September 4th, 2021

Study ID: 29/2021/Oss/IOR

Date of approval: 14th July 2021

NCT04904640

Which stem in total hip arthroplasty for developmental hip dysplasia? A comparative study using a 3D CT-based software for surgical pre-operative planning.

Study Start: May 10, 2021

Primary Completion: July 10, 2021

Study Completion: July 10, 2021

METHOD

A random population of 200 CT scans of pelvis and thigh in an adult population affected by hip dysplasia will be selected. The aim of this study is to evaluate the biomechanical reconstruction of the hip anatomy provided by three different hip stem designs in dysplastic cases, using a 3D CT based software for preoperative planning. Pre-operative planning in hip arthroplasty with dedicated software is a useful guide to provide a better reconstruction of the biomechanical parameters of the replaced hip and to optimize the choice of component, improving the geometric understanding of the hip anatomy and the interaction between the native morphological structure and the prosthetic component. The use of a 3D CT-based software for pre-operative planning may provide a better knowledge of the hip anatomy, simulating the biomechanical parameters more closely than a 2D X-ray-based software. In addition, it is the only way to anticipate the correct interaction between the prosthetic components, or the combined anteversion, a key factor in preventing implant instability. Severe hip deformities, like developmental hip dysplasia, may not be adequately reconstructed by every implant and 3D pre-operative CT may increase the three-dimensional anatomical knowledge of the hip, improving the choice of the correct implant and possibly reducing the possible consequences of intra and post-operative complications. Therefore, the purpose of this study is to pre-operatively plan, in a random series of 200 native pelvis and thigh CT scans performed in patients with hip dysplasia, 3 different types of hip stem designs using the 3D Hip-Op software, with the aim of analyzing, on the CT simulations, the percentage of adequate reconstruction of the optimal biomechanical parameters (combined anteversion between 25°-50°, global offset not inferior to 12% of the native offset, leg lengthening not superior to 3 cm, sagittal and coronal tilt not superior to +/-5°, canal filling not inferior to 80%). The percentage of every stem design providing the optimal reconstruction in dysplastic hips (all the 5 parameters matched) will be assessed. The single parameters, especially the combined anteversion, the offset restoration and the leg lengthening, will be assessed for every simulation.

STATISTICAL ANALYSIS

The analyses were performed using SPSS 14.0 (SPSS Inc, Chicago, IL). Quantitative data were reported as average values, standard deviations and ranges of minimum and maximum. Qualitative data were expressed as frequencies and percentages and tested using chi-squared test. The reliability of the simulations was assessed using Fisher test (categorical variables). Threshold for significance: p=0.05.