Integrating Structured and Unstructured Data in Total Hip Arthroplasty Evaluation: A Comprehensive Analysis for Enhanced Device Safety

Laura Elisabeth Gressler, MS, PhD[1], Jonathan Bona, MS, PhD,[1] L. Joseph Su, MPH, PhD[2], Kevin Sexton, MD[1]

1. University of Arkansas for Medical Sciences, Little Rock, Arkansas, USA
2. University of Texas Southwestern Medical Center, Dallas, Texas, USA

BACKGROUND

- Musculoskeletal conditions impact nearly three-quarters of individuals aged 65 and older and half of those aged 18 and above.[1]
- Total Hip Arthroplasty (THA) is expected to grow by 284% by 2040, particularly among younger populations. [2]
- Approximately 98% of orthopedic devices, including many hip implants, primarily enter the market through the 510k pathway, requiring substantial equivalence in safety and effectiveness. [3]
  - Direct clinical comparative studies between different device types from various manufacturers are scarce due to 510K limitations.
- Real-world data sources, like claims, often lack granularity to identify manufacturers, specific devices, or critical procedure-related characteristics, hampering exploration of potential links between observed adverse events and specific attributes.[4]
- Electronic health records (EHR) offer insight into device usage and performance, enhanced by natural language processing (NLP) for extracting valuable information from clinical notes for post-market surveillance and comparative effectiveness studies.

OBJECTIVE

The objective is to identify device and procedure characteristics of THAs and examine the role of these characteristics on THA revision rates.

METHODS

- **Study Design:** Retrospective cohort analysis
- **Timepoint:** May 1, 2014, to December 31, 2021
- **Dataset:** Arkansas Clinical Data Repository (AR-CDR) - a standalone source of data pulled from cloud-based electronic health records from Arkansans seeking care at the University of Arkansas for Medical Sciences (UAMS)
- **Inclusion**
  - ≥ 18 years of age
  - Diagnoses with osteoarthritis
  - Undergoing primary THA (index date)
- **Exclusion:**
  - Patients undergoing concurrent hip implant removal or revision procedures
  - Missing Structured Data

Outcomes: Primary outcome: all-cause revision of THA

- **Statistical Analyses**:
  - Descriptive analyses conducted for baseline characteristics, including age, sex, race, tobacco use, and the calculated Elixhauser Comorbidity Index
  - Utilized Natural Language Processing (NLP) to identify procedure and device-related characteristics in unstructured data
    - Extracted unigrams, bigrams, trigrams, and tetragrams to identify reporting structures
  - Constructed two statistical models to predict THA revision outcomes:
    - One based on structured data
    - Another incorporating both structured and unstructured data
  - Employed the Random Forest algorithm to model both models
  - Performance evaluation conducted using metrics such as accuracy and AUC-ROC
  - Statistical tests (chi-squared, paired t-test) utilized to compare model performances.

RESULTS

N=1137	Frequency	Percentage
Device Specifics		
Acetabular Liner	192	16.9
Neutral Liner	269	23.7
Biolox Delta	537	47.2
Cluster Cup	269	23.7
Crown Cup	202	17.8
Femoral Head	687	60.4
Screw Bone	485	42.7
Manufacturer		0.0
Biomet	32	2.8
Djo	309	27.2
Exactech	665	58.5
Other	50	4.4
Smith and Nephew	119	10.5
Stryker	62	5.5
Procedure Specifics		0.0
Anesthesia		0.0
General	1022	89.9
Regional	66	5.8
Other	49	4.3
Side		0.0
Left	454	39.9
Right	544	47.8
Bilateral	139	12.2
Surgical Approach		
Anterior	160	14.1
Antero	401	35.3
Direct	295	25.9
Open	579	50.9
Surgical Extent		0.0
Simple	161	14.2
Other	976	85.8

- The final cohort consisted of 1,137 individuals undergoing primary THA.
  - 52.5% were women, 77.7% primarily white, and 52.9% aged 50-69 years.
  - Non-smokers comprised 56.5% of the cohort.
  - Common comorbidities included hypertension (44.2%), diabetes mellitus (13.4%), hypothyroidism (11.4%), and obesity (10.1%).
- Leading pre-operative diagnoses were arthritis (83.3%) and osteoarthritis (82.1%).
- 64 (5.6%) revision procedures were identified
  - Acetabular liners accounted for 59.4% of devices, mainly from Biomet (34.4%) and Stryker (59.4%).
  - Infections were referenced in 31.3% of revisions, with 18.8% on the right side.
- The random forest model predicting THA revision using structured data exclusively had an accuracy of 0.94 and AUC of 0.493 **(Table 2)**
- Incorporating both structured and unstructured data, the model achieved an accuracy of 0.94 and AUC of 0.516.
- The difference in accuracy and AUC between the two models was not statistically significant.

Table 1. Extracted Procedure and Device Related Characteristics

	Model 1: Structured + Unstructured Data	Model 2: Structured Data only	Difference
Accuracy	0.9429	0.9385	0.004
AUC	0.493	0.519	-0.002
Variable Importance	1. Smoking status 2. Age 3. Gender 4. Hypertension 5. Obesity 6. Other neurological disorders	1. Smoking status 2. Age 3. Gender 4. Surgical approach (open) 5. Anesthesia type 6. Manufacturer type (DJ Orthopedics and Exactech)	

Table 2. Summary of Fit Statistics for Random Forrest Models

DISCUSSION

- Unstructured data extraction provided insights into revision probability, highlighting manufacturer type's importance
- This insight streamlines decision-making processes, aiding regulatory actions
- EHRs offer rich insights often obscured in conventional databases like claims
- Real-world data from EHRs complements FDA's postmarket surveillance, overcoming spontaneous reporting limitations
- Integration into standardized note templates holds the potential for enhanced generalizability and active surveillance

Limitations:

- Validation of extraction method and clinical note assessment imperative
- Reliance on clinician-provided data in notes may lead to inconsistencies

Conclusions:

- The feasibility of extracting device and procedure-related characteristics was demonstrated.
- Caution is urged in clinical notes' utility, emphasizing the need for advanced NLP methods and more extensive datasets.
- Strengthening generalizability through diverse database representation and robust causal inference methodologies recommended

REFERENCES

1. United States Bone and Joint Initiative. The Burden of Musculoskeletal Diseases in the United States (BMUS): Prevalence, Societal and Economic Costs. Published 2011. Accessed June 19, 2020. https://www.boneandjointburden.org
2. Singh JA, Yu S, Chen L, Cleveland JD. Rates of Total Joint Replacement in the United States: Future Projections to 2020-2040 Using the National Inpatient Sample. *J Rheumatol*. 2019;46(9):1134-1140. doi:10.3899/jrheum.170990
3. Food and Drug Administration. 2nd Quarter FY 2016 Package MDUFA III (FY 2013-2017) Performance. Published 2016. Accessed November 3, 2019. https://www.fda.gov/media/98640/download
4. Krupka D, Wilson N, Reich A, Weissman J. The Post-Market Surveillance System For Implanted Devices Is Broken. Here's How CMS And The FDA Can Act Now To Fix It. Health Affairs Blog. Published 2021. https://www.healthaffairs.org/do/10.1377/forefront.20210420.717948