# ACCURATE ALIGNMENT CORRECTION AND SATISFACTORY CLINICAL OUTCOMES AFTER PERSONALISED VALGUS HIGH TIBIAL OSTEOTOMY WITH A NEW PATIENT-SPECIFIC INSTRUMENTATION: A FIRST IN MAN STUDY

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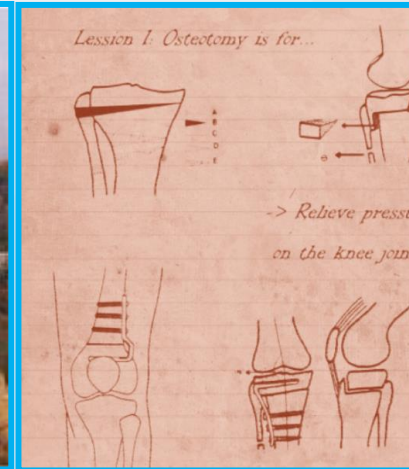
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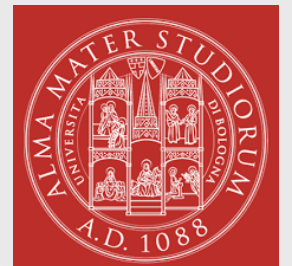
DISCLOSURE

S.Z.:

DePuy and Smith&Nephew   consultant

OTHER AUTHORS:

Nothing to disclose

AIMS

TO ASSESS:

- ✓ **ACCURACY** OF THE CORRECTION OF CORONAL ALLIGNMENT (**HKA**)

- ✓ **ACCURACY** OF THE CORRECTION OF POSTERIOR TIBIAL SLOPE (**PTS**)

- ✓ PATIENT REPORTED OUTCOMES (**PROMs**)

OF A **NEW PERSONALISED (TOKA) SYSTEM** FOR **HTO** IN PATIENTS WITH MEDIAL OSTEOARTHRITIS (OA) AND VARUS KNEE.

METHODS- CRITERIA

STUDY DESIGN: PROSPECTIVE CASE SERIES OF 25 PATIENTS

INCLUSION CRITERIA

- ✓ PATIENTS UNDERGOING OPENING WEDGE HIGH TIBIAL OSTEOTOMY (HTO)
- ✓ PATIENTS WITH MEDIAL OA AND VARUS MALALIGNMENT ($>4°$ and $<20°$)
- ✓ BMI <40
- ✓ AGE 40-65 YEARS OLD

METHODS – SURGICAL PLANNING

Annotated Patient X-Ray

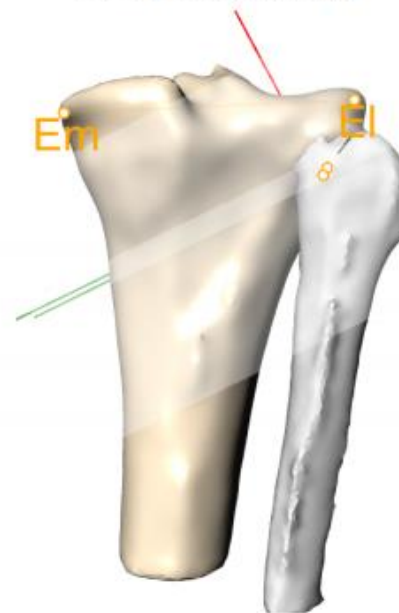**Predicted Post-Operative X-Ray**

| Parameter	Right	
	Pre-Op	Post-Op
% M-L	6	52
HKA (°) Varus: >180°	190.0	179.6
HKA Deviation (°) Varus: +ve	10.0	-0.4
mLPFA (°) Normal: 85-90°	77.2	77.2
mLDFA (°) Normal: 85-90°	86.2	86.2
MPTA (°) Normal: 85-90°	82.9	93.2
LDTA (°) Normal: 86-92°	94.9	94.4

Surgical Planning

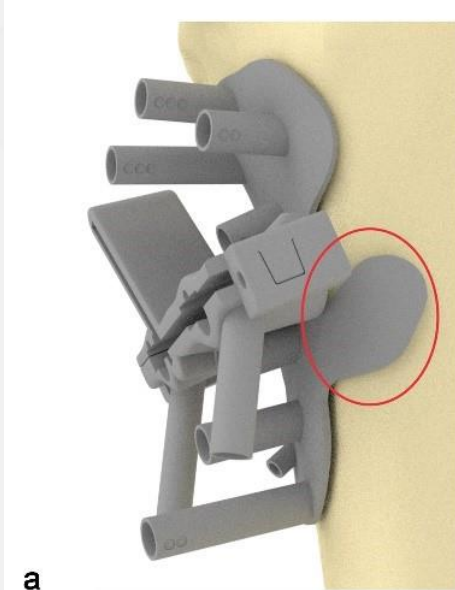| Key Surgery Variables	
Osteotomy inclination to vertical	116.0°
Distance to lateral cortex from hinge	7.4mm
Vertical distance to tibial plateau	17.6mm
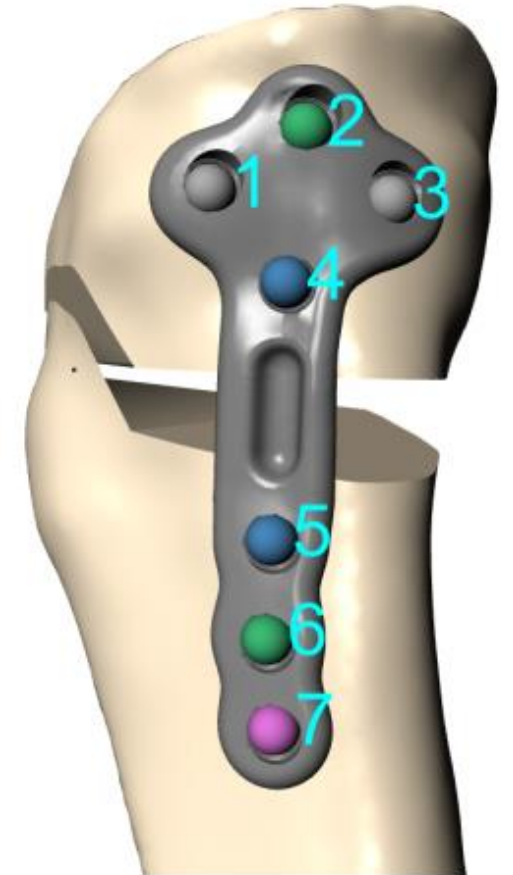
METHODS - SURGICAL TECHNIQUE

✓ **PATIENT-SPECIFIC CUTTING GUIDE SECURED WITH SEVEN DRILL BITS**

✓ **OSTETOMY GAP OPENING SYSTEM USING THE TWO OPENING SCREWS AND HELD WITH CUSTOMIZED WEDGES**

✓ **CUSTOMISED PLATE**
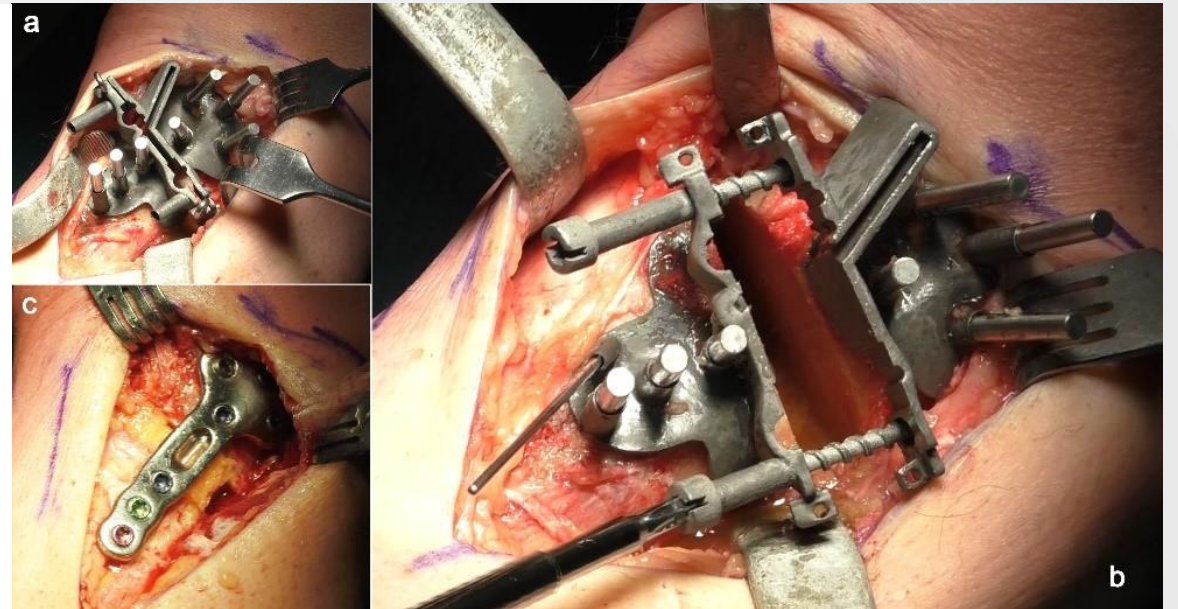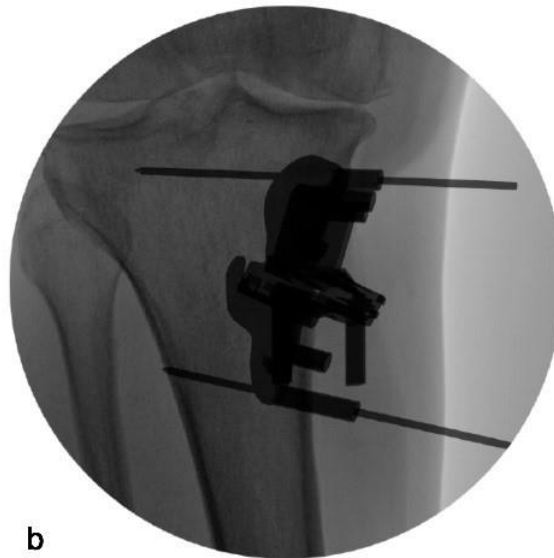
METHODS – PATIENTS EVALUATION

✓ **STANDING LONG LEG RADIOGRAPH TO EVALUATE PRE AND POST OPERATIVE HKA**

✓ **LATERAL RADIOGRAPHS TO EVALUATE PRE AND POST OPERATIVE PTS**

✓ **KOOS SCORE AND ITS SUB-SCALES, EQ5D, KSS SCORE, AND VAS TO EVALUATE PROMS**

RESULTS - HKA & PTS

✓ **THE MEAN DIFFERENCES BETWEEN PLANNED HKA AND ACHIEVED CORRECTION WAS 2,1°**

	Table 3 – HKA Correction Accuracy											
	Whole case series				First 13 surgeries				Last 12 surgeries			
	Mean	SD	Min.	Max.	Mean	SD	Min.	Max.	Mean	SD	Min.	Max.
HKA planned - postop (degrees)	2.1	2.0	-1.1	5.8	2.9	2.1	-0.7	5.8	1.2	1.5	-1.1	3.6

✓ **THE MEAN DIFFERENCE BETWEEN PLANNED PTS AND THAT MEASURED AT SIX MONTHS WAS OF 0.2°**

Table 4 - PTS correction accuracy				
	Mean	SD	Min	Max
PTS planned - postop (degrees)	0.2	± 0.4	-0.6	1.2

RESULTS - PROMs

✓ **KOOS TOTAL SIGNIFICANTLY INCREASED**

✓ **EQ5D, KSS-O, KSS-F SHOWED A FURTHER SIGNIFICANT INCREASE FROM THE THREE-MONTH VALUES AT TWELVE MONTHS POSTOPERATIVELY**

		Table 5 – PROMs assessment at different follow up		**1 Y FU**
PROMs	pre-op	3m	6m	12m
KOOS (total)	56.3 (95%CI 50.4 to 62.0)	**72.9 (95%CI 69.7 to 76.1)***	**82.1 (95%CI 78.6 to 85.5)˜**	81.9 (95%CI 77.5 to 86.3)
EQ-5	6.1 (95%CI 5.4 to 6.8)	**7.0(95%CI 6.6 to 7.4)***	7.5(95%CI 6.9 to 8.2)	**8.1(95%CI 7.6 to 8.6)˜**
KSS-O	58.6 (95%CI 53.1 to 64.1)	**86.2 (95%CI 81.1 to 91.3)***	89.8 (95% 84.8 to 94.8)	**95.8 (95%CI 92.5 to 99.0)˜**
KSS-F	82.2 (95%CI 77.8 to 86.6)	**85.6 (95%CI 81.8 to 89.3)***	89.8 (95% CI 83.4 to 96.2)	**98.6 (95%CI 96.9 to 100.3)˜**
VASrest	2.7 (95%CI 2.0 to 3.5)	**0.4 (95%CI 0.2 to 0.7)***	0.3 (95%CI 0.1 to 0.6)	0.4 (95%CI 0.2 to 0.7)
VASact	6.3 (95%CI 5.6 to 7.0)	**1.8 (95%CI 1.4 to 2.3)***	1.5 (95%CI 0.8 to 2)	1.5 (95%CI 0.9 to 2.1)

CONCLUSION

✓ **TOKA SYSTEM FOR VALGUS HTO SHOWED A SATISFACTORY ACCURACY IN THE CORRECTION OF CORONAL ALIGNMENT AND POSTERIOR TIBIAL SLOPE**

✓ **EXCELLENT CLINICAL OUTCOMES AT 1 Y FOLLOW UP**

✓ **RAPID IMPROVEMENT IN TERMS OF PAIN AND RETURN TO FUNCTION**

REFERENCES

- Ruggeri M, Gill HS, Leardini A, Zaffagnini S, MacLeod A, Ortolani M, Faccia F, Grassi A, Dal Fabbro G, Durante S, Belvedere C. Superimposition of ground reaction force on tibial-plateau supporting diagnostics and post-operative evaluations in high-tibial osteotomy. A novel methodology. Gait Posture. 2022 May;94:144-152.

- Zaffagnini S, Dal Fabbro G, Belvedere C, Leardini A, Caravelli S, Lucidi GA, Agostinone P, Mosca M, Neri MP, Grassi A. Custom-Made Devices Represent a Promising Tool to Increase Correction Accuracy of High Tibial Osteotomy: A Systematic Review of the Literature and Presentation of Pilot Cases with a New 3D-Printed System. J Clin Med. 2022 Sep 27;11(19):5717.