**Locking Proximal Femur (LPF)**

| **Outcomes/ Summary** |
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| The authors retrospectively evaluated all patients (children) who underwent ﬁxation of femoral fractures or osteotomies utilizing straight LCPs at a tertiary pediatric medical center from 2004 to 2009. Thirty-seven patients (25 male/12 female, ages 5-16 years) who underwent 41 straight LCP fixations during the study period were selected. Twenty-five of these patients (25 procedures) presented with acute femoral fracture. Sixteen procedures (12 patients) were associated with elective osteotomy or limb lengthening. Thirty-five of the 41 plates were removed after complete clinical and radiographic union. The mean time from fixation to plate removal was 13 months (range 5-34 months) in the fracture group and 17.6 months (range 7.5-28 months) in the osteotomy group. Complications included 1 patient who required a second procedure within 24 hours due to malreduction of the fracture. 5 procedures (12%) were associated with postoperative fractures or refractures. 2 of these 5 cases involved early fractures after the index surgery (1 at the proximal screw, 1 through the original fracture site with plate breakage). The remaining 3 patients refractured at the original fracture site or regenerative site after plate removal. The average time from plate removal to refracture was 18 days (range 10-30 days). There was no difference in demographics, timing, or techniques between those who fractured and those who did not. Due to their stiffness, LCP may carry the risk of stress shielding the fracture site leading to postoperative fracture or refracture. More studies are required to evaluate the risk factors that could lead to postoperative fracture or refracture, particularly in children. Care should be taken, particularly in the initial 5 weeks, after plate removal.  The authors presented suggested guidelines:   * Consider using a wide vs. a narrow LCP in overweight patients * Delay plate removal until at least 1-year post fracture fixation * Utilize partial weight bearing for at least 1 month post a plate removal procedure |
| This retrospective radiographic study involved all patients who fulfilled the following criteria: (a) age less than or equal to 20 years who visited the author’s hospital from May 2003 to December 2014, (b) had undergone a surgery including a proximal femoral osteotomy with blade plate (BP) or locking compression plate (LCP), (c) had been followed up until 6 months after hardware removal, (d) had preoperative and immediate postoperative hip radiographs and follow-up radiographs until hardware removal, and (e) diagnosed with cerebral palsy, Legg–Calve–Perthes disease, DDH, or idiopathic increased femoral anteversion. The exclusion criteria were as follows (a) patients who had undergone an operation without BP or LCP or with additional other surgical fixation instruments, and (b) those who had inadequate radiographs for review. A total of 417 hips (251 patients) were included in the study. 384 of the 417 hips exhibited poor bone quality. 273 of the hips were treated with a BP. The remaining 144 hips were treated with an LCP. The mean age of the patients was 9.1 +/- 3.1 years (range 4.4-19.3) in the BP group and 9.8 +/- 3.7 years (range 3.3-19.7) in the LCP group. The mean time to hardware removal was 1.2 +/- 0.6 years (range 0.6-7.2) in the BP group and 1.1 +/- 0.6 years (range 0.6-6.3) in the LCP group. The mean follow up was 8.8 +/- 2.2 years (range 2.4-12.1) in the BP group and 3.5 +/- 1.9 years (range 1.2-8.2) in the LCP group.  Overall, complications in the two groups were not statistically different (p=0.74): 3.0% (5/167patients) in the BP group was vs. 3.6% (3/84 patients) in the LCP group. However, the characteristics of complications were different (loss of fixation BP vs. fracture/refracture LCP). There were 7 cases (5 patients) who lost fixation in the BP group. There were no other hardware complications in the BP group. In contrast, there were 3 femoral fractures in the LCP group, 1 early and 2 within 6 months after the plate was removed. All of the complications, in both groups, occurred in CP patients. The risk of complications increased with age (P=0.0002) but not sex, body side, plate type or ambulatory status. While proving excellent stability at the osteotomy site, the use of LCP can function as an aggravating factor in patients with osteoporotic fractures. |
| This retrospective study included 22 patients, 30 hips, that were treated with the DePuy Synthes LCP Paediatric Hip Plate, at the Children’s Hospital associated with the University of Berne, between 2006 and 2008. These children ranged in age from 1-16 years and included 14 girls/8 boys. Their weights ranged from 8-80 kg. Indications for which the plate was used included: hip dysplasia, Perthes’ disease, idiopathic ante/retroversion of the femoral neck, femoral neck fractures and complications after slipped capital femoral epiphysis (SCFE).The authors found the LCP Paediatric Hip Plate to be valuable device for correction of pathological conditions of the proximal femur and for fixation of displaced femoral neck fractures in children. In this series there were no intraoperative complications. Twenty of 22 patients achieved consolidation of the osteotomy by the time of the first postoperative radiograph, 6-8 weeks. In 1 child an additional 2 months of partial weight bearing, but no further surgical procedures, was required for boney consolidation. The remaining child, who complained of hip pain at 2 weeks, required additional surgery due to 3 loose screws. Twenty-one of 22 patients achieved as planned hip correction. The remaining patient was left with less valgus than was planned due to suboptimal placement of the kwires. In 29 of 30 hips, the hardware was removed after a mean duration of 9 months (6-34 month range).Limitations of the study included its retrospective design, its lack of a control group and its small sample size. However, the initial results are encouraging and a larger, better controlled study is warranted. |
| This retrospective study included 10 patients, 11 hips(four left/seven right), seven cases were treated with the DePuy Synthes LCP 3.5mm 140° Pediatric Hip Plate and in four cases 5.0 1400 LCP plate was used. All of the surgical procedures took place between February 2011 and July 2012. The children ranged in age from 7.3-11.8 years(mean age 9.6±1.2years) and included 8 boys/2 girls. Their weights ranged from 16.8-51.2 kg(mean weight 36±9.6kg). The total hospital stay ranged from 3-9 days (mean stay 5.2±1.7days) with a follow up ranged 5.6–23months(mean follow up 15.3±6.3months). Indications for which the plate was used included: congenital femoral defect (two patients), Perthes’ disease (six patients), coxa magna(one patient) and necrosis after pathological fracture(one patient).The authors found the 140° LCP Pediatric Hip Plate to be safe, effective and a valuable tool for correction of varus deformities of the proximal femur. In this series there were no delayed unions or non-union. Callus formation was observed in all cases, at the 6-week postoperative visit. Control and consolidation of the osteotomy was observed at a mean time of 14.1 +/- 2.3 weeks. All patients had an uneventful surgery with a mean hospital stay of 5.2 +/1 1.7 days. The average preoperative neck-shaft angle was 1300 (range 1080-141.5). Six weeks postoperatively the mean neck-shaft angle was 1490 (range from 132°–164°). Planned correction was achieved in 9/11 cases. The lack of correction in the remaining 2 cases was 15.5° and 16.5° respectively. In all 11 cases, the hardware was postoperatively removed at mean time period of 1.1 ± 0.3 years (range 0.7–1.6 years). Additional follow-up was also performed at a mean time of 0.6 years (mean 0.6 ± 0.5 years) after removal of the plate. There were no recurrences or complications requiring further treatment or revision, either in the children with a normal BMI or in the obese patients.While the initial results are encouraging, longer follow up and a larger patient group are needed to compare the 140\_ LCP Pediatric Hip Plate to other devices, for the correction of pathologic varus conditions, of the proximal femur, in children.  There were no adverse events noted in the study. |
| This study involved 11 children (7 boys/4 girls) between the ages of 3-9 years (mean 6.6 years) who presented with hip disease. Six of these children had developmental dysplasia of the hip (DDH). The remaining 5 children presented with a fractured femoral neck. All of these patients were treated with the Synthes Locking Compression Pediatric Hip Plate (LCP-PHP). The 1100 plate was utilized for the 6 patients with DDH. The 1200 plate was used for the 5 patients exhibiting a femoral neck fracture. While the LCP-PHP is an excellent tool for these indications, it can be difficult to implant because of the narrow neck associated with pediatric patients. Complications include damage to the femoral epiphysis, or its blood supply and/or misplacement of screws. In an effort to reduce these intraoperative complications, the authors developed a methodology for manufacturing custom, 3D-printed navigation templates from the patient’s preoperative CT scan. Compared to a 13 patient control group using conventional techniques, the use of a custom navigation template reduced screw insertion time from 57.15 +/-9.25 minutes to 26.50 +/\_ 4.07 minutes, X-ray exposure time from 11.85 +/- 3.15 minutes to 6.00 +/- 0.73 minutes and epiphyseal injury time from 3.29 +/1 1.12 minutes to 0 minutes.The study concluded that the advantages of utilizing a custom navigation template included: the ability to accurately predict the required screw lengths, diameters and positions. The procedure was less technically demanding and did not require the use of expensive real-time, operative navigation. There were some opportunities for improvement noted including producing templates with longer drill tubes, and templates wings. Additionally, more bone markers should have been used to ensure better fitting of the template. The use of CAD designed, 3D-printed navigation templates reduces the risk of iatrogenic damage, decreases operative time and radiation exposure. The authors believe that the technique warrants more widespread adoption. |

**Distal Femoral Osteotomy System(DFOS)**

| **Outcomes** |
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| The study was conducted to assess the efficacy of distal femoral extension osteotomy (DFEO), fixed with a 900 paediatric condylar locking compression plate, and patella tendon advancement (PTA) to improve function in cerebral palsy patients who exhibit crouch gait. For this prospective study, a total of 26 consecutive patients (52 knees) with a mean age of 14.36 years (range 11.6-20) were selected. All of the patients had diplegic and quadriplegic cerebral palsy with crouch gait knee flexion deformity of <30° and gross motor functional classification system (GMFCS) levels II, III, and IV. All patients were followed for a minimum of 12 months postoperatively. The mean duration of surgery was 2 hrs and the mean blood loss during surgery was 100 ml. Of the 26 patients (14 male/12 female), 16 patients were implanted with a 5.0 mm pediatric condylar LCP. The remaining 10 patients required a 3.5 mm plate.There were complications in 4 patients, in 3 patientstransient peroneal nerve palsy occurred which recovered completely and in 1 patient superficial wound dehiscenceoccurred which lead to tendon pull-out or deep infectionwithout any loss of fixation.  The goal of the procedure was to achieve normal knee extension and flexion. The study concluded that postoperatively there were improvements in all 26 patients. The mean knee Flexion Deformity improved significantly from 20.76° ± 6.57 to 0.67° ± 2.62, mean muscle strength of quadriceps improved from 3.01 ± 0.5 to 3.5 ± 0.54, mean extension lag improved from 20 ± 7.14° to 4.13 ± 4.16°. The mean GMFM-D improved from 15.58 ± 6.2 to 26.31 ± 5.8, while the mean FMS for 5 m improved from 2.9 ± 1.09 to 3.65 ± 0.84.  The authors concluded that DFEO combined with PTA provides favourable outcomes in children with crouch gait. The procedure is short, is associated with minimal blood loss and a low complication rate. Further, utilizing a 90° pediatric condylar LCP, for this procedure, has several advantages: (1) It provides better stability in osteoporotic bones. (2) it allows for early mobilization and weight bearing. |
| This study critically analyzed the frequency and risk factors in the development of distal femoral valgus deformities following plate fixation of femoral shaft fractures in children. For this retrospective, radiographic study, a total of 85 skeletally immature patients (range 6-15 yrs) were included. All patients were initially treated between Jan. 2003 and Dec. 2010. All of the children were treated with plate fixation due to diaphyseal femoral shaft fracture. The postoperative outcome of the plate fixation was studied through evaluation of the first femoral radiograph made 2 weeks or less postoperatively and one additional radiograph made at the time of the most recent follow up (for 50 patients’ radiograph was at least 9 months following plate fixation and for 35 patients less than 9 months postop.). Femoral valgus deformity following plate fixation was defined as a change in the anatomic lateral distal femoral angle ≥5° in the valgus direction.  Eighty percent of the patients had their plate bent, intraoperatively, (proximally or distally or both). Ten of the 85 patients (12%) demonstrated valgus progression of ≥5°. No patients demonstrated varusprogression of ≥5°. In three of the ten patient symptoms developed as a result to thedistal femoral valgus deformity which lead at least an unplanned additional surgury.For the patients who developed valgus deformity, the mean distance from the plate to the distal femoral physis was 8 mm (range -2 to 30mm). The patients who did not develop a valgus deformity had a mean distance from the plate to the distal femoral physis of 39 mm (range -5 to 19mm). This result concludes that the patients with a plate to physis distance of ≤20 mm were at significantly higher risk of developing valgus deformity and such patients require long-term monitoring. It was not possible to determine whether removal of the plate reduced the risk of distal femoral valgus deformity as the follow up period was insufficient. |
| This prospective study aims to analyse the postoperative outcome of patients who were treated with the Synthes LCP Pediatric Condylar 90-deg Plate. A total of 38 patients of which 32 patients were diagnosed with cerebral palsy and the remaining 6 patients had other neuromuscular disorder were included in this study. All of the patients required a Distal Femoral extension Osteotomy (DFO) in order to correct a fixed knee flexion deformity. The mean age of the patients was 16.3 ± 4.4 years (range4-27yoa). 13 patients had a unilateral surgical procedure and 25 had bilateral procedures. In 84% of the cases, large-fragment (5.0 mm) implants were used.  The mean blood loss during the surgical procedure was 100.0±42.1 ml (range 50-250ml). The mean surgical duration of 67.9±26.5 minutes (range 30-180min). Out of 63 osteotomies (25 bilateral & 13 unilateral procedures) analysed, there were 2 complications. In 1 femur, the fixation failed at 2 weeks postoperatively and required revision surgery with a longer implant, of the same type but with more proximal screw holes, providing increased stability. In another patient at the 6 weeks postoperative follow up, it was found that 1 screw backed out of its locked threads. Revision surgery was required to exchange the loose screw. There were no infections in this cohort. There were no valgus or varus deformities observed. All of the osteotomies were radiologically consolidated at 3 months postop and at the time of plate removal, mean of 14.2 + 4.3 mo (range 6-26mo) there were on malunions or nonunions. Clinical follow up, at the end of the study was a mean of 35.5+6.7mo (range 22-46mo).  The study concluded that LCP Pediatric Condylar 90-deg Plate provide safe and stable fixation of distal femoral correction osteotomies in patients with neuromuscular disorders. Early weight bearing can safely be allowed at 6weeks postop. The complication rate was low (3%) compared to published literature (19%) associated with a more traditional implant choice, blade plate. The procedure was quick and with minor blood loss. The Synthes LCP Pediatric Condylar 90-deg Plate allows the osteotomy to be performed as distally as possible without growth plate disturbance and all allows for deformity correction in all 3 dimensions.  The results of the study are limited by its small size and lack of a control group. |

**CoLink™ Afx Ankle Fracture Plating System**

| **Summary** |
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| Twenty-seven patients participate in the study comparing compare radiographic and clinical midterm outcomes of posterior malleolar fractures treated with posterior buttress plating versus anterior to posterior lag screw fixation. Sixten patients underwent posterior buttress plating, and eleven underwent AP screw fixation with mean follow-up times of (72.3% @ 54.9) and (73.3% @ 32) months, respectively. Other demographic factors, including age, gender, smoking status, syndesmotic injury, % of plafond involvement and comminution of the malleolus, were controlled for in the patient selection process. The posterolateral plating group demonstrated superior postoperative Short Musculosketal Function Assessment (SMFA) scores compared with the AP screw group with statistically significant differences in SMFA bother index (26.7 vs. 9.2, P = 0.03) with trends toward improvement in the mobility (28.3 vs. 12.9, P = 0.08) and functional indices (20.2 vs. 9.4, P = 0.08). One patient in each group underwent removal of all ankle hardware as they were felt to have hardware-related pain. In neither case was the pain specifically related to the posterior malleolar fixation. (2 patients in each group had a residual gap/step-off. There was no significant difference in the percentage that developed postoperative arthritis between groups. Two patients (20%) developed significant postoperative arthritis (Bargon grade 2 or 3) in the AP screw group versus 6 patients (37.5%) in the PL plate group (P = 0.42). There were no significant differences in the range of motion or the development of ankle arthritis over time. The authors concluded that patients with trimalleolar ankle fractures in whom the posterior malleolus was treated with posterolateral buttress plating had superior clinical outcomes at follow-up compared with those treated with AP screws. |
| This retrospective study included 198 skeletally mature patients, with bimalleolar or trimalleolar ankle fractures treated at a Level 1 Trauma Center. The scope of the study was to define the rate of syndesmotic instability after anatomic reduction of the posterior malleolus when posterior stabilization of a trimalleolar or trimalleolar equivalent ankle fracture was chosen vs when a supine position and initially conservative management of the posterior elements was chosen. Exclusion criteria included pilon fracture, trimalleolar fractures with Chaput fragments and neurologic injury. The cohorts were controlled for age, sex and BMI. 151 patients, 76.3%, were initially positioned supine and treated conservatively with medial and lateral malleolar stabilization. 25% of these patients required supplemental posterior malleolar stabilization. Overall, 73 of these patients, 48.3%, need some form of additional stabilization after the initial stabilization procedure. The other cohort involved 47 patients, 23.7%, who were initially treated prone with anatomic reduction and stabilization of their fractures, including the posterior components, utilizing open reduction and internal fixation techniques. Stability was restored in 97.9% of these patients. Only 2.1% of these patients exhibited instability and required additional intervention. The majority of the patients in both groups exhibited supination external rotation injuries, 89.4% prone vs. 77.5% supine. Of the 22 pronation external rotation injuries, 91% were treated supine. The fibula fracture rates, and location, were similar for the 2 groups. The medial malleolar fracture rates were dissimilar, 76.6% prone vs. 94% supine. The supine group also exhibited smaller posterior malleolar fractures compared to the prone group.  The study concluded that a greater percentage of the patients treated conservatively with only medial and lateral fixation and initially in a supine position required supplemental posterior malleolar fixation in order to achieve syndesmosis stabilization when compared to a group of patients treated prone with open reduction and internal fixation of the posterior malleolar fractures. The study further concludes that it is difficult to prospectively predict which patients will require prone positioning and posterior, as well as medial and lateral malleolar stabilization, even among ankle fractures with relatively small posterior malleolar injuries. Complications were not reported. |
| In this retrospective study of (105) consecutive patients treated between 1992 and 1995 who exhibited with ankle fracture combined with lateral malleolar fracture and were treated with open reduction and internal fixation. (11) patients were lost to follow-up. (94) patients could be contacted at the time of this study. (52) men and (42) women were included with patients’ ages ranged from 18 to 79 years. The purpose of this study was to determine the incidence, relationship with the ankle diastasis, and effect of treatment of the anterior tibiofibular ligament avulsion fracture (Wagstaffe fracture) combined with the Weber type B lateral malleolar fracture. In this series, there were 52 cases (45%) of Weber type B lateral malleolar fractures. Further, 13 cases (25%) of the patients exhibited Wagstaffe type II fractures combined with Weber type B fractures. No patients exhibited with a Wagstaffe type I or type III fracture. Ankle diastases was diagnosed in 20 cases (38.5%) of the Weber type B fractures and 11 (84.6%) of the 13 combined Weber type B and Wagstaffe type II fractures. Of the cases of Weber type B fractures without Wagstaffe fracures 37/38 (97%) had excellent results and one had a only a ‘good’ result, due to a lack of range of dorsiflection. None of these patients reported pain at the last follow-up. 9/13 (69%) of the patients with combined fractures exhibited excellent results at the last follow-up. 15% of the patients in this group exhibited good results. The balance of the patients were rated as fair. In one of these cases an inadequately managed fragment of the Wagstaffe fracture was displaced into the joint and caused chronic ankle joint pain and a 20 degee loss in motion. A secondary procedure was required to remove this fragment. The study concludes that the presence of a Wagstaffe fracture represents a good diagnostic indicator of an ankle diastasis in patients exhibiting a Weber type B fracture. The accurate reduction and fixation of the avulsed fragment is important for restoration of the stable distal tibiofibular joint and to prevent the chronic ankle joint pain caused by impingement of the avulsed fragment. |
| This study was conducted to compare the rate of bone union associated with locking plates vs. non-locking plates in lateral malleolar fractures, using a neutralization plate technique. The hypothesis of this study was that the rate of bone union would be higher in the group where the fracture was treated with a locking plate compared to the group treated with a non-locking plate. There were total of 52patients enrolled in the study. Twenty-three (23) patients were randomly assigned to undergo fixation using a locking plate, and 29 patients were assigned to undergo fixation using a non-locking plate. The study concluded that there is no difference observed in the radiographic rate of bone union for patients treated with a locking vs. a non-locking plate, when used as a neutralization plate, for the treatment of AO/OTA 44B malleolar fractures. |
| This was a prospective, randomized single blind multi-surgeon (4 senior and 5 junior surgeons) study including (71) patients. (35) patients were randomized into the “plate fixation” group and (36) into the “intramedullary nail fixation” group. However, intramedullary nailing was impossible in (7) patients for technical reasons (severely fragmented fracture, diameter of the proximal fibula too narrow and persistent tibiofibular diastasis) and the treatment was converted to plate fixation. Results were produced for (32) patients in the plate group vs. (28) patients in the nail group. The study concluded that although there was no difference in the rate of union, there was a fairly high rate of complications with plate fixation compared to intramedullary nailing. Intramedullary nailing is a percutaneous mini-invasive technique that provides stable fixation and reduces the risk of wound complications. The main limitation is in the treatment of comminuted fractures. Nevertheless, further randomized comparative studies should be performed to show the non-inferiority or the equivalence of this technique in a larger number of patients to clearly validate this surgical indication. |
| This study was a multicenter, randomized trial. In total, (321) adult patients were recruited. (161) patients were treated using IM nail fixation and (160) patients were treated using locking plate fixation. The primary outcome measure was the Disability Rating Index (DRI) score at (6) months. DRI ranges from (0) points (no disability) to (100) points (complete disability) with a minimum clinically important difference of (8) points. The DRI score was also collected at (3) and (12) months. The secondary outcomes were the Olerud–Molander Ankle Score (OMAS), quality of life as measured using EuroQol-5 Dimensions (EQ-5D), complications such as infection, and further surgery. There was no statistically significant difference in DRI score at 6 months [IM nail fixation group, mean 29.8 points, 95% confidence interval (CI) 26.1 to 33.7 points; locking plate group, mean 33.8 points, 95% CI 29.7 to 37.9 points. Complications across the two groups included injury, neurological injury, vascular injury, tendon injury, complex regional pain syndrome, DVT within 6 weeks and pulmonary embolism; However, there were no statistically significant difference in complications. Authors concluded that among adults with an acute fracture of the distal tibia randomized to IM nail fixation or locking plate fixation, there were similar disability ratings at 6 months. However, the recovery, across all outcomes, was faster in the nail fixation group and costs were lower. |
| The study was designed to evaluate and compare the  efficacy of unlocked versus locked plates for the treatment of pilon fractures. There were total of (60) patients enrolled in the study; (25) patients were excluded because of insufficient follow-up, (1) patient died. (34) patients (15 locked and 19 unlocked) were included in the study result. A pilon fracture was defined as a fracture of the distal parts of tibia involving its articular surface at the ankle joint. Locked plate constructs create a fixed angle device that provides rigid fixation of the comminuted articular fragments and preserves the periosteal blood supply. In theory, this type of construct would allow for earlier joint mobilization and bone healing with a decreased rate of infection, nonunion, and loss of reduction. However, in this prospective, randomized trial, the authors did not find a difference in long-term radiographic outcomes, complication rates, or functional results when comparing locked to nonlocked plate constructs. |
| In this randomized, prospective study, the authors compared minimally invasive plate osteosynthesis, locking intramedullary nail stabilization and external fixation combined with limited open reduction and absorbable internal fixation for distal tibial shaft fractures by assessing complications and secondary procedures. (121) skeletally mature patients with displaced distal tibial shaft fractures with or without a fibula fracture were randomized to be treated by minimally invasive plate osteosynthesis (42) patients, locking intramedullary nail (40) patients or external fixation (39) patients combined with limited open reduction and absorbable internal fixation. The study concludes that the minimally invasive plate osteosynthesis, locking intramedullary nail stabilization and external fixation combined with limited open reduction and absorbable internal fixation techniques are all efficient methods for treating distal tibia fractures. With its wide indications, external fixation combined with limited open reduction and absorbable internal fixation leads to minimal soft tissue complication, good functional result and no local soft tissue irritation or implant removal. |

**CLINICAL EVALUATION REPORT 104**

| **Safety, Performance or Both** | **Study Objective(s) and Subject Follow-Up** | **Performance Outcomes** | **Safety Outcomes** | **Study Conclusion or Miscellaneous Comments** |
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| Both | To evaluate the incidence of backache with 26G Quinck and Atraucan spinal needles and to demonstrate the needles handling characteristics.  Follow up was conducted for eight days post-op. | . Spinal anesthesia was successfully performed at one attempt in 92.7% and 86.4% of patients in Groups A and Q. | Backache incidences during a 1-week period postoperatively and handling characteristics of the needles were noted. PDPB was encountered in 62.4% and 44.2% of patients in Groups A and Q, respectively, and the difference was statistically significant. | PDPB may be encountered less in patients who received spinal anesthesia via 26G Quincke spinal needles than when using Atraucan. |
| Safety | The effect of spinal hyperbaric bupivacaine–fentanyl or hyperbaric  bupivacaine on uterine tone and fetal heart rate in labouring  women. Follow-up for 6 hours post-op. | N/A | Following the spinal injection an increase > 10 mmHg in baseline uterine tone in the 30-min period was noticed. 20% women (3) who had a bupivacaine-fenatanyl spinal showed a > 10 mmHg increase in baseline tone compared to none, who had bupivacaine alone. The mean (SD) baseline uterine tone after the spinal injection was 13.3 (7.0) mmHg in the bupivacaine–fentanyl group and 7.7 (2.5) mmHg in the bupivacaine group (p = 0.01). Seven (47%) in the bupivacaine–fentanyl group showed new onset fetal heart rate changes during the 30-min period after the spinal, compared with two (13%) in the bupivacaine group (p = 0.04) | Pain scores, sensory and motor block as well as neonatal  outcomes were comparable between the groups. Raised baseline uterine tone was not more frequent  when using bupivacaine–fentanyl rather than bupivacaine in the spinal component of combined spinal-epidural. |
| Both | To compare the percentage of patients who achieved adequate labor analgesia following DPE or LE with an epidural bolus of 0.125% bupivacaine. | Adequate analgesia at 10 minutes did not differ by neuraxial technique (DPE = 55.3% vs LE = 44.7%; P = .256). However, parturients receiving DPE had shorter median times to adequate analgesia (median [95% confidence interval], 8 minutes [6–10] vs 10 minutes [8–14]). | DPE had a 67% increase in the relative risk of achieving adequate analgesia compared to LE (relative risk = 1.67; 95% confidence interval, 1.02–2.64; P = .042). | Although the percentage of achieving adequate labor analgesia at 10 minutes after epidural bolus did not differ by technique, DPE was linked with shorter median times compared to LE. |

**CLINICAL EVALUATION REPORT 105**

| **Safety, Performance or Both** | **Study Design** | **Study Objective(s) and Subject Follow-Up** | **Performance Outcomes** | **Safety Outcomes** | **Study Conclusion or Miscellaneous Comments** |
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| Both | Single-center retrospective observational study evaluating | Compare the safety and  efficacy of RSB with TEA shortly after having changed from TEA to RSB in pancreas transplant patients. Specific followup time was not stated. | The administered amount of intravenous morphine equivalents (MEQ) was not significantly different between the RSB and TEA groups. The median MEQ consumption per day during the stay at the hospital was 23 mg MEQ/d (interquartile range [IQR], 14e33 mg MEQ/d) in the TEA group compared with 19 mg MEQ/d (IQR, 14e32 mg MEQ/d) in the RSB group (P ¼ .4). The duration of the pain catheters was significantly longer in the RSB group. | No noted complications related to insertion, use, or removal of the RSB  or the TEA catheters. | Based on results the authors concluded that RSB is safe and feasible postoperative analgesic technique similar to TEA in heavily anticoagulated pancreas transplant patients. |
| Safety | Prospective randomized study | Evaluate the feasibility and ease of catheter threading via the caudal route to reach a lower thoracic level in pediatric patients, and to detect the intra- and postoperative effects of epidural block on the recipient’s hemodynamics. Efficacy of its use for perioperative analgesia in pediatric renal transplant was also evaluated.  Followup for 18 hours postoperatively. | N/A | 6.67 % of cases resulted inthreading failure using the caudal route . Intraoperative differences in hemodynamics  and CVP were not clinically significant between  groups. Postoperative HR, MAP, and CVP were generally  higher in the control group. Pain control was better  and fewer postoperative complications were noted in the epidural  group. | Epidural anesthesia in pediatric renal transplant is a valuable addition to general anesthesia as it provides stable perioperative hemodynamics and excellent postoperative analgesia. The use of the caudal route in this age group is feasible and carries a lower incidence of complications compared to patients depending mainly on narcotics for pain control. |
| Safety | Observational study | The macro- and micro-haemodynamic  implications of epidural anaesthesia in children. Specific followup time was not stated. | N/A | Based on the entire 90 min of study-related  monitoring, we found significant increases in cardiac output (p = 0.009), stroke volume (p = 0.006) and stroke volume  variation (p = 0.008), as well as decreases in systemic vascular resistance (p = 0.007) around 30 min after  epidural blockade. There were no significant changes in heart rate, arterial pressure and cerebral or peri-renal  oxygenation during these 90 min. | Autoregulation of the brain and the kidneys was maintained in  children under epidural anaesthesia. |
| Performance | Retrospetive, single center | To compare patients to determine whether the incidence of deviation into the intervertebral foramen differed between 4 types of epidural catheters | Deviation of the epidural catheter into the intervertebral  foramen was noted in 8 of the Hakko and 33 of the Perifix Soft Tip catheter grops. The incidence of deviation was higher in the Perifix Soft tip  catheter group, and lower in the FlexTip Plus and Perifix  FX catheter groups. | N/A | The incidence of deviation was significantly lower with spiral-type catheters than with other types of catheters. |

**XTRAC and VTRAC**

| **Summary** |
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| The study was conducted to evaluate the efficacy of the 308nm excimer laser (XTRAC laser) to treat atopic dermatitis. There were 15 total patients enrolled in the study with 9 being female and 6 being male within the age of 13 to 24 years. One patient was withdrawn from the study due to noncompliance. The patients’ lesions were exclusively on the flexor surfaces of the upper and lower extremities with less than 20% of the body being affected. Treatments were given twice a week (not on consecutive days) for four to eight weeks. Except for Repair emollient, no other medications or treatments were administered. Lesion severity was assessed with a clinical score characterizing the intensity of lesions, a questionnaire assessing their quality of life and a visual linear analogue scale that depicted the severity of pruritus. The initial doses of treatment ranged from 150 to 450 mJ/cm (mean of 1.66 J/cm). Prior to treatment the EASI score mean was 8.5, but decreased to 3.57 after treatment. The mean score of quality of life was 6.57 to decrease to 1.71 following treatments. Pruritus was noted to decrease after one week of treatment. There were no side-effects or complications observed during the study suggesting that the excimer laser is effective in treating atopic dermatitis. |
| The randomized study including 16 patients (13 males and 3 females) ranging in age from 28-55 years old, all enrolled between 2011 and January 2012. All of the patients presented with stable plaque psoriasis involving less than 10% of their body surface area (BSA) located on each side of their body. 15 patients completed the study. The efficacy and safety using two different dose escalation regimens with the XTRAC excimer 308 nm laser system were evaluated. The pulse repetition rate used was 200 Hz with the spot size of was 4 cm2. The standard/low dose regimen started at 70% of the minimal erythema dose (MED), with 20% dose increments. The medium dose regimen consisted of 25% increments ending at 200% MED. The MED was defined as the minimal dose of capable of producing perceptible erythema at an unexposed test area on the upper back. Every patient was assessed prior to the first treatment to gain a baseline score of BSA affected and a Psoriasis Severity and Area Index (PASI) rating. Patients received treatments three times a week with clinical evaluation performed weekly. Treatments were administered 36 times or until clearing of the lesions. If adverse reactions including erythema, pain, itching or crusting were noted the treatment was postponed and later treatments were with a lower dose. Psoriasis severity index scores analyzed at weeks 0, 6 and 12 showed a significant reduction with each regimen (p<0.0001). Six patients cleared, seven had significant improvement with uneven clearance of plaques and two failed. Average remission was four months (range 1–12 months). There was a significant reduction in DLQI (p¼0.014). Adverse effects of blistering and erosions were more common with the medium dose regimen, affecting all 15 patients compared with 12 patients with the low dose regimen. Adverse effects and remission time were followed for 1 year. |
| A prospective study to elevate the usefulness of the Levia NB-UVB phototherapy machine in the treatment of psoriasis. The study was conducted at a dermatology clinic between March 2012 and April 2014. It consisted of 21 patients (6 males and 15 females) between the ages of 25 and 86 years with psoriatic lesions due to chronic plague psoriasis primarily on the scalp, elbows, palms, abdomen, back, knees and legs. 17 patients completed the study. Treatment was administered three times a week for twelve weeks. Target lesion score (TLS), a rating of 0-4 each of erythema, scaling, and thickness and visual analogue scale of pruritus was measured once every two weeks. The primary endpoint, Target Lesion Score (TLS) of three or less, was not achieved (P=0.118), but the secondary endpoints of percentage improvement in TLS (P=0.043) and TLS-50 (P=0.0195) were considerably higher in treated compared to sham-treated lesions. Percentage improvement in pruritus VAS was not significant (P=0.0565). Eight patients reported burns during treatment, but all were mild necessitating a lower dose of treatment. The data demonstrates that all lesions were not cleared, but positive results were obtained at the end of the 12 weeks. 10 of the 21 patients received treatment on the scalp which may have impacted the accuracy of the data. |
| The study included 40 patients (14 males and 26 females) ranging in age from 12 to 45 years diagnosed with vitiligo. Patients were of Fitzpatrick Skin Type 3 and 4. The patients had experienced vitiligo for a duration of 1 to 19 years and were resistant to treatment. NBUVB treatments were administered twice a week with Levia professional targeted UVB machine. 97 lesions were treated. Treatments were continued for a maximum of 30 or until 100% repigmentation was reached. Every patient received an initial dose of 250 mJ/cm2 increasing the energy by 50 mJ/cm2 after each treatment until erythema was observed. Treatment was discontinued for one week and dose reduced if blistering or pain was experienced. Patients were followed-up weekly for any sign of repigmentation (clinically and photographs). The results were graded from Grade 1 to Grade 6. Repigmentation of Grade 5 or 6 (90-100% repigmentation) was labeled as “excellent response” while Grade 2 or less (<50%) repigmentation were labeled as poor responders. 45 lesions (46.6%) achieved 90-100% repigmentation. 15 lesions obtained 50 and 75% repigmentation. There was no substantial repigmentation in 23 lesions. Repigmentation was observed to begin at about 3 weeks and complete repigmentation was gained after 4 to 12 weeks (13.82 doses). Four patients experienced adverse effects including erythema with a burning sensation. Follow-up was continued for three months post treatment revealing that pigmentation was not lost. |
| Study involving 60 patients (25 males and 35females) ranging in age from 8 to 36 years diagnosed with vitiligo on the face, neck and trunk covering less than 5% of their Body Surface Area (BSA). The study took place at the Cutis Skin Institute in Srinagar, Kashmir between February 2013 and January 2014. 30 patients were placed into two different groups, to come twice (Group A) or once (Group B) weekly for targeted ultraviolet B treatment using the Levia Phototherapy lamp. The initial dose of treatment was 200mJ/cm2 and increased by 50 mJ/cm2 following each treatment until erythema or perifollocular pigmentation was observed. If blistering or painful erythema occurred, the treatments were discontinued for one week and the does was decreased by 50 mJ/cm2 for the subsequent treatment. A maximum of 30 treatments were administered. Group A received treatment twice a week on selected lesions with 2-3 days in between. Group B received treatments once a week usually on the same day. Progress was examined both clinically and with photographs. Clinically a scale of excellent (>75% repigmentation), good (50-74% repigmentation) and poor (<50% repigmentation). Adverse reactions observed during treatment included: painful erythema, blistering, koebnerization and extension of lesions. 90 lesions were treated (48 in Group A and 42 in Group B). 625% (30/48) lesions in Group A and 64.3% in Group B responded with excellent results. Initial repigmentation was seen after 4.69 doses in Group A and 4.35 doses in Group B. The authors believe that once a week treatment seem to be as effective as twice a week treatments. |
| The goal of this study was to observe the repigmentation process, with special emphasis on the melanocytes and melanoblasts pattern, at the center and edge of the lesional skin in the patients, with vitiligo, who were treated with MEL/NB-UVB. The study took place from August 2009 to July 2017. Phototherapy treatment was administered to twenty-eight patients (27-Japanese, 1-Chinese) consisting of nine males and 19 females, ranging in age from 9 to 77 years. Each of the patents exhibited several sites of vitiligo. The patients were primarily exposed to monochromic excimer light (MEL) (VTRAC: PhotoMedex, Orangeburg, NY). In a few cases, patients were exposed to narrowband-ultraviolet B (NB-UVB) (Dermary 400: Cannon Medical Systems, Tokyo, Japan) rather than MEL. Both modalities of treatment were not used on the same patient simultaneously. The average number of sessions (exposures) was 86.4 ± 11.9. Punch biopsies (0.6–1.0 mm in diameter, 1.5 mm in depth) were taken from the lesional skin three to 25 months after exposure with two minimal erythema doses MEDs (ascending exposure with 10–15% increase in the dose after checking repigmentation) of MEL or NB-UVB. Repigmentation was observed, in many patients, to a degree of 10–90%. Twenty-five of 28 patients were repigmented with two types of patterns. One pattern was “marginal” (homogeneous repigmentation spread inward from the border of the lesion), and the other was “perifollicular” (pigmented spots occurred around hair pouch at several places). Three patients exhibited no repigmentation. The frequency of the marginal (3/25 = 12.0%) repigmentation pattern was much less than that of the perifollicular (22/25 = 88.0%) repigmentation pattern (P < 0.01). At the center of the white macules of seven out of 12 (58.3%) patients showing the marginal repigmentation pattern, no melanocytes and melanoblasts were observed but at the edge many dendritic melanocytes and melanoblasts/melanocytes were observed. One patient (1/12 = 8.3%) exhibited perifollicular repigmentation at the center only. Two (2/12 = 16.7%) of the 12 patients possessed melanoblasts/melanocytes both at the center and edge. These results suggest that exposure to MEL/NB-UVB induces a marginal or perifollicular repigmentation pattern in the white macules, though the two patterns produce no differences in the distribution and density of melanoblasts/melanocytes in the lesional epidermis. |
| This retrospective study was conducted to evaluate the effectiveness of the 308nm excimer laser when treating chronic hand and foot eczema (CHFE). The study took place over a two-year period (2013-2014). The 30 patients included consisted of eight males and 22 females ranging in age from 11 to 79 years diagnosed with eczema of hand and foot who were uncooperative with other treatments (19 hand, four foot, and seven with both). All of the patients were treated with the XTRAC 308nm excimer laser. An average of 13 treatments were given. Treatment sessions were missed if adverse effects such as blistering developed until healing occurred. Two scoring systems were used for data analysis, the physician’s global assessment (PGA) and the modified total lesion/symptom score. There was a 69% reduction in the physician’s global assessment (PGA) scores from 2.77 at baseline to 0.87 after treatment (P < 0.0001). There was also a decrease in the modified total lesion/symptom scores of 70% from 10.2 to 3.1 (P < 0.0001). 26 patients (87%) who achieved a PGA score of 0 or 1 (clear or almost clear) were defined as responders. The average cumulative dose of treatment for responders was 5314 mJ/cm2. The only adverse effects noted in the study were mild sun-burn like reactions. |
| The study included 18 patients (8 females and 7 males) presenting with four or more vitiligo lesions measuring at least 4 cm in size that did not respond to at least one other type of treatment. The mean patient age was 37.4 years. Lesions were noted to be on the hands, feet, axillae/upper arms, face and neck. A 308-nm excimer based on a self-contained gas system of Xe Cl manufactured by Photomedex was used to provide treatments twice a week for up to 60 times. There was a gap of 72 hours between two consecutive treatments. Treatment was stopped prior to 60 treatments if >90% repigmentation was achieved. Mean cumulative doses were 73.1 J/cm for treating the hands/feet, 18.4 J/cm for the axillae, 9.3 J/cm and for the face. One treatment was skipped, if a patient complained of burning or soreness and a lower dose was prescribed. Three patients were lost to follow up. Photographs were taken before the first treatment, then at 2 weeks, and then monthly until the study was completed. Independent investigators used grades: Grade 0 ≤1% improvement, Grade 1 ≤ 25% improvement, Grade 2 = 26–50% improvement, Grade 3 = 51–75% improvement, and Grade 4≥ 75% improvement to evaluate lesion progress. Following 60 treatments, lesions on the hands and feet showed grade 2 improvement in 2/10 subjects and grade 1 in 8/10. There was grade 4 improvements in 1/3 of the subjects with axillae vitiligo and grade 2 improvements in 2/3 by treatment 60. The face revealed the fastest repigmentation with grade 4 seen in 3/5 subjects by 40 treatments and grade 3 in 2/5 by 30 treatments. Lesions with leukotrichia did not improve. There were no adverse reactions observed. The authors feel that the 308-nm excimer laser is a fast and beneficial targeted treatment for vitiligo. |

**Passio Pump Drainage System**

| **Outcomes/ Summary** |
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| In this study it was found that the catheter placement was often associated with improvement in quality of life due to symptom palliation and increased mobility. These results suggest that the PleurX catheter may be considered for treatment of children and young adults with symptomatic malignant effusions. There  were no acute complications from PleurX placement. |
| Pleurodesis was successful in 92% of these patients at 1 month. Of the patients alive at 6 months, 96% continued to have effective pleurodesis. The median duration of TPC placement was 6 days. The median LOS was 3 days (2 to 7.25). All patients experienced significant improvement in dyspnea scores.  The second arm of the study was a historical control group, involving (33) patients who were treated via conventional pleuroscopic pleurodesis involving the combination of talc and doxycycline and a conventional surgical chest tube.  There was a significantly lower LOS in study group 3 vs. 9 days (p=0.002) There was not significant difference in the mortality and pleurodesis success rates.  The authors concluded that the combination of pleuroscopic pleurodesis (PP) with a tunneled pleural catheter (TPC) could minimize hospitalization and effect pleurodesis at a rate similar to conventional procedures. It also allowed for ongoing control of MPE for those not successfully pleurodesed. |
| Spontaneous pleurodesis occurred in 8 of 24 patients (33.3%), with all eight catheters successfully removed after pleurodesis without reaccumulation of pleural fluid. Mean time to pleurodesis was 131.8 days (range, 14–287 d). Five patients underwent liver transplantation; of these patients, three had spontaneous pleurodesis with ITPC removal before transplantation, and the remaining two patients had successful ITPC removal after transplantation at 9 and 48 days posttransplant. No patients who received ITPC required further pleural drainage procedures. Three of five patients (60%) in whom catheters were placed after TIPS procedures achieved spontaneous pleurodesis, whereas (0) patients achieved spontaneous pleurodesis when TIPS was performed after catheter insertion. (16.7%) of the patients exhibited infected pleural fluid requiring ITPC removal in (75%) of them. (10) patients had died from complications of end-stage liver disease. Among these patients, the mean number of catheter days was 141.8. No deaths occurred in patients receiving liver transplantation.  While the study was limited by its small sample size, the results suggest that ITPCs may be used to successfully and safely palliate dyspnea associated with hepatic hydrothorax and that this population of patients may experience rates of spontaneous pleurodesis that are similar to patients with recurrent malignant pleural effusions. |
| No significant differences in palliation from their effusion as determined based on a lack of reintervention (TP-5%, TPC-2.5%) was demonstrated during the follow-up period (TP-7 months+/- 3 & TPC-6 months +/-2) and the improvement in performance scores. However, the TPC group realized a significantly shorter hospital stay (TP-6+/-4 days, TPC-2+/-2days) as well as a lower rate of operative morbidity (TP-20%, TPC-2.5%) and readmissions (TP-23%, TPC-5%) than patients undergoing TP.  At last available follow-up, mean survival of the two groups was also comparable. None of the patients treated required further intervention for an ipsilateral pleural effusion. TPC should be considered for palliation of patients with recurrent pleural effusion due to advanced heart failure. |
| The rate of catheter-related complications (pain, obstruction, loculations, infection, hemorrhage) was 39% (seven patients) for the AG and 33% (three patients) for the PG (overall ten patients, 37%). The median length of stay (LOS) was 9 days (range2-38) for the Aspira group and 13 days (range 4-62) in the PleurX group.  The authors concluded that indwelling pleural catheters are an efficient option for symptom palliation in patients with terminal cancer and that the safety and efficacy of the two brands of catheters, used in this study, were similar. |
| A total of (12) ITCs were involved in the study: (1) patient underwent primary insertion of bilateral ITCs. (3) patients required placement of a second ipsilateral ITC catheter at 14, 21, and 55 days following their primary insertion. (1) patient developed a separate locule and required the insertion of another ITC without removal of the first. At the time of ITC placement, the fluid obtained was described as sanguineous (n=4), serosanguinous (n=5) or serous (n=2), and not specified on one. The volume drained at ITC insertion ranged from 120 to 1,610 ml (median 700 ml), achieving complete evacuation of fluid in 1, partial in 9 and not documented in 2 (Fig. 2). Cytologic analysis was undertaken in six cases (five MPE, one MA), one was positive and five were negative for malignant cells.  There were (2) major complications noted in the study, (1) pain which was resolved with opioids, (1) late infection (10 weeks after removal of the ITC). At the time of analysis, one patient was alive. The remaining seven patients died outside of hospital. The median survival time from ME diagnosis was 101 days (range 54–201 days). All of the children in the study demonstrated improvement in their symptoms and provided positive feedback on the use of the ITC. The results of this study support the use of ITC as a safe and effective treatment for MEs. |
| The technical success of the procedures was 100% as defined as successful placement of the catheter with drainage of the PE. 50% of the procedures were performed in an outpatient setting. While the other 11 procedures took place in the hospital.Eight (44.4%) of the patients exhibited adverse events (AE) associated with the procedure. In (6) out of these (8) of these patients (75%), the AEs were considered minor. The other (2) patients (25%) had their catheter removed due to, respectively, asymptomatic loculation and catheter dislocation. 14/18 patients died during the follow up period, with a median residual lifetime post implantation of the catheter of 45 days. No deaths were related to the catheter.  The authors concluded that the use of a permanent pleural catheter met the needs of all of the patients, in the study i.e. palliative treatment of their MPEs in an MIS fashion with few adverse events. |
| Patients were followed until death, removal of the IPC, or last documented encounter for patients surviving and followed for a minimum of 18 months.50% of IPC were removed. The remaining 50% of the patients died with the IPC in place. The median time from IPC insertion to removal was 53.5 days. The median time from IPC insertion to death was 183.5 days. A total of 4 (1.85%) of IPC-related pleural space infections occurred. Thirty-four (15.7%) of the patients exhibited trapped lung. Multivariate analysis indicated that there was no difference in the time to IPC removal between the two groups, when adjusting for age, ECOG performance status, trapped lung, cytology, HER2 status, ER status and history of chest radiation. There was also no difference in the risk of IPC infection between the two groups.The use of IPC in patients receiving chemotherapy is safe and is not associated with an increased risk of infection or effect on the duration of time the IPC is required. |
| Spontaneous pleurodesis was achieved in 34.4% of the cases. Post-catheterization complications were observed in 7.2%. Supplementary procedures were unnecessary and 87.7% of the patients reported improved dyspnea. In 64.9% of the cases, the IPCs were inserted during hospitalization with a median hospitalization time of 4 days (range 1-7.5 days). The mean overall cost of patients treated as inpatients was 5,450.3 euro vs. 3,310.2 euro for patients treated as outpatients.  The results of the study demonstrated that the use of the IPC is an effective procedure to improve the symptoms of MPE and with few complications. The main advantage of this method in the management of the patients is that it avoids hospital admission, thus significantly decreasing the costs associated with other procedures such as talc pleurodesis. |
| Statistically and clinically significant improvements were noted in the patients’ QoL (mean change 12.3), dyspnea (LC13- mean change of -20.4, C30-mean change of -32.4), cough (mean change of -15.4) and fatigue baseline (mean change of -12.6) at the 2 weeks. These improvements continued in surviving patients at 14 weeks. Patients who completed the FACIT-TS-G survey demonstrated overall satisfaction with TPC treatment, with over 75% rating it as very good or excellent.The authors concluded that TPCs are associated with a significant improvement in global health status, QoL and dyspnea at the 2-week time point in patients with recurrent MPE. |

**Bioventus\_CER Summaries**

| **Outcomes/ Summary** |
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| Low-intensity pulsed ultrasound (LIPUS) treatment was performed on73 patients using EXOGEN® between October 2010 and October 2013.13 patients were excluded as they did not meet the inclusion criteria, as they were treated with surgery before the end of their therapy treatment. Altogether, 61 non-unions in 60 patients were examined. Patients received follow-up regularly and were examined radiologically and clinically after 6 and 12 weeks, and after 4, 5, 6, and 12 months or completion of bone consolidation. The average age of the patients was 45.4±9.81(18-63) years. The study was primarily comprised of men (91.8%) who had a BMI of 28.9±5.4(21.1-44.2). 26 patients (42.6%)included in the study were smokers. The tibia was affected in 35 patients, and the femur was affected in 11 patients. 14 patients had an osteitis in their history before therapy. At the time of therapy, 37 patients had osteosynthesis with a plate, 13 had intramedullary nail, and 11 had an external fixator. LIPUS therapy was successful and a complete healing of the non-union was observed in 20 cases (32.8%), while 41 cases (67.2%) had to receive further surgery. In patients with healed non-unions, the average time to healing was 5.3±1.9 (2-7) months. The time from beginning LIPUS therapy to achievement of full weight bearing was, on average, 7.5±5.6 (1-23) months. Full weight bearing was not achieved by the end of the study in 15 cases (24.6%).In regard to complications, one patient with a history of osteitis developed an abscess in the fourth week of LIPUS therapy that needed to be treated surgically. The authors reported that most of the patients (70.5%) were unsatisfied with the LIPUS therapy and found that it was not helpful. Further, it was also reported that in a number of patients, LIPUS lead to a significant extension of therapy and disability. In conclusion, a case-to-case basis evaluation is required for the use of LIPUS therapy, as its indications differ considerably from the surgical indications. |
| There is much evidence that low-intensity pulsed ultrasound (LIPUS) provided by Exogen lessened tibial fracture and distal radius fracture healing time as well as consolidation time of spine fusion, but no research has reported success with the use of LIPUS in the acceleration of stress fracture healing. Researchers sought to investigate this question. Nine patients, three males and six females, with stress fractures were treated daily with LIPUS and an immediate return to usual activities. Seven patients had posterior medial tibial stress fractures, one patient had an anterior tibial stress fracture, and on patient had a tarsal navicular stress fracture. The patients received LIPUS treatment for 20 minutes daily. This treatment was administered 5 days a week for 4 weeks. Alongside the LIPUS treatment, only one patient was also treated with the use of an AIRCAST brace at all times, while the rest only wore an AIRCAST brace when not participating in activities or sports. Upon completion of the study, all subjects resumed or maintained sporting activities at the same level as at the time of diagnosis. There was no recurrence of symptoms in any of the patients, and one patient underwent tibial intramedullary nailing upon successful completion of their competition season. The results showed that the number of “step-downs” per minute that the patients could perform increased, and the pain with palpation decreased upon completion of the treatment. Alongside this study, a case report was also presented, telling of a 20-year-old male basketball player with a tarsal navicular stress fracture. His treatment included the Sonic Accelerated Fracture Healing System (Exogen) device, bracing, and crutches. He was able to return to competition 5 weeks after injury. In conclusion, LIPUS significantly minimizes time off from normal activities, but it is a comparatively expensive form of treatment. This treatment method may be useful in the instance of a high demand athlete who cannot afford time away from competition. |
| The purpose of the current pilot study was to explore the feasibility of a definitive trial to establish the role of LIPUS for tibial fracture healing. More specifically, the purpose was to determine recruitment rates in individual centers, adherence to study protocol and data collection procedures, the ability to achieve close to 100% follow-up rates, and the degree to which patients complied with treatment. 484 patients were screened for eligibility, but only 51 patients from Canadian trauma centers met the study criteria. Of these 51 patients, 37 had closed tibial fractures, and 14 had open tibial fractures. Visually identical active and inactivated (sham) EXOGEN 2000+ ultrasound device units with a unit number were labeled and shipped from the manufacturer, Smith & Nephew, to these trauma centers according to a randomized plan established by the Methods and Coordinating Center (CLARITY Methods Center at McMaster University). The CLARITY Methods Center traced all investigational devices under this trial. Each patient received a LIPUS device, verbal instruction on its use, and a booklet containing detailed instructions. Patients were to use the LIPUS device for 20 minutes daily, and treatment was to continue until the CAC determined the fracture demonstrated radiographic evidence of bridging at all four cortices, or until the 52-week follow-up visit, whichever came first. SF-36 PCS, HUI-III, and RUST were used to determine the outcome of the study. The follow-up rate for the study was 84% though, as some patients failed to show up for unknown reasons, one withdrew consent, and one left the country after having healed. Repeated measures of variance analysis found that treatment with LIPUS versus sham therapy was not significantly associated with improvement in SF-36 PCS scores, HUI-III scores, or RUST scores. |
| A multicenter, sham controlled, randomized, controlled trial that prioritized functional recovery was performed to resolve the uncertainty regarding the role of LIPUS in operatively managed patients with tibial fractures. A survey of 450 orthopedic trauma surgeons found that about 45% of respondents used bone stimulators – evenly split between LIPUS and electrical stimulation. The null hypothesis of the study was that there would be no difference in functional recovery or radiographic healing after surgical repair of a traumatic tibial fracture with intramedullary nailing, whether managed with adjunctive LIPUS or a sham device. There were 501 patients that met eligibility criteria for the study. The patients were randomized and given either an active or visually identical inactivated (sham) Exogen 4000+ ultrasound device unit. The patients were verbally instructed on the use of the device and given a booklet with detailed information on the use as well. They were instructed to use the device 20 minutes daily until the fracture showed radiographic evidence of bridging at all four cortices or until the 52-week follow-up visit, whichever occurred first. Outcomes were assessed at discharge and at follow-up visits at 6, 12, 18, 26, 38, and 52 weeks postoperatively. At the conclusion of the study, analysis of the results found that treatment failed to influence SF-36 PCS scores and health utilities index scores. Further, time to radiographic healing was similar between both groups. There were also no differences in time to return to work without limitations, time to full weight bearing, time to return to household activities without limitations, and time to return to leisure activities without limitations. In conclusion, the addition of low-intensity pulsed ultrasound (LIPUS) did not improve functional recovery or accelerate radiographic healing. |
| The aim of this study was to define the success rate and effectiveness of LIPUS treatment associated with delayed union of scaphoid fracture and to further analyze whether initial management or fracture type influences the success rate of LIPUS treatment.29 male patients were chosen for the study. All of the patients were between 18-22yoaexcept one outlier who was 34 years old. Out of the 29 patients, 17 patients had fractures of the scaphoid, 11 patients had fractures in in the proximal third of the bone, and one had a fracture of the distal third. The patients were assigned to one of two groups: the early diagnosed group or the late diagnosed group. The early diagnosed group included 13 patients with fractures diagnosed soon after injury (average 5.5 days after injury, range 0-17 days).The late diagnosed group included 16 patients with fractures diagnosed more than 3 months after injury (average 7 months after injury, range 3-12 months).All patients in the early and late diagnosed groups received LIPUS treatment using an Ultrasonic therapy device (Melmark GmbH, Raisting, Germany). The device was used once a day for 20 minutes. The average treatment duration of LIPUS was 2.3 months. For the early diagnosed group, the average treatment duration was 2 months, and for the late diagnosed group the average treatment duration was 2.6 months. After the LIPUS treatment, the early diagnosed group showed 92% (12 of 13 patients) of the patients’ fractures healed, and the late diagnosed group showed 63% (10 of 16 patients) of the fractures healed. Overall, 22 of 29 (76%) fractures healed. According to fracture location, 9 of 11 (82%) proximal pole, 12 of 17 (71%) of waist, and 1 of 1 (100%) distal pole fractures healed. There was a lack of uniformity in the follow-up protocol since it involved several treating physicians. The results obtained from the study suggest that LIPUS can help heal delayed union scaphoid fractures, especially in fractures diagnosed and treated soon after injury and may serve as an alternative to surgical treatment. |
| The study conducted by these researchers was a randomized, double-blinded, placebo-controlled trial that was undertaken to compare the efficacy of LIPUS against placebo for lower limb bone stress injury (BSI) in a civilian population. 30 patients were invited to participate in the study had a grade II, III, or IV BSI that was confirmed on MRI of either the postero-medial tibia, fibula, or second, third, or fourth metatarsal. Six clinical parameters were recorded, including night pain, pain while sitting at rest, pain while walking and performing activities of daily living, pain when running or jogging, tenderness of the BSI site, and pain when performing a single leg hop. 23 participants were then chosen to either the treatment or placebo arm as they met the inclusion criteria. They were instructed to use the treatment device that they were given at home for 20 minutes daily for 4 weeks (28 consecutive days). Both clinical and radiological outcome measures were compared between treatment and placebo arms. In regard to the radiological outcome measures, both measures did show significant differences between the pre-treatment and post treatment measures with MRI grade decreasing from 3.4 to 1.2 in the treatment arm and 3.2 to 0.8 in the placebo arm, and MRI edema size decreasing from 4.9 to 1.9 in the treatment arm and 5.0 to 0.9 in the placebo arm. In regard to the clinical outcome measures, there were no significant differences in any of the six parameters. The null hypothesis that LIPUS has no effect on lower limb BSI in a civilian population was thus confirmed. |
| From 1998 to 2001, 112 lengthening procedures in 108 childrenwith and without deformity correction were performed by external fixation with the Ilizarov method. (19) of the cases 16.9% did not result in a solid bone consolidation and were considered delayed or non-unions. (17) of these 19 cases were treated with LIPUS (EXOGEN, S&N) for 20 mins/day until solid bone consolidation was achieved. All 17 cases in 13 children (100%) achieved a boney consolidation, without the need for surgical intervention, within 3-12 months. The authors concluded that LIPUS produced healing of the femur ortibia as sufficient as open surgery but with none of the attendant risks. Further after 4 years follow up, LIPUS had no negative effect on the patient’s subsequent growth or growth plate. |
| This study was performed toanalyze the factors that influence the effects of LIPUStreatment for delayed union and nonunion oflong bone fractures. Seventy-two patients were enrolled in the study. Twenty-two cases had long bone fractures in femur, twenty-eight cases in the tibia, thirteen cases in the humerus, one case in the radius, and eight cases in the ulna. 61% percent of patients had undergone a single surgical operation prior to LIPUS treatment, 22% of the patients had undergone two operations prior to LIPUS treatment, and 17% of patients had undergone three or more operations before LIPUS treatment.LIPUS treatment was started within 6 months of the most recent operation. The union rate was approximately 90% when LIPUS treatment was started within 6 months of the most recent operation, whereas the union rate was less than 65%when it was started after 12 months.The effect of LIPUS was evaluatedat the fracture site where radiologicalimprovement was observedas an increase of callus formation orcortical continuity, or indistinctness of thefracture line.The union rate was 75% in all cases observed,with a mean period of 192(118-352) and 226 (56-588) days for the upper and lower extremity respectively. The mean treatment period was further extended to 306 (118-639) days in the patientsfor whom union was not achieved. The authors recommended that LIPUS treatment needs to be started within 6 months of the most recent operation so that it can show some effective result on the fracture repair without causing any serious invasiveness or any undue risk to the patient. Further,It may be considered as the first choice of treatment for cases of postoperative delayed union or nonunion. |
| An investigation was conducted to study the effects of low intensity pulsed ultrasound (LIPUS) on surgically managed diaphyseal fractures of the femur or tibia.The patients were assigned to one of two groups: the LIPUS group or the control group. The LIPUS group was composed of 78 patients (51 males and 27 females, mean age 48.7 years), and the control group was composed of 63 patients (38 males and 25 females, mean age 46.9 years). The fracture site, fracture type (AO classification A/B/C), soft tissue condition, and fixation were all similar in the LIPUS and control groups. All patients in the LIPUS group received treatment using a Sonic Accelerated Fracture Healing System – SAFHS2000J device (Exogen). In the LIPUS group, treatment was started within 3 weeks after the injury with monthly follow-up, consisting of monthly radiography, until union was confirmed. Patients in the LIPUS group observed an overall mean union period of 4.2 months, and the control group observed 4.8 months in comparison. All patients experienced healing of their nonunion, except 4 cases that required revision surgery in the LIPUS group, and 1 case in the control group. The LIPUS group showed approximately 30% shorter union period compared to the control group for femur/type C, tibia/type C, and closed/type C fractures. However, there was no significant difference in union period between the LIPUS and control groups for type A and type B fracture. The study also supports that LIPUS treatment shortened the period of cortical bridging, with callus formation of diaphyseal fractures of the tibia with intramedullary nailing or external fixation. Low-intensity pulsed ultrasound (LIPUS) treatment is particularly useful for type C fractures, since type C fractures cannot tolerate early weight bearing stimulus between the segments, even with surgery. In conclusion, LIPUS appeared to be highly effective for type C fractures that are sufficiently stable at the fracture site and could be a method of great value to manage nonunion. |
| The study presented suggests that low-intensity pulsed ultrasound (LIPUS) provided by EXOGEN enhances bone neogenesis and fracture healing for those who undergo the complex treatment. The study included a total of 17 patients (14 males and 3 females) with 18 severe compound high-energy limb injuries that were selected between 1997 to 2001. 6 patients had sustained war injuries (blast and high-velocity gunshot), 7 had suffered road accidents, and 4 had been involved in work accidents. Of the injuries included in the study, there were 4 fractures observed in the femur,10 in the tibia, 2 in the forearm and2 in the humerus. LIPUS treatment was started at an average of 6 months (range 4 to 38 months) after surgery due to very slow bone formation. However, in two patients, LIPUS treatment was started within a month after injury due to suspicion of hampered bone healing. LIPUS treatment was performed for20-min each day per the protocol, and the patients applied this treatment at their home. The LIPUS treatment was continued until the appearance of clinical and radiological signs of solid bone union. The median time of treatment was 26 weeks, with a range of 13-52 weeks. Sixteen weeks. Sixteen of the eighteen treated fractures united with solid bone union with a range of 13-52 weeks after starting the LIPUS treatment. One fracture, located in the lateral humeral condyle, developed a stable pseudoarthrosis, and one patient was lost to follow-up. The study reported that bone healing was achieved in most of the patients who completed their treatment16/18 fractures - 88.9%). However, it is important to note that the clinical group was relatively small. Based upon this experience, LIPUS with 30-50 mW/cm2 transducers may be a useful adjunct modality in the treatment of severe high-energy injuries. |
| The aim of this prospective, randomized study was to assess the effect of low intensity pulsed ultrasound (LIPUS) on distal radius fractures and the ability of LIPUS to accelerate fracture healing. A total of 81 patients with distal radius fractures,which were dorsally angulated and displaced,were chosen for the study. The average age of the patients was 67.90+ 5.58 (LIPUS) vs. 65.70+ 6.09 (Control), and many of them were osteoporotic.The patients were assigned to one of two groups: the LIPUS group or the control group. The LIPUS group was composed of 41 patients, and the control group was composed of 40 patients. All patients in the LIPUS group received treatment with the low-intensity pulsed therapeutic ultrasonic device. Patients in the LIPUS group were immobilized in a below elbow cast, while the patients in the control group were immobilized by a plaster support and cast. LIPUS was administered, by the patient, for 15 minutes once a day. All patients returned for follow-up with radiographs every week.The healing time for patients in the LIPUS group was 32 days, and in the control group the healing time was 41 days. For patients who received low-intensity pulsed ultrasound (LIPUS) treatment, grey value changes of fracture site were much higher than that of the control group. Dorsal inclination and shortening of the radius were similar between the LIPUS and control group. Out of 81 patients with distal radius fractures considered in this study, 49 cases received good accuracy of reposition, 29 cases showed a little improvement in reposition accuracy and 3 cases had poor accuracy of reposition. There was no difference in reposition accuracy between the LIPUS and the control group. The mean time to fracture healing was reduced by 20% in the LIPUS group. In conclusion, LIPUS is a promising modality for fracture healing disorders and could accelerate fracture healing of the distal radius, as well as promote local bone formation. |
| A study was conducted to examine whether the use of LIPUS accelerates bone maturation during the consolidation phase of tibial distraction osteogenesis. The study included 20 male patients with tibial bone defects. The patients were divided randomly into two groups of 10 patients. Group A underwent 20 minutes a day of stimulation by LIPUS (SAFHA;Exogen Inc., Piscataway, NJ, USA) while rigid fixation was maintained with an inactive device on Group B. As a means to check on progress, radiographs were taken in two planes before and after surgery, and then on a weekly basis during the distraction and consolidation period. Union was achieved in all patients except for one in Group B who showed delayed consolidation of the regenerated bone. Groups A and B both experienced complications that included pin tract infections, delayed union at the docking site, and failure of regenerated bone to consolidate in one. Eight patients in Group A and nine patients in Group B had pin tract infection. One patient in Group A and three patients in Group B had delayed union at the docking site. One patient in Group B had failure of regenerated bone to consolidate.The mean healing index in Group A was 30 days/cm, while the mean healing index in Group B was 48 days/cm. It is apparent that the mean healing index is significantly shorter for Group A than that of Group B. In conclusion, LIPUS stimulation can have an accelerating effect on callus maturation during the consolidation phase in patients managed with tibial distraction osteogenesis and reduce the overall time to removal of the fixation device. However, additional research is needed to verify the use of LIPUS in such situations and to determine the optimal timing of application |
| In this study,the use of LIPUS stimulation investigatedas an adjunct to intramedullary nailing for both radius and ulna diaphysis or metaphysis fractures in children. The authors retrospectively selected forty-four children (37 males and 7 females), with a mean age of 9.4 ± 2.7 years, with both radius and ulna fractures but excluded open fractures from this study.All of the patients were treated with intramedullary nailing followed by cast and splint mobilization. Twenty-five patients treated between January 2013 and March 2016, (21 males and 4 females having mean ageof7.6 ± 3.6and10.2 ± 2.6 yearsrespectively) were postoperatively treated with a LIPUS system (SAFHS 4000J, Teijin, Tokyo, Japan). The remaining 19 patients were treated identically, but without the use of LIPUS.LIPUS treatment was performed once a day for 20 minutesfor each fracture using the suggested parameter configuration (average intensity = 30 mW/cm2, ultrasound frequency = 1.5 MHz, signal impulse duration =200 microseconds,repetition rate = 1 kHz, effective radiated area hj= 3.88 cm2 and temporal average power = 117mW). Complete bone union wasobtained in all patients,withno major complications(defined as pseudarthrosis, delayed union, Infection and skin necrosis, nerve, vascular and tendon injuries), were observed. After surgery, periosteal callus appeared as early as 1-2 weeks in the LIPUS stimulation group. The authors suggested that LIPUS stimulation, even in children,can, safely lead to areduction of the treatment periodfor unstable forearm fractures. |
| There are very few studies that deal with the use of low-intensity pulsed ultrasound (LIPUS) to treat finger and carpal fractures. The study presented compares the treatment results between LIPUS stimulation and Ishiguro’s method for displaced mallet finger fractures in children. Eleven patients, five females and six males, with mallet finger fractures were operated on with Ishiguro’s method, and eight patients, three females and five males, were treated using a LIPUS system (SAFHS 4000J; Teijin,Tokyo, Japan). LIPUS stimulation was used once per day for 20 minutes until bone union. All patients treated with LIPUS stimulation did not have any period of immobilization nor prior treatment of any kind prior to undergoing LIPUS therapy. Radiographs were obtained every week throughout treatment until bone union could be verified and then every 2 weeks until the finger’s functional improvements plateaued. The duration until treatment from injury was significantly longer, and the preoperative gap between fragments was larger in the LIPUS group compared with those in the pinning group. In all cases, complete bone union was obtained in each group, but the duration needed for fracture healing and mean treatment period were significantly longer in the LIPUS group compared with those in the pinning group. This being said, the active extension and flexion of the DIP joint in the final follow-up were significantly larger in the LIPUS group compared with the pinning group. Further, functional recovery determined using Crawford’s evaluation was “excellent” in all 8 cases in the LIPUS group, “good” in 3 cases of the pinning group, and “excellent” in 8 cases in the pinning group. No complications were observed within either group. In conclusion, LIPUS therapy may be recommended as an option to treat type I mallet finger fractures in children for whom initiation of treatment was delayed by up to 8 weeks. |
| An open, prospective investigation was conducted to study the effects of low-intensity ultrasound (LIPUS) on non-unions of fractures at different anatomic locations. 15 patients with non-union were treated with LIPUS in this study. All patients were between the ages of 18 and 60 years old. The injuries that were treated in this study varied, including comminuted fractures of the wrist, scaphoid fractures, talar dome fractures, mid-clavicle fractures, trimalleolar fractures, femur diaphysis fractures, and complex tibial-peroneal fractures. During this study, no other treatments were administered but LIPUS, and the device that was used was the EXOGEN system. LIPUS in combination with a standard scaphoid cast was administered to those with scaphoid non-unions. Except for the clavicle and talus fractures, patients were kept in a cast if the fracture was in the lower limb and was producing symptoms. LIPUS was administered, by the patient, for 20 minutes once a day. All patients returned for follow-up radiographs at 4, 8, 12, 16, and 20 weeks, and three patients had an additional follow-up appointment at 24 weeks. The endpoint of the study was a healed fracture, as judged both a clinical and a radiographic examination. All patients experienced healing of their nonunion, with a healing time ranging from 49 days in a patient with scaphoid nonunion to 168 days in patients with femur, tibial, and fibula fractures. In the 8 scaphoid non-unions, the mean healing time was markedly shorter than in the other non-unions at other sites. LIPUS was well tolerated by the patients, and no side effects were noted. Further, all patients found the portable device to be easy to use. In conclusion, LIPUS is a promising modality for fracture healing disorders, and could become a method of great value to manage a non-union. |
| This pilot study sought to assess results using Exogen for non-union in adults and the limitations of the technique. A continuous retrospective study was conducted in the Rouen University Hospital Center. 60 patients, 38 males and 22 females, were admitted into the study with the inclusion criteria as follows: fracture with first-line surgery, non-consolidated at 6 months, with inter-fragment gap less than 10mm. non-unions secondary to osteotomy or arthrodesis were also included. The external stimulation device that was used for treatment was the Exogen system. The Exogen device was used for 20 minutes daily until consolidation or a maximum of 6 months. Patients were followed up at 6 weeks, and 3 and 6 months after initiation of stimulation. Consolidation was checked clinically and radiologically on plain AP and lateral views at 6 months, and radiological consolidation was confirmed by an independent investigator. During the study, one patient was excluded due to complications from treatment by nailing. Upon completion of the study, the 6-month consolidation rate following external stimulation was 88%, with seven failures out of 59. The mean treatment duration was 151 days. The mean interval to treatment tended to differ according to consolidation following external stimulation: 251 days in the group showing consolidation at follow-up, versus 420 days in the group comprising the seven failures. In conclusion, two essential criteria are to be considered in indicating external therapy: non-union site inter-fragment gap less than 10mm and stable osteosynthesis. The Exogen stimulation system can then be indicated as first-line treatment, as its success rate is better than with any osteo-induction surgery. |
| The aim of the present study is to determine the effect of ultrasound treatment on established tibial non-unions. The Trauma Departments of 96 clinics agreed to participate in the study, and 71 patients, 56 men and 15 women, met all eligibility criteria to be included. Patients did not receive any additional cast or surgical treatment at the start or during the ultrasound treatment, but it needs to be known that initial fracture treatment was conservative in 19 cases and operative in 52 cases. Patients were subjected to low-intensity pulsed ultrasound (LIPUS), utilizing Exogen (S&N Memphis, TN), once a day for 20 minutes. The average duration of ultrasound treatment for all cases was 188 days. The study was completed when the patient exhibited clinical and radiologic healing, which was decided by the treating surgeon, all of whom were independent of the study itself. At the conclusion of the study, the average follow-up duration was 2.7years (range, 1.1– 4.6years). The overall healing rate of established tibial non-unions treated with LIPUS was 52 of 71 cases or 73%. Treatment with LIPUS in combination with pre-existing immobilization showed a statistically significantly higher healing rate compared with nonoperative immobilization alone. The mean healing time was 184 days, and the mean treatment duration for failures was 183 days. The independent radiologic review of all included cases showed no difference in healing rate, but in 19 cases, there was a discrepancy in the rate of bone healing based on the observations of the radiologist and investigators. In conclusion, this study showed that LIPUS is effective in the treatment of established tibial non-unions and can be seen as a good, safe, and cheaper alternative to surgery. |
| The aim of the study was to investigate how LIPUS affects bone healing, at the tissue level, in patients with a delayed union of an osteotomized fibula. A histologic and histomorphometric analysis was used to evaluate a series of bone formation and bone resorptionrelated parameters. A total of 13 patients (9 male, 4 female) whose age ranged from 42-63 years were included in this study. In this randomized, controlled, double blind, prospected study 7 of the patients were treated with LIPUS and 6 patients served as placebo-type controls. The device which was used in this treatment was EXOGEN 2000+® low-intensity pulsed ultrasound device (Smith & Nephew Inc., Memphis, TN, USA). LIPUS was administered, by the patient, while at home, for 20-minutes/day. Patients received LIPUS treatment for an average of 87 days (range 61– 115, median 90 days) and sham-treatment for an average of 83 days (range 72–89, median 85 days).After 2 to 4 months of LIPUS treatment a biopsy was taken from the delayed union of the fibula by performing a standardized biopsy procedure under general or spinal anaesthesia. All of the biopsies showed vital fracture ends with low numbers of osteocyte lacunae, as well as bony callus formation by osteoblasts which deposit osteoid at the fracture ends. The new bone formation areas showed endosteal callus formation in all 13 biopsies (6 control, 7 LIPUS). LIPUS significantly increased osteoid thickness (47%) and mineral apposition rate (27%). The total bone volume and mineralized volume, in the LIPUS Group, were significantly increased by 33% and 34% respectively at the area of newly formed bony callus. At the area of cancellous bone, a 17% increase was noted in the bone volume as well as a 20% in mineralized volume; however,there is no effect on osteoid thickness and mineral apposition rate. The study reported that LIPUS did not affect the outcome, as measured byhistomorphometric parameters, or smokers. Overall, theresults suggest that LIPUS accelerates the clinical fracture healing, of delayed unions of the fibula, by increasing osteoid thickness, mineral apposition rate, and bone volume. These results of the biopsies from the LIPUS Group indicate increased osteoblast activity at the front of new bony callus formation as well as improved stability and increased blood flow, but probably not increased angiogenesis. |
| The aim of this work was to study the effect of LIPUS on bone maturation after tibial callus distraction utilizing the healing index, fixation time, and radiographic bone density in the clinical setting. 21 skeletally mature patients undergoing callus distraction after comminuted tibial fractures were chosen for the study. The patients were assigned to one of two groups: the trial (LIPUS) group or the control group. The trial group was composed of 12 patients, all of which were male, and the control group was composed of nine patients, six males and three females. All patients in the trial group received LIPUS treatment using a Sonic Accelerated Fracture Healing System – SAFHS device (Exogen). The device was used once a day for 20 minutes. Callus distraction of 1 -mm per day was done in both groups with additional 20 minutes of US treatment per day in the LIPUS group. The LIPUS group showed a 14% improvement in radiologic bone density during this time. The consolidation or healing phase started after the end of distraction until the removal of the fixator, which was the defined end of treatment for both groups. During the consolidation period, a 58% increase of bone density in the LIPUS group compared to the control group was evident. Further, the daily increase of bone density was 33% more in the LIPUS group. Clinical follow-up was performed every two weeks, and control radiographs were ordered every four weeks to check on progress throughout the study. At the conclusion of the study, it was evident that the healing index was shortened by 12 days/cm in the LIPUS group. Further, the healing time for patients in the LIPUS group was reduced by approximately 95 days. The results obtained from the study support the clinical use of LIPUS to enhance callus maturation, reduce the healing time, and shorten the period of external fixation in distraction osteogenesis. |
| Thisstudy represented aretrospective analysis of 8 patients with a nonunion of the hamate hook which was treated by fragment excision or open reduction and internal fixation (ORIF). The literature was also reviewed for bone grafting and low-intensity pulsed ultrasound (LIPUS) treatment as alternate options for hamate hook fractures. As previously stated, a total of 8 patients (6 male, 2 female) with nonunion of hamate hook fractures were considered for the study.The mean age of the patients was 38.1 years, ranging from 21 to 67 years.Out of the 8 patients, 1 patient declined further treatment after failed conservative treatment, 4 patients, including the 2 oldest patients (56 and 67 years) underwent subperiosteal fragment excision, and ORIF of the fragment, 3 patients were treatedusing2.0mm cortical self-cutting screws. Patients were followed-up over a period of 3 years. Postoperative radiographs and CT scans confirmed complete removal of the fragment in 4 patients treated by fragment excision and consolidation of the fracture in 3 patients treated by ORIF. The time of rehabilitation is short after fragment excision, whereas the total period of limited activity and physiotherapy is slightly longer after ORIF. This article also mentions that low-intensity pulsed ultrasound (LIPUS) was applied successfully in 3 patients withnonunion of hamate hook fractures. In astudy by Fujioka H., LIPUS was used once a day for 20 minutes during a period of 4 to 4.5 months.3 patients who underwent LIPUS treatment, at the 1-year follow-up,showed no functional deficits such as pain, diminished grip strength,orlimited range of motion. In conclusion, although fragment excise on is the “gold standard” in the treatment of hamate hook non-unions, ORIF with or without bone grafting and low-intensity pulsed ultrasound (LIPUS) has presented themselves as alternate treatment options with promising results. |
| The aim of the present study is to determine whether the use of LIPUS accelerates bone healing associated withdistraction osteogenesis. 62 patients were randomly enrolled to active (32 patients) or placebo (30 patients) devicesfrom four centers in the United Kingdom between 2003 and 2006. The inclusion criteria included patientswho were skeletally mature and required a tibial lengthening of between 2.5 and 10cm. Patients were excluded if they were unable to comply with the protocol, were pregnant, were enrolled in another trial, or if they had associated injuries that would inhibit adherence to the protocol.All patients started the use of their assigned device (active or placebo) approximately 20 days post operatively and used the device for up to 233 days with a follow up every 4weeks. The patients used the Exogen 2000+ device (Smith and Nephew). 5 patients and 2 patients were excluded from the placebo and the active intervention group respectively due to protocol violations. Afterthe Ilizarov framehad been applied and the bone divided, a latency period of seven days was observed in keeping with standard practice for distraction osteogenesis. The distraction phase was then started at a rate of 0.75 mm/day, inthree increments of 0.25 mm.The duration of this phase was ranged from 33 to 133 daysas per the required lengthening, for a minimum distraction of2.5 cm and a maximum of 10 cm, respectively. The principle investigator (AHRWS), who was blinded to the treatment group, determinedthe time to remove the frame after healing at the docking site.Treatment was continued to the maturation phase which was approximately four times as long as the distraction phase, resulting in the patient’s ability to bear weight without the support of the frame.3 patients were excluded from the active group as they had less than tworecorded measurements. The weight bearing was 29.1kg for the remaining active group (29 patients) and 32.2 kg for the placebo group (30 patients). The study reported that there was no significant difference in thelength of distraction or the time to maturation of the regeneratebetween the two groups or in the weight bearing analysis. It is concluded that LIPUS does not acceleratebone healing associated withdistraction osteogenesis and smoking reduces the rate of bone healing byapproximately 50%when compared with patients who did not smoke. |
| The aim of this study was to evaluate the efficacy of LIPUS during distraction osteogenesis (DO). The authors reviewed the medical and radiograph records of30 patients(60 tibiae) who underwent tibial lengthening from October 2009 to October 2015. The inclusion criteria included those who were skeletally mature, underwent simultaneous bilateral tibial lengthening over the nail,and had no medical illness (such as bone metabolic disorders or neuromuscular disorders) or history of trauma. Of the 30 patients, 15 patients (30 tibial segments) were classified as the LIPUS group and 15 patients (30 tibial segments) were classified as the control group. The Sonic Accelerated Fracture Healing System (Exogen Inc., Piscataway, NJ, USA) and BH-1000 ultrasound bone healing device (Orthoheal, Seoul, Korea) were used for the LIPUS. The patients were followed-up every week during the first month, every 2 weeks during the distraction phase, and then, monthly during the consolidation phase. The patients total time for follow-up was an average of 5.6 years (1.7-8.2). In this study,the healing time of the LIPUS group was faster than that of the control group(32.5 days/cm to 36.6 days/cm for the LIPUS group as compared to 44.2 days/cm to 57.5 days/cm for the control group. There were six complications that were observedin the LIPUS group andfive complications that occurred in the control group. Equinus deformity was the most common complication in both groups. One case of impending compartment syndrome was observed as a complication in the LIPUS group. All of the above complications were treated. In the control group,valgusangulation of the tibia wasseen in one patient. The patient refused to undergo any intervention to treat the deformity. However, there were no LIPUS-related complications developed in the LIPUS group. The study concluded that LIPUS is a non-invasive and effective therapy for callus maturation during distraction osteogenesis. It enhances callus consolidation and may have a positive effect on appropriate callus shape and type. |
| The aim of this study is to investigate the use of LIPUS treatment for delayed union of fractures of the fifth metatarsal. The authors retrospectively identified 30 patients from 2013 to 2015 using the LIPUS database. The 30 patients include 9 males and 21 females with an average age of 39.3 (range 14-76). Patients were excluded from the study if they had started LIPUS treatment more than 9 months after their initial injury. The EXOGEN bone healing system was used as the LIPUS treatment in this series. The patients used the LIPUS treatment device daily for 20 minutes, and were followed up at4 week intervals. LIPUS treatment was stopped when clinical and radiographic union of the fracture was achieved, at the completion of the 150 allowed treatments by the device, or when operative treatment was advised. The average duration of LIPUS treatment was 75 days (32-150 days). Progress to bone union was observed clinically and radiologically in 27 patients (90%). Three patients developed non-union of which two required surgery. The authors feel that LIPUS may serve as an adjunct prior to consideration of surgery in delayed bone union of fifth metatarsal fracture, but patients who are smokers may have a higher chance of non-union despite LIPUS. |
| The aim of this study was to determine what factors affected failure of fracture healing afterLIPUS for delayed unions and non-unions. A 1-year observational studywas conductedto assess the effect of low-intensity pulsed ultrasound (LIPUS) therapy on delayed unions and non-unions after long bone diaphyseal fracture. 184 patients with long bone fractures were considered for the study,of which151 fractures following the diagnosis of delayed union or nonunion were chosen and treated with low-intensity pulsed ultrasound therapy.The device that was used was the Exogen system. 101 patients (76% male, average age 36 years) were diagnosed with delayed union and 50 patients (66% male, average age 37 years) were diagnosed with non-union. The device was used once a day for 20 minutes until the fracture was healed or until 1 year from the start of LIPUS therapy had passed. Outcomes were assessed within 1 year after the application of LIPUS therapy and at follow-up once every 4 weeks. Within 1 year of LIPUS therapy, 75 fractures out of 101 united in the delayed union group.The risk for failure of union with LIPUS therapy was increased in atrophic or oligotrophic non-unions, with instability at fracture site, and with those who had a 9mm or more fracture gap size.In the nonunion group, 34 fractures out of 50 united within 1 year of LIPUS therapy, with the risk for failure of union increased by intramedullary nail, instability at fracture site, and by an 8mm or more fracture gap size. The results obtained from the study support that there are four key predictors for failure or success of fracture healing with LIPUS for delayed union or nonunion. These four key predictors are as follows: 1) radiographic type of nonunion, 2) instability at fracture site, 3)maximum fracture gap size, and 4) pre-existing intramedullary nail. In conclusion, LIPUS should be considered as an adjuvant therapy to improve the biological condition for an established atrophic nonunion with instability and/or with larger fracture gap. |
| This study assessed bone stimulation (LIPUS) induced using the Exogen low-intensity ultrasound system in cases of failed consolidation in surgically stabilized long-bone fractures. The study included patients treated using Exogen as part of management of lower-limb long-bone non-union. All patients had undergone surgery, and the non-union site was mechanically and radiologically stable. Fourteen patients were included in the study, eleven of whom were male and three of whom were female. For patients 1 to 7, non-union was primary, and for patients 8 to 14, it was a second or third non-union. As treatment, patients were required to use the Exogen stimulator for 20 minutes/day, in a single daily session. The Exogen stimulator was used for a period of 3 months maximum. All patients were followed up by the surgeon in consultation, with complete X-ray assessment every 3 months, and each patient was compared before and after initiation of ultrasound stimulation. Consolidation was obtained in 11 of the 14 cases (79%): within 3 months of beginning Exogen treatment in 27% (3/11), within 6 months in 27% (3/11), and within 9 months in 46% (5/11). Mean time to consolidation was 5.3 months in initial non-union and 6.4months after revision for non-union. Three patients failed to respond to treatment, with no radiologic improvement in consolidation in the 6 months following the ultrasound treatment. In conclusion, ultrasound stimulation was applied systematically in the present series and enabled consolidation of non-union at 3 months in 79% of cases and at a mean of 5.8 months (173 days) for the patient group. No treatment-linked complications were observed. Unlike other types of external stimulation, low-intensity ultrasound showed a favorable effect on both atrophic and hypertrophic non-unions. These results are encouraging, but a larger series will be needed to validate the application of LIPUS in the management of non-union. |

**BD CERS**

**A Propensity-Matched Comparison of Pleurodesisor Tunneled Pleural Catheter for Heart Failure Patients With Recurrent Pleural Effusion**

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**Summary**

This retrospective study involved reviewing the records of patients who were undergoing treatment for recurrent, symptomatic, pleural effusion secondary to advanced heart failure and who had undergone at least two unilateral thoracenteses. All of the patients were treated by the same surgeons at the Department of Thoracic and Cardiovascular Surgery, St. Vincent Hospital, Indianapolis, Indiana. Eighty (80) patients were selected from the (144) cases that were reviewed. These patients were propensity-matched using sex,age, inpatient status, NYHA Classification and mean Charlson index. There were (40) patients selected each for the (2) treatment cohorts: thoracoscopic pleurodesis (TP) and the use of a tunneled pleural catheter (TPC)(Pleurx catheter;CareFusion, San Diego, CA). Thoracoscopic pleurodesis is considered to be the traditional treatment for this indication.

No significant differences in palliation from theireffusion as determined based on a lack of reintervention (TP-5%, TPC-2.5%) demonstrated during the follow-up period (TP-7 months+/- 3 & TPC-6 months +/-2) and the improvement in performance scores. However, the TPC group realized a significantly shorterhospital stay (TP-6+/-4 days, TPC-2+/-2days) as well as a lower rate of operativemorbidity (TP-20%, TPC-2.5%) and readmissions (TP-23%, TPC-5%) than patients undergoing TP.

At last available follow-up, mean survival of the two groups was also comparable. None of the patients treated required further intervention for an ipsilateral pleural effusion. TPC should be considered for palliation of patients with recurrent pleural effusion due to advanced heart failure.

**A comparison between two types of indwelling pleural catheters for management of malignant pleural effusions**

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**Summary**

The authors retrospectively studied (27) non-pediatric (median age 59.0 years, range 30-92) admitted to Maimonides Medical Center, between January 2013 and March 2015, with a diagnosis of cancer and pleural effusion. Patients without an existing histologic diagnosis of malignancy or with pleural effusions found to be of cardiac origin were excluded from the study. The study group was composed of 17 (63%) women and 10 men. 18 patients (67%) had their MPEs treated with an Aspira (Bard) catheter. 9 patients (33%) were treated with a PleurX catheter (Denver Biomedical, now CareFusion). Both groups were similar in age, sex, body mass index (BMI), oxygen saturation, hemoglobin and serum albumin on admission.

The rate of catheter-related complications (pain, obstruction, loculations, infection, hemorrhage) was 39% (seven patients) for the AG and 33% (three patients) for the PG (overall ten patients, 37%). The median length of stay (LOS) was 9 days (range2-38) for the Aspira group and 13 days (range 4-62) in the PleurX group.

The authors concluded that indwelling pleural catheters are an efficient option for symptom palliation in patients with terminal cancer and that the safety and efficacy of the two brands of catheters, used in this study, were similar.

**Successful Use of Indwelling Tunneled Catheters for the Management of Effusions in Children With Advanced Cancer**

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**Summary**

The authors conducted a retrospective analysis of (8) pediatric patients (ages 5-18 years, median age 16) who were treated, at The Hospital for Sick Children (SickKids) in Toronto, Canada between July 2007 and January 2012. Chart review were performed on all pediatric oncology patients. Those who underwent insertion of a cuffed 15.5 French PleurxITC (CareFusion, McGraw Park, IL) to manage Malignant effusions (ME) were selected. A total of (12) ITCs were involved in the study: (1) patient underwent primary insertion of bilateral ITCs. (3) patients required placement of a second ipsilateral ITC catheter at 14, 21, and 55 days following their primary insertion. (1) patient developed a separate locule and required the insertion of another ITC without removal of the first. At the time of ITC placement, the fluid obtained was described as sanguineous (n=4), serosanguinous (n=5) or serous (n=2), and not specified on one. The volume drained at ITC insertion ranged from 120 to 1,610 ml (median 700 ml), achieving complete evacuation of fluid in 1, partial in 9 and not documented in 2 (Fig. 2). Cytologic analysis was undertaken in six cases (five MPE, one MA), one was positive and five were negative for malignant cells.

There were (2) major complications noted in the study, (1) pain which was resolved with opioids, (1) late infection (10 weeks after removal of the ITC). At the time of analysis, one patient was alive. The remainingseven patients died outside of hospital. The median survival timefrom ME diagnosis was 101 days (range 54–201 days). All of the children in the study demonstrated improvement in their symptoms and provided positive feedback on the use of the ITC. The results of this study support the use of ITC as a safe and effective treatment for MEs.

**Tunneled Pleural Catheter Placement with and without Talc Poudragefor Treatment of Pleural Effusions Due to Congestive Heart Failure**

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**Summary**

This single center (Beth Israel Hospital Boston, MA) retrospective study involved 43 procedures (36 patients) performed over a (10) year period (2005-2015). (15) patients were in Group 1 (Tunneled pleural catheter inserted duringmedical thoracoscopy and talc poudrage) and (28) patients were in Group 2 (Tunneled pleural catheter insertiontechnique and drainage method). The mean age of the patients was 82.5 years (range 61-97). (52.7%) of the patients were women.

All of the patients exhibited improved dyspneaafter pleural intervention. Overall,successful pleurodesis was achieved in44.2%, and catheters were removed in44.2%. After the intervention, NYHA meanscore decreased from 2.49 (group 1 = 2.15;group 2 = 2.67) to 1.82 (group 1 = 1.69,group 2 = 1.90).Pleurodesis wasachieved more frequently in group 1 (80%) than Group 2 (25%). The median time to catheterremoval of all catheters (both groups) was20 days (range, 2–205 d), with Group 1 11.5 days (range 2-22) and Group 2 66 days (range 31-205). Each group had (3) adverse events.

In this retrospective tunneled catheter placement was found to be feasible and often efficacious for patientswith symptomatic, refractory pleuraleffusions caused by CHF. Pleurodesis wasachieved more frequently when catheterplacement was combined with thoracoscopyand talc poudrage (Group 1). However the patients in this treatment group were younger and exhibited a lower baseline NYHA score.

Among the limitations associated with the study were: retrospective cohort without a control, inherent referral and selection bias.