Clubfoot and the Ponseti Method in 2021.

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More than one hundred thousand children are born each year with congenital clubfoot, or talipes equinovarus, mostly in low and middle-income countries (LMIC) where there are often deficiencies in access to health services. The overall burden of disease can be appreciated by adding these incident cases to the hundreds of thousands of cases that have not received treatment or have residual deformities following previous treatment. There are also numerous cases associated with syndromes and neuromuscular diseases, and also patients who have had a relapse after previous treatment including extensive surgical releases. While the disability due to a neglected or untreated clubfoot has not been quantified to our knowledge, consequences may include pain and/or reduced endurance during ambulation, calluses or skin breakdown from altered loading and shear stresses, and the inability to accommodate standard footwear. Perhaps the greatest disability may be rooted in the social stigma, children may be subject to verbal abuse, females may suffer more than males, and in some cultures a young lady may be unable to have an arranged marriage if she has an untreated clubfoot. Addressing the global burden of clubfoot is a multifaceted challenge. On one hand we need trained orthopaedic surgeons who are comfortable with a variety of procedures to provide technical solutions for individual patients. At the population level we need a public health approach in which systems for delivering the Ponseti method are developed and integrated within the health system, focusing on screening for early diagnosis, prompt referral for treatment, and adequate follow-up to address relapses and/or other concerns. It is clear that "one size does not fit all" when either caring for individual patients or organizing services to different regions of a country, contextually relevant solutions must be sought.

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The clubfoot may be defined as equino-cavo-varus segmental malalignment, and treatment recommendations are based on the severity and flexibility of the different components of the deformity, as well as the potential for remodeling with growth. We suggest an algorithmic approach in which serial casting using the Ponseti method is the initial treatment of choice in all age ranges, and additional surgical interventions are utilized to treat residual components of the deformity[1]. Even when complete correction cannot be obtained, casting may reduce the magnitude of surgery required and may stretch out the skin reducing the likelihood of wound healing complications.

The minimally invasive Ponseti method has been adopted in an expanding number of centers globally, becoming the most common approach in the United States after the turn of the century and being introduced in Pakistan in 2008. The corrective phase begins with weekly long-leg casts, and in many centers these casts are applied by non-surgeon health workers such as physiotherapists (task shifting or sharing). Approximately 90% of feet will require a percutaneous release of the Achilles tendon to complete the correction. This can be performed in the outpatient clinic or operating theatre under local anaesthesia (with or without sedation) or with ketamine or general anaesthesia depending on the age of the patient. Maintenance of correction is achieved by wearing a foot-abduction orthosis, with the wear schedule based on the age of the patient. Night-time splinting is continued until patients are 4-5 years of age. Relapses may occur in up to a quarter of patients and are treated by repeating the protocol, and a subset of older children with dynamic supination require a lateral, subcutaneous transfer of

the tibialis anterior. Clubfeet treated by the Ponseti method have been shown to have better range of motion, less stiffness and pain, fewer additional surgical interventions, and better functional outcomes in comparison with feet treated by extensive surgical releases[2-7]. The Ponseti method has also been successful in many neuromuscular clubfeet and also in cases treated previously by soft tissue releases. The limited data available suggests that the method is cost-effective[8-9].While deficiencies in access to orthopaedic care are common in low middle income countries and patients with clubfoot often present after walking age, a growing body of literature suggests that the Ponseti method may achieve a plantigrade foot without the need for extensive surgery in a majority of patients up to ten years of age,[10-13] despite the recognition that the elasticity of soft tissues and the remodeling potential of chondro-osseous structures decreases with age. Residual deformities are common in these older patients but did not appear to impact patient reported outcomes at least in the Nepali population,[12] and in fact residual deformities have been reported at long-term follow-up in patients treated during infancy by the Ponseti method but did not appear to affect the outcomes.[7] In addition, several studies have found that similar results may be achieved when casts were changed two times per week instead of once.[14-16] Barriers to implementing the Ponseti method include spatial access (road infrastructure, transportation, terrain), service availability (trained health providers, equipment/supplies, orthoses), and affordability.[17] Patients from rural and remote communities may need to be admitted to a rehabilitation hostel or similar facility until their treatment has been completed, and an accelerated casting protocol may be advantageous in this circumstance. The abduction orthosis can be fabricated locally, ideally by cobblers or local manufacturers in the patient's region. Consideration should be given to training community health workers to provide early diagnosis and follow these patients in their home communities after correction has been achieved.

For those cases in which the Ponseti casting has failed must be individualized and based on persistent elements of the deformity and their flexibility. The surgeon's "toolbox" includes soft tissue lengthening/release/transfer, osteotomy, talectomy, triple arthrodesis, and gradual correction with external fixation. The most appropriate procedure will depend on the severity and flexibility of components of the deformity, the experience of the surgeon, the resources available, and also the social circumstances including the ease of access to the treatment center and/or rehabilitative services. The treatment of these complex, rigid deformities requires considerable surgical expertise, and the results are inferior to feet treated at an early age with less invasive strategies including the Ponseti method.

A subset of patients may have persistence of *all components* of the clubfoot deformity. Extra-articular soft tissue lengthening, with or without osteotomies, occasionally supplemented by tendon transfer, may achieve the goal of a plantigrade foot. In the most severe cases, often seen in older children or adolescents, consideration can be given to talectomy (rarely), triple arthrodesis, or a one or two stage gradual correction using an external fixator with or without soft tissue releases and/or osteotomies. Treatment with a fixator takes several months, and close follow-up is required to monitor the correction. As such, patients from more rural and remote communities may require local housing until the fixator is removed, given the risks of infection and the challenges with follow-up if they are sent home before correction is achieved. Stiffness is common following correction with a fixator. Triple arthrodesis is usually performed in a single stage through an anterolateral incision, often in concert with soft tissue procedures such as lengthening of the Achilles tendon, posterior release, and tendon transfer. This procedure results in increased transfer of stresses to neighboring joints, often leading to arthritis and sometimes pain at long term follow-up. The foot is shortened which may be cosmetically unacceptable when the deformity is unilateral.

Multiple options are available to address *isolated components* of the deformity. Strategies for treating residual midfoot cavus include plantar fascia release, naviculectomy, or dorsiflexion osteotomy of the medial column (medial cuneiform or first metatarsal base), while options for hindfoot equinus include open heel cord lengthening with or without posterior release of the ankle and subtalar joints, or creating a compensatory distal tibial deformity to enhance dorsiflexion. While an anterior distal tibial plate can be used to guide the growth of the distal tibia in younger children, older children and adolescents require an anterior closing wedge osteotomy of the distal tibia. Persistent heel varus may be addressed with a calcaneal osteotomy, either a lateral closing wedge, a lateral slide, or a combination of these. Options for persistent adductus include abductor release, lateral column shortening (calcaneocuboid wedge resection, cuboid decancellation, calcaneal wedge resection) or closing wedge osteotomy of

cuboid coupled with opening wedge of medial cuneiform. Persistent supination may require a tibialis anterior tendon transfer with or without medial cuneiform or midfoot osteotomy.

In summary, the treatment of clubfoot may be viewed through the lens of the individual orthopaedic surgeon or that of the health system, and addressing the large burden of disease requires a comprehensive, public health approach focusing on prompt diagnosis, access to treatment centers offering the Ponseti method, and access to orthopaedic surgeons who can treat relapses, difficult cases, and/or residual deformities. The trained orthopaedic surgeon should be familiar with the Ponseti method and surgical techniques to address residual and/or complex deformities. The public health approach requires the input of multiple stakeholders including orthopaedic surgeons and their professional organizations, public health specialists, government officials, academic institutions, and potentially donor organizations. Leadership can be provided by orthopaedic surgeons with interest in clubfoot, supported by the Pakistan Orthopaedic Association and the Pediatric Orthopaedic Society of Pakistan. Contextually relevant solutions must be sought, as the "system" would certainly require modifications when caring for patients in central Karachi versus remote villages in Khyber Pakhtunkhwa or Balochistan. This process has started with a national program in 2013 under the leadership of Dr. Anisuddin Bhatti. It is our hope that the program will grow and evolve, resulting in universal access to clubfoot care in Pakistan.

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