

Title:**Clinical Outcomes of Joint Replacement in Patients with HIV****Authors:**

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Background:

From 1981 until today, with the use of highly active antiretroviral therapy (HAART), there has been a decrease in overall AIDS incidence and a substantial increase in survival rates. With early screening and new treatment regimes, these patients have a greater life expectancy, but they also are presenting with degenerative diseases, like osteoarthritis (OA) that might need surgical interventions. Total joint replacement is a very successful procedure for the treatment of advance osteoarthritis. With the new advances in joint replacement the number of HIV+ patients who require a total joint replacement has increased dramatically in recent years. Joint replacement in HIV patients includes potential risks, like infection, nerve palsy, impaired wound healing and formation of hematomas. As of today, there are limited studies about outcomes in joint replacement. Some of these studies^{8, 10} had reported infections rate that goes from 18% to 50 %, but, also there are others studies that had shown excellent results.¹¹

The literature is not in agreement as to whether HIV-positive patients have higher rates of surgical complication than HIV-negative patients. This inconsistency reflects the failure to control for confounding variables in many of these studies. Also many of the studies were retrospective in nature with small numbers of participants.

Objectives/Specific Aims:

We propose to evaluate total joint replacement as an option for patients with HIV. The proposed research attempts to assess the clinical outcomes of performing joint replacement in patients with HIV. Our hypothesis is that patients with HIV will have a significant improvement on their quality of life after a total joint replacement

Specific Aim #1: Determine the prevalence and Clinico-pathological Characteristics of Patients with HIV undergoing joint replacement

To determine the prevalence and clinicopathological characteristics of patients with HIV that undergo a total joint replacement at the service of Dr Bibiloni from the Department of

Orthopaedics at the University of Puerto Rico. For this purpose, all patients will be screened for HIV. Demographic characteristics and preoperative status will be recorded.

Specific Aims #2: Determine the Clinical Outcomes of Total Joint Replacement in Patients with HIV infection.

To determine what is the impact that a total joint replacement will make on the quality of life on patients with HIV infection, based on WOMACs' Scores.

Hypothesis 1: Patients with HIV have significant improvement in clinical outcomes after a total joint replacement from their pre-operative status.

Specific Aims #3: Determine the role of the patient's status of immunosuppression in clinical outcomes

We will determine if the patient's status of immunosuppression has any effect on the outcomes of patients with HIV infection, for this purpose we are going to measure the immunosuppression based on the stages for HIV disease according to the WHO criteria¹² using CD4 cell count.

Hypothesis 2: The outcomes results will not depend on the immunological status of patients with HIV.

Study Design:

We will perform a prospective pilot study to evaluate the use of total joint replacement in patients with HIV. All patients that have to undergo a total joint replacement, under the service of Dr. Juan J. Bibiloni at the Orthopaedic Department of the University of Puerto Rico will be asked to participate by the principal investigator (PI) or a research assistant (RA).

Inclusion Criteria:

1. All patients that undergo a total joint replacement at the service of Dr. Bibiloni.
2. Adults (More than 20 Y/O)
3. A Positive HIV Test

Exclusion Criteria:

1. Sero-negatives Patients
2. Patients with altered mental status.
3. Pregnant Woman
4. Minors. (Less than 20 Y/O)
5. Patients that do not sign informed consent or are unable to sign it.

Those patients that consent will be schedule for a preoperative visit and the following data will be collected:

	Pre-op	Post Op	3 Weeks	6 Weeks	3 Months
HIV Testing	X				
Demographic	X				
Wound		X	X	X	X
WOMAC	X			X	X
Orthopaedic Scores	X			X	X
Pain Scale	X	X	X	X	X
Expect/Satisfaction	X				X

Sample size/ Statistical analysis:

A total of 15 patients will be entering in this study. The probability is 82 percent that the study will detect a difference at a two sided 5% significance level, if the true difference between the treatments is 16. This is based on the assumption that the standard deviation of the difference in the response variables is 20.

Tests for normality and distribution will be performed using the Kolmogorov-Smirnov test. A student’s t-test will be used to analyze parametric data and the Mann-Whitney U test for the non-parametric data, a p<.05 will be considering significant.

Anticipated Results:

We anticipated that our results will show that it is safe to carry out joint replacement in HIV patients, even on patients with a CD4 count less than 200.

Discussion / Significance:

There is very little information regarding the postoperative outcomes of total joint replacement in patients with HIV. There is a need to know the effect of this surgery on the quality of life of these patients, and whether we should begin to use total joint replacement as a standard of care for this group.

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