Introduction: Femoral neck fracture is one of the most common fractures in elderly people, and the total number of femoral neck fractures is increasing as the elderly population grows. To maintain the functional level of these patients, closed reduction and secure internal fixation are of primary importance. However, some complications such as screw cut out can sometimes occur resulting in costly re-operations and functional deterioration (1). Failure to achieve anatomical reduction, sub-optimal screw position, and certain types of unstable fractures have been reported as risk factors contributing to cut out failure (2). To assist anatomical reduction and to maintain reduction during internal fixation, we developed a fracture reduction assisting robotic system (FRAC-Robo) consisting of a motorized traction table with a six degree of freedom force and torque sensor (Fig.1). It can be used in two operating modes, an active mode and a passive mode. The passive mode is an initial setup mode to place the patient’s leg in a provisional reduced position. The active mode is used for the final reduction according to the fracture reduction path based on image guidance. Before using FRAC-Robo in a clinical setting, we conducted two sets of experimental studies to evaluate if the motor and sensor units could generate sufficient force and torque for fracture reduction and if the fail safe system which consists of an emergency stop button and a mechanical overload absorption socket at 300N in traction and 28 Nm in rotation would work before harmful damage could occur.

Material & Methods: In the first experiment, force of traction and torque of rotation during reduction of proximal femoral fractures with a standard manual traction table were measured using a force sensor (Nitta Corporation, Osaka, Japan) which was equipped between the foot boot and the traction device. The coordinate axes were defined as follows; the direction of traction was Fy and the rotation around Fy was My. The subjects of the first study were 7 females with intertrochanteric fractures with an average age of 81 years. There were 4 stable and 3 unstable types. According to a conventional reduction process, one of our senior surgeons performed fracture reduction under fluoroscopic guidance. The traction force and rotation torque were recorded digitally while the fracture was brought into the neutral position. Then, the limb was further pulled in the active mode in increments of 5 millimeters, and then was rotated externally in degrees of hip abduction. In the second experiment, healthy volunteers’ limbs were pulled and then rotated using the FRAC-Robo system, and the forces and torques to the lower extremity were measured to determine how much traction force and rotation torque were tolerable to the lower limbs. The subjects were 62 volunteers (30 males and 32 females), with an average age of 23 years. According to the conventional reduction process, the volunteers’ limbs were placed on an OR table and the FRAC-Robo held one side of the lower limb with the hip in 0 degree of flexion and 30 degree of abduction while the contralateral limb was placed with the hip in 40 degrees of abduction. Volunteers’ limbs were pulled in passive mode until the knee and ankle extended to the neutral positions. Then, the limb was further pulled in the active mode in increments of 5 millimeters, and then was rotated externally in increments of 5 degrees, and finally was rotated internally. Active movement of the robot was stopped when each volunteer felt pain or abnormality in the lower limbs.

Results: The average maximum traction force applied to the lower limbs was 229.5 N (range, 146.3-294.9N), and the average maximum torque was, 3.2 Nm (range, 1.6-4.4Nm) in internal rotation. The average retention of traction force applied to the lower limbs was 163.8 N (range, 103.7-274.0N), and the average retention of torque was 2.4 Nm (range, 1.2-4.8Nm) in internal rotation. In cases with stable fractures, the average retention of traction force was 136.7N, and the average retention of torque was 5.8 Nm in internal rotation. In the remaining cases with unstable fractures, the average retention of traction force was 229.2N, and the average retention of torque was 1.5 Nm in internal rotation. In the volunteer study, the average maximum traction force applied to the lower limbs was 232.9 N (range, 114.0-311.0N), and the average maximum traction force was 7.7 Nm (range, 2.3-14.2Nm) in internal rotation and 6.3 Nm (range, 1.3-15.6Nm) in external rotation. No volunteer complained of abnormality or pain in the lower limbs after the experiment. The values in males were significantly larger than those in females. The average maximum traction force applied to the lower limbs was 268.2 N in males and 201.6 N in females. The average maximum traction force was 9.1 Nm in external rotation and 8.2 Nm in internal rotation in males, and 6.3 Nm and 4.7 Nm in females. According to paired t-test, there was no correlation between maximum traction force and the volunteers’ height, weight, girth of thigh, or girth of calf. There was also no correlation between the maximum torque in rotation and these parameters. Typical patterns of the traction force and torque in rotation were shown in Figure 2. When the limb was pulled, the traction force was proportionate to the pulled distance, whereas the torque sharply increased when the limb was rotated beyond the maximum range of hip rotation.

Discussion: The average force and torque needed for the fracture reduction was smaller than the average force and torque at which each volunteer felt pain or abnormality in the lower limbs. This suggests that the FRAC-Robo can move patients’ limbs effectively and safely in a clinical setting when the force and torque limits are set at 300N in traction and 28 Nm in rotation around the direction of traction. We could not find significant differences in traction force and rotation torque between stable and unstable types of fractures (p value?), but there was a tendency to apply a higher traction force in unstable types than in stable types to retain the reduction. Further study is needed with the FRAC-Robo to clarify effective force and torque to reduce stable and unstable types of fracture. The average traction force and rotation torque in healthy males were larger than those in healthy females. However, we failed to correlate traction force and rotation torque with structural parameters. Difference in soft tissue elasticity may be a key factor. In conclusion, the FRAC-Robo can generate sufficient force and torque for reduction of intertrochanteric femora fractures and the fail safe system which consists of an emergency stop button and a mechanical overload absorption socket at 300N in traction and 28 Nm in rotation is appropriate for clinical use.

References:
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Fig.1 OR set-up of the FRAC-Robo system with fluoro-navigation (a), and the robotic motor unit with 6 DOF force and torque sensor (b)

Fig.2 Graphs of traction force (a) and torque in internal rotation (b), and torque in external rotation (c)