Correlation of Spinopelvic Movement with Lateral Radiographs to Assess Spine Motion Prior to Total Hip Arthroplasty.

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Design: Prospective pilot study

Aims:

1) To evaluate the correlation between a novel pelvic MetaWear sensor that assesses spinopelvic motion with lateral sit-to-stand radiographs.
2) To evaluate the relationship between a novel pelvic sensor with pelvic tilt, sacral slope, and lumbar lordosis.

Background: Spinopelvic relationships are increasingly recognized as an important part of total hip arthroplasty and determinant of stability after THA. A number of recent papers in the literature have correlated stiffness of the spinopelvic parameters and the potential risk of total hip arthroplasty dislocation. Most commonly, assessment is performed with lateral sit-to-stand radiographs where changes of less than 10 degrees in sacral slope have been described as stiff spines and could represent patients at increased risk of instability. Given the dynamic nature of the hip/spine biomechanics, which is further influenced by relative stiffness of the hip/spine complex, it remains to be determined how the patient's actual motion impacts these radiographic parameters. MetaWear sensors positioned on the pelvis can potentially provide meaningful spinopelvic motion parameters and could eliminate the need for additional radiation needed to obtain lateral radiographs. The correlation between the MetaWear sensor obtained spinopelvic motion and radiographic data obtained from the more traditional lateral sit to stand radiographs is needed.

We will prospectively evaluate 40 patients presenting for surgery at the Division of Hip and Knee Arthroplasty at Mayo Clinic. An assessment of pelvic motion will be obtained through MetaWear sensors. Data capture will then be verified by the Research Coordinator. Preliminary data shows in 2019, OrthAlign, Inc. conducted an internal study utilizing one sensor device strapped to the femur and one sensor device attached to the skin by the patient's sacrum using the same devices and adhesive in the proposed study. The study included 10 employees with no prior knowledge of everyone pelvic or spinal mobility. A physical therapist conducted the study according to the protocol consistently across all individuals. Measurements were taken while sitting, standing, and leaning forward. All intended data was able to be collected with no adverse events. Across the patient population, the average change in pelvic mobility between sitting and standing was 11.86° with a standard deviation of 6.99°, minimum of -1.07° and a maximum of 28.25°. In a study using radiographs, Seyler et al.[1] found an average of 19.2°, standard deviation of 9.9°, min of 1.6°, maximum of 37.5° in change in pelvic tilt across 24 subjects. Nine total measurements were taken per individual. Three sets of measurements were taken. Each set contained three measurements under the same conditions. Between datasets, the sensors were removed and

re-applied. The standard deviation within and across datasets were calculated for each patient. The standard deviation withing datasets was just under 3.0° and the standard deviation across datasets was 3.2°. These standard deviations were compared to radiographs study data[2]. The study showed standard deviations between approximated 2.7° and 3.5° for radiograph measurements of sacral slope and APP angle during standing and sitting positions. Therefore, we concluded our study produce feasible pelvic range of motion results between sitting and standing positions with repeatability and reproducibility comparable to radiograph technology.

Methods: Data from the MetaWear sensors will be collected directly into the sensor and downloaded onto a secure Excel sheet after transfer to specialized app on an IPAD. These patients will have a lateral sitting and standing lumbar radiographs which will take approximately 15 minutes. All patients will have a modern and innovative MetaWear sensor placed on their pelvis which should take an additional 15 minutes to place on the research subjects (Figure 1: showing location of the MetaWear sensor placement). The patients will then obtain the appropriate radiographs with the sensors in place and appropriate correlations between sensor data and radiographs will be made. Radiographs being taken include lateral sitting, standing, and pelvis images.

Included Patients: Age 18+

Ability to provide informed consent

40 total

Sex: men & women

Hip pathology: 40 subjects presenting for total hip arthroplasty or joint preservation procedures

Age: 20 patients greater than 70 years, 10 patients between 50-70, and 10 patients 18-50

Pregnancy test: Women in childbearing ages between 18 and 50 will be required to perform a urine pregnancy test prior to inclusion

Excluded patients: Exclude patients with lumbosacral hardware, contralateral THA, or DJD in the contralateral hip, pregnant women, those who have an allergy to glue or adhesives, or those unwilling to be tested.

Withdraw Criteria: If a patient is unable to complete the required imaging due to inability to sit or stand during radiographs, the patient may withdraw from the research study. Poor radiograph images that do not provide appropriate measurements; additionally, if the MetaWear sensor is unable to track patient movement.

Enrollment process: Patients will be deemed potentially eligible by surgical teams in the Division of Hip and Knee Reconstruction and will be approached by a study coordinator from the Department of Orthopedic Surgery. The study coordinator will obtain a master list of

enrolled patients, managed in Ptrax and will determine if the patient demographics constitute an unfilled spot on the list. If this is the case the study coordinator will discuss the study in detail with the patient and if they agree to participate, we will obtain written informed consent. Subjects will receive $25.00 for their participation. Radiographs for the study that are not part of the standard of care and will be covered by the study and not charged to the patient or their insurance.

The main risk of the study is incremental radiation exposure from 2 research related radiographs. An additional risk includes reaction to adhesive tape. No other risks were identified. The adhesive tape is a FLEXcon® dermaFLEX™ which meets ISO 10993 standards for direct skin contact. The contained H-566 adhesive is non-cytotoxic, non-irritating and non-sensitizing, as defined by the ISO-10993 standard

The benefit of the study is to improve the future patient care and add to the body of scientific knowledge in this important area. Radiographs: Lateral lumbar radiographs that are not the standard of care for hip surgery patients at this time and will be obtained for research purposes. This is a lateral standing and lateral sitting radiograph as part of the research and will be covered by the study.

Post-radiographic evaluation: Following attainment of all radiographs the investigative team will perform measurements on all radiographs including PI, PT, SS, LL. Interobserver reliability statistics will be determined. Any discrepancies between reviewers of more than 2 degrees will be resolved by a third reviewer.

Assessment of pelvic motion will be obtained through the MetaWear sensors. Preliminary data shows (Add the prelim data obtained for health subjects here) Data from the MetaWear sensors will be collected directly into the sensor and downloaded onto a secure Excel sheet.

There will be no post-radiographic study follow-up for the patients. If a gross abnormality is identified on research-related radiographs the patient will be notified by the surgical team.

Statistical analysis: No power analysis was performed as this is a pilot study to determine the correlations between PI, PT, SS, LL and patient sensor obtained motion. Statistical analyses will be performed by Mayo Stats (Budget 2K more or less plus 40% indirect)

The total of 40 subjects was chosen to allow balance of age, sex, and hip disease status as these parameters may influence measurements.

Following collection and annotation of all data, a password protected spreadsheet on a departmental-secured server will be shared with a statistician from the Division of Biomedical Statistics and Informatics. Categorial data will be tabulated as counts and percentages and continuous data as means and ranges with standard deviations and confidence intervals as appropriate. Correlations and means between radiographic parameters obtained from lateral radiographs will be calculated and correlated with spinopelvic motion obtained through the MetaWear sensors. Sensitivity analysis or adjusted analyses will be performed for age, sex, and hip pathology as deemed appropriate by the statistician.

Device Description:

Each device is a MetaWear, MotionC wearable sensor. The device contains a circuit board with a MEMS gyroscope, accelerometer, magnetometer, barometric pressure, and light ambient sensor. Not all sensors are used for this study. The circuit is encased in a plastic housing. Real-time communication to a tablet is achieved via BluetoothLE wireless communication. The device is FCC, CE, IC and RoHS compliant.

Adverse Events:

Adverse events will be monitored and reported to the PI who will make the data available to the DSMB. However, we do not anticipate any adverse event occurring with the use of such sensor technology. The only adverse even would be associated with sensitivity to adhesive tape during the MetaWear sensor placement.

References:

[1] Sutter EG, Wellman SS, Bolognesi MP, Seyler TM. "A Geometric Model to Determine Patient-Specific Cup Anteversion Based on Pelvic Motion in Total Hip Arthroplasty." Adv Orthop. 2019 May 2;2019:4780280. doi: 10.1155/2019/4780280. PMID: 31186967; PMCID: PMC6521545.

[2] J.-Y. Lazennec, M.-A. Rousseau, A. Rangel, M. Gorin, C. Belicourt, A. Brusson, Y. Catonné

"Pelvis and total hip arthroplasty acetabular component orientations in sitting and standing positions: Measurements reproductibility with EOS imaging system versus conventional radiographies"

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