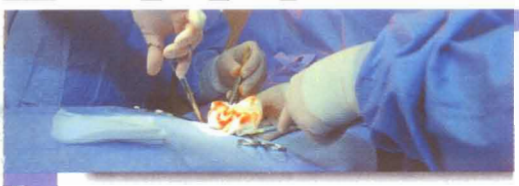


IS THE SUBTALAR IMPLANT THE ANSWER FOR JUVENILE FLATFOOT?

By Thomas J. Cusumano, DPM and Richard T. Braver, DPM

There has been considerable debate over the years about how we should treat symptomatic pes planovalgus deformities. These deformities are of particular concern for the pediatric patient. You may see symptoms such as early fatigue, a decreased desire to participate in athletic activities and avoidance of prolonged walking or standing. Since these symptoms develop gradually, some parents may disregard the child's complaints as trivial. Other parents may be so concerned that they take their child for a full medical workup—to no avail.

What they likely don't realize is that their child's problems stem from the feet, particularly flat or collapsed arches.

Keep in mind that foot pain and leg fatigue are often associated with an everted rearfoot. In children, specifically, this may be the result of an accessory navicular bone, hypermobile foot, Achilles or gastrocnemius equinus. You should also ask the parents about any family history of foot deformities (i.e., bunions with hypermobile or flat feet). If orthotics and other conservative measures fail, then you should consider a surgical workup.

If you detect flat foot early on in a patient's life, you can use the MBA (Maxwell-Brancheau Arthroereisis) subtalar joint implant to prevent further foot deformities. When you're considering using this device, your pediatric patient should have a flexible foot with no tarsal coalitions. You should also be able to maneuver the foot into STJ neutral. Using X-rays and a CT scan can help you further verify joint positions and abnormalities. You can also use the implant as an adjunctive procedure to help support the talus and surgically correct the underlying pathology (i.e., accessory navicular) or you can use the implant to reduce the strain of the posterior tibial tendon after repair. *(Editor's Note: While the MBA implant is commonly used to treat children four to 12 years of age, you can also use it to treat symptomatic flexible flatfoot (i.e. tibialis posterior dysfunction) in adults .)*

In short, by elevating the neck of the talus, the MBA implant stops excessive plantarflexion (a sagittal plane deformity) of the talus. Using the implant also helps you reduce eversion of the subtalar joint (a frontal plane motion), which enables you to stabilize the rearfoot and reduce pronation. However, if you see additional pathology that contributes to the flat foot, then you should address this with the appropriate ancillary procedure (i.e., Evan's calcaneal osteotomy or Achilles lengthening).

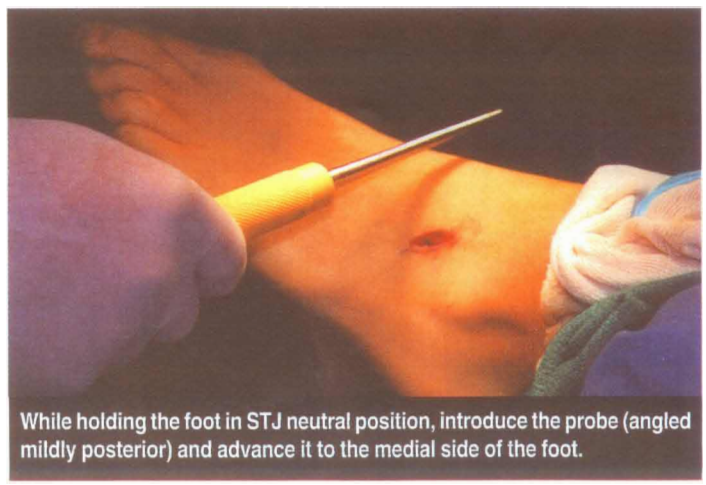
What can the MBA implant do for you? Well, it enables you to limit excessive motion without having to remove bone from the subtalar joint. Using canulated instrumentation, you insert the implant through a small medial and lateral incision.

In comparison with other arthroeresis procedures, you need to make a longer surgical incision in order to access the sinus tarsi. Then you drill a hole into the calcaneous to seat the implant.

Essential Incision Pointers

Based on the principle of canulation with minimal surgical dissection, the MBA color-coded instrument kit contains a probe, guide pin, five sizers with respective trial implants, a nose cone and nose cone extractor. You use the instruments over a guide pin so you can place the MBA implant in the sinus tarsi between the posterior and middle facet.

To begin, insert an 18-gauge needle into the lateral sinus tarsi. This will help you determine the guide pin position and ensure proper placement of a 3 to 4cm surgical incision. Once you've determined the position, make a linear skin incision over the sinus tarsi parallel to the neurovascular structures. This helps you prevent injury to the intermediate dorsal cutaneous and sural nerve. Identify the deep fascia and use a hemostat to bluntly dissect into the sinus tarsi. Proceed to use a metzenbaum or mayo scissor to release the interosseous talocalcaneal ligament.



While holding the foot in STJ neutral position, introduce the probe (angled mildly posterior) and advance it to the medial side of the foot.

Keep in mind that you won't be able to see the ligament, but you will hear a celery-like crunch sound during the release. As you become more experienced in doing this procedure, you can often leave the interosseous ligament intact. Given the increased range of motion, make sure you check out the amount of inversion and eversion before sectioning the ligament.

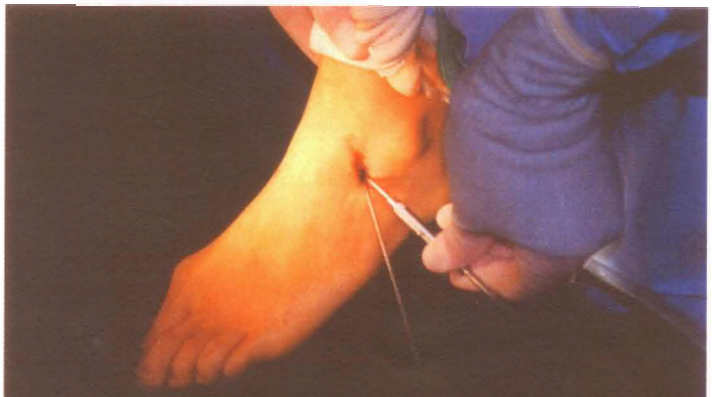
While holding the foot in STJ neutral position, introduce the probe (angled mildly posterior) and advance it to the medial side of the foot. Proceed to make a 1cm medial incision over the probe at a point that is anterior and inferior to the medial malleolus and superior to the posterior tibial tendon. Poke the probe through the skin. Rotate the probe in a circular motion to open the tarsal canal. However, do not excessively dilate this area as this may lead to oversizing of the implant. If you find it difficult to advance the probe, either redirect it or release additional interosseous ligament.

Follow These Sizing Guidelines

Place a 2.0mm guide pin into your lateral incision. This allows canulated use of the sizers, insertion device and trial implants. By using the guide pin, you reduce the risk of incorrect instrument positioning during the procedure and are easily able to retrieve the trial implant.

Use a freer elevator, as an extension of your finger, to probe the lateral calcaneal wall and inferior cortex of the talus. Keep in mind that these are important landmarks and will serve you as reference points when you're placing the implant. While holding the foot in rectus to mild supination, proceed with sequential sizing until you're satisfied with the reduction in STJ motion. Start with the 6.0mm sizer instrument (red), switching to the 8.0mm (brown), the 9.0mm (blue), 10.0mm (gray) and 12.0mm (green) from lateral to medial until you've determined the proper correction. When you're relocating the talus on the calcaneus, be aware that the appropriate sizer should allow 2-4 degrees of subtalar eversion.

Once you've decided on the appropriate sizer, use the insertion device to



Once you've made the final implant placement, confirm the fluoroscopic depth by using a freer elevator to measure the lateral aspect of the implant from the lateral calcaneal wall.

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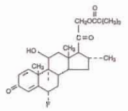
For Topical Use Only

DESCRIPTION: Cloderm Cream 0.1% contains the medium potency topical corticosteroid, clocortolone pivalate, in a specially formulated water-washable emollient cream base consisting of purified water, white petrolatum, mineral oil, stearyl alcohol, polyoxyl 40 stearate, carbomer 934P, edetate disodium, sodium hydroxide, with methylparaben and propylparaben as preservatives.

Chemically, clocortolone pivalate is 9-chloro-6α-fluoro-11β, 21-dihydroxy-16α-methylpregna-1, 4-diene-3, 20-dione 21-pivalate. Its structure is as follows:



CLINICAL PHARMACOLOGY:
Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. (See **DOSAGE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE: Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS: Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS
General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (See **PRECAUTIONS**-*Pediatric Use*).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests: The following tests may be helpful in evaluating the HPA axis suppression:
Urinary free cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C:
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS: The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:
Burning
Itching
Irritation
Dryness
Folliculitis
Hypertrichosis
Acneiform eruptions
Hypopigmentation
Perioral dermatitis
Allergic contact dermatitis
Maceration of the skin
Secondary infection
Skin atrophy
Striae
Miliaria

OVERDOSAGE: Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION:
Apply Cloderm (clocortolone pivalate) Cream 0.1% sparingly to the affected areas three times a day and rub in gently.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED: Cloderm (clocortolone pivalate) Cream 0.1% is supplied in tubes containing 15 grams (NDC 0064-3100-15) and 45 grams (NDC 0064-3100-45).

Store Cloderm Cream between 15° and 30° C (59° and 86° F). Avoid freezing.

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place the trial implant over the guide pin to about the talus and calcaneous. At the entrance of the sinus tarsi, you'll notice how the implant will start to bore into the soft tissue with mild resistance. However, it should not feel tight as a screw does in the bone.

How To Ensure The Final Implant Placement

In order to approximate the final implant placement, take note of the amount of clockwise revolutions you need to position the implant. Inspect it under fluoroscopy. Evaluate this radiopaque implant on a lateral and AP view. It should not be more than 1 cm deep from the lateral cortex of the calcaneous and should not go beyond the midline of the talus neck. Be aware that excessive medial placement may lead to medial extrusion or a significant limitation to the normal subtalar joint motion. If you see that the implant is beyond the recommended point of placement, use a bigger size for a more appropriate fit.

It is not necessary to always use the nose cone as it requires you to make a larger medial incision to allow its retrieval. This is because the MBA trails the cone as you screw it into place. Keep in mind that when you're placing these larger implants, make sure you adequately retract the soft tissue to prevent its traction into the sinus tarsi. The tan trial implants are enclosed in the kit and differ from the 'real deal' implant, which is a silver shaded titanium and has 3 unique 'L' slots in its design for impact stress and shock absorption. It also provides for fibrous in-growth to prevent implant extrusion or displacement.

Final Notes

Once you've made the final implant placement, confirm the fluoroscopic depth by using a freer elevator or the backend of a scalpel handle to measure the lateral aspect of the implant from the lateral calcaneal wall. Remove the guide pin and clinically test the STJ's range of motion, which should optimally be between two to four degrees of calcaneal eversion. Perform subcutaneous and skin closure in layers and follow up with a compressive dressing and a below knee non-weightbearing cast.

Remove the sutures two weeks after the operation. At this time, your patient should be able to return to sneakers and accommodating shoes. He or she should be able to return to sporting activities within two to three months. If you performed ancillary procedures, follow the postoperative standard of care. ■

Editor's Note: For more information on the MBA implant, contact Kinetikos Medical Incorporated at (858) 558-2233.

Dr. Braver (shown at right) is board certified in foot and ankle surgery by the American Board of Podiatric Surgery. A Fellow of the American College of Foot and Ankle Surgeons, he practices in Englewood, NJ. Dr. Cusumano is an Associate of the American College of Foot And Ankle Surgeons.