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Silicone-based simulation models for peripheral nerve microsurgery

Burcin Ustbas Gul[a], **Deniz Kilic Yanilmaz**[b], **Dilan Arslan**[c], **Mehmet Bayramicli**[d], **Ozge Akbulut**[a,*]

[a] *Faculty of Engineering and Natural Sciences, Sabanci University, Istanbul, Turkey*
[b] *Surgitate Medikal Arge Sanayi ve Ticaret A. S., Kocaeli, Turkey*
[c] *Chemistry Department, Hacettepe University, Ankara, Turkey*
[d] *Department of Plastic, Reconstructive and Aesthetic Surgery, Marmara University Hospital, Istanbul, Turkey*

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Abstract *Background:* There is a need for a peripheral nerve model on which surgeons-in-training can simulate the repair of nerve injuries at their own pace. Although practicing on animal models/cadavers is considered the "gold standard" of microsurgical training, the proposed model aims to provide a platform for improving the technical skills of surgical trainees prior to their practice on cadaver/animal models. In addition, this model has the potential to serve as a standardized test medium for assessing the skill sets of surgeons.
Methods: Several formulations of silicone were utilized for the design and fabrication of a model which realizes the hierarchical structure of peripheral nerves. The mechanical properties were characterized via the Universal Testing Machine; the damage caused by the needle on the entry sites was assessed through scanning electron microscopy (SEM).
Results: Mechanical properties of the formulations of silicone were tested to mimic human peripheral nerves. A formulation with 83.3 wt% silicone oil and 0.1 wt% cotton fiber was chosen to be used as nerve fascicles. Both 83.3 wt% silicone oil with cotton fiber and 66.6 wt% silicone oil without fiber provided a microsuturing response similar to that of epineurium at a wall thickness of 1 mm. SEM also confirmed that the entry of the needle did not introduce significant holes at the microsuturing sites.
Conclusions: The proposed peripheral nerve model mimicked human tissues mechanically and cosmetically, and a simulation of the repair of a fifth-degree nerve injury was achieved.
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Introduction

To ensure improved outcomes for patients, several disciplines such as plastic surgery, neurosurgery, and orthopaedic

* Corresponding author.
E-mail address: ozgeakbulut@sabanciuniv.edu (O. Akbulut).

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surgery have integrated microsurgery to their practice.[1,2] Long-term assessment of recovery of nerve injuries that are repaired through microsurgery indicates a faster healing process and retrieval of sensory and motor functions.[3] Microsurgeons-in-training necessitate intense practice to enhance their surgical competence, proficiency, and dexterity,[4] and simulation is taking a growing share in the education of surgeons. Peripheral nerve repair remains a challenge, and several distinct nerve simulation models, from rudimentary gloves to virtual reality platforms, are now utilized to improve the microsurgical skill-sets of doctors.[5] In the tactile realm, working with animal models and cadavers along with live patients is considered the gold standard in medical education.[6] In addition, fresh tissues such as pig leg,[7] human placenta,[8] and avulsed skin[9] are used as practice media, while surgical gloves and medical grade tubes[6,10] are also employed as primitive alternatives. However, these models have their limitations:(i) access to cadavers and live humans/animals is not constantly available[6]; (ii) there are ethical concerns related to working on patients and animal models[11]; (iii) fresh tissues necessitate refrigeration and contain a high risk of transmissible diseases; hence, can be classified as biohazards and require vast amounts of effort for self-protection.[12] Unrealistic synthetic materials such as latex strips and tubes,[13] polyethylene,[14] Gore-Tex[15] and parafilm[16] do not offer the necessary fragility, complexity, and hierarchical outlook of real tissues. Therefore, there is a need for a realistic, non-hazardous, standardized, and accessible tactile platform for peripheral nerve microsurgery training.

Here, we report on the design of a silicone-based, composite peripheral nerve model. This model can be fabricated in a simple setup (e.g., in a non-chemistry lab) that contains only a scale and an oven. The model consists of: (i) a skin layer (i.e., epidermis and subcutaneous fat), (ii) peripheral nerves, (i.e., epineurium, connective tissue, and fascicles), and (iii) a muscle layer. These components are prepared separately and then combined into a single model. The layers are designed out of two-component silicone elastomers that are formulated to simulate the tactile and cosmetic properties of peripheral nerves. We tracked a matrix of silicone formulations to reach the reported elastic modulus of 3–10 MPa for live tissue.[17–19] Scanning electron microscopy (SEM) indicated no damage upon the entry of a needle while still offering fragility towards microsurgical suturing. This model provides a durable and realistic tactile medium for surgical simulations in which surgeons-in-training can learn at their own pace as well as be examined with a standardized platform.

Materials and methods

Tissue-mimicking materials

Two-component liquid silicone elastomer; component A (SL-3358A) and B (SL-3358B), were obtained from KCC Corporation, Korea. Silicone oil was purchased from Sapar, Turkey (PMX200-350 CST). Cotton fibers were received from local providers. Dyes that were used in coloring were obtained from Wacker Chemie AG.

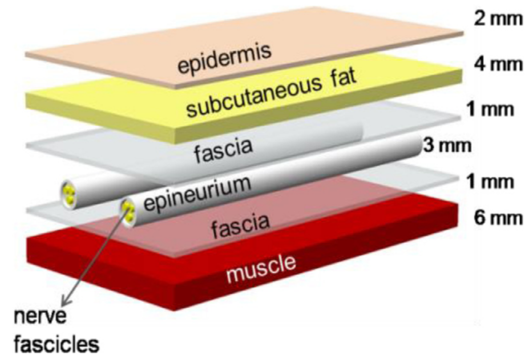

Figure 1 Different layers of the model.

Design of the peripheral nerve model

The model was prepared according to the human anatomy of the peripheral nervous system.[20] The model aimed to mimic ulnar, median, and radial nerves in the upper extremity. Figure 1 demonstrates different layers of the model, which consists of a skin layer, fascia (the connective tissue layers between the skin, nerves, and the muscle layers), and the peripheral nerves (epineurium and fascicles). The simulated epineurium has an inner diameter of 3 mm with a wall thickness of 1 mm. It holds three fascicles which are 1 mm-thick composite structures that contain 0.1 wt% cotton fiber in their formulation. Axons are excluded from the design, since on a benchtop, it would not be possible to fabricate fibers that are 1 μm in diameter.

Preparation of the model

The amount of silicone oil in the formulation spanned a range of 50–83.3 wt% and the remaining weight was equally split between components A and B. The formulations were prepared by blending the components with a hand mixer, keeping the mixture under vacuum for 30 min, and then curing it at 110 °C for 30 min. The reaction was addition curing with platinum catalyst and no by-product was observed. Although the curing step can be carried out at room temperature, we utilized higher temperatures to speed up the process. In addition, the vacuuming step can be eliminated by waiting 2 hours for possible air bubbles to leave the system.

The formulation for the simulated skin layer was prepared by mixing equal amounts of component A and B with 50 wt% silicone oil. A single, red, sinusoidal line of silicone was deposited on the epineurium to enable the confirmation of successful joining of the broken nerve ends. Cotton and wool natural fibers were further added to the formulations between 0.1 and 1 wt% to tune the elastic modulus of the epineurium and fascicles. The samples that do not contain fibers are referred to as *pristine* throughout this study.

Consecutive curing of the muscle layer, fascia layer (before and after the attachment of pre-cured fascicles), subcutaneous fat layer, and the epidermis layer was achieved in a 14 × 7 cm sized mold. The simulated fascicles were cured in a 3D-printed mold for the precise size and shape match; while thin hoses can also be employed to shape these structures. Any mold that can withstand temperatures around 110 °C without deformation can be used to prepare the model.

Mechanical characterization

Several formulations of silicone, either pristine specimens or those that contain natural fibers, were prepared in dog-bone shape according to the ASTM (American Society for Testing and Materials International) standards. The specimens were tested with 200 kN force in the Universal testing machine (UTM), and an average of 4 tests was reported as the test result.

Scanning electron microscopy (SEM)

To track the microsuturing performance of the epineurium and the nerve fascicles, the samples were sputter coated with a thin layer of carbon by Cressington carbon coater and mounted onto the carbon tape. Images were acquired by JSM6010-LV SEM, with SEI detector, using an electron gun voltage of 5 kV.

Assessment of microsuturing in the model

The suturing properties of the designed peripheral nerve samples were assessed by one of the authors (M. B.). Samples were tested by 8/0 and 10/0 non-absorbable polypropylene sutures (Prolene) with BV 175–7 and BV 100–4 needle and 11/0 polyester fiber (Mersilene) with TG 160/4 Plus needle (Ethicon Inc., New Jersey, USA), with the aid of an operating microscope (OPMI Vario 700, Carl Zeiss Meditech AG, Germany).

Results

Selection of materials for the model

For the design of this model, we surveyed a matrix of formulations of silicone since it is commonly used as a tissue-mimicking material in prosthetics,[21,22] film industry, and soft robotics.[23] The ease of fabrication, molding, and coloring have made silicone a remarkable option for simulation models as well.[24] For instance, there are numerous commercially available models (e.g., skin pads) for suturing practice[25]; likewise, silicone tubes have been utilized for microsurgical models.[26,27]

The strength of suturing depends on the elastic modulus of the materials that are used to fabricate epineurium, perineurium, and fascicles.[28,29] The model is hierarchically structured to offer differing elastic moduli for realistic practice. Our measurements showed the elastic modulus of the samples decreased with increasing silicone oil content (Figure 2). The sample with 83.3 wt% silicone oil exhibited the highest similarity to nerve tissues in terms of elastic modulus (3-10 MPa[17,30]), and thus, was chosen as the material to form fascicles. The sample that contains 66.6 wt% silicone oil was preferred for the epineurium since this

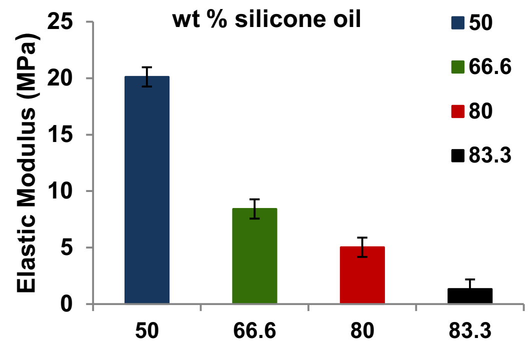

Figure 2 Comparison of elastic modulus of formulations with increasing wt% silicone oil.

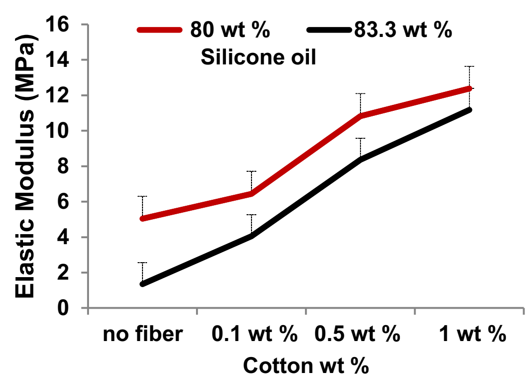

Figure 3 Comparison of elastic modulus of samples that contain 80 and 83.3 wt% silicone oil with increasing wt% of cotton.

formulation has a higher elastic modulus than the inner connective tissues. The specimens also underwent plastic deformation before fracture (images not shown).

For the design of simulated epineurium, we added wool and cotton fibers (0.1 wt%) to the samples that contain 80 and 83.3 wt% silicone oil to further tune the elastic modulus. These fibers facilitate the realistic suturing of the epineurium since they strengthen the medium against tensile forces. Wool and cotton were chosen as reinforcing fibers due to their accessibility at low-cost.[31,32]

We focused on the elastic modulus at the range of 3-10 MPa.[33-37] The aim was to sustain the fragility of the fibers while asserting traction force on the needle during suturing; thus, we have focused on formulations with low elastic moduli. Since cotton fiber-added samples exhibited relatively smaller values than the wool-added ones, we tracked the change in elastic modulus in cotton-added samples in formulations with 80 and 83.3 wt% silicone oil (Figure 3).

The sample with 83.3 wt% silicone oil that contains 0.1 wt% cotton fiber was chosen to be used as the nerve fascicles in the model. Having fibers in the model allowed microsutures on the nerves to remain intact. In brief, utilizing either 83.3 wt% with cotton fibers or 66.6 wt% without fibers can provide microsuturing response similar to that of epineurium at a wall thickness of 1 mm, while the cotton-added sample provides better traction.

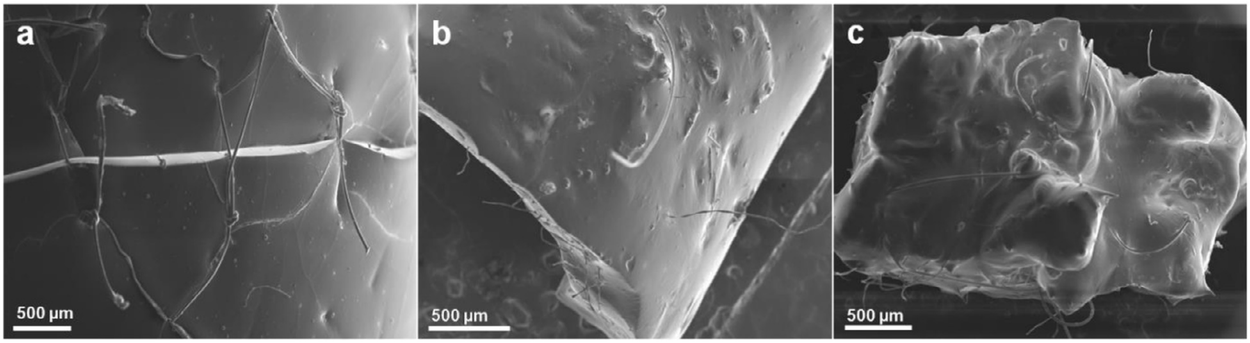

Figure 4 (a) Pristine epineurium model, (b) Epineurium model with 0.1 wt% cotton fibers, (c) Fascicle model with 0.1 wt% cotton fibers with the utilization of 10/0 sutures.

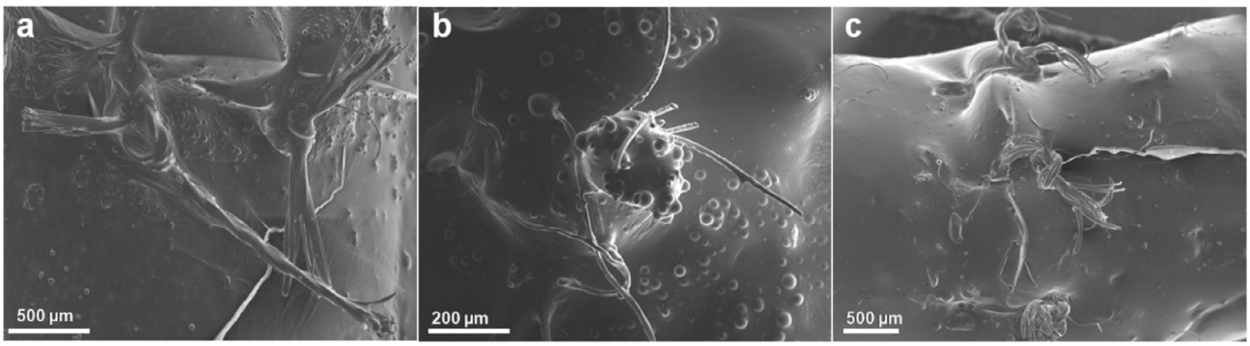

Figure 5 (a) Pristine epineurium model, (b) Fascicle model with 0.1 wt% cotton fibers, (c) Epineurium model with 0.1 wt% cotton fibers with the utilization of 8/0 sutures.

Evaluation of microsuturing on the model

One of the main obstacles during microsurgery is the damage imposed by the entry of needle to the tissue where bleeding is possible. This bleeding, in turn, may result in the disruption of the area of surgery, and hence, obstruct the vision of a surgeon during the operation. Having smaller damage can also enable a faster healing process after the surgery. Therefore, mechanical properties of the model should allow the entry of the needle without introducing a significant hole that may cause leakage.

In order to evaluate the damage around the entry sites of the needle, we have monitored the sutures by SEM. Two different sizes of sutures were utilized for the evaluation of the damage. In Figure 4, 10/0 sutures were used on the formulations of silicone with pristine epineurium models, 0.1 wt% cotton fiber-added epineurium, and the 0.1 wt% cotton fiber-added fascicles. SEM confirms that the sutures inflicted no significant damage at the entry sites and adequately joined the two sides of the epineurium and the fascicles. Figure 5 demonstrates the repairs with 8/0 sutures on the same formulations.

Microsurgical assessment of the model

A fifth-degree peripheral nerve injury was simulated with the model. The anatomy of these nerves was mimicked including the fascia tissue, vasa nervorum, epineurium, connective tissue, and the fascicles. In Figure 6, the nerve model with pristine formulations can be seen. The fascia tissue on the nerves was removed gently (a). A cut on the peripheral nerve was imposed, and the fascicles and connective tissue were observed, blue tissue paper was placed underneath the area of procedure for the ease of visualization (b). Vasa nervorum was aligned on both sides, the fascicles were sutured with 8/0 suture, and the needle was inserted at a 45° angle and removed with circular movements to prevent the generation of excess needle holes. Afterwards, the same procedure was applied to the epineurium to complete the nerve repair. The model has a significant resemblance to peripheral nerve tissues in terms of resistance to suturing.

The critical part of epineural repair is the correct alignment of the nerve ends that are to be sutured. Figure 7 shows a cut on the peripheral nerve model with 0.1 wt% cotton fiber. The alignment of both ends was followed by repair with 8/0 sutures. The thickness of the suture was higher than the one that was used for the pristine formulations to comply with the topology of higher elastic modulus structures. The addition of fiber increased the suture resistance of the epineurium, and structures with fibers hold the sutures better compared to pristine formulations.

Discussion

Peripheral nerve injuries commonly occur in radial, ulnar, and median nerves.[38-40] Although technological aids such as

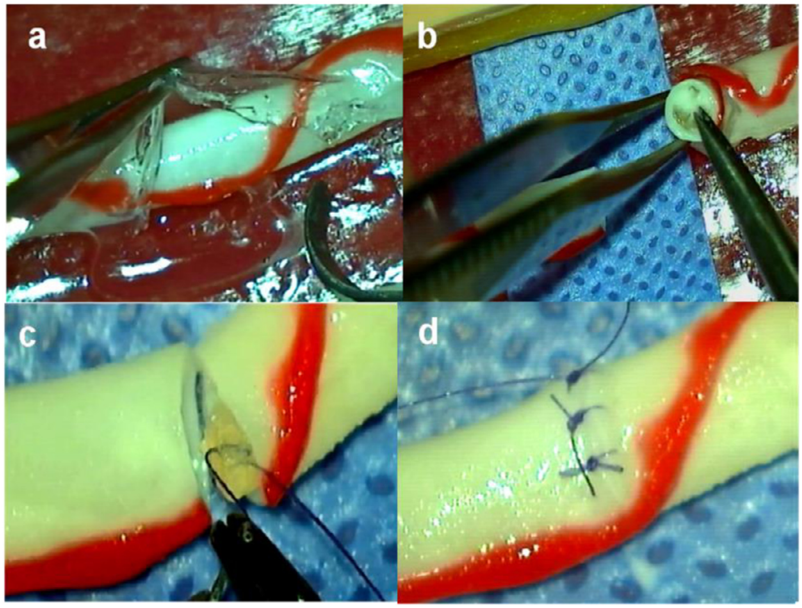

Figure 6 Nerve model with pristine formulations. (a) Removal of fascia tissue to release the peripheral nerve, (b) A cut on epineurium, and a view fascicles and connective tissue, (c) Microsutures on fascicles, (d) Microsutures on epineurium.

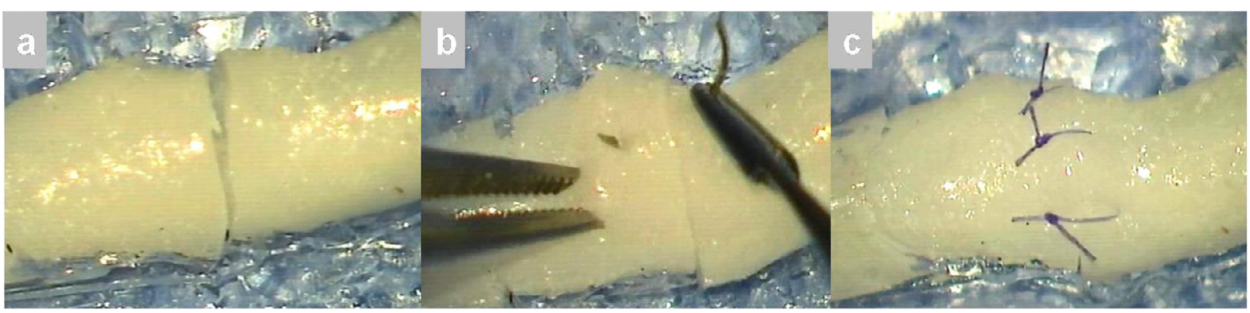

Figure 7 Nerve model with 0.1 wt% cotton fibers. (a-c) Systematic assessment of a nerve cut and microsuturing of the epineurium layer.

operating microscopes and microsurgical suture materials provided significant improvements in peripheral nerve microsurgery, the repair of these nerves still remains as a challenge due to the complex nature of these structures.[41,42] Treatment plan necessitates an accurate classification of the nerve injury[43] and the most severe type of these nerve injuries is the fifth-degree (Seddon's neurotmesis)[44,45] injuries, in which all of the sub-structures of the peripheral nerve (i.e., endoneurium, the fascicles, Schwann cells, axons, and the epineurium) are completely ruptured. Precise alignment at the fascicular level with shorter operation, dissection, and anesthetic times are also crucial for the post-operative functional repair of the nerves. For successful simulations, models should resemble the sub-structures in a realistic manner.[46,47]. The model proposed here offers a standardized and well-characterized system on which microsuturing maneuvers can be practiced repetitively by microsurgeons-in-training.

The model weighs less than 100 g; hence, the cost of materials is around 2 USD. Although, it is a labor-intensive process, we prototyped the model with lean manufacturing principles to (i) include minimum number of molds (with no complicated molds) and (ii) necessitate only a scale and an oven for processing.

Conclusion

The mechanical repair of nerves—alignment and suturing of epineurium and nerve fascicles—requires considerable practice. While cadavers are hard to access, and there are ethical concerns regarding the use of animals for training; primitive synthetic models for this type of tactile simulation have often failed to address the hierarchical and complex structure of the peripheral nerve system. This article aims at describing a fabrication route such that individual laboratories can build their own models with minimum equipment and collectively improve the training materials for microsurgical education. The hierarchical model described here offers surgeons to realistic means of practice at their own pace in a standardized medium. Therefore, surgeons can potentially improve their eye-hand coordination on this model, which in turn, may reduce the number of cadavers/animal models that are routinely used in microsurgical training.

Conflict of interest

The authors have no conflicts of interest to disclose.

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