American College of Foot & Ankle Surgeons

Site Criteria & Selection for the Research Project Entitled:

Subtalar Joint Endoprosthesis for Flexible Flatfoot: Patient and Provider Determinants of Favorable and Unfavorable Mid-term Outcomes

The American College of Foot & Ankle Surgeons is recruiting investigative sites for a multi-center retrospective study looking at predictive variables associated with successful and unsuccessful outcomes when performing subtalar joint arthroereisis in adults and children. Subjects and sites will be compensated for their time. If you are interested in participating in this important study, please complete and return this application.

The following criteria will be used to select eligible sites for this study:

1. A one year contractual commitment by the investigative sites is required.
2. The primary investigator at each site must be in good standing with the American College of Foot & Ankle Surgeons.
3. Volume (minimum of 40) and variety (children and adults) of patients treated for symptomatic non-neuromuscular flatfoot with subtalar arthroereisis during the past 10 years.
4. Past participation in multi-center studies.
5. Professional reputation for scholarly activity.

Please complete the following application in its entirety for consideration.

Name of Applicant _____

Name of Institution _____

Address of Institution _____

_____

Phone Number _____

Fax Number _____

E-Mail Address _____

1. Approximately how many subtalar joint arthroereisis procedures have you performed in the past *5 years* using a metallic, self-locking wedge-type implant while at your current practice address? _____ How many in the past *10 years*? _____

2. Approx. what percentage did you perform on adult patients (18 years or older)? _____

3. What percentage of your arthroereisis procedures were performed for symptoms occurring specifically within the foot/ankle (e.g., arch pain, tendonitis, etc) versus supra-pedal indications (e.g., fatiguing, frequent falls, complaints of clumsiness, etc.)?

   Foot-related indication _____% vs. Supra-pedal indication _____%

4. Have you ever participated in a multi-center trial before? Y/ N _____

   If so, please describe in "additional information" below.

5. Have you previously completed online "Human Subjects Training" like that offered by CITI (https://www.citiprogram.org/Default.asp?)? Y/N_____

6. Are you obligated to use a specific IRB at your practice site? Y/N_____

   If Yes, what is the IRB name: _____

7. Do you have x-ray facilities located WITHIN the confines of your office (e.g., where you are responsible for the read), or do you send out for x-ray services (e.g., where a radiologist provides the read)?

   Please check one:

   X-rays can be performed IN OFFICE _____

   X-rays are always SENT OUT _____

Is there any additional information that the site selectors should know about you?

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You will be informed of a decision by e-mail within 6 weeks of our receiving your application.

Please email or fax the completed application to:

Adam E. Fleischer, DPM, MPH, FACFAS
Principal Investigator
adam.e.fleischer@gmail.com
Fax: 847-775-6554