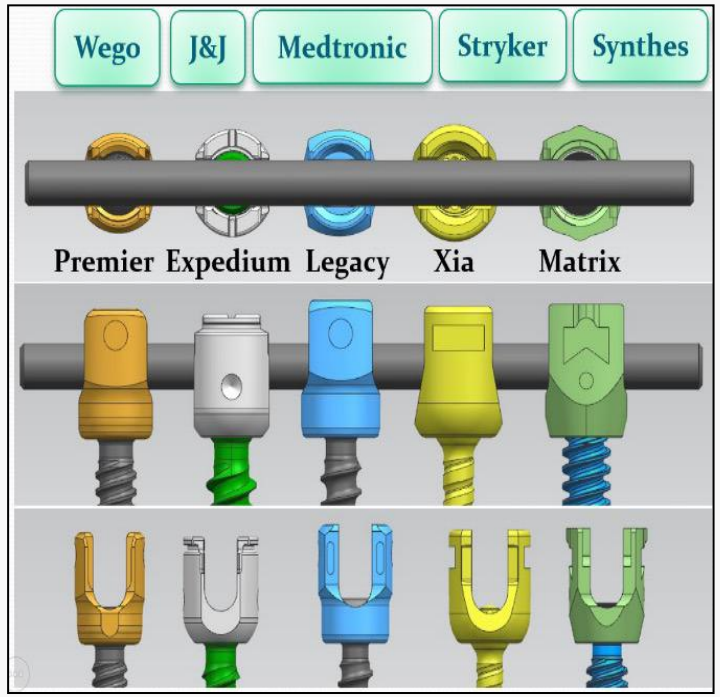
Evidence of Clinical Safety and Efficacy

Supporting Evidence for WEGO Spinal Implants vs. Substantially Equivalent Predicate Devices across non-cervical applications requiring posterior fixation with pedicle screws

Studies on substantially equivalent posterior fixation systems

Equinox has conducted a detailed analysis of 70 clinical studies of **substantially equivalent posterior fixation systems**, published in peer-reviewed journals* WEGO Spine System demonstrated clinical utility and safety in large number of patients undergoing a wide range of applications, providing sufficient data to assess equivalency to clinical comparators

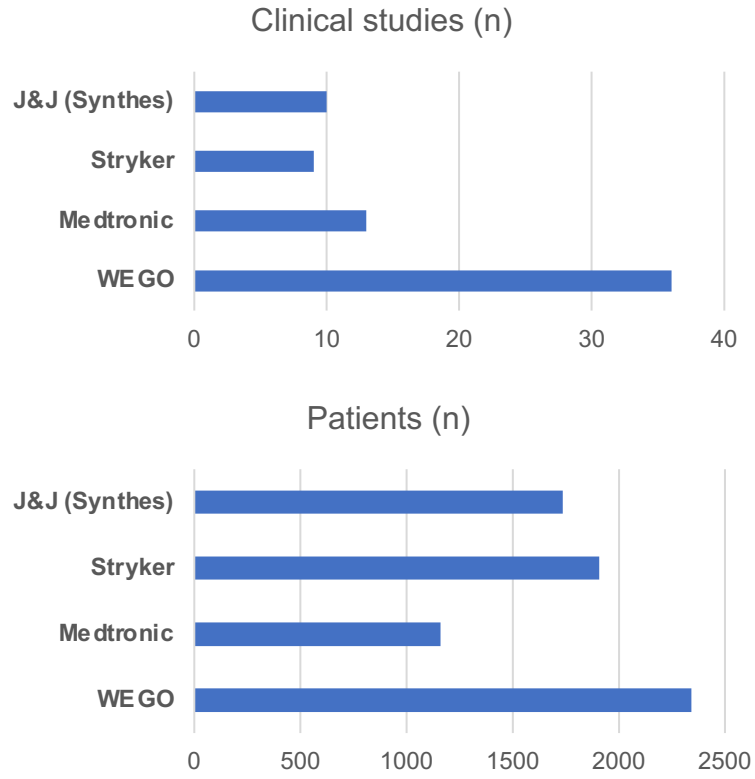


Wego (Weigao) **Premier** / General Spine
Number of studies: 36
Number of patients: 2343

Depuy-Synthes (J&J) **Expedium**
Number of studies: 10
Number of patients: 1736

Medtronic **Legacy / CD Horizon**
Number of studies: 13
Number of patients: 1159

Stryker **Xia 3**
Number of studies: 9
Number of patients: 1908



*Older systems such as the Synthes Matrix not deemed to be a clinically equivalent comparator or predicate device were excluded from the analysis

Clinical Data – Degenerative Diseases

Author	Application	Patient Numbers (n)	Duration (months)	Journal	Clinical outcomes, Conclusion
Ning-Jiang et al. (WEIGAO)	Lumbar spondylolisthesis	146	18	*Chinese Journal of Tissue Engineering Research, 2012*	Clinical efficacy was excellent in 74 cases, good in 41 cases, mild in 13 cases and poor in 6 cases, with good rate of 85.8%. 77 cases achieved a complete reduction, including 32 cases using a short segment fixation and 45 cases using a long segment fixation. 69 cases achieved partial reduction, including 40 cases using a short segment fixation and 29 cases using a long segment fixation. Pedicle screws ruptures were found in 13 screws of eight patients with short segment fixation, while no pedicle screw fracture found in long segment fixation.
Li et al. (WEIGAO)	Lumbar spondylolisthesis	60	6	*Chinese Journal of Tissue Engineering Research,* 2017	To conclude, the pedicle screw system combined with posterior intervertebral cage fusion for spondylolisthesis can rapidly restore the disc height, contributing to better biomechanics of the spine. The system is easy to operate, achieves better efficacy and is recommended.
Ishak et al. (Stryker)	Degenerative or traumatic diseases	1054	76	*Neurosurgical Review,* 2019	This study showed that iCT point-to-point navigation minimizes complications and revision rates. In total, 6059 screws were inserted in 1054 patients. Eight patients required a revision procedure for screw misplacement (0.8%). Total screw misplacement rate was 0.3% (16/6059). In 7 patients, a total of 13 screws had loosened (0.2%) and revision surgery was performed (0.7%).
Hagenmaier et al. (Stryker)	Lumbar spondylolisthesis	72	12	*BMC Musculoskeletal Disorders,* 2013	No significant correlations could be established between the extent of slip reduction and improvement in VAS or ODI. This also accounted for the other radiographic parameters. A fusion rate of 64 percent was seen on CT-scan. Clinical outcome was not related to the obtained radiographic reduction of the slipped vertebra in patients with a lumbar fusion for low grade spondylolisthesis.
Cheng et al. (Stryker)	Lumbar spondylolisthesis	138	48	*International Orthopaedics,* 2009	There was no significant statistical difference in clinical and functional outcome in the two groups. The PLIF group presented a better fusion rate than the PLF group. No patient in the PLIF group presented complications related to hardware biomechanics. Five patients in the PLF group presented complications: three screw fractures and two loosening of the implants, with one patients requiring re-operation
He et al. (Medtronic)	Lumbar spondylolisthesis	73	24	*BMC Musculoskeletal Disorders,* 2020	Standalone oblique lateral interbody fusion (OLIF) may achieve equivalent clinical and radiological outcomes than OLIF combined with fixation for spondylolisthesis. Rate of complications similar between both groups.
Lee et al. (Medtronic)	Lumbar spondylolisthesis	79	12	*The Spine Journal,* 2015	Cortical screws (CS) in PLIF provides similar clinical and radiologic outcomes compared to pedicle screws (PS) in PLIF. On the basis of the present study, we suggest CS to be a reasonable alternative to PS in PLIF. At the 6- and 12-month follow-up points, similar fusion rates were observed in both groups. According to the clinical outcome, CS provided similar improvements in pain amelioration and functional status compared to PS.
Audat et al. (Medtronic)	Lumbar spondylolisthesis	41	36	*Scoliosis,* 2011	Only one case had broken rod in group I that required revision. Superficial wound infection was experienced in two patients and one patient, from group II, developed wound hematoma. The ODI outcomes in both groups was variable on the short term but was almost the same on the long term follow up.

Clinical Data – Degenerative Diseases

Author	Application	Patient Numbers (n)	Duration (months)	Journal	Clinical outcomes, Conclusion
Zhang et al. (WEIGAO)	Spinal Stenosis	61	12	*Therapeutics and Clinical Risk Management, 2020*	Aim: To retrospectively observe the differences in subsection laminectomy with pedicle screw fixation (SLPF) and lamina osteotomy and replantation with miniplate fixation (LORF) in the treatment of continuous Thoracic ossification of the ligamentum flavum (TOLF). Both groups demonstrated a significant improvement in JOA score and ASIA grade. The occurrence rate of perioperative complications was 15.6% (5/32 patients) in group A and 37.9% (11/29 patients) in group B.
Wang et al. (WEIGAO)	Spinal Stenosis	30	28	*Medical Science Monitor,* 2019	This study aimed to evaluate the effectiveness of subsection laminectomy with pedicle screw fixation (SLPF) for the treatment of ossification of the ligamentum flavum of the thoracic spine. SLPF was an effective procedure for the treatment of ossification of the ligamentum flavum of the thoracic spine
Mao et al. (WEIGAO)	Spinal Stenosis	98	36	*International Orthopaedics,* 2014	Successful fusion was achieved in all patients. There were no implant failures. Bilateral decompression via a unilateral approach using unilateral pedicle screw fixation for two-level lumbar stenosis with instability, which can maintain the lumbar lordosis and the disc space height, is an effective and less invasive method than with bilateral constructs.
Lee et al. (Stryker)	Spinal Stenosis, Spondylolisthesis	160	12	*BioMed Research International,* 2015	Cages with different lordotic angles of 4◦ and 8◦ showed insignificant results clinically and radiologically in short-level PLIF surgery. Clinical improvements (VAS, ODI) and sagittal alignment recovery were significantly observed in both groups.
Guerado et al. (Stryker)	Spinal Stenosis, Spondylolisthesis, Disc pathology, Vertebral fractures	110	84	*Injury, 2016*	More bone continuity was found with allograft plus BMP-7 (OP-1) than with allograft alone. The amount of bone mass was greater on the OP-1 side. No adverse effects noted. Allograft on one side plus allograft with BMP-7 on the other achieved a fusion rate of 93 per cent. According to our results, allograft plus BMP-7 enables effective and safe bone fusion in posterolateral lumbar arthrodesis, while allograft alone achieves poorer results.
Xie et al. (Medtronic)	Spinal Stenosis, Disc herniation	108	36	*Orthopaedics,* 2012	Successful radiographic fusion was documented in all patients. No flexion–extension hypermobility or pedicle screw loosening or breakage occurred during the follow-up period. The authors recommend the use of unilateral fixation in lumbar interbody fusion with 1 cage for lumbar degenerative diseases without major instability
Takeuchi et al. (Medtronic)	Spinal Stenosis, Spondylolisthesis	67	34	*Neurosurgical Review,* 2015	In the results, the fusion outcome for the group receiving TL (with the TELAMON C cage and local bone graft) was significantly less than those for the other three groups. Moreover, the VAS (low back pain) score was significantly higher for TL than for the other three groups. Large volume inside the cage (≥2.0 mL) with local bone graft may lead to incomplete interbody bone fusion and residual postsurgical low back pain after PLIF.

Clinical Data – Degenerative Diseases

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Li et al. (WEIGAO)	Disc Herniation	46	12	*Clinical Neurology and Neurosurgery, 2015*	Using Kirschner wires instead of the nerve root retractor to pull nerve root in the patients with a single-level lumbar disc herniation accompanied by the lumbar instability is more effective in reducing the dragging damage of the nerve root at early phases after surgery and in shortening retraction time.
Zhao et al. (WEIGAO)	Disk herniation, lumbar canal stenosis, lumbar spondylolisthesis	23	/	*BioMed Research International,* 2016	Three-dimensional preoperative image reconstruction as digital virtual templating for junior surgeons in placing a pedicle screw (PS) in the lumbar spine is simple and can reduce the procedure time of PS placement. Although the procedure of the placement of PS was under the supervision of the experienced spine surgeon, all PSs in the two groups were inserted successfully without the intervention of the experienced surgeon
Zhao et al. (Medtronic)	Disc Herniation	101	60	*Experimental and Therapeutic Medicine,* 2019	At day 7 post surgery, recorded VAS and JOA scores were significantly improved in the minimally invasive TLIF (m-TLIF) group compared with the conventional TLIF (c-TLIF) group and non-significant differences between the groups were observed at >1 month follow-up. m-TLIF was a safe and effective tool in treating single-level lumbar disc herniation.
Hall et al. (Depuy-Synthes)	Degenerative disc disease	150	12	*Journal of Orthopaedic Surgery and Research,* 2019	The use of V-CBA combined with local autograft in multilevel IPLF resulted in successful fusions in 98.7% of patients. These results are particularly robust given the complex nature of many of these cases: 89 patients had 4 or more surgical levels, and many patients had multiple comorbidities The total pseudarthrosis rate was 0.8%. Sixteen serious adverse events were recorded and included lumbar seroma, cerebrospinal fluid leak, wound dehiscence, pneumonia, urinary tract infection, and myocardial infarction.
Guo et al. (Depuy-Synthes)	Degenerative diseases	202	/	*European Spine Journal, 2019*	The cement leakage (CL) was observed in 165 patients (81.68%) and 335 screws (35.26%), leakage types of S, B and I were seen in 255 (76.12%), 77 (22.99%), and 30 (8.96%) of screws, respectively.
Putzier et al. (Medtronic)	Degenerative disc disease	50	12	*The Spine Journal,* 2016	Fifty patients with single-level segment degeneration of L4/L5 or L5/S1. Twenty-five patients were treated with miTLIF, and the remaining patients were treated with coPLIF (both with transpedicular fixation). The muscle damage after miTLIF was inferior to that after coPLIF; spatially, however, the muscle sparing was predominantly attributed to the MF and, surprisingly, not to the LS.
Pereira et al. (Medtronic)	Degenerative disc disease	252	1	*PLOS ONE,* 2015	For experienced surgeons, MILIF for DLD demonstrated early benefits (short time to first ambulation, early recovery, high patient satisfaction and improved patient-reported outcomes) and low major perioperative morbidity at 4 weeks postoperatively

Clinical Data – Degenerative Diseases

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Zhao et al. (WEIGAO)	Degenerative diseases	44	/	*International Orthopaedics,* 2018	The purpose of this study was to investigate the position of single cage inserted using oblique-oriented technique in transforaminal lumbar interbody fusion (TLIF) on digital images of computed tomography. A longer single cage can be placed into the L4/5 level disk by inserting it using the oblique-oriented technique.
Kai et al. (Medtronic)	Degenerative diseases	68	24	*International Orthopaedics, 2014*	*Two-level unilateral instrumented TLIF is an effective and safe method with reduced operative time and blood loss for multiple-level lumbar diseases. The patients of the two groups had significant improvement in functional outcome compared to preoperatively. There was no significant difference comparing fusion rate, complication rate and duration of hospital stay between the two groups at postoperative follow- up. Screw malposition was found in one case, but the patient had no symptoms of nerve compression. No other device-related complications, such as loosening or breakage, or fusion cage migration, occurred in either group.*
Høy et al. (Medtronic)	Degenerative diseases	100	24	*European Spine Journal,* 2013	Transforaminal interbody fusion did not improve functional outcome in patients compared to posterolateral fusion. Among the study patients nine patients (9 %) had undergone a second operation: three patients in PLF group had removal of the hardware due to loosening or failure. Four patients in the TLIF group had removal of the implant: two due to misplaced cages, one due to non-union.
Cunningham et al. (Medtronic)	Degenerative diseases	52	94	*Clinical Spine Surgery,* 2013	This study strongly supports the use of PLIF to obtain equivalent or superior clinical outcomes compared with PLF for spinal fusion for lumbar IS. PLIF provided better short-term and long-term results than PLF (VAS, ODI).

Clinical Data – Deformity Correction

Author	Application	Patient Numbers (n)	Duration (months)	Journal	Clinical outcomes, Conclusion
Gao et al. (WEIGAO)	Kyphosis	86	24	*The Spine Journal*, 2015	The authors present a retrospective review of results of their modified pedicle subtraction osteotomy (PSO) technique as compared to conventional PSO. The modified PSO provides an alternative method with which to correct kyphotic deformity in patients with post-traumatic thoracolumbar kyphosis. Comparable outcomes (VAS, ODI) and perioperative measures are reported between the two groups
Hu et al. (WEIGAO)	Kyphosis	18	30	*BMC Musculoskeletal Disorders,* 2018	Between May 2012 and May 2015, 18 patients with Pott's kyphosis underwent the Vertebral column decancellation using Surgimap Spine for preoperative surgical planning. Pedicle screws (Weigao Orthopedic, Shandong, China) were then placed three levels above and below the damaged vertebral body by freehand technique. The mean VAS score was reduced from preoperative 7.1 (range, 6–8) to 1.8 (range, 1–3, $P < 0.01$) and the ODI improved from 65.8% (range, 58–74%) to 20.2% (range, 12–38%, $P < 0.01$). At final follow-up, there was radiographic evidence of solid fusion at the osteotomy site and fixed segments in all patients
Hu et al. (WEIGAO)	Kyphoscoliosis	31	29	*BMC Musculoskeletal Disorders,* 2020	Aimed to investigate the technique of asymmetrical vertebral column decancellation (AVCD) for the treatment of rigid congenital kyphoscoliosis. Of the 31 patients in this study, only 5 (16.1%) sustained complications, including wound problems and CSF leakage. No permanent postoperative neurologic complications occurred. The AVCD procedure corrects spinal deformities in both the coronal and sagittal planes by way of a convex-sided Y shape osteotomy, achieves satisfactory realignment without additional neurological complications, and can be considered an alternative treatment for rigid congenital kyphoscoliosis
Hu et al. (WEIGAO)	Kyphosis	46	41	*Journal of Orthopaedic Surgery and Research,* 2016	Pedicle subtraction osteotomy and disc resection with cage placement and long-segment fixation are effective and safe methods to treat thoracolumbar post-traumatic kyphosis. Clinical symptoms and neurological function were significantly improved at the final follow-up. Solid fusion was obtained in all patients at the final follow-up according to radiological evidence, and no implant failures were noted.
Huang et al. (WEIGAO)	Kyphosis	18	31	*BMC Musculoskeletal Disorders,* 2021	The aim of this study was to evaluate the efficacy of transpedicular bi-vertebrae osteotomy technique in the patients with Pott's kyphosis and other post-tubercular spinal deformity. At final follow-up, there was radiographic evidence of solid fusion at the osteotomy site and fixed segments in all patients. Neurological function improved from ASIA scale D to E in 7 patients, C to D in 3 patients. No instrumentation related complication and no deep wound infection were identified.

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Clinical Data – Deformity Correction

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Wang et al. (WEIGAO)	Scoliosis	30	24	*European Spine Journal,* 2010	Aimed to evaluate the advantages of Nitinol shape memory alloy (SMA) rod-based correction by comparing the clinical and radiographic results obtained from using a temporary SMA rod and those from a standard rod in the correction of severe scoliosis (70°– 108° curves). In the traditional group, 6 of 16 cases suffered pedicle screw pull out or loosening, three cases pedicle screws near the apex were abandoned and five cases were replaced with poly-axial pedicle screws. Study shows that temporary use of SMA rod may reduce operative time & blood loss, while improving correction in the coronal plane compared to standard techniques.
Yi et al. (WEGIAO)	Scoliosis	36	30	*Journal of Neurosurgery and Spine,* 2020	Study aims aims to evaluate the clinical (fusion rates / complications), radiographic, and patient-perceived outcomes between TSF versus TLIF with posterior long instrumentation for patients with ASD. Despite similar clinical and radiographic outcomes between both groups, TSF required fewer iliac screws to augment stability of the lumbosacral junction while achieving a higher rate of fusion. Both groups demonstrated significant postoperative radiographic improvement in coronal parameters. The fusion rates for TSF and TLIF groups were 100% and 88.9%, respectively. No statistical differences in patients' reported outcomes were seen between groups.
Benli et al. (Medtronic)	Scoliosis	109	137	*European Spine Journal* , 2007	Although, none of the patients had completely balanced curves preoperatively, in 95.4% of the patients the curves were found to be completely balanced or clinically well balanced postoperatively. Overall, four patients (3.7%) had implant failure. Early superficial infection was observed in three (2.8%) patients. About ten (9.2%) patients were considered to have pseudoarthrosis: four patients with implant failure and six patients with correction loss over 15° at the frontal plane.
Morr et al. (Depuy-Synthes)	Scoliosis	40	29	*European Spine Journal* , 2015	20 patients were treated with thoracic pedicle screws at every level bilaterally (CON) and 20 patients with screws at every level on the concave side and skipped levels on the convex side of the curve (SKP). Both constructs provided acceptable correction of the main thoracic curves. No significant difference was found in postoperative SRS-22 scores. A significant decrease in cost was found with use of skipped screw constructs.
Xue & Zhao (WEIGAO)	Kyphoscoliosis	1	6	*Case Reports in Orthopaedic Research,* 2018	Case study – 13 yr old with Goldenhar syndrome. A posterior T12 vertebral column resection with instrumentation and anterior cage support with bone graft fusion were performed. The fusion level is from T8 to L3, using the Premier spinal system. Patients with Goldenhar syndrome due to a large variety of abnormalities and different severity of symptoms pose a challenge for clinicians. All of this necessitates an individual approach to each single patient and involvement of a team of specialists in treatment planning
Schmidt et al. (Depuy-Synthes)	Lordoscoliosis	42	33	*European Spine Journal,* 2011	This clinical study compared anterior dual rod instrumentation with posterior pedicle screw fixation for idiopathic thoracic lordoscoliosis. Anterior dual rod instrumentation in patients with thoracic lordoscoliosis allows significantly better restoration of thoracic kyphosis than posterior pedicle screw instrumentation

Clinical Data – Fractures / Trauma

Author	Application	Patient Numbers (n)	Duration (months)	Journal	Clinical outcomes, Conclusion
Tian et al. (WEIGAO)	Fractures	62	6	*Orthopaedics,* 2011	Compared to conventional intersegmental fixation, short-segmental fixation combined with intermediate screws more effectively restores fractured vertebral height, is associated with a decrease in the segmental kyphotic angle, and allows earlier ambulation. No complications such as neural injury, delayed wound healing, incision or deep wound infection, CSF leakage occurred in any patient. None of the patients required reoperation, and there were no instrumentation failures, pedicle screw loosening, implant fractures, non-union in fusion cases, or significant loss of fracture height.
Xiong et al. (WEIGAO)	Fractures	69	24	*Journal of Orthopaedic Surgery and Research,* 2020	In conclusion, SSIF-IAP can exert greater interface strength on the fractured vertebra and effectively maintain the height of the fractured vertebra compared with using SSIF-SF; SSIF-IAP can minimize the number of fused levels and promote rapid relief of lumbar back pain and early rehabilitation compared with using LSIF. Taken together, SSIF-IAP is an effective and reliable operative technique for patients with Denis type B TL fracture. There was one case of screw breakage at the 6-month follow-up, with a 4.16% failure rate in the SSIF-SFM group; there was one case of screw loosing at the 1-year follow-up, with a 5.26% failure rate in the LSIF group. However, there was no significant difference between the two groups regarding the failure rate (P = 0.87).
Erichsen et al. (Depuy-Synthes)	Fractures	87	24	*BMC Musculoskeletal Disorders,* 2020	Aimed to compare open posterior stabilization treatment strategy vs. percutaneous posterior stabilization for on non-osteoporotic AO Spine type A3 fractures of the thoracolumbar spine at levels T11 to L2. There was no significant difference regarding our primary functional outcome parameter (ODI) between both groups. Clinical relevant differences in functional and radiographic outcome between the two surgical groups could not be demonstrated. Both treatment strategies are safe and effective showing minor loss of reduction.
Barakat et al. (Medtronic Vs. Depuy-Synthes)	Fractures	40	12	*SICOT-J,* 2019	Usage of USS in thoracolumbar fracture as a short-segment fixation led to a near anatomical reduction when compared to the Legacy system. However, there was no advantage regarding pain reduction and neurological outcome.
Alkosha et al. (Depuy-Synthes)	Fractures	102	12	*Global Spine Journal - AO spine,* 2020	Isolated PSF is a valid choice in managing TLICS-4 thoracolumbar fractures; however, it did not surpass conventional methods in TLICS-3 or TLICS-5 fracture types.
Kitzen et al. (Depuy-Synthes)	Fractures	14	31	*BMC Musculoskeletal Disorders,* 2017	Tricalcium Phosphate bone cement (TCP) showed good histological osseointegration with no adverse events. TCP can therefore be safely used and could be beneficial in treatment of thoracolumbar burst fractures. Analysis of the biopsies showed a variable degree of bone remodelling with incorporation of TCP into newly formed bone matrix. No extensive FBRs, inflammation, granulomatous responses or tissue necrosis observed.

Clinical Data – Osteoporotic Spinal Conditions

Author	Application	Patient Numbers (n)	Duration (months)	Journal	Clinical outcomes, Conclusion
Wu et al. (WEIGAO)	Osteoporotic (OP) spine conditions	36	24	*Journal of Surgical Research,* 2012	Cemented-EPS could increase fixation strength biomechanically. Six months after operation, the JOA and VAS scores in cemented-EPS group improved from 11.4 ± 2.6 and 7.0 ± 1.4 mm to 24.9 ± 1.6 and 2.1 ± 1.3 mm, respectively. No screw loosening occurred in the cemented-EPS group and spinal fusion was achieved. In the cemented-CPS group, four screws loosened (4.2%) according to the radiolucency.
Wu et al. (WEIGAO)	OP spine conditions	157	43	*Archives of Orthopaedic and Trauma Surgery,* 2012	EPS can decrease the risk of screw loosening and achieve better fixation strength and clinical results in osteoporotic lumbar spine fusion. In the EPS group, 20 screws became loose (4.1%) in 6 patients (7.5%), and two screws (0.4%) had broken. In the CPS group, 48 screws became loose (12.9%) in 15 patients (19.5%), but no screws were broken. The fusion rate in the EPS group (92.5%) was significantly higher than that of the CPS group (80.5%). The rate of screw loosening in the EPS group (4.1%) was significantly lower than that of the CPS group (12.9%). 12 months after surgeries, JOA & ODI scores in the EPS group were significantly improved.
Fu et al. (WEIGAO)	OP spine conditions	27	24	*Orthopaedics & Traumatology: Surgery & Research,* 2017	EPS provides excellent instrument fixation in patients with osteoporotic DSD, improving radiographic and clinical outcomes at two years' follow-up. All patients obtained good correction. Preoperative ODI score of 36.7% reduced to 11.9% at two-year follow-up. No screw breakage, loosening or pullout in any patient.
Wu et al. (WEIGAO)	OP spine conditions	125	18	*Clinical and Investigative Medicine (Online),* 2010	In osteoporosis spine surgery, excellent bone-screw interface and fixation strength can be achieved by using MEPS. The recovery rate was 78.1±11.5 % and the clinical results were satisfying. There were no instances of screw loosening or pullout of the MEPS and the screw-bone interface was excellent.
Wu et al. (WEIGAO)	OP + degenerative scoliosis	21	12	*Biomedical Research,* 2017	To evaluate the use and efficacy of EPS in DS patients undergoing long segment fixation (many DS patients have co-existing OP). All cases had satisfactory orthopaedic outcomes and compared with situation before surgery, the imbalance in the sagittal and coronal planes was improved. All screws were held in place 1 year after surgery without loosening, pull-out, and fracture of rods
Ma et al. (WEIGAO)	OP + vertebral compression fractures	26	29	*Clinical Spine Surgery,* 2020	Good anterior column fusion, no pedicle screw loosening, and satisfactory neurological recovery and clinical results were achieved during the 2-year follow-up. No obvious fracture was seen in the whole-spine x-ray examination. No issues were observed with the fixations (eg, fracture and loosening).
Gu et al. (Stryker Vs. Depuy-Synthes)	OP + vertebral compression fractures	68	27	*Journal of Orthopaedic Surgery and Research,* 2015	The VAS significantly decreased after surgery in both groups (PVP Vs. PKP). None of the patients were found to have any postoperative neurological complications. No hardware failure was seen in any patient following the instrumentation and PVP.
Yan et al. (Depuy-Synthes)	OP + vertebral compression fractures	24	18	*Annals of Palliative Medicine,* 2021	Balloon kyphoplasty combined with posterior pedicle screw fixation was an effective treatment for osteoporotic TLBFs. This procedure can reconstruct 3 spinal columns using a single approach with less blood loss, short operation time, and rapid recovery.

Clinical Data – Tuberculosis, Tumour Resection, Inflammatory Disease

Author	Application	Patient Numbers (n)	Duration (months)	Journal	Clinical outcomes, Conclusion
Jin et al. (WEIGAO Vs. Medtronic)	Spinal Tuberculosis	289	72	*The Spine Journal,* 2013	Clearing traditional tuberculous foci combined with sclerotic bone, multiple cavities, and bony bridges so as to increase the curative effect is an effective treatment method for Spinal TB. A total of 265 patients were cured, 24 were incompletely cured, and 9 underwent a second surgery. There were also no cases of postoperative fixation loosening, or breakage.
Yang et al. (WEIGAO)	Spinal Tuberculosis	221	65	*BMC Musculoskeletal Disorders,* 2021	Aimed to compare the diseased (single segment fixation) vs the non-diseased intervertebral surgery (short and long segment fixation) used in the treatment of thoracolumbar and lumbar spinal tuberculosis and to explore the best choice of fusion of fixation range. The diseased intervertebral surgery is a safe and feasible option for the treatment of thoracolumbar and lumbar tuberculosis.
Jin & Wang. (WEIGAO)	Spinal Tuberculosis	106	58	*Archives of Orthopaedic and Trauma Surgery,* 2012	Single-segment pedicle screw fixation and correction surgery can fix and fuse the diseased segment in lumbar and sacral tuberculosis, retain normal movement in the adjacent spinal column, and promote functional recovery of the spinal column postoperatively. No damage to major blood vessels, nerves or organs, or other serious complications, was observed in any of the 106 patients. There were also no cases of postoperative fixation loosening, loss, breakage, or graft displacement
Qian et al. (WEIGAO)	Spinal Tuberculosis	74	12	*International Orthopaedics,* 2016	Prospective randomized study. Isolated posterior instrumentation without debridement is a suitable treatment for selected patients because of minor surgical trauma, fewer complications, and spontaneous fusion. Group B had a better clinical outcome with regard to the operative time, blood loss, VAS score first week post-operatively, and the ESR value in the third and sixth month post- operatively than group A. No implant failures were found in all cases, so no additional surgeries were performed due to bony fusion failure during the follow-up.

Clinical Data – Tuberculosis, Tumour Resection, Inflammatory Disease

Author	Application	Patient Numbers (n)	Duration (months)	Journal	Clinical outcomes, Conclusion
Zhang et al. (WEIGAO)	Ankylosing spondylitis	84	24	*The Bone & Joint Journal,* 2016	The VCD technique is a new, safe and effective strategy for correction of rigid TLKD in AS patients. The main advantage of the new correction mechanism is that it achieved a satisfactory correction by controlled anterior column opening and posterior column closing, avoiding the occurrence of sagittal translation.
Fan-Qi et al. (WEIGAO)	Ankylosing spondylitis	89	24	*Chinese Medical Journal,* 2018	PSO with a cage significantly avoided ST during the osteotomy procedure and might represent a new, safe, and feasible choice for treating patients with AS kyphosis. At the final follow-up, the SRS-22 scores improved from preoperative 1.9 ± 0.6 to 4.5 ± 0.5 in Group A (PSO with a cage) and from 2.0 ± 0.7 to 4.6 ± 0.4 in Group B (PSO). Postoperative correction was achieved in all patients. The sagittal parameters significantly improved in both groups. No obvious correction loss was observed at the final follow-up in either group.
Andrés-Cano et al. (Stryker)	Infection, Degenerative diseases, Fractures	139	18	*Orthopaedic Surgery,* 2018	Incidence of deep infection requiring debridement: 11.51%. In a model of multivariate regression, taking as the dependent variable unsuccessful arthrodesis after 1 year, & adjusting for the other independent variables, the only variable that was significantly associated with an outcome of unsuccessful spinal fusion after 1 year was infection; patients with infection are 12 times less likely to achieve satisfactory radiological fusion
Weise et al. (Stryker)	Degenerative diseases, Fractures, Infections, Tumors	67	16	*Medical Devices: Evidence and Research,* 2008	We conclude that the use of this cannulated screw system for the placement of pedicle screws in the thoracic and lumbar spine is accurate and safe. The total medio-caudal pedicle wall perforation rate was 9.2% (30/326). In 19 of these 30 cases a cortical breakthrough of less than 2 mm occurred. The misplacement rate (defined as a perforation of 2 mm or more) was 3.37% (11/326). There have been no screw breakages or dislocations over the follow up-period
Laine et al. (Stryker)	Degenerative diseases, Fractures, Infections, Tumors	100	/	*European Spine Journal,* 2000	A higher accuracy and reliability of pedicle screw insertion with computer-assisted navigation than with conventional methods was demonstrated under clinical conditions in a randomised controlled trial. The pedicle perforation rate was 13.4% in the conventional group and 4.6% in the computer-assisted group (P = 0.006). Pedicle perforations of more than 4 mm were found in 1.4% (4/277) of the screw insertions in the conventional group, and none in the computer-assisted group

Conclusions

- Robust mechanical and manufacturing assessments have been conducted by global regulators to evaluate the clinical equivalence of the WEGO Spine Range to internationally marketed comparator products. These assessments overwhelmingly support the quality of the WEGO spine implant range.
- WEGO spinal systems have over 10 years of clinical experience, with over 35 publications in international peer-review journals.
- There is a significant volume of published, overseas clinical literature supporting the safety and effectiveness of WEGO pedicle screw and rod systems, in treating a variety of conditions including fractures, deformity correction (scoliosis, kyphosis), degenerative diseases, tuberculosis and general osteoporotic spine conditions.
- WEGO spinal systems have demonstrated clinical utility and safety in large number of patients undergoing a wide range of applications, providing sufficient data to assess equivalency to clinical comparators.