

CIC 6-07-879

CLINICAL INVESTIGATION STUDY PROPOSAL

INSTITUTION: Naval Hospital, Annapolis, Maryland

TITLE: "An Evaluation of the Brostrom Procedure
for Repair of Chronic Ruptures of the
Lateral Ligaments of the Ankle"

INVESTIGATORS:

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Percent of time available for study: 1/3
Projected Rotation Date: July 1976

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A. OBJECTIVES: To evaluate the effectiveness of a new surgical procedure for the repair of chronic ruptures of the lateral ligaments of the ankle.

B. BACKGROUND: Brostrom, in 1966, reported in the Scandinavian literature a simple and relatively anatomic surgical technique for the repair of chronic ruptures of the lateral ligaments of the ankle. Although he reported excellent results in a large number of patients, unfortunately the degree of preoperative and postoperative instability was never quantitated. Despite Brostrom's personal success with this procedure, no subsequent references to this technique have appeared in the English literature.

Chronic instability of the ankle is a major cause of disability at the U.S. Naval Academy. A modification of the Brostrom procedure is currently being employed by the investigators at the U.S. Naval Hospital in Annapolis and during the past 12 months eight procedures have been carried out with excellent initial results.

Bibliography:

1. Brostrom, L.A.: Sprained Ankles. VI. Surgical Treatment of "Chronic" Ligament Ruptures. Acta. Chir. Scand. 132:551-565, 1966.

C. APPROACH: Continue evaluating all ankle reconstructions with preoperative stress X-rays and additional followup stress films at 3 months and 12 months after surgery. Document significant findings with intraoperative photographs. Evaluate operative results by examination and questionnaire at one and two years postoperatively. A total of ten or more cases with a minimum followup of two years should provide an adequate preliminary evaluation of the effectiveness of this procedure and provide additional information regarding the indications for its use. It is estimated that a preliminary report on the surgical technique and initial results should be ready for presentation by late 1975. A continued evaluation at yearly intervals through 1978 is planned.

D. INVESTIGATIONAL NEW DRUG OR HUMAN VOLUNTEER PLANS:
Not applicable.

E. SPECIAL CONSIDERATIONS, NEEDS, SUPPORTING DATA, ETC.:
None.