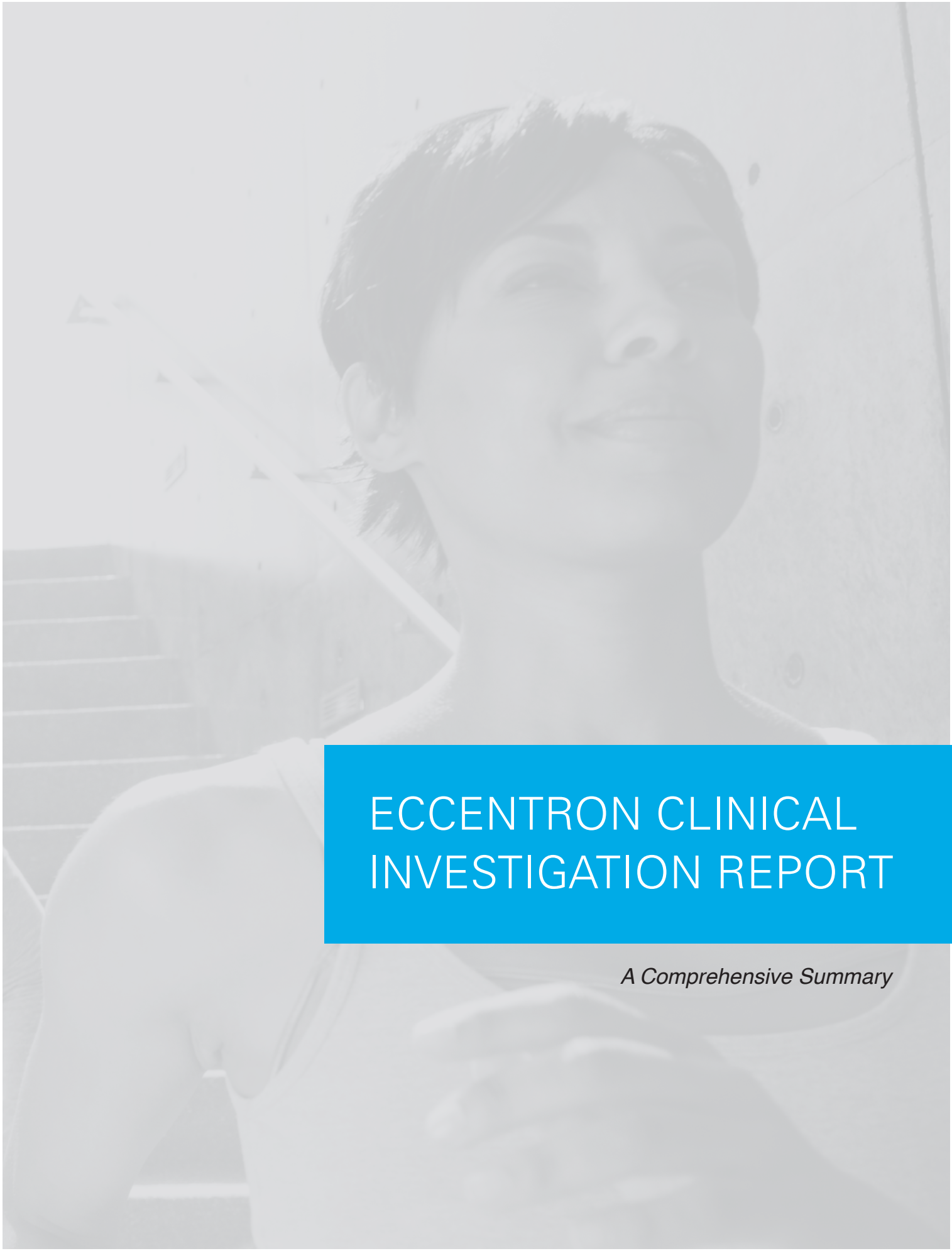


ECCENTRON CLINICAL INVESTIGATION REPORT

A Comprehensive Summary

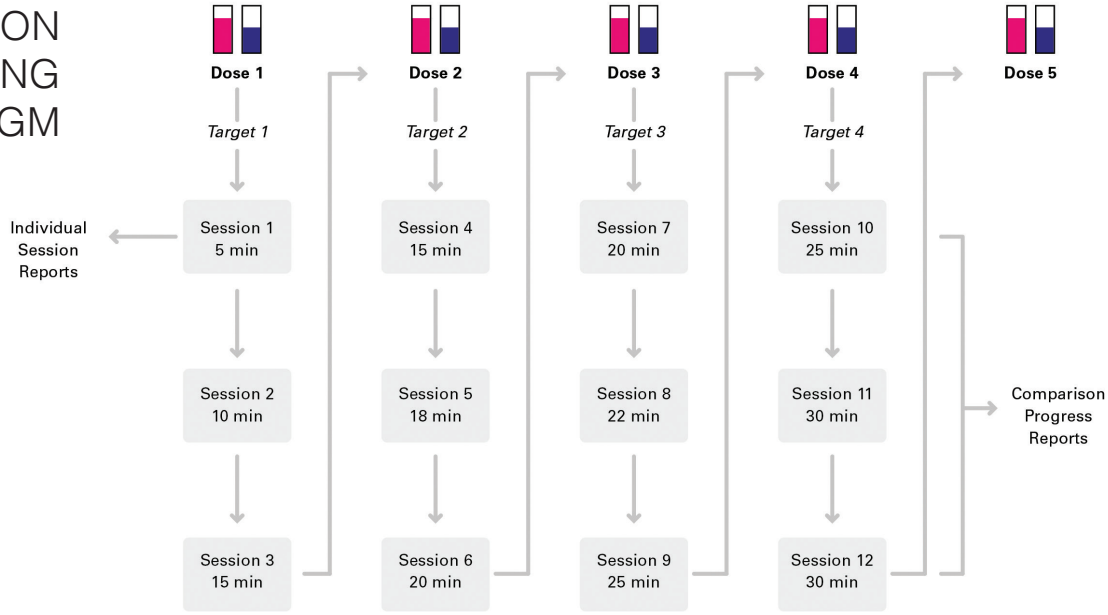
Objective

The primary use of the Eccentron is for muscle strengthening of the lower extremities through eccentric muscle contraction. The primary objective of this clinical investigation was to measure strength changes resulting from an eight-week program of high force eccentric exercise addressing the stated intended use of the system. The hypothesis was – using a similar device, similar strength gains to those cited in previous studies should be achieved.

Background

The effectiveness and benefits of eccentric exercise are well documented in the literature. Several studies were found that investigated the use of eccentric exercise for the purpose of muscle strengthening, incorporating prototypes of the Eccentron.

ECCENTRON TRAINING PARADIGM



Methodology

Twenty-three BTE employee participants completed the study. The demographics of the group are detailed on page 4 under the section titled Eccentron Clinical Investigation Data Summary. All participants signed Informed Consent forms and completed the Physical Activity Readiness Questionnaire (PAR-Q). If any medical conditions, previous injuries, etc. were noted by a participant, the primary investigator obtained additional information in order to determine whether the individual should or should not participate in the study.

Testing consisted of pre and post-training program measures of isometric quadriceps and hamstring muscle strength on an independent evaluation device, the PrimusRS. This testing was performed in a sitting position with the knee at 45 degrees of flexion. Pre-testing was performed 2 days prior to engaging in the exercise program. Post-testing was performed 2 days following the final dosing test.

The exercise protocol began and ended with a dosing test. Additionally, every fourth session, the pre-set target force was re-evaluated in what was termed a dosing test. That test consisted of twelve strides or six repetitions of the participant's attempts to resist the pedals moving toward them, by pushing on those pedals with their safe, maximum effort as the pedals move closer. The pre-set target force is defined by the second highest peak force exerted by the weaker lower extremity. Performing these intermittent dosing tests ensured that the target force remained at fifty percent of safe, maximum strength. If strength gains were being made, the target force remained challenging. If a participant experienced a pain event, the dosing test allowed the participant to safely continue exercising despite the pain event. The diagram displayed above defines the progression of the exercise protocol, including the dosing sessions. There was a gradual ramp-up of the program via increasing duration of sessions from five to thirty minutes.

Participants' performance and feedback were tracked each session. A post-session questionnaire was used after each training episode to record participant feedback. Session Reports were generated within the software at the conclusion of each session. Session Report Data included the following:

- Average force for the left and right lower extremities (LLE and RLE), percent difference (% difference) between the two extremities, and the combined force of both LE
- Peak Force for the LLE and RLE, % difference, and combined force of both LE
- Power generated by the LLE and RLE, % difference, and combined power for both LE
- Target Force, Target Range Minimum, and Target Range Maximum
- Rate of Perceived Exertion (RPE)
- Duration of exercise session
- Total Work performed
- Total Repetitions
- Average Speed

Instruction and supervision through the course of the study were provided by the Director of Training and Clinical Support and the Quality Assurance Specialist. Prior to the first dosing session, the appropriate stride length and seat position were determined by the Director of Training and Clinical Support. Goniometric measurements ensured safe and appropriate joint angles and ranges. These were recorded in the software for each participant. On all subsequent sessions, seat position was reassessed and changes were made and recorded as required. All participants were visually monitored for safety for the duration of every exercise session.

In addition to the performance measures recorded by the Eccentron each session, physiologic metrics were also recorded. These metrics included:

- **Pre-exercise** – resting heart rate, blood pressure, respiration rate, and pain rating
- **During exercise** – mean and peak heart rates
- **Immediate post-exercise** – heart rate
- **Post-exercise recovery** (five minutes) - heart rate, blood pressure, respiration rate, perceived rate of exertion, and pain rating

For the purposes of safety and assessing cardiovascular demand, percentages of age-predicted maximal heart rate were determined for each participant. The following percentages were calculated for each participant: resting HR, 65, 70, 75, 80, and 85.

At the conclusion of the study, all participants completed a brief questionnaire documenting perceived results related to strength gains and functional improvement. A check was done to determine if any participants engaged in any physical activity that would have influenced the results. General comments were also recorded.

Results

The primary purpose of this clinical investigative study was to provide quantitative data to support the intended uses of the Eccentron – as an exercise device that improves lower extremity muscle strength, specifically the quadriceps muscles, and as an evaluative device for measurement of lower extremity strength (using the dosing test). Furthermore, the study was designed to simulate use of the device within a typical clinical setting. At the conclusion of the study, both isometric and dynamic strength gains of the quadriceps and hamstring muscles of both lower extremities were documented. Dynamic strength gains as measured by the Eccentron averaged 70.25% for both lower extremities (BLE) across those participants who completed the program. More specifically, a 69.47% increase was seen for the left lower extremity (LLE) and a 71.05% increase for the right lower extremity (RLE). Isometric strength gains as measured by the PrimusRS averaged 27.89% for the quadriceps and 50.70% for the hamstring muscles. Strength gains were therefore achieved using the Eccentron and the pre-programmed training or exercise protocol. Additionally, the isometric strength gains measured in this study exceeded those of similar studies incorporating prototype devices.

Side effects that were documented during the study included joint soreness and/or pain, joint stress, muscle soreness and fatigue, and delayed onset muscle soreness. These are usual side effects of strengthening programs. Due to the structure of the study, no contraindications were identified. Adequate medical assessment was conducted and professional knowledge and decision making were utilized.

Conclusion

Based on all data collected and analyzed at the conclusion of the study, the Eccentron was deemed a safe and effective device when used as recommended by the manufacturer. Additionally, the strength gain results of this study exceed results reported in previous published studies, establishing equivalency with the studies that employed a similar device and training protocol.

Janna Jacobs, PT, CHT, CEAS, *Director of Training and Clinical Support at BTE. Janna has served as Director of Rehab at skilled nursing and outpatient facilities, is an international lecturer, published author, and an APTA of Maryland certified peer-reviewer.*

ECCENTRON CLINICAL INVESTIGATION DATA SUMMARY

Demographic Data

Number of participants = 23		Gender – 14 males, 9 females		
mean age of males	41.1 yo	SD = 10.6	minimum = 24 yo	maximum = 57 yo
mean age of females	48.1 yo	SD = 13.9	minimum = 23 yo	maximum = 60 yo
mean age of total group	43.9 yo	SD = 12.2		

Physiological Data

Heart Rate (HR): units - beats per minute (bpm); age-predicted maximal heart rate (APMHR)

Resting HR

males	mean	71.82	SD = 9.76
	mean APMHR	42.63%	SD = 4.48
females	mean	68.21	SD = 8.14
	mean APMHR	43.80%	SD = 5.48

Peak HR

males	mean	116.74	SD = 12.80
	mean APMHR	69.44%	SD = 5.75
females	mean	107.77	SD = 15.33
	mean APMHR	69.04%	SD = 10.13

Blood Pressure (BP): units – mm HG
A slight decrease in the recovery BP was seen when compared to the resting BP, but was not statistically significant.

Respiration Rate (RR): units – respirations per minute
A slight increase in the recovery RR was seen when compared to the resting RR, but was not statistically significant.

Muscle Strength Data

ISOMETRIC STRENGTH CHANGES

(obtained using PrimusRS) units are pounds (lbs)

Average percent increase in lower extremity strength of males = 31.96 SD = 9.75
Average percent increase in lower extremity strength of females = 50.91 SD = 13.89

Pre and Post Study Comparisons

		Pre-Study Quads	Post-Study Quads	Percent Change	Pre-Study Hamstrings	Post-Study Hamstrings	Percent Change
males	mean	107.60	129.84	22.24%	74.56	104.95	42.33%
	SD	28.77	32.93	19.48%	19.53	25.16	17.94%
females	mean	62.62	82.21	37.02%	34.99	55.46	64.81%
	SD	13.94	12.21	34.13%	7.53	9.15	39.38%

DYNAMIC STRENGTH CHANGES

(obtained from Eccentron dosing sessions) units are pounds (lbs)

First and Last Dose Force Comparisons

		Left Lower Extremity (LLE)			Right Lower Extremity (RLE)		
		First Dosing LLE	Last Dosing LLE	Percent Change LLE	First Dosing RLE	Last Dosing RLE	Percent Change RLE
males	mean	395.45	596.76	58.68%	382.79	589.63	62.47%
	SD	116.20	112.96	43.27%	108.50	105.97	38.16%
females	mean	220.31	394.57	84.32%	220.00	385.13	81.59%
	SD	44.46	37.84	29.37%	49.52	44.26	33.20%