TITLE: INNOVATIVE TECHNOLOGIES FOR COST-EFFECTIVE HEALTHCARE DELIVERY FOR SALVAGE PROCEDURES OF FAILED TREATMENTS OF OSTEOARTHRITIS: SPECIFIC BIOMIMETICS SOLUTIONS TO REDUCE A GROWING PROBLEM WITH A HIGH SOCIAL AND ECONOMIC IMPACT.(CUSTOMPN)

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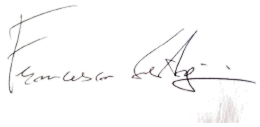

BRIEF SUMMARY

In this prospective multicenter study, a population of adult individuals consecutively treated for revision hips, requiring a custom-made acetabular implant for non-oncological reasons, will be included. The custom-made implant is a personalized implant produced using additive manufacturing, based on the pre-operative CT scan that details the bone damage. Patients eligible for this implant are those with severe acetabular bone damage Paprosky 3 (loss of the superolateral part and one of the two ventro-caudal walls).

Preoperatively, the patient will undergo a clinical evaluation. Data will be collected on the patient's general health status with the Charlson score, the reason for revision, number of revisions, type of implant in place, and the time elapsed between the failed implant and the revision in question. The bone deficit will be studied through CT measurements according to qualitative and quantitative scales. During the surgery, information on intraoperative complications will be collected. In the postoperative period, perioperative complications will be collected according to the Clavien Dindo classification. The clinical radiographic evaluations will be carried out during outpatient follow-up visits at 1, 3, 12, 24, and 36 months after revision. They include the Harris Hip Score clinical score, the EQ-5D, and the patient's satisfaction level (qualitative assessment in 4 grades: unsatisfied, slightly satisfied, moderately satisfied, fully satisfied). The positional parameters of the implant will be evaluated, as compared to the immediate post-operative X-ray: acetabular abduction, acetabular anteversion, center of rotation height, center of rotation medialization, and inclination of the custom-made component. From 12 months onwards, the osteointegration characteristics of the component will be assessed: presence of radial trabeculae at the interface, superolateral and inferior reinforcements, stress shielding, absence of radiolucent lines. Re-revision rates will be determined using the Kaplan-Meier method. The reasons for re-revision will be noted.

DETAILED DESCRIPTION

Osteoarthritis (OA) increased from 247.51 million people in 1990 to 527,81 million in 2019. OA places a huge burden on healthcare services accounting for 1-2,5% of the gross national products and the cost is expected to quadruple by 2030. Total joint replacement (TJR) represents the standard of care of end-stage OA. TJR is projected to nearly double by 2026. Unfortunately, TJR are subject to failure, thus the number of revision procedures is also growing, accounting for 5-6% of all TJR. Failure of TJR represents a dramatic event for patients and National Health Systems. Patients suffer enormous disability, with impact on function, emotional sphere, and loss of autonomy. The average cost of treatment is almost doubled compared to TJR, and in case of periprosthetic joint infections almost tripled. In patients under 65 years (with a failure rate of 9%-12%), the full return to work is reported only in 7%-33% of the cases, and not earlier then 1 year after the surgery, while around 50% retired or remained on welfare benefits. Current technology is not enough to overcome this set of problems, while actual projections predict a 43%-70% increase in revisions by 2030. In particular, revision hips involve various diagnoses and settings: in some cases, the severe bone loss makes the reconstruction very complex. In these cases, acetabular reconstruction can be performed with off-the-shelf implants, but outcomes are not always consistent and reproducible. Thus, in cases of severe acetabular bone loss, it may be very useful to proceed with a customized implant, designed according to the patient's needs. Implants produced in this way are designed based on the patient's pre-operative CT scan using additive manufacturing technology. The purpose is to offer a personalized bone filling of the defect with a highly porous interface that promotes osteointegration. Currently, most of the custom-made implants are performed for oncological cases. On the contrary, there are few indications on the clinical and radiological outcomes of custom-made acetabular reconstructions in revision hips with severe bone loss in non-oncological cases. The purpose of this project is to validate an innovative and reliable technology (custom-made acetabular component produced using additive manufacturing) for managing non-oncological revisions, assessing short term outcomes.

The aims are:

Description of demographic characteristics and bone defect in candidates for acetabular reconstruction with custom-made implants

Perioperative complications and implant survival

Clinical evaluation of custom-made implants in custom-made acetabular reconstructions in hip prosthesis revisions with severe bone loss (clinical score Harris Hip Score; subjective score PROM EQ-5D; post-operative patient satisfaction level)

Radiographic evaluation (positioning and osteointegration) of custom-made implants in custom-made acetabular reconstructions in hip prosthesis revisions with severe bone loss

This is a prospective multicenter study. The study population will consist of adult individuals consecutively treated for revision hips, requiring a custom-made acetabular implant. Patients with a diagnosis leading to an oncological revision will not be included. The custom-made implant is a personalized implant created by an external company based on the pre-operative CT scan that details the bone damage. Patients eligible for this implant are those with severe acetabular bone damage Paprosky 3 (loss of the superolateral part and one of the two ventro-caudal walls). In these cases, off-the-shelf therapeutic options are limited and achieve uncertain outcomes: therefore, a custom-made component with ultra-porous anchoring surfaces can represent a highly advantageous therapeutic choice. After identifying the suitable patient and obtaining their consent for the study, a pre-operative CT scan will be performed as per normal clinical practice for every revision. After uploading it to the dedicated website or app of the company, this CT scan will be used for the manufacturing of the custom-made implant by a third-party company. The company will also provide plastic phantoms for preliminary study of the implant. Upon approval of the implant production, the company will manufacture the implant according to current regulations and production techniques, following previous and established clinical practice. The device will be accompanied by personalized instrumentation, such as cutting guides, positioners, calipers, and plastic simulation phantoms, to facilitate the surgical procedure. The implant and the produced

instrumentation will be delivered to the reference center after performing the patient's surgical planning.

Preoperatively, the patient will undergo an evaluation with the Harris Hip score clinical score. Additionally, data will be collected on the patient's general health status with the Charlson score, the reason for revision, number of revisions, type of implant in place, and the time elapsed between the failed implant and the revision in question. The bone deficit will be studied through CT measurements according to qualitative and quantitative scales.

During the surgery, information on intraoperative complications will be collected. In the postoperative period, perioperative complications will be collected according to the Clavien Dindo classification. The clinical radiographic evaluations will be carried out during outpatient follow-up visits at 1, 3, 12, 24, and 36 months after revision. They include the Harris Hip Score clinical score, the EQ-5D PROM, and the patient's satisfaction level (qualitative assessment in 4 grades: unsatisfied, slightly satisfied, moderately satisfied, fully satisfied). The positional parameters of the implant will be evaluated, as compared to the immediate post-operative X-ray: acetabular abduction, acetabular anteversion, center of rotation height, center of rotation medialization, and inclination of the custom-made component. From 12 months onwards, the osteointegration characteristics of the component will be assessed: presence of radial trabeculae at the interface, superolateral and inferior reinforcements, stress shielding, absence of radiolucent lines. Re-revision rates will be determined using the Kaplan-Meier method. The reasons for re-revision will be noted.

TYPE OF STUDY

Prospective multicenter study

Study population

The study population will consist of adult individuals (minimum age: 18 years) consecutively treated for revision hips (non-oncological reasons) requiring a custom-made acetabular implant. Patients will be enrolled in 4 tertiary centers (multicenter prospective study). Patients eligible for

this implant are those with severe acetabular bone damage Paprosky 3 (loss of the superolateral part and one of the two ventro-caudal walls).

INCLUSION and EXCLUSION criteria:

Inclusion Criteria:

- need of custom-made acetabular implant on the basis of CT and X-ray evaluation ()
- pre-operative CT scan
- adults patients (minimum age: 18 years)
- complete medical charts
- patients' availability

Exclusion Criteria:

- oncological reasons for revision
- other types of revision implant (non custom)
- inadequate medical chart
- lack of pre-operative CT scan

Primary aims: assessing the clinical and radiographic short-term outcomes of custom-made implants for acetabular component revisions due to non-oncological revisions, produced using additive manufacturing.

Primary Outcome Measures:

1.Perioperative complications (Clavien-Dindo classification).

2.Objective clinical outcomes (Harris Hip Score)

3.Subjective clinical outcomes (EQ-5D-5L)

4.Subjective clinical outcomes (satisfaction)

5.Survival rates (Kaplan Meier curve)

Secondary Outcome Measures:

1. Osseointegration of the acetabular component (percentages of cases with good osseointegration of the acetabular component according to Moore's criteria. At least three criteria among: presence of radial trabeculae at the interface, presence of superolateral buttress, presence of inferior buttress, presence of medial stress shielding, absence of radiolucent lines. Range: 0-100%. Best outcome: 100%)

Baseline variables:

1) Sex.
2) Age at first implant.
3) Age at revision
4) Side
5) Weight (kg)
6) Height (cm)
7) Body mass index (Kg/m^2)
8) Charlson score
9) ASA score
10) Type of revision (complete, isolated component, etc)
11) Pre-operative bone stock damage (classification and mm^3)

Statistics

Quantitative data will be reported as mean values, standard deviations, and minimum and maximum ranges. Qualitative data will be expressed as frequencies and percentages and will be tested using the chi-square test. The t-test will be used for correlation between two quantitative variables (means). A Kaplan-Meier curve will be performed with corresponding 95% confidence intervals to estimate implant survival. Significance threshold: $p=0.05$.

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