"Evidence-based implant design using a statistical bone model and automated implant fitting."

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Introduction: A key in the development of better bone implant design is to consider the natural shape variability found in a certain population. Being able to characterize such shape variability, and how this variability can be injected in the process of implant design has become an important issue within implant manufacturers. Ultimately, the aim is to design an implant that can be used across a population ensuring a good fit. While it is clear that no unique implant will fit as well in every bone, it is possible however to tailor the implant design to be as generic a possible. Thus, an important aspect of the design is to evaluate how well the current bone implant fitting is performing before any further analysis. To asses the quality of the fitting one can search for the distances errors produced when placing the implant on the bone surface. However, current rigid registration strategies as the classical Iterative Closest Point (ICP) do not consider aspects like collision detection between objects nor include more specific constraints which can come from anatomical or manufacturer specific criteria. In this paper, a modified Iterative Closest Point (ICP) technique, tailored to the specific task of bone implant fitting was developed. Collision constraint was incorporated to ensure that no points in the implant mesh model fall inside the bone model. In addition, fitting guidelines provided by the implant manufacturer were included as fitting constraints, this in order to find plausible implant fitting. These specific constraints favors fittings of the implant that are collinear as much as possible with the bone main axis, and do not go above the bone plateau.

The constrained ICP algorithm is based on the optimization of the following functional: \argmin \sum_i W_i *|e_i|, where W_i and e_i are the corresponding weight and distance error for point i in the implant mesh model, respectively.

The weights W_i are computed as a linear combination of constraint-specific weights for collision, implant-bone co-linearity and tibia plateau. Furthermore, in order to avoid biases due to the number of points inside the volume, an analytical expression was found to counter this.
To favour bone-implant fittings that are collinear as possible with the bone main axis, the angle between these two axis was computed and used as constraint weight. For this, the main axis of the implant model and the bone are required. This is performed through a Oriented-Bounding-Box (OBB) decomposition of both shapes. Furthermore, for the implant model, only the lower region was used in order to improve the alignment between the bone shaft and the implant. A 4-level OBB decomposition of the implant was then used. A final constraint comes from the fact that the implant cannot be

positioned further up the bone plateau; this constraint was then implemented as penalties to points going up this plane.

The method was tested on two statistical models of tibia bones, generated from segmented CT scans of left human tibia. For the construction of the statistical models, dense-field correspondences for every bone and a reference one was found using a non-rigid registration algorithm, which was applied to the masked CT images in order to recover only the tibia structure. The Active Shape Model (ASM) method was then used to statistically model the shape variability of bones. A first model describes a Caucasian population of 43 bones and a second one, describes Asiatic population of 47 bones. The statistical shape models were used to generate new valid instances, yielding two new datasets of 67 bones for each population and using the first five modes of variation, corresponding to 94% of the total shape variability. For each new dataset 30 instances were generated using 6 different values or weights for each of the first 5 modes of variation alone, and 37 were generated as combination of the first 3 modes between four different values. These combinations were generated assuring that the generated instances are within the 94% of the Gaussian distribution of the model.

For each instance the constrained bone fitting procedure was performed and the distance error at each point on the implant shape was computed. An overall mean distance and standard deviation was then computed to measure quantitatively the quality of the fitting.

Results: For the Asian population a mean distance error of 1.77mm and standard deviation of 0.836mm was found. For the Caucasian population the mean distance error and standard deviation was found of 1.57mm, and 0.625mm, respectively.

Conclusions: A tailored fitting algorithm for bone implant fitting was developed and tested on a statistical model of left human tibia for two different populations. Although the method was presented for tibia bones, the method can be easily adapted to consider other anatomical constraints. The use of statistical models provides a valuable tool to evaluate the impact of shape variability on a given implant design.