STA-PEG

SUBTALAR ARTHRORISIS IMPLANT | SMITH DESIGN

SURGICAL TECHNIQUE

WRIGHT.

STA-PEG

subtalar arthrorisis
IMPLANT

surgical technique presented by
AS DESCRIBED BY STEPHEN SMITH, MD

STA-PEG

subtalar arthrorisis IMPLANT **as described by Stephen Smith, MD**

DESCRIPTION

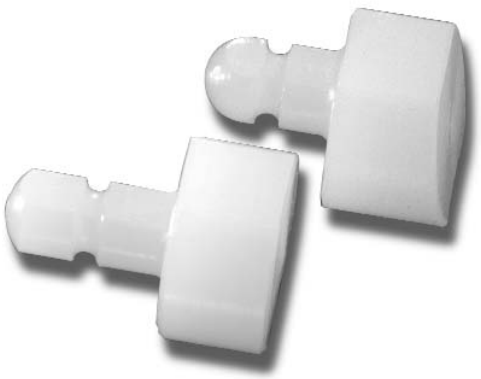
The STA-Peg (Smith Design) is a one-piece, ultra-high molecular weight polyethylene implant, designed for use in selective cases where subtalar arthrorisis is indicated. The implant is placed into the dorsal lateral surface of the calcaneus just anterior to the posterior facet (not in the sinus tarsi). The stem of the implant is inserted into a prepared hole and is secured with bone cement. The anterior leading edge of the talus contacts the superior surface of the implant to prevent excessive pronation of the subtalar joint.

DISCUSSION

The following discussion of implant subtalar arthrorisis of the subtalar joint was provided by Dr. Stephen Smith.*

rationale AND FUNCTION

This operation is an implant-modified subtalar arthrorisis. The implant fits into the dorsal surface of the calcaneus just anterior to the posterior facet. The stem of the implant is inserted into a prepared hole made in the calcaneus, and is secured with bone cement. The head of the implant fits flush against the calcaneus and articulates with the talus. Its purpose is to eliminate abnormal pronation, correct heel valgus, and produce an increase in the medial longitudinal arch.



diagnosis AND TREATMENT

Hyperpronation of the subtalar joint is a pathological state wherein abnormal motion occurs in the rear foot in the direction of pronation with subsequent collapse and flattening of the medial longitudinal arch. Flatfoot is a nondescript term depicting only the external appearance of a low arched foot that, in many individuals, may be perfectly normal for them. Flexible flatfoot and hyper-mobile flatfoot are terms commonly used to describe a pronated foot which is flexible in nature. These feet typically display excessive mobility of the tarsal and subtalar joints that is closely related to generalized ligamentous laxity. In typical cases, the deformity manifests itself only on weight-bearing. Off weight-bearing the foot assumes normal posture, but as soon as weight is borne the foot collapses under the load, taking on the characteristic flatfoot appearance. Flexible flatfoot may thus be defined as a foot that on weight-bearing becomes abnormally pronated and displays exaggerated mobility of the tarsal and subtalar joints.

The diagnosis of the pronated flatfoot requires familiarity and understanding of the components of closed kinetic chain pronation of the subtalar joint, i.e., eversion of the calcaneus with adduction and plantar flexion of the talus. With pronation of the subtalar joint, there also is a considerable amount of anterior (lineal) displacement of the talus in relation to the calcaneus. The extreme of this movement is limited by the abrupt contact between the anterior rim of the talus (posterior facet) and the calcaneal notch.

The purpose of the STA-Peg subtalar arthrorisis implant is to prevent this anterior movement of the talus. The other components of pronation will then be affected in a like manner since all of the components of pronation occur simultaneously; preventing anterior movement of the talus prevents the other components of pronation from functioning. The net result is limitation of pronation and consequently reduction of heel valgus.

Maintenance of this corrected position of the subtalar joint with the use of the STA-Peg subtalar arthrorisis implant provides a stable fulcrum for the peroneus longus. In addition, it establishes a force vector which enables this muscle to plantarflex the medial pillar of the foot to the weight-bearing surface, thus increasing the arch height and reducing the forefoot varus. This posture created by the activity of the new peroneus longus, accompanied by continued growth, allows secondary bony and soft tissue adaptive changes to occur which will become permanent by the time of skeletal maturity. This results in a foot which

displays normal osseous alignment and, therefore, normal function capabilities at the termination of growth.

Untreated flexible flatfoot in childhood may lead to severely disabling secondary deformities and symptoms that become evident in adolescence and adulthood. Hallux abducto valgus, plantar keratosis, metatarsalgia , hammertoes, neuromas, plantar fasciitis, heel spur pain, postural pains of the foot and leg, and arthrosis deformans of the midtarsal and subtalar joints may be directly related to uncorrected flexible flatfoot. Abnormal pronation of the subtalar joint during weight-bearing is the latent etiology for these conditions. It is thus desirable to recognize and diagnose abnormal pronation in early childhood and begin treatment then, either through mechanical orthopaedic support, or in advanced cases, through surgical intervention to prevent the secondary deformities propagating into later life.

Selecting the correct treatment modality with children afflicted with flexible flatfoot merits careful consideration. Surgery is justified for correction of flexible flatfoot in a child only when specific conditions are present. Constant unrelenting pain may be the primary complaint in a small number, but patient symptoms must be divided into objective and subjective types. Pain is a subjective symptom and is rarely the primary complaint, since children invariably accept discomfort as a way of life until they reach the age of self-awareness and are able to communicate and compare their activities with those of their peers. The following subtle alterations in functional behavior patterns may be detected during careful history taking from the child's parents and serve as useful subjective information as to the degree of disability resulting from flexible flatfoot:

- Walking temperance
- Night cramps
- Abstinence from athletics
- Pursuit of sedentary hobbies
- Postural pains of the foot and leg

A child is rarely taken for professional advice because of subjective symptoms. Cramps and postural pains are typically considered growing pains. The majority of children seen by the practitioner with the initial

complaint of flatfoot are brought because of the more obvious objective signs and symptoms that may include the following:

- Absent or depressed arches
- Heel valgus
- Clumsiness
- Abnormal shoe wear
  - Excessive heel wear
  - Distorted shank
  - Broken down counter
- Parent-recognized hereditary deformity

Between the ages of one and six in the mild to moderately pronated foot, treatment is best accomplished with a custom-molded stabilizer to control the heel in a vertical position. Between six years of age and adolescence in the mild to moderately pronated foot, the preferred treatment is a full-length custom-made acrylic in-shoe orthosis formed from a corrected positive mold.

Between the ages of one and three in the severely pronated foot, the initial treatment should begin with a heel control orthotic. If in one to two years there is no change or improvement, surgery is often indicated, followed up with an in-shoe orthotic until the growth spurt of adolescence is completed.

After six years of age in the severely pronated foot, surgery is indicated primarily, followed postoperatively with an in-shoe orthotic until skeletal maturity is reached.

In cases where surgery is indicated, the surgeon has many techniques to select from. There is no one surgical procedure that is agreed upon and specific for a given situation. With many of the non-implant surgical techniques, the timing of the procedure is recommended for late childhood or early adolescence after 80% of the growth of the foot has already taken place and irreversible adaptive bone changes that occurred.

Additionally, all non-implant techniques typically involve major reconstruction such as soft tissue plication, tendon transfer, osteotomy, arthrodesis, and bone grafting alone or in combination. Postoperatively, non-implant procedures require lengthy immobilization and prolonged

convalescence. In patients where surgery is indicated, this implant-modified subtalar arthrorisis procedure has the following clinical advantages:

- Recommended during childhood while bones of the foot are adaptive
- Simplified surgical technique
- Postoperative immobilization is unnecessary
- The quality of the result improves with continued growth

specific indications FOR SUBTALAR IMPLANT ARTHRORISIS

SEVERELY PRONATED FOOT

- Calcaneal stance position greater than 5°
- Loss of arch on weight-bearing
- Manually correctable deformity
- No contributing torsional deformity of the extremity
- Forefoot varus greater than 10°
- Mid-tarsal breech (talonavicularptosis)

RADIOGRAPHIC SIGNS

- X-ray finding of lateral talocalcaneal angle greater than 40°
- dorsal-plantar talocalcaneal angle greater than 30°
- talonavicular joint less than 50% articulated
- anterior break of the Cyma line
- talonavicular and/or naviculocuneiform breech (lateral view)

CONTRAINDICATIONS

In children one to three years of age, surgery should be undertaken only if there has been no improvement after one or two years in a heel control orthotic.

In patients older than six years of age who have not yet reached skeletal maturity, subtalar implant arthrorisis is indicated initially.

- Any evidence of infection or other health condition that would make surgery unnecessarily risky.
- The physiologically or psychologically at risk patient.
- The presence of any clinical or functional abnormalities that preclude the potential of achieving a good result.

CAUTION | In patients with inadequate dorsiflexion, a percutaneous lengthening of the Achilles tendon may be indicated. Generally, lengthening of the Achilles tendon is recommended when the foot cannot be dorsiflexed 90°, when the knee is extended and the subtalar joint is in a neutral position. With the knee extended, the foot should dorsiflex 10° or more past a right angle. If it does not, other more complex problems such as ankle equinus, cerebral palsy, delayed maturation of the cortical spinal tracts, and the like, should be suspected. In these cases, surgery of any kind should be delayed until a definitive diagnosis has been established.

COMPLICATION

In any surgical procedure, the potential for complications exists. Subtalar implant arthrorisis is generally considered a simple procedure, thus the potential for complications is not great. However, the possible occurrence of the following complications should be considered and reviewed preoperatively with patients and their parents as part of the consent procedure:

- Infection
- Pain/stiffness
- Inadequate correction of the pronated foot
- Implant loosening
- Implant wear and/or fragmentation
- Wear particle induced synovitis or bone cysts
- The possible need for additional surgical procedures when results are unsatisfactory

surgical PROCEDURE

In addition, the subtalar implant arthrorisis procedure has potential for any or all of the well known complications associated with surgical procedures where anesthetic agents and/or drugs may be required.

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Stephen Smith. Each surgeon must evaluate the appropriateness of the procedure based on his or her own medical training and experience.

The patient is prepared and draped in the usual aseptic manner and hemastatis is obtained with a pneumatic cuff applied above the knee and inflated to 350mm Hg. A 4cm curved incision is made over the sinus tarsi. | **FIGURE 1** Bleeders are clamped, cut and coagulated. The dissection is then deepened to the extensor digitorum brevis muscle which is retracted distally after being incised from its origin in an "L" shaped fashion. | **FIGURE 2**

The foot is supinated at the subtalar joint exposing the leading edge of the posterior articular facet of the calcaneus. | **FIGURE 3** It is important to square off the distal portion of the calcaneal facet for proper fitting of the implant. This is accomplished by resecting approximately 1/8" from the leading edge of this facet and flush with the superior surface of the calcaneus. | **FIGURE 4** Next, utilizing the STA-Peg guide and drill, a hole is made into the dorsum of the os calcis just in front of the posterior calcaneal articulation. The guide has a flat surface at its tip end which

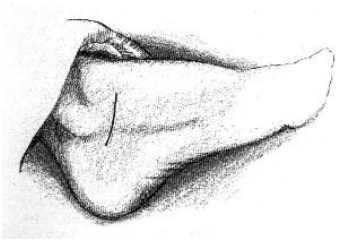


FIGURE 1
Modified Ollier Incision

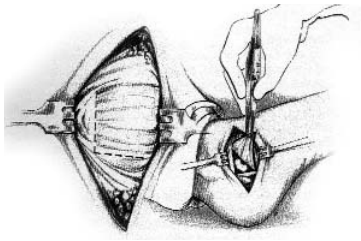


FIGURE 2
Subtalar joint exposed with "L" flap at origin of extensor digitorium muscle

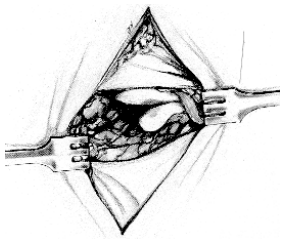


FIGURE 3
Subtalar joint exposure

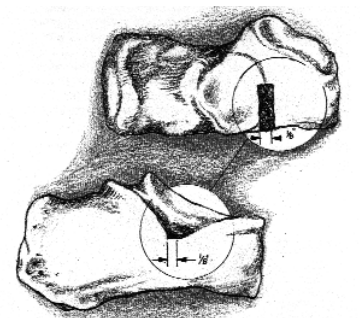


FIGURE 4
Anterior leading edge of calcaneal facet squared off

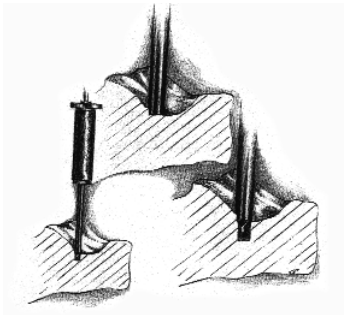


FIGURE 5
Flat surface at tip of drill guide is placed flush against remodeled ledge. A drill hole is then made.

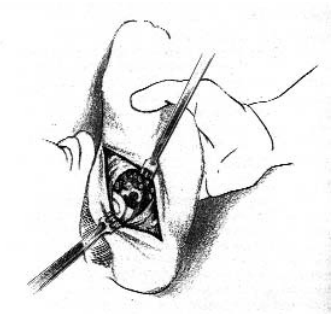


FIGURE 6
Dorsal lateral view of hole and remodeled edge

should be held firmly against the squared off portion of the calcaneal facet. | **FIGURE 5** This will insure the proper location of the hole. | **FIGURE 6**

The color coded STA-Peg sizers are used to determine the appropriate implant. The sizer is inserted so that its posterior margin fits flush with the calcaneal facet where bone was previously resected. After the correct size has been determined, a STA-Peg subtalar arthrorisis implant of the same size is cemented into position using approximately a 0.5cc mix of bone cement. | **FIGURE 7** and | **FIGURE 8** After the cement has set, the wound is irrigated with saline and the extensor digitorum brevis muscle is relocated and sutured into position utilizing 2-0 resorbable interrupted sutures. The skin margins are then approximated and maintained with 5-0 resorbable suture subcuticular closure reinforced with 1/4" steri-strips. Bupivacaine and dexamethasone are instilled into the surgical site, dry sterile dressings are applied and the tourniquet is released.

No casting or other forms of immobilization are necessary. Early motion and weight-bearing are encouraged. The patient is allowed to stand and take a few steps the first postoperative day. Thereafter, activity is gradually increased with full activity being achieved in one to three months. If lengthening of the Achilles tendon was performed simultaneously, a below-the-knee walking cast is worn for four weeks.

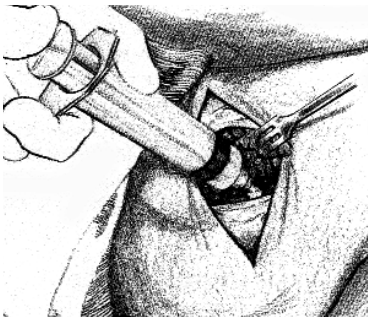


FIGURE 7
Cement is placed in the hole to the level of the dorsal cortex

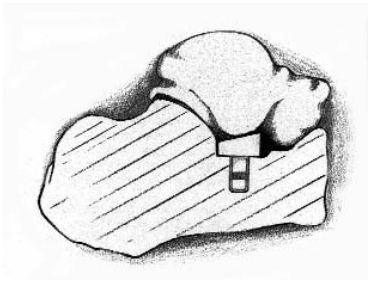


FIGURE 8
Proper sealing of implant

DISCUSSION

IMPORTANT POINTS TO OBSERVE

The STA-Peg subtalar arthrorisis procedure is a modified subtalar arthrorisis to eliminate abnormal pronation, to correct heel valgus, and to produce an increase of the medial longitudinal arch. The goal of the procedure is the prevention of severe, disabling secondary deformities which may emerge in adolescence and adulthood as a result of flexible flatfoot (pronated foot).

STERILIZATION

IMPLANT

The STA-Peg subtalar arthrorisis implant has been sterilized. The implants are sterile so long as the packaging is unopened and undamaged. Inspect for punctures or other damage prior to surgery. If re-sterilization of the STA-Peg implant is required, use ethylene oxide gas, following the recommendations of the sterilizer manufacturer. Do not autoclave or dry heat sterilize. Ultra high molecular weight polyethylene is damaged at autoclave or dry heat sterilization temperatures. Following ethylene oxide sterilization, recommended aeration time is 48 hours at room temperature or 8 to 12 hours at power aeration at 50-60° centigrade. Consult recommendations of aeration manufacturer.

SIZING SET

The STA-Peg sizing set is supplied non-sterile.

The following sequential steps are recommended to clean and sterilize the sizing set or to re-sterilize it after use:

1. Scrub thoroughly with a clean, soft-bristled brush in a hot water-soap solution to remove possible surface contaminants. Use a non-oily mild soap such as Ivory Flakes or Ivory bar soap. Do not use synthetic detergents or oil based soaps, as these may be absorbed and subsequently leach out to cause a tissue reaction.
2. Rinse thoroughly with distilled water.
3. Wrap in a lint-free cloth or place on a clean open tray, and autoclave by one of the following methods:

Method	Temperature	Exposure
High speed instrument sterilizer	270° F/132° C	10 minutes
Standard gravity sterilizer	250° F/121° C	30 minutes
Prevacuum high-temp. sterilizer	270° F/132° C	10 minutes
or	250° F/121° C	30 minutes

NOTE: The use of polymethylmethacrylate bone cement can be helpful in securing, supporting and stabilizing certain appliances in bone, but it neither replaces the function of sound bone for support nor eliminates the need for other support during healing. In using cement for implant fixation, care should be used to insure complete cement support on all parts of the appliance embedded in bone cement to help prevent possible stress concentration, which may lead to failure.

The correct handling of the implant is extremely important. Contouring of the device is to be avoided where possible. It contouring is necessary, it should not be bent sharply, reverse bent, notched or scratched. These alterations can produce defects and stresses which may become the focal point for eventual failure of the implant.

A surgical implant should not be reused. Any implant once used should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns which may lead to failure. We urge you to use only a new appliance of current design.

Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load-bearing, ranges of motion and activity levels permissable. Early load-bearing should be carefully controlled.

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*Stephen D. Smith, DPM, FACFS, Diplomat -ABPS and ABPO, Clinical Professor, California College of Podiatric Medicine; Director of Podiatric Education and Residency Training, Health Care Medical Center of Tustin, CA.

WARNING:

Potential for Complications

A thorough discussion of all potential complications that may be associated with implant reconstructive procedures is not possisble in product labeling. It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedures and the potential complications that may occur in each specific case.

Implants are mechanical devices that can be worn away, fatigued, or broken. An implant site may become infected, painful, swollen, or inflamed. Strenuous implant loading, excessive mobility, the presence of articular instability, implant oversizing, and patient over-activity or misuse increase the potential for complications including wear or fracture of the implant and particle formation. Excessively mobile joints are generally less stable, and an implant alone cannot provide long-term stability in a joint that lacks functional stability; complications necessitating revision surgeries are thus more frequent in unstable joints. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity, or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate in time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon. Therefore, surgeons must balance many considerations to achieve the best result in individual patients. Providing each patient scheduled for implant surgery with documented counseling of potential complications is required.

CAUTION | Federal (United States) law limits this device to sale by or on the order of a physician.

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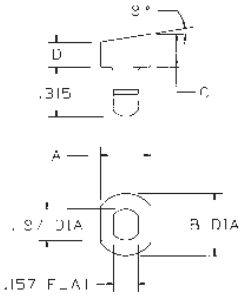
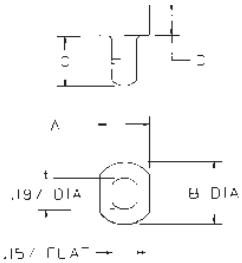


TYPICAL DIMENSIONS | ANGLED DESIGN

SIZE	A	B	C	D
SMALL	.32 (8.1)	.39 (10.0)	.21 (5.3)	.16 (4.0)
MEDIUM	.32 (8.1)	.43 (11.0)	.25 (6.4)	.20 (5.0)
LARGE	.39 (10.1)	.47 (12.0)	.30 (7.6)	.24 (6.0)



TYPICAL DIMENSIONS | SMITH DESIGN

SIZE	A	B	C	D
SMALL	.32 (8.1)	.43 (11.0)	.32 (8.1)	.20 (5.0)
MEDIUM	.39 (10.0)	.47 (12.0)	.39 (10.0)	.28 (7.1)

DRILL GUIDE 6100-0100

DRILL 6100-0150
Drill guide and drill for angled implants only

SIZING TEMPLATE 6100-0050

HOW SUPPLIED

The STA-PEG Implants have been sterilized and packaged as follows:

STA-PEG (ANGLED) DESIGN

QUANTITY	DESCRIPTION	CATALOG #
1 Box	1 Each, Size Small UHMW Polyethylene	2100-0111
1 Box	1 Each, Size Medium UHMW Polyethylene	2100-0112
1 Box	1 Each, Size Large UHMW Polyethylene	2100-0113
1 Sizing Set	1 Each, Sizes: Small (gray) Medium (green) Large (blue) (non-sterile) NOT FOR IMPLANTATION.	2100-0100
1 Box	Drill guide, Stainless steel (non-sterile)	6100-0100
1 Box	Drill, Stainless steel (non-sterile)	6100-0150

STA-PEG DESIGN

QUANTITY	DESCRIPTION	CATALOG #
1 Box	1 Each, Size Small UHMW Polyethylene	2100-0001
1 Box	1 Each, Size Medium UHMW Polyethylene	2100-0002
1 Box	Sizing template, stainless steel (non-sterile)	6100-0050

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