

Date of IRB: June 2010
81st Medical Group
Keesler AFB, Mississippi

Minimal Risk Human Research Protocol
This is a Progress Report _____ / Final Report XX

1. Protocol Number: FKE20090003H

2. Protocol Title: "Evaluation of Fitness Performance Before and After Breast Reduction Surgery for Symptomatic Macromastia in Active Duty Air Force Women"

3. Principal Investigator (PI): Maj Kerry Latham, 81MSG/SGCX, Phone - (228) 376-3132, Email - kerry.latham@us.af.mil *Add your rank and full name, squadron/office symbol, telephone number, email address.*

4. Purpose: The primary objective is to investigate the relationship between reduction mammoplasty and improvement in fitness assessment scores, individually and composite, for active duty Air Force females.

5. Status of the Study. Mark the status of the study (a-g).

- a. _____ No subjects accrued in this study – termination requested.
- b. _____ No subjects accrued in this study – re-approval requested.
- c. _____ Subject accrual not completed.
- d. _____ Subject accrual completed.
- e. _____ Active with follow-up of subjects only – Subject accrual completed after the last IRB Continuing Review.
- f. _____ Active with follow-up of subjects only – Subject accrual completed before the last IRB Continuing Review.
- g. XX Completed. Request closure at this time.

6. Summary of Progress: This report covers the following period of time: December 2008 – April 2010.

a. Since Last Progress Report or Initiation of Study: *Summarize progress toward achieving the objectives of the study; quantify how much data collection has been achieved and/or analysis accomplished.* I had difficulty in reaching some of the patients due to PCS moves, but a number of the patients I was able to contact have responded. Some patients have not re-tested yet so their fitness tests are pending. Reasons for not retesting include pregnancy and new medical problems placing them on profile.

b. For the Entire Study: A total of fifteen patients were enrolled. I have completed the study and am no longer enrolling new patients.

c. I anticipate PCSing or separating on or about: May 20, 2010

d. If this is a FINAL REPORT:

1. Were the protocol objectives met and how will the outcome benefit the DoD/USAF?

The protocol objectives were met. The preliminary data shows no significant difference for the most part in objective fitness improvements. More data needs to be collected as the population size is small. This warrants further investigation and enrollment or pooling of data with other MTFs.

Report Documentation Page				Form Approved OMB No. 0704-0188	
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1. REPORT DATE 12 MAY 2010		2. REPORT TYPE Final Report		3. DATES COVERED 00-12-2008 to 00-04-2010	
4. TITLE AND SUBTITLE Evaluation of Fitness Performance Before and After Breast Reduction Surgery for Symptomatic Macromastia in Active Duty Air Force Women				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Kerry Latham				5d. PROJECT NUMBER FKE20090003H	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
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13. SUPPLEMENTARY NOTES					
14. ABSTRACT Breast Reduction Surgery for the symptoms of macromastia has been well shown to improve symptoms of back and neck pain as well as deep shoulder grooves. It is established to have high patient satisfaction and even have improved pulmonary physiology, and promote overall wellness and weight loss. The purpose of this study is to evaluate if active duty women treated for symptomatic macromastia by bilateral breast reduction show an improvement in PFT (personal fitness test) after surgery compared to before surgery. The 15 active duty women evaluated far have shown no significant improvement in their performance on the PT test. Although they uniformly report that their symptoms are alleviated they do not perform overall better on the run, push-ups, sit ups, or overall score.					
15. SUBJECT TERMS Macromastia; Breast Reduction Surgery; Air Force Physical Fitness Testing					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT 1	18. NUMBER OF PAGES 4	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			

2. Protocol Outcomes Summary: *Provide in abstract format a summary of the protocol objectives, materials, methods, and results.*

BODY OF ABSTRACT: Breast Reduction Surgery for the symptoms of macromastia has been well shown to improve symptoms of back and neck pain as well as deep shoulder grooves. It is established to have high patient satisfaction and even have improved pulmonary physiology, and promote overall wellness and weight loss. It has been speculated to improve physical fitness and exercise however this has not been studied other than by subjective means. In the military, women take annual or biannual fitness tests providing a unique opportunity to evaluate fitness before and after breast reduction.

OBJECTIVES: The purpose of this study is to evaluate if active duty women treated for symptomatic macromastia by bilateral breast reduction show an improvement in PFT (personal fitness test) after surgery compared to before surgery.

METHODS: The active duty women who underwent bilateral breast reduction for symptoms of macromastia were asked retrospectively to participate in the study after IRB approval. 100% of women contacted agreed to participate- except for three who were unable to be contacted. They provided their fitness test scores in the period from before their breast reductions and after their surgery. Four women have not retested due to conditions such as pregnancy and new medical profiles. This is an ongoing study and more data is to be collected but this represents data until this point. The goal is to collect information from 25 patients currently 15 are enrolled.

RESULTS: The active duty women evaluated thus far have shown no significant improvement in their performance on the PT test. Although they uniformly report that their symptoms are alleviated they do not perform overall better on the run, push-ups, sit ups, or overall score.

CONCLUSION: The active duty women treated for symptoms of macromastia at Keesler AFB reported relief of symptoms but no significant improvement in their performance in fitness. Although the surgery is still an important treatment for symptoms of macromastia, the initial data does not show that fitness is significantly affected. Therefore physical fitness profiles or restrictions for macromastia are likely not necessary in addition treatment of this condition is elective and does not take priority over readiness and deployment missions. This data is important to advise on timing of surgery and expected benefits with regard to deployment tempos, readiness, and fitness standards. More patients will further strengthen these preliminary findings of this study.

7. Demographic Information (a-e)

a. Target accrual number. What is the target accrual number approved by the IRB? Twenty to twenty five

b. Non-accrual. If no subjects have been accrued since the last IRB review, the reason(s) for non-accrual should be provided. N/A

c. Total number of subjects accrued since activation of the study. What is the total number of a) adult male subjects (≥ 19 years) = 0; b) adult female subjects (≥ 19 years) = 15; c) pediatric male subjects (< 19 years) = 0; d) pediatric female subjects (< 19 years) = 0.

d. Total number of subjects accrued by the ethnic origin. How many of the subjects accrued to date since activation of the study are in the following six ethnic categories? a) Caucasian = 6; b) Black, not of Hispanic origin = 7; c) Hispanic = 2; d) Asian/Pacific Islander = 0; e) American Indian/Alaska Native = 0; and f) Other or Unknown = 0.

e. Explanation of subject accrual demographics. The demographics of the subject population must not reflect a disproportionate representation of one gender or minority/majority group which was either not approved by the IRB or is not reflective of the study site patient population. Explain how the subject accrual demographics comply with the requirement. The reason (s) for any appearance of inequitable recruitment of the subjects should be addressed.

All women because men do not have symptomatic macromastia – this is a women's study.

8. Summary of Subject Experiences since the Last Report

a. Status of Subjects: Describe the general health status of subjects enrolled since the last report. Did the subjects benefit from their participation and was their experience during your research study as anticipated? No benefit or detriment. It is a retrospectively collected study of information. Treatment is not dependent on participation. There is no control.

b. Summary of Adverse Events: List all the adverse events since the last progress report. *Reminder* these will have already been reported when discovered using the Adverse Event Report form. This is only a summary of those events. None

1) Unanticipated adverse event (s) reported to the IRB. From initial approval of the study to the present has any subject enrolled in your study suffered an unanticipated adverse event, which was reported to the IRB? If the answer is yes, specify the total number of reported events, date(s) submitted to the IRB and summarize briefly the overall nature, significance of the adverse event(s), and if the event is related to the study. N/A

2) Frequency of serious adverse events. From initial approval of the study to the present has the frequency of serious, but **expected**, adverse events been greater than predicted in your study? If the answer is yes, a description of this finding should be provided. N/A

3) Adverse Events Which Occurred at External Sites. From initial approval of the study to the present have there been any external adverse events reports submitted to the IRB where the adverse event was related or possibly related to the drug/intervention and were both serious and unexpected? If the answer is yes, provide a brief summary of the adverse events. N/A

9. Subject Withdrawal

a. Involuntary subject withdrawal. Were any subjects withdrawn from your study because of medical problems or complications? If the answer is yes, a description of the medical problem/complication must be provided for each subject who was involuntarily withdrawn. No

b. Voluntary subject withdrawal. Did any subject voluntarily withdraw from your study for non-medical reasons? If the answer is yes a description of any known reason(s) for each subject withdrawal and /or other clarification must be provided. No

10. Current Risk-Benefit Assessment: Based on the information provided above, give a current assessment of the risk-benefit ratio. Do the benefits still outweigh the risks? In addition, based on your experience thus far, including the adverse events noted above, does the current informed consent document adequately address the known risks and benefits? Yes

11. Current information accuracy assessment. Is the informed consent document / assent form(s) still acceptable, i.e. the information contained in the document is accurate and complete and there is no new information that may have been obtained since the last IRB review which should be disclosed to the subject? If, in your opinion, the consent/assent form(s) is still acceptable this should be stated. If revisions are necessary then an amendment template needs to be completed and returned via email with this report. The current ICD is still acceptable and no changes are needed at this time.

12. Bibliography. Conduct a new literature search and list publications which may be related to your protocol and report significant findings. (This is a requirement for all Progress Reports.) N/A

13. Protocol Personnel Changes: Have there been any Principal (P.I.) or Associate Investigator (A.I.) changes since the IRB approval of protocol or the last annual review? _____ Yes _____X_____ No
If yes complete the following sections (Additions/Deletions). For additions indicate whether or not the IRB has approved this addition and if the new P.I. and /or A.I. have completed the required Investigator Training.

a. Additions: Include Rank / Name, Protocol Function - PI/AI IRB approved; Investigator Training complete.

b. Deletions: Include Rank / Name, Protocol Function - PI/AI, Effective date of deletion.

14. Status of Approved Funding: *Complete as appropriate; some of this information is contained in your protocol and or amendments – suggest you cut and paste info.*

I did not request any funding from the Surgeon General Office (SGO) in my original protocol.

15. Publications/Presentations: *List OR attach any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications and/or presentations. Also include the date of submission/ acceptance, and location and date of presentation.*

“Breast Reduction and a Fitter Air Force” presented at the Society of Air Force Clinical Surgeons Meeting San Antonio Tx May 13, 2010. Capt Kendrix Evans presented preliminary data on seven patients. Date of submission and acceptance was 2/12/2010.

Total Number of Publications: None *(Include articles, book chapters, etc.)*

15.1. List Awards or Exceptional Achievements Associated With Publications/Presentations: None

15. Required Annual Training. I received and have reviewed the document entitled “Annual Investigator Training” which provides information pertaining to my responsibilities and informed consent. _____ Yes _____ No
This is a requirement for all Progress Reports. This is NOT a requirement for Final Reports.

Certification of Principal Investigator

My signature certifies that the above titled research has been conducted in full compliance with the HHS/FDA Regulations and IRB requirements/policies governing human subject research. I understand that a Progress Report is required in order to maintain continuation approval and any changes in the study/methodology must be approved by the IRB prior to implementation. If the study has never been initiated and I am requesting termination (Item 5.c. above), my signature certifies this request. If the study is completed (Items 5.d. & 6.c. above) and I am requesting closure, my signature certifies that the information provided on this form represents an accurate final report.

Signature of Principal Investigator
**KERRY LATHAM, Major, USAF, MC
81MSG/SGCX**

May 12 2010
Date