QCOLLAR®

SCIENCE & RESEARCH BRIEFING

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BACKGROUND

Q30 Innovations' mission is to help protect the brain from the effects of head impacts on the sports field and the battlefield. Since 2012, Q30 has worked with leading medical, academic, engineering and design institutions to research and develop the Q-Collar, an externally worn device that aids in the protection of the brain from effects associated with repetitive sub-concussive head impacts.

To date, the most common attempt to reduce head injuries has been the use of helmets. Helmets may reduce the risk of serious head and brain injuries by reducing the impact of a force or collision to the head, preventing direct contact between the skull and impacting object and spreading the forces of impact over greater surface area. However, helmets do not prevent the rapid acceleration and deceleration movement of the brain inside the head that leads to the twisting and tearing of neurons, which is the cause of traumatic brain injury (TBI).

The Q-Collar addresses this issue from the inside, utilizing jugular vein compression to help reduce "brain slosh", the movement of the brain inside the skull.

In February 2021, the FDA authorized the marketing of the Q-Collar as a class II medical device to help protect athletes' brains during head impacts. The FDA clearance was based on an extensive review of 10 years of research conducted independently by leading medical and research institutions across North America. **The Q-Collar is the only FDA cleared product that helps protect athletes' brains during head impacts.** As reported by the FDA, advanced imaging showed no significant changes in deeper tissues of the brain (white matter regions) in 77% of the group of athletes who wore the Q-Collar, while significant changes in these regions were found in 73% of participants in the non-collar group.

FDA-Approved Claim: The Q-Collar is intended to be worn around the neck by athletes aged 13 years and older during sports activities to aid in the protection of the brain from effects associated with repetitive sub-concussive head impacts.

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The Q-Collar, and the technology on which it is based, has been evaluated in independent laboratory and clinical studies over the past nine years, with the safety and effectiveness of the Q-Collar being the focus of over 25 pre-clinical and clinical trials. Importantly, there have been no adverse events reported during the clinical trials relating to the use of the Q-Collar. Some of this testing has included:

- Pre-Clinical Laboratory Studies
- Human Clinical Trials
- Medical Device Bench & Durability Testing

All studies have been performed by leading research and medical institutions, including West Virginia University, Cincinnati Children's Hospital, University of Toronto, Harvard University, NorthShore University Health System in Chicago, University of Texas and the Naval Medical Research Center at Walter Reed Hospital.

PRE-CLINICAL LABORATORY STUDIES

The laboratory studies conducted to date have demonstrated the safety and effectiveness of the Q-Collar using well-known research models. These studies indicate that compression of the internal jugular veins (IJVs) reduces the risk and severity of brain injury during impact and blast events. Additional laboratory studies provide early indication that the Q-Collar can also reduce hearing loss caused by blast waves and loud sounds of the type and magnitude experienced by military personnel and industrial workers. Below, we summarize the laboratory studies conducted to date.

I. DEVICE EFFECTIVENESS STUDY (RAT IMPACT MODEL)

Two laboratory studies were conducted using a standardized mTBI impact model to evaluate the effectiveness of the Q-Collar in reducing "brain slosh" and axonal injury. In each study, 10 rats were subjected to impact acceleration TBI. Half of the rats wore an IJV compression collar during the impact. Following a 7-day recovery period, the subjects' brains underwent immunohistochemical processing in order to evaluate axonal injury. Each study showed that venous compression in the neck significantly reduced the extent of axonal injury (by an average of 83% and more than 50%, respectively) as compared with the injury experienced by the control group. The studies support the effectiveness of the Q-Collar in helping to reduce the risk or severity of brain injury due to head impacts.

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II. DEVICE EFFECTIVENESS STUDY (RAT BLAST WAVE MODEL)

Researchers in the NeuroTrauma Department at the Naval Medical Research Center investigated whether IJV compression could provide protection to the brain against blast-induced TBI. The study included control animals and intervention animals that wore an IJV compression collar when exposed to blast overpressure. The results of the study showed that a "decrease in brain compliance," or "brain slosh" through IJV compression, can reduce brain damage caused by exposure to blast waves.

III. DEVICE SAFETY STUDY (SWINE IMPACT MODEL)

In response to an inquiry by the FDA, Q30 commissioned a pig study to firmly establish safety to athletes in cases when they may be exposed to a severe impact that would cause intracranial bleeding. The study, which included a control group as well as a group that wore a collar, was conducted at the lab of Dr. Julian Bailes at NorthShore University Health System. The study demonstrated that the Q-Collar would not worsen (but instead may help reduce) intracranial hemorrhage that may occur when the user of the Q-Collar is exposed to a significant impact to the head.

IV. LARGE ANIMAL EFFECTIVENESS STUDY (SWINE IMPACT MODEL)

Researchers at Harvard and Boston Children's Hospital developed a closed head rotational head impact protocol in swine that more realistically resembles an impact to a human with unrestrained head movement post-impact. The study tested whether IJV compression reduces alterations in histological biomarkers of brain injury resulting from a single head impact. Accelerometers were used to measure the impact on 10 swine (4 non-collared/control and 6 collared/intervention animals). The study shows that IJV compression protects against tau phosphorylation and microglial activation indicating a protective effect of the Q-Collar.

V. SMALL ANIMAL BLAST WAVE HEARING LOSS STUDY

Q30 commissioned a small animal study to investigate whether IJV compression would reduce the risk of hearing loss following exposure to blast waves. The study, which included a control group as well as a group that wore a collar, was conducted at the lab of Dr. Julian Bailes at NorthShore University Health System and at the University of Buffalo. The study included two groups of small animals (rats), where one group wore a custom developed collar that applied a compressive force to the IJVs and the other group did not wear a collar. Each animal had baseline and postexposure testing of otoacoustic emission (OAE) and auditory brainstem response (ABR), plus post-exposure cochlear histology. The data shows that IJV compression reduces OAE and ABR threshold shifts as compared with the control group of animals. The cochlear histology investigation likewise showed that there was significantly less cochlear damage in the study group than in the control group.

VI. SMALL ANIMAL SOUND HEARING LOSS STUDY

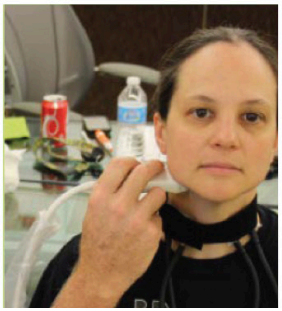
Following the small animal blast wave hearing loss study, Q30 commissioned another small animal study to investigate whether IJV compression could reduce noise-induced hearing damage. The study was concluded at the University of Texas at Dallas and the UT Southwestern Medical Center. In this study, 20 rats were exposed to an octave band noise (8 – 16 kHz, 109 dB SPL) for 2 hours. The experimental group (n = 10) was fit with a custom IJV compression collar during noise exposure; the control group (n = 10) was exposed to the same noise without the collar. All animals underwent baseline, 24-hour post- and 2- or 3-week post-noise exposure testing that included auditory brainstem response (ABR) and distortion produce otoacoustic emission (DPOAE) testing to assess auditory function. Hearing sensitivity in noise was assessed behaviorally using a pre-pulse inhibition of the acoustic startle paradigm. The results provide compelling evidence of protection against temporary hearing loss/ threshold shift and suggest the potential for reduction of permanent threshold shift as well.

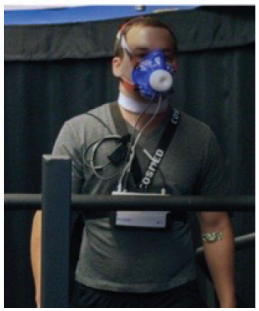
HUMAN CLINICAL TRIALS ON SAFETY AND EFFECTIVENESS

As described below, safety and feasibility testing in athletes and paramilitary (SWAT) personnel have been conducted on the Q-Collar. These studies provide evidence of the Q-Collar's safety and effectiveness.

I. HUMAN PERFORMANCE STUDY

The Cincinnati Children's Hospital Institutional Review Board ("CCHIRB") has approved several non-significant risk feasibility safety studies of the use of the Q-Collar in athletes engaged in activity and/or sports. The initial feasibility study ("Human Performance Study") was completed in the Cincinnati Children's Hospital Human Performance Laboratory and involved evaluation of monitored vital signs, biomechanics, cardiorespiratory capacity, postural control, dynamic stabilization, reactive index, concentration and cognition, memory, strength and power in a population of athletes that showed no statistical effect of wearing a prototype version of the Q-Collar compared to a sham arm band. In addition, CBC renal panel, and urinalysis tests were conducted before and after exercise performed with the device.





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HUMAN SAFETY AND EFFECTIVENESS TESTING (CONT'D)

Blood and urine measures remained in normal ranges and were not disrupted beyond the expected physiologic response to exercise. Cumulatively, the pre- and post-measures indicate that neurologic parameters of executive function, eye-hand coordination, balance, memory and reaction times were unchanged following two hours of physical testing wearing the device. The results of this testing indicate that the Q-Collar is safe to use during maximal aerobic capacity and maximal power testing and has no impact on performance, strength or endurance.

II. SIMULATED HUMAN INTERNAL JUGULAR VEIN (IJV) COMPRESSION STUDY

Mild internal jugular vein (IJV) compression, aimed at increasing intracranial fluid volume to prevent motion of the brain relative to the skull, has reduced brain injury markers in athletes suffering repeated traumatic brain injuries. However, an increase in intracranial volume with IJV compression has not been well demonstrated. This study used transorbital ultrasound to identify changes in optic nerve sheath diameter (ONSD) as a direct marker of accompanying changes in intracranial volume. This study confirms that there is an increase in cerebral volume following mild IJV compression in upright position. These data help support the potential for reduced brain 'slosh' as a mechanism connecting IJV compression to possibly reducing brain injury following head trauma.

III. HOCKEY STUDY

The second feasibility study was performed at Cincinnati Children's Hospital Medical Center ("CCHMC") in adolescent male hockey players wearing the Q-Collar during sporting competitions (practices and games) to test its effect in ameliorating neuroanatomical and neurophysiological changes to the brain. The study measured two widely accepted techniques—diffusion tensor imaging ("DTI") and event-related potentials utilizing electroencephalography. For athletes in the non-intervention group, advanced imaging indicated that there were changes to the white matter from pre-season to mid-season. By comparison, the athletes in the intervention group (collar wearing group) did not show significant changes despite being exposed to similar accumulated g-force head impacts. The results of the hockey study demonstrate that IJV compression, through the use of the Q-Collar, can safely protect the brain from sports-related injury caused by head impacts.

IV. FOOTBALL STUDY

The third feasibility study was performed in adolescent male football players wearing the Q-Collar during football seasons to test its effect in ameliorating neuroanatomical changes to the brain using evidence by DTI. This project utilized a prospective controlled trial to evaluate the effects of mild jugular vein compression (Device; n=31) relative to controls (no-Device; n=30) during a competitive football season. Helmet sensors were used to collect daily impact data (force, direction and number of hits) in excess of 20g (games and practices), and the primary outcome measures, which included changes in white matter microstructure, were assessed by DTI measures. Comparing the two groups, the no-Device group demonstrated significantly larger pre- to post-season DTI change in many white matter regions (corrected $p<.05$). The findings, based on four DTI measures known to relate to brain injury, indicate a consistent reduction of change in diffusivity parameters noted in the no-Device group at post-season.

Based on the published literature, this is a sign of sub-threshold white matter injury due to repetitive head impacts during the competitive season in those subjects not wearing the Device. The results of the Football Study were published and further demonstrate that IJV compression, through the use of the Q-Collar, can safely protect the brain from sports-related injury caused by head impacts. In order to understand the long-term effects of the use of the Q-Collar, several of the participating football players participated in a longitudinal study during their second and third year of playing high school football with the Q-Collar. The findings of the longitudinal studies support the effectiveness of the Q-Collar.

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V. SOCCER STUDY

The fourth feasibility study was performed at Cincinnati Children's Hospital Medical Center in adolescent female soccer players wearing the Q-Collar during a season of competitive soccer. Two high school girls soccer teams participated in this prospective longitudinal study that also used advanced DTI imaging to help determine whether IJV compression provided long-term beneficial protective effects over three timepoints spanning nine months. As in the Football Study, the control and intervention groups both wore accelerometers that were used to collect daily head impact data in excess of 20g. The DTI data revealed significant white matter changes from pre- to post-season scans of the members of the control group. Those changes only partially reversed themselves during the 3-month post-season period. Despite similar head impact exposure, the intervention group (who wore the Q-Collar), did not have significant changes to their white matter. The mitigation of white matter changes in the group who wore the Q-Collar indicates the potential beneficial effect of IJV compression.

VI. SWAT TEAM BLAST STUDY

Researchers at CCHMC performed a study with SWAT personnel who were exposed to low-level blast exposure during breacher training on the neural function of working memory and auditory network connectivity. Eighteen participants (10 with a Q-Collar, 8 without) had baseline fMRI scanning before a breacher training session. The fMRI scan was repeated after the training session. While there was no change in brain activation during the working memory task in the study group (who wore the Q-Collar), the elevation in fMRI activation in the non-collar group was found to correlate significantly with average peak blast amplitude experienced during training. The results suggest that the Q-Collar could reduce the risk and severity of TBI from blast waves in addition to collisions.

VII. TOLERABILITY AND WEARABILITY STUDY

The CCHIRB has approved a tolerability and wear-ability study that allowed Q30 and our researchers to gather critical feedback from high-intensity athletes who have decided to participate in the study. Six NFL players (two tight ends, two linebackers, one center and one safety) and 13 Canadian Football League players have participated in the study. Two of these participants wore the Q-Collar for three seasons. The feedback that they have provided has been analyzed and may help Q30 and its engineers make ongoing enhancements to the

product's design. In early 2018, similar studies were conducted at several Division I NCAA schools (including University of Florida and Notre Dame). In addition, two motorsports drivers have also participated in the study. Through these studies, the participants have reported universally that the Q-Collar is comfortable to wear and does not interfere with their performance, movement and endurance.

VIII. FOOTBALL PIVOTAL TRIAL

The pivotal study that resulted in FDA approval, utilized a prospective controlled trial to evaluate the effects of mild jugular vein compression (n=142) collar/intervention device) relative to controls (n=142 non-collar controls) during a competitive football season. Magnetic resonance imaging data were collected from participants pre- and postseason and head impact exposure was monitored by accelerometers during every practice and game throughout the competitive season. Athletes' accumulated head impact exposure was systematically thresholded based on the frequency of impacts of progressively higher magnitudes (10g intervals between 20 to 150g) and modeled with pre- to postseason changes in DTI measures of white matter as a function of JVC neck collar wear. The findings revealed that the JVC neck collar modulated the relationships between greater high-magnitude head impact exposure (110 to 140g) and longitudinal changes to white matter, with each group showing associations that varied in directionality. Results also revealed that 77% of the collar wearing athletes did not have significant changes to their white matter of the brain, while 73% of the non-collar wearing athletes had significant changes. Importantly, there were no reported adverse events. Collectively, these data indicate that a JVC neck collar can provide a mechanistic response to the diffusion and anisotropic properties of brain white matter following the highly diverse exposure to repetitive head impacts in American tackle football.

IX. SOCCER PIVOTAL TRIAL

Following pilot clinical studies involving female soccer players, Q30 sponsored a larger study with more than 125 athletes. Characterization of, and evaluation of strategies to mitigate, the effects of sub-concussive impacts (SCI) on brain structure and function are crucial to understand potential long-term neurological risks associated with sports participation. In this study, the researchers applied a graph theoretical framework to resting state

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HUMAN SAFETY AND EFFECTIVENESS TESTING (CONT'D)

functional magnetic resonance imaging (rs-fMRI) and diffusion tensor imaging (DTI) data to evaluate the efficacy of a jugular vein compression collar for preserving functional and structural measures of brain network organization in a cohort of female high school soccer players throughout a season of competitive play. Athletes were assigned to a collar (N = 72) or non-collar (N = 56) group before engaging in a season of play, during which head impact data were recorded via accelerometer for every practice and competition. Participants completed neuroimaging sessions before and following the season. Non-collar-wearing athletes exhibited significantly increased resting state fMRI-derived global clustering coefficients ($p = 0.032$) and DTI-derived modularity ($p = 0.042$), compared to collar-wearing athletes. No longitudinal changes in any graph measures were observed for the collar group ($p > 0.05$). The observed increase in graph measures in the non-collar group is congruent with previous studies of SCI and is similar to graph theoretical studies of traumatic brain injury. The absence of alterations in graph metrics in the collar group indicates a potential ameliorating effect of the collar device against network reorganization, in line with previous literature.

MEDICAL DEVICE BENCH AND DURABILITY TESTING

In order to prove that the Q-Collar can be manufactured in accordance with its design requirements and specifications, and will be durable and comfortable to wear, Q30 commissioned extensive bench testing performed by, or under the supervision, of Ximedica, a leading medical device engineering and design validation company. The recently concluded testing included the following:

- Biocompatibility testing of the polymers and colorants used in the Q-Collar;
- cycle and extreme temperature testing (useful life) testing;
- UV resistance testing;
- shelf-life testing and accelerated shelf-life testing;
- ship/transit durability testing; and
- saltwater, chlorine and cleaning resistance testing.

To review corresponding published studies, please visit Q30's Research at https://bit.ly/q30research.

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