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(REVIEW)

The development of a simulator from 1992 to 2016 for inferior alveolar nerve block injection and skill education for delivering local injections of dental anesthetics

Masaru KUDO

The Dental Anesthesiology Science Section Bio-function and Pathology Department Faculty of Dentistry in the Health Sciences University of Hokkaido

Key words : Development, Simulator, Nerve block injection, Local anesthetic injection, Dental

Abstract

Painlessness and comfort are indispensable for clinical practice currently in the surgical stage. Apply anesthesia to the patient and provide painlessness. A procedure is indispensable for the anesthesia method. Skilled local anesthesia injection is especially important in the field of Dental Anesthesiology, and must be mastered by students during their study of dentistry.

Consequently, the author has designed and developed a local anesthesia injection model for dental training, in

Introduction

In this review, I will explain the actual state of dental education regarding the teaching of local anesthesia techniques and procedures, the development of appropriate educational materials, and the effectiveness of using these educational materials. In particular, I will explain the history of the development of simulators for teaching dental anesthesia injection, the effectiveness of using simulators to teach these procedures, and the latest local dental anesthesia injection simulator, the 2016 model.

One feature of this dental department is that we use the Pre-Clinical-Training (PCT) system, using training models to teach dental procedures. We were not able to use the local dental anesthesia model when we started using the PCT system in 1983, because of delays in its development. In order to overcome this delay, the authors forged ahead, using their creativity and ingenuity, and the dental anesthesia model continued to evolve.

As a cumulation of all their work, our university was able

order to improve the safety and effectiveness of hands– on training, and to expand the range of practical training of local anesthetic delivery using this model.

The author will explain the history of 25 years for dental anesthesia injection simulator. In other words, patent acquisition, patent development, its educational effectiveness, local anesthetic injection simulator prototyped in 2016 type, and prospects for the future development of this injection simulator, explain it in detail.

to post photographs in the dental school pamphlet issued by this year's University Admissions Public Relations Division (H. S. U. H., 2017) showing a local dental anesthesia injection model using our patented techniques.

The authors are convinced that cooperating experts and companies will be able to go on to develop innovative and comprehensive dental simulators.

1. The use of local anesthetics makes patient treatment painless.

Anesthesiology is used in clinical medicine to provide analgesia and freedom from worry to patients who are receiving medical services.

In the Dental Anesthesiology Science Section, I am in charge of the methods of teaching anesthesia to fourth-year students in systematic lectures given by the clinical education departments, as well as the clinical training and design and administration of the test for graduation. During dental education, the student has to master the technique of injecting local anesthesia. Skilled local anesthesia injection is es-

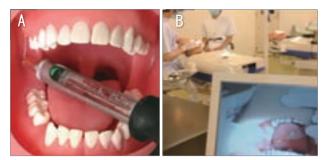


Fig. 1: Dental local anesthetic injection simulator, 2016 prototype; Pre–Clinical–Training (PCT) system used in training 2013 A : Simulator for dental anesthesia injection practice, 2016 prototype.

Administration of inferior alveolar nerve block (mandibular foremen conduction anesthesia injection)

B : Practicing administering an inferior alveolar nerve block in 2013

The setting of the practical exam : at the far left is a student taking an exam. The lower right monitor image shows the view through an installed camera.

pecially important in the field of Dental Anesthesiology, and must be mastered by students during their study of dentistry.

Currently, in this University's School of Dentistry, we use mutual training, that is, students practice by injecting each other, to develop students' injection skill (Taniguchi et al.,2015). Mutual practical training is the particularly mainstream method for teaching mandibular foremen conduction anesthesia injection (Kudo & Ohke, 2011). It is important to prevent procedural accidents during this mutual training, and make sure our clinical skills-education practices are safe. The author has designed and developed a local anesthesia injection model for dental training, in order to improve the safety and effectiveness of hands-on training, and to expand the range of practical training of local anesthetic delivery using this model (Fig. 1A, B). As a result, we have been able to improve our success rate when using mutual training concerning the application of mandibular foremen conduction anesthesia injection (inferior alveolar nerve block) (Kudo et al., 2002) (Kudo & Ohke, 2012).

2. What are the advantages of local anesthesia?

Patients have the general impression that dental treatment is necessarily painful. Patients are particularly afraid of the dentin's being drilled without anesthesia (Mamiya et al., 1996).

Currently, surgical dentistry is considered a medical procedure. When drilling dentin or performing pulpectomy of vital teeth, the dentist must provide anesthesia and painlessness to the patient.

Local anesthesia is the most frequently used anesthetic process in dental clinics. Local anesthetic injection is an intrusive, potentially dangerous medical procedure. Safety checks are required to make sure there is no air in the syringe, that the needle does not puncture the flesh, that the needle is inserted into the target site, to check for correct suction, insertion of the agent, and removal of the needle (Kudo, 2017). Most local anesthesia is applied through submucosal injection, a form of infiltration anesthesia. In other words, the dentist must make a local injection to provide analgesia.

Insufficient skill at giving injections on the part of the clinician who administers a local anesthetic injection may result in incidental disease or complications that are the result of patient anxiety, pain, a strong physical and/or psychological reaction or addiction to the injected agent.

One advantage of local anesthesia, as compared with general anesthesia, is that the patient can cooperate with the clinician during procedures. This also means that the patient's complaints can be expressed, heard and understood. The dentist can ask the patient to cooperate, for example by saying, "Please open your mouth" and "Please bite down." The patient can remain able to respond to questions like, "Is the feeling when you bite down good, or is there a problem?" or "Please tell me if you feel any discomfort."

3. Features and side effects of local anesthesia injections

Lidocaine hydrochloride (HCI) is a typical local anesthetic.

Some of Lidocaine's features are : it is a sodium ion channel agonist, has a membrane stabilizing action on the heart and serves as a muscle relaxant. Clinically, a 0.5 to 60% concentration of this agent is used. When it is used as an anti–arrhythmic injection or for local dental anesthesia, it is diluted to a 2% concentration. Injectable drugs for dental medicine are supplied in cartridges, and include a vasoconstrictor. Usually, the vasoconstrictor formulated for Japanese local dental anesthetic injection is adrenaline diluted 80 thousand times.

The local anesthetic first numbs the sensitivity to pain of the autonomic nervous system, then the sensory nerves, and then the motor neurons, in that order. Therefore, its anesthetic effect separates the sense of pain from the conductivity of the motor neurons. On the other hand, the maintenance concentration of this volatile general anesthetic simultaneously affects autonomic nerve transmission, pain sensation transmitted through the sensory nerves and the motor nerves.

When discussing local anesthesia injections, we must consider negative side effects. That is, we must be aware of local anesthetics' potential to cause acute poisoning. Local anesthetics affect the central nervous system and the heart, and may cause symptoms of acute poisoning. Patients can experience dizziness, wobbliness, trembling, and/or sleepiness. Acute poisoning symptoms include entering a hypnagogic state, suffering a generalized seizure and cardiac arrest.

4. The need for safe practices was confirmed to me after I underwent mutual injection training

In 1985 (Showa 60) and 1986 (Showa 61), the author participated in the mutual practice of local anesthesia injection during clinical practice of dental anesthesia in our School of Dentistry. I went through two cycles (two practice rounds of one week each) of mutual training as a method of practicing giving local anesthetic injections.

We were practicing on the 6th floor of the Dentistry University Hospital, in four outpatient units used for dental anesthesia. 30 students participated, under the direction of two instructors.

During the first cycle, I practiced submucosal injection for treating the mandibular anterior teeth and periodontal ligament injection of an infiltration anesthetic. During the second cycle, I practiced nerve block anesthetic injection : injection at the infraorbital foramen and mandibular foramen.

For students, mutual training to learn local anesthesia injection was a severely traumatic experience, with symptoms including tears, pain, trembling of the hands and fingers, pale faces, fainting, and numbness.

The author was startled to see classmates' hands trembling as they held their syringes and see them faint after getting up out of the treatment chair.

In addition, during mutual training I, myself, become a patient, and another student punctured my oral mucosa and inserted the needle under the instructor's direction. Soon after this procedure, when the needle tip touched my nerve sheath, I felt a strong and spreading sensation, like an electric shock. I will never forget this experience.

In my turn, I became an instructor in 1991 (Heisei 3). In this role, I saw sudden changes in one student who was receiving an injection ; he hyperventilated and showed a vasovagal reflex. I saw sudden changes in an injecting student, who hyperventilated and panicked. Another student refused to participate in the mutual training.

The author saw the difficulties and hazards of conducting mutual training on the use of injections for local anesthesia when instructing 30 students being taught by a few instructors. Medical education uses a model when training for chest compression and artificial respiration, tracheal intubation, and intravenous injection. I thought that some form of simulation should be used to train dental local anesthetic injection in a safe practical educational environment. That is, the idea came to me that a local anesthesia injection training model was needed. I became convinced of the need to develop a model for local dental anesthesia injection training.

5. The dangers of using mutual training to teach inferior alveolar nerve block injection

In 1992 (Heisei 4), the author was asked to consult with a sixth year dental student. The focus of the consultation was a procedural accident in the clinical practice of oral surgery. She experienced a painful sensation like an electric shock during mutual training on giving an inferior alveolar nerve block injection (using the indirect method, ternary system). After a year had passed, she still had numbness of the bottom lip and slower motion on the injected side. She asked me, "How can I overcome this? My mother says I should sue the university, but I want to graduate without making any trouble." The author could not do anything for the young woman except explain possible treatments and their medical effects and consequences. Later, this student graduate and became a dental clinical training doctor.

What is the data on accidents and their sequelae during mutual training on the use of local anesthetic injections? The results of a survey of procedural accidents during 2,573 mutual training sessions on inferior alveolar nerve block injection in 1990 (Heisei 2) and 1991 (Heisei 3) turned up 10.4% instances of trismus, 2.8% instances pain experienced at the point of injection, 4.4% cases if blood aspirated into the syringe, 2 cases of tongue nerve paralysis, and one case of alveolar nerve paralysis (Saito et al., 1992).

Certainly, mutual training involves procedural accidents



Fig. 2: Poster displaying the models available when the PCT system was introduced (1984); enlarged photograph of oral surgical model. A : Photo of the PCT system poster in a library corridor at our university

B : Enlargements of the oral surgical models photos. The poster does not show any conduction anesthesia injection models or infiltration anesthetic injection simulators with inflatable silicone membranes.

and complications. Mutual training of conduction anesthesia injection through the mandibular foremen is especially dangerous.

6. The current state of training in the administration of local dental anesthesia injections

In 2010 (Heisei 22), the author conducted a questionnaire survey concerning local anesthesia injection education as used in dentistry programs in Japan. It was found that six schools used mutual training exclusively, eight schools used model training exclusively, and twelve schools used both forms of training for infiltration anesthesia injections (Ohke et al., 2011).

On the other hand, seventeen schools used mutual training exclusively to teach conduction anesthesia injection, four schools used model training exclusively, and 6 schools used both types (Kudo & Ohke, 2011).

We can see that the application of models is more advanced for the training of infiltration anesthesia injection. On the other hand, the aforementioned study revealed that teaching inferior alveolar nerve block injection is chiefly conducted using mutual training.

7. Why is inferior alveolar nerve block injection needed?

Do we really need conduction anesthesia injection in gen-

eral dentistry? Indeed, it is not needed very often, except for oral cavity surgery and implant surgery. On the other hand, the author sometimes finds that nerve block anesthesia injection is needed through the mandibular foramen after pulp extraction of the gutter–shaped root of lower jaw molars. In addition, conduction anesthesia injection is effective for preventing pain in areas not near the surgical site, such as reported "pain in the lips". And then again, inferior alveolar nerve block injection is needed for other treatments beside oral surgery. Therefore, it is necessary for the dental student to master the skill of using inferior alveolar nerve block injection. This, then, leads me to the belief that there is a need for inferior alveolar nerve block injection models.

8. The Pre-Clinical Training system used at our university and the development of an inferior alveolar nerve block injection training model

In 1992 (Heisei 4), Prof. Koichi Matsuda, at that time the Dean of the Professors of Dentistry (and also the Professor providing the second Lecture on Dental Preservation) introduced the PCT (Pre-Clinical Training) system in order to resolve the gap between the systematic lectures and basic practice. Therefore, we developed proprietary models to teach courses on tooth repair and preservation, endodontic treatment, total dental plate prosthetics, crown and bridge



Fig. 3 : The first version of a conduction anesthesia injection dental anesthesia model

A: Lost wax modeling of the buccal mucosa and mucosa of the pharynx on the resin jawbone of the oral surgical model

B : Front views of the first version of the anesthesia injection simulator

C : Semi-embedded tubular electrode, first version

Outer tube electrode (7 mm wide, 15 mm long) with a conical core. The upper electrode is for teaching the Gow-Gate method. The lower electrode is for mandibular foremen conduction anesthesia injection practice.

D: Mandibular silicone mucosa with gingiva and mucosa as one unit (Replacement part)

prosthodontics, orthodontics, and oral surgery (Fig. 2 A).

In 1991, we started developing a model for local anesthesia injection education under Professor Shinya Noboru, who taught the university dental anesthesiology course. However, the PCT system was introduced in 1992, so the development of the dental anesthesia model was not timely.

The infiltration anesthesia method was listed in the list of applications of the oral surgery model. However, the available models only allowed injection under the silicone mucous membrane, no inflation of the mucous membrane was seen, and the models did not have a section for teaching conduction anesthesia injections, such as the mandibular foremen nerve block type (Fig. 2 B).

The author received a request from Dean Matsuda : "Please make sure you develop a dental anesthetic model and then you and we together can attempt to use it during clinical practice under the PCT system." Professor Shinya also instructed me to develop a training model for teaching local anesthesia injection.

I thought it would be very difficult to develop an infiltration anesthetic training model that would show inflation of the mucous membrane when anesthetic was injected under the silicone mucous membrane. Therefore, we decided to first develop a conduction anesthesia injection model for the dental and oral surgery field. We managed to install electrodes in the appropriate areas for needle penetration and conduction anesthetic insertion.

Repeated discussions were held between the dental anesthesia course staff, the development department staff of Nisshin dental products, and the author.

1) 1992 (Heisei 4) prototype for a needle puncture and insertion model for dental anesthetic conduction anesthesia injection training

(1) The basic design of the 1992 version

We used an oral surgery tooth extraction model that had 32 teeth installed in tooth sockets represented with soft wax. However, the oral surgery tooth extraction model only had gingiva and alveolar mucosa. It did not have gingiva tissue in the puncture area to constrain the injected anesthetic.

Therefore, the author used the lost wax method to reproduce the cheek transition region and pharynx. The model's upper jaw includes the inside of the mandibular ramus, the pterygomandibular raphe, and the uvula. The lower jaw includes the oral cavity base on the inside of mandibular ramus and the pharyngeal mucosal membrane (Fig. 3 A). This work was the first step toward the development of a dental local anesthetic injection simulator. That development work is still ongoing.

We used silicone to install representations of the gingiva and mucous membranes of the oropharynx on the oral surgery tooth extraction model (Fig. 3 B, D).

The prototype produced by Nisshin (Kyoto). The resin and silicone materials used in this model were not disclosed. (2) Electrode design for the 1992 specifications

When the student inserted a needle tip that touched the appropriate site, a buzzer and a lamp indicated success. We installed a 15mm long cylindrical single-channel electrode with an outer diameter of 7mm.

First version of the anesthesia injection model with injection detection. Photo and plan view drawing showing the conical electrode core.

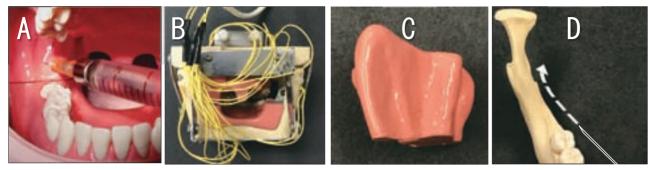


Fig. 4: 1993 model: inferior alveolar nerve block type with exchangeable gingival block

A : Photo of the mandibular foremen version with separate gingiva

- B: Wiring connected to electrodes arranged at the appropriate location for each type of conduction anesthesia (rear of model)
- C : Gingival block for the right side (replacement part)
- D: When the needle is inserted into the silicone, the needle bends to the other side of its knife face.

When a needle contacts both the outer tube and the inner core, the electrodes become conductive. The author proposed the electrode design and Nisshin Dental Products developed and produced the prototype.

(3) Part of the 1992 version with the electrode installed

In the maxillary (upper jaw), the electrodes were installed in the alveolar, the infraorbital, the large palate, and the incisor foramen. Single channel electrodes were installed in the lower jaw, mental foramen, and parts included in the Gow– Gate system. In addition, conical electrode cores were installed at 5° to 15° angles, with the openings of the electrodes protruding halfway out (Fig. 3 C).

(4) The benefits of the 1992 version

This version has the virtue that it is possible to judge the needle insertion direction and the depth it reaches. When the "ping–pong" sound is heard, the students says, "Oh, I did it" and smiles. This shows that using this injection–training model will be experienced as pleasant.

Furthermore, the metal electrodes are not damaged by the needle insertions. The electrodes can be in permanent use unless they are left in contact with some corrosive chemical solution.

(5) Disadvantages of the 1992 version

This model has the structural defect that needle insertion into an inappropriate site cannot be detected.

The oral mucosa and gingiva were made of one piece of silicon that was fastened to the oral surgery model using silicone adhesive. As a result, those mucosal parts of the model could not be replaced. In addition, if someone touched any of the 32 teeth while performing an injection the teeth would fall out.

Silicone is hard, and the student could not change the

needle insertion direction. And after a few needle insertions, the silicon mucous membrane models would get broken and the tube electrodes would be exposed. This mucous membrane was well adhered to the basic model, and could not be replaced.

Note that the direction of needle insertion can be detected by the tube electrodes. However, the electrodes were not so good at evaluating the depth of the needle penetration.

2) The 1993 model

We stopped gluing the mucous membrane silicon on the resin bone so that the silicone membrane could be replaced. However, the jaw silicone mucosa sometimes ruptured after it started to wear. Now, all of the jaw mucosa could be replaced (Fig. 3 D). However, the price of each mucosal, maxillary and mandibular model was 37,000 yen.

3) The 1994 model

In 1994 (Heisei 6), we started using the dental anesthetic conduction injection model in the PCT system for the clinical practice of dental anesthesiology.

(1) Points of improvement

In order to decrease the cost, we left the silicone material in the needle insertion section as it was, except we divided it into blocks. This made it easier to replace the silicone mucosa (Fig. 4 A, B, C : Mandibular foremen version of the anesthesia injection model with separate gingiva).

(2) The benefits of the 1994 model

We made the needle insertion parts of the gingiva separate so they could be replaced, which reduced the cost. The price of one mucosal block was 6000 yen. A block breaks or a needle comes through to the other side after about 20

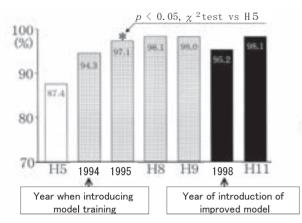


Fig. 5 : Success rate of practice using a simulator to learn inferior alveolar nerve block

Use of the simulator increases the success rate of administering lower alveolar never blocks

injections. One block was provided for each 10 students.

(3) The disadvantages of the 1994 model

The separate silicone mucosa blocks floated and came off when the syringe was operated. To improve this situation, we thought that the silicone should be made in the form of an up-side-down triangle. However, Nisshin Dental Products reported that they could not make such a shape out of silicone.

Another problem was that the silicone gingiva could not be adhered to the basic model using instant adhesive. We tried a silicone caulking compound but we did not get successful adhesion with that. Therefore, the author controlled the floating and removal of the gingiva from the back of the model by using tweezers. All of these problems took a lot of time and were disadvantageous to the implementation of training.

Another problem was that when a needle was inserted into the semi-stiff silicone, the needle was bent to the side

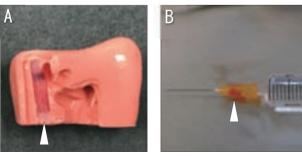


Fig. 6 : Installation of a silicone blood vessel on the removable gingiva model ; suction of liquid

A : Simulated blood vessel containing red liquid set in the gum block

B : When a simulated blood vessel is punctured by a needle, red liquid is sucked into the base of the injection needle.

(Fig. 4 D).

(4) Verification of the effectiveness of skills training using the procedures developed for the mandibular foremen conduction anesthesia injection model

In order to verify the educational effectiveness of using this model, I compared its success rate with the 87.4% success achieved in 1993, before using the model. We saw a meaningful increase in the success rate : 1994 was the first year we used the model and our success rate was 94.3%. In the 2nd year it was 97.1%. (Fig. 5). As well as the data discussed above, we also reported an increase in the success rate of mutual training after we began using the model (Kudo et al., 2002).

4) The 1998 model

The author designed simulated blood vessels that could be installed in the mucosal block. The purpose of this design was to simulate insertion of the needle into a blood vessel due to unskilled action.

The blood vessel was located behind the conical core electrodes. I installed a silicone tube filled with red liquid. I designed it in such a way that red liquid flowed out if the needle was inserted to a depth of 20mm (Fig. 6 A).

In the responses to the questionnaire we used to check our results in 2011 (Kudo & Ohke, 2012), we received the response : "I was surprised when blood came out." This design allows the students to experience a simulation of reverse flow and suction of blood into the syringe due to incorrect insertion of the needle tip (Fig. 6 B).

The experience of simulated blood flow made a strong impression on the students. I believed this would contribute to improved safety awareness on the part of medical personnel.

5) Development frozen from 1999 until 2010

There was no budget for improving this model and so development was frozen during this period. The Objective Structured Clinical Examination (OSCE) includes "infiltration anesthesia injection", so the development of a better means of teaching this technique became a priority for us. Therefore, during this period, each year we purchased some silicone we could use for needle insertion practice parts, and the students practiced on these.

Then, infiltration anesthesia was included as part of the OSCEs given at our University on January 21, 2006 and

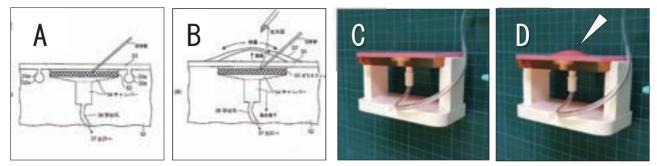


Fig. 7: Drawings of the infiltration anesthesia model from the patent application, Patent Number 5187678 : Dental Injection Simulator The application for a patent for the infiltration anesthesia model was granted under the name : Dental Injection Simulator (Pat. No. 5187678)

A, B : The Dental Injection Simulator plan view. Silicone membrane inflates upon correct injection

- A glass filter was built into the resin block, and a drain pipe was installed.
- C : First prototype of the Dental Infiltration Anesthetic Injection Simulator
- D: When liquid or air is injected between the silicone film and the glass filter, the silicon film bulges.

February 15, 2012.

6) Patented dental injection simulator

We applied for a patent under the name of the "Dental Injection Simulator" on October 9, 2007. We obtained patent No. 5187678 on February 1, 2013 (H.S.U.H. 2013). Figure 7 shows this patent's design (Fig. 7 A, B).

The patented model allows the student to administer an agent simulating a mandibular foremen conduction anesthesia injection. To do this, we provided a gap between the silicone "mucosa" and the resin "bone," and a glass filter was installed in the position representing the bone face, which could be reached by a needle. A drain tube and chamber were installed there (Fig. 7 C, D).

The author used an electronic pressurized injection device to ascertain that the insertion pressure was 300 – 500mmHg when 0.5 cc of local anesthesia agent was applied for 30 seconds to the alveolar mucosa (Kudo, 2005). Therefore, we succeeded in getting the silicone mucosa to inflate in a manner that approximated the in vivo state. We injected 0.5cc of the simulated anesthetic for 30 seconds, and the mucosa inflated. We arranged a seal that prevented the agent from leaking after 1.0cc of the agent injected. We found that the pressure of a 1.0cc injection was about 1000 mmHg.

7) The 2011 specification model

(1) An outline of the 2011 specification design

In 2011, we developed the following models and systems : A needle insertion model ; a model that used electrodes to detect a needle puncture, insertion and liquid injection and announced the detection using a sound and a light ; a model that can receive injected agent from an inserted needle ; and a complex injection trainer to detect the insertion of a needle and injection of the agent (Fig.8 A, B). Incidentally, the composition of the metal used was not dis-

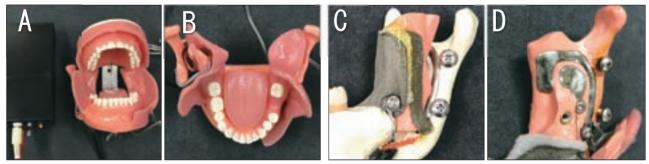


Fig. $8:2011 \mod : a \text{ conductive fabric electrode is directly under the silicone film}; a cast metal electrode is placed on the resin bone A: Front view: buzzer and lighting device on the left side$

B : At the top of the picture : the electrode for needle puncture training is on the left and the silicone chamber (imitating the pterygomandibular space) for liquid injection training is on the right

C: Conductive fabric electrodes are employed so that the training model can detect two levels of needle insertion.

D: The center electrode is located where the needle tip should be placed ; the electrodes surrounding the target define the error area

closed.

(2) Anatomical form with a textile electrode substrate and a metal electrode used in the 2011 specifications

We arranged electrodes on the right side of the model to detect needle insertion, needle insertion direction, and needle insertion depth. More specifically, we placed a textile electrode substrate underneath the silicone mucosa in the area where the needle was to be inserted, and an electrode with an 8mm diameter hole in it to detect the needle insertion point inside this electrode substrate. We also placed a thin plastic film between these two textile electrodes to insulate them from each other. Cast metal electrodes were arranged around the correct needle insertion position to create a two– channel electrode (Fig. 8 C).

Textile substrate electrodes were placed at the point just below the silicone membrane, at the needle insertion point.

We used cast metal electrodes where the needle would penetrate, in order to avoid having the needle tip get caught in the gap between the electrode edges and the resin bone surface.

Of course, the electrodes were given the morphology of the mandibular lingula. The metal used was a soft alloy.

The model was designed so that if a needle is inserted through the substrate electrode at the front of the mandibular lingula, it emits a "peep peep" sound. If it reaches the upper position of the mandibular foremen, it emits a "ping pong" sound. It evaluates the proper penetration of needle (Fig. 8 D).

The model emits a buzzing sound if the needle is inserted in an inappropriate position. Therefore, it was designed to sound a buzzer if it went 10 mm behind mandibular foremen.

A functional test was made on the this model 12 hours after its production. For this test, we inserted 0.5cc of air using a syringe at the end of the liquid drain tube. The mucosa bulged about half of the volume of the tip of the little finger, and there was no leakage even when we injected as much as 1.00cc. The composition of the silicone used by Nissin was not disclosed.

For a report on the invention and effectiveness for education of this infiltration anesthesia injection model, please see : "The development and practical application of a local anesthesia simulator capable of receiving liquid agent injections", printed in the University's Dentistry Magazine in 2008 (Kudo, 2008).

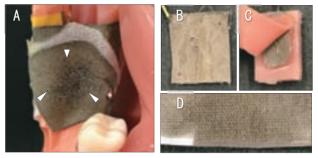


Fig. 9: Disadvantages of the 2011 model and ways of overcoming them

A : The conductive fabric electrode suffered from breaks and short circuits.

B : Two conductive fabric electrodes are bonded together

C : Silicone film is glued to both sides of each electrode

D: Conductive fabric electrode coated with silicone

(3) The benefits of the 2011 model

The right side of the model enables us to check the appropriateness of the needle insertion position. In addition, the needle insertion direction can be modified. This model did not break down, no matter how many times the needle was inserted and pulled out. In this model with its thin silicone layer, we were able to mitigate the problem of the bending of the blade face of the needle when performing needle penetration.

This model permits evaluation of the needle insertion point. Consequently, students can have simulated experiences of inserting in positions where the needle must not be inserted, such as 10 mm behind the mandibular foremen and in the direction down toward and below the lateral pterygoid muscle.

(4) The disadvantages of the 2011 model

There was a short circuit between the substrate electrodes and the textile electrodes that are used to evaluate the appropriateness of the needle insertion position. The cause of this short was a break and scuffing of the textile electrodes. We also found a puncture in the plastic film that was used for insulation. Ten or more injections caused a short or a broken circuit (Fig. 9 A). There were two countermeasures that we attempted : two–layered cloth electrodes (Fig. 9 B), a cloth electrode clamped between two soft silicone pads that were 0.5mm thick (Fig. 9 C), silicone applied to the cloth electrode to form a coating film (Fig. 9 D). We found that the cloth electrode silicone coating had excellent results.

We found a needle trapped on the edge of the cast metal electrode. We saw that we had to redesign the shape of the needle tip so it would not get trapped. In addition, we recog-

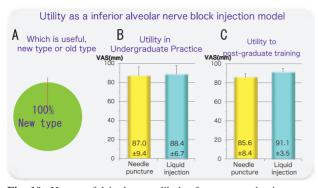


Fig. 10 : How useful is the mandibular foremen conduction anesthesia injection model? Results of a questionnaire survey of instructors.

- A : Which is more useful, the new type or the old type?
- B: Usefulness for student practice
- C: Usefulness for training residents

nized the need to teach students an injection method that keeps the blade face of the needle from striking bone and becoming dull.

The injection model leaked liquid between the drain tube and the silicone membrane. The cause was inadequate bonding between the silicone and the vinyl.

(5) The assessment of the 2011 specification model by our instructors

We conducted a questionnaire survey of some younger dentists (5 years or less after they had obtained their national dental licenses) and reported the results (Kudo et al., 2011).

The survey results are shown in Figure 10 (Fig. 10 A : Results of questionnaire survey of instructors).

a. Comparison with the old model (1998 model) and an evaluation

The answer to the question : was the new model more ef-

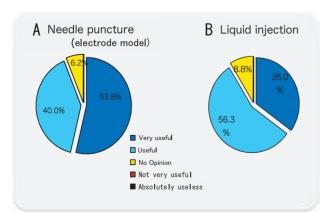


Fig. 11 : The usefulness of practicing on the model before mutual training ; a questionnaire survey of clinical students A : Usefulness of the needle puncture model B : Usefulness of the liquid injection model

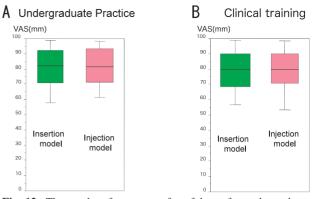


Fig. 12: The results of a survey of usefulness for undergraduate and graduate clinical training; evaluation of usefulness using the VAS 100 (Visual Analogue Scale)

A : Usefulness of needle puncture model : Very useful ; $53.8\%\,,$ Useful ; 40.0%

B : The liquid injection model : Very useful ; 35.0% , Useful ; 56.3%

fective than the old model was yes, given by 100% of the respondents (Fig. 10 A).

The respondents particularly highlighted the effectiveness of the needle puncture and insertion practice. We noted that there was a request to change the conduction anesthesia injection model so that it could inject a liquid agent.

b. The students' positive assessment of the usefulness of practicing mandibular foremen conduction anesthesia injection using the models

The needle puncture practice : 87.0 \pm 9.4%, Liquid injection practice : 88.4 \pm 6.7% (Fig. 10 B).

c. The graduates' positive assessment of the models' usefulness after leaving school

The result was needle puncture practice : $85.6 \pm 8.4\%$, Liquid injection practice : $91.1 \pm 3.5\%$ (Fig. 10 C).

(6) A questionnaire survey of clinical students about the 2011 specification model

In 2011, we conducted a questionnaire survey of 87 students. We were able to gather answers to the questionnaire from 80 students (a collection rate of 92%).

Figure 11 shows the questionnaire survey result from the students about the 2011 model.

a. The usefulness of practicing on the model before mutual training

The result was shown in Figure 11. The needle puncture model : Very Useful : 53.8%, Useful : 40.0% (Fig. 11 A).

The liquid injection model : Very Useful : 35.0%, Useful : 56.3% (Fig. 11 B).

b. Evaluation of usefulness on the basis of the VAS (Visual Analogue Scale) 100 score

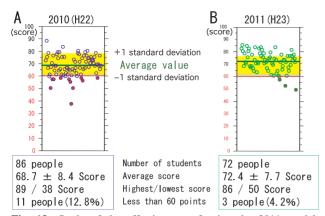


Fig. 13: Study of the effectiveness of using the 2011 model, based on students' performance on the injection procedure test A : In 2010, the average was 68.7 points. 12.8% of students got fewer than 60 points.

 $B: In \ 2011,$ the average was 72.4 points. 4.2% of students got fewer than 60 points.

Usefulness of training puncture insertion of 50 Percentile; 82.0 (10P; 58.0, 90P; 99.0), Liquid injection of 50 Percentile; 81.5 (10P; 61.0, 90P; 95.5) (Fig. 12 A).

The result of a question about usefulness during undergraduate training : Puncture insertion : 50 Percentile ; 79.5 (10P ; 53.5, 90P ; 99.0). Liquid injection ; 50 Percentile ; 81.5 (10P ; 61.0, 90P ; 95.5) (Fig. 12 B).

c. The effectiveness of the introduction of the 2011 model was examined by checking the students' scores on the procedures test. The findings were : in 2010, the average was

 68.7 ± 8.4 points, (Fig. 13 A) and 12.8% received less than 60 points. On the other hand, in 2011, the average was 72.4 \pm 7.7, and 4.2% received fewer than 60 points (Fig. 13 B). These findings were in the desired direction, but not by a particularly large degree. The number of students who scored lower than 60 decreased by 7 people, i.e., from 11 to 3 students. I think that this is a great achievement in support of injection training using a simulator.

The above results demonstrated the great utility of the 2011 type before practical training, after mutual practice, and after participatory practice.

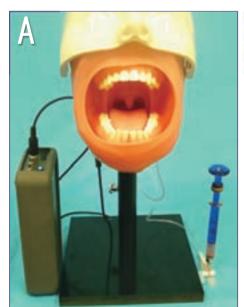
8) The 2012 specification model

With the goal of shortening the preparation needed before and after setting up for instruction, we pursued making it more convenient to prepare and replace the mucous membranes and blocks (Fig. 14 A, Fig. 15). The basic design divided the lower jaw at the median into left and right sides. The left and right lower jaw models were fixed to the frame of the upper jaw model with screws (Fig. 15 B).

(1) Right side : Improved needle puncture and insertion model

A thicker sponge sheet was placed between the cloth electrode on the base and the inside cloth electrode in order to prevent electric shorts and broken circuits (Fig. 15 A).

(2) Left side of the model ; Liquid injection portion ; mandi-





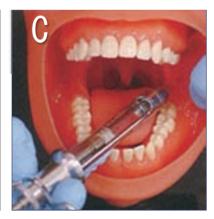


Fig. 14 : The 2012 specification model The jaw contains two different modules and the gingiva are covered by a silicone membrane A : Overall image from the front, with buzzer

B : The right module has a needle puncture and penetration sensing electrode

C: The left module is for practicing liquid injection into a simulated pterygomandibular space

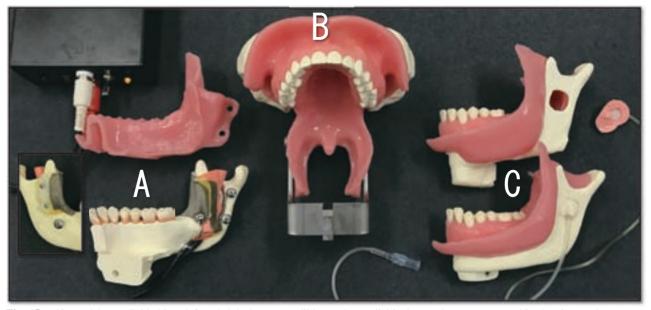


Fig. 15 : This model was divided into left and right lower mandibles at the medial incisors. They are separated in the picture above. A : Both needle puncture and needle insertion electrodes are included.

B: The maxilla and frame base of this model

C: Liquid injection module, with drainage tube outside the mandibular branch of the facial nerve

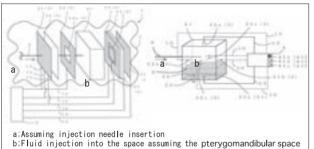


Fig. 16 : Three-dimensional view of patented technology introduced in the 2012 model (Injection Simulator, Japanese Patent No. 5380579)

bular foremen anesthesia injection

A liquid injection model and an infiltration anesthetic injection model (mandible dens molar, cheek, and buccal submucosa) are provided.

This liquid injection type model can receive a needle tip inserted into the appropriate position and can receive an injection of the appropriate amount of liquid agent (Fig. 14 C, Fig. 15 C).

We employed the design of the patent for the Infiltration anesthetic injection (patent No. 5187678, Invention name : Dental Injection Simulator, February, 2013) to design this model, as well (Fig. 7) (H.S.U.H. 2013).

In addition to the glass filters in the lower mandible dens molar buccal side, we also installed filters in the pterygomandibular space and the upper rear side of the mandibular lingula, where a tube could be led to the gap (Fig. 15 C).

9) We invented an injection simulator in 2012, and applied for a patent

We invented an injection simulator that could sense a needle puncture, needle insertion, and liquid injection in the appropriate positions, and applied for a patent.

Shown in Figure 16 are some of the three-dimensional view drawings for the patent application (Fig. 16).

This patent was registered on October 4, 2013. The patent was obtained after the very short period of 16 months after application. This short approval time was one of the effects of a policy to link intellectual property development to improving the economy, initiated by the cabinet of Prime Minister Abe.

10) Improved 2013 model

We established the goal of creating a local anesthesia injection trainer that was attractive in appearance and could sustain at least 30 injections. Therefore we designed a model that could sustain 100 punctures with nerve block delivery needles (Fig. 17 C) (H.S.U.H. 2013).

(1) Mandibular model with only one side for needle insertion and/or puncture

We produced this model using part of the design under patent No. 5380579. A 3-channel electrode is used for elec-

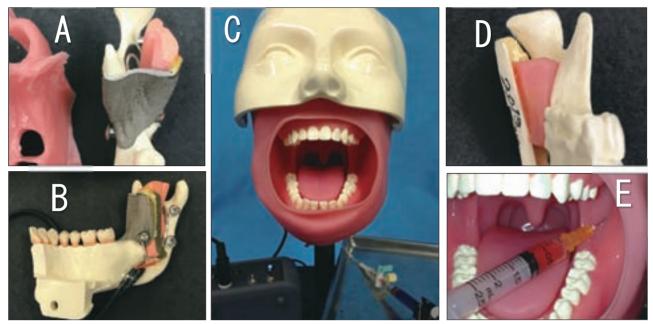


Fig. 17: The 2013 specification model was an attempt to improve the durability of the needle puncture and liquid injection model. A, B: Needle puncture and insertion module (3 electrode channels are used). The edges of the electrode have been smoothed where the needle touches it.

- C : Front view of the 2013 specification model
- D: Improved injection model: the back and inside of the gap are covered with resin in order to prevent needle penetration
- E : Red liquid aspirated into syringe (simulates the experience of inserting a needle in a blood vessel)

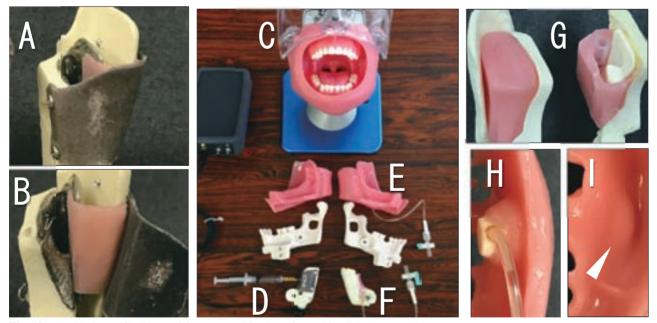


Fig. 18: The 2014 specification model was a modification of one side of the jaw model.

Electrodes, internal space design, convenience, durability and economic efficiency were all improved.

- A : Needle puncture module. A silicone-coated conductive fabric electrode was used
- B : The silicone–coated electrode was removed ; a new type of cast electrode was used.
- C: Overall view : The model attached to a desk stand
- D : Electrode module parts for needle puncture and insertion
- E: Silicone gums with the infiltrated anesthetic injection model under the molar buccal mucosa
- F: Liquid injection module

G: Cross-section of the injection module, forming the lower side of the tongue in the silicone gap, with a built-in glass filter, and a simulated blood vessel

H : Infiltrated anesthetic injection model : Glass filter and drainage pipe placed on the inner surface of the silicone gingiva, under the molar buccal mucosa

I : Inflated anesthesia injection model, with a bulging silicone membrane

tronic sensing. In this application, appropriate needle punctures and insertions are signaled by a "peep peep" sound. An appropriate amount of liquid injection is signaled by a "ping pong" sound. In addition, if a needle is inserted into the back of the pterygomandibular space, it triggers a buzzer.

To accomplish this, we needed to expand the range of the electrodes (17 A, B). The metal electrode position was adjusted, and the range was expanded.

(2) Mandibular model with only one side for liquid injection

It is possible to inject infiltration anesthetic into the mucosa of the dens molar buccal side (a composite model of conduction anesthetic and infiltration anesthetic injection). The injection model is adjusted to have a gap capacity of 1.5cc (Fig. 17 D, E).

This model was produced by Nisshin Dental Products, under the guidance of the author. The composition of the silicone and metal are not disclosed.

11) The 2014 specification is a highly advanced model

The point of improvement for this year's model is modu-

larization. This simulator design was intended to provide better durability, operability, and economy while looking more realistic, providing a clear detection of needle punctures and insertions, and certainty of the success of the injection.

We designed a complex type of mandibular foremen model for teaching the administration of local anesthetics and infiltration anesthetic injections (Fig. 18 E, H, I). We employed the design of the puncture sensing electrode from Patent No. 5380579 (Invention name : Injection Simulator, Date applied for : May 31, 2012, Date registered ; October 4, 2013).

These two models have a lower mandible that can be separated in the center, left from right, and detachable modules that can be integrated with the jaw bone on the left and right jaw models.

(1) Needle insertion aspect : Electrodes at the inside of the lower mandibular branch

The right side of the needle insertion section : electrode module on the inside of the mandibular ramus. Figure 19 shows the upper surface view of the electrode module and

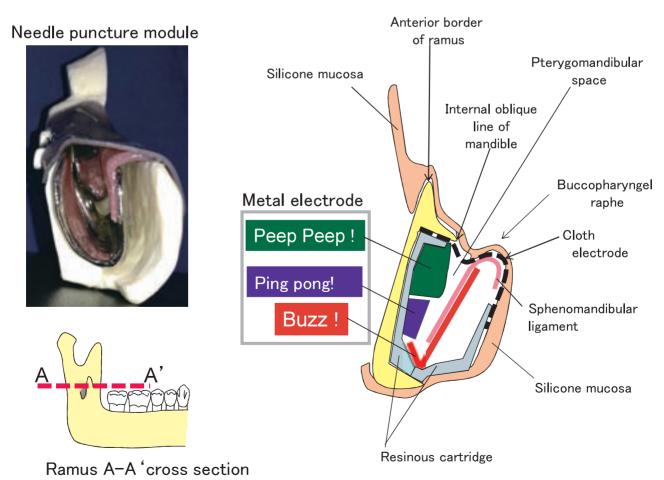


Fig. 19: Top view of the electrode module, and the design of the needle puncture and needle insertion electrode module

the design of the electrode module for needle puncture and insertion (Fig. 19).

It signals the needle puncture and insertion positions with three different sounds and three different colors of lights. From the front zone to the lingular portion of the mandibular lingula it sounds a buzzer. In the area of the bony side of the pterygomandibular space it makes a "peep peep" sound to indicate appropriate placement. Insertion in the front upper, back, inside, and solid portions of the sphenomandibular ligament causes a buzzer to sound to indicate inappropriate placement (Fig. 18 A, B; Fig. 19).

We employed this design to produce a prototype for the practical application of this design.

A disadvantage of the needle insertion detection electrodes is that liquid cannot be injected there. Also, this device cannot recognize the identification of an appropriate space if the needle is pulled back 1mm from the bony surface. No "ping pong" sound is emitted if this happens.

To prevent short circuits and breaks in the textile electrodes, silicone film was glued to both sides of the textile electrodes (now renamed the textile electrodes patched with silicon film) in order to prevent breakup of the silicone.

The four corners of the silicone–covered textile electrodes were fixed in place using screws, in order to decrease the tension on the textile electrodes and the adhering silicone.

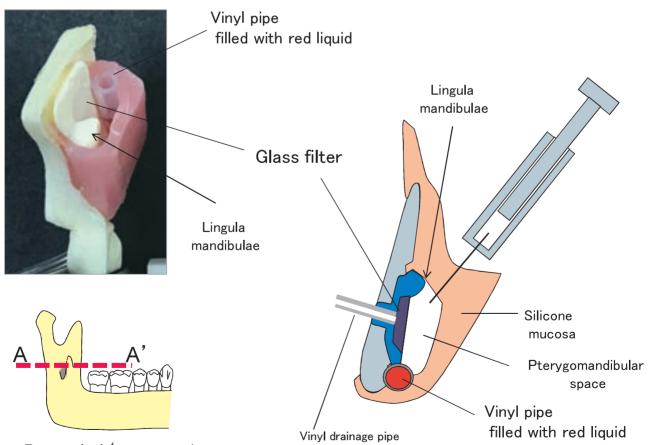
In order to prevent electric shorts or broken circuits, Nissin Corporation put silicone coats on both sides of the cloth electrodes, from 200 to 300µm thick. This cleared up our broken and short circuit problems (Fig. 18 A, B).

We also changed the material used to make the cast metal electrode to mild steel (Fig. 18 B; Fig. 19).

(2) The liquid injection module

We set up a liquid injection module on the left side of the model (Fig. 18 F, G). Figure 20 shows the design of the liquid injection module that imitated the pterygomandibular space (Fig. 20). We applied for a patent on this liquid injection module, which was granted as Patent No.5187678, obtained on October 4, 2013, under the invention name "Dental Injection Simulator." We employed this design to produce a prototype for the practical use of this design.

We used material that gave a sensation simulating having the side of the needle touch something, as it is felt in clini-



Ramus A-A 'cross section

Fig. 20: The photograph shows a liquid injection module cut transversely at the height of the mandibular lingula in the imitated pterygomandibular space. The figure shows a cross-section of the module.

cal practice. A glass filter was installed on the bony surface approximating the appropriate position (Fig. 18 G). A tube (serving as the chamber for adjusting the amount injected) and the injection pressure adjuster (a drain liquid flow adjustment cock) were connected next to the filter. By connecting a 5cc syringe to the end of the tube, one can evaluate the injection parameters, such as the speed, amount, and performance of the suction test.

In addition, with this type, we can perform infiltration anesthesia into the buccal side of the mandibular first molar (Fig. 18 E, H, I). That is, this introduced design aspects covered by Patent No. 5187678 (Kudo, 2013).

This simulator is therefore useful for assessing the students' skills at infiltration anesthesia injection and inferior alveolar nerve blocking.

(3) Faithfully reproduce the anatomical form

Repeated modifications and improvements of the electrodes were made. Now I will proceed to explain the especially important points of this model.

First of all, the cast electrode used in this module simulated the morphology of the mandibular tongue. Secondly, creating a sensation to be felt by the fingers when the needle tip touches the resin "bone" or cast metal electrode closely approximated the experience of working on an actual patient. To do this, to reproduce the feeling of hitting the bony surface, we roughened the cast metal surface by using a carborundum tipped grinding tool held at an angle of 120 degrees, from three directions. In addition, the mandibular lingula was sloped to prevent the inserted needle from being stopped before it reached the lingula. As a result, the model was set up so that if the needle was incorrectly inserted in the gap behind the lingula, the student would sense first some rasping and then smooth passage (Fig. 18 B ; Fig. 19).

The liquid injection module made it possible to deliver an infiltration anesthetic injection to the mucosa on the buccal side of the dens molar. The silicone membrane was made to be exchangeable without bonding to the resin bone (Fig. 18 E & H, Fig. 20).

Liquid leakage was the problem with the 2014 specification liquid injection module. Figure 21 shows a puncture inspection method and a repair method. For the leak test, the module is put in water and air is injected from the drain port. If bubbles come out there is a leak, indicating a puncture (Fig. 21 A). We can apply silicone adhesive to the leak



Fig. 22 : A leaflet about the 2014 model made by Nissin. The Dental local anesthetic injection model with a needle puncture and insertion module was released by Nissin.

site, and repair the silicone pterygomandibular space with tape (Fig. 21 B).

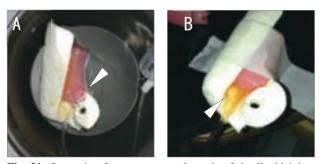


Fig. $\mathbf{21}$: Inspection for punctures and repair of the liquid injection module in the 2014 specification

A : Leak test photo : air is injected from the drain port and leaks are revealed when foam comes out

B : Applying silicone adhesive to the leak site and fixing the silicone gap with tape

In 2014, this simulator was written up as a topic in the Dental Journal of Health Sciences University of Hokkaido Magazine (Kudo, 2014).

Nisshin Dental Products started producing and selling this simulator in September 2014. The "needle insertion type" was the first trainer used for anesthetic injection education in Japan (Fig. 22).

This simulator is already being used at four universities. It

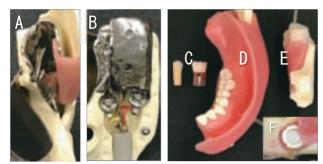


Fig. 23: 2015 model. The form of the cast electrode was improved ; view of the upward drainage of injection module ; infiltration anesthesia model with attached resin tooth for preservation and restoration.

A : The form of the cast electrode was improved, its surface was modified

B : Electrode module wiring

C: Resin teeth for teaching caries treatment and pulp excision

D : Infiltrated anesthetic injection model with silicone gums representing the mandibular molar buccal gingiva

E : Liquid injection module for teaching inferior alveolar nerve block (Drains upward)

F : Model for teaching cutting mucosa and removing infiltrated injected anesthetic, glass filter surface

is in the process of being offered for sale to Chinese and New Zealand dental organizations.

This indicates there is a great need for means of safe

practice in the field of dentistry education. In the future, we would like to expand the "liquid injection type" so that it can be used to train for injection speed, as the "needle insertion type" is.

(4) Lectures and deployments to introduce the use of this model for student practice

This module was introduced at the 42nd Japan Dental Society of Anesthesiology Academic Competition on October 12, 2014. A lecture given by the author was titled : "Deployment of safe skill education using a dental local anesthetic injection trainer" (Kudo, 2014).

The lecture covered the current status of local anesthetic injection practice using each model within our PCT system and the Clinsim[®] (a general simulation system by J. Morita Mfg. Corp). There were 153 people in the audience at the lecture.

12) 2015 Specification Model

We improved the morphology of the pharyngeal mucosa, muscles, space, and mandible in terms of anatomy and improvement of the electrodes. We designed a complex type of mandibular foremen model for teaching the administration of

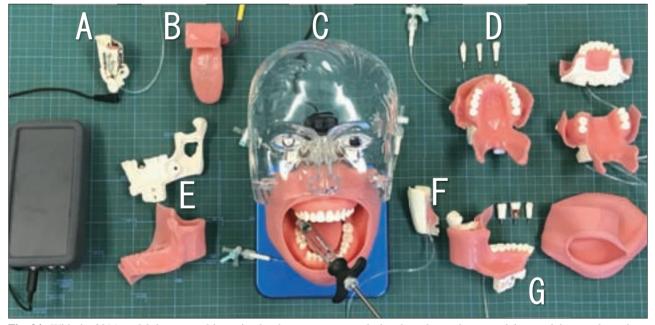


Fig. 24 : With the 2016 model the patented invention has become more practical and can be used as a module containing an electrode to evaluate whether a student has injected an appropriate volume of liquid.

A : Electrode module for sensing the amount of liquid injected.

- C : Dental local anesthetic injection simulator (mounted on a desk stand)
- D: Infiltration anesthetic injection model with the labial mucosa of the maxillary anterior teeth installed
- E: Resin mandible to mount a module on
- F: Liquid injection module for performing liquid injections only in the pterygomandibular space
- G : Infiltration anesthetic injection model for the buccal side of the mandibular molar

B: Vibrating tongue model

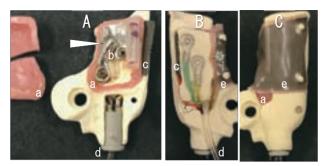


Fig. 25: Prototype model in 2016: Shape of the electrode module for evaluating the needle puncture site and amount of liquid injected.

A : Shows the inside of the module after cutting and removing the silicone film that cover the sensing electrode

a : The silicone film

b: Cast electrode for sensing the needle puncture position

c : Conductive fabric electrode behind the gap to sense when the needle has been inserted too far

d : Drain for the injected liquid

B: The right outer surface of the electrode module

e : Silicone-coated lower electrode that is used as a substrate detector

C : The left outer surface of the electrode module

local anesthetics and infiltration anesthetic injections (Fig. 23 A, B, E). We used an electronic needle puncture and insertion module (needle insertion type) and a liquid injection module (liquid injection type).

We used the 2014 model system and gingival alveolar mucosa for this model (Fig. 23 D). A silicone membrane containing a glass filter was glued to the resin bone (Fig. 23 F). To comply with endodontic and conservative restoration therapy practice, the second premolar resin teeth were used for teaching repair procedures, and the first molar resin teeth were used for teaching endodontic therapy. The resin teeth were screw–fixed from below (Fig. 23 C).

13) The 2016 model

We made a prototype high-performance dental local anesthetic injection simulator, using the University's education facility and equipment budget. We tried to produce a fullspecification injection simulator by integrating our designs and utilizing the knowledge and production technologies (Fig. 24) we had developed up to that point. In other words, we gathered together two fabrication patents, our creative ingenuity, and the fabrication techniques we had acquired and focused them on a practical application. This simulator was manufactured by Nisshin Corporation.

(1) Prototype of needle puncture, insertion of needle and liquid injection module using a patented design

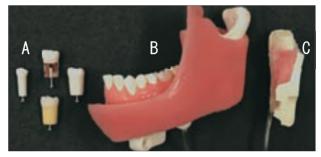


Fig. 26 : On the left side of the 2016 model is an infiltration anesthetic injection module capable of holding resin teeth for teaching caries treatment and pulpectomy

A : Resin teeth for teaching caries treatment and pulpectomy

B : Infiltration anesthetic injection model the molar buccal mucosal region (Silicone gums already bonded)

C : Liquid injection module for mandibular foremen conduction anesthesia injection (tube drains downward)

This module can be used to evaluate the success of a mandibular foremen local anesthetic injection by analyzing a series of flow levels of the liquid injection (Fig. 24 A; Fig. 26).

When beginning to test the prototype, after several injections, the author did not find any problems. However, liquid could oxidize the metal electrode. In addition, the contact points such as bolts and screws, as well as the contacts connected by electric wires, could develop increasing contact resistance and generate heat. This could possibly cause a fire. Therefore, this module is specified for single use.

a. A silicone film covering the pterygomandibular and surroundings

The silicone bulkhead thickness was increased to 1mm or more, in the interest of preventing breaks. In addition, the surface of the needle insertion location was given a dimpled texture at the needle insertion location so that silicone cracks would be limited automatically. As a result, rupture of the silicone mucosa would be prevented (Fig. 25 Aa).

b. Preventing breaks in the textile electrodes and short circuits

Silicone film was glued to both sides of the textile electrodes (now to be called the textile electrodes patched with silicon film) with the intention of preventing breakup of the silicone.

The four corners of the silicone–covered textile electrodes were fixed in place using screws, in order to decrease the tension on the textile electrodes and the adhering silicone (Fig. 25 B, C).

c. Electrodes that will not be deformed by being jabbed by a needle tip

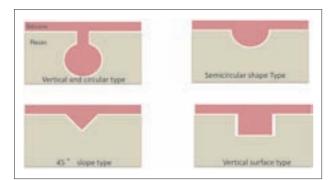


Fig. 27 : Configurations of the silicone film and adhesive surface (longitudinal section) on a resin block

It is necessary to have an electrode that does not deform at the tip of the needle and that does not catch the needle point. A body with a reduced gap at the edge of the electrode was cast. The casting alloy used was mild steel (Fig. 25 Ab).

d. The anatomical form of the pterygomandibular space

The capacity of the pterygomandibular space is 1.5cc. We positioned the center of the mandibular foremen in the center of the inside of the mandibular ramus, and installed a metallic mandibular lingula with the correct anatomical form to cover the foremen (Fig. 25 Ab).

e. The form of the mandibular ramus

The front and back edges of the mandibular ramus measure 32mm, the distance between the articular head and gonial angle is 71mm, and the distance between the front edge of the mandibular ramus to the internal oblique line of mandible is 10mm (Fig. 24 E, Fig. 25 A).

f. An alarm when a needle is inserted into a hazardous area

If a needle is inserted inside of the pterygomandibular space (inside of the raphe of the pharynx), or beneath it, the tongue will vibrate. A vibrator was installed inside the silicone tongue (Fig. 24 B).

The simulator will give an alarm by blinking the right eye on the representation of the face, and will indicate a successful injection by illuminating a blue light in the left eye. This is in the prototyping stage.

In the future, we would like to expand the "liquid injection type" so that it can be used to train for injection speed, like the "needle insertion type" does. I think that it is necessary to make the production cost less than 10,000 yen in order for it to become widely used.

(2) Improvement of the liquid injection module

The capacity of the gap was increased to 2 cc. That is, a resin cup was attached to the silicone pterygomandibular

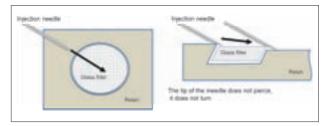


Fig. 28: The "tiled roof" design prevents the tip of the injection needle from being hooked and turned

space (Fig. 24 F, Fig. 26 C).

Fig. 25 : Ramus mandibulae module of the 2016 Prototype

(3) Integration of our University's models and other models

We made successive modifications and improved the electrodes. A liquid injection module was made available for infiltration anesthetic injection in the buccal side of the dens molar mucosa. We reported on the usefulness of a combined model for the local anesthetic injection and preservation restoration procedures (Kudo & Ohke, 2012).

In the future, we would like to promote the integration of our model with a damaged bridge prosthesis model, a pedodontics model, and an oral surgery model.

I think that developing a simulator that can be offered to other universities is necessary for the development of our university and the promotion of the educational effectiveness of this approach.

(4) Combining our device with market–available simulators and expansion of the sales channel

This dental patient robot, Shim Lloyd[®] (Morita, 2012) does not have the ability to allow evaluation of dental local anesthetic injections. If our model were used or our patent were to be combined with currently sold simulators, our contribution to the public would be enhanced and the profit gained by our university would be increased.

9. Basic problems and preparations to create injection simulators

1) Design of the adhesive surface joining silicone to resin

To prevent silicone from peeling off the resin, a section with many vertical faces is now the predominant solution. However, this is difficult to create. Therefore, a semicircular cross section that can easily be extended a bit into the vertical plane was chosen (Fig. 27).

We also hope to contribute to advances in the science of adhesion.

2) Designing to prevent needle tips from catching

We used the design of a tiled roof (Fig. 28) for inspiration. We implemented this by making a design like a tiled roof, with the pattern of the "tiles" flowing from the insertion direction of the injection needle, at the insertion point and in a range from 30 to 45 degrees.

3) Preventing silicone from tearing

I wanted to improve the silicone to add advanced characteristics and improved viscosity. However, this was not a job that could be done in a dental university in the available workplaces. Silicone improvement is a job for technically powerful development and manufacturing companies such as Toray and Toshiba.

To prevent mechanical damage at the tip of the inserted needle, use a hard, stiff injection needle. Do not touch the tip of the needle to the base of the model. Also, do not get stuck by the tip of the needle, handling it as you would during a careful injection (Kudo, 2017).

The author is thinking about the issues presented by bonding silicone and rubber that have different properties.

4) Oral tissues that cannot be replicated at all, at present

In order to closely approximate clinical practice, we would like to move on to the creation of lips, buccal mucosa, the periosteum, bone marrow, periodontal ligaments, and dental pulp. We need immediate collaborative production involving clinicians and a corporate development department.

10. Progress and our picture for the future

The picture we see for the future of our dental local anesthetic injection simulator is that when the simulated "patient" is subjected to a scary, painful experience the simulator will indicate that it is afraid and in pain by its attitude and behavior.

For example, if a syringe is directed toward the simulator's eye, it will hyperventilate and show signs of panic.

A brutal injection will induce a vasovagal reflex. This will be expressed by changing the face representation's color from skin tones to blue.

A too rapid injection and/or a high-pressure injection will induce a strong adrenaline reaction. Then this simulator's face color will change from skin tones to red.

If blood is found during the syringe suction test, there is a

too fast injection, or too much is injected, then acute poisoning symptoms may be demonstrated. The simulator will close it eyes and start to vibrate.

We would like to have simulator practice for student education, measurements on the national test, internist doctor's education, and by local dental associations, so that its contributions to painless dental care can be made manifest.

Acknowledgments

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Pereses of the serves

1992年 東日本学園大学(現,北海道医療大学)歯学研究科修了(歯科麻酔学)
1995年 北海道医療大学歯学部歯科麻酔学講座 講師
2001年 北海道医療大学大学院歯学研究科(講師)担当
2005年 日本歯科大学新潟生命歯学部歯科麻酔・全身管理科 非常勤講師
2009年 日本歯科大学生命歯学部歯科麻酔学講座 非常勤講師
日本歯科麻酔学会 認定歯科麻酔専門医・社員・広報委員・安全医療委員、日本障害
者歯科学会認定医、日本有病者歯科学会 認定医・指導医・評議員・安全医療管理委員