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13. ABSTRACT (Maximum 200 Words) Airborne operations regularly expose paratroopers to risk of head impact. Even relatively mild head impacts, while not life threatening, can cause short-term impairment from dizziness, headaches, memory loss, lack of ability to concentrate, and irritation. These symptoms jeopardize soldier survivability and mission success. There is an obvious need to protect the soldier in these environments and reduce the head injury rate to a minimum. The objectives of this research program are to a) propose helmet configurations that will protect paratroopers from blunt head injury, and b) assess the best of these in a field study in the operational airborne environment. In Phase I, two helmet configurations were identified that improved blunt impact protection, compared to the standard airborne troop helmet configuration, and were otherwise acceptable for airborne use. The research protocol for the Phase II cohort study, to assess the effect of improved impact protection on jump-related head injury rates, has been approved and preparations are complete. Subject recruitment is proceeding at a slow rate due to unit deployments. No results are available yet.				
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Table of Contents

Cover.....	1
SF 298.....	2
Table of Contents.....	3
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	14
Reportable Outcomes.....	14
Conclusions.....	15
References.....	16
Appendices.....	17

Introduction

Since the inception of military parachute operations in World War II, airborne units have operated behind enemy lines and have relied on speed and surprise to ensure mission accomplishment. Such daring missions require selected, trained, and highly disciplined soldiers. The strength of airborne forces comes from the skill, courage, and discipline of the individual paratrooper (Department of the Army, 1990).

U.S. Army airborne operations regularly expose paratroopers to a risk of head impact during flight (unexpected turbulence or evasive maneuvers), aircraft exit (impact with the door frame or fuselage), descent (riser slap or collision with other jumpers), the parachute landing fall (PLF), and after landing (obstacle strikes during dragging in high winds). Even relatively mild head impacts, while not life threatening, can cause short-term impairment from dizziness, headaches, memory loss, lack of ability to concentrate, and irritation. Given the necessity for speed and aggressiveness in the airborne operational environment, these symptoms become militarily significant, no matter how temporary, by seriously jeopardizing soldier survivability and the success of the unit's mission. There is an obvious need to protect the individual soldier and reduce the injury rate to a minimum, in large part to preserve the efficiency of the fighting soldier and unit for combat, but also because a high injury rate would have a detrimental effect on morale, recruiting, and cost (Davison, 1990).

This report describes the progress made to date in the research project, "Efficacy of countermeasures against traumatic brain injuries sustained in airborne operations." This project has completed two years of a planned three-year program, consisting of two phases: a hardware development and laboratory test effort (Phase I), and a field study (Phase II). This is a significant project, with considerable potential short- and long-term payoff for warfighter safety and effectiveness. If successful, this research will a) improve the impact protection and retention characteristics of current combat helmets, b) demonstrate a significant reduction in frequency and rate of closed head injuries resulting from airborne operations, c) improve the combat fighting efficiency of airborne units, d) result in operationally relevant and effective impact protective requirements for airborne helmets, and e) reduce long-term Department of Defense (DOD) and Veterans Administration (VA) health care costs of combat soldiers.

Body

Phase I: Fort Rucker laboratory studies

Phase I of the project involved the design, testing and evaluation of candidate paratrooper helmet configurations compatible with the Personnel Armor System for Ground Troops (PASGT) helmet. At the conclusion of the testing, promising candidate systems were recommended for field trials in Phase II of the study. Three systems were selected as being financially and logistically feasible for inclusion in Phase II. The three systems are referred to as the Type A, Type B and Type C configurations. The Phase I test process and results are presented in detail in McEntire et al. (in press), and are described briefly below.

Laboratory impact tests were conducted on many different helmet configurations and liner materials. Only the results of the helmet configurations selected for inclusion in the Phase II field study are presented. The impact tests were conducted on a monorail impact tower, with a size C headform, conforming to the specifications of the American National Standards Institute (ANSI-Z90.1, 1992). The impact anvil for all tests was a 1.9-inch hemispherical anvil securely affixed to the base.

Three different impact velocities were utilized to assess helmet protection against different hazards. Test velocities were determined after reviewing parachute kinematics and previous Army impact standards for ballistic helmets. Army static line paratrooper operations are conducted with either the T-10C or MC1-1B/C parachutes. Typical rates of descent vary depending on the parachute type, suspended load, and relative air density. Descent rates range from a low of 14 feet per second (fps) to as high as 23 fps for the MC1-1C and T-10C parachutes respectively (FM 57-220).

There are no helmet impact protection requirements for the Army infantry and paratrooper helmet. In 1999, the US Army Special Operations Command (SOCOM) announced procurement of a commercial off-the-shelf ballistic helmet. This helmet was for use by SOCOM soldiers to include airborne operations. The published announcement specified helmet impact performance to limit headform acceleration to below 150 G when tested at an impact velocity of 10 fps.

The target impact velocities utilized in the USAARL laboratory tests to evaluate the proposed study helmets were 10, 14.1, and 17.3 fps. The low impact velocity (10 fps) is at the level specified by the SOCOM CBD announcement. The next two velocity levels (14.1 and 17.3 fps) are within the rate of descent range for standard static line parachutes.

It is likely that paratrooper head impact velocities will be lower than the parachute rates of descent for several reasons: First, as combat loads are suspended 15 feet below the paratrooper, this brief reduction of weight allows the parachutist descent rate to reduce prior to the parachute landing fall (PLF). Second, the PLF technique allows the paratrooper to absorb the impact energy with his body, reducing the head velocity prior to head contact with the ground.

Therefore, the range tested is a reasonable representation of the impact range that paratrooper heads could encounter. Testing was not conducted above 17.3 fps because in preliminary testing, it did not appear that impact loads could be reduced significantly without altering the external Kevlar ballistic shell (which was not permitted).

The target impact sites were the front headband, rear headband, and lower left and right nape areas. The rear and nape areas were averaged together to represent general performance to the back (posterior) of the helmet. The back of the helmet is considered to be a frequently impacted area during parachutist landing falls and was therefore strenuously tested. Helmets are identified in the figures as "A" (the standard paratrooper helmet configuration), "B" (the Skydex[®] impact pad, frontal and crown PIL pads, and the CGF three-point retention harness),

and "C" (the helmet configuration with the Oregon Aero size #7 pads and the CGF three-point retention harness).

All helmet configurations selected for inclusion in the present study exhibited improvements at 10, 14.14 and 17.32 feet per second (fps). The mean results are provided in Tables C1 and C2, and are illustrated in Figure C1.

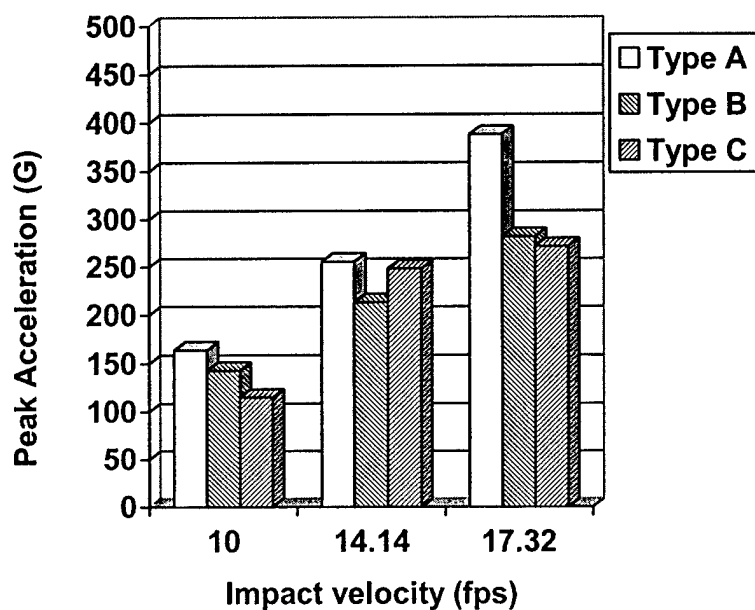
Table C1. Summary of frontal impact test results (average of medium & large size PASGT); Peak headform acceleration (G) and % improvement over standard baseline helmet (helmet A).

Velocity (ft/sec)	Helmet A	Helmet B	Helmet C
	G	G (%)	G (%)
10	164	143 (12.8)	115 (29.9)
14.14	255.5	213.5 (16.4)	248.5 (2.7)
17.32	388	282 (27.3)	271.5 (30)

Table C2. Summary of rearward impact test results (average of medium & large size PASGT); Peak headform acceleration (G) and % improvement over standard baseline helmet (helmet A).

Velocity (ft/sec)	Helmet A	Helmet B	Helmet C
	G	G (%)	G (%)
10	103.55	87.6 (15.4)	64.3 (37.9)
14.14	359.65	196.7 (45.3)	182.5 (49.3)
17.32	502	379 (24.5)	400.4 (20.2)

Frontal Impacts



Rearward impacts

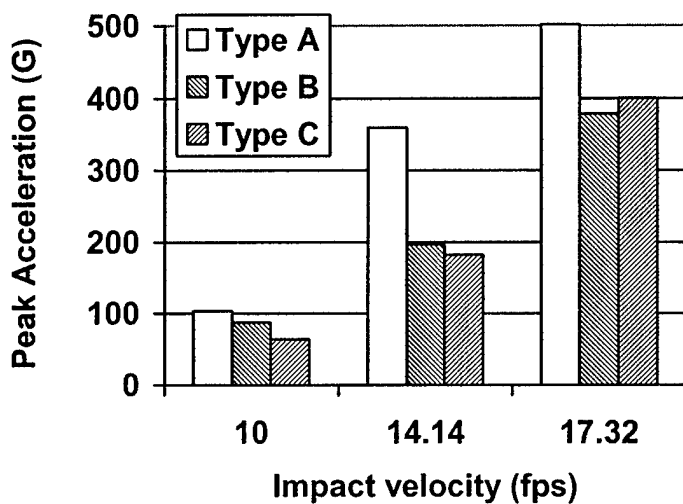


Figure C1. Impact performance of study helmet liners

Detailed impact results of the standard paratrooper helmet (helmet type A) and the modified paratrooper helmets (helmet types B and C) are provided in tables C3 and C4. Table C3 contains the results for the medium size helmets tested while table C3 contains the results for

the size large helmets. These two tables have the data clustered by impact velocity. Included with the results for each velocity cluster is the overall mean for all four impact sites and the mean for the three rear most impact sites (back). Also shown in tables C3 and C4 is the measured change from baseline (helmet type A) and its respective percent change.

The same test headform (ANSI Z-90, size C) was used in testing both helmet sizes. This was done because the headform's circumference, length, and breadth measurements fall at the dividing line between the two helmet sizes. (An individual with these head measurements could wear either size helmet.)

There are limitations to this test methodology. There are no blunt impact test methods specified for the PASGT helmet, as it was designed as a ballistic helmet (i.e., to deflect high speed projectiles such as bullets or shrapnel). Therefore, the headform size, headform fitting procedures, impact locations, and impact velocities are somewhat arbitrary and are based on expert consensus and previous experience with helmets designed for blunt impact protection. Also, the PASGT is heavier, and less well restrained, than conventional impact protective helmets—test variation can result from orienting the test headform, and this heavy helmet can shift as it is being raised for the test. As a consequence, there is considerable variability in the impact test results. The tests appear to be more suited and reproducible for the improved configurations (types B and C) that have definite impact-absorbing features, than for the baseline PASGT helmet that has only 'bump' protection from blunt force. The novel impact sites toward the posterior aspect of the helmets (e.g., right and left nape) appear particularly variable—for this reason, the three test sites (e.g., right and left nape, and rear) have been averaged. This presents a more balanced and stable view of helmet performance at the important rear locations. In the following discussion, both the raw and averaged data are presented for completeness.

Seventy-two drop tests were conducted in this phase of the project. In the 48 possible comparisons between the one baseline and two experimental helmet configurations, the experimental configurations performed better in 44 tests (Tables C3 and C4, below). The four exceptions are described below.

Inspection of table C3 (size medium helmets) reveals the only increase in headform acceleration over the baseline helmet (Type A) occurred with the type B helmet, impacted on the rear at an impact velocity of 10 feet per second (fps). This was a 14 G increase over the baseline performance of 80 G (a 17% increase). There are two possible explanations for this result. First, comparison of the 80 G result to the other 3 impact sites tested on the type A helmet show it to be 23 G lower (e.g., better) than the next highest. Comparison of the medium Type A helmet results with those of the large size (in Table C4), fails to confirm this pattern. This difference suggests that the 80 G may be unusually good performance for the baseline helmet. More importantly, the Skydex nape pad used in type B helmet was selected especially because of its performance at higher (and more dangerous) velocities. This is illustrated by considering the helmet's peak G reduction in the rear impact at the 14.1 and 17.3 fps impact velocities. In these two tests, the type B helmet reduced the peak G by 207 and 232 for the 14.1 and 17.3 impact velocities respectively.

Table C4 provides the results for the size large test helmet. For the type B helmet, the 14.1 fps frontal impact produced a result greater than the baseline helmet. This increase was only 2 G, which is a negligible percentage increase (less than 1 percent). The type C helmet also produced a higher peak G level at this condition (14.1 fps, frontal impact). This increase was 14 G, or 6 percent, over the baseline (230 G). This is not too surprising since the type C helmet only has a single trapezoidal pad in the front of the helmet while two identical pads are positioned in the rear. The effect of this front to rear configuration difference is that the combined rear pads displace the headform forward in the helmet, causing the forward pad to compress and reduce the available stopping distance. This is supported by the fact that all the frontal impact test results are greater than the rear for every impact velocity of the type C helmet. Since the intent is to protect the most frequently injured area, we believe that it is most important to maximize protection to the rear areas of the head. Ensuring an improvement in performance of the helmet front would mean reducing stopping distance available at the rear, where improvement is most needed.

Also, there is evidence that the baseline helmet peak G value (230 G) may be low for this test condition (14.1 fps, frontal impact). During exploratory testing to evaluate other candidate helmet materials, the baseline helmet was tested two other times at 14.1 fps at the front. These two exploratory tests provided peak G values of 247 and 271 G, both above the type C helmet performance of 244 G. As discussed above, some test performance variation is to be expected as the helmets are fitted onto a metallic headform and consistent fit and strap adjustment is difficult to achieve.

The type C helmet also produced peak acceleration in excess of the baseline at the 17.3 fps, left nape test condition. This was a 125 G increase over the baseline helmet (33 percent). However, performance at the right nape location, with the same test conditions, was approximately 100 G better—an unexpected difference as the helmets are symmetrical and there is no reason to expect a right-left difference. This exceedance is believed to result from test variability, as an artifact of the test methodology. Performance variation could result from orienting the test headform, and this particularly heavy helmet can shift as it is being raised for the test. These two sites (left nape and right nape) were selected because they challenge the impact protective padding materials and it is thought the helmet's nape area is a potential impact site when parachutist perform poor landing falls.

Despite the four isolated tests in which baseline configurations appeared to perform better, impact performance (averaged for impact velocity and helmet type), showed a clear improvement overall (ranging from 10% to 46%). Performance is also improved in helmets B and C when collapsing across impact location or size. Overall, helmet configuration B improves impact performance by 24.6% and helmet C improves by 28.1%.

Table C3.

Size medium helmets, peak headform accelerations during helmet impact, clustered by impact velocity.

Impact velocity (fps)	Impact site	Type A (Peak G)	Type B			Type C		
			Peak (G)	Change ¹ (G)	Percent ² change	Peak (G)	Change ¹ (G)	Percent ² change
10.0	Front	152	121	-31	20%	129	-23	15%
	Rear	80	94	+14	17%	57	-23	29%
	Left nape	114	93	-21	18%	84	-30	26%
	Right nape	103	96	-7	7%	74	-29	28%
	Mean (all) ³	112	101	-11	10%	86	-26	23%
	Mean (back) ⁴	99	94	-5	5%	72	-27	27%
14.1	Front	281	195	-86	31%	253	-28	10%
	Rear	395	188	-207	52%	125	-270	68%
	Left nape	291	192	-99	34%	249	-42	14%
	Right nape	434	264	-170	39%	283	-151	35%
	Mean (all) ³	350	210	-140	40%	228	-122	35%
	Mean (back) ⁴	373	215	158	42%	219	-154	41%
17.3	Front	445	247	-198	44%	268	-177	40%
	Rear	522	290	-232	44%	212	-310	59%
	Left nape	530	508	-22	4%	511	-19	4%
	Right nape	530	444	-86	16%	514	-16	3%
	Mean (all) ³	507	372	-135	27%	376	-131	26%
	Mean (back) ⁴	527	414	-113	21%	412	-115	22%

Notes: 1. Change is the peak G difference from the Type A helmet. A negative number is an improvement while a positive number is a decrement in performance.

2. Percent change is the calculated percentage change from the Type A helmet.

3. Mean (all) is the average of the four impact sites (front, rear, left nape, and right nape).

4. Mean (back) is the average of the three rearmost impact sites (rear, left nape, and right nape).

Table C4.
Size large helmets, peak headform accelerations during helmet impact,
clustered by impact velocity.

Impact velocity (fps)	Impact site	Type A (peak G)	Type B			Type C		
			Peak (G)	Change ¹ (G)	Percent ² change	Peak (G)	Change ¹ (G)	Percent ² change
10.0	Front	176	165	-11	6%	101	-75	43%
	Rear	134	95	-39	29%	58	-76	57%
	Left nape	116	75	-41	35%	56	-60	52%
	Right nape	74	73	-1	0%	58	-16	22%
	Mean (all) ³	125	102	-23	18%	68	-57	46%
	Mean (back) ⁴	108	81	-27	25%	57	-51	47%
14.1	Front	230	232	+2	0%	244	+14	6%
	Rear	322	161	-161	50%	118	-204	63%
	Left nape	316	151	-165	52%	163	-153	48%
	Right nape	400	224	-176	44%	157	-243	61%
	Mean (all) ³	317	192	-125	39%	171	-146	46%
	Mean (back) ⁴	346	179	-167	48%	146	-200	58%
17.3	Front	331	317	-14	4%	275	-56	17%
	Rear	510	270	-219	43%	250	-260	51%
	Left nape	382	313	-69	18%	507	+125	33%
	Right nape	538	449	-89	16%	408	-130	24%
	Mean (all) ³	440	337	-103	23%	360	-80	18%
	Mean (back) ⁴	477	344	-133	28%	389	-88	18%

- Notes: 1. Change is the peak G difference from the Type A helmet. A negative number is an improvement while a positive number is a decrement in performance.
2. Percent change is the percentage change from the Type A helmet.
3. Mean (all) is the average of the four impact sites (front, rear, left nape, and right nape).
4. Mean (back) is the average of the three rearmost impact sites (rear, left nape, and right nape).

The Phase I effort to improve the blunt impact protection of the basic combat helmet proved to be more difficult than anticipated. This was primarily due to the operational constraints placed on the research team, the most severe of which specified that no modification could be made to the existing Kevlar ballistic helmet shell or the outward appearance of the helmet. This understandable restriction limited the space available between the head and the helmet shell in which to insert various energy-absorbing materials. Additional time was required to survey industry and academia for novel materials that could be used in this unique application.

Despite requiring 12 months rather than the planned eight, the Phase I study was successful in designing, testing, and validating candidate helmet configurations that, according to the best assessment tools available, would outperform currently fielded paratrooper head impact

protection. Helmets B and C were incorporated in the Phase II research protocol as the experimental helmet configurations to be compared to the airborne PASGT configuration.

Phase II: Fort Bragg field study

Protocol preparation and approval

After assembling and coordinating the research protocol with other collaborating agencies (i.e., the Defense and Veterans' Brain Injury Center [DVBIC] and Womack Army Medical Center [WAMC]), the approval process began in early 2002. Several unanticipated events conspired to delay protocol approval until mid-October 2002, at which time we were cleared to recruit subjects:

When initially submitted for review by the local IRB at the U.S. Army Aeromedical Research Laboratory (USAARL), a speedy approval was anticipated at the minimal risk level. While this was the opinion of the local IRB, the Surgeon General's Human Subjects' Research Review Board (HSRRB) determined that a second level review was required because of the funding mechanism. The HSRRB ruled that the field trial was greater than minimal risk, which caused a delay of approximately two months. In the end, a total of 6 separate IRBs insisted on reviewing the protocol (Walter Reed Army Medical Center, the Uniformed Services University of the Health Sciences [USUHS], the MEDCOM Clinical Investigation Review Office [CIRO], Womack Army Medical Center, the HSRRB, and USAARL). The lack of any centralized research approval process in MEDCOM leaves every IRB with potential liability with no choice but to perform a separate complete review. These unanticipated additional reviews and the inevitable revisions caused additional delays of approximately 6 months.

Research preparations

While protocol approvals were being sought, preparations were underway to assemble the Fort Bragg team, consisting of 3 employees of TRUE and two part-time consultants. DVBIC agreed to support the study with existing personnel employed at Fort Bragg and in Washington DC. Also, investigators were recruited from WAMC, to ensure close collaboration with the local medical treatment facility, and from the 82nd Airborne Division, to build rapport with the operational unit under study. Other preparations have included:

- Preparation of research study staff handbook
- Emergency notification rosters and SOPs
- Development and testing of baseline and post-injury test batteries
- Shipment and assembly of helmet components at Fort Bragg
- Training of Jumpmasters and airborne safety personnel

These preparations were in place by May 2002.

Subject recruitment

About the time the protocol was finally approved, the brigade at Fort Bragg supporting the study was deployed overseas. Another brigade was identified, but just prior to recruitment briefings in early 2003, it was deployed to support Operation Iraqi Freedom. A smaller airborne unit has recently been made available to the study, resulting in 105 enrolled subjects, but we require almost 1000 subjects, followed over a two-year period, to achieve the desired statistical power. We have been assured that when the larger brigades return to Fort Bragg, they will be made available to participate in our study. We anticipate that this will occur in the summer/fall of 2003.

Data analysis

The only data analysis thus far consists of a balance analysis, conducted in May 2003, on the baseline data from the initial group of subjects.

Balance analysis

The initial randomization of 3 platoons of soldiers resulted in even assignments of helmets (Helmet A = 34; Helmet B = 36; Helmet C = 36). The purpose of this analysis is to determine whether the platoons thus far assigned to the study helmets are balanced in terms of demographic and jump history variables that might confound the outcome analysis.

The balance analysis conducted on the first 106 soldiers randomized into the Helmet Study determined that none of the demographic or jump history variables is unbalanced across units, suggesting the study is on course for its test for the effect of helmet type upon long term outcome (Table C5). Differences were not found (null hypotheses could not be refuted) for any of the tested variables: age, race, marital status, handedness, years on active duty, and number of military jumps. Balance in nominal variables was measured with Chi-Square; balance in interval level variables was measured with ANOVA. The only variable which showed a tendency towards imbalance across the platoons was marital status ($p=.10$), and we will continue to monitor platoon differences on marital status. If necessary we will alter the randomization schedule to insure a more even distribution on this variable, but we do not envision the need for that change.

Table C5. Results of balance analysis

Variable	Helmet Type		
	Helmet A	Helmet B	Helmet C
Percent Caucasian (N.S.)	79%	89%	78%
Percent Married (N.S.)	53%	42%	28%
Percent Right Handed (N.S.)	82%	75%	83%
Average Age (S.D.) (N.S.)	23.1 (4.0)	22.6 (3.5)	22.4 (4.0)
Average Years Active Duty (S.D.) (N.S.)	3.4 (2.8)	2.8 (2.6)	3.2 (3.8)
Average Number Mil. Jumps (S.D.) (N.S.)	22.8 (16.8)	21.1 (18.8)	17.2 (17.5)

N.S. = not significant; S.D.= standard deviation

Key Research Accomplishments

Despite delays in the research program, there have been several significant achievements thus far.

- Over 25 potential enhancements to the blunt impact protection capabilities of US Army ground troop helmets have been rigorously evaluated.
- It was discovered that some systems already fielded by various armed forces do not perform well under standard impact testing, making these data of great importance to safety agencies DoD-wide.
- Two novel helmet configurations have passed testing and have been nominated for further evaluation in operational airborne conditions. These tests alone would normally be sufficient to demonstrate effectiveness in operational use.
- The protocol for the Phase II cohort study of three helmet configurations has been approved through all required IRBs, and subject recruitment is underway, albeit slowly.

Reportable Outcomes

- McEntire BJ, Brozoski F, Trumble C, Crowley JS. (in press) Improved impact protection for the PASGT helmet, Part I: results of development and testing. Fort Rucker, AL: US Army Aeromedical Research Laboratory. USAARL Technical Report.
- McEntire BJ, Brozoski F, Trumble C, Crowley JS. (in press) Improved impact protection for the PASGT helmet, Part II: characteristics of improved systems. Fort

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- Crowley JS, Warden D. (2002) Helmet research programs in the US Army Medical Department. *Presentation to the 2002 USUHS Head Injury Symposium, Bethesda, MD.*
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Conclusions

Despite delays, Phase I of this research program was very successful. The meticulous laboratory test program resulted in two helmet configurations that provide better blunt impact protection than the airborne PASGT helmet that is currently used. Blunt head injury is a significant source of morbidity in military operations, yet the prescribed headgear for US Army troops is not required to meet any blunt injury protection standard. The Phase I results alone will be of great use to helmet developers, providing justification and back-up data to support improvements in head injury protection to warfighters.

As noted above, the Phase II study is 15 months behind schedule as a result of factors that were largely unforeseeable and beyond our control. In order to complete this important research program, we have determined that an additional two years effort will be required. Because maintaining the research teams at Fort Bragg and USAARL is a fixed cost, the research funds have been consumed at only slightly less than the fully operational rate. Therefore, funding will be required for the two additional years. Our request and a proposed budget for this period is attached in the Appendix.

We have applied to MRMC for funding to support this extension. The Military Operational Medicine Research Program is attempting to secure funding, but this source is uncertain. It is hoped that funding can be secured to complete this important study. The delays that we have encountered do not indicate weakness of the study design or execution, but represent best efforts to achieve research of the highest quality in an environment of increasing human use scrutiny and operational realities.

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McEntire BJ, Brozoski F, Trumble C, Crowley JS. (in press) Improved impact protection for the PASGT helmet, Part I: results of development and testing. Fort Rucker, AL: US Army Aeromedical Research Laboratory. USAARL Technical Report.

McEntire BJ, Brozoski F, Trumble C, Crowley JS. (in press) Improved impact protection for the PASGT helmet, Part II: characteristics of improved systems. Fort Rucker, AL: US Army Aeromedical Research Laboratory. USAARL Technical Report.

Appendix

Request for additional two years of funding



DEPARTMENT OF THE ARMY
U.S. ARMY AEROMEDICAL RESEARCH LABORATORY
FORT RUCKER, AL 36362-0577

REPLY TO
ATTENTION OF
MCMR-UAC-S

1 May 2003

MEMORANDUM THRU

Commander, U.S. Army Aeromedical Research Laboratory, Fort Rucker
AL 36362-0577

TRUE Research Foundation, Attention: Ms. Terri Nakamura, 8610 North
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FOR U.S. Army Medical Research Acquisition Activity, ATTN: Ms. Sil
Heller, 820 Chandler Street, Fort Detrick, MD 21702-5014

SUBJECT: Defense and Veterans Head Injury Program (DVHIP) Project
Award Number: DAMD17-01-2-0031, "Efficacy Of Countermeasures Against
Traumatic Brain Injuries Sustained In Airborne Operations"--Request
for Extension with Funding

1. Subject research program was approved on 27 December 2000 as a
3-year effort. As a result of unanticipated delays (detailed below),
the program cannot be completed as scheduled. The purpose of this
memorandum is to request a two-year extension of the project, with
funding.

2. This research program consists of two phases or research
protocols.

a. The first, Phase I: "Design and Testing of Candidate
Paratrooper Helmet Modification," was designed to: (1) assess the
blunt impact protection afforded by the current U.S. Army paratrooper
helmet, (2) review state-of-the-art materials and strategies that
could improve paratrooper head protection, (3) design an array of
candidate head protective systems, (4) test the various protective
system options, and (5) select two improved systems for evaluation.
This phase of the program has been successfully completed, with the
selection of two experimental helmet configurations that have been
shown to provide approximately a 30 percent improvement in blunt
impact protection.

b. The second study phase in the program is a field trial in an
operational U.S. Army airborne unit, in which the existing airborne
troop helmet is compared to the two experimental configurations
developed in the Phase I study. The 82nd Airborne Division at Fort
Bragg, NC, is the host unit for the field study, which compares head
injury rates and outcomes among the three experimental groups. To

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date, all necessary approvals from the study unit and the relevant institutional review boards (IRBs) have been obtained, materials have been acquired and assembled at Fort Bragg, and the contracts for study personnel at Fort Bragg are in place.

3. While this research program has been successful in terms of producing improved head protection for airborne soldiers and is within budget thus far, there have been substantial delays that make it impossible to complete the program within the 3-year time span. There are three principal reasons for this 15-month program delay:

a. First, the Phase I effort to improve the blunt impact protection of the basic combat helmet proved to be more difficult than anticipated. This was primarily due to the operational constraints placed on the research team, the most severe of which specified that no modification could be made to the existing Kevlar ballistic helmet shell or the outward appearance of the helmet. This understandable restriction limited the space available between the head and the helmet shell in which to insert various energy-absorbing materials. Additional time was required to survey industry and academia for novel materials that could be used in this unique application. This effort eventually proved successful, but after 12 months rather than the planned eight.

b. Second, when we eventually submitted the protocol for review by the local IRB at the U.S. Army Aeromedical Research Laboratory (USAARL), we anticipated a speedy approval at the minimal risk level. While this was the opinion of the local IRB, the Surgeon General's Human Subjects Research Review Board (HSRRB) determined that a second level review was required because of the funding mechanism. The HSRRB ruled that the field trial was greater than minimal risk, which caused a delay of approximately two months. In the end, a total of 6 separate IRBs insisted on reviewing the protocol (Walter Reed Army Medical Center, the Uniformed Services University of the Health Sciences [USUHS], the MEDCOM Clinical Investigation Review Office [CIRO], Womack Army Medical Center, the HSRRB, and USAARL). The lack of any centralized research approval process in MEDCOM leaves every IRB with potential liability with no choice but to perform a separate complete review. These unanticipated additional reviews and the inevitable revisions caused additional delays of approximately 6 months.

c. Third, about the time the protocol was finally approved, the brigade at Fort Bragg supporting the study was deployed overseas. Another brigade was identified, but just prior to recruitment briefings in early 2003, it was deployed to support Operation Iraqi Freedom. A smaller airborne unit has recently been made available to

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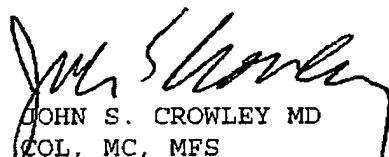
the study, resulting in 105 enrolled subjects, but we require almost 1000 subjects, followed over a two-year period, to achieve the desired statistical power. We have been assured that when the larger brigades return to Fort Bragg, they will be made available to participate in our study. We anticipate that this will occur in the summer of 2003.

4. In order to complete this important research program, we have determined that an additional 2-year effort will be required. This period exceeds the estimated delays explained above because proper follow-up of injured subjects will extend beyond the 2 years of exposure (i.e., parachute jumps while wearing experimental helmets), which was underestimated in the original research proposal. Because maintaining the research teams at Fort Bragg and USAARL is a fixed cost, the research funds have been consumed at only slightly less than the fully operational rate. Therefore, funding will be required for the two additional years. A proposed budget for this period is enclosed.

5. I hope that funding can be secured to complete this important study. The delays that we have encountered do not indicate weakness of the study design or execution, but represent best efforts to achieve research of the highest quality in an environment of increasing human use scrutiny and operational realities.

6. The point of contact for this study is the undersigned at (334) 255-6917 or john.crowley@se.amedd.army.mil.

Encl


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