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| **Number** | **Work package** | **Title** | **Lead partner** | **Nature** | **Dissemination** | **Delivery date** | **Person months** | **Risk** | **Impact (I) 1-5** | **Likelihood (L) 1-5** | **Risk factor (IxL)** | **Mitigation strategy** | **Comments** |
|  |  |  |  |  |  |  |  |  | **1=very low, 5=very high** | **1=very low, 5=very high** | **< 6 = low > 15 = unacceptable** |  |  |
| D1.1 | WP1 | Prototype of two directional 4D scanner | WUT | P | CO | 12 | WUT:6 | 1) 4D measurement system will not reach the level of accuracy, frequency and usability for human movement | 3 | 3 | 9 | Fall-back to use of retro-reflective marker system (namely VICON); use for specific purposes only, eg scaling |  |
| D1.2 | WP1 | Database of functional measurements (healthy) | RUNMC | R | PU | 15 | RUNMC:16 | 1) The measurements with PET are not sufficiently sensitive to identify differences at the level of the individual muscle to provide suitable input to the model | 3 | 3 | 9 | We have included multiple methods to measure the contribution of the various muscles to functional movements, such that there is a certain redundancy. Lack of sensitivity in one method does not jeopardize the validity of the outcomes of the functional assessments. |  |
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| D1.3 | WP1 | Validation of the marker-free movement analysis method | WUT | R | PU | 15 | WUT:4 RUNMC:3 | 1) Inaccurate localization of anatomical structures | 3 | 4 | 12 | Introduction of additional markers. Finally, fall-back to use of retro-reflective marker system (namely VICON) |  |
|  | 2) Comparison with Vicon data suggests too weak impact of 4D data (assessment of real skeleton movement measurement). | 2 | 4 | 8 | Fall-back to use of retro-reflective marker system (namely VICON) |  |
| D1.4 | WP1 | Interface algorithms between 4D data and TLEM system | WUT | R | PU | 20 | WUT:5 UT:4 | 1) Incompatibility between 4D system output data and TLEMsafe model | 4 | 1 | 4 | Fall-back to use of retro-reflective marker system (namely VICON) |  |
| D2.1 | WP2 | MRI Imaging protocol that allows for the extraction of parameters as required for the MS model | MAT | R | PU | 6 | MAT:14 RUN:3 UT:5 | Protocol turns out not to be good enough later on | 3 | 4 | 12 | Continuous improvement of protocol  Make new scans for bad MRI protocol scans  (indeed was the case, so likelyhood = 5?)  Risk is less than 5. We have already made some mistakes in the healthy cohort, and therefore likelyhood this will occur in the patient cohorts has decreased. |  |
| D2.2 | WP2 | Software tool for extraction of relevant muscle parameters | MAT | P | PU | 18 | MAT:6 | Image-parameter estimation not fast enough (>1h) in automated procedure | 3 | 3 | 9 | Limit the area of interest for imaging at the cost of reduced accuracy | time schedule adjusting scan protocol? |
| D2.3 | WP2 | Report on accuracy of parameter extraction | MAT | R | PU | 24 | MAT:8 RUNMC:2 | Not all model-parameters may be estimated accurately from imaging techniques | 3 | 5 | **15** | it will be considered to use datasets of MRI and joint strength measurements to improve the accuracy of the model. The joint strength measurements may help creating a better link between the PSCA found by MRI and the joint strengths of the model; a sensitivity study is performed to identify parameters at risk; might have to accept this risk to some extent |  |
|  | Image-analysis not subject specific enough  Variation amongst (healthy) subjects too large (e.g. male-female) resulting in low accuracy | 3  3 | 3  4 | 9  12 | Improve scaling techniques, include more specimen  Switch to multi-atlas approach or investigate additional post processing tools |  |
| D3.1 | WP3 | Report on subject specific analysis | UT | R | PU | 30 | UT:18 MAT:2 RUNMC:2 | Subject-specific model does not result in better prediction than generic model | 3 | 4 | 12 | Seek healthy subjects that are very different in their M-S system; if subjects are similar; no differences may be measured and predicted; consider other subj-specific parameters |  |
|  | Some parameters results turn out to be very sensitive & difficult to measure accurately | 2 | 5 | 10 | Priority list of the parameters that require accurate measurements and detailed optimization; consider alternative measures |  |
| D3.2 | WP3 | Report on sensitivity analysis to assess of imaging errors; show better prediction of subject specific models | UT | R | PU | 18 | UT:8 ABT:5 |  |  |  |  |  |  |
|  | Very sensitive parameter not estimated accurately from functional tests and medical imaging scans | 3 | 5 | **15** | See D1.2 and D2.3. Improving parameter optimization algorithm. |  |
| D3.3 | WP3 | Demonstrate implementation of adaptive capacity of patients in TLEM | UT | R | PU | 48 | UT:6 ABT:2 | Adaptive capacity implemented in subject-specific model is not valid | 3 | 3 | 9 | Additional and improved features in the model (cost function, muscle activity and excitation) to better simulate the patient-specific movement. | Risk low within project; high for future implementation |
| D4.1 | WP4 | Prototype of surgeon-model VR system | WUT | P | PU | 15 | WUT:24 RUNMC:3 ABT:4 BRA:2 MAT:5 | Prototype not working | 5 | 1 | 5 |  |  |
| Incompatibility with ABT  Incompatibility with BRA | 4  4 | 1  1 | 4  4 |  |  |
| D4.2 | WP4 | Validated surgeon-model VR prototype system | WUT | P | RE | 24 | WUT:8 RUNMC:3 ABT:4 BRA:3 | User-interface for S-M visualization and interaction will not satisfy surgeons' needs | 5 | 2 | 10 | Good management will minimize risk and in worst case this task will be delayed. Also close cooperation with potential end-users will minimize this risk. |  |
| Unclear requirements for surgeon-model interaction | 4 | 3 | 12 | Improve requirements while developing and evaluating the application; enhance involvement of surgeons |  |
| D5.1 | WP5 | Data base of pre-operative MRI and records of surgical steps in detail | RUNMC | R | PU | 36 | RUNMC:12 UT:5 | Post-OR model does not correspond well enough with real situation | 3 | 3 | 9 | Take additional MRI or X-rays post-OR. |  |
|  | pre-op MRI scan cannot be obtained within reasonable time | 5 | 2 | 10 | Go to other center for MRI scan; put pressure on imaging dept. A solution has been found for this problem: we can mark the TLEMsafe MRI scan protocol as ‘clinical’. Working that way, we can scan our patients outside of the extremely scarce ‘science time’ on the scanners. The skeletal radiologist proposed this herself. |  |
| D5.2 | WP5 | Functional measurements of patients before and after surgery | RUNMC | R | PU | 40 | RUNMC:15 WUT:15 | Inclusion of patients problematic; either number of patients referred to RUNMC too low or number of patients who are able and willing to participate | 3 | 4 | 12 | Recruit different types of patients.  There are much more soft-tissue sarcoma patients (50/year) than we initially thought (10-15/year). We will most likely include 5 or less osteosarcoma patients and 10 or more soft-tissue sarcoma patients. So the overall inclusion of the sarcoma patient group is unlikely to cause problems.  The hip patient group is still problematic; there are far too few hip dysplasia patients with femoral shortening at the RUNMC (3-5/year). We are currently looking into additional patient categories to include (i.e. large THA’s). |  |
|  | Osteo or soft tissue sarcoma patients are unable to do the exercises because of their weak bones and/or muscles. | 3 | 5 | **15** | Make the pre-OR measurement session optional for the soft-tissue sarcoma patients, and perform only part of the exercises. This limits the proper modelling of the M-S system of the patients. The osteosaroma patients cannot do pre-OR functional tests at all because of their weak bones. |  |
|  |  |  |  |  |  |  |  | In sarcoma patients, going through the informed consent procedure, making the MRI scan, and performing the optional functional task session pre-OR is problematic due to the short time between first intake and surgery, and the high emotional burden placed on these patients. | 4 | 4 | **16** | Careful design of the informed consent procedure and scheduling of the pre-OR MRI scan. Combine MRI scan with another visit to the clinic to reduce burden. Make the pre-OR functional task session optional. |  |
|  |  |  |  |  |  |  |  | Functional assessment of patients with osteosarcoma pre-OR is not possible, due to weak bones and/or because it is impossible to schedule a functional task session pre-OR. | 4 | 5 | **20** | Change the way we model the patient. For this specific patient group, it will have to be done without pre-OR functional measurements. |  |
| D6.1 | WP6 | Report on pre-operative functional prediction of the patients | UT | R | PU | 30 | UT:7 RUNMC:1 |  |  |  |  |  |  |
| D6.2 | WP6 | Report on the comparison of the predicted and measured effect of the surgical intervention | UT | R | PU | 44 | UT:8 RUNMC:2 | Prediction of patient functioning is less accurate than expected |  | 3 |  | Improve scaling; consider more extensive calculations at the cost of increased processing time; figure out what are sensitive parameters |  |
|  | Discrepancy between predicted and measured effects |  | 3 |  | Improve accuracy with better scaling, focus more on the more important ADL activities |  |
| D6.3 | WP6 | Quantification of adaptive capacity of patients which is required for the TLEM model | UT | R | PU | 44 | UT:5 | Incorrect adaptation models |  | 4 |  | Most adaptation processes are unknown yet, and also depend on cognitive and motivational aspects. The results will at least improve relative to existing methods as these ignore the adaptive capacity |  |
| D7.1 | WP7 | Software that produces surgeon-friendly output of functional predictions | ABT | P | PU | 24 | ABT:5 UT:2 RUNMC:2 BRA:2 | Analysis speed is not high enough for interactive handling | 2 | 4 | 8 | Simplify model; use non-interactively; address several surgical options in one run |  |
|  | Functional outcome is not useful for surgeons | 4 | 2 | 8 | Have more discussions with surgeons on their needs |  |
| D7.2 | WP7 | Demonstrate numerical algorithms to reduce calculation time | ABT | R | CO | 40 | ABT:17 UT:5 | Prediction of patient functioning is too time consuming | 3 | 3 | 9 | Increase speed by implementing standardized (part)solutions; consider reducing the accuracy |  |
| D7.3 | WP7 | Prototype that facilitates surgical pre-planning and predicts functional outcome | ABT | R | PU | 44 | ABT:2 RUNMC:1 BRA:3 UT:3 | Relevant interfaces to other modules (in and outside of the project) are not defined or implemented as intended, expected or required | 3 | 2 | 6 | Define interface tests and integration test plans to sort out interfacing problems at design phase rather than after implementation only. |  |
|  | Prediction of functional outcomes after surgery cannot be done for all relevant functional tasks | 3 | 3 | 9 | focus on simple (functional) tasks first, such as strength test |  |
|  | Prediction of functional outcomes after surgery is not valid at a patient-specific level | 3 | 4 | 12 | Further study is needed before implementation in clinical practice | Risk low within project; high for future implementation |
|  | Not enough resources are allocated to this task | 4 | 4 | **16** | involve other partners to make a 'pilot' navigation system |  |
| D8.1 | WP8 | Test report about the new module using ‘dummy’ surgery | RUNMC | R | CO | 32 | BRA:21 RUNMC:4 UT:5 ABT:4 WUT:3 MAT:2 | Module not ready for use in time | 4 | 2 | 8 | Use an agile approach for development, add features in small steps ensuring the software can be used all the time even though features are missing |  |
| Study protocol not ready in time | 4 | 2 | 8 | Start discussion about content, goals and methods early, at least 6 months ahead. |  |
| D8.2 | WP8 | Test report about the application of the model on 3 cadaver bodies | RUNMC | R | PU | 40 | BRA:6 RUNMC:1 MAT:2 WUT:2 ABT:2 UT:3 | Study protocol works for dummy surgery but not for cadavers. | 3 | 2 | 6 | Involve clinical experts in the definition.Try out finished parts in a real life setting as soon as possible. |  |
| D8.3 | WP8 | Final prototype of a navigation module that can be utilized clinically | BRA | R | PU | 48 | ABT:2 RUNMC:1 BRA:3 UT:3 |  |  |  |  |  |  |