Making Healthcare Safe and Accessible:
Olive Healthcare's Non-Invasive, High Precision
Wellness and Medical Diagnostics Solutions

The Technology & Foundation White Paper

Olive Healthcare
Healthy Today, Better Tomorrow

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This document serves as a comprehensive guide to Olive Healthcare's NIRS technology and its application within the wellness product line. An overview of the technology, along with summaries of key studies that provide the foundation for the development of the products and core technology is presented.

Our commitment to excellence is demonstrated through rigorous clinical studies, ensuring the highest quality and precision. We continually advance our technology through collaborations with prestigious institutions and esteemed partners, staying true to our mission.

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Introduction: Elevating Healthcare with Cutting-Edge NIRS Technology

Founded in 2016 in Seoul, South Korea, Olive Healthcare emerges as a pioneering leader in the domain of wellness devices and medical diagnostic equipment, driven by its expertise in groundbreaking NIRS (Near-Infrared Spectroscopy) technology.

Our core mission is to seamlessly integrate healthcare services into individuals' lives, offering the tools and insights needed for healthier living. We aim to provide values to enhance the quality of people’s lives in various healthcare areas.

Our commitment to this mission is epitomized by our strategic incorporation of state-of-the-art NIRS technology, a non-radiative and non-invasive diagnostic system that, when blended with artificial intelligence algorithms and extensive big data processing, enables highly personalized healthcare services.

With the exclusive patent license secured from UCI, we have built a substantial portfolio of new patents, all centered around the core technology that powers our medical and wellness devices, solidifying our technological infrastructure and our core capabilities.

In recent strides, our breast cancer diagnostic device, Eileen, has excelled in research and clinical trials, boasting remarkable sensitivity and specificity. The product is now advancing through the validation trials stage, promising a breakthrough in breast cancer diagnosis.

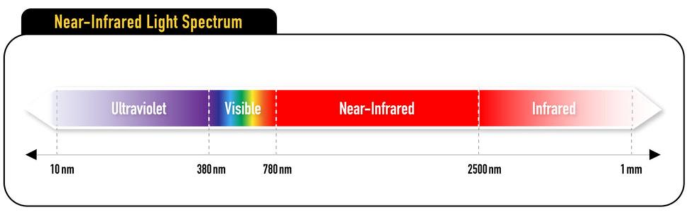
Our product line has been further enriched with the world's first near-infrared-based handheld body fat analyzer, Bello, and Fitto, a pioneering muscle analyzer, both contributing to advancements in health management.

As we continue to progress, Olive Healthcare remains dedicated to developing a range of health products and service solutions, spanning diverse sectors such as skincare, senior care, and beyond.

NIRS (Near-infrared Spectroscopy): The Core Technology

Illuminating the Unseen World

NIRS, or Near-Infrared Spectroscopy, lies at the core of Olive Healthcare's innovative wellness devices and medical diagnostic equipment. It is the art of interpreting matter's interaction with light, specifically in the near-infrared range just beyond the bounds of our naked eye's perception.

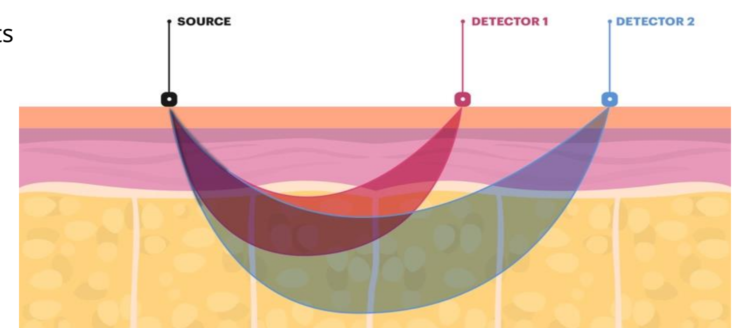


A powerful analytical technique, NIRS is instrumental in a wide array of applications, extending across medical, pharmaceutical, agricultural, and food science fields.

Through NIRS, we gain access to intricate knowledge about substances, including the complexities of the human body. Its capabilities make it the driving force behind our healthcare solutions, offering unprecedented insights into health and well-being.

Fundamentals of NIRS

1. **Interaction of Light:** When light interacts with an object, it undergoes a complex process. Some of the light is absorbed, while the rest is reflected, and this interaction depends on the molecular composition of the object. Different substances exhibit unique interaction patterns at specific wavelengths.



2. **Quantitative Measurement:** NIRS quantifies these interactions of near-infrared (NIR) light, allowing for the revelation of an object’s composition and properties.

3. **Versatile Applications:** NIRS finds applications in various fields, including medical monitoring (such as tracking tissue oxygenation and blood flow), neuroimaging (for non-invasive brain function studies), quality control and testing in the food and agriculture industry, as well as a wide range of biological and chemical analyses.

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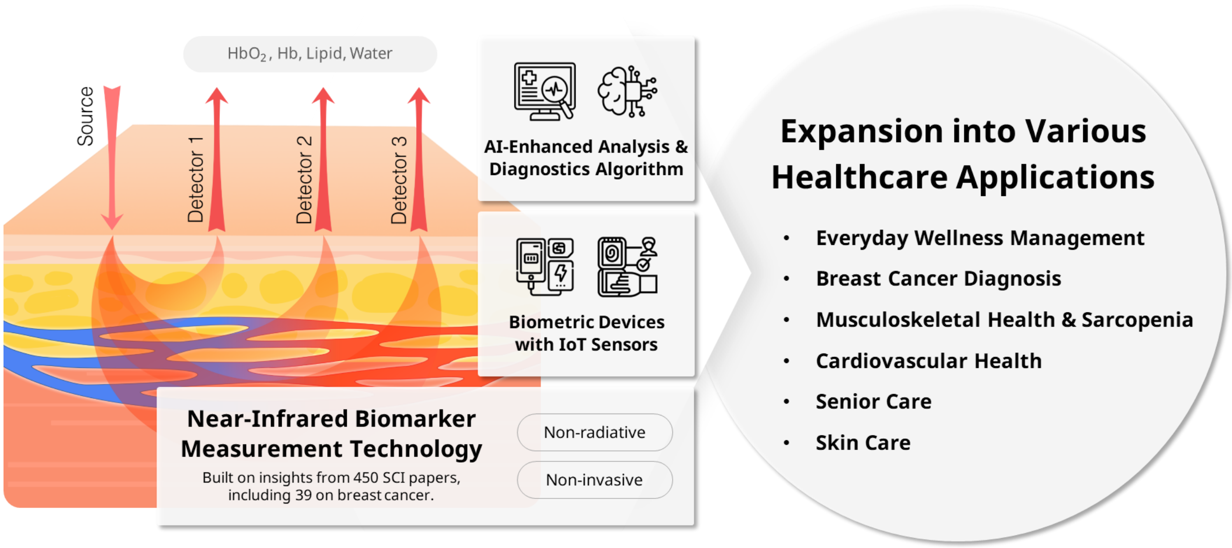
Advanced Precision with DMW-NIRS (Discrete Multi-Wavelength Near-Infrared Spectroscopy)

In our devices, we leverage cutting-edge DMW-NIRS technology, elevating NIRS to new heights through the incorporation of multiple near-infrared light wavelengths and advanced AI technology. Our AI technology is what enables the measurement of chromophore concentration from the use of only several wavelengths, further enhancing the accuracy. This innovation allows for the precise measurement of critical tissue components, including water (H_2O), lipids, oxyhemoglobin (HbO_2), and deoxyhemoglobin (HHb).



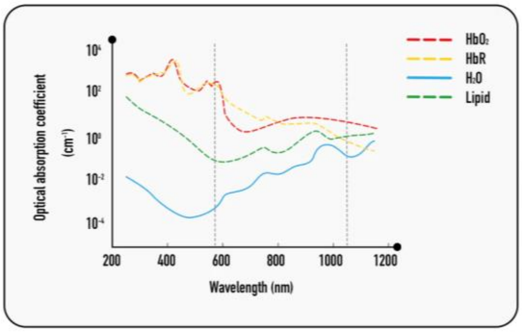
Olive Healthcare's exclusive advanced diagnostic algorithm, offering real-time data insights and a wide range of applications, positions it at the forefront of substance analysis. It excels in diagnosing specific conditions such as breast cancer and assessing muscle health. DMW-NIRS is a potent tool for evaluating various health parameters, including cancer, in a non-invasive and radiation-free manner.

Advantages of Olive Healthcare’s DMW-NIRS Technology

1. **Speed and Accuracy** Rapid and precise results provide real-time insights for informed decision-making.
2. **Simultaneous Analysis** The capability to analyze multiple components at once allows for efficient and speedy analysis, optimizing the user experience.
3. **Flexibility and Expandability** NIRS is a versatile tool adaptable to various applications, making it an ideal solution for personalized healthcare.

DMW-NIRS Technology in Wellness Devices

Our wellness products, Bello and Fitto, harness the remarkable power of NIRS to provide users with precise insights into their everyday wellness. The process is user-friendly and provides real-time, actionable data to help individuals make informed decisions for their well-being:



1. **Measurement**: With press of the button, the interaction of the near-infrared light emitted from the device's 8-wavelength NIR LED light source with the body's tissues is meticulously measured by our medical-grade sensors.

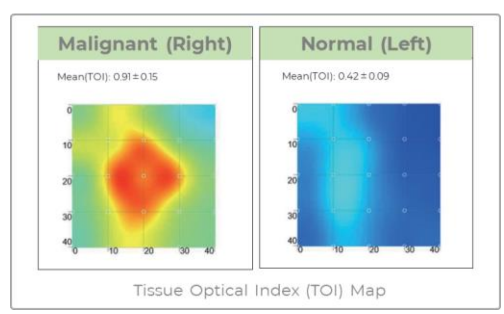
2. **Quantitative Analysis**: NIRS technology quantitatively analyzes chromophores, specific components of molecules responsible for light absorption. It examines key tissue components, including lipids, water (H_2O), and deoxyhemoglobin (HHb).

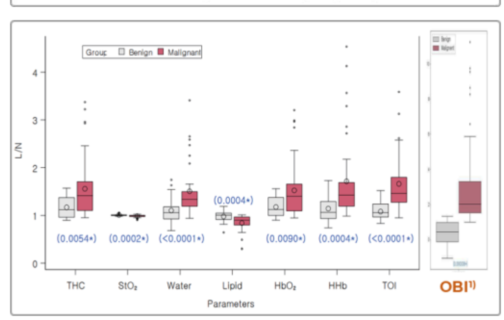
   These chromophore values are subsequently calculated and analyzed by Olive Healthcare's AI diagnostic algorithm to generate various biomarker indices, facilitating the understanding of fat and muscle conditions within our bodies.

3. **Comprehensive Health Insights**: Users receive an analysis report, referred to as 'scan results,' that provides essential biomarkers encompassing critical health parameters, the fat and muscle composition. These insights are instrumental for various aspects of everyday wellness, from weight management and muscle training to bodybuilding and metabolic health monitoring, with key metrics such as body fat percentage, lean muscle mass, body balance, and muscle quality.

DMW-NIRS Technology in Medical Diagnosis

The applications of this technology extend to the diagnosis of medical conditions, including cancer, sarcopenia, and skin disorders. For example, during the cancer development process, known as angiogenesis, significant changes occur in water, lipids, and hemoglobin levels. Using NIRS, real-time monitoring and measurement of these alterations is possible in a painless, non-invasive, radiation-free way. Advanced diagnostic algorithms and malignancy index, which has been meticulously developed through rigorous clinical studies, trials, and validation processes provides a tool for cancer diagnosis with exceptional accuracy and reliability.





From Clinical Trial with Yonsei University Severance Hospital

Efficacy and Safety Test of DMW-NIRS for Dense Breast Patients

- Sensitivity: 97.3%, Specificity: 95.7%, AUC: 0.993)
- Study involving 62 breast disease patients (37 malignant, 25 benign)
- Early detection of malignant tumors as small as 7mm possible
- Confirmation of correlation with adverse prognosis basal tumors such as HER-2 receptor positive and estrogen receptor negative

Product Portfolio

Product	 **Bello & Fitto**	 **Senior Care**	 **Eileen: Functional Breast Imager**	 **DMW-NIRS-Based Skin Analyzer**
	NIRS-Powered Portable Body Composition Analyzers	Frailty Monitoring System by Muscle & Gait Analysis	Breast Cancer Diagnostic Imaging Device	Collagen Analyzer for Personalized Skincare
Purpose	• Everyday wellness management • Monitoring & prevention of metabolic health risks	• Legacy Solution Replacement: (SPPB and SARC-F tests > Frailty Index) • Provide IT-based managerial functionalities for the independent and active senior population	• A non-radiative, non-invasive breast cancer diagnosis solution with high precision, quick diagnosis time, and an affordable cost that will benefit all healthcare sectors, including patients	• Skin health assessment through measurements of parameters such as skin redness, moisture and collagen levels • Customized skincare solutions and product recommendations based on the results
Metrics	• Body Fat % • Visceral Fat Level • Belly Fat % • BMR • Metabolic Health Index • Muscle Mass • Body Balance • Muscle Quality • Muscle Grade • Body Fat %	• Frailty Index (Developed from Fitto Index and Gait Analysis data from sensor-based gait analysis device)	• Olive Breast Cancer Index: Malignancy Index consisting of THC, StO_2, water, and lipid	• TBA
Key Features	• Non-invasive measurement and real-time physiological composition analysis • Segmental measurement and analysis of areas of interest	• A systematic diagnosis of sarcopenia • An effective and accessible solution for forecasting frailty in the elderly • Enhance preventive measures and support healthy muscle management	• Analysis based on actual physiological changes in the region • Comprehensive analysis with DICOM Image Reading and PACS Scan Results Reporting	• TBA

Clinical Trials and Validation

Highlights from Major Clinical Studies:
Validity of NIRS for Body Composition Assessment

Body composition assessment plays a pivotal role in managing health conditions like obesity, type 2 diabetes, and cardiovascular diseases. Traditional methods such as dual-energy X-ray absorptiometry (DEXA) and magnetic resonance imaging (MRI), while highly accurate, suffer from limitations including cost, radiation exposure, and lack of mobility.

Our journey into NIRS-based wellness management devices began during the development of medical equipment utilizing NIRS technology. We recognized the immense potential for extending and adapting this technology to offer accurate, safe, and accessible body composition analysis, with high correlation to clinical standard used in healthcare industry. This realization led to the creation of innovative solutions for non-invasive health monitoring, furthering our commitment to accessible, precise wellness management.

This section highlights major clinical studies that validate the correlation and accuracy of NIRS technology for body composition analysis compared to traditional or clinically used methods, including computed tomography (CT) and DEXA, as well as the widely-used BIA technology, with its popularity derived from its accessibility.

Study 1. Validation of Diffuse Optical Spectroscopic Imaging (DOSI) for Body Composition

This study aimed to address the need for a non-invasive body composition assessment method and introduced the promising DOSI technology in our research device. It emphasized safety, real-time monitoring, and precision in body fat and muscle mass measurements. This foundational research demonstrated the high reproducibility and reliability of the device, validating its effectiveness for segmental body composition assessment. Conducted in collaboration with a major rehabilitation institution, this research presents exciting potential and opportunities for developing a portable body composition analysis device, which could revolutionize non-invasive health monitoring.

Title	Validation of Diffuse Optical Spectroscopic Imaging (DOSI) for the assessment of body composition		
Period	Sep 2017 – Aug 2018	**Report Date**	Apr 2, 2019
Institution	Department of Rehabilitation Medicine, Seoul National University Bundang Hospital (Professor Jae-Young Lim)		
Participants & Criteria	60 adults, 30 men and 30 women aged 20 and above, who are capable of independent walking and daily activities: Body Fat Percentage: Normal Group < 25% (men) or 32% (women); Overweight/Obese Group ≥ 25% (men) or 32% (women).		
Purpose	Evaluation of Reproducibility and Validity for a Portable Local Body Composition Measurement Device Based on Near-Infrared Spectroscopic Imaging Technology		
Summary	This study addresses the demand for non-invasive body composition assessment. It focuses on evaluating our NIRS-based research device, ensuring safety and real-time monitoring, as well as precise calculations of body fat mass and muscle mass. The study introduces Diffuse Optical Spectroscopy Imaging (DOSI) technology, a non-invasive method using near-infrared light to quantify tissue constituents. The research found that the device's measurements exhibited exceptional reproducibility across various regions and strong correlations with reference variables for muscle and fat quantities. This positions it as a valuable tool for obtaining fat-related information and hints at the potential for a portable body composition analyzer. In conclusion, Olive Healthcare's NIRS-based research equipment excels in reproducibility and reliability. Further investigations are needed for continuous measurement across various exercise scenarios and to design an effective probe for the portable body composition analyzer. This study reaffirms Olive Healthcare's commitment to advancing non-invasive health assessment and wellness monitoring.		

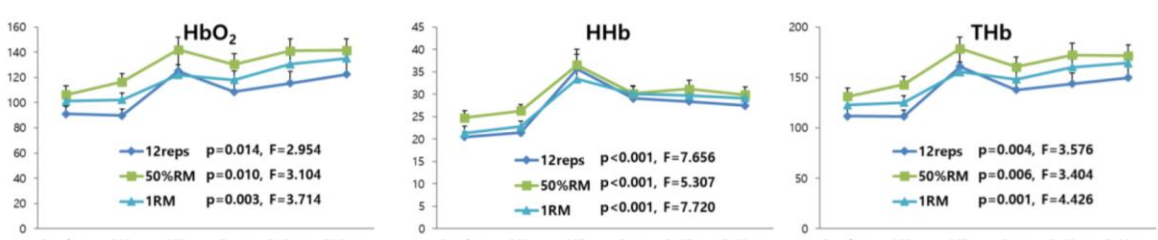


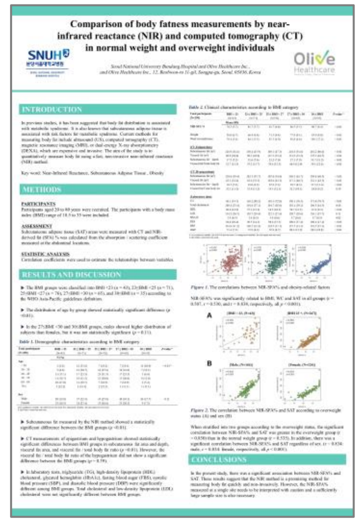
Figure 1. Changes in hemoglobin parameters at resting, fatigue and recovery periods

Study 2. Reliability and Validity of Near Infrared Ray-based Measurement of Subcutaneous Fat

Expanding on prior achievements recognizing the potential for developing a non-invasive, portable body composition analysis device using near-infrared light, a subsequent study probed the potential of our device as a surrogate marker for abdominal fat, with a specific emphasis on visceral fat—an essential aspect of cardiometabolic risk evaluation.

This research, involving 290 participants and comparing results against CT scans, proved that NIR-estimated Visceral Fat Area (VFA) outperformed other adiposity surrogates, demonstrating superior precision and VFA prediction, while demonstrating remarkable proficiency in detecting visceral obesity.

These findings further underscores the non-invasive and precise assessment capabilities of our NIRS device, especially in evaluating cardiometabolic risks associated with visceral fat levels. Together with prior studies, it cements our NIRS-based analyzers as indispensable tools for non-invasive health monitoring.

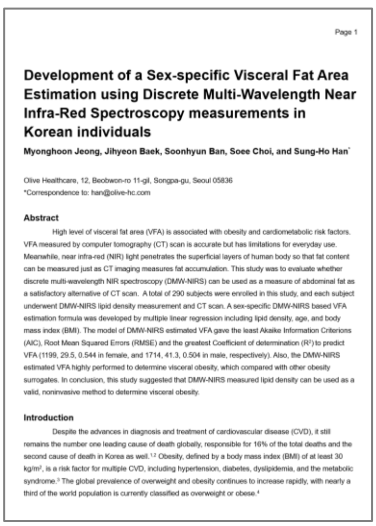


Title	Reliability and Validity of Near Infrared Ray based measurement of subcutaneous fat compared with CT		
Period	Aug 2018 – Aug 2019	**Report Date**	Sep 28, 2020
Institution	Department of Family Medicine, Seoul National University Bundang Hospital (Professor Ju Young Kim)		
Participants & Criteria	290 participants, male and female, aged 20 to 80, with a body mass index (BMI) ranging from 18.5 to 35		
Purpose	Analyzing the correlation between abdominal subcutaneous fat area and visceral fat area results obtained from abdominal CT scans with subcutaneous fat measurements based on NIR technology and assessing their correlation with metabolic syndrome.		
Results	The aim of this study was to validate the reliability and validity of the NIRS-based subcutaneous fat measurement device. To achieve this, the study compared the device's measurements with those obtained from abdominal CT scans abdominal subcutaneous fat and visceral fat area, as well as, including measurements of blood test markers related to metabolic syndrome. The study also assessed the reliability of the device by having two examiners measure the same subjects using the device. Correlation analyses were performed to evaluate the validity, including correlations between the NIRS-based subcutaneous fat measurements, abdominal CT results, and metabolic syndrome markers. Additionally, inter-rater reliability analysis was conducted to assess the consistency of measurements made by two examiners using the near-infrared subcutaneous fat measurement device. The results of the analysis showed a positive correlation between the NIR-based subcutaneous fat measurements and the measurements obtained from abdominal CT scans, confirming the validity of the device. The device also demonstrated high inter-rater reliability, indicating consistency in measurements made by different examiners. However, the NIR-based subcutaneous fat measurements showed either no		

Results	significant or low correlations with visceral fat area and blood test markers related to metabolic syndrome. This suggests that additional development, analysis, and research are needed for the measurement device. In conclusion, the NIR-based subcutaneous fat measurement device has achieved statistically significant validity and reliability, making it a valuable tool for assessing abdominal subcutaneous fat due to its safety, non-invasiveness, convenience, and rapid measurement capabilities. Based on these results, we verified and further refined Bello Fat Index.

Publication: Development and Validation of a Sex-specific Visceral Fat Area Estimation using Near Infrared Spectroscopy

Study 2 is to be published with the following abstract:



Page 1

Development of a Sex-specific Visceral Fat Area Estimation using Discrete Multi-Wavelength Near Infra-Red Spectroscopy measurements in Korean individuals

Myonghoon Jeong, Jihyeon Baek, Soonhyun Ban, Soee Choi, and Sung-Ho Han*

Olive Healthcare, 12, Beobwon-ro 11-gil, Songpa-gu, Seoul 05836
*Correspondence to: han@olive-hc.com

Abstract

High level of visceral fat area (VFA) is associated with obesity and cardiometabolic risk factors. VFA measured by computer tomography (CT) scan is accurate but has limitations for everyday use. Meanwhile, near infra-red (NIR) light penetrates the superficial layers of human body so that fat content can be measured just as CT imaging measures fat accumulation. This study was to evaluate whether discrete multi-wavelength NIR spectroscopy (DMW-NIRS) can be used as a measure of abdominal fat as a satisfactory alternative of CT scan. A total of 290 subjects were enrolled in this study, and each subject underwent DMW-NIRS lipid density measurement and CT scan. A sex-specific DMW-NIRS based VFA estimation formula was developed by multiple linear regression including lipid density, age, and body mass index (BMI). The model of DMW-NIRS estimated VFA gave the least Akaike Information Criterions (AIC), Root Mean Squared Errors (RMSE) and the greatest Coefficient of determination (R^2) to predict VFA (1199, 29.5, 0.544 in female, and 1714, 41.3, 0.504 in male, respectively). Also, the DMW-NIRS estimated VFA highly performed to determine visceral obesity, which compared with other obesity surrogates. In conclusion, this study suggested that DMW-NIRS measured lipid density can be used as a valid, noninvasive method to determine visceral obesity.

Introduction

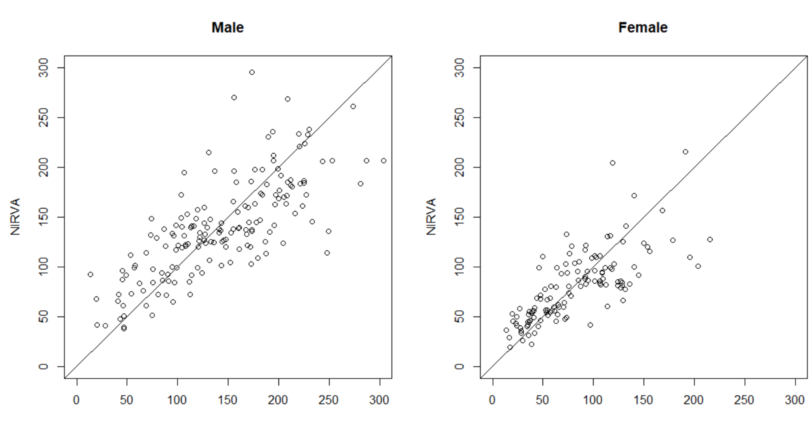
Despite the advances in diagnosis and treatment of cardiovascular disease (CVD), it still remains the number one leading cause of death globally, responsible for 16% of the total deaths and the second cause of death in Korea as well.[1,2] Obesity, defined by a body mass index (BMI) of at least 30 kg/m^2, is a risk factor for multiple CVD, including hypertension, diabetes, dyslipidemia, and the metabolic syndrome.[3] The global prevalence of overweight and obesity continues to increase rapidly, with nearly a third of the world population is currently classified as overweight or obese.[4]

Abstract

High level of visceral fat area (VFA) is associated with obesity and cardiometabolic risk factors. VFA measured by computer tomography (CT) scan is accurate but has limitations for everyday use. Meanwhile, near infra-red (NIR) light penetrates the superficial layers of human body so that fat content can be measured just as CT imaging measures fat accumulation. This study was to evaluate whether discrete multi-wavelength NIR spectroscopy (DMW-NIRS) can be used as a measure of abdominal fat as a satisfactory alternative of CT scan. A total of 290 subjects were enrolled in this study, and each subject underwent DMW-NIRS lipid density measurement and CT scan. A sex-specific DMW-NIRS based VFA estimation formula was developed by multiple linear regression including lipid density, age, and body mass index (BMI). The model of DMW-NIRS estimated VFA gave the least Akaike Information Criterions (AIC), Root Mean Squared Errors (RMSE) and the greatest Coefficient of determination (R2) to predict VFA (1199, 29.5, 0.544 in female, and 1714, 41.3, 0.504 in male, respectively). Also, the DMW-NIRS estimated VFA highly performed to determine visceral obesity, which compared with other obesity surrogates. In conclusion, this study suggested that DMW-NIRS measured lipid density can be used as a valid, noninvasive method to determine visceral obesity.

Figure 1. Sex-stratified scatter plot of Visceral fat area (cm2) vs. NIR-estimated VFA* (cm2) for male and female.

*visceral fat area.



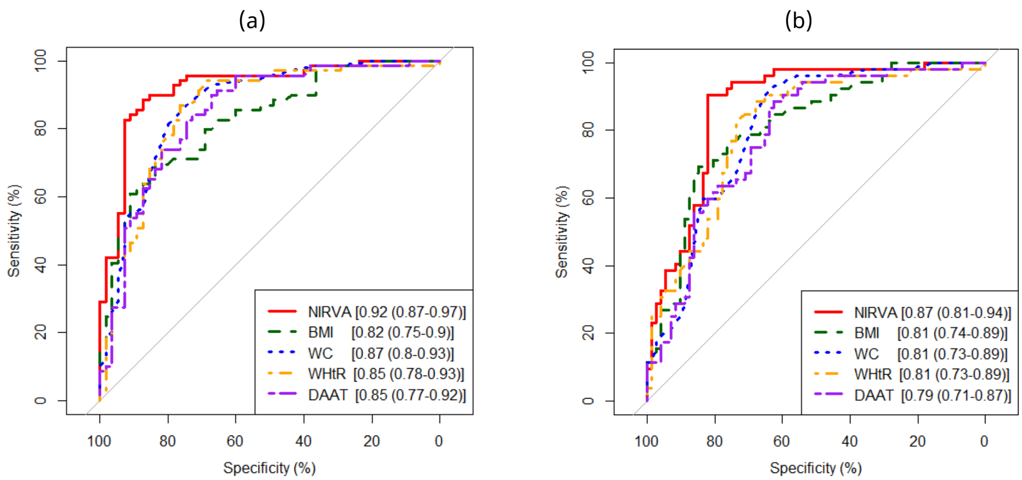


Figure 2. ROC curves (AUC) for visceral obesity for female.

Criteria for visceral obesity were as follows: (a) VFA <70 cm2 for women (Han et al. 2008), (b) VFA <91.1 cm2 for women (Arang Lee et al. 2018).

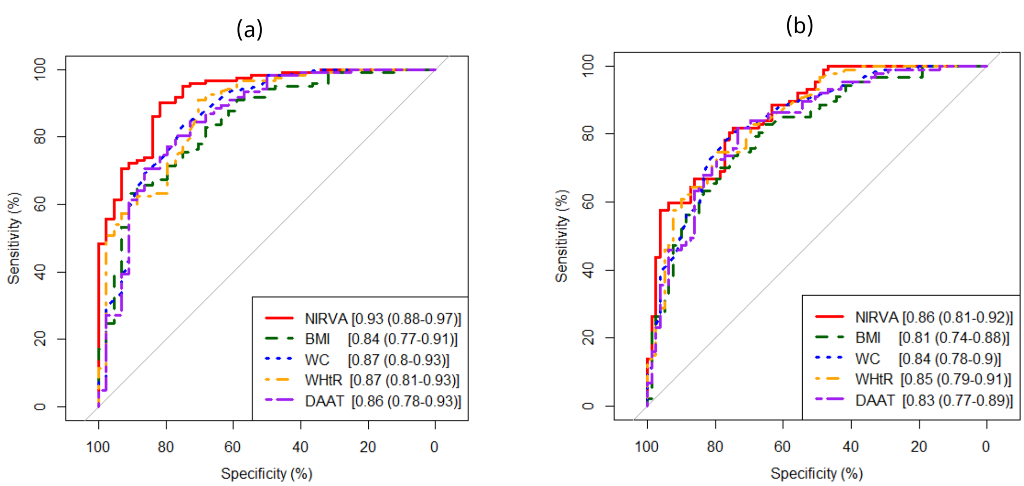


Figure 3. ROC curves (AUC) for visceral obesity for male.

Criteria for visceral obesity were as follows: (a) VFA <100 cm2 for men (Han et al. 2008), (b) VFA <134.6 cm2 for men (Arang Lee et al. 2018).

Study 3. Research and Validation Studies at TWL (2020)

In 2020, prior to the launch of the subsequent model of Bello, Bello 2, and Fitto, we conducted a series of studies involving 104 participants in collaboration with the American clinical institution, TWL. The subsequent rounds of studies aimed at refining and validating the analysis algorithm using clinical research data.

In the first phase, this algorithm underwent further testing for accuracy using the NHANES dataset, where it demonstrated a high correlation with DEXA scans for the whole body, trunk, and limbs.

Title	Research and Validation Studies at TWL		
Period	Jul 2020 – Oct 2020	**Institution**	TWL (US based clinic)
Participants & Criteria	104 participants, comprising 50 males and 54 females aged from 20s to 60s		
Purpose	This study aimed to validate the reliability and consistency of Bello Fat Index which has been established through multiple clinical studies and muscle index of the new device under development (Fitto). This research aims not only to validate the effectiveness of the collected data alongside the results from standard devices for body composition analysis such as DEXA but also to conduct clinical studies to validate various muscle quantity and muscle quality indicators in different regions of the arms, legs, and torso.		
Results	• Verification of the reliability of Bello Fat Index and algorithm improvement • Validation of muscle quantity and development of muscle quality indicators		

Linear			Polynomial		
Total Lean Mass					
r = 0.968		95% CI = (0.03 ± 5.3) kg	r = 0.973		95% CI = (0.00 ± 4.9) kg
Segmental Lean Mass *					
RA	r = 0.959	95% CI = (0.01 ± 0.57) kg	RA	r = 0.964	95% CI = (-0.01 ± 0.53) kg
LA	r = 0.948	95% CI = (0.00 ± 0.63) kg	LA	r = 0.962	95% CI = (-0.01 ± 0.54) kg
RL	r = 0.954	95% CI = (0.00 ± 1.16) kg	RL	r = 0.952	95% CI = (-0.01 ± 1.18) kg
LL	r = 0.951	95% CI = (-0.02 ± 1.18) kg	LL	r = 0.951	95% CI = (-0.02 ± 1.19) kg

Table 3.1. Lean (soft tissue) Mass Prediction Performances

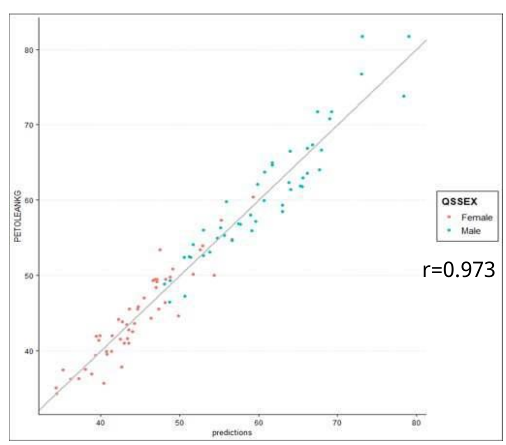
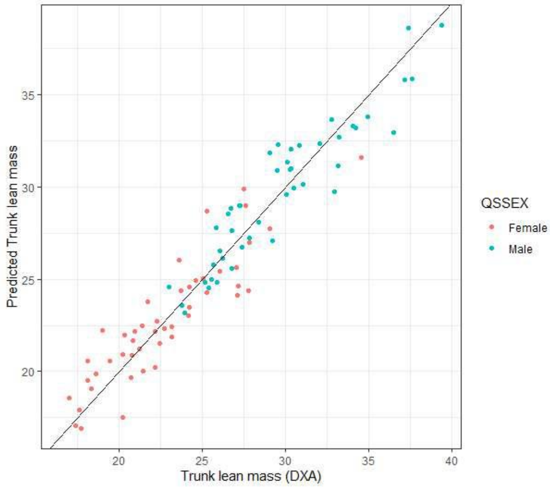


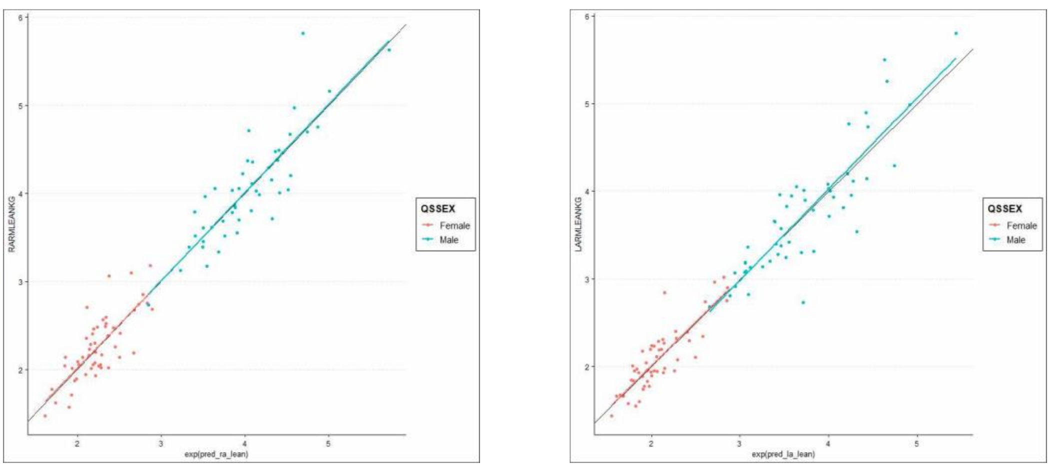
Figure 3.2. Correlation to DEXA for Whole-Body Lean Mass. The linear correlation between the values produced by our analysis algorithm and DEXA for total muscle mass is very high, at 0.97 or above.



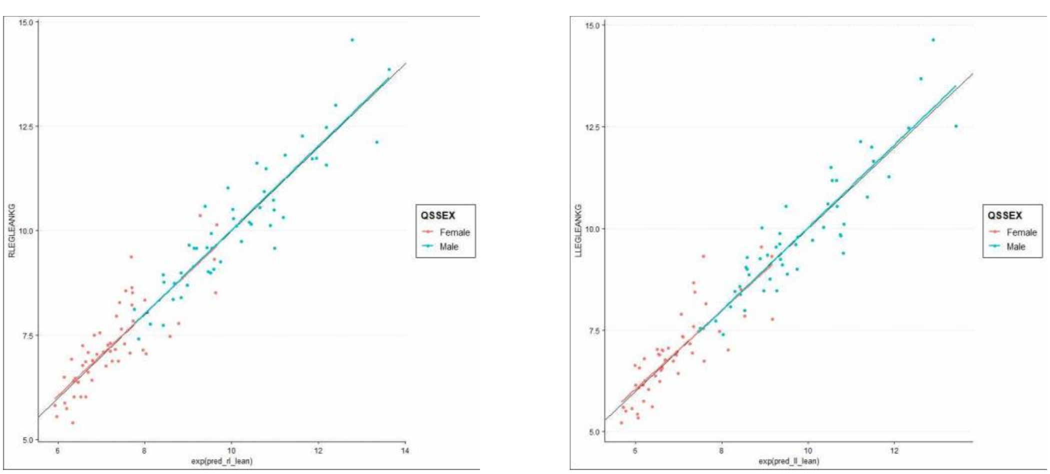
Trunk r=0.96

Figures 3.3-3.5.

Segmental Comparisons for Trunk and Limbs: High Correlation to DEXA



Arms r=0.964; r=0.962



Legs r=0.952; r=0.951

Study 4. Development Of A Portable Medical Device For Monitoring Muscle Quality Using NIR Local Area Body Composition Measurements: An Exploratory Study on the Correlation Between NIRS-Based Body Composition and Skeletal Muscle Quality

This study, conducted in collaboration with Yonsei University Severance Hospital, one of South Korea's premier general hospitals in 2021, was a government-funded project. DMW-NIR technology was employed to quantitatively calculate four components within human tissues using absorption spectra: oxyhemoglobin, deoxyhemoglobin, water, and lipids. This precise measurement of tissue characteristics in local areas was enabled through the measurement of changes in oxygen saturation and moisture levels, allowing for the analysis of muscle characteristics like muscle quality and muscle fatigue. The study's primary objective was to acquire muscle characteristic data to support the diagnosis of muscle atrophy and sarcopenia while laying the groundwork for the development of medical devices related to muscle condition diagnosis.

Subsequently, utilizing the obtained results, we conducted data analysis and quantification of indicators necessary for the development of our muscle diagnostic device, Fitto. Moreover, we confirmed its potential as a medical device for diagnosing sarcopenia.

Title	Exploratory Study on the Correlation Between Body Composition Scores Measured by NIRS-Based Local Body Composition Device and Muscle Quality in a Healthy Population for Supplementary Diagnosis of Sarcopenia		
Period	2021.09.13 – 2021.12.30	**Report Date**	2022.02.21
Institution	Yonsei University Severance Hospital		
Purpose	To obtain muscle characteristic data to support the diagnosis of muscle atrophy and sarcopenia using a NIR-based localized body composition measurement device and to serve as preliminary exploration of the correlation between scores measured by Fitto prototype and muscle quality in healthy individuals.		
Method	1. Recruitment of healthy young adults aged 20-39 of both genders for the measurement of regional (predefined 20 locations: arms, legs, back, and abdomen) near-infrared scores, including a measurement evaluation (3 times per location). 2. Evaluation of abdominal skeletal muscle Hounsfield Units (HU), muscle area, and fat area using QCT, which is utilized in existing clinical standards; measurement of limb fat mass and whole-body fat mass using bioimpedance analysis (BIA; InBody720); muscle function evaluation (grip strength, chair rise test, peak weight-corrected jump power); analysis of metabolic indicators, including blood glucose and cholesterol through blood sample analysis. 3. Additional measurement of near-infrared scores for the leg area after performing a jump. 4. Analysis of the correlation between near-infrared scores and QCT-based abdominal skeletal muscle HU to explore the areas showing optimal correlation. 5. Correlation analysis of near-infrared-based local body composition device scores with QCT-based/BIA-based skeletal muscle mass, fat area, muscle function, and metabolic indicators. 6. Analysis of the correlation between near-infrared scores and the bone mineral density of the lumbar spine, femoral neck, and the entire femur assessed through Dual Energy X-ray Absorptiometry (DEXA).		

Method	7. Calculation of ICC values for the results measured three times per location to assess repeatability. Repeatability was evaluated by another examiner's re-measurement of near-infrared scores per location.
Results	• Among the parts that met the criteria for repeatability, both inter-rater agreement and intra-rater agreement exceeded an ICC threshold of 0.75 for the following areas: both forearms (sites 1 and 4), left shoulder, upper abdomen, both thigh areas, and the central calf area on both sides. • Lipid chromophore values, indicative of myosteatosis, showed a consistent negative correlation with muscle mass and muscle function indicators, as reported in previous CT-based studies. • In terms of correlations with blood test indicators, TOC, lipid, and water values of site 3 exhibited a significant correlation with fasting insulin. Lipid values of site 19 showed a significant correlation with Gamma-GT, indicating a potential relation to liver dysfunction, and StO2 values exhibited a significant correlation with glycosylated hemoglobin. These findings suggest that the chromophore values measured by the device may be related to metabolic diseases. However, since this study involved a sample of individuals without a medical history, further research on individuals over 40 years of age with metabolic diseases such as diabetes and metabolic syndrome is needed. • When assessing changes in chromophore values in leg areas (sites 9, 10, 12, 13, 17, 18, 19, 20) after performing a jump, significant reductions in lipid values were observed in sites 9, 10, 12, and 17, and significant increases in water values were observed in sites 12, 13, 17, and 19. The jump movement appears to cause significant changes in chromophore values, emphasizing the importance of stable measurement after jumping when using this device. • Safety Results: No adverse reactions were observed before or after the examination and there were no abnormal signs of vitality, indicating the safe use of this medical device.
Discussion	The study highlighted the device's ease of measurement, notably in regions such as the wrists and ankles, eliminating the necessity for intricate preparations. It implied a potential link between the device's chromophore values and markers of metabolic diseases. Nonetheless, additional research involving individuals with metabolic conditions is imperative. The study also stressed the importance of consistent measurements, especially following a rest period, as jump movements induced noticeable fluctuations in chromophore values.
Conclusion	This study unveils the potential of NIRS-based local body composition measurements in evaluating muscle quality among individuals with normal muscle mass. It calls for future research to center on individuals with metabolic conditions and to enhance measurement protocols for greater accuracy. The clinical evidence underscores that the chromophore values obtained with this device serve as meaningful indicators for assessing muscle quality and quantifying muscle-related changes, encompassing metrics like fat deposition within muscles and muscle composition.

Study 5. Research and Validation Studies at TWL (2022)

In the second phase, our objective was to enhance the accuracy of Fitto's body fat percentage measurement and validate Muscle Index against reference methods, including DEXA and BIA devices.

Our model exhibited an even higher correlation with DEXA compared to other comparison variables, including a medical-grade BIA-based body composition analyzer, as shown in the diagram below. The results showcased an improved accuracy in the body fat percentage measurement applied by Fitto and a successful validation of Fitto’s Muscle Index.

<table>
<tr><th>Title</th><td colspan="3">Research and Validation Studies with TWL</td></tr>
<tr><th>Period</th><td>Aug 2022 – Oct 2022</td><th>Report Date</th><td>Nov 2022</td></tr>
<tr><th>Institution</th><td colspan="3">TWL</td></tr>
<tr><th>Participants & Criteria</th><td colspan="3">• Total Pool size: 206 adults, aged 20-50, with an equal gender ratio, categorized into 5 different groups based on BMI.
• 5 BMI Groups: BMI below 18.5 (5%, 13 individuals), BMI 18.5-24.9 (30%, 75 individuals), BMI 25-26.9 (30%, 75 individuals), BMI 27-29.9 (20%, 50 individuals), BMI 30-39.9 (15%, 37 individuals)</td></tr>
<tr><th>Purpose</th><td colspan="3">To enhance Bello's body fat analysis model and validate the Fitto muscle index (for assessing muscle quality in 21 different body regions), we conducted comparative clinical trials using DEXA and BIA as control groups, with an emphasis on the accuracy of body fat percentage, a critical factor for Lean Mass calculations.
We assessed the correlation between Fitto and DEXA, BIA, and physical performance data for the following criteria:
• DEXA: Appendicular Lean Mass, Fat Mass, Total Mass
• BIA (Tanita MC-780U Plus P): Appendicular Skeletal Muscle, Fat Mass, Weight, Height, BMI, and other collectible metrics
• Physical performance data: to understand the correlation between body composition and mobility, including the handgrip strength test, the 5-time sit-to-stand test (following the SPPB Protocol), questionnaires related to metabolic disease history, and body measurements such as height, weight, BMI, waist circumference, thigh circumference, and calf circumference.
This comprehensive approach allowed us to validate the performance of Fitto's muscle indicators and ensure that Bello's body fat analysis model meets the highest standards of accuracy and reliability.</td></tr>
<tr><th>Results</th><td colspan="3">• Algorithm updates to further enhance accuracy
• Validation of Muscle Index accuracy and improvement of body fat percentage data in Fitto</td></tr>
</table>

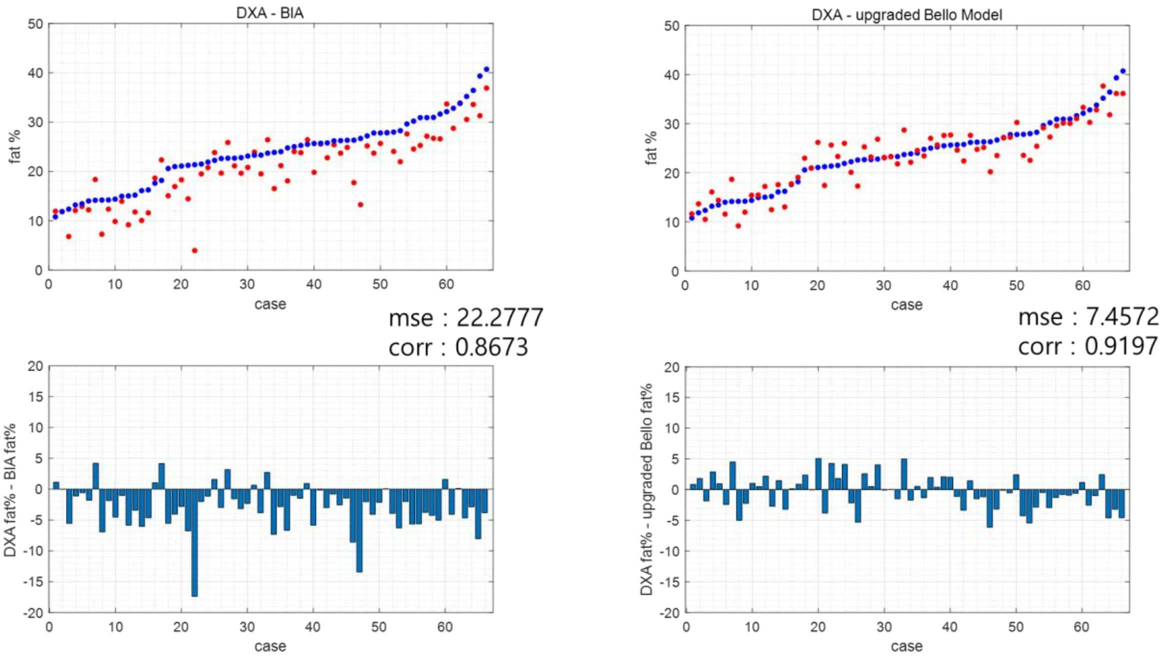


Figure 3.6. Comparison of BIA-based devices and Olive Healthcare's FITTO for the correlation against DEXA in male participants.

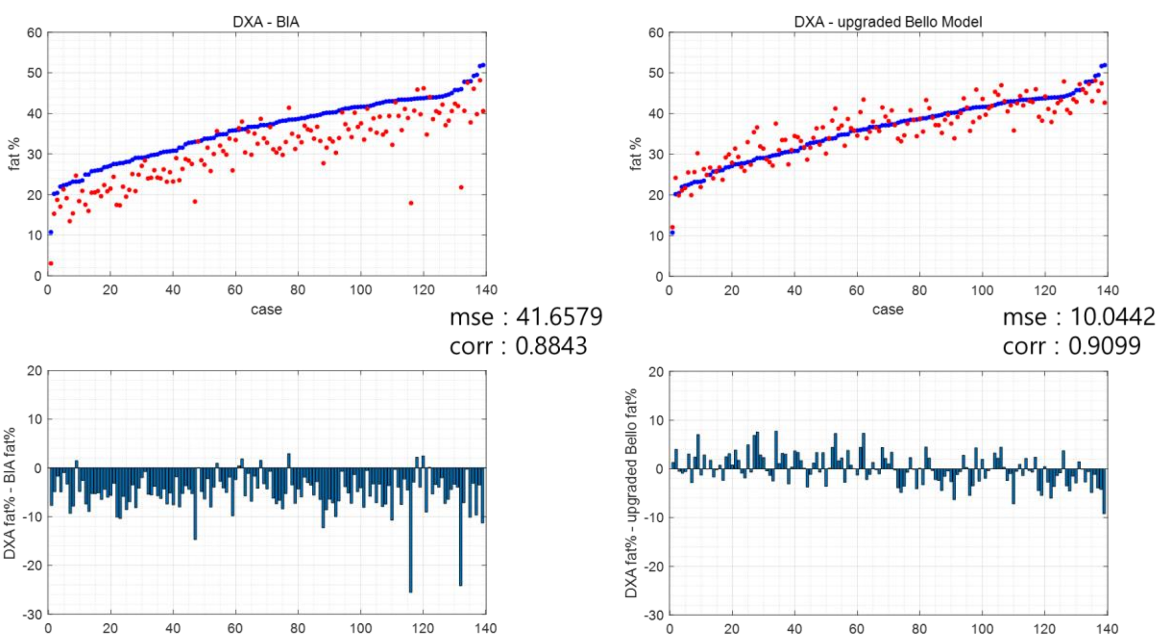


Figure 3.7. Comparison of BIA-based devices and Olive Healthcare's FITTO for the correlation against DEXA in female participants.

Study 6. Validation of Muscle Mass and Strength and Gait Parameters in the Elderly using Fitto and Beflex Devices

The importance of muscles in the aging process leading to frailty in healthy elderly individuals is widely recognized. However, measurable index for muscle mass and strength required to carry out daily life are not clear-cut. Traditional frailty indicators, such as thigh and calf circumferences, suffer from measurement variability, and there has been a lack of a generally applicable method for real-time monitoring of elderly walking outside designated facilities.

In this context, there is a need for research that utilizes digital devices capable of measuring muscle and gait, such as Fitto and Beflex, to combine gait analysis data with index reflecting muscle mass and muscle functionalities and strength, to predict the degree of frailty in the elderly. The outcome would be an effective aging assessment solution that empowers the growing elderly population to proactively manage their health, potentially reducing the burden of age-related health concerns, and enhance the quality of life.

<table>
<tr><th>Title</th><td colspan="3">Validation of Muscle Mass and Strength and Gait Parameters in the Elderly using Fitto and Beflex Devices</td></tr>
<tr><th>Period</th><td>2023.09 – 2024. 02</td><th>Report Date</th><td>To be reported in 1Q 2024</td></tr>
<tr><th>Institution</th><td colspan="3">Konkuk University Medical Center</td></tr>
<tr><th>Purpose</th><td colspan="3">To validate the feasibility of Fitto & Beflex diagnostic solutions for monitoring and assessing aging and frailty by comparing body composition and gait analysis indices with conventional aging and frailty indices.</td></tr>
<tr><th>Method</th><td colspan="3">• Conducted by institutes: Konkuk University Medical Center and KU Research Institute on Health and Aging with a participant pool of 90 (45 male and 45 female) adults over age 65 without chronic illnesses that may require long-term hospitalization (e.g., cancer, early-stage stroke, dementia).
• Procedure: A cross-sectional survey. Muscle Index measured using Fitto for 21 areas of the body (estimated time required: 5 minutes) and gait indicators measured using Beflex (5 minutes) were correlated with measurements from Inbody 770 (used in clinics to measure body composition, as a part of diagnostic procedure for sarcopenia) and conventional frailty index.
• The primary endpoint is the concurrence of total lean mass produced by Fitto and Inbody 770. Secondary endpoints include the agreement of total lean mass for 5 segmental body parts (trunk and limb), and the degree of agreement for frailty risk levels according to SPPB (Short Physical Performance Battery) and SARC-F (questionnaire for assessing sarcopenia) with Fitto and Beflex measurements.</td></tr>
<tr><th>Progress</th><td colspan="3">1. Measurements and data acquisition were completed in Oct 2023, and data analysis is currently in progress.
2. In conjunction with this clinical trial, discussions are underway with various stakeholders with target clients including government agencies, elderly care institutions, insurance companies, local government bodies, social workers, senior fitness specialists, nursing homes, and major corporations (financial institutions, telecommunications companies, etc. with senior-related services), among others. These discussions are focused on the finalization and commercialization of our senior care solution with the Gerontology Research Institute at Konkuk University.</td></tr>
</table>

Intellectual Properties

IP: Total 64 registered, 34 pending

- Reference Technology: Exclusive License for UCI Ref. Tech (2 Cases)
- Design & Trademarks: 23 Design, 33 Trademarks

	KR	US	EP	UK	JP	CN	UAE	PCT	Hague	Total
IP	***22***	***4***	***4***	***0***	***4***	***3***	***0***	***5***	***0***	***42***
Registered	15	1	0	0	1	1	0	0	0	18
Published	0	0	3	0	0	2	0	3	0	8
Application	7	3	1	0	3	0	0	2	0	16
Design	***9***	***6***	***3***	***0***	***0***	***5***	***0***	***0***	***0***	***23***
Registered	9	5	3	0	0	5	0	0	0	22
Application	0	1	0	0	0	0	0	0	0	1
Trademark	***17***	***4***	***5***	***1***	***5***	***0***	***1***	***0***	***0***	***33***
Registered	9	3	5	1	5	0	1	0	0	24
Application	8	1	0	0	0	0	0	0	0	19
Total	**48**	**14**	**12**	**1**	**9**	**8**	**1**	**5**	**0**	**98**

Key Intellectual Properties

No	Type	Title	Technical Classification	Application Date	Application Number	Registration Date	Application Country
1	Patent	Multi-wavelength laser diode beam synthesis device	IoT / Reference	2013-06-27	10-2013-0074950	2015-02-09	KR
2	Patent	APD gain stabilization method of the medical laser receiver	IoT / Reference	2013-06-27	10-2013-0074949	2014-09-30	KR
3	Patent	Homodyne-based diffused light spectroscopy method and system	IoT / FD	2016-05-24	10-2016-0063675	2018-01-16	KR
4	Patent	Homodyne-based multi-channel body composition analysis apparatus and method	IoT / FD	2016-06-14	10-2016-0074040	2017-10-26	KR
5	Patent	A multi-wavelength bio signal analysis apparatus based on a frequency domain and a method thereof	IoT / FD	2017-01-04	10-2017-0001539	2019-07-16	KR
6	Patent	A signal processing device that analyzes bio-signals and Biological signal analysis device	IoT / CW	2018-02-21	10-2018-0020555	2019-07-25	KR
7	Patent	Biological signal analysis apparatus and method using machine learning	AI	2018-08-17	10-2018-0095928	-	KR
8	Patent	A multi-wavelength bio signal analysis apparatus based on a frequency domain	IoT / FD	2019-03-28	10-2019-0036102	2019-11-05	KR
9	Patent	A multi-wavelength bio signal analysis apparatus based on a frequency domain	IoT / FD	2019-03-28	10-2019-0036138	2019-11-05	KR
10	Patent	A multi-wavelength bio signal analysis apparatus based on a frequency domain and a method thereof	IoT / FD	2019-03-28	10-2019-0036183	2019-11-22	KR
11	Patent	A multi-wavelength bio signal analysis apparatus based on a frequency domain and a method thereof	IoT / FD	2017-02-17	PCT/KR2017/001771	-	WO
12	Patent	A multi-wavelength bio signal analysis apparatus based on a frequency domain and a method thereof	IoT / FD	2018-09-17	16/085,762	-	US
13	Patent	A multi-wavelength bio signal analysis apparatus based on a frequency domain and a method thereof	IoT / FD	2018-11-12	2019-512591	-	JP
14	Patent	A multi-wavelength bio signal analysis apparatus based on a frequency domain and a method thereof	IoT / FD	2018-12-17	17831183.3	-	EP
15	Patent	A signal processing device that analyzes bio-signals and Biological signal analysis device	IoT / CW	2018-03-06	PCT/KR2018/002619	-	WO
16	Patent	A signal processing device that analyzes bio-signals and Biological signal analysis device	IoT / CW	2018-11-13	16/189,393	2020-04-21	US

Key Intellectual Properties

No	Type	Title	Technical Classification	Application Date	Application Number	Registration Date	Application Country
17	Patent	A signal processing device that analyzes bio-signals and Biological signal analysis device	IoT / CW	2018-11-23	18 800 822.1	-	EP
18	Patent	A signal processing device that analyzes bio-signals and Biological signal analysis device	IoT / CW	2018-11-12	201880001980.3	-	CN
19	Patent	A signal processing device that analyzes bio-signals and Biological signal analysis device	IoT / CW	2020-08-20	2020-544435	-	JP
20	Patent	Biological signal analysis apparatus and method using machine learning	AI	2018-08-24	PCT/KR2018/009808	-	WO
21	Patent	Biological signal analysis apparatus and method using machine learning	AI	2020-05-01	16/864667	-	US
22	Patent	Biological signal analysis apparatus and method using machine learning	AI	2020-06-26	18 930 409.0	-	EP
23	Patent	A management system that provides behavioral habits improvement	Etc.	2020-06-26	10-2020-0078492	-	KR
24	Patent	A management system that provides behavioral habits improvement	Etc.	2020-09-24	PCT/KR2020/012931	-	WO
25	Patent	Breast cancer diagnosis system	Big Data	2020-09-25	10-2020-0124448	-	WO
26	Exclusive License	Quantitative broadband absorption and scattering spectroscopy…	IoT / FD	2002-07-09		2008-09-23	US
27	Exclusive License	Portable DOSI device for non-invasive tissue characterization	IoT / FD	2014-01-13		2017-09-26	US
28	Trademark	Olive Healthcare, bello, bello mini, Fitto etc.	-			2018-12-12 – 2020-09-23	KR, US, EP, CN, JP
29	Design	Abdominal fat measuring instrument, portable terminal with image design, breast cancer diagnosis device, etc.	-			2018-05-29 – 2020-09-18	KR, US, EP, CN, JP
30	Patent	Methods for analyzing body composition	IoT / FD	2021-10-07	10-2021-0133284	-	KR
31	Patent	Methods for analyzing body composition	IoT / FD	2021-12-10	17/547,824	-	US
32	Patent	Methods for analyzing body composition	IoT / FD	2021-12-17	2021-205612	-	JP
33	Patent	Methods for analyzing body composition	IoT / FD	2021-12-20	21215839,8	-	EP

Key Intellectual Properties

No	Type	Title	Technical Classification	Application Date	Application Number	Registration Date	Application Country
34	Patent	Breast Cancer Diagnosis System	Big Data	2020-09-25	10-2020-0124448	2022-09-14	KR
35	Patent	Breast Cancer Diagnosis System	Big Data	2022-09-13	10-2022-0114965	2023-09-01	KR
36	Patent	Breast Cancer Diagnosis System	IoT / FD	2022-09-13	10-2022-0114914	2023-08-01	KR
37	Patent	Near Infrared Processing Probe for Breast Cancer Diagnosis System	IoT / FD	2022-09-13	10-2022-0114937	2023-06-01	KR
38	Patent	Method for Operation of Breast Cancer Diagnosis System	IoT / FD	2022-09-13	10-2022-0114985	2023-09-01	KR
39	Trademark	Olive Healthcare	-	2018-12-12	40-2018-0174915	2019-11-22	KR
40	Trademark	Bello/bello/bello mini	-			2018-12-28 – 2020-12-17	KR, US, JP, EP
41	Trademark	braintingle	-	2020-08-25	40-1833-2050000	2021-11-17	KR
42	Trademark	Fitto	-	2020-09-15	40-1844-8470000	2021-01-21 – 2022-03-15	KR, US, JP, EP
43	Trademark	Eileen	-	2021-09-16		2022-02-01 – 2022-05-02	KR, US, JP, EP
44	Trademark	9 block therapy	-			2022-05-13 – 2022-05-24	KR, US, JP, EP
45	Trademark	9 Step treatment	-	2022-03-21	40-2022-0051420	-	KR
46	Trademark	9 Step Treatment	-	2022-03-21	40-2022-0051496	-	KR
47	Trademark	9 Class Treatment	-	2022-03-21	40-2022-0051503	-	KR
48	Trademark	9 Class Treatment	-	2022-03-21	40-2022-0051510	-	KR
49	Design	Abdominal fat measuring instrument	-	2018-05-29	30-0997-6190000	2019-03-07 – 2022-07-12	KR, US
50	Design	Portable device displaying graphic design	-	2019-11-05	30-1073-0540000	2020-08-27	KR
51	Design	Display panel or portion thereof with graphical user interface	-	2020-09-18	30-1119-6340003	2021-07-14	KR

Key Intellectual Properties

No	Type	Title	Technical Classification	Application Date	Application Number	Registration Date	Application Country
52	Design	Portable device displaying graphic design	-	2019-11-05	30-1073-0510000	2020-08-27	KR
53	Design	Display panel or portion thereof with graphical user interface	-	2020-09-18	30-1119-6340001–3	2021-07-14	KR
54	Design	Breast Cancer Diagnosis System	-	2020-09-18	30-1141-2590000	2021-03-12 – 2021-12-06	KR, US, EP
55	Design	Wireless Probe	-	2020-10-08	30-1129-8100000	2021-03-12 – 2021-09-28	KR, US, EP
56	Design	Display panel or portion thereof with graphical user interface	-	2021-03-15	29/774,216	-	US
57	Design	Graphical user interface for breast cancer screening for display panel	-			2021-08-13 – 2021-11-26	CN
58	Design	Muscle measurement device	-	2022-01-17	30-2022-0002076	2022-12-26	KR
59	Patent	Cancer diagnosis based on wavelength-specific intensity of reflected light for multi-wavelength signals		Application in-progress	-	-	KR
60	Patent	User-customized skin tone using the spectral state of light reflected from the skin		Application in-progress	-	-	KR
61	Patent	Limb muscle mass and muscle quality		Application in-progress	-	-	KR

Olive Healthcare

Certifications

Region	Certification	
US		**US FCC Certification**
CAN	Industry Canada	**US FCC Certification**
EU		**EU CE RED, RoHS, WEEE**
UK		**UK CA Certification**
JPN		**JAPAN TELEC Certification**
SGP	INFOCOMM MEDIA DEVELOPMENT AUTHORITY	**SINGAPORE IMDA**
AUS NZL		**AUSTRALIA, NEW ZEALAND RCM**
KOR		**KOREA KC Certification**

Prospective Studies (2023 – 2024)

FITTO Challenge							
Program	Fit Challenge Program for Improving Selex Customer Health						
Purpose	A challenge program jointly operated with MHN (Brand: Selex), a prominent domestic health and nutrition company, measuring Muscle Quantity and Quality changes in exercise areas for fitness enthusiasts among MHN's core customers						
Partners	Maeil Health Nutrition	**Period**	Dec 2023	**Subjects & Participants**	150	**IRB**	N
Program	Monitoring Muscle Quantity and Quality Changes Before and After Exercise						
Purpose	Monitoring Muscle Quantity and Quality changes before and after exercises for fitness instructors						
Partners	IDEA Korea	**Period**	Jan 2024	**Subjects & Participants**	Fitness Instructors (~30)	**IRB**	N
Program	Muscle Enhancement Challenge Program						
Purpose	Challenge program targeting general fitness enthusiasts among Centreal Pilates's primary members, with rewards for members achieving the most muscle enhancement during the challenge, and monitoring daily changes in Muscle Quantity and Quality of challenge participants						
Partners	Centreal Pilates	**Period**	Mar 2024	**Subjects & Participants**	General fitness enthusiasts	**IRB**	N
Collaborative Research, Index Development, and Content Creation							
Program	Developing a Guide for Analyzing and Defining Key Muscles, Muscle Quantity, and Muscle Quality for Daily Health Management						
Purpose	Develop key muscle metrics for health with academic experts						
Partners	Korea National Sport University	**Period**	Mar 2024	**Subjects & Participants**	Professional athletes and sports & training academia	**IRB**	Y
Analyzing Key Muscle Groups for Golf							
Program	Developing an Analysis Guide with Definitions of Key Muscle Groups to Improve Golf Skills and Correlate Their Muscle Quality						
Purpose	Develop a guide with on exercise contents, exercise areas, and index for enhancing golf performances						
Partners	Korea Golf University	**Period**	May 2024	**Subjects & Participants**	Professional athletes and sports & training academia	**IRB**	Y
Skin Care							
Program	Foundational Clinical Research for Measuring Skin Moisture and Collagen						
Purpose	Foundational Clinical Research for Measuring Skin Moisture and Collagen						
Partners	Dream Dermatologics	**Period**	Dec 2023 – Dec 2024	**Subjects & Participants**	General public and individuals with skin conditions	**IRB**	Y