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Follow-Up after Primary TKA with the Sigma PFC implant in Patients with Metal Allergy or Hypersensitivity

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Presenter disclosure Information

Natalie Mengis disclosed no conflict of interest

Consultant: OPED

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Introduction

Metal allergy or **hypersensitivity** is a controversial topic in total knee arthroplasty (TKA).

The existing data gives **no clear recommendation** whether a hypoallergenic implant is favorable compared to the standard metal alloys (cobalt, nickel, chromium).

The **aim** of this study was to **objectify the subjectively good postoperative results** of TKA in patients with a metal allergy or hypersensitivity and thus to be able to give an **orientation concerning the treatment with standard implants** in this patient collective.



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Material and Methods



167 patients (182 knees) with known metal allergy/hypersensitivity to nickel, cobalt or chromium were treated with a cemented TKA using the Sigma PFC implant (DepuySynthes, Umkirch, Germany) between January 2013 and March 2020 in our institute.

134 patients could be enrolled into the trial. Clinical outcome was assessed comparing the NRS scale, the UCLA score and the WOMAC score, pre- and postoperatively. Furthermore, the Oxford Knee Score, the EQ5D3L and the revision rate was enquired.

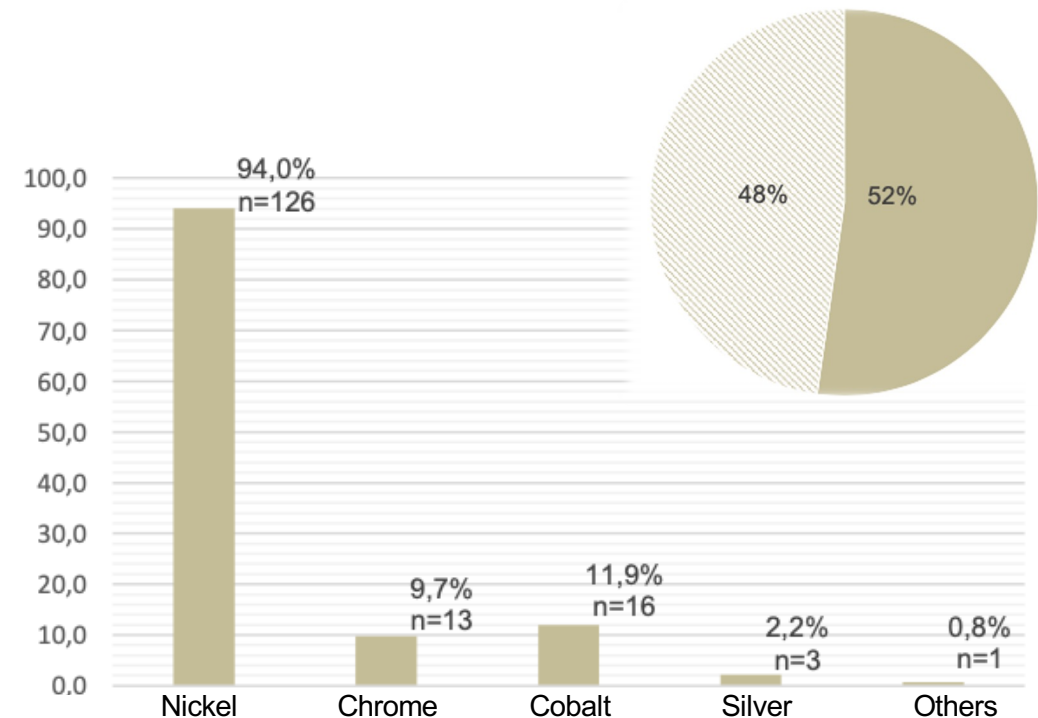
The mean follow-up was 36.34 ± 22.28 (4.00-87.00) months.

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Material and Methods

The patient collective consisted of 113 female patients with an average age of 61.5 ± 8.75 (42-83) years and 21 male patients with an average age of 59 ± 5.56 (49-71) years.

52 % of the included patients (n=70) had a **proven metal allergy** based on cutaneous and in-vitro testing. In the remaining **48 %** (n=64), the metal allergy/hypersensitivity was **suspected due to skin reaction** to metallic objects observed by patients.



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Results

Patient satisfaction on a numeric rating scale (NRS 0-10) showed **good and very good results** after TKA with a mean of 8 ± 2 .

The queried **pain level decreased significantly** from $8,18 \pm 1,34$ pre- to $1,72 \pm 2,02$ postoperatively ($p > 0,0001$).

The **UCLA and WOMAC** score showed a **similar positive performance** and improved to $6,28 \pm 1,37$ ($3,38 \pm 1,40$ preoperative) and $83,92 \pm 18,79$ ($41,62 \pm 16,64$ preoperative) respectively ($p > 0,0001$).

The mean **Oxford Knee Score** was $39,88 \pm 7,19$ and the **EQ5D** showed **good results** in all 5 dimensions of the questionnaire after surgery.





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Results

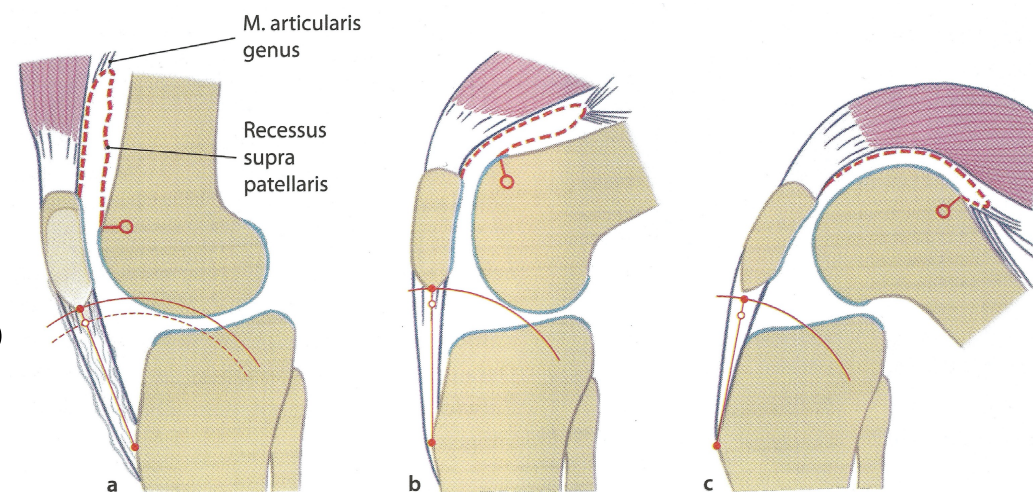
A total of **10 patients** needed **revision after TKA**.

Brisement force was performed in **5 patients**,

3 patients were treated with **open arthrolysis and inlay replacement** and further

2 patients underwent **synovectomy and biopsy** (no infection detected).

Implant loosening has not been observed during the follow-up.



Jagodzinski, M., Müller, W. (2016). Die postoperative Rehabilitation. In: Das Knie. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-45001-3_7

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Conclusion

The results of this study show **similar outcomes compared to the non-allergic population** displayed in the current literature after standard TKA, in **short- and mid-term follow up**.

The **use of a standard implant** with a cobalt, nickel, chromium alloy **does not seem to lead to inferior results** in patients with known metal allergy/hypersensitivity compared to the general population.

The non-inferiority theory of standard implants to hypoallergenic implants should be investigated in further studies comparing these implants.





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