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Original Article

Evaluating a 14-week neck strengthening protocol for neuromuscular indicators associated with head and neck trauma

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A R T I C L E I N F O

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A B S T R A C T

Increased neck strength has been linked to a potential decrease in traumatic brain injuries (TBI). The purpose was to determine the efficacy of a neck-strengthening protocol using a novel neck-strengthening device to increase isometric neck strength and rate of force development (RFD). Utilizing self-generated centripetal force, participants trained for 14 weeks. A linear mixed model was used to analyze the relationship between post-assessment measurements and pre-assessments measurements, while accounting for repeated measure random effect at the individual level, and a regular random error term. RFD values were 4.344 times higher in the clockwise direction and 5.978 times higher in the counterclockwise direction when comparing pre and post assessment measurements. Isometric neck strength increased significantly ($p < 0.05$) in the cervical extension ($p = 0.010$) and left lateral flexion ($p = 0.009$) directions. The results can be used in strength training and clinical settings to potentially reduce the incidence of TBI.

1. Introduction

Head and neck trauma such as mild traumatic brain injuries (mTBI) are complex pathophysiological processes that affect the brain shortly after the head and neck withstand distressing biomechanical forces.[1–3] Concussions are the most common form of traumatic brain injury (TBI) worldwide. Out of the estimated 8 million people who suffer from TBI in the United States each year, 75%–90% of the cases are mTBI.[2] TBIs contribute to a significant number of deaths and permanent disabilities, such as Post-Concussive Syndrome and Chronic Traumatic Encephalopathy (CTE).[4]

Concussions and other head and neck trauma resulting from bodily impact occur due to a multi-planar event.[5–7] Due to the multi-axial nature of the head/neck complex, a bodily impact occurring in a powerful manner results in a rapid acceleration requiring adequate muscle response to attenuate said forces. The neck muscular tissue type and contractile effort therefore required to attenuate a bodily impact force are associated with Type IIx fibers, the stretch reflex, stretch shortening cycle and the series elastic component.[8] In other words, the capability of a muscle to optimally respond to an eccentric load followed by a fast-powerful concentric contraction. The eccentric-concentric effort on part of the neck musculature is an important aspect to consider when developing a training program. Thus, in theory training programs should focus on dynamic neck muscular activation to reinforce the fast reflexive effort characterized by the surround neck musculature. Previous research has demonstrated the effectiveness of plyometric training programs for lower body power effort and improvements in Type IIx muscle fibers. Type IIx muscle fibers, less referred to as Type IIb, are associated with the fastest twitch response to proprioceptive and mechanoreceptive stimulus, the stretch reflex. As such, training neck musculature in a similar manner may improve Type IIx fibers and reduce the short latency period when responding to a bodily impact improving the attenuation of force and correcting head alignment.[8–12]

Previous research found that effective neck strengthening programs are correlated with lower mTBI.[13] Stronger neck muscles are more effective in decreasing acceleration, rapid change in velocity, and displacement after a collision, potentially reducing the risk of mTBI.[14,15] The ability of the neck musculature to adequately attenuate force upon bodily impact is directly correlated to the surrounding musculature's strength and muscle fiber type. Strengthening programs that elicit a dynamic neck strength adaptation of type-IIa and type-IIx muscle fibers may be considered a potential primary prevention method for mTBIs.[14–16]

This study aims to determine the efficacy of a neck strengthening protocol to increase isometric and dynamic neck strength as neuromuscular indicators. The effectiveness of a 14-week neck training protocol to

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Abbreviations:

TBI	Traumatic Brain Injury
RFD	Rate of Force Development
CW	Clockwise
CCW	Counterclockwise
mTBI	Mild Traumatic Brain Injury
CTE	Chronic Traumatic Encephalopathy
PPR	Pounds per Revolution
CE	Cervical Extension
CF	Cervical Flexion
LCLF	Left Cervical Lateral Flexion
RCLF	Right Cervical Lateral Flexion
NSAT	Neck Strength Assessment Tool
RPM	Revolutions Per Minute
COVID-19	SARS-CoV-2 Disease or Coronavirus Disease 2019
LMM	Linear Mixed Model
CI	Confidence Interval
INS	Isometric Neck Strength
min	Minute

improve isometric neck strength, rate of force development (RFD), and pounds per revolution (PPR) using a novel neck strengthening device, the TopSpin360 helmet, will be assessed.[17] It is hypothesized that there will be an increase in isometric neck strength, RFD, and PPR.

2. Methods

2.1. Ethical approval

The University's Institutional Review Board reviewed and approved this study (#19–0118) and informed consent was collected from each participant.

2.2. Participants

Written informed consent was given to all eighteen participants. Each participant was older than 18 years of age and reported no medical history of the following conditions: severe head or neck injuries, chronic or acute musculoskeletal neck injuries, cervical spine degenerative disc disease, migraines or headache disorder, head or neck surgery, labyrinthine/inner ear problems, vertigo, thyroidectomy, heart disease, or hypertension. Individuals who were pregnant or planned to become pregnant were not eligible to participate. The participants represented a wide-range of healthy college-aged population who reported participating in various fitness and athletic events. Some of the subjects reported participation in inherently high-risk athletic events, such as Brazilian jiu jitsu, club sport basketball and volleyball, and various intramural sports. It should be noted, this study occurred during the SARS-CoV-2 (COVID-19) pandemic and resulted in low participation and recruitment due to restrictions in university activities. Nevertheless, the research team was able to recruit from a viable population pool to produce pilot study data.

2.3. Training and testing

The training programs and testing methods explicitly followed previously collected research.[17,18] The neck strength assessment occurred in two planes of motion with four movements (cervical extension [CE], cervical flexion [CF], left cervical lateral flexion [LCLF], and right cervical lateral flexion [RCLF]) utilizing a portable isometric neck strength assessment tool (NSAT).[18,19] The NSAT is a portable fixed tension scale instrumentation system that can measure isometric neck strength in both seated and standing positions. It is as reliable as the fixed frame dynamometry scale and portable and cost-effective.[18] The participants performed each movement for three trials and maintained an isometric neck contraction for 3 s per trial. The isometric neck strength was measured in kilograms. The RFD and PPR were assessed using the neck strengthening device, a self-propelled weighted pendulum fixed at the top of a football helmet.[15] Participants were fitted and instructed on how to wear and use the neck-strengthening device. Participants positioned their bodies and utilized the helmet in accordance with the manufacturer's guidelines.[15] The RFD and PPR were assessed and recorded using a tablet's neck-strengthening device application in both clockwise (CW) and counterclockwise (CCW) directions. The peak RFD was recorded as the highest score during the 50 revolutions.

Participants completed a warm-up and upper back strengthening exercises at the beginning of each session (Table 1).

The neck-strengthening device, TopSpin360, was utilized throughout the 14-week neck strength intervention. Each session lasted 10–15 minutes (min) and averaged 12 sets per training session. There were 2–3 days of rest between each training session (Table 2).

2.4. Statistical analyses

To detect whether there is an increase in Rate of Force Development/lbs per revolution after a 14-week novel neck strengthening program, a linear model is considered with the following linear model assumption:

$$Y_i = \mu + \beta X_i + \epsilon_i, \quad (1)$$

with Y_i as the i_{th} subject's post-program CW (or CCW) measurement, X_i as the i_{th} subject's pre-program CW (or CCW) measurement, μ as the intercept, and ϵ_i as the random error term following normal distribution with mean zero and variance σ^2. If the null hypothesis of

$$H_0 : \beta = 0 \text{ vs } H_1 : \beta > 0. \quad (2)$$

being rejected, we may conclude that there is an increase in Rate of Force Development after the program.

Concerning the Isometric Neck Strength data, the participants were assessed for three trials, each in four movements (CE, CF, LCLF, and RCLF) in both the pre-and post-assessments. A Linear Mixed Model (LMM) is considered for analyzing the relationship between post-assessment measurement and pre-assessment measurement, while accounting for repeated measure random effect at the individual level, and a regular random error term. Specifically, the full model considered is:

Table 1
Upper back exercises protocol.

Exercise	Upper Back Exercises Protocol
Ball “Y" Scapation	Lay with your stomach on an exercise ball, feet touching the ground, elbows fully extended, and arms out in front of the body. Shoulders should be abducted at about 120°. From there, lower arms and touch hands to the ground while maintaining full elbow extension. Next, slowly raise arms and return to the original position. Throughout the exercise, thumbs should be pointed up.
Ball “W" Scapation	The participant should lay on an exercise ball with their stomach down and elbows bent and pressed into the ball. From there, slowly raise arms upward and retract the shoulders and then return to the starting position. The palms of the hand should be directed downward the whole exercise.
External Rotation	Hold an elastic band with your arm at a 90-degree angle away from your side and your elbow bent to a 90-degree angle. Your forearm should face forward, and then roll your shoulder back from there so your forearm faces up.
Standing Serratus Punch	Wrap an elastic band around your upper back and hold the end of the band out in front of your body with your elbow fully extended. In that position, begin to protract your shoulder blade forward and return to the starting position

Table 2
Neck strengthening protocol.

Exercise	Duration	Description
Warm-Up	Weeks one through fourteen, at the beginning of each session	Consists of two sets of 100 revolutions at low intensity (40%–50% RPM Peak). The first 50 revolutions will occur in a clockwise direction, and the last 50 revolutions in a counter-clockwise direction, totaling 200 revolutions between the two sets.
Stage One	Weeks one through four	Consists of three sets of 100 revolutions. Within each set, the first 50 revolutions are in the clockwise direction, and the last 50 revolutions are in the counter-clockwise direction. Revolutions are performed at 90%–100% RPM Peak while the participant remains seated.
Stage Two	Weeks five through nine	Consists of four sets of 100 revolutions. Within each set, the first 50 revolutions are in the clockwise direction, and the last 50 revolutions are in the counter-clockwise direction. Revolutions are to be performed at 90%–100% RPM Peak while the participant remains seated for the first two sets and stands for the last two sets. The participant must place both feet shoulder-width apart with their non-dominant foot forward when standing.
Stage Three	Weeks ten through fourteen	Consists of five sets of 100 revolutions. Within each set, the first 50 revolutions are in the clockwise direction, and the last 50 revolutions are in the counter-clockwise direction. Revolutions are performed at 90%–100% RPM Peak while the participant stands for each set. The participant must place both feet shoulder-width apart with their non-dominant foot forward when standing.

(RPM = Revolutions Per Minute).

$$Y_{ij} = \mu + \beta X_{ij} + \gamma_i + \epsilon_{ij}, \tag{3}$$

with Y_{ij} as the *ith* subject's post-program measurement (CE, CF, LCLF, or RCLF), μ as the intercept of the regression model, covariate X_{ij} as the *ith* subject's corresponding pre-program measurement, and β as the effect of the covariate, for the *ith* subject and the *jth* measurement, where $i = 1,2,\cdots,19$, and $j = 1,2,3$. Also, γ_i is a random term describing variations within the *ith* subject's measurements, which follows a normal distribution with mean zero and variance σ_x^2. ϵ_{ij} is the random error term with mean zero and variance σ^2. To evaluate the effect from the pre-assessment measurement, a reduced LMM is considered. The reduced model equates the post-assessment measurement with an overall average effect, random effect at the individual level, and a random error term. Specifically, to test the significance of $\boldsymbol{\beta}$ as in equation (3), the following model is considered:

$$Y_{ij} = \mu + \gamma_i + \epsilon_{ij}, \tag{4}$$

for $i = 1,2,\cdots,19$, and $j = 1,2,3$. The null and alternative hypotheses for testing β are:

$$H_0 : \beta = 0 \ \text{ vs } H_1 : \beta \neq 0. \tag{5}$$

For the change over time data collection, participants were measured 3 to 5 times for the 35 sessions. To model the effect of the sessions over time, another LMM is proposed between every measurement and each of the 35 sessions, while accounting for repeated measure random effect at the individual level, and a regular random error. Specifically, the full model considered is:

$$Y_{ij} = \mu + \beta_s Session_j + \gamma_i + \epsilon_{ij}, \tag{6}$$

Y_{ij} as the *ith* subject's measurement (RFD.CW, RFD.CCW, RPM.CW, and RPM.CCW), at Session time j, denoted as $Session_j$, where $i = 1,2,\cdots,21$, and $j = 1,2,\cdots,5$. Also, γ_i is a random term describing variations within the *ith* subject's measurements, which follows a normal distribution with mean zero and variance σ_x^2. ϵ_{ij} is the random error term with mean zero and variance σ^2. To evaluate the effect significance from the sessions, a similar reduced model as in (4) is considered, for $i = 1, 2,\cdots,21$, and $j = 1, 2,\cdots,5$. The null and alternative hypotheses for testing β_s are:

$$H_0 : \beta_s = 0 \ \text{ vs } H_1 : \beta_s \neq 0. \tag{7}$$

A p-value <0.05 was considered for statistical significance. All statistical analyses were performed using R Statistical Software.[20] Linear Mix Models were fitted using "lme4" package.[21] Kenward-Roger test results were obtained through "pbkrtest" package.[22]

3. Results

Of the 20 eligible participants, all 20 consented to participate in the study, with one withdrawing before the intervention and another during the intervention (not due to injury). Thus, 90% of the participants completed the entire duration of the intervention. Participants were between 18 and 29 years of age, with nine males and nine females.

For detecting whether there is an increase in RFD/lbs per revolution after a 14-week novel neck strengthening program, the analysis result is in Table 3, $\boldsymbol{\beta}$ estimate for CW is 2.649 with a p-value of 0.01. Thus, for CW, for every unit increase of in the pre-program measurement, the post-measurement increased by 2.649. Similarly, $\boldsymbol{\beta}$ estimate for CCW is 1.913 with a p-value of 0.034. Thus, for CCW, for every unit increase of in the pre-program measurement, the post-measurement increased by 1.913.

After removing an outlier to assess the variance better, the slopes for CW and CCW measurements are 4.344 and 5.978, respectively, with highly significant p-values (Table 4). This suggests that post-assessment RFD CW measurements are 4.344 and RFD CWW 5.978, times greater than the pre-assessment RFD CW and RFD CCW measurements (see Table 5).

In Fig. 1, the reference line is a line where pre-assessment is the same as the post-assessment. Since all the data pairs are above the line, thus the post-assessment measurements for RFD CW are all greater than the pre-assessment measurements.

In Fig. 2, the pattern is similar to CW and shows an increase in RFD between the two assessments. The red circle is an outlier that significantly impacts the overall fitness of the linear model. The participant represented by the red circle saw an increase in RFD, but their measurements only increased two times. Other participants experienced a four to five-times increase in RFD values (see Table 6).

The third figure illustrates that post-assessment measurements for isometric neck strength are all greater than the pre-assessment measurements (See Fig. 3).

Table 7 contains results for the model considered in equation (3). In Table 7, results show that for the CE and CF metrics, the slope $\boldsymbol{\beta}$ is estimated as 0.281 and 0.221, which suggests that for every unit increase in the Pre measurements, the post measurements are increased by 0.281 kg and 0.221 kg. The second column shows the F-statistics of the Kenward-Roger test by comparing the full model with the reduced model. Its p-values of 0.01 and 0.065 are in the third column. This indicates that the slopes are significantly above zero if a one-sided test is considered, and

Table 3
Pre- and post-assessments RFD measurements.

Revolutions	Estimate	*Std. Error*	*t*-value	*p*-value (one sided)
CW	2.649	1.021	2.594	0.010
CCW	1.913	0.974	1.964	0.034

(RFD = Rate of Force Development; CW = Clockwise; CCW = Counterclockwise; *Std. Error* = Standard Error).

Table 4
Pre- and post-assessments RFD measurements after removing an outlier.

Revolutions	Estimate	*Std. Error*	*t*-value	*p*-value
CW	4.344	1.226	3.544	0.003
CCW	5.978	1.499	3.989	0.001

(RFD = Rate of Force Development; CW = Clockwise; CCW = Counterclockwise; *Std. Error* = Standard Error).

Table 5
Pre- and post-assessments RFD measurements in the CW direction.

Participant	Pre RFD CW	Post RFD CW
1	5.05	13.30
2	1.27	8.45
3	1.23	5.34
4	1.51	NA
5	1.97	18.57
6	0.50	2.97
7	3.10	20.92
8	0.61	14.80
9	3.10	20.44
10	0.42	4.50
11	1.23	15.59
12	1.06	24.53
13	0.34	8.86
14	0.36	2.35
15	0.66	9.00
16	1.23	12.77
17	0.10	8.86
18	0.44	5.64
19	3.53	17.04

(RFD = Rate of Force Development; CW = Clockwise).

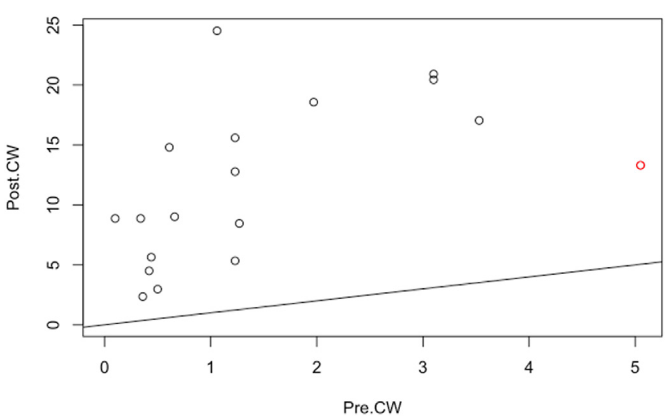

Fig. 1. Pre-and post-assessment measurements in the Clockwise (CW) direction.

thus, each individual's CE and CF significantly increase with the training. The fourth and fifth columns provide a 95% confidence interval (*CI*) for σ_x. Since all intervals only contain positive numbers, this suggests that the estimates of σ_x's are positive. Thus, the random term γ_i should be included in all four models, and we can conclude that there are different changes in all four metrics at the individual level over the training period.

To assess the normality assumption of the random error term in equation (3), marginal residuals were first obtained by using Empirical Bayes method through R package "HLMdiag".[23] Shapiro-Wilk test was then conducted to evaluate the normality assumption. The *p*-values from the Shapiro-Wilk test were recorded in the last column of Table 7. Since the first three *p*-values are 0.406, 0.182, and 0.982, it can be claimed that the normality assumption is valid for the models for CE, Cf, and LCLF, whereas the p-value for RCLF is almost zero, and thus the normality assumption is not valid. Fig. 4 include Q-Q plots for the residuals, and the patterns are consistent with the calculated *p*-values.

While there was an increase in Isometric Neck Strength (INS) between

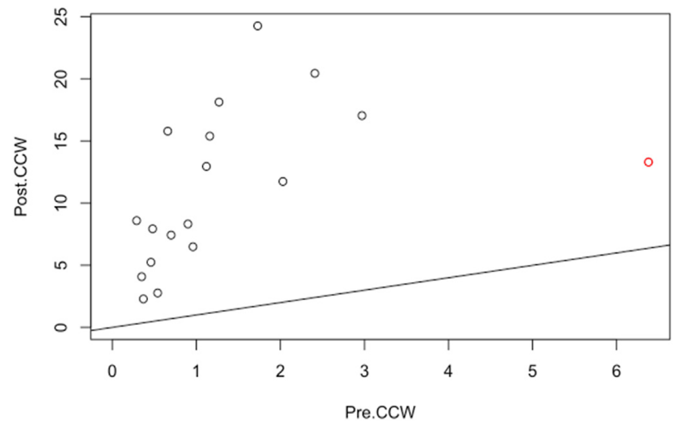

Fig. 2. Pre- and post-assessment measurements in the counterclockwise (CCW) direction.

Table 6
Pre- and post-assessments RFD measurements in the CCW direction.

Participant	Pre RFD CCW	Post RFD CCW
1	6.38	13.30
2	090	8.32
3	0.96	6.49
4	0.70	NA
5	1.73	24.26
6	0.54	2.77
7	2.41	20.44
8	0.66	15.79
9	2.97	17.04
10	0.35	4.08
11	1.16	15.39
12	1.27	18.13
13	0.48	7.93
14	0.37	2.29
15	0.70	7.43
16	2.03	11.74
17	0.29	8.59
18	0.46	5.24
19	1.12	12.95

(RFD = Rate of Force Development; CCW = Counterclockwise).

the beginning and end of the 14-week intervention for LCLF and RCLF, the increase in INS was not as significant as the increase in RFD with the results show in Table 8.

For the change over time analysis, the slope for a session indicates the estimated RFD gains for RFD CW is 0.132 kg and for RFD CCW 0.137 kg (Table 8). The *F*-statistics of the Kenward-Roger for both RFDs have a *p*-value close to zero. This concludes that the gain is also highly significant per session for RFD CW and RFD CCW. The fourth and fifth columns provide a 95% *CI* for σ_x. Since all intervals only contain positive numbers, this suggests that the estimates of σ_x's are positive. Thus, the random term γ_i should be included in all four models, and we can conclude that there are different changes in all four metrics at the individual level over the training period. Analysis for revolutions per minute (RPM) CW and RPM CCW similarly follows.

4. Discussion

This study aimed to capture muscular adaptations and identify the increase in isometric neck strength and RFD utilizing solely the novel multiplanar dynamic neck strengthening device after a 14-week intervention. The authors hypothesized the isometric neck strength, RPM, and RFD values would increase for the participants after the 14-week intervention. The main findings of this research include a significant increase in RFD in both the CW and CCW directions. Thus, demonstrating the neck

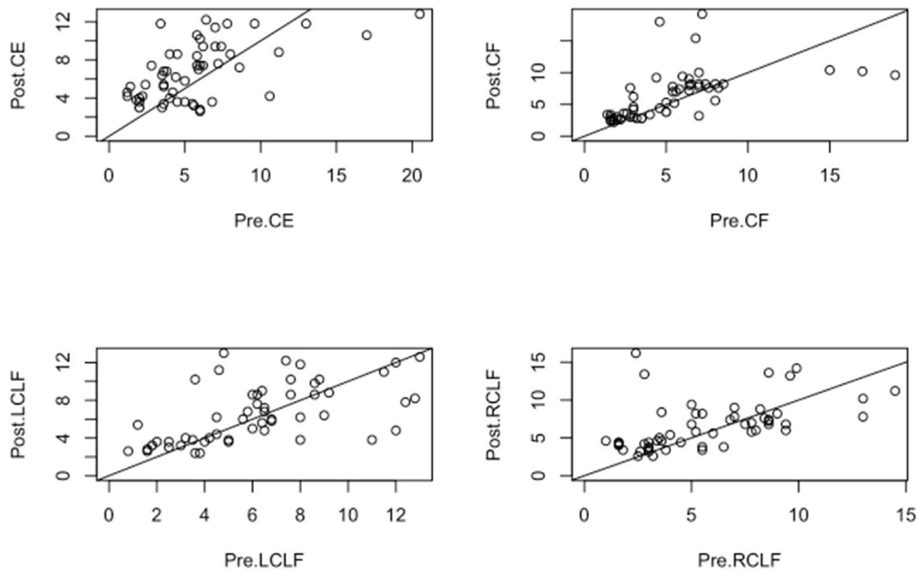

Fig. 3. Isometric neck strength measurements in the four ranges of motion (ROM) for each participant (CE = cervical extension; CF = cervical flexion; LCLR = left cervical lateral flexion; RCLF = right cervical lateral flexion).

Table 7
Linear mixed model analysis.

Movement	β	*F*-stat	*p*-value	2.5%	97.5%	Normality Test
CE	0.281	7.154	0.010	1.527	3.344	0.406
CF	0.221	3.561	0.065	2.228	4.619	0.182
LCLF	0.338	7.370	0.009	1.708	3.385	0.982
RCLF	−0.064	0.148	0.702	2.069	4.491	< 0.001

(CE = Cervical Extension; CF = Cervical Flexion; LCLR = Left Cervical Lateral Flexion; RCLF = Right Cervical Lateral Flexion).

Table 8
Change over time analysis.

Variables	β	*F*-stat	*p*-value	2.5%	97.5%
CW RFD	0.132	1671.094	< 0.001	1.689	3.307
CCW RFD	0.137	1295.175	< 0.001	1.845	3.547
CW RPM	1.667	2787.829	< 0.001	15.378	29.768
CCW RPM	1.651	2584.491	< 0.001	18.723	35.696

(RFD = Rate of Force Development; RPM = Revolutions Per Minute; CW = Clockwise; CCW = Counterclockwise).

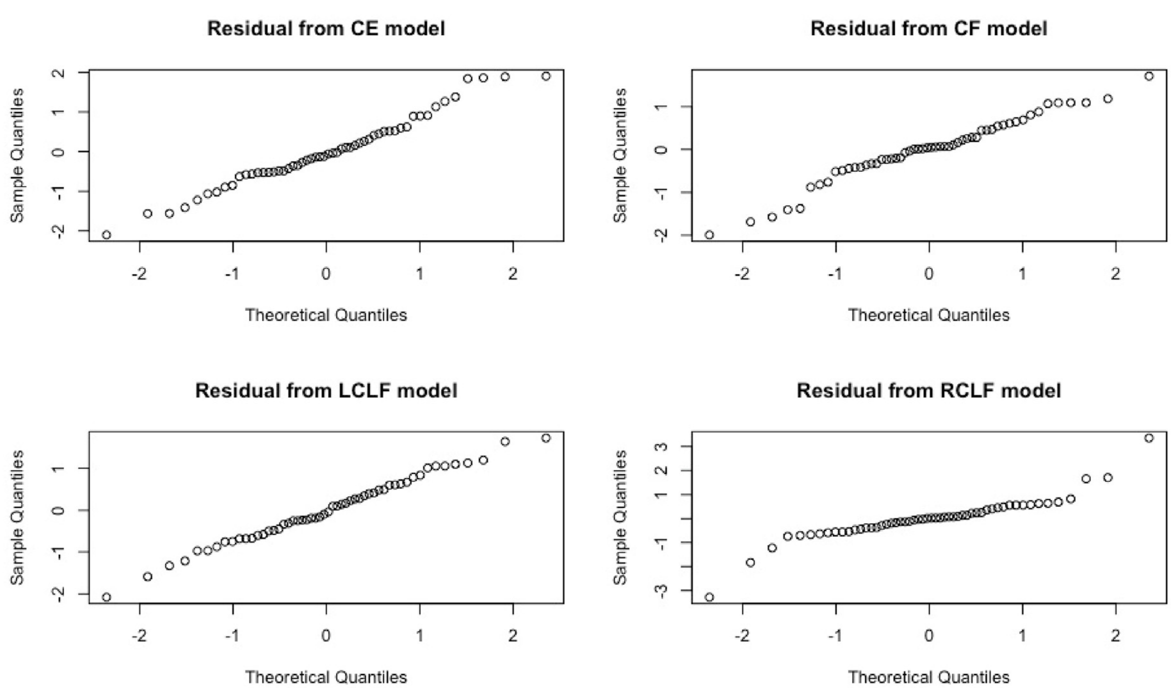

Fig. 4. Normality test (CE = cervical extension; CF = cervical flexion; LCLR = left cervical lateral flexion; RCLF = right cervical lateral flexion).

strength protocol as a viable tool to improve dynamic neck strength. Previous research has indicated the importance of dynamic neck training to induce a proprioceptive response and attenuate forces in a dynamic manner. Kramer et al. identified significant improvements in neck dynamic responses following a 10-week proprioceptive resistance training protocol compared to that of a traditional resistance training protocol.[24]

The results may further provide evidence to support the need for dynamic neck strengthening with an emphasis of eccentric-concentric and proprioceptive neuromuscular stimulus resulting in contractile force, associated with Type IIx muscle fibers. These findings are contrary to previous studies examining traditional neck strengthening methods.[25] Mansell et al. assessed dynamic neck strength stabilization following an 8-week traditional training protocol. The participants improved in isometric neck strength metrics; however, indicated no change in dynamic neck strength stabilization. This may be due to the adaptation of Type IIa, slower contractility, versus Type IIx muscle fibers. The authors of this study recommended future research aimed at the assessment of dynamic neck strength protocols similar to plyometrics.[25]

The authors theorize the increase in dynamic neck strength in this current research study, is attributed to the stimulus and recruitment of Type IIx muscle fibers as the training method elicits fast and powerful contractions occurring continuously to increase the speed and centripetal force of the pendulum atop the device.[15] As previously mentioned in the Introduction the improvement of Type IIx muscle fiber activation is theorized to play a critical role in attenuating force after a bodily impact similar to that experienced by those who suffer a concussion or mTBI.[8,15,17,26] In addition, the data indicated an increase in isometric neck strength, albeit the results were not as significant as the increase in RFD.

There were several limitations to this study. The recruitment and intervention occurred during the COVID-19 pandemic. The population size of the study was influenced by the limited number of participants available to complete the intervention and follow health and safety guidelines. Each participant signed an informed consent addendum highlighting our research team's risks and safety precautions. The participant population in this study had an age range of 18–29. Future studies using the TopSpin360 should feature a more significant age gap to represent the general population.

Neck training protocols that focus on multiplanar, dynamic exercises to increase RFD are suggested to be more beneficial than traditional, single-planar, isotonic exercises. The results of this 14-week intervention provide a neck-strengthening protocol that follows the above suggestions. The protocol effectively increases isometric neck strength in four ranges of motion and RFD. This method benefits strength and conditioning coaches, athletic trainers, physical therapists, and clinicians, providing the general population with an effective tool to potentially prevent mTBI.

The authors identify the short training duration as a potential limitation. The limited training duration may have a negative impact on the potential for maximum adaptation of Type IIa and Type IIx muscle fibers. It may imply a need for further research on inherently high-risk population groups. The authors recommend the need for and the importance of this research to determine if there is a decrease in mTBI and concussions sustained throughout a given training period and beyond. In addition to conducting research on difference populations groups, future studies could also examine physiological variables. This could capture the actual physiological changes that occur leading to an increased RFD.

5. Conclusion

Programs that elicit a dynamic neck strength adaptation of Type IIa and Type IIx muscle fibers may be considered a possible primary prevention method for mTBIs.[14–16] It is essential to develop stronger necks so that individuals may increase head and neck stiffness during a bodily impact.[13,16,26–29] The increase in participants' dynamic and isometric neck strength further supports the potential application of said neck strength protocol in decreasing the risk of sustaining an mTBI for individuals who participate in inherently high-risk activities.

Ethical approval statement

The University's Institutional Review Board reviewed and approved this study (#19–0118) and informed consent was collected from each participant.

CRediT authorship contribution statement

Lindsey Harn Schroeder: Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Conceptualization. **Margaret C. Tyndall:** Writing – original draft, Methodology, Investigation. **Alexander Thomas McDaniel:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Yishi Wang:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Jennifer L. Kale:** Investigation.

Conflict of interest

The authors have no professional relationships with companies or manufacturers who will benefit from the results of this present study. An internal institutional grant funded this study. The results of the present study do not constitute an endorsement of the product by the authors.

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