chronOS Bone Graft Substitute

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A prospective clinical study evaluated the use of a composite bone void filler (ChronOS Strip, DePuy Synthes, West Chester, PA, USA), combined with bone marrow aspirate plus local autologous bone, in a series of patients undergoing instrumented posterolateral spinal fusion with interbody support. Seventy-six patients were enrolled and treated per protocol at 13 clinical sites. At 24months, 55/76 patients (72%) were evaluated, with 49/76 (65%) having sufficient data to determine the primary endpoint. The primary endpoint, posterolateral fusion success, was achieved in 48/54 (88.9%) patients at 12months and in 45/49 (91.8%) patients at 24months. At all follow-up time points, statistically significant improvements were observed when compared to baseline in back and leg pain and functional status as measured by visual analog scale, Oswestry Disability Index and 12-Item Short Form health surveys. This prospective multi-center series provides evidence that the composite bone void filler, when applied posterolaterally with instrumentation, bone marrow aspirate and/or local autologous bone and concomitant interbody support, can be used to achieve a successful posterolateral fusion, resulting in improvements in clinical outcomes in patients with degenerative disc disease [1)].

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In this prospective study, patients undergoing XLIF with an Oracle cage filed with the artifiial bone ChronOs Strip (Synthes, USA) were evaluated. The group consisted of 61 patients, 33 women and 28 men, with an average age of 50.9 years (range, 21 to 73 years). A total of 64 segments were operated on. Stand-alone interbody fusion was performed in 14 segments, lateral plate fiation in 19, transpedicular (TP) fiation before XLIF was carried out in 14 and TP fiation after XLIF in 17 segments. At one-year follow-up, dynamic X-rays to exclude instability, and CT images were obtained in order to evaluate the extent of bone fusion outside the implant (complete fusion, partial fusion, no fusion) and inside it (% of the bone fusion surface area). In addition, bone mineral density following fusion mass bone quality (expressed in Hounsfild units [HU]) was assessed inside the implant at the site of ChronOs Strip placement, using a region of interest (ROI) analysis. For the evaluation of fusion bone quality inside the implant on CT scans with HU qualifiation, the authors propose the following scale: 1. no fusion (0-99 HU) 2. Uncertain fusion (100-190 HU) 3. Probable fusion (200-299 HU) 4. Reliable fusion (300 and more HU) All results were statistically evaluated in relation to the gender, age, treated segment, surgical diagnosis, method of fiation, implant height and intervertebral space reduction at one-year follow-up. RESULTS: Fusion outside the implant was complete in 18 segments (28%) and partial in 27 (42%); in 19 segments (30%) it was not detected. The bone fusion surface area inside the implant was 54.5% (0-100%) on the average. It was related to age and implant height; the surface area increased with increasing age and with increasing implant height. Solid bone fusion inside the implant, as assessed on CT images using HU, was reliable in 36 segments (56%), probable in 11 (17%), uncertain in 10 (16%) and was not detected in seven segments (11%). A signifiant relationship was found between the quality of bone fusion and the type of fiation. Of the segments treated by stand-alone XLIF, 29% showed no fusion while the segments managed by lateral plate fiation had 32% of them with probable fusion. Correlations were also found with the height of an implant (the higher the implant, the more reliable its fusion), with age (the higher age, the higher bone density) and with the spinal level (the lower level, the lower bone density). In 45 (70%) segments, bone mineral density inside the implant was higher than the density of surrounding spongious bone. The average density inside the implant was 333.7 HU (14-1075) and that of the surrounding bone was 244.6 HU (66-500). The intervertebral space was reduced by an average of 1.1

mm (0-6.2). All treated segments were found stable on dynamic X-rays. DISCUSSION: The use of a tricortical bone graft collected from the iliac crest is associated with pain at the harvest donor site in 2.8% to 39% of the cases, and this has been an impetus for many surgeons to use bone substitutes. In terms of the final outcome, i.e., solid bone fusion, the difference between the resorption rates of allogenous graft/artificial bone and ingrowth of autologous bone (from vertebral bodies) plays the most decisive role. CONCLUSIONS: The change of (3-tricalcium phosphate to bone tissue is not always reliable and this can largely be expected when the resorption rate of ChronOs strip is low, i.e., at higher patient age and with a higher height of the implant.The authors recommend increasing the probability of solid fusion in XLIF by using lateral plate fixation.The method of assessing bone fusion by measuring bone density on CT scans proved to be useful because of its objectivity, and it can replace the current assessments based only on subjective judgement [2)]

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Kanter AS, Gandhoke GS, Welch WC, Arnold PM, Cheng JS, Okonkwo DO. A prospective, multi-center clinical and radiographic outcomes evaluation of ChronOS strip for lumbar spine fusion. J Clin Neurosci. 2015 Nov 18. pii: S0967-5868(15)00442-7. doi: 10.1016/j.jocn.2015.08.012. [Epub ahead of print] PubMed PMID: 26602602.

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Hrabálek L, Čecháková E, Buřval S, Adamus M, Langová K, Vaverka M. [Use of artifiial bone in lateral interbody fusion of the lumbar spine: a prospective radiographic study]. Acta Chir Orthop Traumatol Cech. 2014;81(6):392-8. Czech. PubMed PMID: 25651294.