









Experimental Study of In-Body Devices Misalignment Impact on Light-Based In-Body Communications

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Abstract. Optical wireless communication (OWC) has emerged as a promising technology for implantable medical devices because it provides private and secure wireless links for patients, low-power consumption, and high-speed data transmission. The OWC system's receiving end typically relies on a photodetector with a limited field-of-view, necessitating direct line-of-sight connections for effective transmission. The directional nature of light-tissue interaction on the in-body communication can be problematic as the quality of the optical signal is rapidly deteriorated due to the properties of biological tissues, including scattering, absorption, and reflection, leading to a substantial loss of optical beam power reaching the photodetector's sensitive area. In this sense, any misalignment that occurs in the in-body device can directly impact the power level and further degrade the received signal quality. Numerous studies have been conducted on this topic in free-space environments; nevertheless, only a few results have been found for in-body cases. In this work, we experimentally demonstrate the impact of the in-body device misalignment on the OWC-based in-body communication system. Three cases were investigated: aligned systems, as well as lateral and angular misalignments. We considered an 810 nm Near-infrared (NIR) LED as a transmitter because the optical signal of the mentioned wavelength propagates better than other wavelengths through biological tissues. For the experiments, we used pure muscle and fat tissues with 15 mm thickness at different temperatures (23 °C and 37 °C). We also tested with thicker meat samples (30 mm, 38 mm, and 40 mm, consisting of muscle + fat layers) at 37 °C. This study adhered to ANSI Z136.1–2007 safety standards. First, the results reveal that optical power still reaches the receiver in an aligned reference case at a meat thickness of 40 mm. Second, the in-body device misalignment significantly degrades the optical power density received, which is more pronounced under lateral than angular conditions. These misalignment effects must be carefully considered for further system enhancement when using OWC for the in-body communication system.

Keywords: Biological tissue · Optical wireless communication · in-body device misalignment · In-body communication · Near-infrared

1 Introduction

An implantable medical device (IMD) is one of the in-body medical devices that provides various benefits to patients, including real-time health monitoring and precise body treatment purposes [1–4]. For this reason, it is crucial to conduct extensive research in advancing wireless IMD systems to enhance the quality of life for patients. Light-based communication, also known as optical wireless communication (OWC), is well-suited technology for various IMDs because it facilitates energy-efficient and high-speed data communication for nerve recording and prostheses [5]. Numerous researchers have investigated OWC for in-body data transmission, and experimental evidence has confirmed its feasibility [6–13]. OWC presents an attractive option for in-body communication due to its low power consumption, typically ranging from a few microwatts to less than 10 milliwatts, even at high data rates; in contrast, conventional radio frequency (RF) requires power consumption in tens of milliwatts which higher than OWC [5]. OWC works typically under aligned connections, where the transmitter and receiver are in the same line (direct line-of-light), enhancing the protection of medical implants against unauthorized access and ensuring the patient's comfort and well-being [14]; this attribute of OWC contributes to its efficacy in addressing privacy concerns [15]. Besides, OWC offers advantages over traditional RF communication, including avoiding radio interference [16]. OWC covers light spectrums, including ultraviolet, visible light, and infrared.

OWC commonly employs a photodetector with a limited field-of-view (FOV) at the receiving end [17], which presents a significant challenge in providing seamless wireless network connectivity. In essence, OWC transmissions heavily rely on line-of-sight links [18]. Consequently, propagation through OWC channels is usually configured to be highly directional [19]. In the context of in-body communication applications, the performance of OWC links for transmitting data within the human body can be significantly degraded due to the high level of signal loss (attenuation) caused by natural phenomena in the biological tissue such as absorption, scattering, and reflection, along with the occurrence of random misalignment between the transmitting and receiving ends. In the OWC system, generating rather narrow beams for the optical links is a common practice, though their strength rapidly diminishes as it propagates across the tissue, affecting the quality of the received signal [20]. Accordingly, it is imperative to account for variations in receiver/transmitter orientation when employing OWC for the in-body communication system. The position of in-body devices might change and it creates two events of misalignment, i.e., lateral (the device is shifted) or angular (the device is tilted) from its original position due to undesirable events, for instance, an inadequately set transmitter/receiver of IMDs. The in-body device contains transmitter and receiver parts to communicate with out-body counterpart device. This changing position can significantly impact the signal quality in the OWC link. Improving OWC for in-body communication remains a prominent research subject due to the need to address certain limitations, such as how to overcome signal losses due to factors on light-biological tissue interactions and misalignment event [5]. Misalignment is one of

the crucial reasons in degrading the OWC systems' performance which will be elaborated in this paper.

Investigating the influence of receiver position and orientation is essential to understanding how the OWC system will operate in a realistic environment [17–19]. Nonetheless, there is still little research on this topic, specifically in the in-body communication context. A seminal work in [21] observed the efficacy of light-based in-body communication and found that the dependability and effectiveness of the transdermal connection are significantly affected by transmitter (out-body device) misalignment. However, the research in [21], it was carried out through simulated scenarios rather than realistic environments and it was considered as a shorter range application (transdermal application). For this study, we consider a deeper link compared to [21], where the effect of misalignment will be more pronounced than across very short links.

Figure 1 illustrates the type of receiver's misalignment in the context of OWC-based in-body communications, i.e., lateral and angular, that will be investigated in this paper. The scenario is derived from literature [22]; they focused on the transmitter part (external or out-body device), while this study will more emphasize the in-body device, thereby reasoning a novelty aspect and worth being carried out. The signal quality received by in-body device is greatly influenced by the alignment between positions of on-body and in-body devices. Nevertheless, ensuring the operation in ideal conditions is challenging due to the possibility of misalignment on the in-body device, for example inadequately set the antenna of IMDs, as addressed by various researchers done in RF technology [23–26]. To the best of our knowledge, this is the first paper that elaborates on the in-body device misalignment effect on OWC performance conducted in a realistic setting.

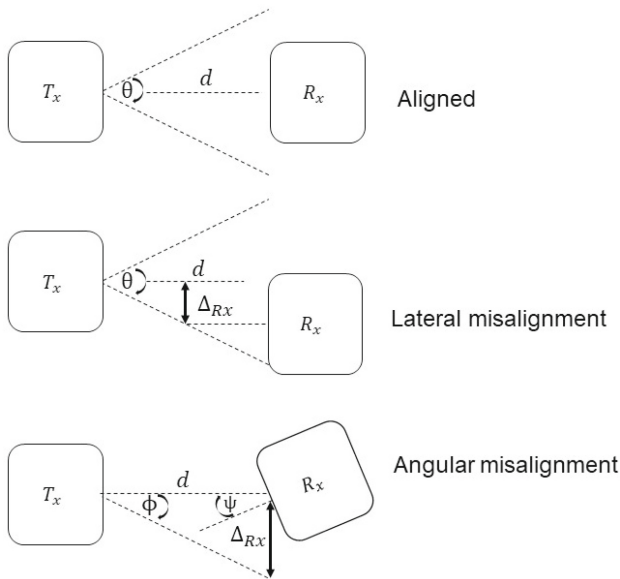


Fig. 1. In-body device's misalignment modelling, modified from [22]. The communication system consists of transmitter (T_x) and receiver (R_x) where d denotes as distance between T_x and R_x , Δ_{R_x} represents the distance of misalignment, ψ denotes a half of receiver's FOV, ϕ denotes a half of transmitter's FOV, and θ denotes transmitter's FOV.

For this reason, this paper will fill the gap by investigating the impact of misalignment on the performance of OWC links for in-body communication. Specifically, this study focuses on the angular or lateral misalignment that may occur at the in-body device in practical applications. Our experimental investigation was based on trials using *ex vivo* fresh pork meat samples (fat and muscle tissues with 15 mm thickness). Measurements were taken at two different temperatures, i.e., 23 °C and 37 °C. A Near-infrared (NIR) LED with a wavelength of 810 nm was chosen due to the light's favorable penetration capabilities in biological tissues [16]. The rationale behind presenting the results at 23 °C and 37 °C was to emphasize the significance of preheating meat samples in the measurement, as previous research mostly neglect this when they examine samples at room temperature without prior heating [27]. In addition, thicker meat samples composed of fat and muscle layers were also used (30 mm, 38 mm, and 40 mm), which were measured when the sample temperature was set at 37 °C.

Contribution: (i) This study contributes to explore the potential risk factors associated with postoperative misalignment: lateral and angular cases. (ii) We showed the importance of temperature matching to the human body (around 37 °C) for *ex vivo* experiment on light-based in-body communications. (iii) Compared to [21] that used thin pork meat samples, our study considered using thicker meat sample. (iv) fat has been found to be a good propagation channel compared to muscle for light-based in-body communications.

2 Methodology

Figure 2 shows the experimental setup in OWC-based in-body communication employed in this study to represent the in-body device's misalignment. This setup refers to Fig. 1, which encompasses three cases: aligned configuration (transmitter–receiver in the same line), angular (receiver is slightly tilted), and lateral (receiver is slightly shifted). In the aligned reference case, the transmitter was directed or exposed towards the surface of the meat sample, while the receiver was positioned precisely on the opposite side. In the angular misalignment case, the receiver was inclined at an angle of $\psi = 30^\circ$ from its original position. While in the lateral misalignment case, the receiver was displaced by $\Delta_{Rx} = 2$ cm from its original position. In this experiment case, the transmitter is considered as out-body device, whereas receiver is considered as in-body device.

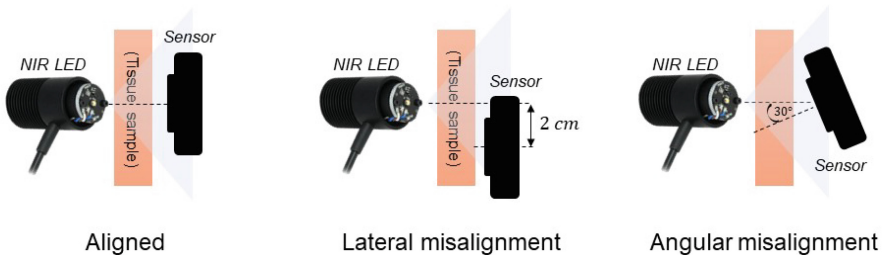


Fig. 2. Experimental setup of three different cases.

An experimental test-bed was constructed primarily using commercially available components produced by Thorlabs (Fig. 3). The test-bed comprises transmitter units (Thorlabs LED driver DC2200 and M810L3 LED modules) and a receiver unit (PM100D optical power meter and S121C optical sensor). The LED has $\theta = 80^\circ$ (narrow beam angle) and it operates at 810 nm and is driven by 500 mA maximum current. The LED driver is fed to the LED through the provided port. The LED driver can be controlled using the provided digital display on its front panel. A constant current mode of the LED driver was used for this study. By controlling the LED driver, the input current to the LED was varied, i.e., 20% (100 mA), 40% (200 mA), 60% (300 mA), 80% (400 mA), and 100% (500 mA). The transmitted power of the LED, depending on the applied electrical current, was set to be 74.2 mW, 153 mW, 230 mW, 303 mW, and 372 mW for 100 mA, 200 mA, 300 mA, 400 mA, and 500 mA, respectively. Data modulation over a power carrier can also increase signal bandwidth, enabling higher data rates transmission [28]. However, the transmitted power must be set below a certain limit as it can create heat and damage biological tissues. In this study, the fully transmitted optical and incident power of LEDs were measured at 372 mW and 525 mW/cm², respectively, driven by 500 mA. It should be emphasized that the LED remains within the safe range, as it falls below the maximum permissible limit of the LED's incident power specified in the ANSI.Z136.1–2007 safety standard, which is 2W/cm² for a one second exposure.

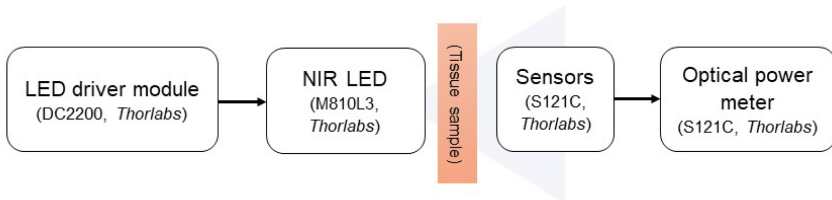


Fig. 3. Test-bed for experiment.

This study utilized two fresh pork meat samples as the optical medium, i.e., pure muscle tissue and pure fat tissue. Each sample had dimensions and thickness of approximately 50 mm × 50 mm and 15 mm, respectively (Fig. 4). When initially purchased from the market, the fresh samples were at 11 °C (measured using a thermometer). Subsequently, they were heated to 23 °C and 37 °C for measurements. To do this, we designed a small chamber heated by an off-the-shelf heater; it is plexiglass box equipped with temperature control (STC-1000) and a blower. To preserve meat sample quality from potential detrimental effects such as excessive evaporation and damage caused by high temperatures, it was imperative to carefully control and maintain their temperature below 40 °C [3]. The received optical power density of the meat sample was measured using the mentioned optical power meter. The attenuation was manually adjusted to 0 dB, and the mentioned optical power meter provides various measurement modes. However, only a single parameter, specifically power density (in W/cm² unit), was utilized for this study.

Figure 5 shows the pork meat samples with different thicknesses. Figure 5(a), (b), (c), are then denoted as sample #1, #2, and #3, respectively. The #sample 1 was composed by 25 mm fat + 5 mm muscle tissues. The #sample 2 is composed by 15 mm muscle +

23 mm fat; therefore, it can be denoted by more fatty tissue. The #sample 3 is composed by 20 mm muscle + 20 mm fat, that can be denoted as musculus tissue. The objective of this scenario is to clearly present the results in OWC for in-body communication, explicitly highlighting how fat is a suitable medium for propagation, similar to RF communication schemes [27, 29, 30]. Additionally, our investigation reveals that a thicker fat sample can yield a satisfactory reception power level, whereas a sample with more muscle (musculus) may not even transmit a signal, viewing from three different cases: aligned, lateral, and angular.

It is affirmed that ethical aspects are not applicable to this study, as it did not involve any human or live animal subjects. The fresh pork meats utilized in the study were procured from a local market selling various meat cuts, including those derived from pork, thereby exempting the study from being classified as an animal experiment.

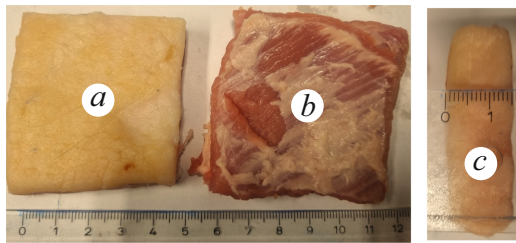


Fig. 4. Photographs of pork meat samples: (a) fat tissue, (b) muscle tissue, and its (c) thickness.

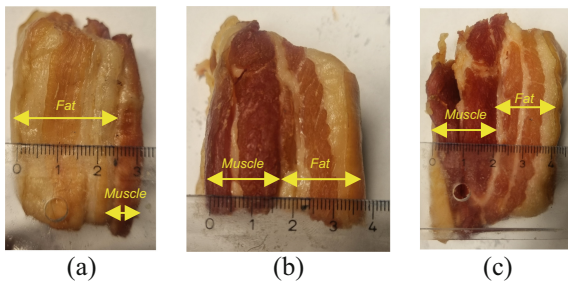


Fig. 5. Photographs of the used pork meat samples with different thicknesses: (a) 30 mm, (b) 38 mm, and (c) 40 mm.

3 Results and Analysis

3.1 Fat and Muscle Tissues Comparison

Figure 6(a) and (b) show the results of optical power comparison measurements observed on a power density scale (mW/cm^2) for fat and muscle tissue samples, respectively. The power density was measured after the NIR light passed these pork meat samples. The graph encompasses both samples under cold (23°C) and warm (37°C) conditions. In

top-level analysis, the amount of received power is changes linearly with the transmitted optical power: the higher the transmitted power, the higher the received power, and vice versa. On the other hand, meat samples were heated to a particular temperature close to the human body (around 37 °C), resulting in an increased transparency of the biological tissue, allowing for better light propagation through the tissue. These findings suggest that when conducting experiments involving meat samples in the context of the in-body communication system employing OWC, the meat samples should be heated or warmed to match human body temperature conditions rather than kept at room temperature because the power results are better at 37 °C where this temperature is more realistic than 23 °C. Most of the papers in the literature did not consider tissue temperature matching in which they used the temperature room. Note that in a realistic scenario, a temperature of 23 °C is basically not possible as the temperature is well below human life-sustaining temperatures. For this reason, matching to ~ 37 °C for any experiments using *ex vivo* samples should be considered.

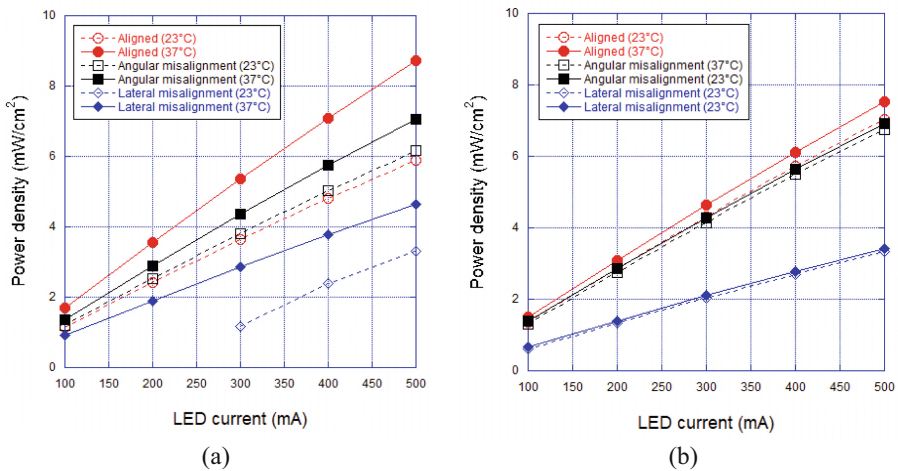


Fig. 6. Results of measurement on different tissue samples: (a) fat tissue, (b) muscle tissue.

3.2 In-Body Device's Misalignment Comparison

The results of the measurements for the aligned, angular, and lateral cases, can be seen in Fig. 7(a), (b), and (c), respectively. In the aligned scenario, the receiver is positioned perpendicular to the transmitter, resulting in the attenuated received power density being solely influenced by the natural characteristics of the biological tissue, such as absorption, scattering, and reflection. Meanwhile, in the misalignment cases, the received power density will be lower than the aligned configuration, not only due to the natural properties of the biological tissue but also affected by the imperfection of the transmitter–receiver positioning. The misalignment in the OWC's receiving end leads to a suboptimal arrangement, and it can contribute to weakening the received power density compared to the aligned link.

According to the results, the receiver experiences higher power loss in the lateral misalignment case compared to the angular misalignment one. In the lateral misalignment case, when it delineates a realistic situation, the transmitter unit (an out-body device operated by the doctors or nurses) can be adjusted manually by shifting the transmitter over the patient's skin to keep aligned with the receiver end (in-body device), establishing an aligned connection. In contrast, the angular misalignment situation is more complex than the lateral misalignment as it may necessitate surgical intervention because the receiver's position is not ideal, resulting in financial burdens and potential psychological risks for the patient. However, this measurement demonstrates that further surgery is unnecessary, as the power loss remains within acceptable limits when the device is angular misalignment approximately 30° from its original position (aligned); this situation is accepted for fat and muscle tissues with 15 mm of thickness. The FOV of the photodiode is still tolerable in this case. Further investigation should be conducted, such as varying the photodiode's angle, for instance, 45° , 60° , 75° , etc.

This study has confirmed existing literature that communication through biological tissue using OWC is feasible, allowing for secure data transmission due to its limited aligned configuration [16]. This technology can be applied to various in-body devices such as pacemakers, defibrillators, insulin pumps, brain implants, cochlear implants, etc. Nevertheless, this advantage comes with a trade-off. Supposing there are physical disruptions that can impact the positioning of the in-body device (receiver end), resulting in misalignment occurrences (lateral and angular misalignments). These misalignments subsequently lead to a decline in the signal quality received. Further, a study addressing this factor is crucial to developing a reliable receiver-end device, for instance, by incorporating the automatic gain controller feature, which has been successfully implemented in many OWC free-space scenarios [31–34]. Besides, the results of this study could also be beneficial for the in-body device's positioning idea as in the capsule endoscopy use case [23], we could suggest setting optical sensors where muscle tissue is thinnest where abdominal muscles have this “six-pack form,” so that they do not have a constant thickness.

The findings depicted in Fig. 7 also confirm that fat tissue serves as a suitable propagation medium compared to muscle at approximating the human body's average temperature of 37°C [30]. Fat tissue is more vulnerable to temperature changes than muscle tissue. The received power density measured in these three scenarios remains within a safe range as defined by the ANSI.Z136.1–2007 safety standard.

Further investigation should address the characterization of out-body device misalignment (transmitter side). It is important to differentiate whether the results are identical to those observed on the receiver side when in angular or lateral misalignment cases. Accordingly, it is advisable to conduct experiments involving shifting and tilting on both the transmitter and receiver to distinguish how far the impact of their misalignments, assuming their equivalence.

3.3 Experiments on Different Thicknesses of Meat Sample

After obtaining individual comparison data between fat and muscle layers with a thickness of 15 mm each, the subsequent experiment involved three samples with different thicknesses (i.e., 30 mm, 38 mm, and 40 mm) consisting of fat and muscle layers. To

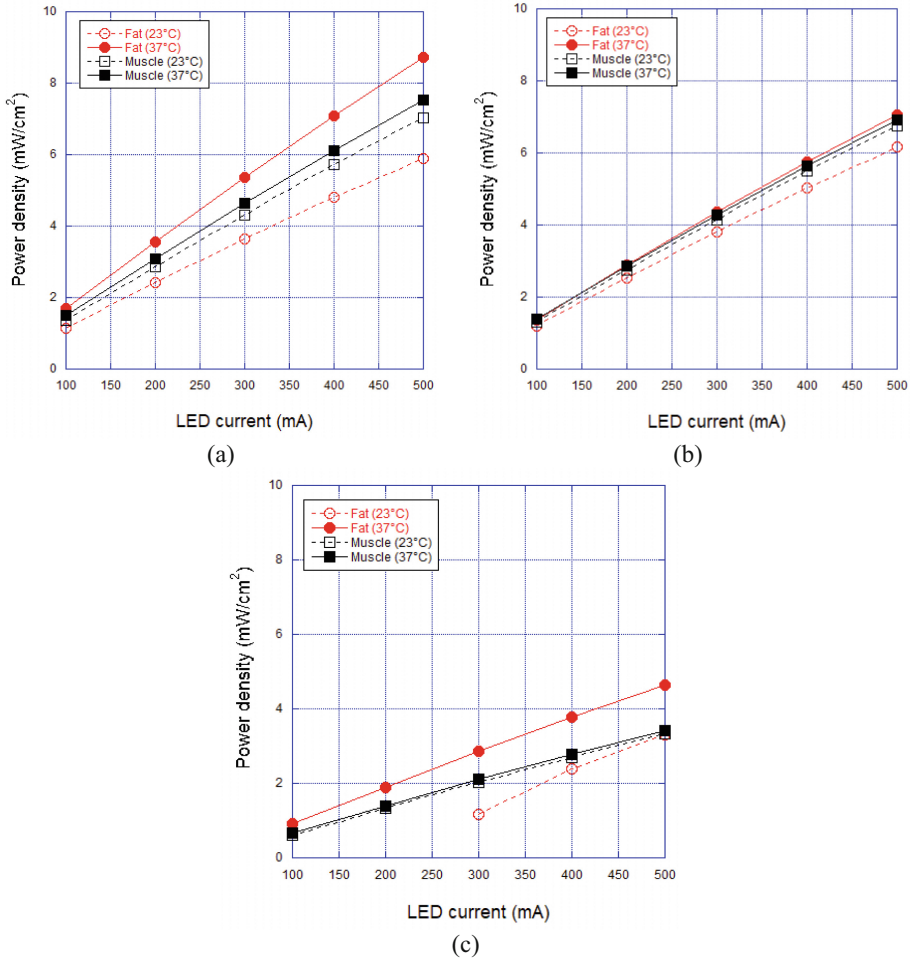


Fig. 7. Measurement results in different scenarios: (a) aligned, (b) angular, and (c) lateral.

better understand how much misalignments affects the OWC performance, measurements were also conducted in a free space channel with a separation distance of 40 mm. In alignment cases, the NIR light beam was directed towards the sensor (receiver). The receiver position is changed from the origin for misalignment cases.

As shown in Fig. 8, the maximum power density in the free space scenario (LED’s driving current = 500 mA) is 63.7 mW/cm² in which the power density observed in the free space test remains within the safe limits outlined in the standard. The corresponding power densities for lateral and angular misalignments were 59.4 mW/cm² and 7.25 mW/cm², respectively. On average, the received power in lateral and angular misalignments amounted to 93% and 11% of the aligned situation, respectively. These findings suggest that the received power density loss in lateral misalignment is more significant than that caused by angular misalignment.

Figure 9 depicts a photograph of the experimental setup in this study, wherein an 810 nm NIR LED emits optical power to the sensor as a receiver through a pork meat sample. The sensor was used to measure the received power density. The photograph visualizes experiment on aligned reference case under 30 mm of tissue thickness.

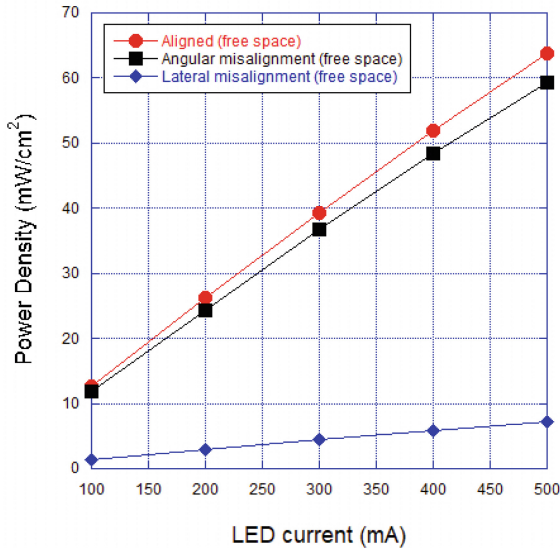


Fig. 8. Measurement results in a free space experiment (40 mm of distance).

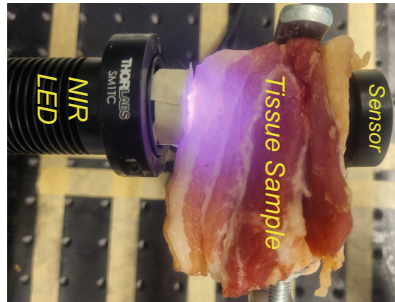


Fig. 9. A photograph of experimental setup (aligned reference case).

As shown in Fig. 10, optical power can still be received at a depth of 40 mm in the aligned cases for #samples 1, 2, and 3. However, the power received in #sample 1 is higher than #samples 2 and 3 due to a more significant proportion of fat layer composition. Conversely, #sample 3 exhibits the lowest optical power reception due to a higher percentage of muscle layer composition. Significant optical power attenuation is evident in angular misalignment for #sample 1. Moreover, #samples 2 and 3 do not receive any optical power in cases of misalignment. Accordingly, misalignment factors

should be considered when designing OWC-based in-body device system (or later can be called as optical implants) for tissue thicknesses up to 40 mm.

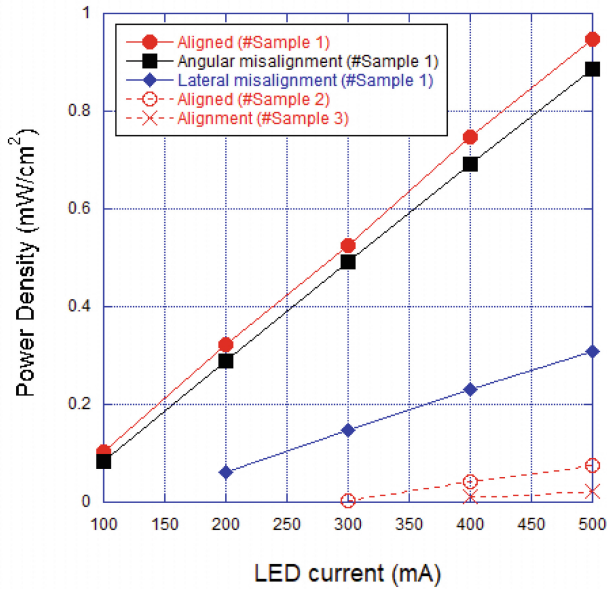


Fig. 10. Measurement results in different sample thickness.

The result shows that fat tissue has better propagation than muscle tissue for optical channels (Fig. 6), a finding consistent with observations conducted in RF case as done by [29]; where this study explored the potential use of the fat layer as a propagation medium for ultra-wideband (UWB) based medical applications through experiment and simulation approaches. The fat layer demonstrated less decreased RF signal loss than other tissues under investigation [29]; RF waves propagated through the fat tissue from the abdomen to the back of an individual, with a power loss of 60 dB.

By seeing overall measurements, we have clearly investigated the aligned, lateral, and angular misalignments in pure muscle and fat tissues at different temperatures and varying meat thicknesses.

3.4 Limitations of the Study

In this study, we have explored the impact of misalignment in in-body OWC systems using an 810 nm NIR LED transmitter on *ex-vivo* testing. We only focus on specific scenarios and conditions, such as postoperative misalignments, temperature matching, and tissue thickness. The experiment only used two samples (fat and muscle) with a thickness of 15 mm each, which may oversimplify the complexity of in-body tissue environments. On the other hand, concerns may arise regarding the generalizability of the findings to diverse clinical or real-world settings, potentially limiting the broader

applicability of the results. Future studies should consider more thickness of meat sample in order to capture the full spectrum of conditions encountered in actual clinical scenarios, and using meat temperatures ranging 36 – 40 °C to match the average of human body. Therefore, the results will be more realistic. Our investigation only justified the choice of the 810 nm peak wavelength for its penetration capabilities. Hence, concerns are raised about the exclusive focus on a single wavelength. In future, we can employ NIR LED with different wavelength ranging NIR I ($\lambda = 700\text{--}900$ nm) and NIR II ($\lambda = 1000\text{--}1700$ nm) windows [35]. One potential broadband NIR LED that can be used further experiments including MBB1L3 ($\lambda = 470\text{--}850$ nm), MBB2L1 ($\lambda = 770$ nm, 860 nm, and 940 nm), MBB2LP1 ($\lambda = 770$ nm, 860 nm, and 940 nm), which are provided by Thorlabs. The last limitation of this study is the experiment relies on static conditions and may not account for real-time biological dynamics, such as movement or deformation of tissues during normal bodily activities. These aspects should be considered in the future works, which is involve dynamics situation.

The initial findings of this study also highlight the significance of considering the losses incurred from misalignment when designing robust OWC systems. Moreover, it is recommended to incorporate a digital system for subsequent analysis. It transmits data in bitstreams to determine the threshold at which the optical communication link can still be reliable while considering the optical signal losses resulting from misalignment. This approach takes into account not only the allowable limit of received power as adhered by ANSI.Z136.1–2007 safety standard, but also acknowledges the trade-off between received power and sensitivity. Furthermore, future investigation should consider the impact of misalignment on the OWC link by analyzing parameters such as throughput, signal-to-noise ratio (SNR), bit-error rate (BER), and other quality of service (QoS) indicators.

Previous studies have demonstrated that optical communication links can still be maintained with a tissue thickness up to 40 mm in aligned position under a received power of tens μW [16]. Additionally, other studies have revealed that OWC system can be demonstrated at extremely low-intensity levels with the communication speed trade-off [36]. Based on prior research, it is hypothesized that communication can persist even though misalignment at the in-body device occurs, with a trade-off resulting in a decrease in the wireless data communication speed. However, there is a threshold of communication link loss due to excessive misalignments where the optical signal received is very weak in which we will address it in future studies.

4 Conclusion

This study has investigated the in-body device misalignment impact on the performance of OWC-based in-body communication in different realistic scenarios. The experiment utilized a NIR LED with a wavelength of 810 nm, as it is known to have better penetration capabilities through biological tissue than other wavelengths. Two samples (fat and muscle) with a thickness of 15 mm each were used in the experiment at a temperature of 23 °C. The meat sample was also heated to a temperature closer to the average human body, 37 °C, for comparison. The study evaluated three cases of misalignment on the receiver side: aligned (considered the ideal or baseline condition), angular, and lateral

misalignments. Experiments on different thicknesses of meat samples were conducted carefully as well. The results showed that a meat sample with a fatty layer has the potential to achieve a desirable level of reception power density, as evidenced in #sample 1 and #sample 2, while a sample with a higher proportion of muscle does not possess the capability to transmit a signal properly, even though it is an aligned case, as proved in #sample 3.

The findings indicate that a misalignment situation on the in-body device point-of-view can negatively impact the performance of OWC for an in-body communication system, as the light that propagates through biological tissue may not reach the photodetector's sensitive area on the in-body device due to limited FOV. Furthermore, the signal quality received in the lateral misalignment case was poorer than in the angular misalignment case, primarily due to decreased received power density. Future studies will consider the tissue thickness, misalignments in the transmitter side, combination of lateral – angular misalignment, and practical methods to find alignment position.

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