

**Examination of microbial growth prevalence in musculoskeletal tissue and the effectiveness of the unique mechanical and chemical processing methods to ensure safe allografts.**

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# Introduction

**The use of human tissues for transplantation has the potential to cause unintentional disease transmission. The presence of bacteria in donor material and/or microbial contamination during processes pose a potential risk and is therefore a critical factor in Musculoskeletal (MS) tissue banking.**

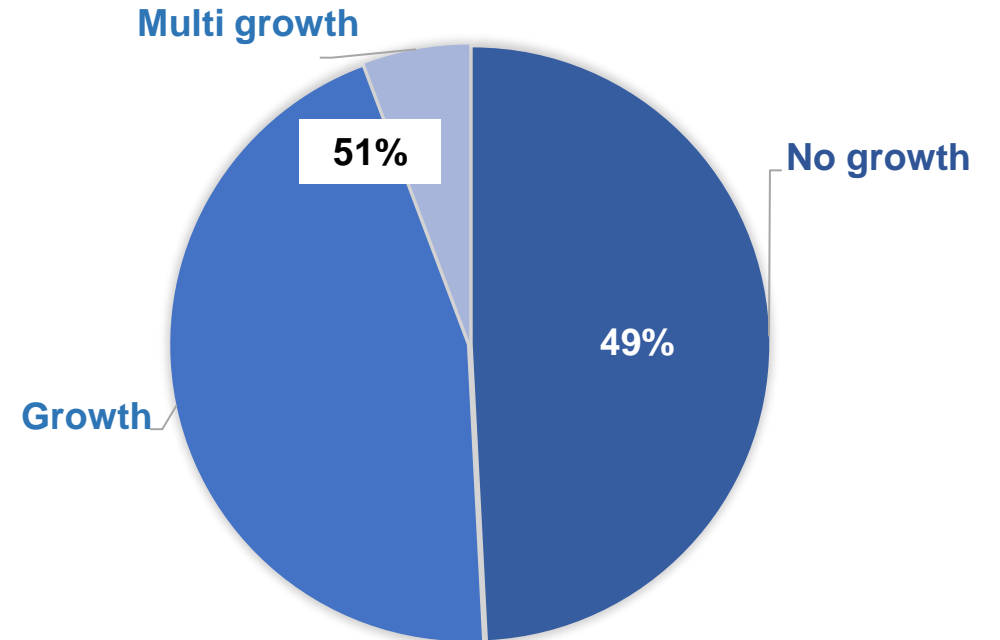
- This may further be exasperated by uncontrolled recovery environments, expanded death to recovery time and donor circumstance.
- The Vitanova team seek to understand the risks better and to identify potential methods to reduce the prevalence of bacterial growth in donor material.

# Method & Results

A sample of 122 consecutive deceased Musculoskeletal donors were examined to determine the prevalence of microbial growth and identify the most common species

- Soft tissue samples are obtained during the donor recovery process from the rectus femoris muscle against the femur bone
- The sample is placed in a Thioglycolate medium and tested by an external pathology laboratory for aerobic and anaerobic microbial growth

PREVALANCE OF MICROBIAL GROWTH

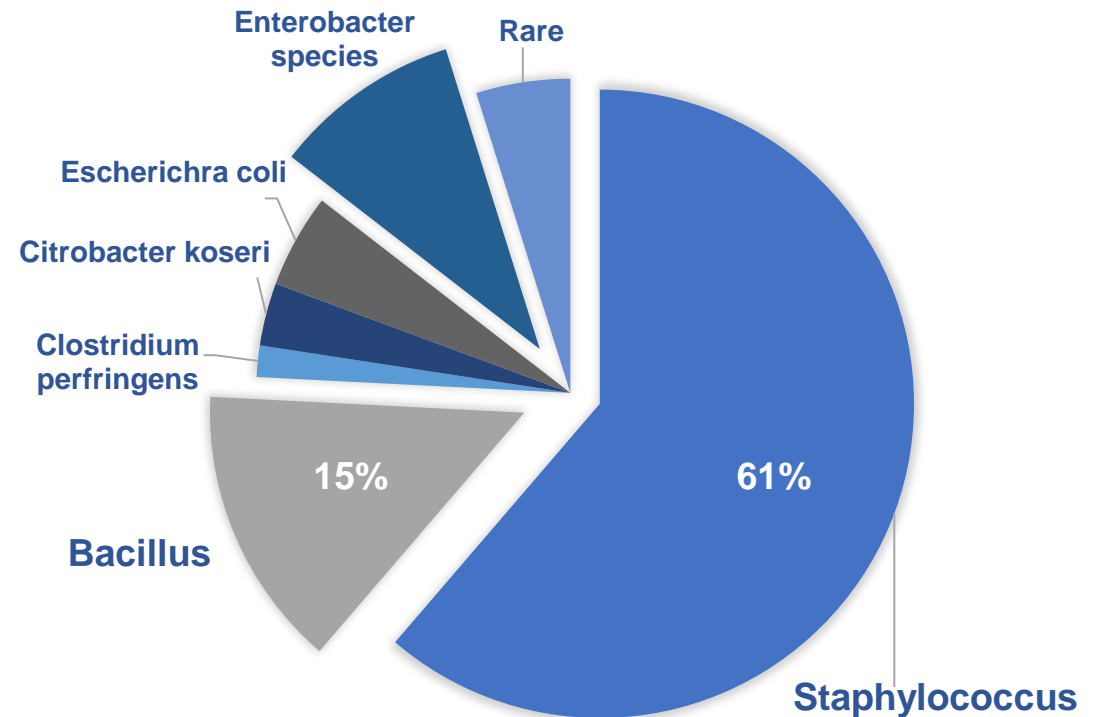


In 7 cases (6%) more than one bacteria was identified

# Method & Results

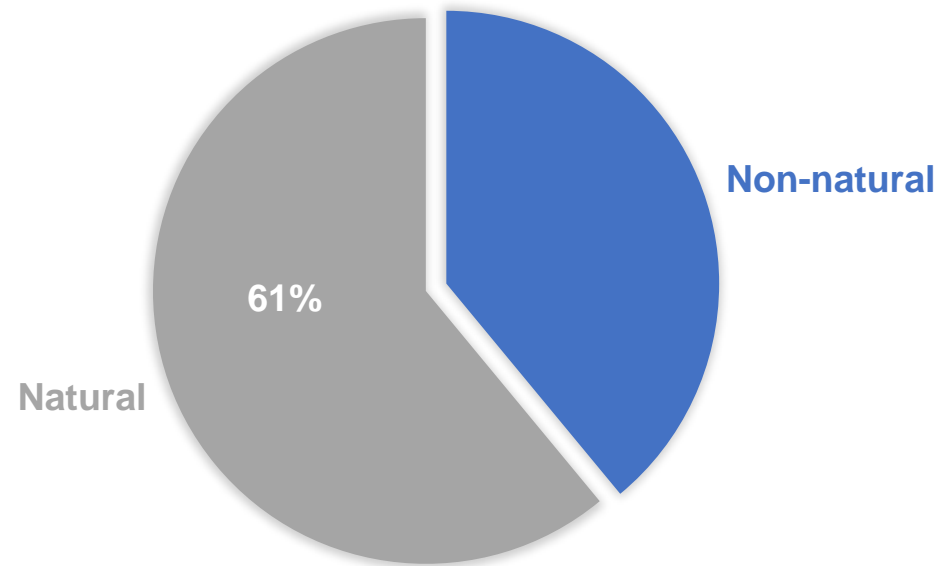
The most common species identified was Staphylococcus – consistent with several study results in tissue banks from other parts of the world.

- Most bacteria identified occurs naturally on the human skin, in the mouth and nose, in soil & water
- Not possible to determine which may be harmful and which not



# Donor circumstance

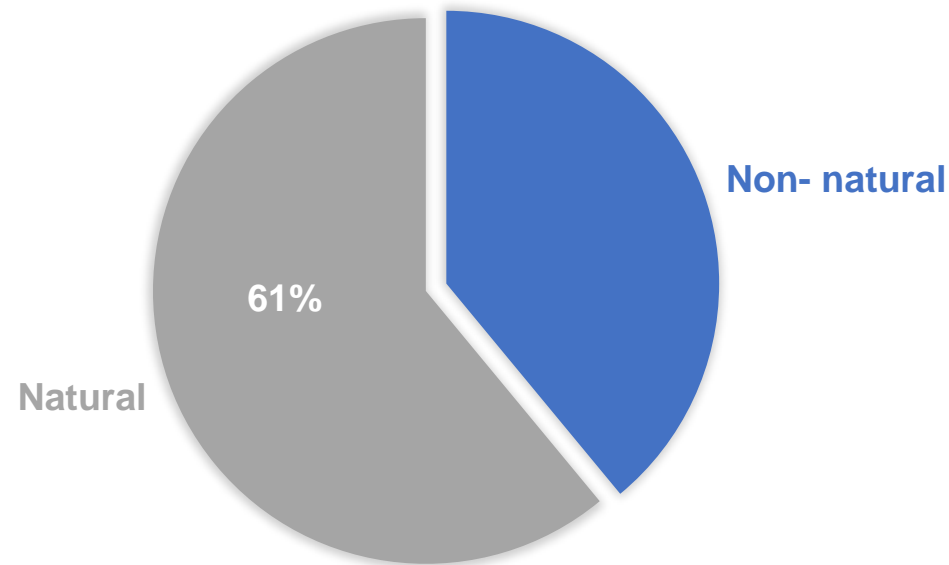
POSITIVE GROWTH AS RELATED TO CAUSE OF DEATH



54% Neurological cause of death  
23% Cardiac related death  
11% Respiratory related death  
6% Death caused by brain tumour  
3% Abdominal and Diabetes respectively

# Donor circumstance

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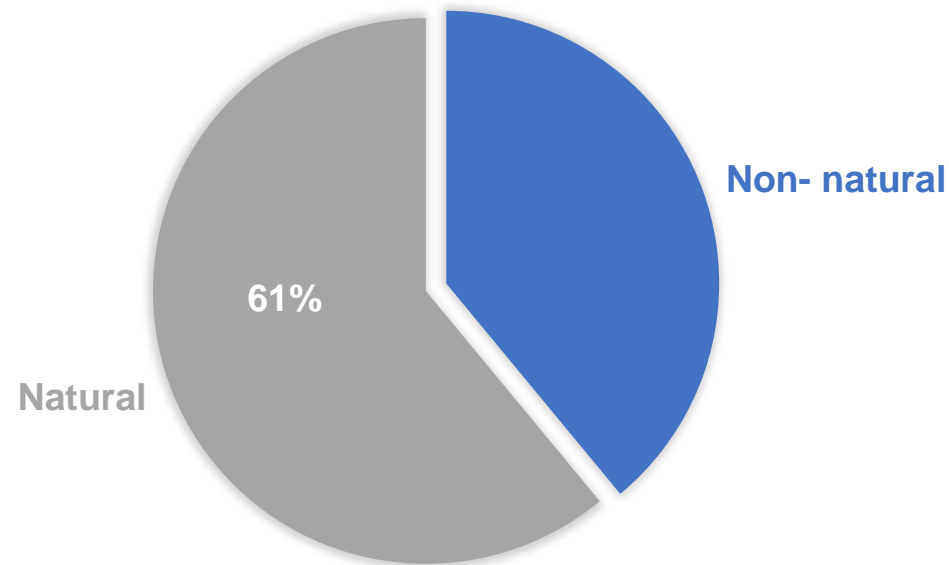


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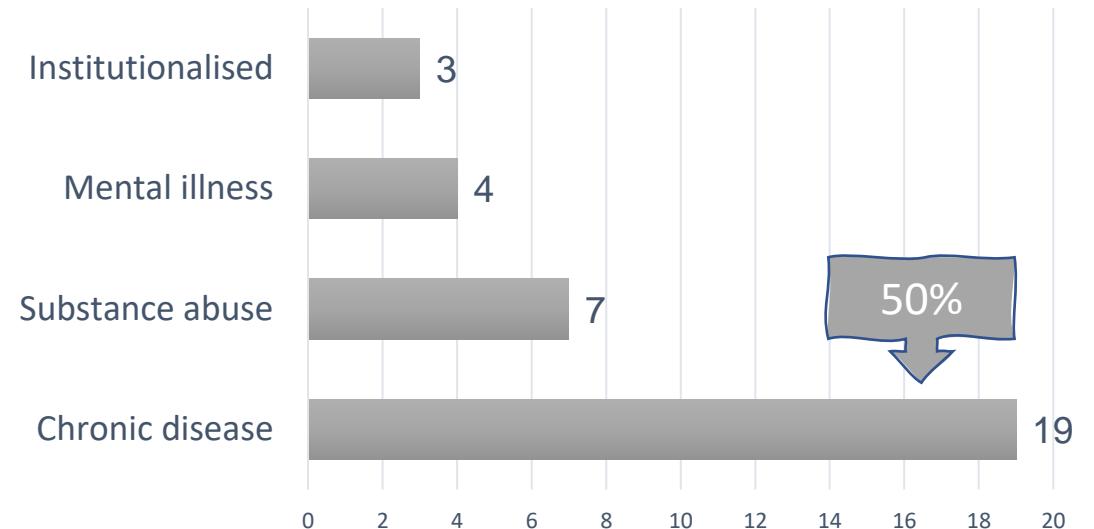
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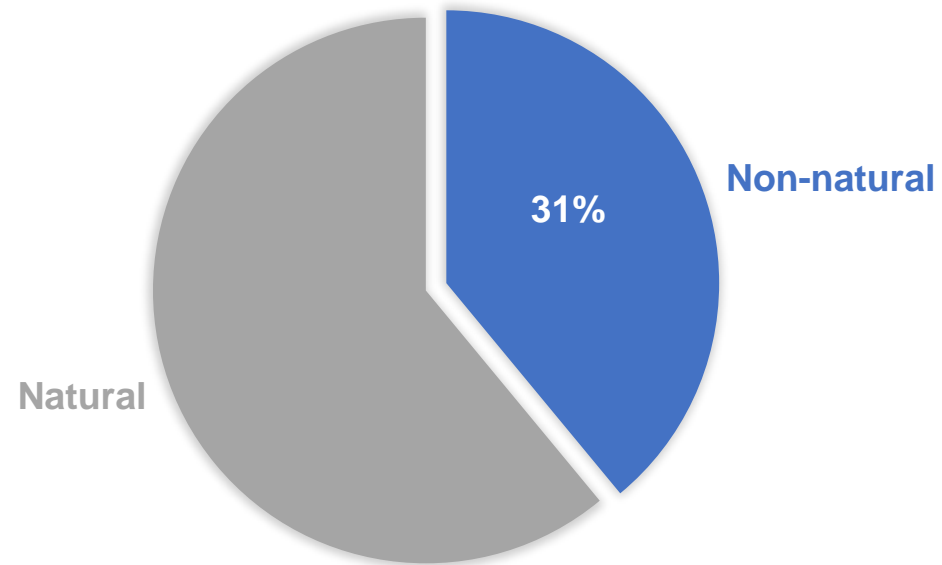
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MEDICAL / OTHER CONDITIONS

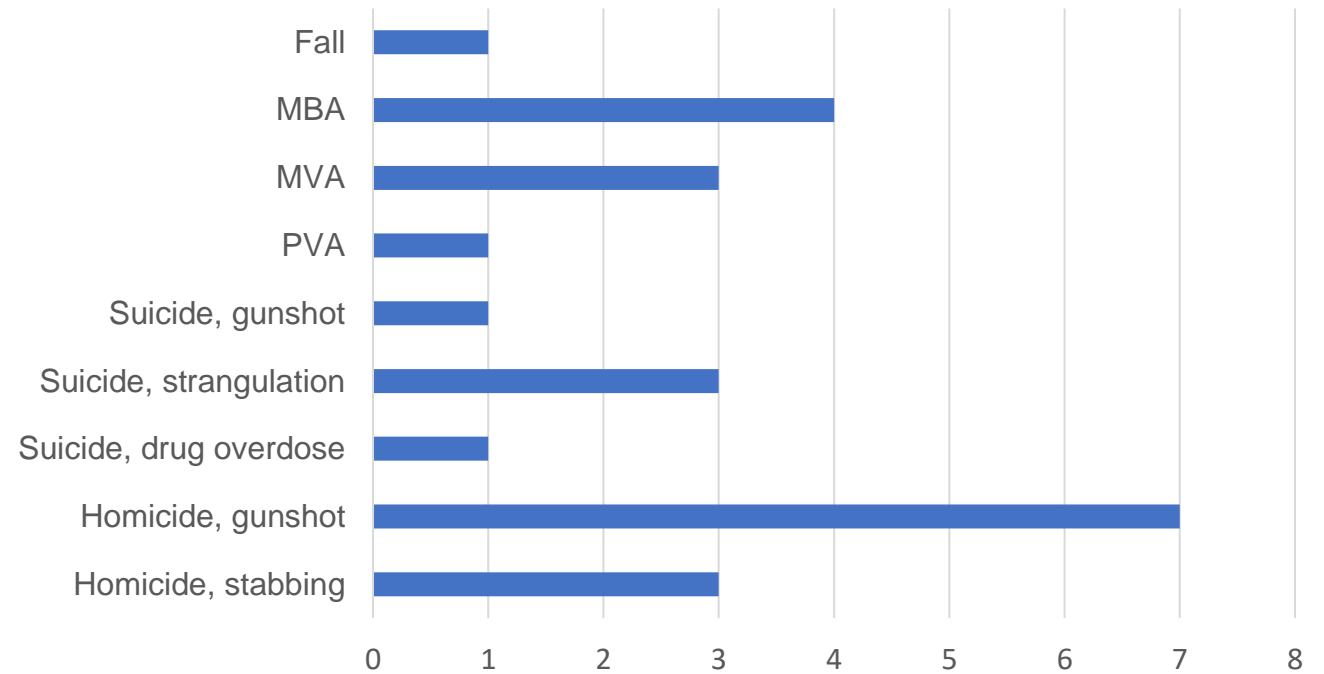


# Donor circumstance

POSITIVE GROWTH AS RELATED TO CAUSE OF DEATH



NON-NATURAL CAUSES OF DEATH





# Donor circumstance

- Donor recovery took place in both forensic pathology facilities and funeral homes, of which the conditions are varied
- Recovery took place between 1 & 6 days after death but mostly on day 3
- Clear indication that there was less growth detected in donors recovered on day 1 & 2
- Donors recovered on day 5 had the highest prevalence of growth
- Due to small sample per day, these findings may not be considered 100% conclusive

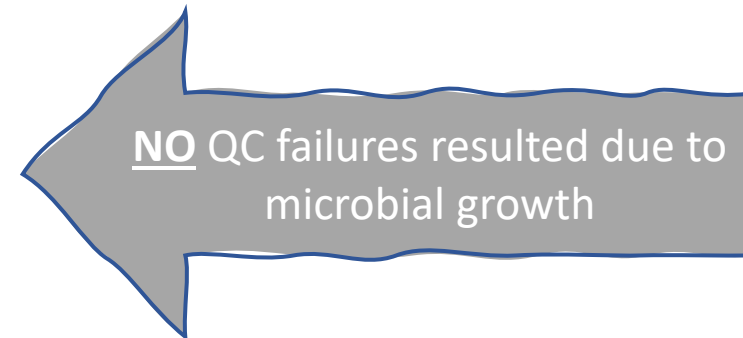
Days after death	Donors Recovered	% GROWTH
1	3	33%
2	12	44%
3	20	54%
4	6	43%
5	17	63%
6	4	50%

# Method & Results

- A bone sample of each donor with growth is subjected to both mechanical and chemical processing
- The process includes:
  - Cutting
  - High pressure water wash
  - Centrifugation
  - Sonication
  - Chemical processing
    - No antibiotic treatment
- The sample is then submitted for another round of aerobic and anaerobic microbial testing at an external pathology laboratory
- Only donor material with sample results which indicate “no growth” are released for production processing

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NO QC failures resulted due to microbial growth

# Conclusion

- It cannot be determined how many growth results were due to environmental contamination during recovery processes or during sample testing or whether the donor circumstance caused the bacterial growth
- Due to low donor numbers, and since a significant number of donors are recovered on day 3 – 5, we cannot eliminate donor recovery after day 2
- The high prevalence of bacterial growth reiterates the need for stringent mechanical and chemical processing protocols as well as terminal sterilisation to ensure allograft products that comply to a minimum sterility level and are safe for transplantation