Sensors in Medical Devices – Regulatory Considerations

Orthopedic Surgical Manufacturers Association

April 2025
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Sensors in Medical Devices

History of Sensors in Medical Devices

- Long history of using sensors in medicine - the first modern sensors used in medicine were simple mechanical devices (e.g. thermometer, stethoscope, blood pressure cuff) beginning in the 1800s.
- In the early 20th century, the development of electronic sensors revolutionized the field of medicine. These sensors could measure a wider range of parameters, with greater accuracy and sensitivity.
  - Some of the most important early electronic sensors included the electrocardiogram (ECG), the electroencephalogram (EEG).
- In the 1950s and 1960s, the development of integrated circuits led to the miniaturization of sensors. This made it possible to develop implantable sensors, such as pacemakers.
- In recent years, there has been a rapid development of new sensor technologies, such as optical sensors, magnetic sensors, and electrochemical sensors.

Sensors in Medical Devices

We have reached another inflection point in medicine

- Increased use of smart technology and communication protocols (e.g. Bluetooth) has led to exponential increase in the amount of data that can be collected.
- Consumer electronics can monitor:
  - ECG
  - Heart rate
  - Sleep, activity
  - Blood oxygen
  - Hyrdration
- Use of AI allows us to analyze vast quantities of data

Use of sensors and associated data will:

- Allow for personalized medicine and tailoring treatment to the individual needs of each patient.
- Develop remote patient monitoring, which allows healthcare providers to monitor patients' vital signs and other health data from a distance which can increase access to healthcare
- Drive increased engagement with patients

Regulatory Considerations

- What is the intended use of the sensor?
  - Collecting data only
  - Collecting data with the intent to support clinical decision making
  - Using data to adjust therapy/device operation
- FDA may take issue with implied or assumed claims
  - Collecting data only – reasonable assumption of clinical impact?
  - FDA feedback became more conservative over time in previous examples in neuromod space (therapy adjustment)
- Moving from non-active to active implants raises new regulatory hurdles:
  - Radio reg
  - EMC
  - Battery considerations
  - RoHS/WEE
  - Software
  - Cybersecurity/privacy

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Intro to wearables in spine

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Wearables in Spine today

Wearables are non-invasive sensing devices worn by a person

- Can include smartphones
- Used in spine research for 20+ years

Two broad categories

1. Medical devices
2. Non-medical (consumer + research)

Increasing utilization of "consumer" devices (ex. BYOD)

Example evolution: ActiGraph wearables

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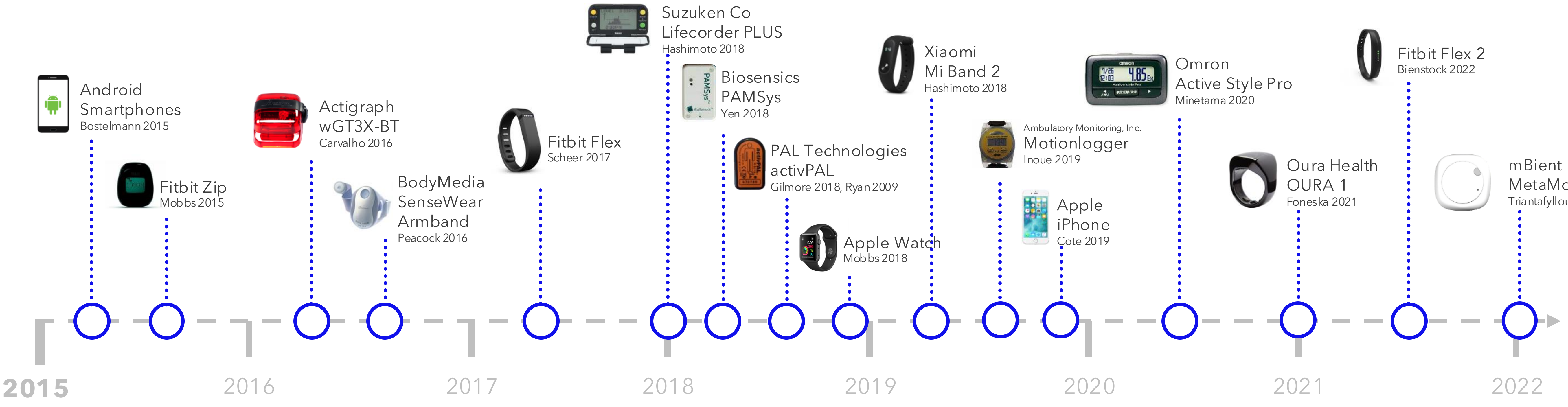
Many devices, similar data, similar sensors

Wearables in spine



Timeline of wearables used to quantify performance in spine patient populations. Dates represents the year of first publication in spine research that includes a particular device.

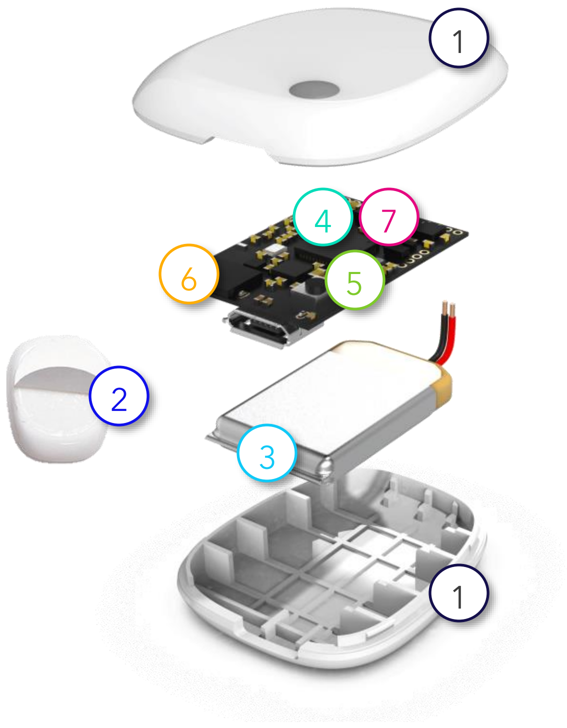
Haddas, Ram, et al. "Spine patient care with wearable medical technology: state-of-the-art, opportunities, and challenges: a systematic review." The Spine Journal 23.7 (2023): 929-944.

Similar sensors

Wearables in spine

Fitbit Flex

MetaMotionS



#	Component	Definition
1	**Housing**	Protective casing
2	**Attachment Mechanism**	Interfaces between the housing and the wearer
3	**Power Source**	Powers circuitry, generally rechargeable
4	**Microcontroller**	Coordinates the functions of all components
5	**Communications Module**	Transmits and receives data
6	**Memory**	Stores sensor data, device config, and settings
7	**Sensors**	Converts physical phenomena into measurable changes in electrical signals.
	Inertial Measurement Unit (IMU)	Measures acceleration, rotation rate, magnetic field
	Accelerometer (Acc)	Measure linear acceleration
	Photoplethysmograph (PPG)	Measure small variations in light intensity
	Barometer	Measure atmospheric pressure
	Gyroscope (Gyr)	Measure angular velocity (rate of rotation)
	Magnetometer (Mag)	Measure strength and direction of magnetic field
	Electrocardiograph (ECG)	Measures voltage fluctuations between electrodes

Similar sensors

Wearables in spine

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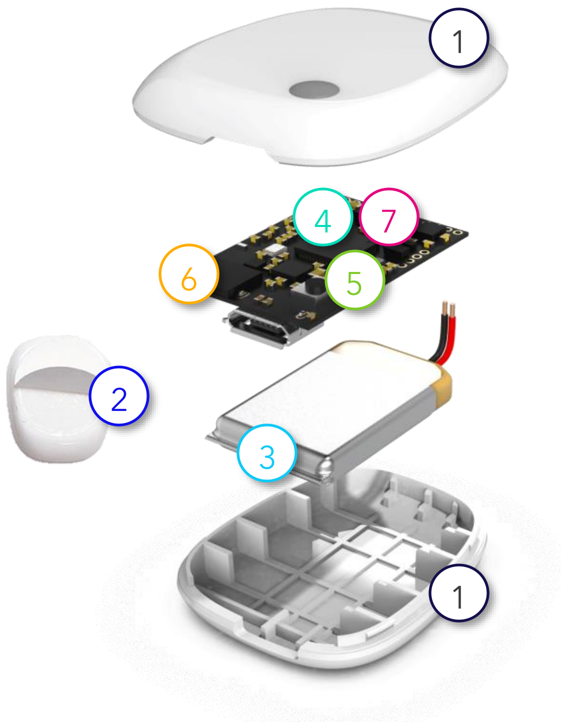

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Step count, activity level, posture

Heart rate, HRV, breathing rate

Similar data

Wearables in spine

Data you recognize

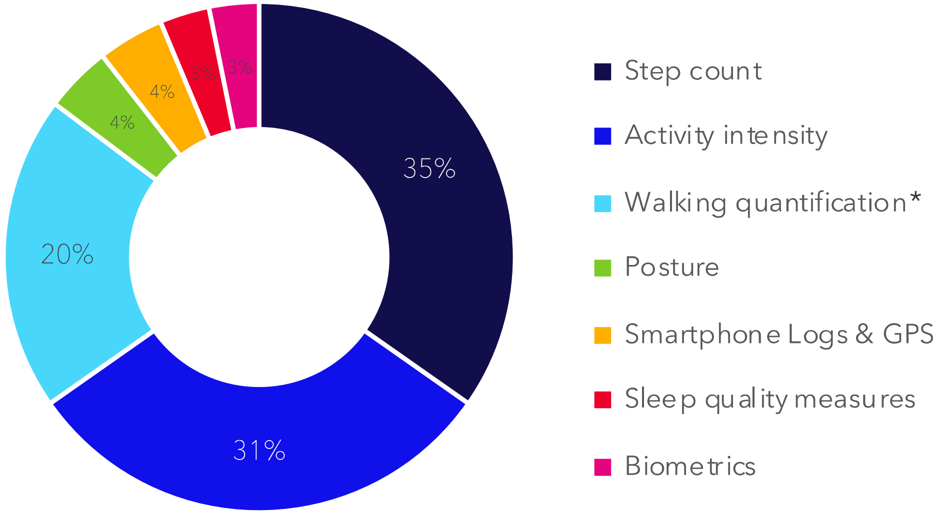
Most widely published data types:

1. Step count
2. Activity levels

Trend in research to measure longer with a patient's own device

- Digital phenotyping
- Apple/Android health data aggregation tools
  - Health Kit
  - Google Fit

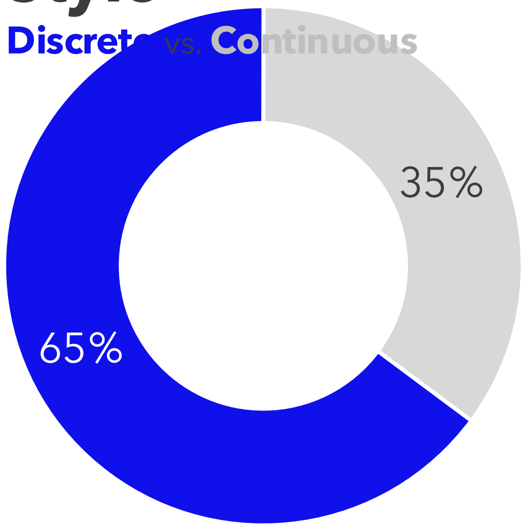
Wearable Metrics



*Walking quantification includes wearable-derived measurements of walking speed, distance, duration, number of walking bouts, and/or stairs climbed

Monitoring Style

Discrete vs. Continuous



	Discrete	Continuous
Average	6.5 days	266.8 days
Range	0 - 15	30 - 730

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Wearables offer unique insights

Wearables in spine

Why wearables?

Wearables

Patient-Reported Outcome Measures

Definition: Self-reported assessments of physical function recorded on validated surveys.

Examples: ODI, VAS, RMDQ, mJOA, ZCQ

Pros

- ✓ Captures patients' perceptions of their disease burden
- ✓ Extensively validated

Cons

- x Heavily influenced by mood, anxiety depression, cognition
- x Recall bias
- x Burdensome to administer and follow up

What a patient thinks they can do

Capacity

Definition: Measures of PF collected in a laboratory setting. Assesses a patient's maximum ability.

Examples: Gait lab assessment, TUG, 6MWT

Pros

- ✓ Measure changes in PF specific to a single pathology
- ✓ Thoroughly evaluate capacity

Cons

- x Expensive & time consuming to administer
- x Single point measurement
- x Hawthorne Effect

What a patient can do

Performance

Definition: Measures of PF collected in a patient's real-life environment. Assesses patient daily behavior.

Examples: Step count, activity count, HR variability

Pros

- ✓ High level of ecological validity
- ✓ Long measurement period yields more accurate representation

Cons

- x Primarily general measures of health; not specific to spine
- x Miss important ADLs
- x Requires user compliance

What a patient actually does

Smuck, Matthew, et al. "Objective measurement of function following lumbar spinal stenosis decompression reveals improved functional capacity with stagnant real-life physical activity." The Spine Journal 18.1 (2018): 15-21.

Thank you

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