TITLE: THE USE OF BONE REPAIR MATERIALS FOR MAXILLARY ALVEOLAR CLEFTS

PRINCIPAL INVESTIGATOR: Michael H. Mayer, M.D.
Jeffrey Hollinger

CONTRACTING ORGANIZATION: Walter Reed Army Medical Center
Washington, DC 20307-5001

REPORT DATE: September 30, 1992

TYPE OF REPORT: Final Report

PREPARED FOR: U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.
The objective of this study is to compare the standard of care for bone regeneration, the autogenous bone graft to experimental materials consisting of a biodegradable carrier and a bone inductive protein (BIP). The animal model for the study is the canine with artificially created bilateral maxillary alveolar clefts. The results are pending as the maxillae have only just been sent for histological slide preparation for subsequent histological and histomorphometric evaluation.
FOREWORD

Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

Where copyrighted material is quoted, permission has been obtained to use such material.

Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

Citations of commercial organizations and trade names in this report do not constitute an official Department of the Army endorsement or approval of the products or services of these organizations.

In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45 CFR 46.

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Principal Investigator's Signature Date
The objective of this study is to compare the standard of care for bone regeneration, the autogenous bone graft, to experimental materials consisting of a biodegradable carrier and a bone inductive protein (BIP).
The need for bone regeneration materials to correct traumatically-induced hard tissue deformities of the craniofacial skeleton, deformities secondary to ablative surgery, and congenital deformities is well documented. In this study, a previously described canine model with artificially created bilateral alveolar clefts is utilized to compare autologous iliac crest bone grafts to the bony defects, with bone inductive protein and a biodegradable carrier, and biodegradable carrier alone.

The bilateral alveolar clefts were first created. They were allowed to mature for several months to permit the development of an oronasal fistula lined with epithelium. The canines were then randomized into four treatment groups consisting of a control group (sham operation), autologous bone graft (iliac crest), bone inductive protein + biodegradable carrier, and biodegradable carrier alone and the clefts grafted. After allowing for osseous regeneration, the animals were sacrificed and the maxillae harvested. Photographs and radiographs were obtained. The bony specimens have been forwarded for processing prior to histological and histomorphometric evaluation.
No conclusions have been reached as the histological and histomorphometric evaluations are pending.