HELP YOUR PATIENTS FIGHT BACK AGAINST BUNION PAIN

PROstep™ is a minimally invasive procedure shown to get patients back on their feet faster with less pain.[1,2]

For more information visit:
PROstepMIS.com

CLINICAL DOSSIER

PROstep™
Minimally Invasive Surgery

TRUST YOUR LEADER IN MINIMALLY INVASIVE SURGERY[3]

CLINICAL
3rd generation minimally invasive surgery with over 8 years of clinical history

PRODUCTS
Instruments and implants designed for minimally invasive F&A surgery

TRAINING
Cadaveric training led by minimally invasive surgery innovating surgeons

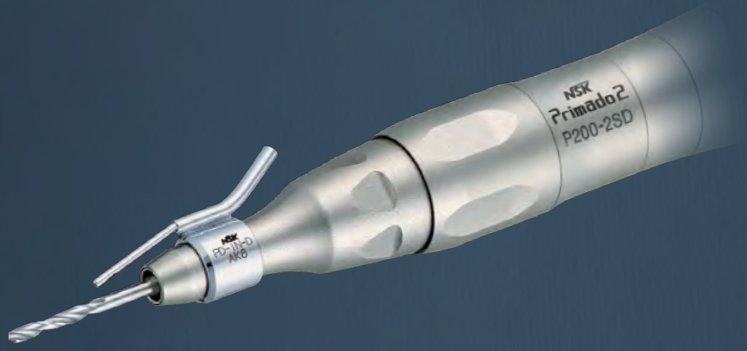
SUPPORT
Count on Wright for field experts and continuing medical education

PROstep™ PROCEDURES

The PROstep™ System is used for the following procedures:

- Chevron
- Akin
- Cheilectomy
- Calcaneal Osteotomy

3rd GENERATION OF MIS



OVER

50,000

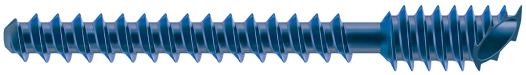
PROCEDURES PERFORMED WORLDWIDE WITH WRIGHT TECHNOLOGY[4]

PROstep™ POWER BOX

- Optimized for minimally invasive foot and ankle procedures
- LOW speed and HIGH torque
- Integrated irrigation to help keep the burr cool during use

PROstep™ MICA™ SCREWS

- PROstep™ MICA™ Screw Designed for Minimally Invasive Fixation
- Chamfered head can be positioned flush to bone for anatomical fixation
- Fully threaded allows for compression
- Sterile packed for sterility and traceability



PROSTEP™ BURRS

- Laser marked lines for ease of length identification
- Sterile packed for sterility and traceability

MINIMALLY INVASIVE SURGERY INSTRUMENTATION

- Instruments designed specifically for minimally invasive foot and ankle procedures

The Wright **PROstep™ MIS** Advantage

- There is less pain with a PROstep™ MICA™ compared to a traditional open procedure.[5]
- The PROstep™ MICA™ technique has shorter operative times and shows no increase in surgical complications—potentially less blood loss than open procedures.[5] There is also minimal risk of neurovascular and tendon injury in chevron-akin MIS procedures like PROstep™.[6]
- Minimally invasive surgery techniques are being adopted in all surgical specialties because of the advantages they bring to the surgeon and patient.[7,8]
- PROstep™ MICA™ is an effective, minimally invasive surgical intervention that provides correction of forefoot and midfoot conditions comparable to first and second-generation surgical techniques.
  - » Internal fixation PROstep™ MICA™ screws
  - » Surgery specific, single-use, PROstep™ MICA™ burr
- PROstep™ MICA™ internal fixation provides a stable fixation that avoids the rotational instability and the complications usually associated with K-wire use.
- Because it is minimally invasive, the PROstep™ MICA™ technique has improved cosmesis and is associated with a higher level of patient satisfaction.[5]

Wright Medical offers best in class surgeon training programs to educate physicians on PROstep™ MIS techniques. Surgeon training is essential to successful surgery outcomes.[6]

PROstep™ MICA™ Surgery for Correction of Hallux Valgus

Hallux Valgus (HV), frequently referred to as bunions, is the most common forefoot deformity. It is characterized by abnormal angulation, rotation, and lateral deviation of the great toe at the first metatarsophalangeal joint.

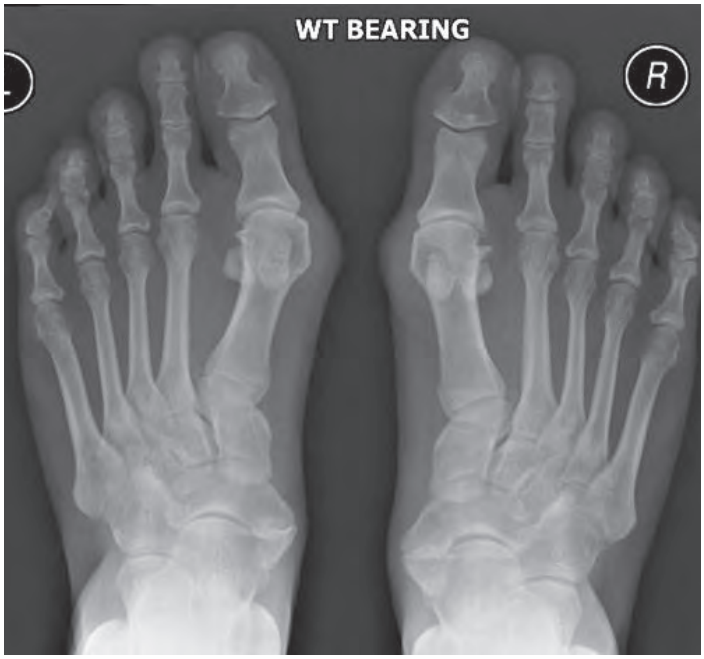
Epidemiology studies indicate that across all age groups the prevalence of hallux valgus is greater in women (38%) compared with men (21%), with increasing prevalence as age increases. The higher prevalence among women may be due to footwear that is either poor or less forgiving, resulting in earlier and more frequent presentation.[9,10]

The often cited female prevalence can obscure the importance and the characteristic details of hallux valgus deformities in males,[11] which are commonly hereditary in nature mainly transmitted by the mother, with early onset and higher severity when compared to women.[11]

While studies show that sex and inheritance are important, other anatomical and biomechanical factors, such as anatomical metatarsal variants, including a long first metatarsal (probably most important in men), a rounded articulation, and metatarsus primus varus, play an important role. These variants increase the vulnerability to first-ray hypermobility, pes planus, and ligamentous laxity.[12]

HV also carries a noticeable impact on health related quality of life.[13] Studies indicate that there are progressive reductions in both general health and foot -specific quality of life with increasing hallux valgus severity leading to greater impairment on pain and functional assessment scales.[13]

Despite the high prevalence of foot problems and the significant impact foot impairment can have, foot problems often go unreported, because many people, particularly older individuals, consider foot pain an inevitable consequence of aging rather than a medical



condition.[14] Early, non-operative treatment can be useful in the management of hallux valgus symptoms. Options include nonsteroidal anti-inflammatory medications, steroid injections, activity modifications, shoe modifications, and orthotics or rocker bottom shoes. Prefabricated foot orthoses and rocker-sole footwear were similarly effective at reducing foot pain in people with first metatarsophalangeal joint osteoarthritis in a clinical study, although the prefabricated foot orthoses had greater adherence and fewer associated adverse events.[13]

If pain persists, however, a minimally invasive, surgical intervention, like PROstep™ MICA™, is an option. Surgical interventions aimed at correcting or slowing the progression of HV deformity have a number of beneficial effects on localized pain relief. Surgical correction of hallux valgus allows improved ambulation and quality of life scores.[9,13]

Surgical Intervention

Surgical correction of hallux valgus rebalances the first ray, correcting features that characterize the joint deformity.[2] There have been more than 150 different techniques described for surgical correction of hallux valgus.[2,15]

Regardless of technique, the technical goals of surgery are to correct the HVA/IMA, create a congruent MTP joint with sesamoid realignment, remove the medial eminence, retain functional range of motion of the MTP joint, and maintain normal WB mechanics. The clinical goals are to produce a functional, painless first ray and the ability to wear shoes of the patient's choice, such as high heels for women.[16] The latter is of particular importance to patients, as an inability to wear the shoe of choice is strongly associated with dissatisfaction with the outcome of hallux valgus treatment.[9]

First Generation

First generation procedures, such as the open scarf corrections, are generally effective when appropriately executed.[1] Open procedures include soft tissue release and medial exostostomy combined with either proximal or distal osteotomy of the first metatarsal.

Unfortunately, the outcome of an open surgical correction can be unsatisfactory to the surgeon and undesirable for the patient. Cadaveric study indicates that the standard orthopaedic approaches to foot and ankle surgery all carry a risk of cutaneous nerve injury; wide patient variability in the anatomic location of nerve branches complicates this risk potential.[17] Clinical evidence also indicates that open procedures can be associated with significant postoperative pain, stiffness and disability.[1,5]

Open Scarf Procedure

Open Scarf Procedure

Second Generation

A second generation technique, a distal transverse osteotomy of the first metatarsal stabilized with a K-wire, is an inexpensive hallux valgus correction, but does not provide rigid stable fixation, introducing the potential for dorsal and plantar displacement of the metatarsal head.[1] The use of a K-wire can be associated with complications of superficial infection, stress fracture, and delayed union.[5] There have also been clinical reports of metatarsal and proximal phalanx lateral cortical fractures, overcorrection of the joint deformity, stiffness of the metatarsophalangeal joint, and in a small number of cases, chronic regional pain syndrome.[5]

Second generation MIS technique

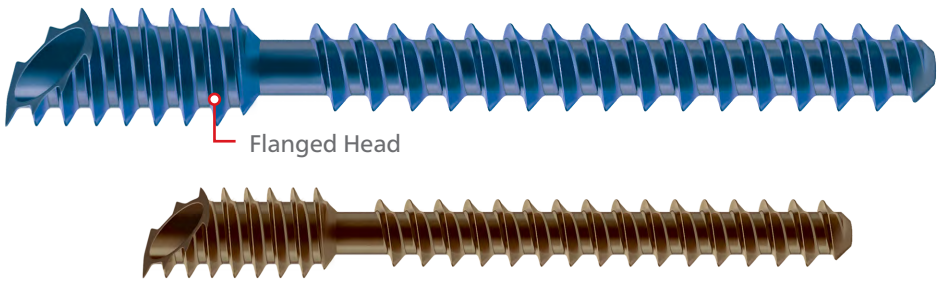
Third Generation

Today, a third generation, minimally invasive surgery (MIS) is available that combines a modified chevron-Akin technique with internal fixation to add extra stability to the surgical correction.[5,18] PROstep™ MICA™ is a chevron-shaped osteotomy of the first metatarsal and an Akin-type osteotomy of the proximal phalanx of the hallux, both performed percutaneously using a specially designed burr under image x-ray guidance, a mini C arm that allows assessment of bony alignment. The surgical site is then internally rigidly fixed with the PROstep™ MICA™ screw, also aided by the mini C arm. The screw has been specifically designed with a flanged head to maintain circumferential cortical fixation when inserted flush to the bone.[18]

PROstep™ MICA™ is indicated for hallux valgus deformity with experience with severe deformity corrections that have been corrected using 100% displacement of the osteotomy.[18]

Unlike open procedures with large incision sites, the PROstep™ MICA™ technique has only minimal risk of neurovascular and tendon injury.[6] The main neurovascular structures at risk are the superficial peroneal nerve and the arterial blood supply to the first metatarsal head. An anatomical study of minimally invasive surgical correction of HV found no greater incidence of nerve injury or blood vessel damage and no tendon injury.[6]

PROstep™ MICA™ Screws for MIS surgery



A prospective, randomized trial comparing the Redfern/Vernois PROstep™ MICA™ technique described by Redfern and Vernois with a scarf-Akin osteotomy for the correction of hallux valgus was published.[5]

Fifty-one subjects were randomized into two surgical groups. Outcome measures at three timepoints (preoperative and 6- and 26-weeks postoperative) included AOFAS Hallux Metatarsophalangeal-Interphalangeal Score, a visual analog pain score, hallux valgus angle (HVA), and intermetatarsal angle (IMA). HVA and IMA correction and report of complications were comparable in both techniques. The PROstep™ MICA™ technique, however, had shorter operative times, improved cosmesis, and a higher level of patient satisfaction.[5]

Another recently reported randomized trial comparing the Redfern/Vernois technique to an open scarf-Akin osteotomy in 50 patients found similar surgical correction between the two procedures, but significantly lower pain levels in the early postoperative phase (post-operative day 1 and post-operative week 6), significantly shorter scar length, and a greater proportion reporting high satisfaction for patients with correction using the Redfern/Vernois technique.[1]

Preoperative photograph of the patient's bilateral bunions

One year postoperative, the correction is maintained, and the patient reports she is able to comfortably wear closed-toe shoes

Postoperative, weightbearing left and right AP X-rays following PROstep™ MICA™ (Minimally Invasive Chevron Akin) surgery

PROstep™ Cheilectomy Surgery for Correction of Hallux Rigidus

Hallux rigidus (HR) is the second most common pathology affecting the great toe, after hallux valgus deformities.[19] Like hallux valgus, HR is associated with degenerative changes of the first metatarsophalangeal joint.[19] Symptoms are related to degeneration of the first MTP joint and results from cartilage wear, altered joint mechanics, and progression of osteophyte formation. Patients experience pain that seems to worsen on push off gait, dorsiflexion of the great toe, and stiffness.[19] A patient history will reveal pain with weight-bearing activities that is lessened by rest or a weightless state.[20] This pain usually arises from shoe-related pressure on prominent osteophytes or impingement of dorsal osteophytes.

Epidemiology studies indicate that the prevalence of hallux rigidus is greater in women by a 2 to 1 margin.[19]

Coughlin and Shurnas reported findings in 110 patients who had undergone surgery for hallux rigidus.[21] The authors noted that on final evaluation, about 80% of the patients showed bilateral involvement. In the bilateral cases, 98% of the patients had a positive family history. Although 62% of the patients in the Coughlin and Shurnas report were women, other investigators have reported a slight male predominance.

Early, non-operative treatment can be useful in managing symptoms of HR. Options include nonsteroidal anti-inflammatory medications, steroid injections, shoe modifications, orthotics, and activity modifications.[19] If pain persists, however, minimally invasive surgery is an option.[19,22]

PROstep™ Surgical Intervention

While there are several surgical options, cheilectomy is attractive because there is minimal bone loss, joint range of motion is preserved, and the potential for other procedures to be employed if needed.[23] The PROstep™ procedure has been effectively used for this surgical correction. The incision required for the PROstep™ technique is small (4-8mm) dorsal to the first metatarsal neck.[18,24] This small incision has improved cosmesis relative to the open procedure which requires longitudinal incision that extends 3cm distal and proximal to the first metatarsophalangeal joint.[24]

Redfern and colleagues have reported on their experience in using a minimally invasive cheilectomy for correction of HR.[15] Clinical results from 44 consecutive feet provided a mean subjective percentage improvement in symptoms of 90%, with 86% of cases returning to ordinary footwear and normal daily activity/employment 1 week following surgery.[18] Other clinical studies have reported similar success with the minimally invasive percutaneous technique.[15,25,26]

Traditional Cheilectomy incision

PROstep™ Cheilectomy incision

PROstep™ Surgery in Osteotomies of the Calcaneus

Osteotomies performed in the calcalneal space are undertaken to correct the deformities of a malaligned calcaneus and alleviate the functional limitations that are associated with them.[27] The ultimate goal of all osteotomies is to relieve pain, improve alignment and walking, and reduce the likelihood of arthritis.

The structure of the calcaneus requires a unique surgical approach in surgical corrections of the calcaneus. Various surgical options have been available—closed reduction and percutaneous fixation, open reduction and internal fixation, limited open reduction, and subtalar arthrodesis.

Traditional Open Calcaneal Osteotomy incision

PROstep™ Calcaneal incision

Calcaneal osteotomy is an operative technique used to correct hindfoot deformities and injury. Traditional open operative approaches involve a lateral incision that begins at the proximal tip of the fibula, turns 90° at the heel and continues laterally to the calcaneus. This extensile, L-shaped, approach has been favored because it provides excellent exposure and access to manipulation and fixation of the calcaneus.[28]

Unfortunately, this approach, while widely used, is also associated with a complication rate estimated at 10-28%[29,30] including flap necrosis and wound infection.[28] Minor and major wound complications are of concern because of the thin and vulnerable skin over the lateral calcaneal wall.[28]

A minimally invasive surgical procedure minimizes the wound complication rate,[28,29,31] has shorter operating times, reduces the length of hospital stays, and improves cosmesis by reducing the incision length to two, minor puncture entries. Minimally invasive calcaneal osteotomies also reduce the risk to anatomical structures posed by the open approach[30] and avoid affecting incisions that may be required for other elements of hindfoot reconstruction.[32]

A retrospective, case controlled cohort comparison of the open osteotomy technique and a minimally invasive calcaneal osteotomy in 81 patients reported significantly fewer wound complications and no reports of post-operative neuropathy in the MIS group.[29] An anatomic study comparing these same two approaches demonstrated fewer anatomic injury with a minimally invasive approach than traditional open surgery.[30]

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AP-010047B_28-Feb-2019