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<td>Chan, Leanne Sheena Yan; University of Hong Kong Faculty of Dentistry</td>
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A clinical trial on the effect of modified manual toothbrush and electric toothbrush on oral hygiene and gingival health of Hong Kong Stroke Patients
A Clinical Trial on the Effect of
Modified Manual Toothbrush and Electric Toothbrush
on
Oral Hygiene and Gingival Health
of
Hong Kong Stroke Patients

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ABSTRACT

Introduction: The ability of stroke patients in using a manual toothbrush for proper dental plaque control may be lower than normal adults. No clinical study has been implemented on investigating the effectiveness of a modified toothbrush and an electric toothbrush on the oral hygiene and gingival health of stroke patients so there is a need to evaluate this in stroke patients. Aim: To compare the effectiveness of a modified manual toothbrush and an electric toothbrush on improving the oral hygiene and gingival health of stroke patients. Objectives: To compare longitudinally the plaque removal ability of a modified manual toothbrush and an electric toothbrush and its corresponding improvement on gingival health in stroke patients. Methods: 75 stroke patients were randomly allocated into one of the following groups: 1) using a modified manual toothbrush for 1-month; 2) using an electric toothbrush for 1-month. Subjects were instructed individually. Plaque Index (PI) and Gingival Index (GI) were measured at baseline and 1-month examination. Satisfactions of the patients were asked after 1 month usage of the assigned toothbrush. Results: 56 subjects complied during the 1-month study period. There was a statistically significant reduction in mean PI score when comparing the baseline mean PI score with the 1-month mean PI score for both the modified manual toothbrush group (paired t-test, p<0.0001) and the electric toothbrush group (paired t-test, p<0.0001). Reduction in mean GI score after 1-month was observed in both groups but it was not enough to be statistically significant (paired t-test, p>0.05). More stroke patients were satisfied with the electric toothbrush than the modified toothbrush (Chi-square test, p<0.05). Conclusion: The 1-month results showed that there was no statistically significant difference between the modified manual toothbrush group and the electric toothbrush group in removing plaque and improving gingival health.
1. **INTRODUCTION**

1.1. **Terminology**

**Stroke**

It is the most common adult neurological disease, it is defined as a syndrome of rapid onset of cerebral deficit lasting more than 24 hours or leading to death, with no cause apparent other than a vascular one (Kumar & Clark, 2009).

**Transient ischemic attack (TIA)**

This is also known as a ‘mini stroke’ which is a sudden focal deficit lasting from seconds to 24 hours with a complete recovery (Kumar & Clark, 2009).

1.2. **Classification and Prevalence of Stroke**

Stroke can be classified as ischemic or haemorrhagic stroke. Ischemic stroke is subdivided into cortical, subcortical, posterior circulation and lacuna infarct, while haemorrhagic stroke is subdivided into intracerebral and subarachnoid haemorrhage. Intracerebral haemorrhage can be further divided into supratentorial and infratentorial haemorrhage (Yu, 2008).

Stroke is the most common adult neurological diseases, the 2nd & 3rd leading cause of death in China & HK respectively. The majority of stroke victims survive, however often with increased morbidity and disability. In western countries, the prevalence of ischemic stroke is 84% and that of haemorrhagic stroke is 16%. For Hong Kong (HK), the prevalence is 70% and 30% respectively (Yu, 2008).
1.3. **Outcome of Stroke**

Due to structural brain damage, functional impairment is expected and the manifestations depend on which part and the extent of the brain is damaged. The effects principally are unilateral numbness, weakness and partial or complete paralysis of the arm, leg and/or face on the side of the body contra-lateral to the affected side of the brain. For example, the patient may have left side hemiplegia if the right brain is damaged. Cognitive impairment is also often seen in these patients.

1.4. **Problems of stroke patient related to oral hygiene maintenance**

Due to the impaired neuromuscular function, a stroke survivor may experience difficulty in toothbrushing because of impaired manual dexterity on the paralysed side, affecting their ability to maintain a healthy oral condition (Scully & Cawson, 2005). Weakness of the facial area or paralysis of extremities may make oral hygiene procedures extremely difficult (Ostuni, 1994) and is compounded by oral motor and sensory deficits that hinders their ability to clear the mouth of food debris resulting in deteriorated oral hygiene, halitosis, caries and an increased risk of other microbial infections, notably the *Candida* species (Pow, Leung, Wong, Li, & McMillan, 2005). In a study conducted by Hunter some stroke patients reported that they were unable to use one hand properly. As a result of this, they were unable to floss and clean their mouth effectively (Hunter, Clarkson, Fraser, & MacWalter, 2006).
1.5. Background information on electric and modified manual toothbrush

The most widespread means of maintaining oral hygiene by actively removing plaque at home is toothbrushing. Dental plaque is implicated in the aetiology of dental caries, gingivitis and periodontitis. It is a bacterial biofilm that is not easily removed from the surface of the teeth. It has been estimated that between 400 and 1000 species may, at some time, colonize oral biofilms. Therefore, to maintain the oral health, regular personal plaque removal measures must be undertaken. There is substantial evidence which shows that plaque and periodontal disease can be controlled most reliably through toothbrushing supported by other mechanical cleansing procedures (Lindhe, Lang, & Karring, 2008).

The effectiveness of using a manual toothbrush on cleaning is dependent on the manual dexterity and skill of using the brush (Saxer & Yankell, 1997a, 1997b). For stroke patients they may have problems in grasping, manipulation or control of the toothbrush, decreasing their effectiveness in using a normal manual toothbrush. The dental health care provider may need to modify oral hygiene instruments for ease of use, perhaps in consultation with an occupational therapist (Rose, Mealey, Minsk, & Cohen, 2002).

Commercial electric toothbrushes were first introduced in the early 1960s. The mode of action of the early electric toothbrushes is a back and forth action. Nowadays, the rotary action brushes and high frequency vibration brushes are commonly found in the market (Robinson et al., 2005). Two independent systematic reviews confirmed that oscillating rotating toothbrushes have superior efficacy over manual toothbrushes in reducing plaque and gingivitis (Robinson et al., 2005; Sicilia, Arregui, Gallego, Cabezas, & Cuesta, 2002). Electric toothbrushes with this mode of action reduce plaque by 7% and gingival
bleeding by 17% than that by manual toothbrushing (Robinson et al., 2005). Disadvantages of electric toothbrush include its weight, cost and its vibration (Dougall & Fiske, 2008). The consensus of the research reports on toothbrushing of the World Workshops in Periodontics in 1966 states: “in those who have difficulty in mastering suitable hand brushing technique the use of an electric brush with its standard movements may result in more frequent and better cleansing of the teeth.”(Lindhe et al., 2008) From the statements above, it can be hypothesized that electric toothbrush may be beneficial to stroke survivors who have impaired manual dexterity.

A recent review (Dougall & Fiske, 2008) also suggested that various toothbrush adaptations, e.g. enlarged handles, hand attachments and elongated handles, can improve and aid patient’s ability to maintain oral hygiene. The modified handle can provide a stable grip for the patients to manipulate the toothbrush during cleaning. Commercial electric toothbrushes can also be a beneficial oral hygiene adjunct for many people with disabilities as its action compensates for the loss of skilled manipulation required when using an ordinary brush.

However, most studies comparing the efficacy of electric and manual toothbrushes were mainly conducted on healthy subjects. Therefore a randomized controlled clinical trial to investigate the effectiveness of modified manual toothbrush and electric toothbrush on improving oral hygiene of stroke patients is needed. The intended study period is 6 months, and this report is based on the initial study findings after 1 month.
1.6. Aims and objectives

The aim of the study was to compare the effectiveness of a modified manual toothbrush and an electric toothbrush on improving oral hygiene and gingival health of stroke patients. The objectives were:

- To compare longitudinally the plaque removal ability of a modified manual toothbrush and an electric toothbrush on stroke patients
- To compare longitudinally the ability of a modified manual toothbrush and an electric toothbrush in improving gingival health on stroke patients

The null hypothesis to be tested is that the use of a modified manual toothbrush and an electric toothbrush has the same effect on 1) the dental plaque and 2) the gingival health condition of the stroke patients.
2. MATERIALS AND METHODS

2.1. Study population

The target population of the study was adults with a history of stroke or TIA in Hong Kong. The subjects were not hospital in-patients and were undergoing rehabilitation.

The inclusion criteria for the study were:
- aged 18 and above
- have a history of stroke or TIA and
- have at least 10 non mobile teeth present

The exclusion criteria for the study were:
- currently using an electric toothbrush
- being a smoker
- having heavily rehabilitated dentition (e.g. full mouth crowns), severe gingival enlargement, wearing orthodontic brackets or appliances
- having poor health condition (e.g. dementia)
- involved in other oral health studies

Verbal and written explanations regarding participation in the study were given to the volunteers, and they were required to sign a witnessed consent form. (Appendix IV)

2.2. Subject recruitment and withdrawal

In this study, subjects were recruited from the Hong Kong Stroke Association (HKSA).
This association is a support and self-help group for stroke sufferers and their family
members; it was established by a group of stroke sufferers in August 1997 and was registered as an independent charity organisation. An invitation letter explaining the study was sent to the association. (Appendix II)

Consent forms were obtained and the study purpose and procedures were explained to the potential study subjects. Those who fulfilled the inclusion criteria were accepted into this study. A free oral examination was also provided to all those who would like to participate in this study.

A study subject could withdraw from the study at any time for any reason and without any adverse consequences. The investigators could also remove a subject from the study if the subject was subsequently found to be suffering from a severe systemic disease that may influence the study outcome or in the event of adverse reactions or gross deviation from the study protocol.

2.3. Study design

A single blinded, parallel clinical trial was conducted with adult subjects. Ethical approval for the study was given by the Institutional Review Board of the University of Hong Kong. The duration of this study is to be conducted over a 6 month period, as a long term study is defined as being greater than 3 months (Deacon et al., 2004). At the initial appointment, a baseline assessment of the subjects’ oral health status was
performed. This was followed by a 1-month review. 3- and 6-month reviews will be performed in due course.

2.4. Toothbrushes

The electric toothbrush used in this study was the Braun Oral-B® AdvancePower 400 (Braun GmbH, Kronberg, Taunus, Germany) - a battery powered tooth-brush with 9600 sideward-movements/min. ("Braun Oral-B AdvancePower 400 D 4010,"") (Appendix IX)

The manual toothbrush used was a soft bristled Sensodyne® toothbrush with a small brush head. It was modified by inserting the handle into foam tubing making it thicker (Appendix VIII).

Patients were asked to use their assigned toothbrush with Oral-B Tooth and Gum Care® toothpaste which contained the active ingredient stannous fluoride (3.75 mg/g - 909 ppm F).

2.5. Experimental steps

Before the clinical examination, relevant medical and dental histories of the subjects were collected. A clinical examination was then carried out using disposable mouth-mirrors attached to an intra-oral LED light source and WHO probes. The oral hygiene status and the gingival health conditions of the study subjects were recorded.

Each subject was randomly issued either a modified manual toothbrush or an electric toothbrush. Verbal and written instructions on the operation and maintenance of the assigned toothbrush were given. They were also instructed to use the allocated toothbrush
exclusively in conjunction with the toothpaste provided for the next 6 months (24 weeks). At the initial appointment, assessment of dental caries, plaque and gingival status, and oral soft tissues were performed.

During the 1-month review, information on the subject’s use of the assigned toothbrush was recorded. Then a clinical examination was carried out using the same instruments and procedures as those in the baseline examination. The examiners were not informed of which toothbrush the subjects had used. The oral hygiene status and the condition of the gingivae and oral soft tissues were assessed. Subjects were asked to bring their toothbrush to each review where the degree of bristle wear was assessed. Any brushes showing marked wear were replaced.

Another re-assessment of the plaque and gingival status of the subjects will be recorded in the third month. At the end of the sixth month, another re-assessment of the plaque and gingival status will be charted and proper oral hygiene instructions on toothbrushing will be given to all subjects.

2.6. **Decayed Missing Filled Tooth Index, plaque scoring, gingival scoring, Community Periodontal Index**

The Decayed Missing Filled Tooth index (DMFT), recommended by the World Health Organization (WHO), was used in this study. All permanent teeth were examined. The number of carious teeth (D), tooth loss (M) and restored teeth (F) were recorded.

In each of the visits, the oral hygiene status of the subjects was assessed using the Plaque Index (PI) developed by Silness and Løe (1964). The PI was charted in all the permanent
teeth in quadrants 1 and 3. For subjects with less than 10 teeth in the respective two quadrants, the PI of all teeth in all four quadrants were charted. The PI was scored at four sites (mesio-buccal, mid-buccal, disto-buccal and entire lingual/palatal).

The following codes were used for recording the oral hygiene status:

0 = no plaque
1 = a film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque can be seen only by using the probe on the tooth surface.
2 = moderate accumulation of soft deposits within the gingival pocket, or the tooth and gingival margin which can be seen with the naked eye.
3 = abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

In addition to the PI, the health condition of the gingivae of the subjects was assessed by the use of the Gingival Index (GI) (Löe & Silness, 1963). The GI was charted in all the permanent teeth in quadrants 2 and 4. For subjects with less than 10 teeth in the respective two quadrants, the GI of all teeth in all four quadrants were charted. The GI was scored at four sites (mesio-buccal, mid-buccal, disto-buccal and entire lingual/palatal).

The following codes were used for recording the gingival health condition:

0= normal gingivae
1= mild inflammation - slight change in colour, slight edema, no bleeding on probing of the marginal gingival
2= moderate inflammation - redness, edema and glazing, bleeding on probing of the marginal gingival
3= severe inflammation, marked redness and edema, tendency to spontaneous bleeding
The mean GI and mean PI per tooth were calculated by summing up all the respective scores of each site and then dividing by the number of sites.

The Community Periodontal Index (CPI) recommended by the WHO, was used to assess the periodontal status. There are three indicators in this index: 1) presence or absence of gingival bleeding, 2) supra-gingival or sub-gingival calculus, and 3) shallow or deep periodontal pockets. A WHO probe was used in this study. For each subject, the mouth was divided into 6 parts (sextant) where the periodontal status of one tooth per sextant (6 teeth in total) was examined. Each tooth was examined on 6 different sites, and only the site with the highest score in each sextant was recorded. The sextant was excluded if less than two teeth were present and indicated for extraction. When no index tooth was present in one sextant, then all the remaining teeth in that sextant were examined and the highest score among those teeth was recorded. However, the distal surface of the third molar was excluded.

2.7. Interview on oral health knowledge, attitude and behavior

Before the group allocation, subjects were asked a series of questions on oral health during the interview. The questions were divided into three categories: oral health knowledge, oral health attitude and oral health behavior.

Three questions were asked to find out the oral health knowledge of the subjects, such as causes and preventions of dental caries. Eight questions were asked on subjects’ oral health attitude such as whether tooth loss is a natural phenomenon. Four questions were
asked on the oral health behavior of the subjects such as toothbrushing frequency.

2.8. Examiners training and study blindness

Before the recruitment of the subjects, three clinical examiners in this study were trained in the application of the diagnostic criteria and procedures in assessing the oral hygiene status and gingival health condition of the subjects. Training sessions on patients attending the Prince Philip Dental Hospital were held before the implementation of the study. Duplicate examinations were carried out on approximately 10% of the study subjects throughout the study to monitor examiner reproducibility. The assignment of toothbrushes to the study subjects was carried out by other persons and therefore the clinical examiners would not be aware of which toothbrush a subject was using. To prevent bias, the examiners did not have access to the subject’s previous recordings during the clinical examinations.

2.9. Statistical analysis

The main outcome variables used in assessing the effectiveness of the study toothbrushes are the PI and the GI scores. From the results of similar studies conducted by other researchers (Deery et al., 2004), a difference in the mean plaque/gingival score of around 0.4 between an electric toothbrush and a manual toothbrush is anticipated, the anticipated standard deviation of the mean scores is around 0.5. Using a statistical significance level of 5% and a power of 80%, a minimum size of 30 is required in this study.
A larger initial sample size of 75 in total were recruited at the baseline to allow for drop-out in this 24 week longitudinal study and the possibility that the difference between the index scores is smaller than anticipated.

Around 120 stroke patients from HKSA were screened before the subject recruitment because some of them did not satisfy the inclusion criteria due to inadequate number of sound teeth for examination or were unable to cooperate in the dental examination.

2.10. Data analysis

The information collected in this study was entered into a computer. The data was checked for errors. The software SPSS for Windows was used in the data analysis. The outcome measures were the PI and GI scores at the subject level. The mean of the PI and GI scores of the subjects were considered as the primary efficacy variables. Paired and independent t-tests and chi-square test were used to assess the statistical significance of the differences found. All tests were two-sided and the statistical significance level was set at 5%
3. RESULTS

3.1. Subjects

56 of the 75 participated subjects with a mean age of 57.3 (37 male, 19 female; male to female ratio was 1.94 to 1) were evaluated at the 1-month review. At the baseline visit, random allocation resulted in 37 subjects being allocated an electric toothbrush and the other 38 subjects were allocated a modified manual toothbrush (Table 3.1). The dropout rates for the modified manual toothbrush group and the electric toothbrush group were 34.2% and 16.2% respectively (Table 3.2). The overall drop-out rate is 25.3%.

### Table 3.1 Demographic data of the study population (%)

<table>
<thead>
<tr>
<th>Group</th>
<th>Electric Toothbrush</th>
<th>Modified Manual Toothbrush</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of subjects (n)</td>
<td>31</td>
<td>25</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>21/10</td>
<td>16/9</td>
</tr>
<tr>
<td>Age (years; mean ± SD)</td>
<td>56.9 ±7.1</td>
<td>57.7 ±9.4</td>
</tr>
</tbody>
</table>

### Table 3.2 Reasons for dropout at the 1-month review

<table>
<thead>
<tr>
<th>Group</th>
<th>Electric Toothbrush (n=37)</th>
<th>Modified Manual Toothbrush (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not attending the review</td>
<td>4 (10.8%)</td>
<td>9 (23.7%)</td>
</tr>
<tr>
<td>Did not use the assigned toothbrush</td>
<td>2 (5.4%)</td>
<td>4 (10.5%)</td>
</tr>
</tbody>
</table>
Year of Stroke

The duration of being diagnosed with stroke ranged from 3 months to 28 years. Of which the most common period ranged from 5 to 9 years which was evident in both groups. Only 4 subjects were diagnosed with stroke for over 15 years (Table 3.3). There was no significant difference between the two test groups in terms of the duration of being diagnosed with stroke (p=0.46, Chi-square test).

Hand Agility

All the subjects were asked to rate (significant, moderate, mild, no effect) how stroke affected their hand agility. In table 3.3, it shows that the majority of the subjects (64.3%) considered the effect of stroke on their hand agility as significant. There were no significant differences in the perceived hand agility between both groups (p=0.26, Chi-square test).

Education Level

All of the subjects received formal education, of which a majority (96.4%) attained up to primary and/or secondary education and again no significant difference was found between the two groups (Table 3.3).
Table 3.3 Background information of the study population

<table>
<thead>
<tr>
<th></th>
<th>All subjects (n=56)</th>
<th>Electric Toothbrush (n=31)</th>
<th>Modified Manual Toothbrush (n=25)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Year of Stroke</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-4</td>
<td>11 (19.6%)</td>
<td>8 (25.8%)</td>
<td>3 (12.0%)</td>
<td>0.46</td>
</tr>
<tr>
<td>5-9</td>
<td>31 (55.4%)</td>
<td>17 (54.8%)</td>
<td>14 (56.0%)</td>
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<tr>
<td>10-14</td>
<td>10 (17.9%)</td>
<td>5 (16.1%)</td>
<td>5 (20.0%)</td>
<td></td>
</tr>
<tr>
<td>15-19</td>
<td>3 (5.4%)</td>
<td>1 (3.2%)</td>
<td>2 (8.0%)</td>
<td></td>
</tr>
<tr>
<td>&gt;20</td>
<td>1 (1.8%)</td>
<td>0 (0.0%)</td>
<td>1 (4.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Hand Agility</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Significant</td>
<td>36 (64.3%)</td>
<td>17 (54.8%)</td>
<td>19 (76.0%)</td>
<td>0.26</td>
</tr>
<tr>
<td>Moderate</td>
<td>9 (16.1%)</td>
<td>6 (19.4%)</td>
<td>3 (12.0%)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>8 (14.3%)</td>
<td>5 (16.1%)</td>
<td>3 (12.0%)</td>
<td></td>
</tr>
<tr>
<td>No effect</td>
<td>3 (5.4%)</td>
<td>3 (9.7%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Education Level</strong></td>
<td></td>
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<tr>
<td>No Education</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Primary Education</td>
<td>25 (44.6%)</td>
<td>14 (45.2%)</td>
<td>11 (44.0%)</td>
<td></td>
</tr>
<tr>
<td>Secondary Education</td>
<td>29 (51.8%)</td>
<td>16 (51.6%)</td>
<td>13 (52.0%)</td>
<td></td>
</tr>
<tr>
<td>Tertiary Education</td>
<td>1 (1.8%)</td>
<td>0 (0.0%)</td>
<td>1 (4.0%)</td>
<td></td>
</tr>
<tr>
<td>Above University Education</td>
<td>1 (1.8%)</td>
<td>1 (3.2%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
</tbody>
</table>

Chi-square test
3.2. Inter-examiner reproducibility

The inter-examiner reproducibility was assessed by the Kappa statistic. For the PI, the Kappa statistic at baseline and 1-month ranged from 0.62 to 0.75 and from 0.49 to 0.76 respectively. For the GI, the Kappa statistic at baseline and 1-month ranged from 0.40 to 0.68 and from 0.45 to 0.66 respectively. The Kappa statistic indicated that the inter-examiner reproducibility was moderate to good.

3.3. Clinical examination

During the baseline examination, the oral condition was recorded using DMFT, CPI, PI and GI.

3.3.1 DMFT

In Table 3.4, the mean DMFT value of the electric toothbrush group was 11.8 (SD=7.07) and that of the modified manual toothbrush group was 10.1 (SD=6.38). There was no statistically significant differences in DMFT values between the two groups (p=0.35).

<table>
<thead>
<tr>
<th>Table 3.4 DMFT table</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electric Toothbrush</strong></td>
</tr>
<tr>
<td>Mean Decayed teeth D (SD)</td>
</tr>
<tr>
<td>Mean Missing teeth M (SD)</td>
</tr>
<tr>
<td>Mean Filled teeth F (SD)</td>
</tr>
<tr>
<td>Mean DMFT (SD)</td>
</tr>
</tbody>
</table>

Independent samples test
3.3.2 Community Periodontal Index

The majority of the subjects had CPI scores of 2 (27.8%), 3 (48.1%) or 4 (18.5%). While only 1.9% and 3.7% had CPI scores of 0 and 1 respectively. A mean of 0.4 sextants per mouth had a CPI score of 0, while the values for the CPI scores 1, 2, 3 and 4 were 1.1, 2.9, 1.3 and 0.3 sextants respectively (Table 3.5).

<table>
<thead>
<tr>
<th>CPI Score</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean no. of sextants affected</td>
<td>0.4</td>
<td>1.1</td>
<td>2.9</td>
<td>1.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Maximum CPI score among the population (%)</td>
<td>1.9%</td>
<td>3.7%</td>
<td>27.8%</td>
<td>48.1%</td>
<td>18.5%</td>
</tr>
</tbody>
</table>

3.3.3 Plaque Index and Gingival Index

Baseline result

At the baseline, the mean PI was 0.85 (SD=0.38) for the electric toothbrush group and 0.80 (SD=0.29) for the modified manual toothbrush group. For the GI, the mean was 0.95 (SD=0.35) for the electric toothbrush group, while the modified manual toothbrush group had a mean GI of 1.01 (SD=0.42). No statistically significant differences were found between both groups for the baseline PI (t-test, p=0.56) and baseline GI (t-test, p=0.54) (Table 3.6).

One month result

For the 1-month result, the electric toothbrush group had a mean PI of 0.56 (SD=0.25), while in the modified manual toothbrush group the mean PI score was 0.60 (SD=0.28).
The mean GI was 0.79 (SD=0.34) for the electric toothbrush group, while the mean GI was 0.95 (SD=0.41) in the modified manual toothbrush group. No statistically significant difference was found in the 1-month PI (p=0.56) and 1-month GI (p=0.11) results between the two groups (Table 3.6).

<table>
<thead>
<tr>
<th>Index</th>
<th>Time</th>
<th>Electric Toothbrush</th>
<th>Modified Manual Toothbrush</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>Baseline</td>
<td>0.85 (0.38)</td>
<td>0.80 (0.29)</td>
<td>0.56</td>
</tr>
<tr>
<td>(SD)</td>
<td>One Month</td>
<td>0.56 (0.25)</td>
<td>0.60 (0.28)</td>
<td>0.56</td>
</tr>
<tr>
<td>GI(SD)</td>
<td>Baseline</td>
<td>0.95 (0.35)</td>
<td>1.01 (0.42)</td>
<td>0.54</td>
</tr>
<tr>
<td></td>
<td>One Month</td>
<td>0.79 (0.34)</td>
<td>0.95 (0.41)</td>
<td>0.11</td>
</tr>
</tbody>
</table>

Table 3.6 Whole mouth mean Plaque Index (PI) and mean Gingival Index (GI) (Between group comparison)

There was a statistically significant difference between the baseline and 1-month results for the mean PI score within the electric toothbrush group (paired t-test, p<0.0001) and the modified manual toothbrush group (paired t-test, p<0.0001) (Table 7).

<table>
<thead>
<tr>
<th>Index</th>
<th>Group</th>
<th>Baseline (Mean SD)</th>
<th>One Month (Mean SD)</th>
<th>P- value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>Electric</td>
<td>0.85 (0.38)</td>
<td>0.56 (0.25)</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>Modified Manual</td>
<td>0.80 (0.29)</td>
<td>0.60 (0.28)</td>
<td>0.000*</td>
</tr>
<tr>
<td>GI</td>
<td>Electric</td>
<td>0.95 (0.35)</td>
<td>0.79 (0.34)</td>
<td>0.063</td>
</tr>
<tr>
<td></td>
<td>Modified Manual</td>
<td>1.01 (0.42)</td>
<td>0.95 (0.41)</td>
<td>0.400</td>
</tr>
</tbody>
</table>

* statistically significant within group, Paired t-test
For GI results, no statistically significant differences were found between the mean baseline and 1-month results within the electric toothbrush group (paired t-test, p=0.063) and the modified manual toothbrush group (paired t-test, p=0.40) (Table 7).

Plaque Index at different sites

In Table 3.8, when comparing the mean PI score at different sites between the baseline and 1-month review of the electric toothbrush group, a statistically significant difference was found at the buccal (0.68 vs. 0.38, paired t-test, p<0.0001), palatal/lingual (1.07 vs. 0.80, paired t-test, p<0.0001) and approximal (0.83 vs. 0.52, paired t-test, p=0.005) sites, showing that there was a significant improvement in the PI at those sites.

As for the modified manual toothbrush group, a statistically significant difference was found at the buccal site (0.63 vs. 0.39, paired t-test, p=0.001), the palatal/lingual site (1.13 vs. 0.89, paired t-test, p=0.001) and approximal sites (0.71 vs. 0.56, paired t-test, p=0.006).

When comparing the mean PI scores between the electric tooth group and the modified manual toothbrush group, no statistically significant difference was found at buccal, palatal/lingual and approximal sites (t-test, p>0.05).
Table 3.8 Mean Plaque Index score at different sites at baseline and 1-month review

<table>
<thead>
<tr>
<th>Site</th>
<th>Group</th>
<th>Baseline Mean (SD)</th>
<th>One Month Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0.68 (0.44)</td>
<td>0.38 (0.30)</td>
<td>0.000*</td>
</tr>
<tr>
<td>Buccal</td>
<td>Electric</td>
<td>0.63 (0.33)</td>
<td>0.39 (0.27)</td>
<td>0.001*</td>
</tr>
<tr>
<td></td>
<td>Modified Manual</td>
<td>N.S.#</td>
<td>N.S.#</td>
<td></td>
</tr>
<tr>
<td>Palatal/Lingual</td>
<td>Electric</td>
<td>1.07 (0.45)</td>
<td>0.80 (0.30)</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>Modified Manual</td>
<td>1.13 (0.44)</td>
<td>0.89 (0.40)</td>
<td>0.001*</td>
</tr>
<tr>
<td>Approximal</td>
<td>Electric</td>
<td>0.83 (0.43)</td>
<td>0.52 (0.27)</td>
<td>0.005*</td>
</tr>
<tr>
<td></td>
<td>Modified Manual</td>
<td>0.71 (0.33)</td>
<td>0.56 (0.29)</td>
<td>0.006*</td>
</tr>
<tr>
<td></td>
<td>N.S.#</td>
<td>N.S.#</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* statistically significant within group, paired t-test
# no statistically significant difference between group at that time point, independent t-test

Gingival Index at different sites

For the electric toothbrush group, when comparing the mean GI score at different sites between baseline and 1-month review, it showed no statistically significant difference at the buccal, palatal/lingual and approximal sites (paired t-test, p=0.06, 0.16 and 0.07 respectively) (Table 3.9).

As for the results of the modified manual toothbrush group, no statistically significant difference was found at buccal, palatal/lingual and approximal sites (paired t-test, p=0.28, p=0.64 & p=0.42 respectively) (Table 3.9).

Although no statistical significant difference was found, there was a generally decrease in mean GI score in buccal, palatal/lingual and approximal sites in both group at 1-month visit.
When comparing the mean GI scores between the electric toothbrush group and the modified manual toothbrush group, no statistically significant difference was found at buccal, palatal/lingual and approximal sites (t-test, p>0.05).

Table 3.9 Mean Gingival Index score at different sites at baseline and 1-month review

<table>
<thead>
<tr>
<th>Site</th>
<th>Group</th>
<th>Baseline Mean(SD)</th>
<th>One Month Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Electric</td>
<td>0.80 (0.38)</td>
<td>0.65 (0.34)</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>Modified Manual</td>
<td>0.84 (0.44)</td>
<td>0.76 (0.44)</td>
<td>0.28</td>
</tr>
<tr>
<td></td>
<td>N.S.#</td>
<td>N.S.#</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palatal/Lingual</td>
<td>Electric</td>
<td>1.13 (0.43)</td>
<td>0.98 (0.42)</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>Modified Manual</td>
<td>1.27 (0.49)</td>
<td>1.23 (0.54)</td>
<td>0.64</td>
</tr>
<tr>
<td></td>
<td>N.S.#</td>
<td>N.S.#</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approximal</td>
<td>Electric</td>
<td>0.93 (0.36)</td>
<td>0.76 (0.37)</td>
<td>0.07</td>
</tr>
<tr>
<td></td>
<td>Modified Manual</td>
<td>0.96 (0.42)</td>
<td>0.90 (0.38)</td>
<td>0.42</td>
</tr>
<tr>
<td></td>
<td>N.S.#</td>
<td>N.S.#</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* statistically significant within group, paired t-test

# no statistically significant between group, independent t-test

3.3.4 Satisfaction with toothbrushes

When asked about the satisfaction of the two test toothbrushes, most (93.6%) of the subjects in the electric toothbrush group were at least satisfied. No subjects were dissatisfied with the electric toothbrush. For the subjects in the modified manual toothbrush group, 60.0% of them were at least satisfied with the toothbrush. When comparing the satisfaction between the two groups, there was a statistically significant difference (Chi-square test, p=0.023) showing that the subjects in the electric
toothbrush group were generally more satisfied with their toothbrush than those in the modified manual toothbrush group (Table 3.10).

Table 3.10 Satisfaction with toothbrushes

<table>
<thead>
<tr>
<th></th>
<th>Electric Toothbrush (n=31)</th>
<th>Modified Manual Toothbrush (n=25)</th>
<th>Whole population (n=56)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very satisfied</td>
<td>7 (22.6%)</td>
<td>4 (16.0%)</td>
<td>11 (19.6%)</td>
<td></td>
</tr>
<tr>
<td>Satisfied</td>
<td>22 (71.0%)</td>
<td>11 (44.0%)</td>
<td>33 (58.9%)</td>
<td>0.023*</td>
</tr>
<tr>
<td>Neutral</td>
<td>2 (6.5%)</td>
<td>8 (32.0%)</td>
<td>10 (17.9%)</td>
<td></td>
</tr>
<tr>
<td>Dissatisfied</td>
<td>0 (0.0%)</td>
<td>2 (8.0%)</td>
<td>2 (3.6%)</td>
<td></td>
</tr>
</tbody>
</table>

Chi-square test

3.4. Questionnaire

Subjects were asked a series of questions on oral health. The results were split into three areas: knowledge, attitude and habits.

3.4.1 Oral health knowledge

Open ended questions were asked and it was found that nearly half of the subjects thought that poor oral hygiene and sweet foods contributed to tooth decay. 64.2% of subjects identified at least one of the actual causes of dental decay. Nearly two thirds (60.7%) of the subjects thought that proper toothbrushing could prevent tooth decay and 69.6% of the subjects knew at least one of the proper preventive measures of decay. When asked what methods could prevent periodontal disease, nearly half (42.9%) of the subjects considered proper toothbrushing as useful (Table 3.11).
Table 3.11 Oral health knowledge of the participated subject

<table>
<thead>
<tr>
<th>Causes of tooth decay (may choose more than one answer)</th>
<th>% of subjects (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor oral hygiene/poor toothbrushing technique</td>
<td>46.4</td>
</tr>
<tr>
<td>Bacteria/plaque</td>
<td>0.0</td>
</tr>
<tr>
<td>Sweet foods</td>
<td>48.2</td>
</tr>
<tr>
<td>Irregular dental check ups</td>
<td>0.0</td>
</tr>
<tr>
<td>'Hot air'/Chinese medicine beliefs</td>
<td>1.8</td>
</tr>
<tr>
<td>Sour foods</td>
<td>1.8</td>
</tr>
<tr>
<td>Others</td>
<td>17.9</td>
</tr>
<tr>
<td>Don’t know</td>
<td>23.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Methods that can prevent tooth decay (may choose more than one answer)</th>
<th>% of subjects (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper toothbrushing</td>
<td>60.7</td>
</tr>
<tr>
<td>Reduce the intake of sweet foods</td>
<td>17.9</td>
</tr>
<tr>
<td>Use of fluoridated toothpaste</td>
<td>1.8</td>
</tr>
<tr>
<td>Regular dental check ups</td>
<td>8.9</td>
</tr>
<tr>
<td>Rinsing after meals</td>
<td>17.9</td>
</tr>
<tr>
<td>Taking Chinese medicine</td>
<td>0.0</td>
</tr>
<tr>
<td>Others</td>
<td>14.3</td>
</tr>
<tr>
<td>Don't know</td>
<td>21.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Methods that can prevent periodontal disease (may choose more than one answer)</th>
<th>% of subjects (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper toothbrushing</td>
<td>42.9</td>
</tr>
<tr>
<td>Use of medicated toothpaste/mouthwash</td>
<td>7.1</td>
</tr>
<tr>
<td>Regular dental check ups/scaling</td>
<td>1.8</td>
</tr>
<tr>
<td>'Hot air'/Chinese medicine beliefs</td>
<td>3.6</td>
</tr>
<tr>
<td>Not smoking</td>
<td>0.0</td>
</tr>
<tr>
<td>Eating fruits and nutritional supplements</td>
<td>0.0</td>
</tr>
<tr>
<td>Rinsing after meals</td>
<td>1.8</td>
</tr>
<tr>
<td>Others</td>
<td>12.5</td>
</tr>
<tr>
<td>Don't know</td>
<td>41.1</td>
</tr>
</tbody>
</table>
3.4.2 Oral health attitude

When asked about tooth loss, nearly half of the subjects though that it was a natural phenomenon. 69.6% of subjects disagreed that healthy teeth are congenital and not affected by the environment. Almost all of the subjects stated that oral health was very important to them (96.4%) and the health of teeth affects aesthetics (91.1%) and overall health (92.9%). More than half disagreed that it was not important to prevent tooth exfoliation (73.2%) and that false teeth were more convenient than natural teeth (80.4%). Almost all subjects (96.4%) agreed that regular dental examinations could prevent dental problems (Figure 3.1).

Fig 3.1 Oral health attitude (n=56)
3.4.3 Oral health behaviours

The oral health behaviours of the subjects were also investigated. All subjects brushed their teeth at least once a day while most subjects (75.0%) brushed twice a day (Fig 3.2). In contrary, only 3.6% and 5.4% of the subject claimed that they floss their teeth or use an interdental brush once or twice daily, slightly more subject (37.5%) used mouthrinse once or twice daily (Fig 3.3). When asked what problems they have encountered when brushing their teeth, the most common difficulty was in controlling the amount of force used to control the toothbrush (28.6%) and in controlling the direction of the toothbrush (21.4%). Most subjects (73.2%) rated their toothbrushing skills as average. However, 76.8% rated the health of their teeth and gums as average or unhealthy. 69.7% of subjects had their last dental visit 1 or more years ago. (Table 3.12)

Fig 3.2 Frequency of toothbrushing each day
Fig 3.3 Frequency of using other oral health products

<table>
<thead>
<tr>
<th>Activity</th>
<th>Less than once a day</th>
<th>1-2 times a day</th>
<th>3 times or more a day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flossing</td>
<td>3.6%</td>
<td>5.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Interdental brush</td>
<td>89.3%</td>
<td>54.4%</td>
<td>5.4%</td>
</tr>
<tr>
<td>Mouthrinse</td>
<td>96.4%</td>
<td>62.5%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
Table 3.12 Oral health behaviours

<table>
<thead>
<tr>
<th>Problem/Category</th>
<th>% of subjects (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Problems encountered when brushing teeth</strong></td>
<td></td>
</tr>
<tr>
<td>Difficulties in controlling the direction</td>
<td>21.4</td>
</tr>
<tr>
<td>Difficulties in controlling the force</td>
<td>28.6</td>
</tr>
<tr>
<td>Loss of grip of toothbrush</td>
<td>12.5</td>
</tr>
<tr>
<td>Toothbrush handle is too thin</td>
<td>14.3</td>
</tr>
<tr>
<td>Others</td>
<td>17.9</td>
</tr>
<tr>
<td><strong>Last dental visit</strong></td>
<td></td>
</tr>
<tr>
<td>Less than 6 months ago</td>
<td>12.5</td>
</tr>
<tr>
<td>6 months – 1 year</td>
<td>17.7</td>
</tr>
<tr>
<td>1 year – 3 years</td>
<td>30.4</td>
</tr>
<tr>
<td>More than 3 years</td>
<td>25.0</td>
</tr>
<tr>
<td>Never</td>
<td>14.3</td>
</tr>
<tr>
<td><strong>Toothbrushing skills rating</strong></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>17.9</td>
</tr>
<tr>
<td>Average</td>
<td>73.2</td>
</tr>
<tr>
<td>Bad</td>
<td>8.9</td>
</tr>
<tr>
<td><strong>Oral health rating</strong></td>
<td></td>
</tr>
<tr>
<td>Healthy</td>
<td>23.2</td>
</tr>
<tr>
<td>Average</td>
<td>41.1</td>
</tr>
<tr>
<td>Unhealthy</td>
<td>35.7</td>
</tr>
</tbody>
</table>
4. DISCUSSION

4.1. Subjects

A convenience sample was obtained due to time constraints and limited resources. The Hong Kong Stroke Association (HKSA) was the organization of choice for this collaboration as it has been established for over ten years (since 1997) and it has several branches located in different areas of Hong Kong. The study was conducted in their premises which offered convenience to the stroke sufferers, as locomotor disability is common among them. A study has shown that the odd ratio of a stroke sufferer reporting difficulty in locomotor is 3.86 (Adamson, Beswick, & Ebrahim, 2004). Therefore it was a great incentive for them to be able to participate in this long-term study at their nearest HKSA branch where they usually have gatherings and activities with their fellow stroke sufferers. However as this was a convenience sample, the subjects included in the study may not represent the whole stroke population in Hong Kong.

The study drop-out rate was moderate (25.3%). 13 subjects were unable to attend the 1-month review assessment visit because they were not in Hong Kong, needed to go to hospital or had personal reasons, while 6 subjects who attended the 1-month review did not comply with the instructions, i.e. they did not use the assigned toothbrush and
toothpaste within the assigned period. Out of these subjects, 4 were from the modified manual toothbrush group, they found the thickened handle inconvenient to use and difficult to adapt to. Nevertheless, the majority of patients showed they were satisfied with their modified manual toothbrush. 2 subjects from the electric toothbrush group complained of discomfort from vibrations of the toothbrush and therefore stopped using it. More subjects in the modified toothbrush group compared with electric toothbrush group did not comply. From the result of the satisfaction with toothbrushes, a significant difference was found between two groups (p=0.023). The subjects in the electric toothbrush group were generally more satisfied with their toothbrush. This may be due to electric toothbrushes being more appealing than a modified manual toothbrush, especially those who have a fascination with electrical items (Dougall & Fiske, 2008). Moreover, the subjects who brushed with the unaffected side could not find the advantage of using the modified manual toothbrush. In fact, the stroke patients having hemiplegia can learn to brush with their unaffected side and the dexterity of the affected hand varies from patient to patient.

4.2. Study design and method

In this clinical trial, each subject was randomly allocated either a modified manual toothbrush or an electric toothbrush. This randomization avoided selection biases
between the two groups (Schulz & Grimes, 2002). This clinical trial was a single-blinded study. Examiners were blinded against the type of toothbrush being allocated to the subjects. This prevented examiner bias towards an expected result during the recording of the GI and PI. However, effective blinding was difficult to achieve as some of the subjects showed their assigned toothbrush to the examiner during examination. In the study, subjects were not blinded against the type of toothbrush others were being allocated. It would be optimal to keep them blind as to which toothbrush others were using, as it may affect the effort they put into brushing as well as prevent their own bias towards certain toothbrushes. However, it was extremely difficult to achieve as the subjects would frequently interact with one another at their HKSA gatherings.

The outcome measures were quantified by levels of plaque and gingival inflammation using oral hygiene quantification indices. The indices selected were the Silness and Löe, 1964 Plaque Index (PI) (Silness & Löe, 1964) and for gingival inflammation the Löe and Silness 1963 Gingival Index (GI) (Löe & Silness, 1963). They were chosen due to their common usage, being standardized outcome measures for assessment of oral hygiene, and their ease of usage under time constraints. In particular, the GI was chosen over the Sulcular Bleeding Index (Muhlemann & Mazor, 1958) because it did not require mandatory probing of the gingivae to obtain a score, as many stroke
sufferers have bleeding tendencies from taking anticoagulant drugs.

Part mouth scoring was used due to time constraints as well as catering towards the subjects comfort and tolerance to extended periods in a dental chair. However the use of partial mouth scoring in comparison to full mouth scoring has shown to have statistically significant and similar results to one another (Bentley & Disney, 1995).

4.3. Toothbrushes

In a previous student project, a similar modified manual toothbrush was distributed to Parkinson’s Disease Patients In Hong Kong (Cheung et al., 2009). They suggested that the patients found it easier to grip, to control the force and to control the direction of modified manual toothbrush. The patients’ full mouth mean PI score also decreased significantly after using the brush for 1 month. The same modified manual toothbrushes were distributed to one group of the stroke patients, which is similar to the findings of this study.

For another group of stroke patients, a battery-operated power toothbrush (Braun Oral-B AdvancePower 400) was used to investigate its effect on their oral hygiene. It may compensate for the loss of skilled manipulation in toothbrushing when stroke patients brush their teeth. Some clinical studies have shown that battery operated
toothbrushes are significantly more effective than a manual toothbrush (Bustillo, Cartwright, & Battista, 2000; Dörfer, von Bethlenfalvy, & Pioch, 2001; Naresh, Galustians, & Qaqish, 2001). This study showed that both toothbrush groups exhibited a lower plaque score in the 1-month review, but there was no significant difference between the groups.

In the 1-month review, all the modified manual toothbrushes and electric toothbrushes were examined for signs of wear. For the modified manual toothbrush, wear was generally found after 1-month of use. Since manual toothbrush wear can adversely affect its efficacy (Warren, Jacobs, & Low, 2002), a new manual toothbrush was distributed to replace those showing signs of wear. Another clinical trial found that the efficacy of 3-month-old brush heads was to be as effective as new brush heads in plaque removal on a rotation-oscillation-powered toothbrush even when the brush heads display marked wear (Hogan, Daly, & Curtis, 2007). For our study, only a few brush heads in the electric toothbrush group showed significant wear which were subsequently replaced due to the patients’ insistence, otherwise the brush heads for the electric toothbrush were not replaced in the 1 month review.

In the study design, subjects were given basic instructions on how to use, operate and maintain the toothbrushes. They were asked to brush according to their normal
practice. There was no detailed oral hygiene instruction given regarding brushing time and techniques. This was done to ensure that the difference between the baseline and 1-month results were due to the efficacy of the two different types of toothbrushes only rather than the improved oral hygiene practice.

4.4. Results

4.4.1 Plaque and Gingival Index

A statistically significant difference was observed in both the modified manual toothbrush group (p<0.0001) and electric toothbrush group (p<0.0001) in reduction of PI during the 1-month study period (Table 3.7). It is possible that the effect of the toothbrushes under investigation may help to reduce the amount of plaque. In addition, the reduction in PI in both groups may also be due to the “Hawthorne Effect” (McCarney et al., 2007). This means participants may become subconsciously more aware of their oral hygiene after the introduction of this research project, despite the fact that oral hygiene instructions were not provided to the subjects. The subjects may have brushed their teeth with more effort before reassessment as they were informed to attend follow-up visits. However, there was no significant difference between using the modified manual toothbrush and electric toothbrush for plaque removal (p=0.56). Since both electric and modified manual toothbrush groups have
a similar reduction in PI during the 1-month period and therefore may lead to no significant difference between the two groups.

There was an improvement in the GI in the 1-month results in both groups, however they were not of a statistically significant level (electric toothbrush, p=0.063; modified manual toothbrush, p=0.40). This may be due to the fact that plaque removal takes shorter time to have clinical effect than for the gingivitis to resolve.

At individual PI sites, a significant difference was found in both the electric toothbrush group and modified manual toothbrush group. There was a significant reduction in the buccal, palatal/lingual and approximal sites. The same findings were observed in the modified manual toothbrush group. This might indicate that even though the subjects were not satisfied with the modified manual toothbrush, they were still able to perform plaque removal on all sites.

For the GI results, no statistically significant difference was found in both the electric and modified manual toothbrushes groups. As gingival health might require more time to improve to a significant level, it is important to note that this is only the result of 1-month’s time, therefore 3-month and 6-month results will be needed to affirm the speculations mentioned above.

The current results of this study are consistent with another study, Dentino, et al , who
compared powered and manual toothbrushes for 6 months without providing any professional oral hygiene instructions, concluded there is no significant difference in GI in any time point and a significant difference in PI only at 3 and 6 months (Dentino et al., 2002). This study may not yield a significant result at the end as Haffajee AD, et al found that there is no significant difference in the GI and PI between manual and electric toothbrush in any time point during a 6-month period (Haffajee, Thompson, Torresyap, Guerrero, & Socransky, 2001). However, most if not all studies conducted on efficacy between manual and electric toothbrushes are used on healthy subjects, whereas this study focuses on stroke subjects who generally have an impaired manual dexterity as well as oral motor and sensory deficits (Pow et al., 2005).

4.4.2 Dental caries and periodontal condition

When comparing the status of dental caries experience and periodontal disease of the general public to the stroke patients (Table 4.1), it was found that more stroke patients presented with periodontal pockets than the general public (Department of Health, 2002). This may be related to their poor manual dexterity affected by the stroke. For the history of dental caries, the prevalence of dental caries on stroke patients is similar to those of the general public, as is the prevalence of untreated dental caries.
Table 4.1 table comparing the status of dental caries and periodontal condition between stroke subjects and general public

<table>
<thead>
<tr>
<th>% of people presented with</th>
<th>Stroke subjects (42-75 years old)</th>
<th>General public (35-44 years old adult)</th>
<th>General public (65 to 74 years old non-institutionalized older persons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of caries</td>
<td>96.4</td>
<td>97.5</td>
<td>99.4</td>
</tr>
<tr>
<td>Untreated caries</td>
<td>58.9</td>
<td>32.0</td>
<td>52.9</td>
</tr>
<tr>
<td>Calculus</td>
<td>27.8</td>
<td>49.9</td>
<td>43.0</td>
</tr>
<tr>
<td>Periodontal pocket</td>
<td>66.6</td>
<td>46.0</td>
<td>55.3</td>
</tr>
</tbody>
</table>

4.4.3 Oral health knowledge (Table 4.2)

The correct causes of dental decay include ‘poor oral hygiene or brushing technique’, ‘sweet food’ or ‘bacteria or plaque’. However no stroke subjects were able to identify bacteria as the cause of tooth decay (Table 3.11). This might due to the lack of oral health education targeted towards these special needs group.

The stroke subjects had comparable knowledge on the prevention of periodontal disease to other groups in Hong Kong (Department of Health, 2002)(Table 4.2). Less than half of the subjects in each of all 4 groups were able to identify ‘proper brushing technique’ as a prevention measure for periodontal disease. More than 30% of subjects in each group did not know how to prevent the disease.

The stroke subjects’ knowledge in the prevention of periodontal disease is lacking compared to that in the prevention of tooth decay, which may indicate a greater need to educate them on periodontal disease and its prevention.
Table 4.2 Comparison among stroke subjects, Parkinson’s subjects and general public regarding oral health knowledge

<table>
<thead>
<tr>
<th>Items</th>
<th>Stroke subjects</th>
<th>Parkinson’s subjects</th>
<th>General public (35-44 years old adult)</th>
<th>General public (65 to 74 years old non-institutionalized older persons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify at least one of the correct causes of dental decay</td>
<td>64.2%</td>
<td>82.9%</td>
<td>&gt;75.1%</td>
<td>&gt;46.6%</td>
</tr>
<tr>
<td>Did not know the causes of tooth decay</td>
<td>23.2%</td>
<td>17.7%</td>
<td>7%</td>
<td>28.1%</td>
</tr>
<tr>
<td>At least one of the correct preventive measures of tooth decay</td>
<td>69.6%</td>
<td>82.9%</td>
<td>&gt;83.6%</td>
<td>51.3%</td>
</tr>
<tr>
<td>Did not know preventive measures of tooth decay</td>
<td>21.4%</td>
<td>9.8%</td>
<td>6.9%</td>
<td>30.9%</td>
</tr>
<tr>
<td>Identify ‘proper brushing technique’ as a prevention measure of periodontal disease</td>
<td>42.9%</td>
<td>43.9%</td>
<td>40.9%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Did not know prevention measure of periodontal disease</td>
<td>41.1%</td>
<td>41.5%</td>
<td>33.1%</td>
<td>62.1%</td>
</tr>
</tbody>
</table>

4.4.4 Oral health attitude

In table 4.3, it showed that less stroke subjects (48.2%) thought that ‘tooth loss is a natural process’ compared with Parkinson’s subjects (63.4%) (Cheung et al., 2009) and 62.7% of older adults in the general public (Department of Health, 2002). Tooth loss at old age is not a natural process in life, thus a conscious effort and self-reliance on adopting an effective brushing habit is needed to maintain optimal oral health.
Almost all of the stroke subjects stated that teeth are important (96.4%) and affects overall health (92.9%). 96.4% of them agreed that regular check-ups can prevent teeth problems. This indicates the subjects are generally conscious about oral health and its relationship to general health.

Table 4.3 Comparison among stroke subjects, Parkinson’s disease subjects and General public regarding oral health attitude

<table>
<thead>
<tr>
<th></th>
<th>Stroke subjects</th>
<th>Parkinson’s subjects</th>
<th>General public (35-44 years old adult)</th>
<th>General public (65 to 74 years old non-institutionalized older persons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tooth loss is a natural process</td>
<td>48.2%</td>
<td>63.4%</td>
<td>41.2%</td>
<td>62.7%</td>
</tr>
<tr>
<td>Oral health are important</td>
<td>96.4%</td>
<td>97.6%</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Oral health affects overall health</td>
<td>92.2%</td>
<td>97.6%</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Regular check-ups can prevent teeth problems</td>
<td>96.4%</td>
<td>97.6%</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

### 4.4.5 Oral health behaviours

75% of the stroke patient performed toothbrushing at least twice a day and all brushed their teeth every day (Fig 3.2). This is comparable to the data in Parkinson’s subjects (Cheung et al., 2009) and the general public (Department of Health, 2002) (Table 4.4). For flossing and using interdental brushes, the findings in the stroke patient showed that these are not common oral hygiene practice and is similar to the general public in Hong Kong.
Compared with flossing and using interdental brushes, mouthrinsing is rather common, 37.5% of the stroke patients used mouthrinse at least once a day (Fig 3.3). The more frequent use of mouthrinse may be explained by poor hand agility of the participants and they believed that mouthrinsing would help them to maintain better oral hygiene.

Most stroke patients (73.2%) rated their tooth brushing skills as average, and 76.8% of them rated the health of their teeth and gums as average or unhealthy. Perhaps this is because stroke subjects may perceive or rate their oral health to reflect their impaired manual dexterity in brushing their teeth.

Table 4.4 Comparison among stroke subjects, Parkinson’s subjects and the general public regarding oral health behaviours

<table>
<thead>
<tr>
<th></th>
<th>Stroke subjects</th>
<th>Parkinson’s subjects</th>
<th>General public (35-44 years old adult)</th>
<th>General public (65 to 74 years old non-institutionalized older persons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toothbrushing every day</td>
<td>100%</td>
<td>97.5%</td>
<td>99.1%</td>
<td>98.7%</td>
</tr>
<tr>
<td>Did not use flossing or use flossing less than once per day</td>
<td>96.4%</td>
<td>N/A</td>
<td>89.3%</td>
<td>98.4</td>
</tr>
<tr>
<td>Rating own tooth brushing skills as average</td>
<td>73.2%</td>
<td>51.2%</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Rating own gums as average or unhealthy</td>
<td>76.8%</td>
<td>87.8%</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>
4.4.6 Overall comments on results of questionnaire

The subjects generally had a positive oral health attitude and were conscious about their oral health. They tried to keep up with oral hygiene practice despite the reduced hand agility. This is reflected in the baseline mean PI of around 0.6 and GI of around 1. The oral hygiene practice may need to be reinforced in this group of subjects because of reduced manual dexterity and this is reflected in their negative perception on the outcome of oral hygiene practice.

4.5 Limitations of the study

Like most indices, the PI and GI have various degrees of subjectivity in them. Whereas signs of gingival bleeding and oedema can be assessed fairly objectively, changes in the colour of the gingivae included within the GI criteria introduced a subjective element to the index scoring (Benamghar, Penaud, Kaminsky, Abt, & Martin, 1982). When gingival tissues are subjected to repeated probing, this can induce minor damage, making them more likely to bleed after a second probing whether this is by the same or second examiner creating inconsistencies between examiners during calibration (Eaton, Rimini, Zak, Brookman, & Newman, 1997). In addition, the scoring criteria of the GI assumes the gingival condition of a patient progresses in a stereotypical way, thus a score may be awarded based on symptoms
that may not reflect the true nature of the gingival condition, introducing an element of error (Benamghar et al., 1982).

The difficulty with the PI is that when a probe is used to scrape the tooth surface, plaque is removed leaving a plaque free surface for the second examiner to encounter. Therefore subjectivity in estimating plaque occurs when there is more than one examiner using this index (Fischmann, 1986).

Other sources of error may include examinations being conducted under suboptimal conditions. Some patients were wheelchair-bounded and had to be examined in an upright position. To prevent the prolonged flexion of these subjects’ neck and back, the examination was performed in a shortened period. In addition this was done to prevent examiner muscle fatigue. In this study, there were 3 examiners. All performed calibration exercises to ensure as much inter-examiner consistency as possible before examinations on the subjects were performed. However, the kappa values of the data reflected variable levels of agreement among examiners. Perhaps GI is more subjective than PI, which is reflected from the lower levels of agreement among examiners. In addition, PI and GI sometimes may not reflect the changes in periodontal health as Robinson et al. (2005) suggested that doubt persists in what level of plaque removal and reduction in gingivitis will result in clinically significant
improvements in periodontal health. The probability of the development of periodontal disease is affected by genetics and other modifying factors, such as diabetes mellitus.

A 1-month review was conducted where the PI and GI of the subjects were charted and asked to complete a questionnaire on whether they used the assigned toothbrushes daily during the period of the study. The actual compliance of the usage of the assigned toothbrush could not be made completely transparent, but by asking the subjects to bring back their assigned toothbrushes during reviews to assess their usage was a good indication. Follow up 3-month and 6-month review will also be conducted in the future.
5. CONCLUSION

When interpreting the results of this study, caution is required as 1 month is a comparatively short period for a clinical trial on effectiveness of toothbrush. Results from longer term follow-up will be reported. Despite this reservation, the 1-month result shows that:

- There was no statistically significant difference between the modified manual toothbrush group and the electric toothbrush group in removing plaque. Therefore, the first null hypothesis cannot be rejected.

- A decrease in mean Gingival Index score were observed in the modified manual toothbrush group and the electric toothbrush group but the decrease was not enough to be statistically significant. Therefore the second null hypothesis cannot be rejected.

- Electric toothbrush and modified manual toothbrush were both effective in removing dental plaque, this was reflected by the significantly lower mean Plaque Index score observed in stroke patients for 1-month duration.
6. ACKNOWLEDGEMENTS

We would like to express our gratitude to the following persons and parties for their generous help and support throughout our Community Health Project:

Prof. E.C.M. Lo

Dr. A.H.H. Wong

Dr. D.S.W. You

Dr. M.C.M. Wong

Dr. W. Zheng

Mr. K.H. Yik

Ms. K.S. Yik

Mr. K.H. Lau

Mr. K.C. Kan

Mr. Y.C. Chan

Hong Kong Stroke Association

Oral-B, Procter & Gamble (Hong Kong) Limited

GlaxoSmithKline Hong Kong
7. REFERENCES


achievement and maintenance of inter-examiner consistency in the assessment of plaque and gingivitis during a multicentre study based in general dental practices. *Journal of Clinical Periodontology*, 24(3), 185-188.


cardiovascular disease and stroke. 133, 37S-44S.
## Project outline

<table>
<thead>
<tr>
<th>Date</th>
<th>Activities</th>
</tr>
</thead>
</table>
| November 2009    | Project planning  
|                  | Collecting background information  
|                  | Sending out introductory letter |
| December 2009    | Initial contact with the Hong Kong Stroke Association  
|                  | Project plan finalization  
|                  | Aims and objectives determination |
| January 2010     | Determination of methodology, schedule and content of visits  
|                  | Documentation of data collecting form, consent form and questionnaires |
| February 2010    | Site visit to Tuen Mun, Lei Cheng Uk, Sheung Shui, Kornhill Centre  
|                  | Preparation for field work  
|                  | Seeking sponsorship and ordering toothbrush and toothpaste  
|                  | Documentation of toothbrush instruction |
| Early March 2010 | Calibration of examiner  
|                  | Material gathering and arrangement of transportation  
|                  | First Visit to Tuen Mun, Sheung Shui and Lei Cheng Uk Centre for baseline data collection |
| Late March 2010  | Second visit to Tuen Mun and Sheung Shui Centre for baseline data collection  
|                  | Report Writing |
| April 2010       | Revisit to Tuen Mun, Sheung Shui and Lei Cheng Uk Centre for 1-month data collection  
|                  | Data analysis  
|                  | Report Writing |
| July 2010        | Revisit to Tuen Mun, Sheung Shui and Lei Cheng Uk Centre for 3-month data collection |
| September-      | Revisit to Tuen Mun, Sheung Shui and Lei Cheng Uk Centre for 6-month data collection  
<p>| October 2010     |                                                                             |</p>
<table>
<thead>
<tr>
<th>Centre</th>
<th>Address</th>
<th>Dates of Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Territories West</td>
<td>G/F, Hing Cheung House, Tai Hing Estate, Tuen Mun</td>
<td>9\textsuperscript{th} February, 2010</td>
</tr>
<tr>
<td>新界西</td>
<td>新界西屯門大興邨興昌樓地下</td>
<td>4\textsuperscript{th} March, 2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>22\textsuperscript{nd} March, 2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8\textsuperscript{th} April, 2010</td>
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<td></td>
<td>27\textsuperscript{th} April, 2010</td>
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<tr>
<td></td>
<td></td>
<td>29\textsuperscript{th} July, 2010</td>
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<tr>
<td>New Territories East</td>
<td>G/F, Ping Chi House, Tai Ping Estate, Sheung Shui</td>
<td>12\textsuperscript{th} February, 2010</td>
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<tr>
<td>新界東</td>
<td>新界東上水太平邨平治樓地下</td>
<td>6\textsuperscript{th} March, 2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25\textsuperscript{th} March, 2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10\textsuperscript{th} April, 2010</td>
</tr>
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<td></td>
<td></td>
<td>28\textsuperscript{th} April, 2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3\textsuperscript{rd} July, 2010</td>
</tr>
<tr>
<td>Kowloon West</td>
<td>G/F, Hau Lim House, Lei Cheng Uk Estate, Sham Shui Po</td>
<td>10\textsuperscript{th} February, 2010</td>
</tr>
<tr>
<td>九龍西</td>
<td>九龍西深水埗李鄭屋邨孝廉樓地下</td>
<td>9\textsuperscript{th} March, 2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10\textsuperscript{th} March, 2010</td>
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<tr>
<td></td>
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<td>8\textsuperscript{th} April, 2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20\textsuperscript{th} July, 2010</td>
</tr>
</tbody>
</table>
Dear Madam,

Re: Clinical Trial on the Effectiveness of Different Toothbrushes for Stroke Patients

As a group of 4th year students at the Faculty of Dentistry, University of Hong Kong, we cordially invite your organization to participate in our Community Health Project on the topic “Clinical Trial on the Effectiveness of Different Toothbrushes for Stroke Patients”.

The aims and objectives of our project are:

a. To investigate the effectiveness of using modified manual toothbrush and electronic toothbrush on stroke patients
b. To improve the oral health status of stroke patients
c. To provide dental services including oral examination, basic preventive treatment and oral health education for stroke patients

Our study includes conducting questionnaires on oral health knowledge and behaviour, In addition, oral examinations will be performed as well as some simple dental preventive treatment (e.g. fluoride treatment and simple restorations).

<table>
<thead>
<tr>
<th>Proposed Dates</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st visit 1st-5th March, 2010</td>
<td>Questionnaire, basic examination, distribution of toothbrushes, toothbrushing instruction</td>
</tr>
<tr>
<td>1-month visit Early April, 2010</td>
<td>Re-examination, preventive treatment</td>
</tr>
<tr>
<td>3-month visit July, 2010</td>
<td>Re-examination, preventive treatment</td>
</tr>
<tr>
<td>6-month visit September – October, 2010</td>
<td>Re-examination, preventive treatment</td>
</tr>
</tbody>
</table>

The project will be carried out in early March and the venue can be decided by your organization. A site visit may be required to ensure there is enough space for dental equipments to be placed. We hope that this project can carry benefits to the patients.

Should you have any enquiries regarding our project, please contact our group representatives Ms. Vani Liu at XXXXXX or Mr. Peter Yim at XXXXXX.

Yours faithfully,

Dr. Wong Ho Hang, Anthony
Group Advisor

Liu Wai Yin, Vani
Group Representative

Periodontology & Public Health, Faculty of Dentistry
3/F, Prince Philip Dental Hospital, 34 Hospital Road, Hong Kong.
TEL: (852) 2859 0301 FAX: (852) 2858 7874
10th February, 2010

Dear Mr. Tsui,

**Sincere invitation to be a sponsor of Community Health Project 2010**

I am writing this letter on behalf of the Community Health Project 2010, BDS Group 4.2, Faculty of Dentistry, The University of Hong Kong seeking for sponsorship to support our project this year.

Each year, our dental year four students will perform community health project of different topics. We are a group of the year four students consisting of 9 people. This year we are carrying the project of the topic, “Clinical Trial on the Effectiveness of Different Toothbrushes for Stroke Patients”. The aims and objectives of our project include investigation of the effectiveness of using modified manual toothbrush and electronic toothbrush on stroke patients and improve their oral health status.

To achieve the aim, the project is jointly organized with The Hong Kong Stroke Association. Our study will be comprised of examinations of oral health status at regular interval after using different types of toothbrushes and a questionnaire on oral health knowledge. In addition, simple dental preventive treatment (e.g. fluoride treatment and simple restorations) will be provided for the stroke patients in latter visit.

With your company being recognized as one of the leading companies in Hong Kong, we would be grateful to have you to become our sponsor. It is to our appreciation for your offer of electronic toothbrushes and products to the project. Acknowledgement will be given to your company on posters and other promotional items. Your generous support will surely bring our project to a successful one.

Should you have any queries, please feel free to contact Cheung Chi Hang, Alex. We are looking forward to hearing from you soon.

Thank you for your kind attention.

Yours faithfully,

Cheung Chi Hang, Alex
Group Representative
BDS Group 4.2, Faculty of Dentistry

---

Appendix III
Sponsor Letter to Oral B

Dear Mr. Tsui,

**Sincere invitation to be a sponsor of Community Health Project 2010**

I am writing this letter on behalf of the Community Health Project 2010, BDS Group 4.2, Faculty of Dentistry, The University of Hong Kong seeking for sponsorship to support our project this year.

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Should you have any queries, please feel free to contact Cheung Chi Hang, Alex. We are looking forward to hearing from you soon.

Thank you for your kind attention.

Yours faithfully,

Cheung Chi Hang, Alex
Group Representative
BDS Group 4.2, Faculty of Dentistry
Clinical trial on the effect of toothbrushes

5 February, 2010

Dear parent/guardian of the stroke members of the Hong Kong Stroke Association:

To improve the oral health of people with mental handicap, the Faculty of Dentistry of The University of Hong Kong is conducting a clinical study on toothbrushes. The purpose of this study is to compare the effectiveness of two toothbrushes (an electric powered toothbrush and a modified manual toothbrush) in removing dental plaque and in maintaining gum health. The duration of this study is 24 weeks.

If you agree to participate in this study, you will receive a detailed oral examination in the association. Through drawing lot, we will provide you with a toothbrush. Our research staff will teach you how to use the assigned toothbrush. The toothbrush should be used for two minutes each time, in the morning and in the evening of each day, to clean the teeth and the mouth for a period of 24 weeks. We will conduct a detailed examination to assess your oral health status after 4, 12, and 24 weeks. During the study, we will provide you with a tube of fluoridated toothpaste for use in toothbrushing. The toothbrushes and toothpaste are safe and do not have adverse health effects if used according to instructions.

Participation in this study is free and completely voluntary. You can choose not to participate or to withdraw at any time, without giving any reason. In both circumstances there will be no adverse consequences and your right in the association will not be affected. The information collected in this study will be kept confidential and used by authorized research staff only. We respect the privacy of all study participants and will not release or publish any information that will reveal the identity of your child.

If you have any queries during this study, you can call the study investigators – Prof. Edward Lo (2859 0292) or Dr. Anthony Wong (2859 0291).

Yours sincerely,

Prof. Edward C.M. Lo
Faculty of Dentistry
The University of Hong Kong

Dr. Anthony H.H. Wong
Faculty of Dentistry
The University of Hong Kong
PARTICIPANT CONSENT FORM

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.

2. I agree to take part in the above study.

3. I understand that the participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, and without any adverse consequences.

Name of Participant: __________________________ Signature: __________________________

Date: _______ Year _______ Month _______ Day

Name of Witness: __________________________ Signature: __________________________

Date: _______ Year _______ Month _______ Day

Name of Investigator: __________________________ Signature: __________________________

Date: _______ Year _______ Month _______ Day
牙刷效能之臨床研究

新健社的中風患者或家屬啟:

為增進中風患者的口腔健康，香港大學牙醫學院現正進行一項牙刷的臨床研究，本研究項目是測試兩款牙刷（一款電動牙刷及一款手動牙刷）對清除牙垢及保持牙肉健康之效能。此項研究將歷時二十四周。

服務你的新健社已同意參與這項研究。如你參與，你將會在宿舍內接受一次詳細的口腔檢查，我們會以抽籤形式免費派發一支牙刷。我們的研究員會教導他使用牙刷的方法，希望他每日早晚使用牙刷清潔口腔約兩分鐘，為期二十四五周。我們會於第四，十二，及二十四周後安排他再次接受詳細的口腔檢查，以跟進口腔的情況。本研究期間，我們將會派發一支含氟化物之牙膏以供他使用。這些牙科產品在按照指導使用之下，並不會危及身體健康。

參與這項研究是完全自願及免費的。你可選擇不參與，你亦可選擇隨時退出而不給予理由。在以上兩種情況下，你的權利不會受到任何影響。此項研究收集的資料將會保密及只供研究人員使用。我們尊重參與者之私隱，不會發佈或出版任何揭露你子女身份的資訊。

當您參加這項研究時有任何疑問，可致電此研究之研究員盧展民教授（電話：2859 0292）或黃浩行醫生（電話：2859 0291）。

香港大學牙醫學院
盧展民教授
黃浩行醫生
謹上
2010年2月5日
牙刷效能之臨床研究

參與者同意書

1. 本人已詳閱及明白上述研究之須知，並有充分機會提問。

2. 本人同意參與上述研究。

3. 本人明白參與上述研究純屬自願，可在任何情況下停止參與研究，而不須要承擔任何後果。

參與者 姓名：__________________  參與者 簽名：__________________

日期：_______年____月____日

見證人姓名：__________  簽名：__________________

日期：_______年____月____日

研究人姓名：__________  簽名：__________________

日期：_______年____月____日
Clinical Trial On The Effectiveness Of Different Toothbrushes For Stroke Patients

Date: Baseline / 1 / 3 / 6 months
Centre: Tuen Mun / Sheung Shui / Lee Cheng Uk Estate
Name: _____________________________
Age: __________ Gender: M / F
Examiner: 1 / 2 / 3

Dentition Status and Treatment Need

<table>
<thead>
<tr>
<th>18</th>
<th>17</th>
<th>16</th>
<th>15</th>
<th>14</th>
<th>13</th>
<th>12</th>
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</tbody>
</table>

Plaque index and gingival index

<table>
<thead>
<tr>
<th>18</th>
<th>17</th>
<th>16</th>
<th>15</th>
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<td>Palatal</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

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<tr>
<th>48</th>
<th>47</th>
<th>46</th>
<th>45</th>
<th>44</th>
<th>43</th>
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<th>31</th>
<th>32</th>
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<th>35</th>
<th>36</th>
<th>37</th>
<th>38</th>
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</thead>
<tbody>
<tr>
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<td>Mesial</td>
<td>Distal</td>
<td>Lingual</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Q1 and Q3 : Plaque Index ; Q2 and Q4 : Gingival index

Periodontal Status (CPI)

<table>
<thead>
<tr>
<th>16 / 17</th>
<th>11</th>
<th>26 / 27</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Soft Tissue Status

Abscess

Ulcer

Others
 Specify: ___________
Oral Health Questionnaire

Please tick the following boxes. You may only tick one box per question (unless stated otherwise).
All the results will be kept confidential

Rehabilitation centre: □ Tuen Mun □ Sheung Shui □ Lee Cheung Uk Estate

1) What year were you diagnosed with a stroke?

2) State the effect the stroke has had on your manual dexterity
   □ 1 Significantly
   □ 2 Moderate
   □ 3 Mild
   □ 4 No effect

3) Educational attainment:
   □ 1 No education
   □ 2 Primary education
   □ 3 Secondary education
   □ 4 Tertiary education
   □ 5 Above university education

A) Oral health knowledge
4) What do you think causes decay? (You may choose more than one answer)
   □ 1 Poor oral hygiene/poor tooth brushing technique
   □ 2 Bacteria/plaque
   □ 3 Sweet foods
   □ 4 Irregular dental check ups
   □ 5 'Hot air'/Chinese medicine beliefs
   □ 6 Sour foods
   □ 7 Others, please specify: ____________
   □ 8 Don't know

5) What methods can be used to prevent tooth decay? (You may choose more than one answer)
   □ 1 Proper tooth brushing
   □ 2 Decrease the intake of sweet foods
3 Use of fluoridated toothpaste
4 Regular dental check ups
5 Rinsing after meals
6 Taking Chinese medicine
7 Others, please specify: ____________
8 Don’t know

6) What methods can be used to prevent gum swelling and bleeding (periodontal disease)? (You may choose more than one answer)
1 Proper toothbrushing
2 Use of medicated toothpaste/mouthwash
3 Regular dental check ups/scaling
4 ‘Hot air’/Chinese medicine beliefs
5 Not smoking
6 Eating fruits and nutritional supplements
7 Rinsing after meals
8 Others, please specify: ____________
9 Don’t know

B) Oral health attitude
7) Tooth exfoliation is natural.
1 Agree 2 Disagree 3 No comment

8) Healthy teeth are congenital and not affected by the environment.
1 Agree 2 Disagree 3 No comment

9) Oral health is very important to me.
1 Agree 2 Disagree 3 No comment

10) The health of teeth affects aesthetics.
1 Agree 2 Disagree 3 No comment

11) It is not important to prevent tooth exfoliation.
1 Agree 2 Disagree 3 No comment
12) Oral health will affect your overall health.

☐ 1 Agree ☐ 2 Disagree ☐ 3 No comment

13) False teeth are more convenient than natural teeth

☐ 1 Agree ☐ 2 Disagree ☐ 3 No comment

14) Regular check ups can prevent teeth problems.

☐ 1 Agree ☐ 2 Disagree ☐ 3 No comment

C) Oral health habits

15) How many times do you brush a day?

☐ 1 Less than once a day
☐ 2 Once a day
☐ 3 Twice a day
☐ 4 3 or more times a day

16) Please state the frequency of the use of the following oral health products:

<table>
<thead>
<tr>
<th>Product</th>
<th>less than once a day</th>
<th>1-2 times a day</th>
<th>3 times or more a day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Floss</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Interdental brush</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Mouthrinse</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

17) What problems have you encountered brushing your teeth? (You may choose more than one answer)

☐ 1 It is hard to control the direction of the toothbrush
☐ 2 It is hard to control the amount of strength used to control brushing
☐ 3 Loss of grip of toothbrush, it is hard to grasp the toothbrush tightly
☐ 4 Toothbrush handle is too thin, it is hard to grasp the toothbrush tightly
☐ 5 Others, please specify: ____________

18) When was your last visit to a Dentist?

☐ 1 Less than 6 months ago
☐ 2 6 months – 1 year
☐ 3 1 year – 3 years
☐ 4 More than 3 years
☐ 5 Never
19) How would you rate your tooth brushing?
   □ 1 Good
   □ 2 Average
   □ 3 Bad

20) Do you think your teeth and gums are healthy?
   □ 1 Healthy
   □ 2 Average
   □ 3 Unhealthy

End of questionnaire, Thank you.
口腔健康問卷調查

請在適當空格內填□號。每一條問題只可選擇一個答案 (題目指明除外)。

一切資料絕對保密。

復康中心：□屯門 □上水 □李鄭屋邨

1) 閣下在多久前中風？______年

2) 中風對閣下手部靈活程度的影響

□1大
□2一般
□3小
□4沒有

3) 教育程度：

□1沒有接受過常規教育

□2小學

□3中學

□4大學

□5大學以上

甲) 口腔健康知識

4) 你認為甚麼會引起蛀牙？ (可選擇多於一個)

□1口腔衛生欠佳/欠缺有效刷牙方法

□2細菌/牙垢膜
甜食  □

沒有定期牙齒檢查  □

熱氣/中醫解釋  □

酸的食物  □

其他，請說明：_________  □

不知道  □

5) 你認為甚麼方法可預防蛀牙？(可選擇多於一個)

有效的刷牙方法  □

減少進食甜食  □

使用含氟素的牙膏  □

作定期檢查  □

進食後漱口  □

進食中藥  □

其他，請說明：_________  □

不知道  □

6) 你認為什麼方法可以預防牙肉紅腫流血(牙周病)？(沒有答案提供，可選擇多於一個)

有效的刷牙方法  □
使用含有藥性的牙膏/漱口水
作定期檢查/洗牙
避免進食熱氣食物、喝涼茶或中藥
不吸煙
吃水果和滋潤的食物
進食後漱口
其他，請說明：_________
不知道

乙) 口腔健康態度

7) 牙齒脫落是自然的事情。

同意 □ 不同意 □ 沒有意見

8) 牙齒的健康是先天所定，不受後天影響。

同意 □ 不同意 □ 沒有意見

9) 牙齒的健康對我非常重要。

同意 □ 不同意 □ 沒有意見

10) 牙齒好壞會影響儀容。

同意 □ 不同意 □ 沒有意見

11) 防止牙齒脫落不重要。
12) 牙齒健康問題會影響身體。

13) 假牙比真牙更為方便。

14) 定期檢查可以有效預防牙齒問題。

丙) 口腔健康習慣

15) 你每天刷多少次牙？

16) 閣下使用下列口腔護理產品的次數是：

<table>
<thead>
<tr>
<th>口腔護理產品</th>
<th>少於每天一次</th>
<th>每天一至兩次</th>
<th>每天三次或以上</th>
</tr>
</thead>
<tbody>
<tr>
<td>牙線</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>牙縫刷</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>漱口水</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

17) 你刷牙時遇到甚麼困難？(可選擇多於一項)

1. 很難控制牙刷的方向
2. 很難控制刷牙的力度
3. 牙刷經常掉下，很難抓緊
4. 牙刷手柄太幼，很難抓緊
5. 其他，請說明：

18) 你上一次看牙醫是在何時？
1. 少於6個月
2. 6個月至一年
3. 1年至3年
4. 多於3年
5. 從不

19) 你覺得自己刷牙刷得如何？
1. 好
2. 一般
3. 差

20) 你覺得你的牙齒和牙肉健康嗎？
1. 健康
2. 一般
3. 不健康
Appendix VII
Toothbrush Instructions

Modified Manual Toothbrush Instructions

 ✓ Decreases the effects of ataxic hand movements by making the toothbrush handle larger and heavier

 ✓ Use the assigned toothpaste and toothbrush to brush everyday

 ✓ After each use, use water to clean and air dry the toothbrush handle
電動牙刷使用指引

一) 電動牙刷使用方法:
依照圖示，插入兩顆7.5伏特AA電芯。
若每日使用兩次，每次兩分鐘，電芯將約維持三個月。
使用時，除去保護蓋，用水沾濕刷頭，把適量的牙膏擠上。
將刷頭放在牙齒上，然後開動電動牙刷。
依照圖示，更換刷頭 (a: 新刷頭，b/c: 需要更換)。

二) 電動牙刷刷牙方法:
刷頭在牙齒間移動時，要緩慢平穩。
把刷頭固定於牙齒上數秒，才移至下一顆牙齒。
不需要用力壓得太緊或來回刷，只須停在牙齒上讓刷頭發揮其清潔效能。

三) 電動牙刷的護理
刷牙後，需要在水槽下徹底沖淨刷頭。從刷柄上除下刷頭，在水槽下分別沖洗乾淨及抹乾。

四) 每天使用指定牙膏刷牙。

五) 在使用電動牙刷的開初數天，牙肉可能會輕微出血。一般情況下，數天後出血現象會停止。如果牙肉出血持續兩星期以上，應向牙醫師查詢。
Electric toothbrush Instructions

✓ Instructions of use

- Insert batteries as shown, use two 1.5A type AA
- Batteries will last approximately 3 months when brushing twice a day for two minutes
- Before use, remove protective cap, wet brushhead and apply toothpaste
- Place the brushhead on teeth and switch it on
- Replace brushhead as indicated (a: new, b/c: replace)

✓ How to brush with your electric toothbrush

- Slowly and steadily place the vibrating brushhead on the tooth for a few seconds before moving onto the next tooth
- Do not brush with excessive force or brush back and forth, just place the brushhead on the tooth for its full effectiveness

✓ Electric toothbrush care

- After use, clean the brushhead under running water
- Remove the brushhead from the handle and clean the two under running water and wipe them dry

✓ Use the assigned toothpaste and toothbrush to brush everyday

✓ During the first days of use, gums may bleed slightly. Under normal circumstances, the bleeding should stop in a few days. If the bleeding persists for more than two weeks, please consult your dentist.
Appendix IX
Electric Toothbrush Photo
## Equipments check list

<table>
<thead>
<tr>
<th>Items</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For clinical examinations and treatments</strong></td>
<td></td>
</tr>
<tr>
<td>Portable Dental Chair</td>
<td>3 Chairs</td>
</tr>
<tr>
<td>LED Light</td>
<td>3 pieces</td>
</tr>
<tr>
<td>CPI probe</td>
<td>30 pieces</td>
</tr>
<tr>
<td>Mirror</td>
<td>200 pieces</td>
</tr>
<tr>
<td>Metal Box</td>
<td>1 boxes</td>
</tr>
<tr>
<td>Fluoride varnish</td>
<td>2 tubes</td>
</tr>
<tr>
<td><strong>For disinfection</strong></td>
<td></td>
</tr>
<tr>
<td>Autoclave</td>
<td>1</td>
</tr>
<tr>
<td>Alcohol gel</td>
<td>1 bottle</td>
</tr>
<tr>
<td>Disinfectant</td>
<td>1 bottle</td>
</tr>
<tr>
<td><strong>For OHI</strong></td>
<td></td>
</tr>
<tr>
<td>OHI model</td>
<td>2 set</td>
</tr>
<tr>
<td><strong>Consumables</strong></td>
<td></td>
</tr>
<tr>
<td>Gauze</td>
<td>2 packs</td>
</tr>
<tr>
<td>Gloves (sizes XS, S)</td>
<td>4 boxes</td>
</tr>
<tr>
<td>Face mask</td>
<td>2 box</td>
</tr>
<tr>
<td>Gown</td>
<td>4 packs</td>
</tr>
<tr>
<td>Microbrush</td>
<td>200 pieces</td>
</tr>
<tr>
<td>Kitchen towel</td>
<td>3 rolls</td>
</tr>
<tr>
<td>Rubbish bag</td>
<td>15 pieces</td>
</tr>
<tr>
<td><strong>Stationerlies</strong></td>
<td></td>
</tr>
<tr>
<td>Pencil</td>
<td>10 pieces</td>
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<tr>
<td>Eraser</td>
<td>1 piece</td>
</tr>
<tr>
<td>Writing Board</td>
<td>3 pieces</td>
</tr>
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</table>
Appendix XI
Approval letter from Institutional Review Board of the University of Hong Kong

Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB)

Prof. Edward Lo
Faculty of Dentistry
The University of Hong Kong
22-Feb-10

Dear Prof. Lo,

IRB Reference Number: UW 10-091

The HKU/HA HKW IRB is authorized by a joint agreement of the University of Hong Kong and Hospital Authority Hong Kong West Cluster to review and monitor clinical research. It serves to ensure that research complies with the Declaration of Helsinki and acts in accordance to ICH GCP guidelines, local regulations and Hospital Authority and the University policies.

I write to inform that your research application/submission has been approved by an expedited process with details shown below. You are also requested to adhere to the conditions listed.

Protocol title: A randomized clinical trial on the effect of a powered and a manual toothbrush on the oral hygiene and gingival health of stroke patients

Study site(s): As stated in application form

IRB reviewer: Professor Ronnie Poon, Deputy Chairman of the HKU/HA HKW IRB

Document(s) approved: 01. Clinical research ethics review application form

Document(s) reviewed: 02. Research protocol

03. Information sheet and consent form - English and Chinese

04. Short CV of principal investigator

1. Do not deviate from, or make changes to the study protocol without prior written IRB approval, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues.

2. Report the following to HKU/HA HKW IRB: (i) study protocol or consent document change (use "HKU/HA HKW IRB RE001F#"), (ii) serious adverse event (use "HKU/HA HKW IRB RE001F#"), (iii) study progress (use "HKU/HA HKW IRB RE001F#"), (iv) new information that may be relevant to a subject's willingness to continue participation in the study.

3. Report study progress to HKU/HA HKW IRB at a 12-monthly interval until study closure.

Yours sincerely,

W. H. Lee
HKU/HA HKW IRB Secretary
兩則消息

1. 社員牙齒檢查

香港大學菲臘牙科醫學院派出導師和學生，親自來到新界社替社員們檢查牙齒。九龍西和九龍東分區定於今年3月9日在李鄭屋中心舉行，而我們新界西分區，則早於3月6日，星期六全日舉行。上、下午各檢查20個社員。

這天，新界西隆重其事，正、副區長，各區委分配不同的工作職位，例如負責總指揮、佈置場地、登記、招待與安排先後次序、電話聯絡過來的社員……等，潘國範主席、區長和委員一直在會場直至全部社員檢查完畢，一切有系統，秩序井然，使港大導師和學生感到賓至如歸。各委員為了社務，盡心盡力，我甚為感動。

這次港大的2位導師，9位牙科學生到大興中心CRN的辦事處，來替我們服務；分配了3個同學負責檢查牙齒及3個同學負責記錄，另外3位同學負責問卷調查，都很認真和細心。他們服務的範圍替中風患者檢查口腔和牙齒。如有牙石，則輕微清除牙石；如有燻牙、蛀牙等，吩咐社友一個月後再回來大興中心補牙，與加氟。有部分社員獲派送兩枝牙膏及一枝有柄的牙擦；指定用該牙擦及牙膏，並依時回來檢查，驗証這牙擦及牙膏的效果如何。

陳耀泉（新界西）