Distraction Osteogenesis—Poised for Everyday use in Orthopedic Surgery

a report by

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Osteoplastic surgery—to form and mold bone for the correction of congenital and acquired bone deficiencies and deformities—demands that the surgeon employ a variety of methods, materials, and techniques. The evolution and convergence of new and evolving technologies for the restoration of skeletal integrity, regardless of anatomic site, are providing orthopedic surgeons with the means of addressing patient needs in community settings, whereas only a short time ago patients would likely have been referred to niche specialty clinics and academic centers.

Compared with all the modalities employed in osteoplastic surgery, distraction osteogenesis (DO) serves as an excellent example of the evolution of the understanding of bone physiology, coupled with the on-going development of medical devices that facilitate the physiological process. The improved devices then enable the surgeon to more effectively harness the physiology of new bone growth to serve patients. This convergence of evolved technique and specialised tools allow for the correction of complex deformities and deficiencies in everyday orthopedic practice at a faster pace, safer, better, and with greater cost-effectiveness.

Evolution of DO and Osteoplastic Surgery

DO can be described as a surgically induced process in which a bone (of endochondral or membranous origin) is subject to corticotomy or osteotomy, respecting periosteal blood supply, then being mechanically separated at a precise daily rate and rhythm. The result is the predictable production of healthy, permanent new bone in the distraction gap.

DO was described in 1904 by A Codivilla, MD, at the 18th meeting of the American Association of Orthopedic Surgeons (AAOS), where he presented a paper entitled “On the means of lengthening, in the lower limbs, the muscles and tissues which are shortened through deformity”. Dr Codivilla described 26 cases in which he inserted transosseous nails through the calcaneus and/or tibia, enclosed them in plaster, and used them to distract the lower leg against a pelvic stop in order to lengthen the bone and soft tissues of the femoral or tibia/fibula regions (after having created an osteotomy at the desired site of lengthening). He was able to straighten and lengthen the affected limbs by 3–8cm. His use of skeletal traction evolved specifically to avoid pressure necrosis and other complications that result from generating tensile forces through the soft tissues alone.

Codivilla’s early work was reinforced by Abbott in a formal report in 1927. DO was then seminally advanced by Gabriel Ilizarov who, at the Kurgan (USSR) Institute for Experimental Orthopedics and Traumatology in the 1950s, began to systematically use skeletal distraction across planned osteotomies to ‘regulate the genesis and growth of tissues in arms and legs through the application of tensile stress’. He described a ‘universal apparatus’ consisting of percutaneous transosseous pins proximal and distal to a planned osteotomy, with the pins fixed to ring-like external halos encircling the extremity, connected by extensible rods so as to enable the precise, gradual elongation of the distance between the proximal and distal bone fragments. The Ilizarov external fixation apparatus and its variants are currently the most frequently employed mechanical devices for DO.

In 1972 Clifford Snyder et al. demonstrated that canine mandibles, previously foreshortened by surgical means, could be restored to normal length by DO. Using an external fixation device for DO, Karp, Thorne, McCarthy, and Sissons at the New York University confirmed Snyder’s work and demonstrated, in canine

mandibles, that DO as previously applied to enchondral bone is also efficacious for producing new membranous bone de novo in the craniofacial skeleton.1

The method has been used widely in orthognathic and craniofacial surgery since then.

The term DO, however descriptive, is not exhaustive. More precisely, tensile stress across cut bone ends to elongate or reshape a skeletal member (following Wolff’s law) necessarily forces remodeling and adaptive remodeling of the surrounding soft tissues. From a clinical perspective, a more precise term for the process of tissue generation by application of tensile stress may be mechanically induced growth (MIG).

Bone-based MIG is truly pan-somatic, and the clinician who adopts this viewpoint is more likely to avoid many of the soft tissue complications that may accompany the process, including compromised blood supply with skin and soft tissue necrosis, compartment syndromes, paresthesias and paralysis, realignment—osteogenesis under tensile stress, and architectural remodeling as a consequence of Wolff’s law. It is the multiplicity of medical devices developed recently and capable of generating the linear and multiplanar forces necessary for DO that creates ease of use and practicability for most orthopedic practices.

Evolution of DO and Associated Bone Positioning Devices

Current devices that provide controlled distraction forces, including some with multiplanar capabilities, can generally be divided into three types—external fixation devices, intramedullary devices, and implantable devices with plate and screw fixation. Devices in each of these categories provide features and benefits to address the myriad demands of osteoplastic surgery. No single device or category of device is optimal for every circumstance.

The most commonly used device for DO in the extremities remains the Ilizarov external fixator. This

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and secondary musculoskeletal injury and deformity due to overlying tight fascia and ligaments.

Knowledge of anatomy, blood supply, and the physiology of wound healing coupled with comprehensive pre-operative planning are the essential ingredients for any successful reconstructive surgical procedure. The monumental works of Dr Dror Paley et al., and Drs Kirienko, Villa and Calhoun, serve as lucid, comprehensive guides to the planning and correction of virtually any complex deformity of the extremities.6,7

These authors consistently employ the principles of DO to form new bone and guide bony regeneration. Their surgical armamentarium includes the well-known array of osteotomy techniques, bone grafting methods, and fixation alternatives. Newer fixation devices that provide precise force generation in multiple planes harness the most powerful forces for bone regeneration and

device has been upgraded, modified, and modernized, allowing the surgeon more than 600 assembly modifications to address myriad bone deformities and fixation requirements. The learning curve required of the orthopedic surgeon for the correct set-up and use of this device may be an inhibitory factor to its widespread adoption for everyday practice. Other potential drawbacks include traction on skin and soft tissues by the multiple pins attaching the device to bone, both proximal and distal to the distraction (osteotomy) site. The result of the continual soft tissue pin traction is pain and pin-tract complications. Nevertheless, the Ilizarov external fixator has proven its worth in facilitating DO over time.

More recently, a modification of the Ilizarov design has offered means for the correction of acute and long-standing angulation deformities of long bones, with or without associated DO. This device provides the

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Surgeon with multiplanar options. The learning curve is steep and the problems associated with multiple skin penetrations remain.

For linear DO of the femur and tibia, a telescoping two-piece intramedullary rod was introduced in 2001. This allows the surgeon to preset distraction length at insertion. The device is activated by deliberate rotational movement of the extremity initiated by the patient. Monitoring of DO progress occurs as the patient places an external monitor over the device; the monitor detects the phase movement of a magnetic field generated by a magnet internal to the device. In this manner, tracking of the incremental and total distraction distance is recorded and can be monitored by patients and doctors. This device, though ingenious, does have some relative disadvantages. The most problematic of these is that it cannot be reversed if it becomes evident that the device is advancing too rapidly.

Recently, several DO devices have received a series of US Food and Drug Administration (FDA) clearances, including devices for long bones of the extremities, the small bones of the hands, wrists, feet, and ankles, and long bones of the upper extremities in children. These implantable devices bridge the osteotomy gap and use simple screw and plate fixation to the bone. A single proximal skin penetration by an activation pin, which can be removed following the activation phase, and a unique cross helical gear drive mechanism contribute to the utility and adaptability of these devices. Patients use a provided tool to create the two- to four-a-day increments of distraction, according to physician direction. The distraction rate and rhythm can be easily modified or reversed. Potential drawbacks for these devices include the need for extensive exposure for accurate installation.

The advent of new DO devices based on well-known surgical techniques creates the potential for widespread adoption of DO for problems encountered in everyday practice, where time is at a premium, and the surgeon finds lengthy device set-up and extensive knowledge of device geometry difficult to achieve. Simple intramedullary rodding technique and plate and screw fixation alternatives provide compelling ease of use, particularly where linear DO is required, and correction of angulation is not a primary consideration.

**The Unmet Need**

Despite the great advances in osteoplastic surgery over the last few decades, there appears to be a large unmet need for extremity reconstruction and functional restoration. In developed societies the indications for skeletal remodeling, where DO could often serve as the best procedural alternative, seem to exist in numbers far in excess of the incidence of actual use of the technique. These numbers are admittedly difficult to quantify, but arise from private surveys among practicing orthopedic surgeons, incidence indications among professional societies and public health data, and the marketing studies of companies producing orthopedic products.

It is indisputable that there are millions of individuals in the developing world who could benefit from modern osteoplastic surgery, as anyone who has volunteered on a medical mission in any of these societies can affirm. The challenge facing the developed world is to introduce knowledge and technologies to those working in disadvantaged environments that allow resident practitioners to care for those they are responsible for. The advent of DO devices that are easy to use and economical, coupled with teaching and outreach, has the potential to restore vast reservoirs of forthcoming human productivity. Modern telecommunication for teaching and device usage can play an essential role in facilitating the benefits of osteoplastic surgery in all societies.

**DO in the 21st Century**

Unlike most orthopedic surgery procedures, where once the surgical intervention is over aftercare involves referral to the occupational or physical therapist for remobilization and the retraining of musculoskeletal function, DO is a process that requires rather intense doctor–patient interaction over time to assure the production and architectural integrity of new bone formation. In fact, patient (or caregiver) compliance is critically important. Failure to adhere to physician instruction for device activation at home, two to four or more times per day, can result in either premature consolidation at the distraction site (failure of the patient to activate sufficiently) or fibrous non-union (excessive activation by the patient). Either circumstance creates the potential need for additional intervention and risks the likelihood of a good outcome.

Device manufacturers can assist doctors and patients in achieving optimal outcomes by providing the means to allow remote monitoring of the DO process using modern telemedicine technologies. The ingredients are straightforward—connectivity among stakeholders (doctors, patients and device manufacturers), patient education and consent, data security, telephonic or Internet-based data transmission, data acquisition by device-based sensors, and data analysis and reporting to relying parties (surgeons and their patients).

Adoption of telemedicine-based process management, coupled with easier to use devices and adoption of the principles of deformity correction, will bring osteoplastic surgery, and DO as a protean technique, to the large number who await its benefits.