Overall Impression:

This manuscript presents a triboelectric energy harvester and self-powered sensor for total knee replacements. The design and fabrication of the generator is first discussed. A prototype generator is then fabricated and experimentally tested under a simplified sinusoidal profile to simulate normal gait. An electrical circuit is then proposed for energy harvesting and sensing purposes and simulations are performed to predict the behavior of the triboelectric system.

Overall, the topic of this paper is pertinent to the smart materials/energy harvesting/biomedical community, and it is recommended for publication after minor revision. Several comments to address are provided below.

Specific Comments:

The authors discuss using the triboelectric generator for both energy harvesting as well as sensing. The energy harvesting treatment is given sufficient attention in the current manuscript, however, the sensing portion is lacking. In fact, the first mention of using the triboelectric generators for sensing occurs on page 15 when it is alluded to during the initial discussion of the electronic architecture, and it is not clearly stated until page 21 when discussing the ADC. It seems to the reviewer that the idea of using the triboelectric generator as a sensor has not been fully developed by the authors and it is suggested that this discussion either be removed from the manuscript or significantly revised. In the case of a revision, there are several questions that should be answered prior to publication:

- How does the applied force correlate to the generated voltage? The authors discuss proportionality: is it linearly proportional? Also, it appears from the results (e.g. Fig. 8) that the triboelectric generator output does not track the input force (which is sinusoidal). How will this affect the sensing ability?
- Why is the 1000N case asymmetric (Fig. 8)? How will this affect sensing?
- What forces can be sensed in vivo? Axial or shear? Total force? Medial/lateral compartmental forces?
- Can the center of pressure be determined? Can the points of contact between the femoral component and the UHMWPE bearing be determined?

The authors show a maximum generated power of ~6 µW of power for a 2300N sinusoidal load and a load resistance of 58 MΩ. The proposed frontend electronics are shown to require ~4.5 µW of power. The authors then claim that the harvested can provide sufficient energy. This statement is only true if the electronics present an effective impedance to the triboelectric generator that is close to the optimal resistance of 58 MΩ, which is extremely high. What is the effective load resistance that the electronics presents to the triboelectric generator? The reviewer suspects that it is significantly lower (kΩ range?) and that there will be a significant impedance mismatch, thus a reduction in actual harvestable power that can be obtained.

How does the proposed triboelectric generator handle shear loading? It seems that it may be susceptible to failure under shear (failure in the rubber separation layer). How might this affect the stability of the TKR implant, specifically at the UHMWPE/tibial tray interface?
The authors should consider using a realistic gait pattern (e.g. according to ISO 14243 standard, or from biomechanics simulation) for the testing and analysis. How will the generator/sensor perform under a realistic profile?

More details of the modeling should be provided. It its current state, it is difficult to understand how the models are used to generate the results. How are the dynamics of the harvester accounted for in the electrical SPICE model?

What mechanical loading conditions (force amplitude, frequency, load resistance) are used in the SPICE simulations? Does the optimal resistor used in the SPICE simulations match that found experimentally?

Page 12, line 38: It appears as though there is a calculation error. 100V pk-to-pk would result in a 50V amplitude, which would be 35.35V RMS not 18V RMS.

In the introduction section, the authors claim that significant deformations are required for piezoelectric generators and cite this as a drawback of implantable TKR designs using piezoelectrics. According to the piezoelectric constitutive equations, charge is produced under an applied strain. While conventional cantilever beam-based piezo energy harvesters do require significant deformation to achieve high strain at the root (where the PZT is typically located), the ‘33’ mode compressive piezo harvesters employed in the papers cited do not require significant deformation. In fact, the required deformation is significantly less in compressive PZT harvesters (~5-20 µm) than in the proposed triboelectric harvesters (~0.5 mm).

In the introduction (p. 3, line 35), it is mentioned that there is a natural cyclic separation in total knee replacements that can be leveraged with the triboelectric generator, however the static ligamentous forces as well as the forces from bodyweight will keep all of the TKR components in contact with one another.

In the introduction section (p. 3, line 45), the authors claim that all previous TKR energy harvesting works employ piezoelectric-based harvesters, however, electromagnetic harvesting has also been proposed (see: Luciano V, Sardini E, Serpelloni M and Baronio G 2012, Analysis of an electromechanical generator implanted in a human total knee prosthesis IEEE Sensors Applications Symp. (SAS) pp 1–5).

Figure 3(b): should there be negative charges shown in this figure?

Table 2: it is suggested to add a reference to show where the values come from.

There are several typographical errors and poor English throughout the manuscript. Some examples include (note: not an exhaustive list):

- Page 7, line 37 – “to preliminary examine”
- Page 11 – line 7: missing “in”: “frequencies is shown Fig. 9”
- Page 12, line 38: TEG is undefined.
- Figure 9 caption: the wording is informal and also improper English is used