OUTCOME MEASURES: PNR, PJK, postop CD.
METHODS: ASD patients with preop, 6-week postop (6W), and 2-year postop (2Y) radiographic data included. PNR: 10-year mismatch (undercorrection; unimproved) from a patient's age-adjusted PT at 6W and maintained at 2Y. Pelvic responder (PR): PT ±10 match age-adjusted goals. Patients were stratified by incremental additions of corrective alignment schemas: (a) improvement in Schwab SVA, (b) matching age-adjusted PI-LL, (c) match postop "ideal" and "theoretical" Roussouly, (d) improvement in proportionality spinal score at 6W. PNR, PJK, and CD development by 2Y were compared within groups, as well as simultaneous improvement/match of the suggested corrective measures (exclusively). In a subanalysis, patients were stratified by severity of baseline PT, low (<20°), moderate (20-30°), and severe (>30°) to determine which alignment schema is necessary to achieve less PNR, PJK and postop CD.
RESULTS: A total of 468 patients (56.3 yrs, 76.5% F; 25.6% PNR, 40.6% PR) met inclusion criteria. Rates of postop PJK (PNR:49.2% vs PR:59.5%) and CD (18.3% vs 25.8%) were significantly less in the PNR group, $p<0.05$. Sole improvement in Schwab SVA (73.2%) did not impact PNR, PJK or CD ($p>0.050$). Undercorrected age-adjusted PI-LL presented with more PNR (60.1%), whereas overcorrected had increased PJK (68.2%), $p<0.001$. Matching Roussouly at 6W decreased PNR (17.8% vs mismatch:42.3%, $p=0.002$). 6W proportional spine, had lower rates of PNR (19.7%, severely disproportioned: 58.8%, $p<0.001$), with postop moderately disproportioned GAP with highest rates of PJK ($p=0.010$). Incremental addition of alignment schemas was assessed for effect on malalignment outcomes. Schwab and age-adjusted use (20.9%) had less incidence of PNR (28.6% vs 38.7%) than just Schwab. Addition of the Roussouly (18.3%) presented with less PNR (20% vs 30.4%) and PJK (38.5% vs 60.3%) than only Schwab & age-adjusted. Lastly, addition of proportion (16.7%) had 0% occurrence of PNR and CD. Stratifying by baseline PT severity, the low group demonstrated the least incidence of PNR (7.7%) and CD (10.3%) and PJK (41.3%) when matching theoretical Roussouly at 6W (all $p<0.050$). This remained the same for moderate PT for PNR and PJK, except Schwab improvement decreased postop CD occurrence (21.2%, $p=0.049$). Severe PT assessment determined PNR (20%), PJK (37.5%) and CD (19.4%) were the lowest with improvement of proportion at 6W ($p<0.050$).
CONCLUSIONS: Following ASD corrective surgery, 25.6% of patients showed residual pelvic malalignment, qualifying as pelvic nonresponders. Use of complex realignment schemas (SRS-Schwab, age-adjusted, Roussouly shape, GAP) decreased rates of pelvic nonresponse, PJK and postop cervical deformity development. Severe (>30°) baseline pelvic tilt requires particular emphasis of proportionality in addition to other realignment ideals.
FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

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11. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: five-year treatment results from a prospective randomized double-blind sham-controlled multicenter study

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BACKGROUND CONTEXT: Current literature suggests that degenerated or damaged vertebral endplates are a significant cause of vertebrogenic chronic low back pain (CLBP). Modic changes are one objective MRI biomarker for this specific subset of patients. Intraosseous basivertebral nerve (BVN) ablation, using radiofrequency energy under image guidance, was compared to a sham control in a randomized controlled trial (RCT) and demonstrated superiority at 12 months. Two-year data from the treatment arm of this RCT showed maintenance of clinical improvements at 2 years following ablation of the BVN.
PURPOSE: This study reports the 5-year clinical outcomes in this cohort of patients.
STUDY DESIGN/SETTING: Prospective, open label, single arm five-year follow-up of the SMART RCT. The primary requirements for inclusion in the original RCT were CLBP with a duration greater than 6 months; CLBP nonresponsive to at least 6 months of nonsurgical management; and Modic Type 1 or 2 changes at the vertebral endplates of the levels targeted for treatment. BVN ablation was performed under image guidance in an outpatient setting for those patients randomized to the treatment arm.
PATIENT SAMPLE: This five-year follow-up study was conducted in the U.S. at the 13 study sites that treated patients in the original RCT. In the US BVN ablation arm, 117 patients were successfully treated and targeted, and comprise the per protocol (PP) population for this study.
OUTCOME MEASURES: Patient-reported outcomes of Oswestry Disability Index (ODI), visual analog score (VAS), responder rates, postablation treatments, and patient satisfaction were collected. The primary outcome was mean change in ODI from baseline. Comparisons between the postablation and baseline values were performed using a paired t-test at the 0.05 level of significance.
METHODS: A single telephonic study visit was conducted by an independent research nurse between June 2019 to November 2019 (a minimum of 5 years post-BVN ablation). Self-reported patient outcomes were collected via interview using validated questionnaires that were sent in advance of the visit. No additional interventions were required in the 5-year+ follow-up study.
RESULTS: One hundred of the 117 US treated patients (retention rate 85%) were available for review with a mean follow-up of 6.4 years (range 5.4 to 7.8 years). Mean ODI score significantly improved from 42.81 to 16.86 at 5 years of follow-up, a reduction of 25.95 points ($p<0.001$). Mean reduction in VAS pain score was 4.38 points (baseline of 6.74, $p<0.001$). Of total patients, 66% reported a >50% reduction in pain, 47% reported a >75% reduction in pain, and 34% reported complete pain resolution. Responder rates were maintained at five years with 75% of patients exceeding a combined threshold of ≥15-point ODI and ≥2-point VAS for function and pain improvement, and 65% reporting they had returned to their pre− low back pain activity level.
CONCLUSIONS: CLBP patients treated with BVN ablation exhibit sustained clinical improvements in function and pain with high responder rates at a mean of 6.4 years following treatment. BVN ablation appears to be a durable, minimally invasive treatment for the relief of vertebrogenic CLBP.
FDA DEVICE/DRUG STATUS: Intracept procedure (Approved for this indication).

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12. Health care costs and characteristics of spinal fusion patients receiving concentrated bone marrow aspirate (BMAC), iliac crest autograft or bone morphogenic protein (BMP) therapy: a retrospective cohort study utilizing administrative claims

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BACKGROUND CONTEXT: To aid in fusion, surgeons may choose to use a biologic or other grafting agent in posterior lumbar spinal fusion procedures. This study explored the differences in cost and a variety of outcomes of bone marrow aspirate concentrate (BMAC), iliac crest autogenous bone grafting (autograft) and recombinant human bone morphogenetic proteins (rhBMP) -2 and -7. Autograft complications include pain, risk of infection and donor morbidity. BMP drawbacks are high cost and at risk of stimulating too much bone growth. While BMAC has been shown to promote bone and soft tissue healing, possible risks include bleeding and infection or nerve damage.
PURPOSE: A market assessment was conducted to explore the clinical value of each product. The study also looked at patient demographics, outcomes, and cost across the grafting products.