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The Functional Outcome of Zimmer Biomet's Nexgen Total Knee Arthroplasty as Compared with Healthy Older Adults

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Disclosures

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Professor Biant also receives payment for educational events from Medacta International, and is President of the British Association for Surgery of the Knee, an honorary Fellow of the UK Biological Knee Society, and is on the committee for the International Cartilage Regeneration and Joint Preservation Society (ICRS). She is also a consultant for Bioventus and Contura and is on the Editorial Board for JISAKOS.

Dr Tawy is the Manager of the ICRS Patient Registry.

Mr McNicholas is President of the UK Biological Knee Society and Chair of ICRS Patient Registry.

Background

- **Osteoarthritis (OA)** of the knee causes severe **pain** and **limits joint function** and mobility[1].
- End-stage OA is primarily treated with **total knee arthroplasty** (TKA).
- **20%** of TKA patients are **unhappy** after a TKA[2].
- Dissatisfaction is often due to **poor post-operative function and instability**, particularly during midflexion[3].

Zimmer-Biomet NexGen TKA

- In 2021, Zimmer Biomet's high-flexion NexGen TKA was the most revised knee implant in the UK (183,105)[4].
- The revisions were associated with instability[4].
- In 2022, Zimmer-Biomet recalled the NexGen Stemmed Option Tibial Component when combined with the LPS Flex or LPS Flex GSF femoral components due to their revision rates[5].

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Aim

- Compare the functional outcome of patients with a high-flexion design TKA to healthy age-matched controls.

Purpose

- Determine whether knee biomechanics is restored post-operatively in patients with a high-flexion design TKA .

Methods - Recruitment

Patient cohort invited by letter

Inclusion criteria:

- Underwent TKA at least one year previously
- Implanted with a primary Zimmer Biomet NexGen TKA

Exclusion criteria:

- Had further orthopaedic surgery within the last year (e.g. contralateral TKA)

Healthy older adults recruited through advertisements at local sports clubs

Inclusion criteria:

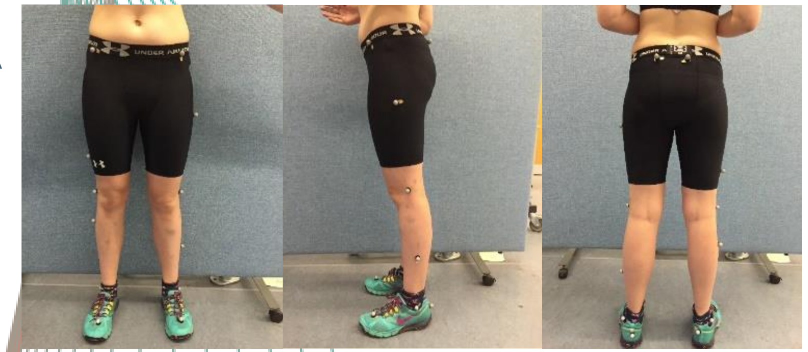
- Aged 55-80 on the day of assessment
- Able bodied
- Normal lower limb function
- Able to perform a deep knee bend and walk unaided for ≥5 minutes

Exclusion criteria:

- Musculoskeletal, neurological or sensory deficit
- Knee pain
- Diagnosis of hip, knee or ankle osteoarthritis

Methods – Data Collection

A



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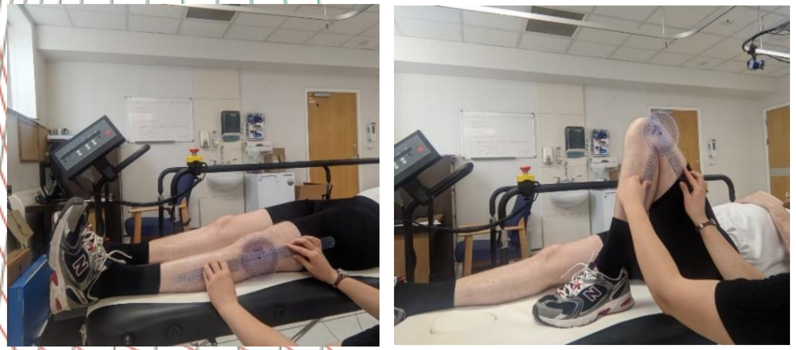

C

- 1-hour appointment at a local physiotherapy clinic
- Informed consent was obtained (University of Manchester Research Ethics Committee 2: 2021-7967-18678)
- Gait analyses with a motion capture system: Pluto MED treadmill & 8 Vicon Bonita cameras (A)
  - PluginGait biomechanical model utilised
  - Participants walked for 2 minutes on level ground and 2 minutes on 7.5º decline
  - Walking speed was self-selected
  - Data processed in Vicon Nexus software and post-processed in Matlab software
- Bilateral knee range of motion quantified with a goniometer (B)
- Anterior-posterior dynamic stability of the knee measured with a motorised arthrometer (C) (GNRB, Genourob, Laval)

Methods – Statistical Analyses

Sample Size

- **Primary Outcome:** Knee flexion angle at toe off; a time at which the knee is in midflexion.
- With 90% power and α =0.017, a difference of 5°, and a standard deviation of 4.25°, the required sample size was **21 knees per cohort**.

Analyses

- Normality of data determined with Shapiro-Wilk tests
- Intra-group analyses: Independent t-tests were performed if data were normative and Mann-Whitney tests if not.
- Intra-group analyses: Paired t-tests were performed if data were normative and Wilcoxon signed-rank tests if not.
- Level of significance: **α = 0.05**.

Results – Demographics

- 20 patients with 23 TKRs and 23 older adult volunteers took part.
- The patient cohort was older and heavier than the control group.

Variable	Patient Cohort (mean ± standard deviation)	Healthy Volunteers (mean ± standard deviation)	p-value
Sex (Male:Female)	11:9	10:13	-
Age (years)	71.3±7.4	62.9±4.8	**0.001***
Mass (kg)	88.0±19.7	73.1±12.2	**0.005***
Height (m)	1.69±0.11	1.67±0.08	0.550
BMI (m)	30.4±4.6	25.9±3.6	**0.001***
Side of TKA (Left:Right)	11:12	N/A	-
Years since TKA	9.8±3.1	N/A	-

Results – Gait Biomechanics

Spatio-temporal Parameters

- The control group walked faster and had longer stride lengths than the patient group (see table).

Gait Variable	Level Walking (Mean±SD)			Downhill Walking (Mean±SD)		
	Control	TKA	p-value	Control	TKA	p-value
Walking Speed (km/h)	3.05±0.80	2.48±0.57	**0.021***	2.86±0.82	2.33±0.54	**0.043***
Stride Length (m)	1.00±0.15	0.74±0.20	**<0.001***	0.95±0.18	0.77±0.17	**0.002***
Cadence (steps/min)	109.3±17.3	114.2±33.3	0.543	110.9±26.0	104.2±25.6	0.162

Kinematics

- Patients failed to exhibit an initial peak during the loading response phase of gait (see figure*)
- Level Gait: There was a statistically significant difference between the operative knee and the right knee of the control group during toe off (p = 0.042).
- Downhill Gait: The operative knee performed worse than both knees of control group during swing (p = 0.003, p = 0.009) and in maximal extension (p = 0.014, p = 0.028).

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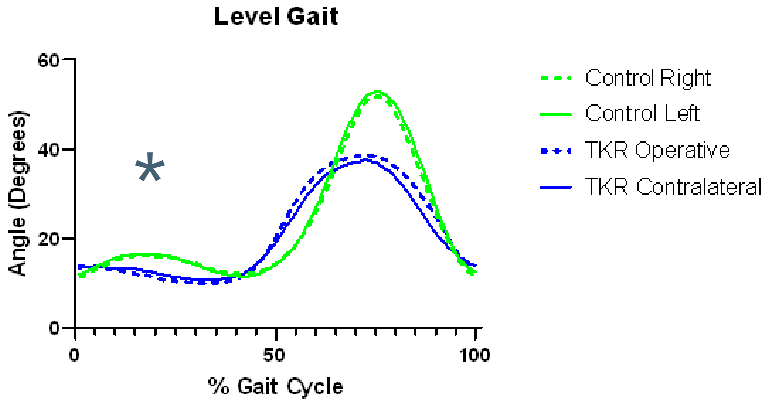

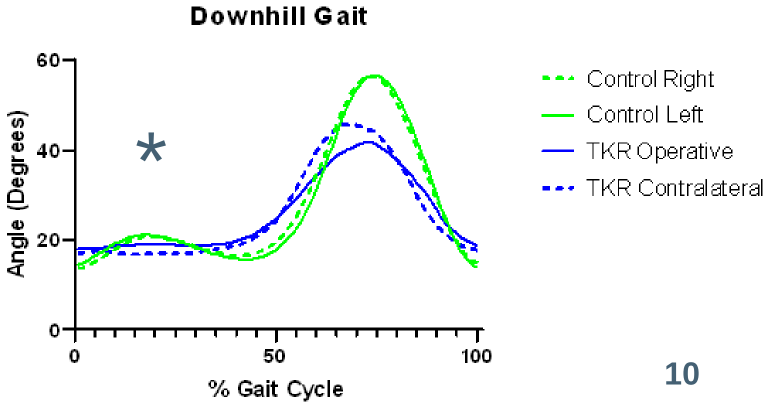

Results – Knee Range of Motion & Stability

	Flexion (mean±SD°)		Extension (mean±SD°)		Range of Motion (mean±SD°)	
Control	**Left**	**Right**	**Left**	**Right**	**Left**	**Right**
Active	138.6±7.9	136.4±8.4	1.4±1.7	1.2±1.4	137.2±8.8	135.2±9.2
Passive	141.0±7.3	139.3±7.7	0.8±1.5	0.8±1.4	140.2±8.0	138.5±8.4
	Flexion (mean±SD°)		**Extension (mean±SD°)**		**Range of Motion (mean±SD°)**	
TKA	**Operative**	**Contralateral**	**Operative**	**Contralateral**	**Operative**	**Contralateral**
Active	119.6±12.0	118.6±11.0	2.1±2.0	2.6±1.9	117.5±11.9	116.0±10.8
Passive	121.±12.2	121.3±10.7	1.0±2.2	1.5±1.9	120.0±12.0	119.8±10.7

Knee Range of Motion (RoM)

- Maximal knee flexion and RoM of patient knees were statistically and clinically (>5º) poorer under passive and active conditions (p < 0.0001 for all conditions).
- No differences between the operative knee of patients and either knee of controls in extension (p = 0.181 & 0.774 for left knee and p = 0.075 & 0.812 for right under active and passive conditions).

Knee Stability

- Control laxities: 4.7±1.6mm on the left, and 4.8±1.5mm on the right (difference of 0.8±0.9mm).
- TKA laxities: 4.9±2.4mm in the operative knee, and 5.5±2.4mm in the contralateral knee (0.6±1.4mm).
- There were no statistical differences between the groups (p > 0.05 for all conditions).

Discussion & Conclusion

- Knee flexion angle at toe off differed between groups during level walking.
  - The implant may impact the knee's movement pattern during midflexion.
- Knee extension was restored following TKA during level gait and in RoM exercises.
- Knee flexion range had reduced since intra-operative measurements (130.9±5.8°)
  - This implies the high flexion design envelope of this implant was not utilised long-term.
- Limitations in knee flexion extended to gait pathologies.
  - This is consistent with previous research[6,7].
  - Differences may be age-related and not implant-related, as the control group were significantly younger.
  - This is corroborated by the fact that the contralateral knee in the TKA group also had poorer knee flexion.
- Strength and conditioning exercises may be required long after TKA to reduce the loading on the knee and improve flexion range.
- There were no statistical differences between stability of the operative knee and the knees of the control group.
  - The anterior-posterior translation of the implant was thus akin to a natural knee[8,9].

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