Prospective Subtalar, Double, or Triple Arthrodesis Study with CCS Screws

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Purpose of the Study

The objective of this study is to prospectively evaluate the mid-term results and intraoperative and postoperative complication rate in patients who underwent subtalar, double or triple arthrodesis using CCS screws.

Background & Significance

Triple arthrodesis of the hindfoot was first described by Ryerson (1) in 1923, as a dual-incision approach to arthrodesis of the talonavicular (TN), subtalar (ST), and calcaneocuboid (CC) joint for a rigid deformity secondary to paralytic conditions. Double arthrodesis of the hindfoot is describe as the arthrodesis of the talonavicular (TN) and subtalar (ST) joints. As these types of diseases became less common and more of a historic significance, the double and triple arthrodesis was adapted to address the rigid arthritic adult flatfoot or to address the posttraumatic degenerative changes (2-4). To date, this procedure is highly successful in correcting deformity and relieving both mechanical and arthritic pain (4;5).

Although double and triple arthrodesis is a valuable tool for hindfoot correction, it is not without postoperative complications, including malunions and nonunions, lateral wound breakdown, and induction of adjacent joint osteoarthritis (5-7). Therefore several modifications of the initial techniques have been suggested. Sparing the calcaneocuboid joint, for example, with isolated fusion of the talonavicular and the subtalar joint only, can achieve comparable good results. Advantages of this technique include reduction of the operative time and the risk of nonunion (8-11).

Implantat description:

APTUS SpeedTip® CCS 5.0 & 7.0 are cannulated compression screws (Figure 1 and Figure 2). All APTUS cannulated screws are made of titanium alloy (ASTM F136, ISO 5832-3). All of the titanium materials used are biocompatible, corrosion-resistant and non-toxic in a biological environment. The main indication for use of APTUS cannulated screws is the treatment of fractures, osteotomies, and arthrodesis of bone with the appropriated screw size. In following cases the use of APTUS cannulated screws is contraindicated:

- Preexisting or suspected infections at or near the implantation site
- Known allergies and/or hypersensitivity to foreign bodies
- Inferior or insufficient bone quality to securely anchor the implant
- Patients who are incapacitated and/or uncooperative during the treatment phase
- The treatment of at-risk groups is inadvisable

All APTUS cannulated screws systems have a specific color coding: APTUS 5.0 dark blue, APTUS 7.0 turquoise. Special implant screws have their own color. To ensure that the lengths of the screws to be used are measured correctly, only original Medartis K-wires of 250 mm in length may be used. The K-wires should be selected depending on the screw size: ø 1.6 mm for APTUS 5.0 and ø 2.2 for APTUS 7.0.

Study objectives:

The objectives of presented prospective multicenter study are to:

- Determine intraoperative and perioperative complications;
- Assess osseous union following arthrodesis;
- Assess postoperative alignment including the cases with possible malalignment/malunion;
- Assess postoperative pain relief at the time of mid-term follow-up;
- Assess the patients' mid-term functional outcome and level of patient satisfaction;
- Determine the rate of secondary surgical procedures for any reason including hardware removal.

Hypothesis 1:
The rate of intraoperative complications is very low.

Specific aim 1:
All intraoperative complications including injury of neurovascular structures and/or tendons will be prospectively documented. All intraoperative technical difficulties (for example, breakage of the screw) will be prospectively documented. The rate of the intraoperative complications will be calculated by an independent observer.

Hypothesis 2:
The rate of perioperative complications is very low.

Specific aim 2:
All perioperative complications including wound healing problems and/or superficial/deep infection and/or deep vein thrombosis will be prospectively documented. The rate of the perioperative complications will be calculated by an independent observer.

Hypothesis 3:
The rate of delayed osseous union or non-union is very low and is comparable with the lower range published in the current literature.

Specific aim 3:
The osseous union will be measured by Duke's independent radiologist. Fusion will only be measured in the patients 6 week radiograph, 3 month radiograph, and 6 month CT scan and radio graph. No additional measurements of fusion will need to be taken, unless the patient still has a non-union at 6 months. At that time the radiologist will go ahead and measure for fusion at 1 and 2 year post –op.

Hypothesis 4:
The fixation of a subtalar, double, or triple arthrodesis will result in neutral hindfoot alignment stable over the time.

Specific aim 4:

The hind foot alignment will be measured by Duke's Independent radiologist. The subject's radiographs at 6 weeks, 3 months, 6 months, 1 year and 2 years post operatively will be used to make these measurements.

Hypothesis 5:
The subtalar, double, or triple arthrodesis will result in substantial pain relief.

Specific aim 5:
The patients will rate their pain on a visual analogue scale (VAS) from 0 points (no pain) to 10 points (maximal pain) preoperatively and postoperatively at the 3 month, 6 month, 1 year, and 2 year follow-up visits. The intra-individual changes over the time will be statistically analyzed.

Hypothesis 6:
The subtalar, double, or triple arthrodesis will result in substantial functional improvement.

Specific aim 6:
The functional status will be assessed using the American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot score and Foot & Ankle Disability Index (FADI) score preoperatively and postoperatively at the 3 month, 6 month, 1 year, and 2 year follow-up visits. The intra-individual changes over the time will be statistically analyzed.

Hypothesis 7:
The rate of secondary surgical procedures for any reason including hardware removal.

Specific aims 7:
All postoperative complications requiring any secondary surgical procedures including hardware removal will be prospectively documented. The rate of the perioperative complications will be calculated by an independent observer.

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Design & Procedures

This proposal is a collaborative effort of Medartis. We have obtained funding for research, performed investigations, and published investigations together. This is a prospective investigation to assess the clinical outcomes of patients with a subtalar, double, or triple arthrodesis with the Medartis APTUS SpeedTip CCS 5.0 and 7.0. We are planning on enrolling 50 patients to ensure a precision rate of ±7.5% and ±10%.

Patients needing a subtalar, double, or triple arthrodesis of the hindfoot will be asked to be enrolled in this study. After informed consent, the patients will be asked to complete the following patient reported outcomes questionnaires (standard of care for all patients in the Foot and Ankle section): VAS for pain, AOFAS, and FADI. After informed consent, they will then be scheduled for surgery in a routine fashion. Postoperative paient reported outcome questionnaires will include VAS for pain, AOFAS, FADI, and the modified Coughlin rating scale. REDCap database will be used. The Duke Office of Clinical Research will be used as a central location for data processing and management. REDCap provides a secure, web-based application that is flexible enough to be used for a variety of types of research, provide an intuitive interface for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. These systems offer easy data manipulation with audit trails and reporting for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

The following surgical procedure steps and follow-ups are standard of care at Duke University.

Surgical technique (standard dual-incision approach) (4):

Positioning

Anesthesia is administered at the discretion of the surgical team. Recommended prophylactic intravenous antibiotics are administered within one hour of the initial incision. The patient is positioned in a modified lateral decubitus position, rotated approximately 30 degrees away from the operated extremity, to allow for a traditional dual-incision approach with access to the lateral hindfoot (subtalar and calcaneocuboid joints) and the medial hindfoot (talonavicular joint). Should the surgeon elect to perform a double arthrodesis through a single medial approach, then the patient is positioned supine with a support under the contralateral hip to allow optimal exposure to the talonavicular and subtalar joints.

Approach

The longitudinal oblique lateral incision starts at the distal end of the lateral malleolus and extends over the sinus tarsi toward the base of the 4th metatarsal. The lateral incision only needs to be extended beyond the calcaneocuboid joint if a triple arthrodesis is performed. The branches of the sural nerve are identified and protected throughout the procedure. The peroneal tendons are identified and retracted plantarly. The muscle belly and overlying fascia of the extensor digitorum brevis are isolated superior to the peroneal tendons and elevated to visualize the subtalar joint and, if a triple arthrodesis is planned, to visualize the calcaneocuboid joint as well. A joint distraction device is anchored in the lateral talar body and the lateral calcaneus to improve subtalar joint exposure; if a triple arthrodesis is planned, then this distraction device may be repositioned to also improve calcaneocuboid joint exposure. To further improve subtalar joint exposure, the interosseous ligament should be transected, allowing greater subtalar joint distraction. A blunt retractor placed lateral to the posterior subtalar joint and deep to the calcaneofibular ligament also improves subtalar joint access.

The medial incision begins at the medial malleolus and extends to the naviculo-cuneiform joint. A plane is created between the posterior tibial and anterior tibial tendons to expose the capsule overlying the talonavicular joint. This capsule is incised to expose the talonavicular joint. The thick fibers of the spring ligament complex in the plantar medial aspect of the talonavicular joint may be carefully divided. While the tibialis anterior tendon must always be protected, with talonavicular joint arthrodesis, tight posterior tibial tendon fibers may be divided. The joint distractor anchored in the navicular and talar neck allows for optimal talovicluar joint exposure. Any impinging or obstructing osteophytes should also be removed, thereby further improving exposure.

Joint Preparation

The residual joint cartilage is removed from all joints to be included in the arthrodesis using a sharp elevator and/or chisel. For the subtalar joint, only the posterior and middle facet articulations are prepared; accessing the anterior facet articulations places the talar vascular supply on the inferior aspect of the talar neck at risk. The lateral talonavicular joint is often difficult to access from the medial approach but, with further elevation of the extensor digitorum brevis muscle and fascia, it may a prepared via the lateral exposure. The joints should be irrigated with sterile saline. To promote bleeding and optimize chance for fusion, the subchondral bone is feathered with a chisel and/or drilled using a 2 mm drill bit. The elevated bone from chiseling and/or reamings from drilling and elevated bone serve to increase surface area for healing and afford local bone graft to promote healing.

Reduction and Fixation

With the ankle maintained in a neutral position, the subtalar joint surfaces are reduced to a physiologic position with 5-7 degrees of hindfoot valgus. Guide pins for two 7.0mm Medartis screws are placed from the posterior/plantar calcaneal tuberosity across the prepared subtalar joint into the talar body, slightly divergent, with one into the posterocentral medial talar body and the other into the antero-central medial talar body. Optimal pin position is confirmed on multiple intraoperative fluoroscopic views: lateral foot, Broden's view, Axial view, and mortise view of the ankle. The hindfoot screws may be inserted (via stab incisions over the two pins) at this point or screw insertion may be delayed until the talonavicular (and calcaneocuboid joints are reduced and pinned. The talonavicular joint is reduced to restore the optimal joint congruency and to establish a congruent talar body-first metatarsal alignment

in both the AP and lateral planes. Two 5.0mm Medartis screw guide pins are placed from the medial navicular across the talonavicular joint into the talar neck/body and their proper positions are confirmed with intraoperative fluoroscopy in multiple planes: lateral, AP, and oblique foot views. With these views, optimal talonavicular joint congruency and talar-first metatarsal alignment are also confirmed. Alternatively, one may enter the TN joint anteriorly and after two TN screws, the third screw may optionally be placed from the navicular to the calcaneus
Fixation of the subtalar joint is performed using two 7.0mm Medartis compression screws placed over the guide pins via stab incisions in the posterior/plantar calcaneal skin. Similarly, Fixation of the talonavicular joint is performed using three 5.0mm Medartis compression screws, two placed from the medial navicular across the talonavicular joint into the talar neck/body and the third from the dorsal navicular, across the talonaviclar joint into the talar head and extending to the anterior calcaneus. The tibialis anterior tendon must be protected during screw insertion.

Via the lateral approach, the calcaneocuboid joint is reduced and pinned from the anterior calcaneal process to the cuboid. Optimal joint reduction and proper pin position are confirmed on intraoperative fluoroscopy, again using three standard views of the foot. Once confirmed, a 5.0mm Medartis compression screw is placed across the calcaneocuboid joint while protecting the sural nerve and peroneal tendons.

Surgical technique (single medial approach) (8;9):
An approximately 6-8 cm long skin incision is made from the medial malleolus toward the navicular. The skin incision is made 5 mm above the course of the posterior tibial tendon. The sheath of the posterior tibial tendon is incised and then tendon then is inspected. The talonavicular joint is identifed and its capsule is incised. A joint spreader is used dorsolaterally to improve talonavicular joint exposure. Residual joint cartilage is removed using a sharp elevator or chisel. Similarly, the subtalar joint is exposed and with the neurovascular bundle carefully protected, a joint spreader is anchored in the medial talar neck/body and the sustentaculum tali of the calcaneus. The deltoid ligament is protected. The joints are prepared, reduced and fixed as described for the dual-incision technique above.

Closure
The tourniquet is released prior to closure and meticulous hemostasis obtained. A drain is used at the surgeon's discretion. Wounds are closed in routine fashion with absorbable suture for deeper layers and monofilament suture versus staples fort the skin. With the ankle in neutral position and over abundant padding, a splint is placed.

Additional information
Additional bone graft will not be routinely used. However, in select cases, bone graft may need to be used; this will be at the surgeon's discretion to optimize the chance for healing/fusion and this will be carefully documented. To optimally correct deformity, tendo-Achilles lengthening or tendon transfer(s) may be warranted in select cases and the addition of these procedures will carefully documented.

Documentation process:
Dr. Easley, the PI, will be the primary individual responsible for maintaining the integrity of the proposed study. Only key personnel on listed on the study will be able to review the written medical records. The

data will be saved in REDCap. REDCap accounts are stored within the DTMI LDAP server hosted by the Duke Office of Information Technology (OIT). Authentication occurs via the OIT implementation of Kerberos. All connections to the system, both external and internal, occur over encrypted channels. Access to components of the system is role-based and can only be granted by administrators of the system. All collected information is stored on a standalone database server hosted by Duke Health Technology Services (DHTS). The database server resides behind the DHTS internal firewall and access to the server is controlled via firewall rules. All collected data is backed up daily, both on the local server and by the DHTS enterprise backup system. All names and identifying information will be removed from the medical images prior to publication.

All adverse events that are directly related to the device must be reported, as well as any adverse events that: (i) is more likely than not related to study activities; and (ii) represents a new risk; and (iii) is unanticipated. In addition, an expected event that is occurring at a frequency or intensity greater than originally anticipated must be reported to the IRB, sponsor, and coordinating site. All Serious adverse events must be reported within 24 hours.

Once consented subject will be given a study Id (ex.0101). The study id and subject identifiers will be kept on an enrollment log only by the site in which the subject is being treated.With the subject's ID and visit dates only, each site's coordinators will record patient data into redcap. This will help keep patients identity confidential.

Clinical assessment:
All patients will be seen preoperatively and postoperatively in the outpatient clinic by their provider or their provider's physician assistant. The clinical examination involves careful preoperative and postoperative assessment of ankle alignment, ankle stability, and ankle range of motion. Ankle range of motion will be determined with a goniometer placed along the lateral border of the leg and foot. All goniometer measurements will be performed in the weight-bearing position, comparable with the method described by Lindsjö et al. (18). The patients will rate their pain on a visual analogue scale (VAS) from 0 points (no pain) to 10 points (maximal pain) (19). Patients will also indicate their satisfaction with the procedure using modified Coughlin rating for category scale (appendix 1): very satisfied, satisfied, partially satisfied, and not satisfied (20). Patients' function status will be assessed using the American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot score (appendix 2) (21). Additionally, the Foot & Ankle Disability Index (FADI) score will be calculated (appendix 3) (22). Patients will be asked to complete the study-related questionnaires during their routine clinic visits. If a patient is unable to return to clinic, however, the questionnaires may be completed with a study team member over the phone or mailed to the patient for completion. The documentation process is summarized in the table 3 below.

Surgical assessment:
A case report form will be provided in the operating room by a member of the study team to document any operative adverse events, bone graft used (if used), deformity correction, tendo-Achilles lengthening or tendon transfer(s)as well as product category and lot numbers.

Radiographic assessment:

All affected ankles will be evaluated preoperatively and postoperatively using a four film series of conventional radiographs including anteroposterior and lateral views of the foot, mortise view of the ankle, and Saltzman view (23) of the hindfoot . Only weight-bearing radiographs of the foot and ankle will be acceptable because non-weight-bearing radiographs are often misleading (24-26). Furthermore, the standing position may help to standardize the radiograph technique, allowing more reliable comparison of interindividual and intraindividual radiographs. The radiographs should include a sphere calliper in order to hold standardize radiographs taken.

The full interpretation of these radiographs and computed tomography scans are to be made by Duke's radiology team as standard of care. There will be one Duke independent radiologist who will only make measurements of the osseous union fusion and hind foot alignment. This independent radiologist will access the subject's radiographs and CT scan from PACS and record the measurements in an excel spreadsheet that is saved on the DHTS server.

Selection of Subjects

Patients will be identified in the clinic by an attending orthopaedic foot and ankle surgeon or his physician assistant based on clinical exam and radiographic findings. Inclusion criteria include anyone over age 18 who has ankle and subtalar arthritis and has failed nonoperative management. Typically, these patients have multiple medical comorbidities and therefore the only exclusion criteria will be patients who are not healthy enough to undergo surgery. Patients of all racial, religious, and cultural backgrounds will be included in this study.

Indications:

- Primary subtalar, double, or triplearthrodesis
- Rheumatoid or posttraumatic osteoarthritis of the hindfoot with involvement of subtalar, talonavicular, and calcaneocuboid joints (2;12).
- Symptomatic rigid pes planovalgus et abductus with end-stage posterior tibial tendon dysfunction (for exampke, grade IV) (4;13-15).
- Neuromuscular disease mediated hindfoot deformities (16).
- Tarsal coalitions (17).
- Indication for calcaneocuboid arthrodesis: severe degenerative changes in the calcaneocuboid joint and/or severe abductus deformity of the forefoot.
- Between the age 18-75

Contraindications:

- Acute or chronic infection.
- Poor vascular status of the lower leg (relative contraindication for double arthrodesis through a single medial approach).
- Women that are pregnant.

Subject Recruitment and Compensation

Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate. Patients will be screened for eligibility in each center by the local research coordinator/ key personnel in close coordination with the surgeon co-investigators. This surgical intervention has no predilection for race, religion, cultural background, etc. Therefore, all demographic groups will have access to this study and should be represented.

Data Analysis & Statistical Considerations

A Kolmogorov-Smirnov normality test will be performed to determine if data were normally distributed. A paired t-test and Wilcoxon signed rank test will be used for comparison of paired normally and non-normally distributed data, respectively. A P value of < 0.05 will be considered to be statistically significant. Data will be analyzed using SPSS version 20.0 (SPSS Inc., Chicago, Illinois) and SigmaPlot version 12.5 (Systat Software Inc., San Jose, California).

Data & Safety Monitoring

During collection, data will be indexed by the patient's medical record number. After data collection, a case number will be assigned to the data, and the medical record number (the only identifying data collected) will be stripped from the database. The code linking medical record number to case number will be kept on the shared drive in the folder mentioned above. When the study is complete the code linking medical record numbers to case numbers will be destroyed. During data collection and review protected health information will be available only to the primary investigator and will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study. All Duke essential documents will be stored on a DHTS server.