 | 2.00 | 0.67 |
| Control (N= 18) | 0.51 | 2.00 | 0.77 |

p value must be < 0.05 (2-tailed)

**Amplitude of Vibratory Movement**

The complete statistical analysis of right amplitude of vibratory movement results is shown in table 4.1. The genuine group had an immediate increase in vibratory movement after treatment, but not only did it not maintain the amplitude, it had gotten stiffer one month after treatment. The sham and control group had a slight trend of increase of vibratory movement after treatment, where sham group had an increase but not completely maintained it one month later; and the control group had a consistent increasing trend. All differences were not statistically significant.

The complete statistical analysis of left amplitude of vibratory movement results is shown in table 4.2. The results showed that although the difference the groups was not significant, the within group difference was significant for both genuine and sham group. The subjects' vocal folds had gotten stiffer immediately after the treatment, but had improved one month after treatment. The sham group had a consistent increasing trend throughout time and the increase was significant by one month post-treatment. The control group also had the increasing trend, but not supported by statistics.

Table 4.21

*Amplitude of vibratory movement of the left vocal fold ratings between subject and across time (descriptive)*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 24.000 | 8.208 | 23.000 | 7.327 | 30.000 | 10.260 | -1.000 | 6.000 |
| Sham | 22.350 | 6.642 | 25.880 | 9.393 | 30.590 | 10.290 | 3.530 | 8.240 |
| Control | 22.220 | 6.468 | 23.330 | 7.670 | 25.560 | 9.218 | 1.110 | 3.340 |

p value must be < 0.05 (2-tailed)

Table 4.22

*Kruskal Wallis across 3 groups analysis of the amplitude of vibratory movement of the left vocal fold*

| Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|
| Chi-square | df | p | Chi-square | df | p |
| 0.55 | 2.00 | 0.76 | 1.95 | 2.00 | 0.38 |

p value must be < 0.05 (2-tailed)

Table 4.23

*Friedman within group analysis of the amplitude of vibratory movement of the left vocal fold*

| | Overall | | | Pre-post | | Pre-Fu2 | | Post-Fu2 | |
|---|---|---|---|---|---|---|---|---|---|
| Group | $X^2$ | df | #p | Z | *Asymp Sig | Z | *Asymp Sig | Z | *Asymp Sig |
| Genuine (N = 20) | 6.000 | 2.000 | 0.050 | -1.340 | 0.180 | -2.450 | 0.014 | -1.130 | 0.260 |
| Sham (N = 17) | 9.250 | 2.000 | 0.010 | -1.730 | 0.080 | -2.650 | 0.008 | -1.630 | 0.100 |
| Control (N= 18) | 2.000 | 2.000 | 0.370 | -0.450 | 0.650 | -1.340 | 0.180 | -1.000 | 0.320 |

# p value must be < 0.05 (2-tailed)
*Asymp sig must be < 0.016 (2-tailed)

**Supraglottic Compression**

The complete statistical analysis of supraglottic compression anterior-posteriorly (AP) results is shown in table 5.1 and 5.2 for the complete statistical analysis of supraglottic compression medio-laterally (ML). The results pattern was variable among AP and ML and between different groups. However, none of the changes were supported by statistics. After acupuncture treatment, the compression decreased for sham group, both AP and ML. But after the treatment, the effect could not be maintained one month later. As for the genuine group, after the acupuncture treatment, either there was no change or the compression had gotten more severe, and the compression reduced one month post-treatment. The control group showed a mixed result of increasing in compression (AP) and reducing in compression (ML). Some sort of spontaneous recovery was observed one month later, where AP had returned to its original compression, and ML's compression had decreased.

**Glottal Closure**

The glottal closure was given a score: complete = 0, posterior gap and anterior gap = 1, and hourglass shape, spindle gap, irregular shape and incomplete = 2. The analysis was based on

whether it was a positive change or negative change or no change at all. Please refer to the following table 6 for the results. The results showed that sham group had the most number of subjects with positive change (35%), but also negative change of up to 53%. Up to 70% of the subjects in the genuine and control group had no change in the glottal closure after treatment and only about 15-22% of the subjects had positive change.

Table 6

*The change in glottal closure across time*

| | Positive change | Negative change | Remain the same |
|---|---|---|---|
| Genuine (N = 20) | 3/20 (15%) | 3/20 (15%) | 14/20 (70%) |
| Sham (N = 17) | 6/17 (35.3%) | 9/17 (53%) | 2/17 (11.8%) |
| Control (N = 18) | 4/18 (22%) | 0/18 (0%) | 14/18 (77%) |

## Discussion

The objective of the present study was to investigate the effectiveness of acupuncture treatment on treating benign vocal fold lesions. It was hypothesized that the mass of lesion, area of redness and supraglottic compression would reduce, and the amplitude of vibratory movement of vocal folds would increase and glottal closure would have a positive change after the acupuncture treatment. The present study employed visual-perceptual ratings of strobolaryngoscopic images of subjects recorded at three time-points: pre-acupuncture assessment, post-acupuncture assessment and one month after treatment.

### Mass of Lesion

The findings showed that there was no significant change in between-groups or within-group over time. Thus, this acupuncture protocol was not effective in reducing the mass of lesion. Although there was no significant difference between subjects or within subjects, the genuine group did have a consistent reduction of mass of lesions for both left and right vocal

folds. One of the reasons was that nodules and polyps have a different healing timeline, and the data should be analyzed separately for different pathologies rather than averaging them out. Therefore, in future studies, the number of subjects with separate diagnosis should be balanced during data collection. Another possible reason is that acupuncture's effect might require a more intensive protocol than weekly treatments, and require a longer period of time to create a significant difference. Therefore, future studies should experiment with lengthening the acupuncture treatment or increasing the intensity, for example, a daily 2-hour treatment. This could be due to the fact that the acupuncture effect reaches the mass of lesion slower than expected because the growth control factors induced by the acupuncture affect the network of organizers that have not be evident to be in charge of specific organs (Shang, 2009). Therefore, the acupuncture growth control effects might have a generalized effect and resulting in only a mild effect to the targeted organ. Moreover, the wound healing process of the vocal folds require time for the fibronectin, a type of tissue associated to forming attachments between the epithelial and basement membrane zone, to do its job in tissue re-organization (Branski, Verdolini, Sandulach, Rosen & Hebda, 2000). Therefore, more than 12 weeks of treatment might be needed to resolve the mass of lesion.

As for the sham group, the right mass of lesion increased after the treatment and maintained it one month after treatment. This could be due to the subjects having further vocal misuse because they thought the treatment could allow them to use their voice more liberally. However, after the treatment, they were having heightened awareness of their voice and became more careful, therefore the mass of lesion remained the same. This was consistent with the left mass of lesion where at first, the mass of lesion did not change, but could be due to heightened awareness of their voice after treatment, the mass of lesion decreased in size.

The control group had inconsistent results for left and right vocal fold masses, where the right vocal fold had larger mass after treatment but smaller mass 1 month later, and where the mass of the left vocal fold remained the same throughout both assessments. If the control group's results fluctuated, then there must be some other factor that was causing the mass to reduce or increase in size. There could be various changes of daily habits in the use of voice of these subjects that reduced or increased the mass of lesion. Therefore, in future voice studies, vocal hygiene program should be incorporated to control vocal behavior outside of clinic room.

**Area of Redness**

There was no significant difference within subject changes, but when comparing between the groups, there was a significant difference between sham and control group in the changes through time. Although sham group had a slight increase in area of redness on the left side, the decrease in area of redness on the right side was large enough to make a significant difference between the groups. In the control group, there was a consistent increase of inflammation without treatment through time. Thus, no treatment could result in further inflammation instead of a spontaneous natural healing of the vocal folds. However, the sham group showed inconsistent results between the left and the right vocal folds. The left vocal folds had gotten more inflamed and right side had reduced inflammation. Such inconsistency could be explained by placebo effect. The body reacted to the belief that acupuncture treatment was given and induced the healing process of anti-inflammation to the side of the bigger mass of lesion, which was the right side. As for the genuine group, the results were inconsistent between the two sides of vocal folds as well. This could be due to the fact that acupuncture's purpose was not anti-inflammatory, although the acupuncture points of *zhaohai* and *lianquan* were known to increase hydration to the throat area according to TCM. The actual effect of stimulation to those two

acupuncture points is still unknown in the Western science. The inconsistent results could also imply that possible vocal misuse behavior throughout the weeks existed for some subjects and this study had small amount of time-point assessments to examine the effect of acupuncture through the healing process. The assessments only represented a snapshot of the vocal fold condition at the time. Any vocal misuse before the assessment was not controlled. Therefore, vocal hygiene program should be incorporated into the acupuncture treatment to maximize the effect of the acupuncture. In general, this acupuncture protocol is not effective in reducing inflammation of the vocal folds.

**Amplitude of Vibratory Movement**

There was no significant difference within group for the right side of the vocal fold vibratory movement. This could be because the mass of lesion was still quite large comparing to the mass on the left vocal fold. Masses on the vocal fold would limit the vibratory movement (Colton & Casper, 1990), therefore, even if change existed, it would not be as apparent as left vocal fold. An interesting trend, however, was noticed for the left vocal folds. After the treatment, the amplitude reduced, but once acupuncture treatment had ceased, or never started, which was the scenario of sham and control group; there was improvement in the amplitude of vibratory movement on both sides of the vocal folds. Such improvement was even statistically significant for both genuine and sham group. Therefore, it provides strong evidence that acupuncture does not improve the vibratory function of the vocal folds; rather no treatment was more effective in restoring vibratory function.

**Supraglottic Compression**

There was no significant difference in the results, which means the changes could be explained by other factors than the acupuncture treatment. In the genuine group, after treatment

either made the compression more severe or remained the same, and one month later, the compression had reduced. So, the acupuncture's effect could have been tightening the supraglottic structures to allow it to loosen later. In the sham group, a placebo effect was observed, where a reduction of compression was observed immediately after the treatment, but could not be maintained. The results of the control group implied that spontaneous recovery for ML compression was more likely than AP compression.

**Glottal Closure**

Most of the subjects in the genuine group had no change in glottal closure. Since glottal closure is directly related to the mass of lesion, if no significant changes in the mass of lesion exist, then glottal closure should not have changes towards positive or the negative side. Therefore, the results are consistent. As for the sham group, placebo effect had taken place and created inconsistent results where more than half of the subjects had worse glottal closure after treatment. As for the control group, the results imply that natural healing process does not act this quickly in resolving masses and improving the glottal closure.

**General Limitations of the Current Study**

The present study has a small effect size of 0.11, and it was calculated that a study with at least 783 participants (*alpha level* = 0.05, power = 0.8) to detect a small effect size ($r$ = .1) (Field, 2009). Therefore, with a small sample size, it would not be adequate to detect significant difference between three groups and within group.

The second limitation is that since acupuncture is a traditional Chinese medicine, the parameters of improvement are unknown in the Western scientific field. Therefore, the parameters used may not be suitable in rating the healing of vocal fold lesions, and possible

improvements were not observed. In future studies, it is suggested that parameters of examining the vocal fold lesions should refer to TCM's theories and incorporate with Western parameters.

The third limitation of this study is that voice behavior outside of the clinic room is not controlled. Therefore, in future studies, vocal hygiene should be incorporated into acupuncture studies, so abusive behavior to the voice can be controlled, and results may become more consistent throughout the parameters.

## Conclusion

In summary, this article presents an acupuncture-sham-control study on the healing of benign vocal fold lesions using visual-perceptual ratings of videostroboscopy. Five parameters were used to rate the stroboscopic videos. Results from statistics showed that amplitude of vibratory movement significantly improved 1 month after treatment for the left side of the vocal fold. The other parameters showed some signs of improvement, but the results were inconclusive in whether acupuncture treatment is effective in healing benign vocal fold lesions. To conclude, the results of the present study does not support the hypothesis that acupuncture can reduce the mass of lesion, area of redness, supraglottic compression, increase amplitude of vibratory movement, and improve glottal closure.

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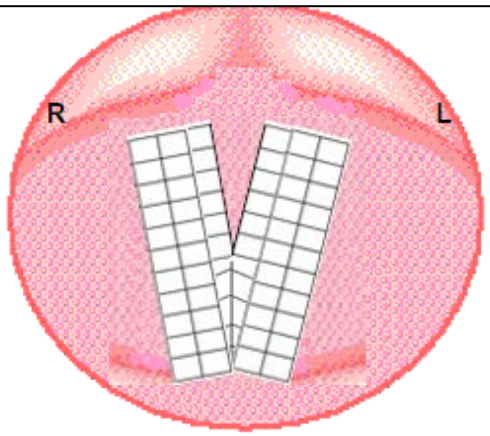
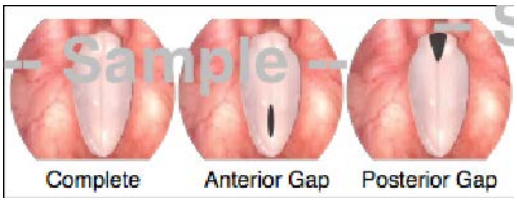
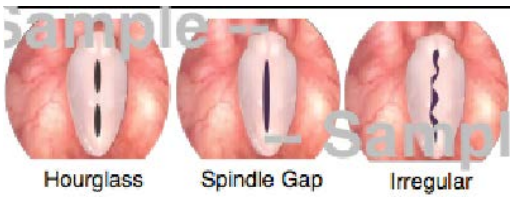
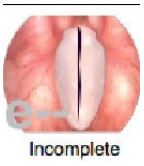
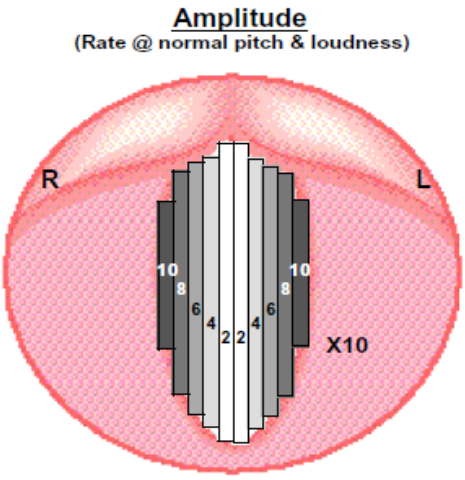
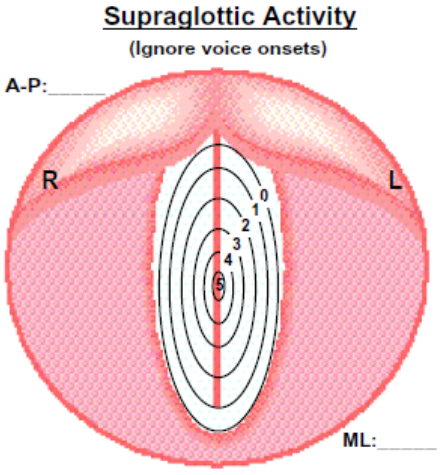
## Appendix I

**Stroboscopic Assessment From (SAF)** Some parameters were adapted from SERF (Poburka, 1999)

| Please mark the extent of lesion on the grid | Please circle the glottal closure |
|---|---|
|  Right: Number of boxes = _____ Left: Number of boxes = _____ Redness R: # of boxes: _____ Redness Left: # of boxes: _____ |    **Glottal closure:** Appearance of glottis during the most closed portion of the glottal cycle |
| Please mark the extent of vibratory movement from midline according to the scale (2,4,6,8,10) | Please mark the degree of compression according to the scale (0-5 |
|  **Amplitude** Extent of vibratory movement of vocal folds laterally to midline. |  **Supraglottic activity** *Medio-lateral compression(ML)* true vocal folds being obscured by the ventricular folds. *Antero-posterior compression* (A-P) compression of shortening of the aryepiglottic folds. |

## Appendix II - tables

Table 1.1

*The percentage agreement between raters for each parameter*

| Parameter | | Percentage agreement | |
|---|---|---|---|
| | | exact | Within one point |
| Mass R | Judge 1 & 2 | 54.0% | 89.0% |
| | Judge 2 & 3 | 59.4% | 95.7% |
| | Judge 1 & 3 | 57.0% | 93.3% |
| Mass L | Judge 1 & 2 | 57.0% | 92.7% |
| | Judge 2 & 3 | 66.6% | 95.1% |
| | Judge 1 & 3 | 56.3% | 90.0% |
| Redness R | Judge 1 & 2 | 53.9% | 80.0% |
| | Judge 2 & 3 | 61.0% | 84.2% |
| | Judge 1 & 3 | 59.3% | 81.8% |
| Redness L | Judge 1 & 2 | 57.0% | 82.4% |
| | Judge 2 & 3 | 65.4% | 87.8% |
| | Judge 1 & 3 | 63.6% | 86.7% |
| Glottal Closure | Judge 1 & 2 | 74.5% | - |
| | Judge 2 & 3 | 75.8% | - |
| | Judge 1 & 3 | 81.8% | - |
| Amplitude R | Judge 1 & 2 | 80.0% | 100% |
| | Judge 2 & 3 | 81.0% | 100% |
| | Judge 1 & 3 | 77.5% | 99.0% |
| Amplitude L | Judge 1 & 2 | 67.8% | 100% |
| | Judge 2 & 3 | 73.0% | 93.0% |
| | Judge 1 & 3 | 67.0% | 100% |
| Supraglottic (AP) | Judge 1 & 2 | 54.0% | 95.0% |
| | Judge 2 & 3 | 60.6% | 97.6% |
| | Judge 1 & 3 | 50.3% | 95.8% |
| Supraglottic (ML) | Judge 1 & 2 | 55.8% | 96.3% |
| | Judge 2 & 3 | 67.9% | 100% |
| | Judge 1 & 3 | 63.0% | 97.0% |

Table 1.2

*The total percentage agreement within raters for all parameters*

| Rater | exact | Within one point |
|---|---|---|
| Judge 1 | 61.4% | 92.6% |
| Judge 2 | 67.2% | 91.5% |
| Judge 3 | 63.5% | 92.5% |

Table 2.21

*Left mass of lesion ratings between subject and across time (descriptive)*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 1.20 | 1.15 | 1.15 | 1.14 | 1.10 | 1.02 | 0.05 | 0.10 |
| Sham | 1.47 | 1.01 | 1.47 | 1.12 | 1.41 | 1.00 | 0.00 | 0.06 |
| Control | 1.00 | 1.08 | 1.00 | 0.91 | 1.00 | 0.77 | 0.00 | 0.00 |

Table 2.22

*Kruskal Wallis across 3 groups analysis of left mass of lesion*

| Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|
| Chi-square | df | p | Chi-square | df | p |
| 0.08 | 2.00 | 0.96 | 0.17 | 2.00 | 0.92 |

p value must be < 0.05 (2-tailed)

Table 2.23

*Friedman within group analysis of left mass of lesion*

| Group | Chi-square | df | p |
|---|---|---|---|
| Genuine (N = 20) | 0.00 | 2.00 | 1.00 |
| Sham(N = 17) | 0.23 | 2.00 | 0.89 |
| Control (N= 18) | 0.07 | 2.00 | 0.96 |

p value must be < 0.05 (2-tailed)

Table 2.31

*Total mass of lesion ratings between subject and across time (descriptive)*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 2.85 | 1.95 | 2.60 | 2.06 | 2.40 | 1.63 | 0.25 | 0.45 |
| Sham | 3.12 | 1.73 | 3.18 | 1.84 | 3.12 | 1.83 | -0.06 | 0.00 |
| Control | 2.67 | 1.97 | 2.83 | 1.92 | 2.55 | 1.79 | -0.16 | 0.12 |

Table 2.32

*Kruskal Wallis across 3 groups analysis of total mass of lesion*

| Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|
| Chi-square | df | p | Chi-square | df | p |
| 0.24 | 2.00 | 0.88 | 0.90 | 2.00 | 0.64 |

p value must be < 0.05 (2-tailed)

Table 2.33

*Friedman within group analysis of total mass of lesion*

| Group | Chi-square | df | p |
|---|---|---|---|
| Genuine (N = 20) | 0.56 | 2.00 | 0.75 |
| Sham(N = 17) | 0.54 | 2.00 | 0.76 |
| Control (N= 18) | 1.11 | 2.00 | 0.57 |

p value must be < 0.05 (2-tailed)

Table 3.11

*Area of redness on the right vocal fold ratings between subject and across time (descriptive)*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 1.500 | 1.357 | 1.150 | 1.040 | 1.650 | 1.182 | 0.350 | -0.150 |
| Sham | 1.240 | 1.678 | 0.760 | 1.200 | 0.590 | 1.064 | 0.480 | 0.650 |
| Control | 1.890 | 2.111 | 2.330 | 2.828 | 2.500 | 3.382 | -0.440 | -0.610 |

Table 3.12

*Kruskal Wallis across 3 groups analysis of area of redness on the right vocal fold*

| Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|
| Chi-square | df | p | Chi-square | df | p |
| 3.86 | 2.00 | 0.14 | 4.57 | 2.00 | 0.10 |

p value must be < 0.05 (2-tailed)

Table 3.13

*Friedman within group analysis of area of redness on the right vocal fold*

| Group | Chi-square | df | p |
|---|---|---|---|
| Genuine (N = 20) | 1.90 | 2.00 | 0.39 |
| Sham(N = 17) | 3.31 | 2.00 | 0.19 |
| Control (N= 18) | 2.47 | 2.00 | 0.29 |

p value must be < 0.05 (2-tailed)

Table 3.21

*Area of redness on the left vocal fold ratings between subject and across time (descriptive)*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 0.85 | 1.04 | 1.25 | 1.16 | 1.10 | 1.12 | -0.4 | -0.25 |
| Sham | 0.53 | 0.80 | 0.65 | 1.06 | 0.76 | 1.15 | -0.12 | -0.23 |
| Control | 1.39 | 1.50 | 1.39 | 2.12 | 2.11 | 3.53 | 0.00 | -0.72 |

Table 3.22

*Kruskal Wallis across 3 groups analysis of area of redness on the left vocal fold*

| Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|
| Chi-square | df | p | Chi-square | df | p |
| 3.46 | 2.00 | 0.18 | 0.27 | 2.00 | 0.87 |

p value must be < 0.05 (2-tailed)

Table 3.23

*Friedman within group analysis of area of redness on the left vocal fold*

| Group | Chi-square | df | p |
|---|---|---|---|
| Genuine (N = 20) | 3.11 | 2.00 | 0.21 |
| Sham(N = 17) | 1.41 | 2.00 | 0.49 |
| Control (N= 18) | 2.60 | 2.00 | 0.27 |

p value must be < 0.05 (2-tailed)

Table 4.11

*amplitude of vibratory movement of the right vocal fold ratings between subject and across time (descriptive)*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 22.00 | 6.16 | 23.00 | 7.33 | 21.00 | 4.47 | 1.00 | -1.00 |
| Sham | 21.18 | 4.85 | 27.06 | 9.85 | 24.71 | 8.74 | 5.88 | 3.53 |
| Control | 21.11 | 4.71 | 22.22 | 6.47 | 25.56 | 9.22 | 1.11 | 4.45 |

Table 4.12

*Kruskal Wallis across 3 groups analysis of amplitude of vibratory movement of the right vocal fold*

| Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|
| Chi-square | df | p | Chi-square | df | p |
| 3.66 | 2.00 | 0.16 | 3.41 | 2.00 | 0.18 |

p value must be < 0.05 (2-tailed)

Table 4.13

*Friedman within group analysis of the amplitude of vibratory movement of the right vocal fold*

| Group | Chi-square | df | p |
|---|---|---|---|
| Genuine (N = 20) | 1.5 | 2.00 | 0.47 |
| Sham(N = 17) | 4.75 | 2.00 | 0.09 |
| Control (N= 18) | 4.33 | 2.00 | 0.11 |

p value must be < 0.05 (2-tailed)

Table 5.11

*supraglottic compression anterior-posteriorly (AP) ratings between subject and across time (descriptive)*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 1.600 | 0.681 | 1.750 | 0.910 | 1.500 | 0.761 | -0.150 | 0.100 |
| Sham | 1.410 | 0.939 | 1.060 | 0.899 | 1.240 | 1.240 | 0.350 | 0.180 |
| Control | 1.500 | 0.857 | 1.610 | 0.850 | 1.500 | 0.924 | -0.110 | 0.000 |

Table 5.12
*Kruskal Wallis across 3 groups analysis of supraglottic compression anterior-posteriorly (AP)*

| Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|
| Chi-square | df | p | Chi-square | df | p |
| 5.14 | 2.00 | 0.08 | 0.60 | 2.00 | 0.74 |

p value must be < 0.05 (2-tailed)

Table 5.13
*Friedman within group analysis of supraglottic compression anterior-posteriorly (AP)*

| Group | Chi-square | df | p |
|---|---|---|---|
| Genuine (N = 20) | 3.94 | 2.00 | 0.14 |
| Sham(N = 17) | 4.50 | 2.00 | 0.11 |
| Control (N= 18) | 1.23 | 2.00 | 0.54 |

p value must be < 0.05 (2-tailed)

Table 5.21
*supraglottic compression medio-laterally (ML) ratings between subject and across time*

| | Pre-treatment | | Post-treatment | | Follow up 2 | | Post-pre | Fu2-pre |
|---|---|---|---|---|---|---|---|---|
| Group | mean | SD | mean | SD | mean | SD | Difference | Difference |
| Genuine | 1.600 | 0.821 | 1.600 | 0.754 | 1.550 | 0.686 | 0.000 | 0.050 |
| Sham | 1.290 | 0.470 | 1.240 | 0.562 | 1.470 | 0.624 | 0.050 | -0.180 |
| Control | 1.500 | 0.618 | 1.330 | 0.485 | 1.440 | 0.616 | 0.170 | 0.060 |

Table 5.22
*Kruskal Wallis across 3 groups analysis of supraglottic compression medio-laterally (ML)*

| Post-pre difference | | | Fu2-pre difference | | |
|---|---|---|---|---|---|
| Chi-square | df | p | Chi-square | df | p |
| 0.41 | 2.00 | 0.81 | 2.26 | 2.00 | 0.32 |

p value must be < 0.05 (2-tailed)

Table 5.23
*Friedman within group analysis of supraglottic compression medio-laterally (ML)*

| Group | Chi-square | df | p |
|---|---|---|---|
| Genuine (N = 20) | 0.26 | 2.00 | 0.88 |
| Sham(N = 17) | 3.25 | 2.00 | 0.20 |
| Control (N= 18) | 2.33 | 2.00 | 0.31 |

p value must be < 0.05 (2-tailed)

## Appendix III - Figures

*Fig. 1. The guide tube, short needle and long needle*

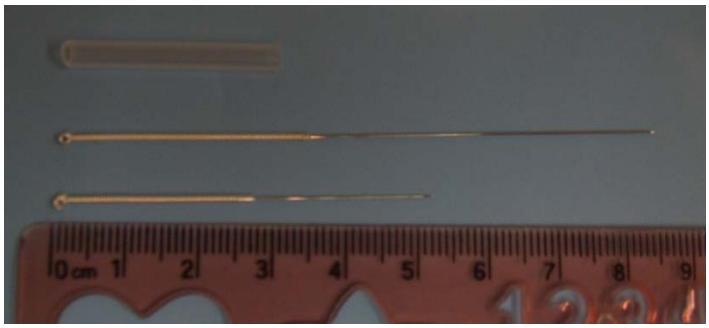


*Fig. 2 genuine acupuncture with stand and shortened guide tube*

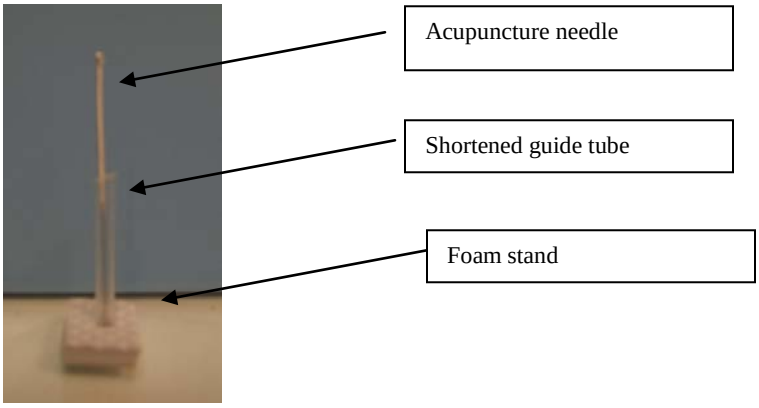



*Fig. 3. Sham acupuncture with stand and short needle with needle-holding tag*