Quantitative evaluation methods of biomaterials incorporation into the bone tissue in fracture healing cases – Evidence Based Medicine oriented clinical experience

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There is a lack of consensus in the assessment of fracture healing of long bones fractures among orthopedic surgeons. The decision to intervene in an effort to promote fracture healing may be influenced by varying definitions of nonunion and delayed union.

The daily practice assessment of fracture healing is mostly a clinically relevant. Quantitative methods of fracture healing evaluation, potentially useful for Evidence Based and Rationale Fracture treatment are rarely used. More sensitive and reliable methods to monitor fracture healing and to detect its early changes are required due to the development of new agents and biomaterials to induce the repair process. The aims of this study were to determine quantitative and qualitative features of fracture healing.

Materials and Methods. Various methods were employed and developed for use in the clinical research setting. Ultrasonographically enhanced ultrasonometry and digital image and DICOM file evaluation methods were developed to assess conventional radiography, DEXA scan and volumetric computed tomography during the period following fractures of the appendicular skeleton. Cases of long bones fracture healing were assessed utilizing originally developed methods including Ultrasonometric measurement, RODIA SYSTEM ® and 3D Reconstructor. Fracture cases were enrolled and underwent CT and X-ray imaging during fracture healing. Quantitative assessment in the fracture gap was performed on conventional radiogram Optical Density and CT density changes (Hounsfield units [HU]). The analysis was performed by evaluation of regions of interest (ROI) covering the fracture gap. Results. The healing rate by optical density, CT density or ultrasound wave propagation time across the fracture gap was presented after the study. External callus formation was observed in examined cases and was detected earlier with CT technique. CT DICOM images allowed for more complete 3D and detailed visualization of healing compared with conventional X-rays. The limitations of the X-ray evaluation are determined. Quantitative evaluation show good intraobserver and interobserver reproducibility. It is suitable for statistical analysis required for Evidence Based Medicine. Conclusion. Our originally developed methods of fracture healing assessment are reliable tools that are able to monitor changes in normal bone healing and may serve as useful objective image analysis in monitoring fracture healing in clinical trials.

Keywords: Fracture healing; CT; quantitative assessment; image analysis, ultrasound