INTRODUCTION: Current methods of correcting angular long bone deformity include cortical osteotomies with cast, internal fixation or external fixation. The osteotomy with casting and internal fixation is method requiring precision at the time of surgery. The correction obtained at the time of surgery is the definitive correction. The placement of the external fixator does not require as much precision in alignment at the time of surgery, because continued correction of the limb can be made post operatively until the desired alignment is obtained. However, the external fixator can be painful and can be complicated with pin tract infections. Correction of seriously deformed limbs in some cases can potentially lead to a lifelong disability [4, 5]. Nitinol is a specially formulated alloy of nickel and titanium with the striking property that it undergoes a complex crystalline solid phase change called martensite-austenite transformation. As the metal in the high-temperature (austenite) phase is cooled, the crystalline structure enters the low-temperature (martensite) phase. It can then be easily bent, twisted, compressed, or stretched. As the metal is reheated, the high temperature phase is recovered assuming the original shape and stiffness. Application of Nitinol in the field of orthopaedic surgery is rapidly in progress and presently includes compression bone staples [1], Nitinol rod for correction of scoliosis [3], and shape memory expansion clamp used in cervical surgery [2]. This proposal is aimed to demonstrate the usefulness of Smart Intramedulary Rod (SIMR) made of Nitinol as a therapeutical tool for correction of deformed immature long bones. Our hypothesis is that due to the force generated by the SIMR, bone will gradually remodel and deform to that of the trained SIMR.

MATERIALS and METHODS: On the engineering side, Nitinol rods of different radius of curvature (30, 50, 70, 90, 110 mm) were fabricated, placed in a specially designed aluminum fixture, and heat treated at different temperature and time duration, Fig 1. Effect of oven time and temperature, quenching time and temperature, and autoclave heating on the material properties as well as the inherent strain energy of the rod was studied using both standard tension test and 3-point bending.

On the clinical side, eight young adult rabbits were utilized as animal model to determine the efficacy of SIMR for correction of bone deformity. To prove our basic hypothesis, SIMRs were so designed and implanted into rabbit tibias to create deformities - noting that the same principal can straighten a deformed bone. The SIMRs of length 80 and 90 mm (2 mm in diameter) were trained to memorize curvatures of 50, 70, 90, 110 mm. SIMRs with different curvatures were made to generate a variety of force ranges. The low and high phase temperatures of the SIMRs were set, respectively, at 0-4 and 36-38 degrees centigrade. After preparation of the rabbit, the mid line of the knee joint was incised longitudinally 2 cm and patellar tendon was split. Insertion point on the anterior tibia proximal to the tibial tubercle was used to enter the medullary canal. The SIMR was submerged in sterile iced saline. During the surgery the temperature of the rod was kept below 4 degrees centigrade to keep it flexible. The trained SIMR was hand driven into the tibia medullary canal. The patella tendon and the wound were then closed with non-absorbable suture. On weekly basis AP and lateral x-rays of the operated tibia and the contra lateral tibia were obtained for analysis. Rabbits were sacrificed at 6 weeks post surgery and 3-D CT scans of both tibias were obtained after rod removal. 3-D CT scans were used to create cross-sectional images in 1.5-mm increments for analysis.

DISCUSSION: For surgical correction of deformed bone the SIMR is shaped to the normal anatomic alignment of the long bone. Then utilizing the flexible state of the SIMR, the rod can be passed into the medullary canal and across the angular deformity. Once it becomes rigid at the body temperature, the rod will place a force on the cortical bone to allow remodeling of the deformed bone to the memorized rod over time. This is similar to the external fixator in correcting the deformity over time, but instead of the fixator placing a force on the bone, the rod is placing a force on the bone allowing the bone to remodel overtime to the memorized SIMR. This animal study showed positive and encouraging results.