Wear Of Spinal Guided Growth Sliding Titanium Lsz-4d Implants For Early Onset Scoliosis Treatment

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Introduction: Early onset scoliosis (EOS) is diagnosed when severe scoliotic deformation is observed in young patients with unfinished spine growth. In this case it is necessary not only to correct the deformity but also retain further growth of the spine. Fusion-less instrumentation such as VEPTR, periodically extended (twice a year) growing rods or guided growth sliding devices such as the Shilla or LSZ-4D are commonly used. However due to the absence of fusion movement of rods against fixtures is possible and may result in undesirable wear debris formation. Wear of this instrumentation is likely to be more pronounced for growth guidance sliding instrumentation where rods are able to slide in the fixtures as the child is growing. Excessive wear debris is known to cause aseptic loosening, bone osteolysis and failure of metal-on-metal and metal-on-polymer total hip and knee replacements (THR, TKR). While absolute amounts of wear debris produced by THR and TKR have been measured [1], there is limited information on quantitative values of volumetric wear of spinal implants, especially used for EOS treatment. This study is aimed to analyze the wear damage on retrieved guided growth sliding LSZ-4D devices made of titanium alloy Ti6Al4V including quantitative volume wear loss measurements of retrieved implants as well as measurement of metal ion content in patient’s blood and tissues surrounding LSZ-4D sliding device.

Methods: Visually inspected LSZ-4D sliding devices made from alloy Ti6Al4V and consisted of 2 rectangular section rods and 40±8 fixture elements (20±4 hooks and 20±4 clips) were implanted in the study group of 25 patients on 10±2 spine levels for 6±2.3 years (3 males, 22 females, age 11.4±1.2). Locked fixtures were normally located on one spinal level (in thoracic spine level) while unlocked fixtures were located at distal and proximal ends of the device thus enabling sliding while spine is growing (fig. 1). Devices were retrieved at routine surgery to exchange sliding devices with traditional fusion instrumentation when the child became skeletally mature. Volume wear loss was measured on devices retrieved from 3 patients by taking images of wear scars using a Bruker interferometer microscope. The interferometry data was then incorporated into MATLAB software (The MathWorks Inc., Natick, MA, USA). The system then calculates the displaced volume in parallel planes with 1 pixel spacing lines along the length of the groove. The median height over 20 pixels is calculated at the end of each line. Using linear interpolation, the volumes under the lines are calculated and summed over the length of the groove. This volume wear loss measurement was previously validated using gravimetrical...
measurements. Content of Ti, Al and V ions in the whole blood of patients and tissues surrounding unlocked fixture - rod junction in the lumbar part of the spine was measured using inductively-coupled mass spectrometry (Nexion 300D ICP-MS spectrometer; PerkinElmer Inc., Shelton, CT 06484, USA). Levels of ions in the study group of patients were compared with those in a control group, which were matched for age and consisted of 10 individuals without any implants (9 female and 1 male). Statistical analysis was carried out using non-parametric Mann Whitney U test (SPSS 22.0 software). A p-value≤0.05 was considered a significant result.

Results: Volume wear loss for the whole LSZ-4D sliding device averaged for 3 patients was 12.5±1.5mm$^3$ per year assuming liner wear rate. Individual contribution from rods, hooks and clips was 5±1.2mm$^3$, 3±1mm$^3$ and 4.5±1.5mm$^3$ per year respectively (fig. 2). Visual examination of wear scars on rods revealed larger size of wear scars on the distal and proximal parts of rods and smaller size in the central region near the spine level with the locked screws. The wear of hooks and clips was also uneven. Approximately 30% of them were severely damaged with deep wear scars; another 20% revealed minor damage and the rest (50%) had minor scratches with no measurable damage. Five of 25 patients in the study group had metallosis related complications: 3 patients developed seromas over the implanted device in the lumbar part of the spine, and 2 had fistulas. Patients with implanted LSZ-4D devices had increased content of metal ions in whole blood of between 2.8 to 4 times the level of individuals in the control group for Ti and V respectively. Whist for tissues adjacent to implants there was 1500, 30 and 100 times increases for Ti, Al and V respectively. Patients who developed complications did not have higher content of metal ions.

Discussion: Volume wear rate measured in our work for sliding LSZ-4D device made of titanium alloy, is similar to values (15-26 mm$^3$ per year) reported for metal-on-metal THR made of CoCr alloys known for their superior wear resistance [1]. Taking into account the poor wear resistance of titanium alloy, it indicates that the ranges of motion and/or loads in spinal sliding growth-guidance devices are lower compared to THR articulations. Similar increase of metal ions in patients’ blood was reported in literature after implantation of traditional fusion spinal instrumentation [2,3]. However, values of metal ions in tissues surrounding LSZ-4D device are much higher compared to those reported previously for spinal implants [4]. It might be assumed that the observed amounts of titanium alloy debris led to the high content of metal ions in the tissues surrounding the sliding implant and that this caused local clinical complications such as seromas or fistulas. Therefore application of additional wear resistant coatings on this spinal instrumentation will be beneficial.

Significance: Guided growth sliding devices (such as the Shilla or LSZ) for surgical treatment of early onset scoliosis have appeared lately as an alternative to growing rod instrumentation, which have the disadvantage of repeated surgery for periodical extension and an increased rate of proximal junction kyphosis. However, it is important to investigate if sliding devices generates excessive wear debris, since metallosis is known to be one of the main reasons for the preliminary failure of total hip and knee prosthesis. Understanding the wear of these sliding rods and fixtures is clinically important and may indicate ways to minimize the wear of these components.
Figure 1. Illustration of LSZ-4D sliding growth guidance device

Unlocked clip has deeper groove for sliding of the rod.
Figure 2. Average volume wear for retrieved components of LSZ-4D device made of titanium alloy Ti6Al4V.