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Coordinate measurements for prosthesis wear evaluation:
Validation of a CMM based method for measurement of wear volume in hip joint prosthetic components

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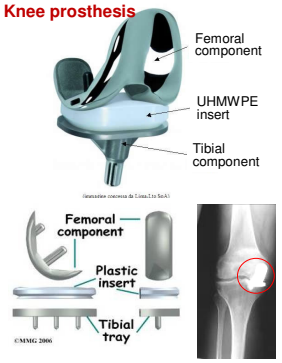
Outline

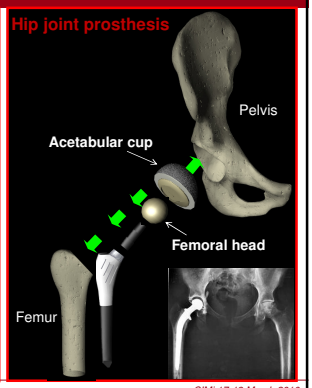
- State of the art in the measurement of wear of hip-joint prosthetic components
- Limitations of CMM-based wear volume measurement methods: unknown uncertainty, no validation
- Uncertainty evaluation of volumetric measurements of wear using a CMM
- Optimization of CMM probing strategy for accuracy improvement
- Comparison with gravimetric measurements for validation of CMM method
- Conclusions

Orthopaedic replacements

Knee prosthesis



Hip joint prosthesis



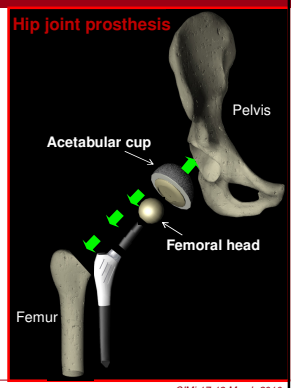
Facts on hip joint prosthesis

Hip replacement:

- Is currently the most successful orthopedic operation, with 97% of patients reporting improved outcome
- 800 000 replacements per year worldwide
- Replacement cost : 40000 $ or more (in USA)
- Materials:
  - Femoral heads: **ceramic, metal**
  - Acetabular cups: **ceramic, metal, UHMWPE**
- During the first 10 years, less than 10% require revision surgery

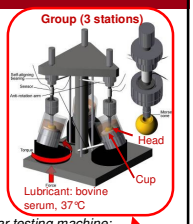
[Affatato et al., Trib. Int., 2008]
[Bills et al., Wear, 2007]

Hip joint prosthesis



Wear testing of prosthetic components

- Preclinical evaluation of prostheses
- Controlled loading and relative motion
- Environment simulates physiological conditions
- Test cycles: 0.5×10^6, 1×10^6 , 1.5×10^6 , 2×10^6 ...
- Wear measurement: gravimetric method
- Testing procedure: ISO 14242-1:2002



Knee joint wear testing machine:

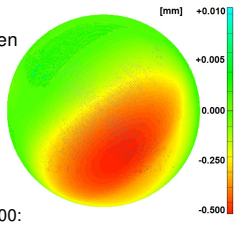
Hip joint wear testing machine:

Wear measurement: gravimetric method

- Gravimetric method is the standard measurement practice adopted by orthopedic industry for development of new joints and materials
- ISO 14242-2:2000 defines a detailed gravimetric measurement procedure (e.g. requires a balance with 0.1mg accuracy)
- Main limitations:
  - Gravimetric method does not provide information on change of form of the wear surface
  - Not helpful in case of clinically explanted prosthesis
  - Other damages not involving material loss (e.g. plastic deformations) are not measurable

Wear volume measurement: CMM method

- CMM measurements have recently been used as an alternative to gravimetric method.
- Limitations at state of the art:
  - Measurement uncertainty has not been evaluated
  - Typical points spacing: 0.5x0.5 or 1x1 mm

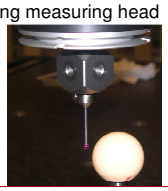


- CMM use is allowed by ISO 14242-2:2000:
  - "maximum axial-position error" of: $D = 4 + 4L \times 10^{-6}$ [D in µm, L in m] → 6.5 mm³
  - "relocation of the test specimen does not affect the measured volume by more than 0,05 %" → 4.3 mm³
  - "points spacing no greater than 1 mm" → 16 mm³

Volume errors on a 32 mm hemisphere:

Experimental investigation

- Measured specimens:
  - 30 femoral heads with *in-vivo* or *in-vitro* wear
  - 9 new femoral heads measured before and after wear for comparison with gravimetric method
  - 1 calibrated sphere D=30mm (U_D= 0.2µm, Roundness: 0.1µm)
- CMM: Zeiss Prismo Vast 7, with scanning measuring head
- CMM performance from specific tests on 30mm calibrated sphere:
  - "Scanning probing error" on specific path with over 15 000 points: within ± 1 µm
  - Maximum error on diameter measurement: within ± 1 µm



Main uncertainty components

[**ISO 14253-2** Procedure for Uncertainty MAnagement – PUMA]

- CMM probing uncertainty
- Points spacing
- Specific alignment for worn heads
- Surface roughness
- Software for volume calculation

Main uncertainty components

- CMM probing uncertainty 1 µm ⇒ **U_{CMM} = 1.6 mm³**
- Points spacing 0.3 x 0.3 mm ⇐ **$U_{spacing}$= 1.5 mm³**

Points spacing	$U_{spacing}$	Nr. of points / hemisphere	Scanning path length	Scanning time
0.1 x 0.1 mm	0.16 mm³	321699 points	16085 mm	89 min.
0.3 x 0.3 mm	1.5 mm³	17872 points	5362 mm	30 min.
0.5 x 0.5 mm	4.0 mm³	6434 points	3217 mm	18 min.
1 x 1 mm	16 mm³	1608 points	1608 mm	9 min.

Main uncertainty components

- CMM probing uncertainty 1 µm ⇒ **U_{CMM} = 1.6 mm³**
- Points spacing 0.3 x 0.3 mm ⇐ **$U_{spacing}$= 1.5 mm³**
- Specific alignment for worn heads **$U_{s.align.}$ = 1.0 mm³**
- Surface roughness **$U_{rough.}$ = 0.5 mm³**
- Software for volume calculation **$U_{software}$= 0.3 mm³**

Expanded combined uncertainty for CMM measurement of wear volume: **$U_{volume,CMM}$ = 2.5 mm³**

Validation: comparison to gravimetric method

- Validation experiments: CMM and gravimetric measurements on 9 ceramic femoral heads

Procedure:

1. Gravimetric measurement of unworn specimens
2. CMM measurement of unworn specimens
3. Controlled wear of specimens
4. Gravimetric measurement of worn specimens
5. CMM measurement of worn specimens
6. Comparison of Gravimetric and CMM results, keeping into account the material density: *Density = 3.98 ± 0.02 mg/mm³*

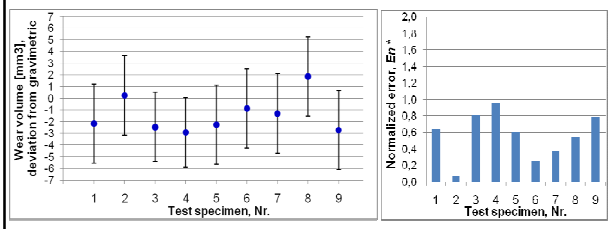
Validation: comparison to gravimetric method

- Validation experiments: CMM and gravimetric measurements on 9 ceramic femoral heads

Specimen	Nominal diameter [mm]	Wear volume, CMM [mm³]	U Wear volume, CMM [mm³]	Wear volume, Gravimetric [mm³]	U Wear volume, Gravimetric [mm³]
Head #1	32	**106.1**	3.4	**108.3**	0.55
Head #2	32	**142.5**	3.4	**142.2**	0.72
Head #3	28	**81.3**	3.0	**83.7**	0.42
Head #4	28	**124.2**	3.0	**127.1**	0.64
Head #5	32	**301.7**	3.4	**303.9**	1.5
Head #6	32	**233.2**	3.4	**234.1**	1.2
Head #7	32	**203.0**	3.4	**204.3**	1.0
Head #8	32	**111.5**	3.4	**109.7**	0.55
Head #9	32	**109.8**	3.4	**112.5**	0.57

Validation: comparison with gravimetric method

- Validation experiments: CMM and gravimetric measurements on 9 ceramic femoral heads



*Normalized error: $E_N = \frac{|Value(CMM) - Value(gravimetric)|}{\sqrt{U(CMM)^2 + U(gravimetric)^2}}$

Conclusions

- Uncertainty of CMM wear volume measurements of hip prosthesis has been calculated
- Evaluation of the main uncertainty components has allowed the optimization of CMM probing path
- Validation of CMM wear volume measurements has been achieved through comparison with gravimetric measurements
- Future developments:
  - Same approach can be used to validate measurement of other prosthesis geometries (e.g. knee prosthesis)
  - Validation of other measurement methods, e.g. based on Optical or CT scanning

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Thank you for your attention!