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Chapter

Biological and Preclinical Evaluations of Designed Optically Guided Medical Devices with Light Scattering Modules for Carpal Tunnel Syndrome Treatment and Surgical Procedure

Ching-Cheng Huang and Ming-Che Chiang

Abstract

A novel technique and product applied to carpal tunnel microscopic surgical procedures through the designed medical devices were prepared and studied. The novel design of the medical device could be developed and applied for new carpal tunnel microscopic surgical procedures instead of the traditional carpal tunnel surgical procedures. Also, a new medical device with optical LLLT module was designed for wound healing in carpal tunnel syndrome treatments. Furthermore, assistive surgical healing dressings for carpal tunnel syndrome treatments via minimally invasive surgery (MIS) such as air-foam soft cleaning sponges and hydrogel surgical dressings with polymeric films were designed for more comfortable treatments. Biological and clinical evaluations of carpal tunnel surgical procedure using the new designed medical devices are studied. For commercialized reasons, guidance such as ISO 10993-1:2009(E) for biological evaluation of medical devices must be considered. Furthermore, the clinical evaluation of modified medical devices would be carried out.

Keywords: clinical evaluation, carpal tunnel syndrome, surgical procedure, minimally invasive surgery, scalpel

1. Introduction

Novel optically guided medical devices were designed for the clinical needs of carpal tunnel surgical procedure. The word “carpus” means “wrist.” The wrist is the joint between your hand and the lower part of your arm and is surrounded by a band of fibrous tissue as a support for the joint. The tight space between the wrist bone and the fibrous band is called the carpal tunnel. The median nerve could pass through the carpal tunnel to receive any kind of sensations from the thumb, index, and middle fingers of the hand. Hence, any condition that causes swelling or a change in position of the tissue within the carpal tunnel would

repress and damage the median nerve. Repression and irritation of the median nerve would cause numbness and tingling of the thumb, index, and the middle fingers of the hand which is a clinical condition known as “carpal tunnel syndrome.” Although it is a gradual process, for most people carpal tunnel syndrome will worsen over time without some form of treatment. For this reason, it is important to be evaluated and diagnosed by doctor early on. In the early stages, it may be possible to slow or stop the progression of carpal tunnel syndrome. Two kinds of treatments could be employed in the stages such as nonsurgical treatments and surgical treatments. If diagnosed and treated early, the symptoms can often be relieved without surgery. If diagnosis is uncertain or if symptoms are mild, nonsurgical treatment would be recommend first. The nonsurgical treatments may include wearing a brace or splint at night; keeping the wrist in a straight or neutral position reduces pressure on the nerve in the carpal tunnel. It may also be useful to wear a splint during the day when doing activities that aggravate symptoms. In addition, nonsurgical treatments may include using the medical devices with light, electrode, etc. Also, nonsteroidal anti-inflammatory drugs (NSAIDs) could be a chosen way for nonsurgical treatments. Some medical devices such as photo- and electrotherapies could help relieve pain and inflammation for carpal tunnel syndrome. Furthermore, nerve gliding exercises, activity changes, and steroid injections would also be recommended as kinds of nonsurgical treatments for carpal tunnel syndrome. About nerve gliding exercises, some patients would benefit from exercises of nonsurgical treatments that help the median nerve move more freely within the confines of the carpal tunnel. About activity changes, symptoms often occur when the hand and wrist are in the same position for too long—particularly when the wrist is extended or flexed. About steroid injections, corticosteroid or cortisone is a powerful anti-inflammatory agent that could be injected into the carpal tunnel. If nonsurgical treatment could not relieve or stop the progression of carpal tunnel syndrome after a period of time, surgical treatments of carpal tunnel syndrome such as “carpal tunnel release” would be recommended and employed. Open carpal tunnel release could be employed as a kind of surgical treatment. In open surgery, a small incision must be made in the palm of target hand and views the inside of your hand and wrist through this incision [1]. During the procedure, the transverse carpal ligament will be divided in the roof of the carpal tunnel. This increases the size of the tunnel and decreases pressure on the median nerve. When the ligament heals after surgery, there is more room for the nerve and tendons. The other way, endoscopic carpal tunnel release was employed. In endoscopic surgery, one or two smaller skin incisions must be obtained and called portals for using an endoscope to observe inside target hand and wrist. A special knife is used to divide the transverse carpal ligament, similar to the open carpal tunnel release procedure [1].

In this report, we propose a series of novel techniques and medical devices of treatments for carpal tunnel syndrome. The novel design of the medical device could be developed and applied for new carpal tunnel microscopic surgical procedures instead of the traditional carpal tunnel surgical procedures. For the design of new medical devices, selections of materials or suitable materials for biomedical applications such as polymethacrylate, polyester, polyamide, polyimide, polyester, polynorbornene, polytetrafluoroethylene, polydiphenylacetylenes, and polymeric resins could be substantially considered and employed [1–19]. Also, the surface modification technology could be considered to change the surface microenvironment of materials for specific need [20–24]. Furthermore, the biological and clinical evaluations of materials and medical devices must be considered for the application and design.

2. Materials and methods

2.1 A new design of optical guided medical device with an electrical scalpel

New designed optical guided medical device with an electrical scalpel and a light scattering module was studied. The optical guided medical device with an electrical scalpel and a light scattering module contains a scalpel with a blade, an optical guided system with a scattering propagation, a power controller, and a connectable power supplier (**Figure 1**) [1].

2.2 A new design of laser optical guided medical device with a scalpel

New designed optical guided medical device with a scalpel was studied. Laser light sources could be employed as optical guided modules, and a series of laser optical guided medical devices with a scalpel are designed on the demands of clinical applications. The laser optical guided medical device with a scalpel contains a scalpel with a blade, an optical guided laser source with a designed strengthen arm, a power controller, and a connectable power supplier (King-Yard Tech. Co., TW). The different colors of laser light could be chosen depending on the clinical demands (**Figure 2**) [2, 3].

2.3 Assistive surgical healing dressings for carpal tunnel syndrome treatments via minimally invasive surgery (MIS): air-foam soft cleaning sponges and hydrogel surgical dressings with polymeric films

An air-foam soft cleaning sponge was designed for deeply soft cleaning the surgical skins before and after carpal tunnel syndrome treatments (Parsd Pharm. Tech. Co., TW) (**Scheme 1**). The high medical grade Cenefom PVA raw sheet is a synthetic sponge essentially composed of cross-linked polyvinyl alcohol (PVA) through an air-foaming process, which could provide characteristics of lint-free and fiber-free, high hydrophilic, low chemical residues, and high cleanness of air-foam soft cleaning sponges. The sponges would be employed as assistive anti-adhesion dressings and satisfied for carpal tunnel syndrome treatments via minimally invasive surgery. The designed soft cleaning sponges must be a kind of open-celled microstructure, highly absorbent porous medical material that wicks aqueous solutions quickly. Their high-water content allows vapor and oxygen transmission to the wounds such as pressure sores, leg ulcers, surgical and necrotic wounds, lacerations, and burns. They seem to play an important role as emergency burns treatment alone or in combination with other products, thanks to their cooling and hydrating effects. In

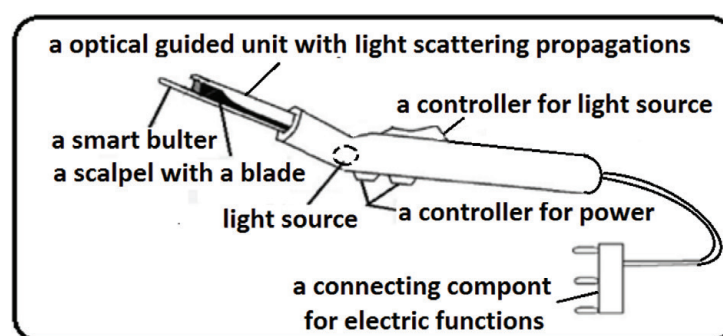


Figure 1.
New design of optical guided medical device with scalpel and its key functional components [1].

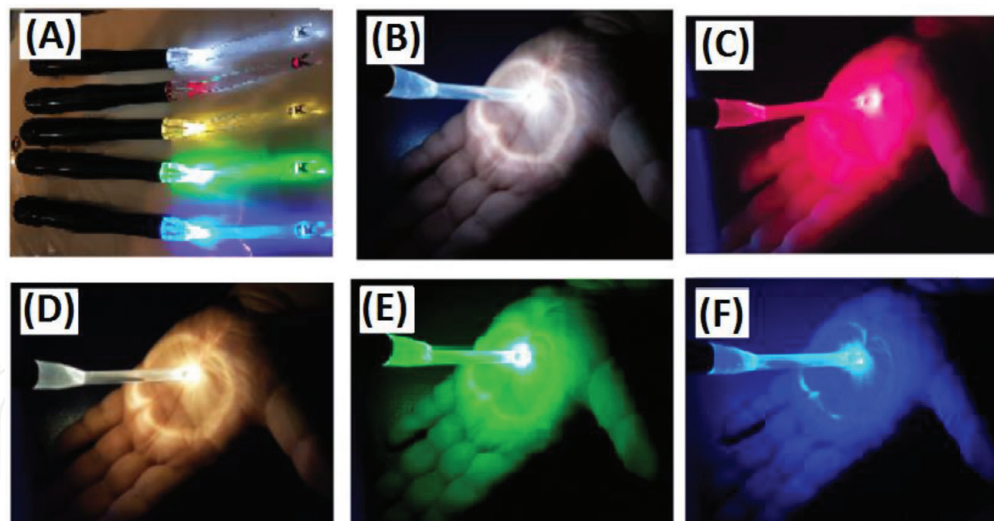
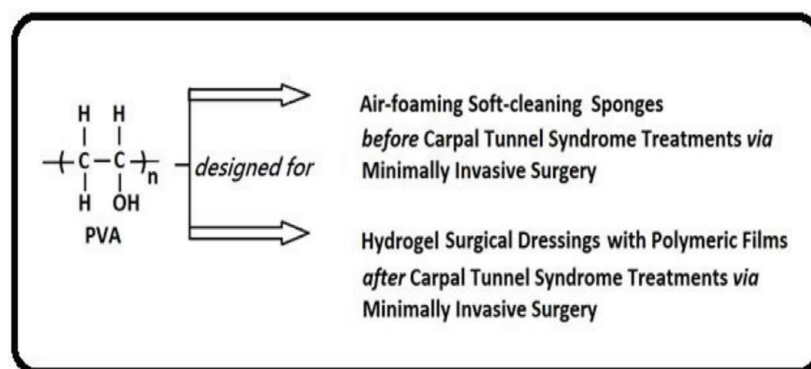


Figure 2. (A) A series of new designed laser guided medical devices with a scalpel and different colors of laser light sources for various clinical demands (King-Yard Tech./Chuang Sheng Medicine Equipment Co., TW). (B) The white light focus on a hand, (C) the red light focus on a hand, (D) the orange light focus on a hand, (E) the green light focus on a hand, and (F) the blue light focus on a hand.



Scheme 1. Assistive surgical healing dressings for carpal tunnel syndrome treatments via minimally invasive surgery: air-foam soft cleaning sponges and hydrogel surgical dressings with polymeric films such as PU films.

usual, the cross-linked or non-cross-linked polyvinyl alcohol (PVA) was employed to prepare hydrogel surgical dressings. The polyurethane film was used to be a protecting material, practically, for surgical dressings. The new surgical dressings were designed with well-protecting and surgical wound healing functions, which could provide good surgical wound managements after carpal tunnel syndrome treatments via minimally invasive surgery. That is, the hydrogel surgical dressing with a polymeric film was designed for the outside surgical wound healing after carpal tunnel syndrome treatments via minimally invasive surgery (Chuang Sheng Medicine Equipment Co., TW) (**Scheme 1**). The polymeric film was used with the hydrogel surgical dressing for protecting the outer surgical wound from environments.

3. Results and discussion

3.1 New design of fabrication optical guided medical device with scalpel for carpal tunnel syndrome

In this study, traditional and conventional medical methods for carpal tunnel surgical procedure were modified, and novel optical guided medical device with

scalpel was designed for carpal tunnel syndrome. For clinical demand, new design and fabrication of optical guided medical device with scalpel were necessary. Some essential components could be considered for the clinical need for carpal tunnel surgical procedure. Therefore, a new medical device was designed and had optically guided components with scalpel including a scalpel with a blade, an optically guided system with scattering propagation, a power controller, and a connectable power supplier (**Figure 1**). An individual head containing a surgical scalpel and an optically guided system could be considered in this study. Practically, the scattering propagation could be achieved by using the design of multiple stages in the optical guided cutting component [1]. Furthermore, the electrical supply, which could provide the function of optical guidance and electric cutting, was also considered as one part of the medical device as shown in **Figure 1**. The relative large operating area would be observed by traditional carpal tunnel surgical procedures as shown, respectively, in **Figure 3A**. Furthermore, the fabrication optical guided medical device with scalpel for carpal tunnel syndrome was carried out, and the new medical device could be used for carpal tunnel syndrome as shown in **Figure 3B–E**. The new designed light laser guided medical devices with a scalpel were employed in carpal tunnel surgical procedure (**Figure 3F**).

3.2 Characterization of the designed optical guided medical device with scalpel

The modified medical devices containing a head as a surgical scalpel under optical guidance were designed, and the newly designed head as a surgical scalpel was shown in **Figure 1**. The multiple stages for light scattering propagations were designed. The light scattering propagation occur because of the light transfer delay among different light waves, which satisfy the clinical demand during carpal tunnel surgical procedure to show the light pass route under the skin [1]. The polyacrylate was designed as a material for optical guidance instead of glass. The thermal deformation temperature was obtained as 93.9°C under 0.455 MPa (ASTM D648-07B). The new designed laser guided medical devices with a scalpel and a green light source was employed in carpal tunnel surgical procedure as shown in **Figure 3F**. The designed strengthen arm of medical devices increases the safety of carpal tunnel syndrome treatments via minimally invasive surgery. The surgery treatments would produce internal and external surgical damages. **Figure 4A** showed the surgical wounds of internal and external surgical damage after traditional carpal tunnel syndrome treatments. Comparably, **Figure 4B** showed the surgical wounds of internal and external surgical damage after the carpal tunnel syndrome

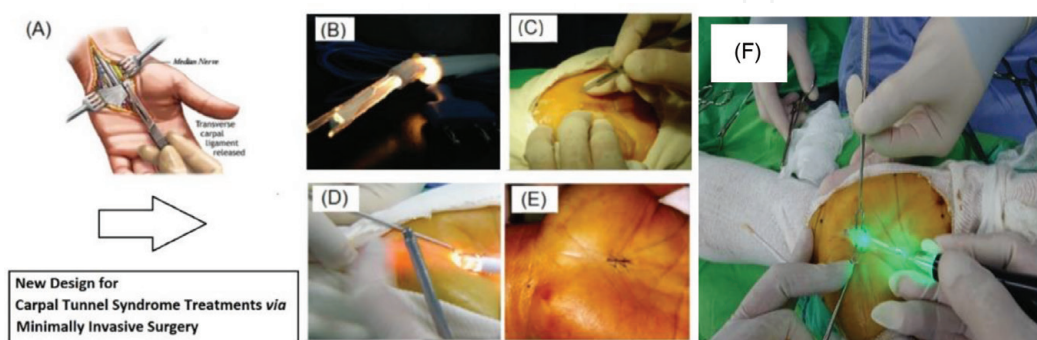


Figure 3. Photos of (A) traditional design of medical devices for carpal tunnel surgical procedure (http://www.medicinenet.com/carpal_tunnel_syndrome/article.htm), (B) new design of optical guided medical device with scalpel in this study, and (C)–(E) new design of optical guided medical device with scalpel was employed in carpal tunnel surgical procedure. (F) The new designed light laser guided medical devices with a scalpel were employed in carpal tunnel surgical procedure.

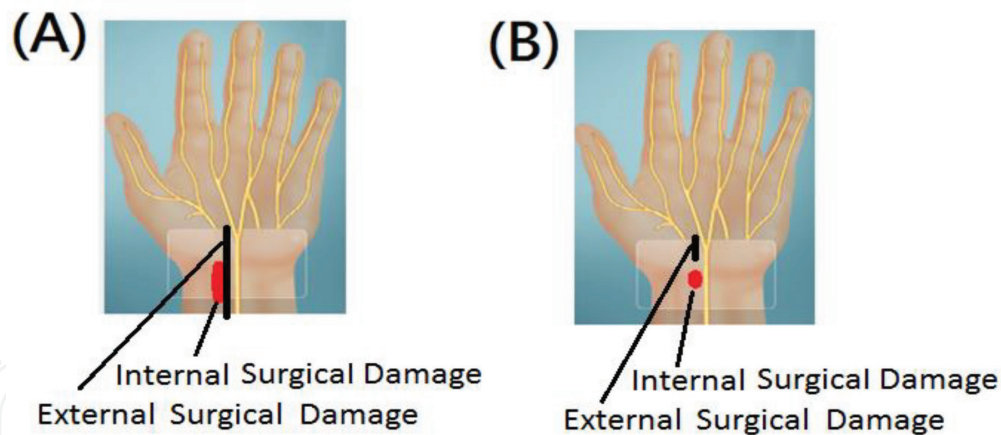


Figure 4. (A) The surgical wounds of internal and external surgical damage after traditional carpal tunnel syndrome treatments and (B) the surgical wounds of internal and external surgical damage after the carpal tunnel syndrome treatments via minimally invasive surgery.

treatments via minimally invasive surgery with new designed laser guided medical devices. Remarkably, the relative small surgical wounds could be obtained by using new designed laser guided medical devices.

3.3 Characterization of the designed assistive dressings of air-foaming soft cleaning surgical sponge before carpal tunnel syndrome treatments via minimally invasive surgery

The surgical wounds of internal and external surgical damage would be observed after the carpal tunnel syndrome treatments whether the new designed laser guided medical devices via minimally invasive surgery or not (**Figure 4A and B**). For the specific clinical demands, designed assistive dressings of air-foaming soft cleaning surgical sponge must be designed before carpal tunnel syndrome treatments via minimally invasive surgery. The air-foaming soft cleaning PVA surgical sponge was prepared. The air-foaming soft cleaning PVA surgical sponge is a kind of synthetic sponge essentially composed of cross-linked polyvinyl alcohol, which was employed as assistive anti-adhesion dressings for carpal tunnel syndrome treatments via minimally invasive surgery. It is a kind of open-celled microstructure, highly absorbent porous material that wicks aqueous solutions quickly. It is compressible when dry and expandable when wet and has high tensile strength, good elongation, and excellent resistance to most chemicals. PVA sponge is hydrophilic and can hold up to 12 times its dry weight in water. Cell size can be varied depending on the required use; the finer the cell, the better the capillary action. The wet sponge can withstand temperatures approaching 70°C and the dry about 100°C. PVA sponge is effectively inert and will not, in itself, support microbial growth. Extremely soft when wet, air-foaming soft cleaning PVA surgical sponges are hypoallergenic, which are suitable and ideal for soft and sensitive skin, specific in the use of surgical treatments such as carpal tunnel syndrome treatments via minimally invasive surgery.

Air-foaming soft cleaning PVA sponge with interlinked cell structure is perfect for any application where absorbency, durability, and versatility are key points. Air-foaming soft cleaning PVA requires different handling and processing than other more widely used foams. Strong chemical and abrasion resistance of air-foaming soft cleaning PVA sponges go through stringent quality control and super cleaning medical grade Cenefom PVA raw materials prepared in medical and clean room environments. Because of biocompatible properties, air-foaming soft cleaning

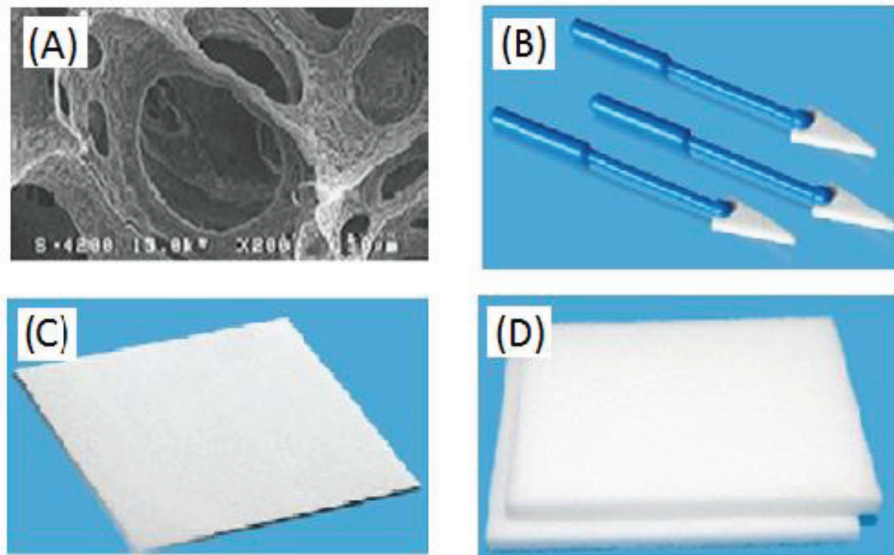


Figure 5.

The designed assistive dressings of air-foaming soft cleaning surgical sponge for carpal tunnel syndrome treatments via minimally invasive surgery (Medical grade Cenefom PVA foam in PARSD Pharmaceutical Technology Co.). (A) The SEM photo of the surgical sponge with an open-cell microstructure, (B) the photo of the surgical swab, (C) the photo of the dried surgical sponge, and (D) the photo of the wet surgical sponge.

PVA sponges were documented as being used for medical purposes. Available in a wide range of pore sizes and water-holding capacity could be selected for different clinical purposes (**Figure 5**). Furthermore, air-foaming soft cleaning PVA sponge and thin membrane provide strong chemical and abrasion resistance, non-linting, non-abrasive, latex Free, non-phthalate, biocompatible, UV resistant, withstanding temperatures of up to 70°C when wet and 100°C dry without deformation, extremely durable, available in a wide range of pore sizes.

3.4 Characterization of the assistive hydrogel surgical dressing with polymeric films designed for using after carpal tunnel syndrome treatments via minimally invasive surgery

Advanced dressings are designed to maintain a moist environment at the site of application, allowing the fluids to remain close to the wound but not spread to unaffected, healthy skin areas [25]. Several biomedical polymers are employed to be materials of hydrogel dressings such as polyvinyl alcohol, polymethacrylate, collagen, alginate, polyelectrolyte, water-soluble polymers, etc. [8–10, 14–16]. The relevance of the moist wound environment as a factor accelerating the healing process was first observed by Winter in 1962 but only recently has received more serious attention [26]. Dressings designed for moist wound healing are represented by hydrogel and hydrocolloid products. Both induce autolytic debridement, which facilitates the elimination of the dead tissue [27]. Hydrogel-based wound dressings are one of the most promising materials in wound care, fulfilling important dressing requirements, including keeping the wound moist while absorbing extensive exudate, adhesion-free coverage of sensitive underlying tissue, pain reduction of pain managements through cooling ability of hydrogel, and a potential for active intervention in the wound healing procedures [28, 29]. Because of the moisture provided to the wound from the moist hydrogel dressing with a moist swollen layer, common healing phases such as granulation, epidermis repair, and the removal of excess dead tissue become simplified. In addition to aiding the wound treatment stages, the cool sensation provided by the assistive hydrogel surgical dressing to the wound offers relief from pain for at least 6 hours. When hydration is provided

for the wound bed, discomfort experienced from changing the dressing becomes reduced, and the risk of infection also becomes decreased. Hydrogels are widely used as debriding agents, moist dressings, and components of pastes for wound care because of the moist ability of amphiphilic materials and structures such as semi-interpenetrating polymeric networks and interpenetrating polymeric networks (IPN). The IPN structure could be prepared from multiple cross-linking reactions via thermal or photochemical procedures. However, they do not need further wound fluids to become gels and are suitable for dry wounds [28, 29]. The so-called “moisture donor” effect of hydrogel surgical dressing helps autolytic debridement, increasing collagenase production and the moisture content of necrotic wounds [25]. At the same time, a protective polymeric film was used. Assistive hydrogel surgical dressing could absorb and retain contaminated exudate within the gel mass through expansion of cross-linked polymer chains resulting in isolation of bacteria and detritus molecules in the liquid. Their high-water content allows vapor and oxygen transmission to the wounds such as pressure sores, leg ulcers, surgical and necrotic wounds, lacerations, and burns. Assistive hydrogel surgical dressing seems to play an important role as emergency burns treatment alone or in combination with other products, thanks to their cooling and hydrating effects [26]. Hence, the hydrogel surgical dressing with a polymeric film was designed for using after carpal tunnel syndrome treatments via minimally invasive surgery as shown in **Figure 6**.

3.5 LLLT for carpal tunnel syndrome treatments after minimally invasive surgery

Figure 6A shows a new design of optical guided medical device with LLLT sources and its key functional components for wound healing. Furthermore, **Figure 6B** shows clinical applications of new designed medical devices for carpal tunnel syndrome treatments via minimally invasive surgery and the wound healing of internal and

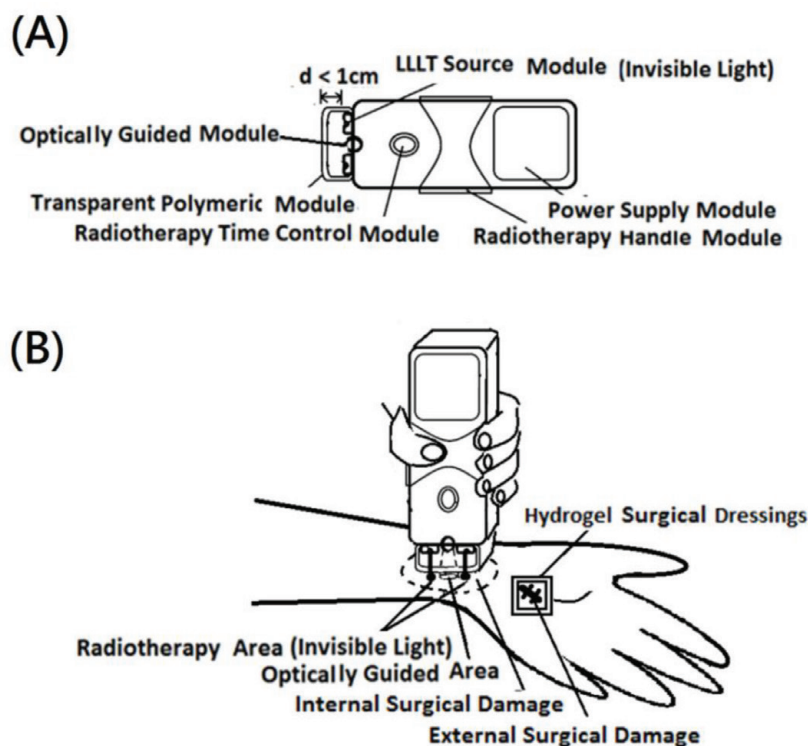


Figure 6. (A) New design of optical guided medical device with LLLT sources for wound healing (Transverse Industries Co-design) and its key functional components. (B) Clinical applications of new designed medical devices for carpal tunnel syndrome treatments via MIS and the wound healing of internal and external surgical damages after elective surgery.

external surgical damage after elective surgery. Practically, a series of new designed medical devices with LLLT sources were employed for healing in internal and external surgical damages. Most important, the designed medical devices with LLLT sources were used for internal surgical damage such as the target ligament healing and reducing inflammation under the skin. The medical device with LLLT sources showed no damage H-bonding or molecule interaction. LLLT sources are not enough to change and damage cell or tissue molecule structure, have no remarkable increasing temperature ($<0.1\text{--}0.5^{\circ}\text{C}$), and observed biological response being due to photobiostimulation. Most important, the designed medical devices with LLLT sources provide a kind of invasive immediately continuous treatments with no heat, no pain, no medicine, and no needle for internal surgical damage healing after MIS to greatly reduce the potential harms to the body and enhance convenience of healing wounds. LLLT, phototherapy, or photobiomodulation refers to the use of photons at a nonthermal irradiance to alter biological activity. LLLT uses coherent light sources (lasers), noncoherent light sources consisting of filtered lamps or LED, or laser, and, on occasion, a combination of both. The main medical applications of LLLT are reducing inflammation and pain and promoting regeneration of different tissues and nerves [30, 31]. In the past, laser therapies have been used increasingly for the esthetic treatment of fine wrinkles, aged skin, and scars, a process known as photo-rejuvenation (**Table 1**) [32]. Recently, this approach has also been used for inflammatory acne (**Table 1**) [32]. LLLT involves exposing cells or tissue to low levels of light sources. This process is referred to as “low level” because the energy or power densities used are low compared with other forms of laser therapy such as cutting or thermally coagulating tissue. More recently, clinical treatments with LLLT have been found to stimulate or inhibit an assortment of cellular processes or cellular photobiostimulation [33]. The basic biological mechanism would be thought to be through absorption of specific light by mitochondrial chromophores, in particular cytochrome *c* oxidase (CCO), which is contained in the respiratory chain located within the mitochondria [34–36], and perhaps also by photoacceptors

Supplier	Device name	Wavelength (nm)	Clinical applications
PhotoMedex (Manchester, UK)	OMNILUX	415(±5)/633(±6)/830(±5)	Acne, photodamage, nonmelanoma skin cancers, skin rejuvenation, vitiligo, and wound healing after elective surgery
OPUSMED (Montreal, Canada)	LumiPhase-R	660	Skin firmness, rhytid depth, and wrinkles
Lightwave technologies (Phoenix, AZ)	Lightwave professional deluxe LED system	630/880	Antiaging and skin rejuvenation
Dynatronics (Salt Lake City, UT)	Synergie LT12	660/880	Antiaging, skin firmness, wrinkles, skin tone, and texture for face and neck
Transverse (Taipei, TW)	TI-816	830/660	REHACARE, pain management, skin rejuvenation, wound healing after surgery, and nerve regeneration

Table 1.
 The designed medical devices with different LLLT sources for relative clinical applications [30].

in the plasma membrane of cells. A cascade of events occurs consequently in the mitochondria, which leads to biostimulation of various systems in specific clinical applications (**Table 1**) [37]. Furthermore, absorption spectra obtained for cytochrome *c* oxidase in different oxidation states could be recorded and found to be similar to the action spectra for biological responses to the light [37]. The absorption of laser light energy could cause photodissociation of inhibitory nitric oxide (NO) from cytochrome *c* oxidase [38], leading to enhancement of enzyme activity [39], electron transport [40], mitochondrial respiration, and adenosine triphosphate production (**Table 1**) [41, 42]. LLLT is now used to treat a wide variety of ailments (**Table 1** and **Figure 6**) [30, 43–54]. In turn, LLLT alters the cellular redox state, which induces the activation of numerous intracellular signaling pathways, and alters the affinity of transcription factors concerned with cell proliferation, survival, tissue repair, and regeneration (**Table 1** and **Figure 6**) [34, 35, 44–54]. The medical devices with different LLLT sources are designed for relative clinical applications as listed in **Table 1**.

3.6 Clinical evaluation of carpal tunnel surgical procedure with the new designed medical devices

The clinical evaluation of carpal tunnel surgical procedures with the new light guided medical device was studied by a design of “clinical evaluation table of carpal tunnel surgical procedure.” Also, three kinds of finger activities such as clenching, finger splaying, and touching from the index finger to thumb could be employed for clinical evaluation of carpal tunnel syndrome as shown in **Figure 7A–C**, respectively. Difficulty in the movement or coordination of the fingers in one or both hands hints possibility of carpal tunnel syndrome. It is because the median nerve would pass through the carpal tunnel to receive any kind of sensations from the thumb, index, and middle fingers of the hand. Numbness and tingling of the thumb, index, and the middle fingers in the hand are clinical evaluations for carpal tunnel syndrome by using three kinds of finger activities (**Figure 7**). The area of numbness and tingling of the thumb, index, and the middle fingers in the hand could be marked in the “clinical evaluation table of carpal tunnel surgical procedure” (**Table 2**). The red part involves the muscular dystrophy position of carpal tunnel syndrome as shown in **Table 2a**. The red marks of suture as shown in **Table 2b** indicate the cut position of carpal tunnel surgical procedure. Also, the “Suggesting Procedure before carpal tunnel surgical procedure” and “Suggesting Procedure after carpal tunnel surgical procedure” could be reported in the designed clinical evaluation table of “Carpal Tunnel Syndrome Treatments via minimally invasive surgery by using designed medical devices.”

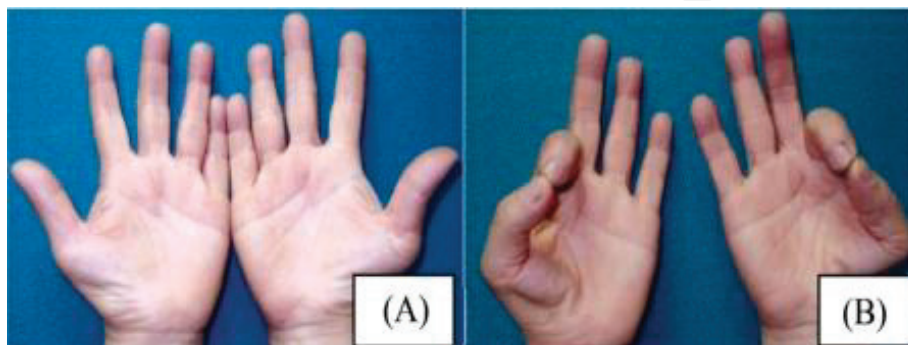


Figure 7. Photos of two kinds of finger activities such as (A) finger splaying and (B) touching from the index finger to thumb for clinical evaluation of carpal tunnel syndrome [1].


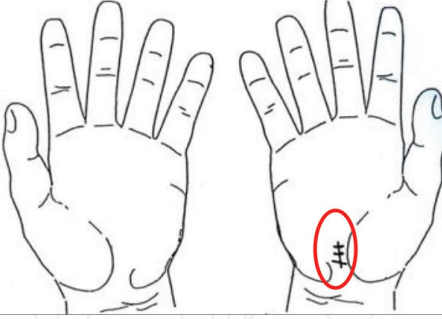
(a) Before carpal tunnel surgical procedure	(b) After carpal tunnel surgical procedure
	
<ul style="list-style-type: none"> • Suggesting procedure: (Date: mm, dd, yyyy) 	<ul style="list-style-type: none"> • Suggesting procedure: (Date: mm, dd, yyyy)
<ol style="list-style-type: none"> 1. Carpal tunnel syndrome treatments via minimally invasive surgery 	<ol style="list-style-type: none"> 1. The wound healing of internal and external surgical damage after minimally invasive surgery 2. LLLT for internal surgical damages 3. The air-foaming soft cleaning surgical sponge for soft cleaning external surgical damages 4. The hydrogel surgical dressing for external surgical damages

Table 2.
 The clinical evaluation table of “Carpal tunnel syndrome treatments via minimally invasive surgery by using designed medical devices” [1].

4. Summary

This study provides a novel design and fabrication of optical guided medical devices with a light scattering module for carpal tunnel syndrome. The LED light or laser could be employed as optical guided modules. A new medical device with optical LLLT module and a series of assistive surgical healing dressings such as air-foam soft cleaning sponges and hydrogel surgical dressings were also designed for wound healing in carpal tunnel syndrome treatments. Last, the designed medical devices such as optical guided medical devices and assistive surgical dressings could be found as a powerful device not only for carpal tunnel syndrome but also for related clinical applications.

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Author details

Ching-Cheng Huang^{1*} and Ming-Che Chiang²

1 Department of Biomedical Engineering, Ming-Chuan University,
Taoyuan, Taiwan

2 Neurosurgery Department, Taichung Veterans General Hospital,
Taichung, Taiwan

*Address all correspondence to: junas.tw@yahoo.com.tw

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