# 4. Risk Analysis and Control Summary

## Risk Analysis

Risk depends on the prosthesis type, there are many different prosthesis types, we tried to generalize it to all types of prosthesis. Obviously, it also depends on the patients' health, the skill of the surgeon and other components. We separated the Risk Analysis into two parts, the risks of the prosthesis and the risks of the datalogger in the prosthesis.

**Prosthesis Part:**

- Mechanical loosening: crack of the implant, stress shielding, wear and tear, limited range of motion
- Infection: a bacterial infection due to a film on the implant or allergic reaction
- Dislocation: the femoral head leaves the liner of the implant
- Wear/osteolysis: gradual loss of material from the implant and the body's response to wear debris, involving the resorption of surrounding bone tissue
- Implant fracture: fracture of the implant itself related to the design of the implant
- Corrosion: happens at the metallic part of the prosthesis.
  Different types of corrosion: pitting, intragranular and galvanic
- Wrong angle choice: a more horizontal angle of the acetabular component resulted in a greater success rate of hip prosthesis
- Crack of the prosthesis because of less mechanical strength due to the addition of the datalogger

Qualitative severity levels

Semi-quantitative probability levels

| | Negligible | Minor | Serious | Critical | Catastrophic |
|---|---|---|---|---|---|
| Frequent | | | | Mechanical loosening | |
| Probable | | | | | infection |
| Occasional | | | dislocation | Wear/osteolysis, corrosion | Implant particle release |
| Remote | | | | Wrong angle choice | |
| Improbable | | | Implant fracture | | |

**Datalogger Part:**

- Magnetic / electrical fields: necessary for wireless communication
- Patient leakage current: not well isolated case / low energy = low risk
  Line voltage: not well isolated case / low energy = low risk
- Erroneous data transfer: broken antenna, defect electrical circuit, software issue
- Memory failure: defect electrical circuit, software issue
- Incorrect measurement: wrong calibration, software issue, leads into wrong interpretation of the data
- High temperature/Electric shock: defect in electric circuit, worst case coagulation of proteins

Qualitative severity levels

Semi-quantitative probability levels

| | Negligible | Minor | Serious | Critical | Catastrophic |
|---|---|---|---|---|---|
| Frequent | Magnetic fields, Electric fields | | | | |
| Probable | | | | | |
| Occasional | | | Incorrect measurement | | |
| Remote | Patient leakage current,<br>Line voltage | Erroneous data transfer,<br>Memory failure | | High temperature | |
| Improbable | | | | | |

<u>**Risk Mitigation Strategies:**</u>

### Mechanical Loosening:

- **Material Improvement:** Invest in durable materials with high fatigue resistance to minimize crack formation and wear. Follow the most used Combination of materials.
- **Optimized Design:** Ensure the prosthesis design considers stress distribution and range of motion, reducing stress shielding and allowing for natural movement.

### Infection:

- **Antimicrobial Coatings:** Implement coatings that prevent bacterial film formation on the implant's surface.
- **Sterile Procedures:** Ensure strict adherence to sterile surgical protocols during implantation to reduce the risk of infection.

### Dislocation:

- **Improved Fixation:** Enhance the design to improve stability, preventing the femoral head from dislocating from the liner.
- **Surgeon Training:** Educate surgeons on proper implant placement to minimize dislocation risks.

### Wear/Osteolysis:

- **Advanced Materials:** Utilize materials that generate minimal wear debris and are biocompatible.
- **Regular Monitoring:** Implement regular monitoring of wear rates and bone density to detect osteolysis early.

### Implant Fracture and Corrosion:

- **Material Selection:** Choose corrosion-resistant materials and regularly assess for potential corrosion risks.
- **Quality Control:** Rigorous testing and quality checks to ensure implant durability and resistance to fractures.

### Wrong Angle Choice:

- **Improved Surgical Guidance:** Use advanced imaging or guidance systems to assist surgeons in achieving optimal angles during implant placement.

**Crack because of Datalogger:**

- **Reduction of size:** Try to reduce the size of the datalogger as much as possible, to guarantee good mechanical properties of the prosthesis.
- **Reduced function:** Reduce the different function of the datalogger. It's not possible to create a datalogger with a lot of functions because with the functions the size of the datalogger increases. Reduce the function just to the most important features.

**Magnetic/Electrical Fields and Leakage Current:**

- **Isolation and Shielding:** Implement robust insulation and shielding to prevent interference with magnetic/electrical fields and reduce the risk of patient leakage current  datalogger is inside the prosthesis

**Data Transfer Errors, Memory Failure, Incorrect Measurement:**

- **Redundancy:** Incorporate redundant systems and fail-safes in data transfer, memory storage, and measurement calibration to minimize errors.
- **Regular Maintenance:** Schedule regular checks and maintenance to detect and rectify any potential issues promptly.

**High Temperature:**

- **Thermal Management:** Implement thermal controls in the electrical circuits to prevent overheating and potential protein coagulation.

**Overall:**

- **Comprehensive Testing:** Thoroughly test the prosthesis and datalogger system under various conditions to identify and rectify potential risks pre-market.
- **Continuous Monitoring:** Establish a post-market surveillance system to monitor the performance of the prostheses in real-world conditions and promptly address emerging issues.
- A lot of mechanical risks should be reduced by the data collection and processing.

**→ All risks are reduced to residual risks after the risk mitigation strategies!**

Risk**-benefit** assessment:

The benefits of a hip prosthesis with datalogger were performed in the description of the device. Here are some more benefits, applied to the risks of the hip prosthesis.

1. **Improved Monitoring:** The datalogger embedded in the hip prosthesis allows for continuous monitoring of various parameters related to the prosthesis and the patient's activity.
2. **Early Detection of Issues:** Real-time data collection helps in early identification of potential problems such as wear, stress, or abnormal movement, enabling timely intervention.
3. **Enhanced Patient Safety:** Continuous monitoring enhances patient safety by providing insights into the prosthesis performance, reducing risks associated with unnoticed complications.
4. **Personalized Rehabilitation:** Collected data can aid healthcare providers in customizing rehabilitation plans based on a patient's individual activity levels and prosthesis usage patterns.