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Towards a European database of explanted UHMWPE inserts: potential and challenges

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Introduction: Monitoring the clinical performance of UHMWPE liners has proven to be an important tool to assess the reliability of UHMWPE formulations currently on the market and for developing future solutions.

This project was initiated in 2022, through the collaboration of researchers from the Czech Republic, Spain, and Italy, with the aim of creating a shared retrievals database to enable more comprehensive monitoring of UHMWPE liner performance across Europe.

Methods and Materials:

The explants included in the database come from the collections of the three research centers and were collected over a period of more than 15 years. At present, the database contains >500 retrievals. Each center has contributed only suitable portions of its database, based on the completeness and standardization of the data. However, additional data is being incorporated, following a review of past analyses. Each database is an independent XLS file, containing pre-defined columns with anonymized patient data, manufacturer data (irradiation, thermal treatment etc.), orthopedic evaluation (links to revision protocols), and material characterization (MicroFTIR microindentation).

Each retrieval was analyzed by micro-FTIR and the maximum and average values of oxidation index (OI), trans-vinylene index (VI), and crystallinity index, (CI) were evaluated. All indexes were calculated in a standardized way by means of a freely available Python package [1]. The micromechanical properties of selected UHMWPE liners were also determined, by means of non-instrumented and instrumented microindentation hardness testing, from two locations (maximum oxidation area and central region of the sample). The final data analyses were performed with freeware Python scripts and libraries for data processing [2].

Results and discussion:

Our initial concern was to verify that standardized sample treatment, measurements, and data collection protocols from three independent research groups yielded reliable and consistent results. In fact, the aggregated results confirm some well-known trends in the literature [3], such as the correlation between the degree of oxidation and the crystallinity of the material, as well as the statistical

significance of the difference in oxidative degradation of UHMWPEs with different sterilization. Furthermore, containing both manufacturer and clinical data, as well as systematically processed data from microFTIR and micromechanical measurements, the database offers an opportunity to correlate structural characterization of the failed materials with clinical evaluations (such as reasons of TJR failures), across three countries (Figure 1).

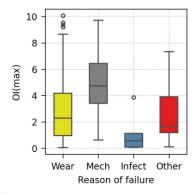


Figure 1 Oxidative degradation (max OI) versus causes of failures for UHMWPE hip liners

In summary, it has been demonstrated that our UHMWPE database contains enough information to show relevant results [4]. However, there are still significant limitations:

- 1) Different laboratories have varying data cataloging practices. Making the data compatible with the database requires extensive effort.
- 2) The current database still lacks comprehensive data on specific types of UHMWPE (HXLPE, Antioxidants containing), with the adoption of "modern" PEs progressing more slowly in Europe compared to the US.
- 3) Additionally, the database currently represents only three specific regions of Europe and specific areas within each country, limiting the generalizability of the results. The project is still under active development [5] and partners from other countries are welcome.

References

- [1] https://pypi.org/project/mpint
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