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Development and testing of a device to detect trigger points, and local twitch responses in dry needling intervention ☆,☆☆

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ABSTRACT

Trigger point dry needling (TrpDN) has emerged as a promising intervention for the treatment of myofascial pain. This involves insertion of a sterile filament needle directly into the trigger point (Trp), with the aim of eliciting a local twitch response (LTR). This sudden, involuntary contraction of the muscle fibers confirms the breakdown and success of TrpDN intervention. Not all LTRs are perceptible through visual observation or tactile sensation during the intervention. In search of noticeable LTR, clinicians perform Hong's technique (back-and-forth movements of needle in muscle). This results in muscle damage and causes pain and discomfort thereby limiting functional movements of patients. One important factor in the diagnosis and post intervention follow-up of TrpDN is the pain pressure threshold (PPT). Currently most of the clinicians use thumb pressure and subjective scales for confirming trigger points. These methods can introduce biasness due to its reliance on subjective factors.

- In this present study, an effort has been made to assemble a device to overcome the challenges faced during assessment and treatment of trigger points.
- This device can provide audiovisual feedback for LTR and can measure PPT.

Specifications table

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More specific subject area:	*Pain Management*
Name of your method:	*Local twitch response and pain pressure threshold device*
Name and reference of original method:	*NA*
Resource availability:	*The author can make the data available upon a reasonable request*

Background

Trigger point dry needling (TrpDN) has emerged as a promising therapeutic intervention for the management of Trigger point (Trp). This technique involves the insertion of a thin, sterile, filament needle directly into the trigger point, with the aim of eliciting a local twitch response (LTR) [1–3]. The local twitch response is a spinal cord reflex that occurs when the needle penetrates the trigger

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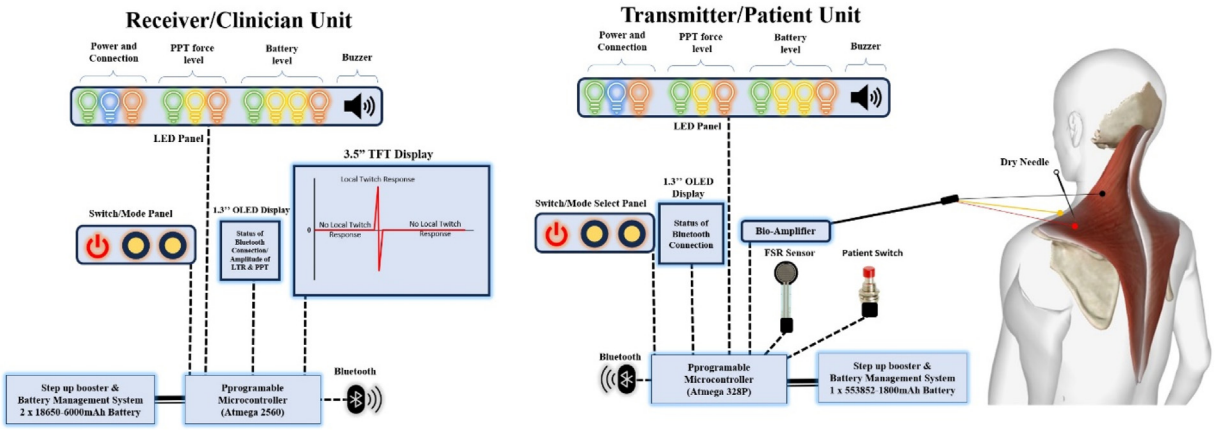

Fig. 1. Diagrammatic representation of Receiver/Clinician and Transmitter/Patient Unit.

point, leading to a sudden, involuntary contraction of the muscle fibers [4,5]. The importance of the local twitch response in the context of trigger point dry needling cannot be overstated. It is confirmed that the local twitch response is a crucial component of the therapeutic mechanism validating the success of intervention [1,6,7].

The standard dry needling approach is initially identifying the trigger point via palpation and assessing the pain pressure threshold (PPT) using an algometer for trigger point confirmation; a PPT below 4 Kg/cm^2 confirms the presence of a trigger point [8,9]. The thin filament needle is then inserted into the trigger point by penetrating skin and subcutaneous tissues, causing a local twitch response (LTR) in the muscle. However, not every needle insertion leads to LTR which is thought to be an important component of the dry needling technique, as it confirms the deactivation of the Trp [3,10]. So, Hong's technique (back-and-forth movements of needle in muscle) is performed by clinician to elicit the local twitch response confirming the effectiveness of intervention. It has been observed that not all local twitch responses are visible during the TrpDN procedure [11,12]. The clinician repeatedly performs back-and-forth movements of the needle to get a noticeable LTR. This leads to muscle damage, pain, discomfort, soreness and inflammation [13]. These factors make dry needling intervention more uncomfortable and painful. So, A more comfortable, effective, and less damaging TrpDN intervention is necessary, and this can only be achieved by the integration of technology.

Pain pressure threshold assessment stands as a cornerstone in Trp diagnoses and to check effectiveness of intervention by comparing pre and post tenderness [14]. The maximum compressive force of 4 Kg/cm^2 on tender point confirms the presence of active trigger point [8,15]. Force more than this denotes that some noxious stimuli other than a trigger point is involved in pain production. So, PPT plays crucial role in diagnosis of trigger points. Conventional pain assessment techniques, such as subjective pain scales and manual pressure application methods, are susceptible to various limitations, including inter-rater variability, lack of quantifiability, and inconsistency in application [16]. Objective assessment of pain is necessary to overcome these limitations and validate the presence of trigger point, to compare pre and post intervention outcomes, and to avoid any unnecessary damage produced by needle.

In response to these difficulties, the development of device for TrpDN was done in this research. This will lead to a revolutionary change in Trp assessment and treatment. The developed TrpDN-PPT/LTR device can measure pain thresholds and provide real-time audiovisual feedback for non-perceptible LTR produced while performing TrpDN intervention. This can make TrpDN treatment safer and more comfortable.

Method details

The development process involved numerous crucial milestones. First, a complete evaluation of existing devices was undertaken to identify design elements and functions critical for clinical utility in practicing trigger point dry needling. Based on these reviews, a prototype of the digital TrpDN-PPT/LTR device was designed, emphasizing safety, accuracy, portability, and user-friendly graphical user interface for easy operation. In next step, the prototype underwent testing in both lab and clinical settings.

Hardwar set-up

The device was assembled in two units (Fig. 1): a patient unit or transmitter unit (Tx-Unit), and a clinician and receiver unit (Rx-Unit). The Tx-Unit receives raw signals from the patient, then interprets and sends them to the Rx-Unit. The Rx-Unit further interprets the received signals and displays the graphical and numerical representations of the interpreted data on displays, providing real-time audiovisual feedback to the clinician. Both the units connect automatically with each other wirelessly via Bluetooth serial communication. The units are equipped with 3.5″ TFT and 1.3-inch OLED display that provides information about LTR, Bluetooth connection status, PPT/LTR Mode, and any device malfunctions.

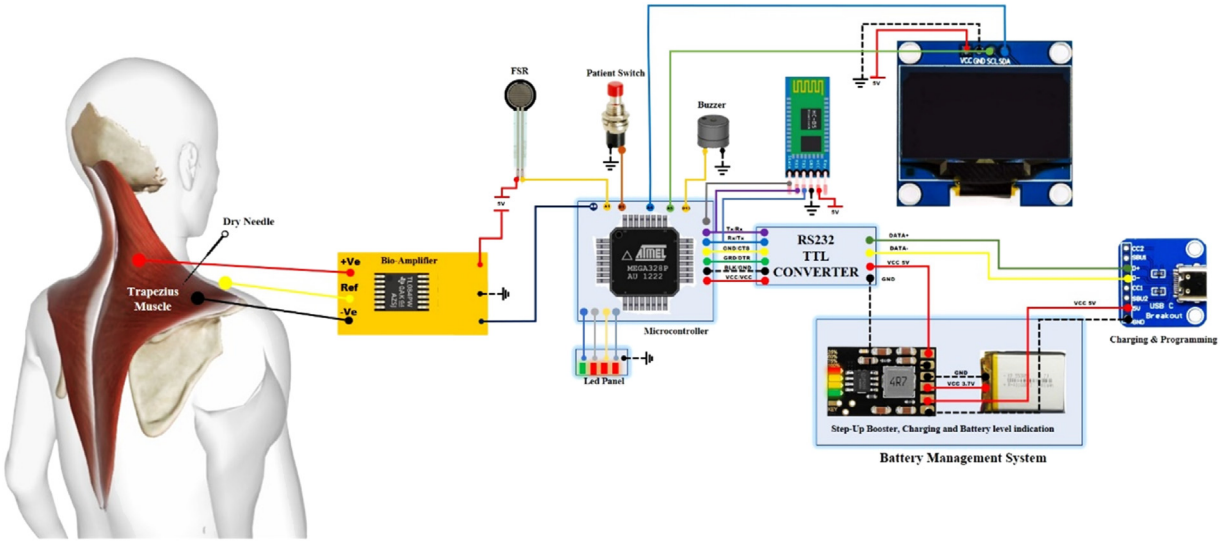

Fig. 2. Circuit Diagram for Transmitter/Patient Unit (Tx Unit).

Transmitter/Patient unit (Tx-Unit)

The circuit diagram for the Transmitter/Patient unit is shown in Fig. 2. The Tx Unit is powered by an ATmega328P microchip (Atmel Corporation, San Jose, California, United States). Two analog input pins of the microcontroller are connected to two sensors: a Bio-Amplifier and a Force Sensitive Resistor (FSR) for LTR detection and PPT measurement, respectively. The Bio-Amplifier amplifies the LTR signals 1000 times, which are not perceivable to the naked eye.

One digital input pin is used to switch the program between LTR and PPT modes. Another digital pin, connected to a push button, becomes active during PPT mode and acts as a patient switch to cease the PPT reading on the display when the patient first perceives pain. The data received from the sensors undergoes further software processing to reduce any type of artifact and normalization of signals, which makes the device more reliable and accurate. The processed signal is then sent to the Rx-Unit via wireless Bluetooth communication.

This unit also features some advanced functions. This single device can be used for both LTR detection and PPT measurement. The PPT mode can be switched on by pressing the mode button, and this mode is programmed considering the evidence-based data available for PPT and TrpDN. When measuring PPT, three LEDs (green, yellow, and red) indicate the applied force. The green light indicates the start of measurement, the yellow light indicates the safe range of PPT for a trigger point. The maximum value of PPT for an active trigger point should not be >4 Kg/cm^2. If the value of the applied compressive force goes beyond this limit, the red-light glows, along with a beep sound indicating that the pain is not due to a trigger point. This ensures that the measurement taken by the clinician is within the normal limit, as checked by the device.

Another evidence-based feature is the patient switch, which provides the facility of locking the reading on the display while measuring PPT. When the patient first feels pain, they press the push button, resulting in an audible buzzer, a glow of the red LED, and the freezing of the PPT reading on the screen. This indicates that the measurement has been recorded. This feature makes the device time-saving and more accurate, as it reduces the time lag between the patient's indication and the investigator's recording of the reading.

Receiver/Clinician unit (Rx-Unit)

The circuit diagram for the Receiver unit is shown in Fig. 3. The Rx-Unit is powered by an ATmega2560 microchip (Atmel Corporation, San Jose, California, United States). This unit is connected to a 3.5″ TFT and a 1.3″ OLED display. The signals sent by the Tx-Unit are received by Rx-Unit via Bluetooth serial communication. The received signals are then analyzed by the microcontroller and displayed in graphical and numerical form on the TFT and OLED display, respectively. The OLED display also indicates the status of the Bluetooth connection and the activation of the patient switch by freezing the reading on the display.

In the LTR mode, when the local twitch reflex occurs during the back-and-forth movements of needle in the muscle, the signals for the reflexive changes are picked up by the Bio-Amplifier, which increases the amplification up to 1000 times. This picked signal is then transmitted to the receiver unit and plotted as a spike wave on the TFT display. The same value is interpreted in numerical form between 0 and 99 and is displayed on the OLED display, indicating the strength of the LTR gained. The device is also capable of providing audio feedback to the clinician for the LTR. Therefore, whenever the LTR occurs during the TrpDN procedure, the beep sound produced by the buzzer confirms the trigger point breakage.

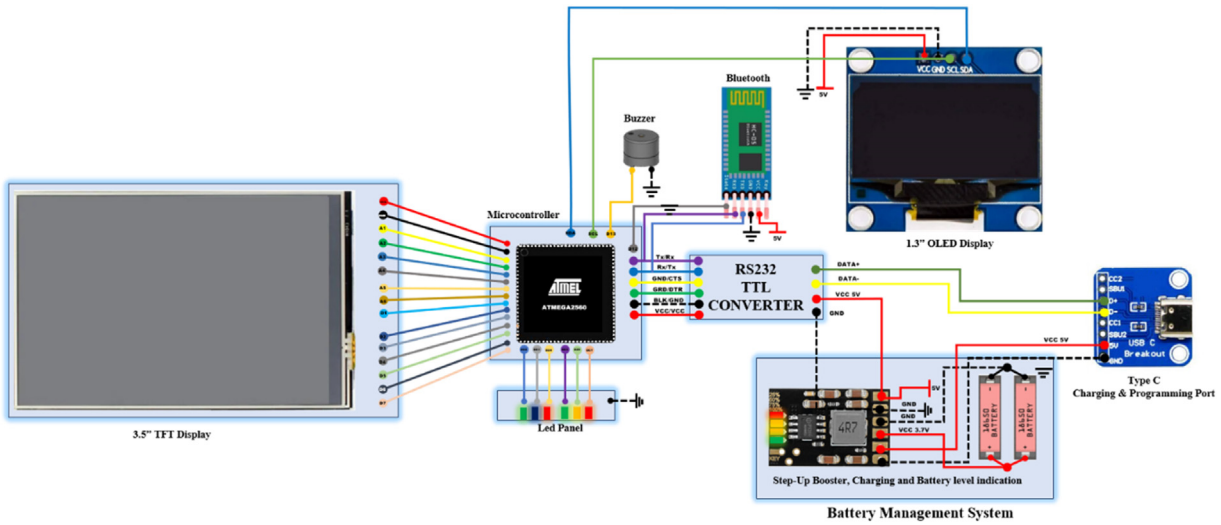

Fig. 3. Circuit Diagram for Receiver/Clinician Unit (Rx Unit).

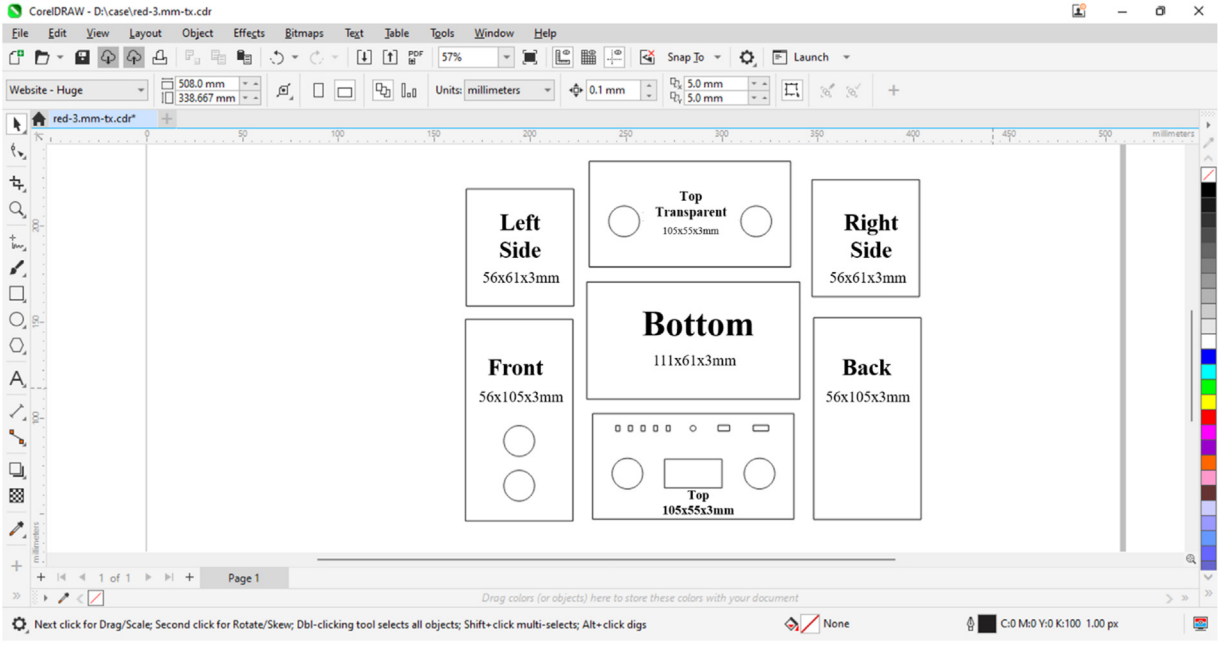

Fig. 4. Drawing of outer case of Transmitter/Patient Unit (Tx Unit) for laser cutting.

Both units have multiple LED indicators representing the status of power, battery level, Bluetooth connection, and sensor connection. The transmitter and receiver units are powered by rechargeable li-ion batteries of 1800 mAh and 6000 mAh, respectively, which makes them portable. The microcontrollers, Bluetooth, and other components used are low power-consuming thereby increasing the battery's longevity.

The outer case of the device constructed using a 3 mm acrylic sheet and was designed and cut using CorelDRAW software (Version 21.1.0.269, Corel Corporation, Ottawa, Canada) and a CO_2 laser, respectively. The designing and cutting were done in three units: Tx-Unit (Fig. 4), Rx-Unit (Fig. 5), and Finger Unit (Fig. 6), while considering their component sizes and respective output and input ports. All the units were designed in multiple parts/layers and attached to form the complete case/attachment. The Finger Unit was designed to provide a secure attachment mechanism for an FSR sensor on the clinician's finger, enabling the accurate measurement of compressive forces during PPT measurement.

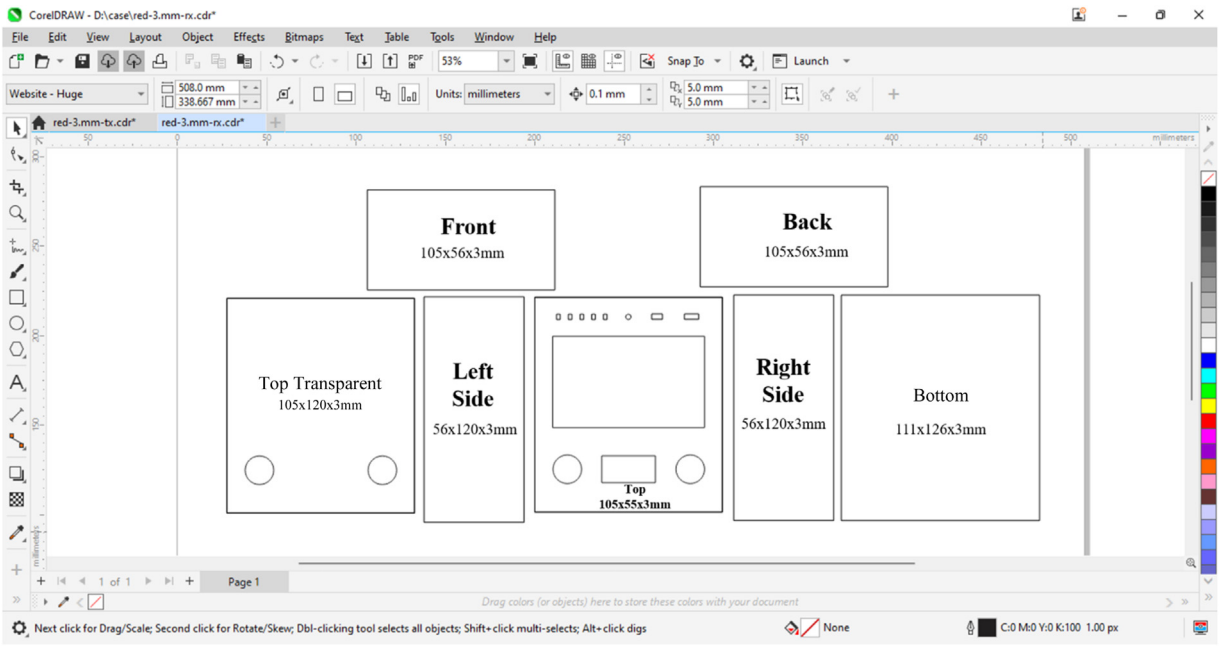

Fig. 5. Drawing of outer case of Receiver/Clinician Unit (Rx Unit) for laser cutting.

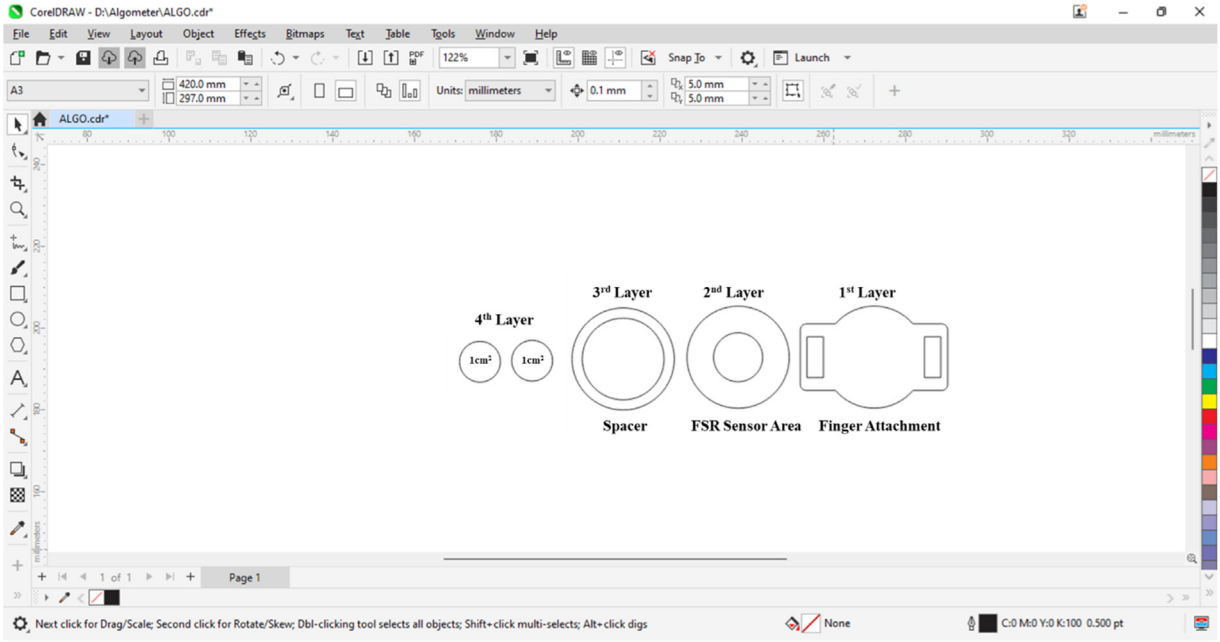

Fig. 6. Drawing of outer case of Finger Unit for laser cutting.

Method validation

Testing of the device was conducted separately for both the Local Twitch Response (LTR) and Pain Pressure Threshold (PPT) modes. The LTR mode was tested in a clinical setting, while the PPT mode underwent testing in both the laboratory and clinical environments.

Testing of local twitch response mode

The clinical validation of the LTR mode was conducted in the rehabilitation center of the MYAS-GNDU Department of Sports Sciences and Medicine, Guru Nanak Dev University, Amritsar, Punjab, India. The inclusion criteria for participants were an age between 20 and 30 years, and they had to meet the palpation testing criteria for trigger points as described by Fernández-de-las-Peñas and Dommerholt. The criteria were fulfilled if any two of the following three symptoms were present: 1) Taut band, 2) Hypersensitive band/nodule, or 3) Pain recognition/referral. Out of 42 participants, 30 qualified for the inclusion criteria. The participants were briefed on the procedure and asked to provide written informed consent for participation.

The upper trapezius muscle was targeted for TrpDN as it has a higher prevalence of trigger point formation compared to other muscles [17]. Subjects were randomly divided into two groups, and the NPRS and PPT were assessed before the intervention. The NPRS allowed patients to rate their pain on a scale from 0 to 10, and it was measured when a constant compressive force of 4 Kg/cm^2 was applied using an algometer (Pain Test FPX 25 Algometer; Wagner Instruments, Greenwich, USA).

The algometer was placed on the trigger point, and a compressive force was gradually increased at a speed of ~1 Kg/s. The participants were instructed to say "stop" as soon as they experienced pain or discomfort, and the compression was then stopped. Three consecutive measurements were recorded at 1-minute intervals, and the average was used for data analysis.

Group-1 (TrpDN-PPT/LTR-DEVICE) received trigger point dry needling assisted by the LTR device, while Group-2 (TrpDN) received only trigger point dry needling. The participants were positioned in a prone lying on a couch, and a 0.25 mm x 40 mm needle was used for the trigger point dry needling. For the TrpDN-PPT/LTR-DEVICE group, the active and passive electrodes of the Bio-Amplifier device were connected around the trigger point area, and the reference electrode was placed on the bony mid-clavicular region. All participants were treated by a trained dry needling practitioner, and Hong's technique (i.e., back-and-forth movements of needle in the trapezius muscle) was performed until three noticeable LTR were observed. The spike shown on the TFT display confirmed the LTR in the TrpDN-PPT/LTR-DEVICE group, while the visible or perceptible feedback was used for the TrpDN group. Post-treatment readings for NPRS at 4Kg/cm^2 of compressive force and PPT were taken after 24 h and compared using statistical analysis.

Testing of pain pressure threshold mode

The testing of the PPT mode was carried out in three phases: 1) investigator training, 2) laboratory, and 3) clinical testing. In these phases, the developed PPT-LTR device was tested under controlled environmental conditions. This involved comparing the force measurements obtained with the developed device to those acquired using reference standard instruments, namely the Kistler force plate (Kistler Group, Switzerland) and FPX 25 algometer (Wagner Instruments, Greenwich, USA).

1. *Investigator Training*
   Prior to the data collection, the investigator underwent a 1-week training session, with 30 min of practice each day to learn the use of the PPT mode. During this training, the investigator practiced holding the force reading on the algometer for at least 5 s at a range of pressures, from 0.5 Kgf/cm^2 up to 10 Kgf/cm^2, in increments of 0.5 Kgf/cm^2. This allowed the investigator to become proficient in applying and measuring the various force levels required for the study.
2. *Lab Testing*
   The Kistler force plate, manufactured by the Kistler Group in Switzerland, was used to obtain real-time force measurements. The force plate recorded the applied perpendicular force, and the readings were displayed on the accompanying software. A sample rate of 500 Hz was used for the measurements. The MARS software, also developed by the Kistler Group in Switzerland, was utilized to record and document the vertical force measurements. The force plate underwent calibration after every 5 measurements, constituting 1 set.
   For the lab testing, the trained investigator applied the perpendicular compressive force on the Kistler force plate, while another investigator operated the MARS software. The first investigator applied compressive forces ranging from 0.5 Kgf/cm^2 to 10 Kgf/cm^2, in increments of 0.5 Kgf/cm^2, for a duration of 5 s. The second investigator analyzed the readings displayed by the MARS software at the specific compressive forces applied using the developed device. The force values shown by the force plate at the aforementioned levels were used for data analysis. The force values displayed by the algometer in Kgf/cm^2 were converted to $Newton/cm^2$ to allow comparison with the force platform readings, using the known conversion of 1 $Kgf/cm^2 = 9.8N/cm^2$. For each force value, 5 measurements were taken, constituting 1 set, and 3 such sets were performed, resulting in a total of 15 measurements for each force value and a grand total of 300 measurements that were recorded and compared. The measurements obtained from both devices were compared using statistical tests.
3. Clinical Testing
   The clinical testing phase involved evaluating the assembled algometer against the commercially available PPT device in a real-world clinical setting with a sample of 50 patients experiencing musculoskeletal trigger point pain in their muscles. This included assessing the device's ability to detect trigger points and quantify pressure pain thresholds. Data collection procedures were standardized and performed by the same trained investigator who was involved in the training and lab testing phases. The inclusion criteria remained the same as those used during LTR mode testing. The patients were positioned comfortably in a prone position and examined for trigger points in the upper trapezius muscle. The tender area was marked to minimize error. PPT measurement began with the commercially available FPX 25 algometer and a 1cm2 probe was used for testing. The pressure was gradually increased on the marked area of the patient's body at a steady rate of 1 kg/cm^2 per second. Patients were instructed to

Table 1
Tests for Normality-Shapiro-Wilk test.

Variable	Shapiro-Wilk Test			
	Group	Stage	Statistic	p-value
NPRS	TrpDN-PPT/LTR-DEVICE	Before Intervention	0.929	0.262*
		After Intervention	0.947	0.473*
	TrpDN	Before Intervention	0.940	0.386*
		After Intervention	0.941	0.401*
PPT	TrpDN- PPT/LTR-DEVICE	Before Intervention	0.933	0.299*
		After Intervention	0.894	0.077*
	TrpDN	Before Intervention	0.951	0.538*
		After Intervention	0.957	0.636*

* Statistically not significant ($p > 0.05$), the distribution of the data is equal to normal distribution.

Table 2
Intragroup comparison of pre and post mean values for all the groups.

Variable	Group	Stage	Mean±SD	Mean Diff.	t-Value	p-Value
NPRS (0–10)	TrpDN- PPT/LTR-Device	Before Intervention	5.73±1.16	3.06	8.178	<0.01*
		After Intervention	2.67±1.39			
	TrpDN	Before Intervention	5.47±1.25	1.20	2.500	0.025*
		After Intervention	4.27±1.53			
PPT (KG/CM2)	TrpDN- PPT/LTR-Device	Before Intervention	2.30±0.50	−1.82	−7.581	<0.01*
		After Intervention	4.12±0.80			
	TrpDN	Before Intervention	2.03±0.59	−0.22	−1.029	0.321

* Statistically significant ($p < 0.05$).

indicate when they felt pain or discomfort by saying “stop” as pressure was applied to the tender point in the muscle. The reading of the FPX 25 algometer was noted at the point when the patient indicated pain. After a one-minute rest period to allow sensitivity to recover, the same steps were repeated using the PPT mode of the developed PPT-LTR device on the same point on the patient’s body. Patients were given a switch and instructed to press it as soon as they felt pain or discomfort. The reading shown on the OLED display of the Rx Unit was recorded. The readings from both devices were then compared using statistical tests.

Data management and analysis

The data of this study was managed and analyzed using a combination of statistical software. Specifically, statistical analyses were conducted using IBM SPSS for Windows version 27.0. In addition, GraphPad Prism 10 was utilized for data visualization and graphical presentation.

Statistical analysis for ltr mode

Shapiro wilk test was used to test distribution of data and result showed that distribution of data was equal to normal distribution for both NPRS and PPT (Table 1). Paired *t*-test was used to compare the NPRS and PPT value of TrpDN-PPT/LTR-DEVICE and TrpDN group. Statistically significant improvement was noted for NPRS in TrpDN-PPT/LTR-DEVICE ($t = 8.18$, $p < 0.001$) and TrpDN ($t = 2.5$, $p < 0.025$) group. PPT for TrpDN-PPT/LTR-DEVICE ($t = -7.58$, $p < 0.01$) showed significant improvement while TrpDN ($t = -1.03$, $p < 0.32$) group showned no significant improvement (Table 2). Significant decrease in NPRS in both the group showed that TrpDN intervention is equally effective via both the methods in treating pain produced due to trigger point. PPT reduced significantly in TrpDN-PPT/LTR-DEVICE group as compared to TrpDN group. Resulting that post dry needling soreness was less in group receiving dry needling intervention using the developed device (TrpDN-PPT/LTR-DEVICE). Hence, Dry needling done using TrpDN-PPT/LTR-DEVICE caused less muscle damage and resulted in less pain and soreness as compare to the traditional method.

Statistical analysis for ppt mode

Comparison of force shown by TrpDN-PPT/LTR-DEVICE with Kistler force plate and FPX-25 algometer was done using independent student *t*- test (Table 3), Pearson correlation (Table 4), Bland–Altman at 95 % and Cronbach’s α (Table 4) at 99 % Confidence interval. Statistically no significant difference was observed between the force values obtained from developed device (TrpDN-PPT/LTR-Device) with the other standardized equipment, i.e. FPX 25 Algometer ($t = -0.362$, $p = 0.718$) and Kistler force plate ($t = -0.037$, $p = 0.971$). Pearson correlation between values of force shown by developed device vs force plate (Fig 7(A), $r^2=0.99$, $p < 0.0001$) and developed device vs FPX-25 algometer (Fig 7(B), $r^2=0.96$, $p < 0.0001$)) were high. The Cronbach’s α for lab and clinical validity were 1.00 and 0.99, respectively. The Bland–Altman analysis also showed high level of agreement for lab (Fig 8(A), Bias 0.085, 95 % CI[−1.02 to 1.24]) and clinical validity (Fig 8(B), Bias 0.06, 95 % CI[−1.26 to 0.38]).

Table 3
Intragroup comparison of pre and post mean values for groups.

Variable	Group		Mean±SD	Mean Diff.	t-value	p-value
FORCE	Laboratory Testing	Kistler Force Plate (N/cm^2)	51.36±28.36	−0.09	−0.037	0.971*
		TrpDN-PPT/LTR-Device (N/cm^2)	51.45±28.30			
	Clinical Testing	FPX 25 (Kgf/cm^2)	1.93±0.83	−0.06	−0.362	0.781*
		TrpDN-PPT/LTR-Device (N/cm^2)	1.99±0.82			

* Statistically not significant ($p > 0.05$).

Table 4
Cronbach's α and Pearson correlation for groups.

Variable	Group		Cronbach's α	Pearson Correlation (R2)
FORCE	Laboratory Testing	Force Plate	1.00	0.99*
		TrpDN-PPT/LTR-Device (N/cm^2)		
	Clinical Testing	FPX 25	0.99	0.96*
		TrpDN-PPT/LTR-Device (N/cm^2)		

* Statistically significant ($p < 0.05$).

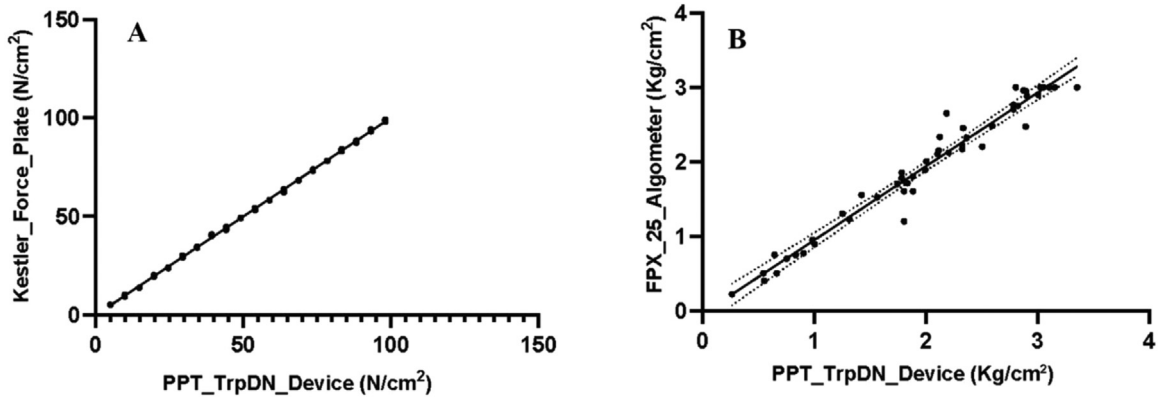

Fig. 7. Pearson correlation: Lab (A) and Clinical (B) testing.

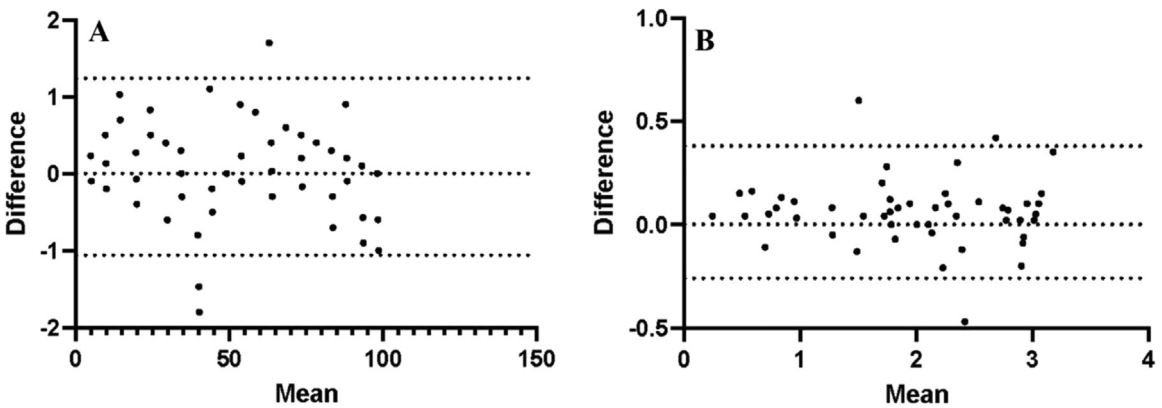

Fig. 8. Bland-Altman plot: Lab (A) and Clinical (B) testing.

The developed TrpDN-PPT/LTR device demonstrated promising results during rigorous laboratory testing, as it showed a strong correlation and agreement with established reference standard instruments. The device's PPT and LTR mode were particularly effective when applied to patients suffering from trigger point pain. It accurately detected trigger points, precisely measured pain pressure thresholds, and provided valuable audiovisual feedback regarding the patients' LTR - a key indicator of myofascial trigger point activity. Importantly, the device's portability and user-friendly interface were key factors that made it highly acceptable and accessible to both healthcare providers and patients, thereby improving the overall usability and potential for integration of the device into routine clinical practice for the assessment and management of trigger point-related musculoskeletal pain conditions.

Limitations

Not applicable.

Ethics statements

Study was approved by institution ethical committee of Guru Nanak Dev University, and all the participants are asked to provide written inform consent for voluntary participation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Manoj Kumar Sharma: Conceptualization, Methodology, Investigation, Data curation, Validation, Writing – original draft, Visualization, Software. **Sarika Chaudhary:** Supervision, Visualization, Writing – review & editing. **Hardika Sood:** Formal analysis.

Data availability

Data will be made available on request.

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