Knee Surgery, Sports Traumatology, Arthroscopy (2023) 31:1193–1195
https://doi.org/10.1007/s00167-023-07385-0

EDITORIAL

Personalisation and customisation in total knee arthroplasty: the paradox of custom knee implants

Mo Saffarini[1] · Michael T. Hirschmann[2,3] · Michel Bonnin[4]

Published online: 19 March 2023

Advancements in research and technology over the past decades have accelerated the transition from standardised or 'mean-value' medicine towards personalised or 'precision' medicine, where medical decisions, treatments and products are tailored to each patient depending on their predicted response and risk factors. The idea of personalized treatments can be traced back to Hippocrates, who advised that "it is more important to know what sort of person has a disease than to know what sort of disease a person has" [26], though wider-scale implementation of personalised medicine required new diagnostic and informatic approaches, which originated in the fields of genomics and bioinformatics.

Personalised medicine is increasingly applied in various fields of orthopaedics, notably in total knee arthroplasty (TKA) [3, 9], where the proportion of unsatisfied patients seems to remain constant despite numerous initiatives to enhance surgical techniques and implant designs [17]. The popularisation of personalised TKA is propelled by three main drivers: (a) the fall of the dogma of mechanical alignment [16, 23], (b) a greater appreciation of the variability of knee phenotypes [8, 10, 11], and (c) the evolution of diagnostic, planning and assistive technologies [13].

Personalised TKA involves the adaptation of specific parameters or features, to match the pre-arthritic anatomy and/or restore native kinematics, usually using one or more tools or means. It is important to distinguish between the parameters being personalised (e.g. coronal, sagittal or rotational alignment, joint line obliquity, flexion/extension gaps, condylar curvature) and the tools used to facilitate personalisation (e.g. 3D imaging, preoperative planning software, PSI, navigation, robotics). The parameters to be personalized and tools for personalization are often conflated because the former represent input (dimensions and angles) that is necessary to design or adjust the latter (cutting jigs and machine programs).

Custom TKA implants represent a combination of both personalised parameters and tools for personalisation. This parameter-tool duality increases the potential to address multiple challenges simultaneously while remaining compatible with different personalisation strategies and other assistive technologies [25]. Furthermore, custom implants offer three features that are rarely attainable when using off-the-shelf implants, which are not designed to be implanted in variable positions:

(1) Optimisation of bone-implant fit: the implanted components are designed to follow the contours of the resected bone surfaces, thus avoiding any prosthetic over- or under-coverage, and hence minimizing the risks of soft-tissue impingements [1, 2, 15];
(2) Decoupling of the patellofemoral compartment from the tibiofemoral compartment: the trochlear groove can be oriented to optimise patellofemoral kinematics independently from the femoral condyles that should be aligned to optimise tibiofemoral kinematics, which eliminates the need for external rotation of the femoral component [14, 19, 22, 24];
(3) Restoration of native condylar curvature: the sphericity or 'ovoidicity' of prosthetic condyles can be adjusted to match the unique anatomy of the individual, to maintain equal ligament tensions throughout the range of knee flexion [6, 27].

The concept of custom knee implants is not entirely novel; as early as the 1940s, Smith-Peterson took moulds

✉ Mo Saffarini
mo@resurg.com

[1] ReSurg SA, 22 Rue Saint-Jean, 1260 Nyon, Switzerland

[2] Department of Orthopedic Surgery and Traumatology, Kantonsspital Baselland, CH-4101 Bruderholz, Switzerland

[3] Department of Clinical Research, Research Group Michael T. Hirschmann, Regenerative Medicine and Biomechanics, University of Basel, CH-4001 Basel, Switzerland

[4] Centre Orthopédique Santy, Hôpital Privé Jean Mermoz, Ramsay Santé, 69008 Lyon, France

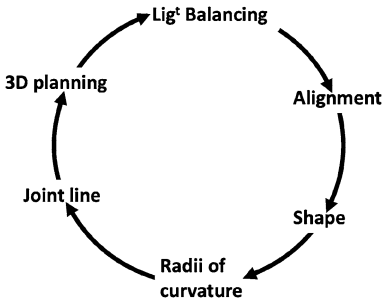

Fig. 1 The relationship between personalised parameters

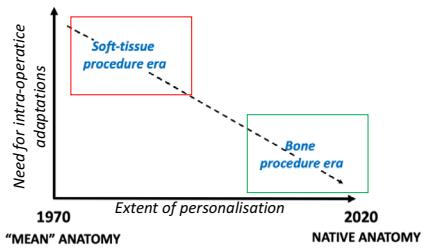

Fig. 2 The custom implant paradox: the more we personalise implants the more we standardise surgical techniques

of the femoral condyles to produce personalised 'resurfacing implants' [12]. The industrialised advent of modern knee arthroplasty neglected the need for personalisation; in the 1970s, Freeman and Insall introduced 'mechanical implants' requiring planar bone resections [21]. Modern knee implants enabled the standardization of surgical techniques and instruments, as well as large-scale industrialisation of production processes, which in turn allowed surgeons and manufacturers to focus on enhancing the biomaterials to maximise implant longevity.

The inventors of modern knee arthroplasty emphasized that "TKA is a soft-tissue procedure", as it requires intra-operative adaptations of the soft tissues to the bone cuts, and vice-versa. However, the adjustment of one parameter might compromise other parameters, making it difficult to optimise all aspects simultaneously (Fig. 1). For instance, rotating the femoral component to optimise patellofemoral kinematics could compromise tibiofemoral kinematics and/or lead to prosthetic over-hang or under-coverage… Likewise, balancing the flexion gap may require further bone resections and/or soft-tissue release, which could lead to laxity in extension, lower the joint line, and/or compromise patellar height…

Personalisation of TKA reduces the need for intra-operative adaptations: the better the tools we have for personalisation the more we can standardise our surgical techniques (Fig. 2). And while total elimination of intra-operative adaptations may seem an over-ambitious asymptote, custom implants enable a considerable leap towards that goal. The 'custom implant paradox' is that 'the more we personalise TKA implants the less we need intra-operative adaptations and the more we standardise the surgical techniques'.

A recent systematic review and meta-analysis [20] concluded that there are no benefits of using custom TKA in terms of functional outcomes, but the literature available at the time was limited to one implant brand that only enabled partial customisation of implants with mechanical alignment. Since then, more recent studies on newer custom implant brands—that allow full customisation of implants with personalised alignment—have demonstrated promising outcomes in terms of personalised coronal alignment targets [4], correction of extra-articular deformities [5] and patient satisfaction rates [7, 18].

With increased access to technology for personalisation, it is important to consider TKA as a full process rather than a set of implants. The TKA process includes pre-operative imaging and planning, supply chain and hospital workflow, surgeon training and education, customised instruments and implants, as well as standardized surgical techniques and traceability. Customising the TKA process simplifies and facilitates each step therein.

While custom implants may not be as beneficial to experienced surgeons, who are 'accustomed' to 'cheating' by adapting cuts and soft tissues to optimise outcomes, they could help inexperienced surgeons achieve better outcomes. Custom implants alone may not be the ultimate solution to eradicate dissatisfaction following TKA, but might be a promising complement to a holistic solution, using multiple strategies and technologies to improve outcomes.

Data availability Not applicable.

References

1. Beckers L, Müller JH, Daxhelet J, Ratano S, Saffarini M, Aït-Si-Selmi T, Bonnin MP (2021) Considerable inter-individual variability of tibial geometric ratios renders bone-implant mismatch unavoidable using off-the-shelf total knee arthroplasty: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s00167-021-06623-7
2. Beckers L, Müller JH, Daxhelet J, Saffarini M, Aït-Si-Selmi T, Bonnin MP (2022) Sexual dimorphism and racial diversity render bone-implant mismatch inevitable after off-the-shelf total knee arthroplasty: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc 30(3):809–821
3. Blakeney WG, Vendittoli PA (2020) The future of TKA. In: Rivière C, Vendittoli PA (eds) Personalized hip and knee joint replacement. Springer, Cham (CH), pp 169–174. https://doi.org/10.1007/978-3-030-24243-5_15
4. Bonnin MP, Beckers L, Leon A, Chauveau J, Müller JH, Tibesku CO, Aït-Si-Selmi T (2022) Custom total knee arthroplasty

facilitates restoration of constitutional coronal alignment. Knee Surg Sports Traumatol Arthrosc 30(2):464–475
5. Daxhelet J, Aït-Si-Selmi T, Müller JH, Saffarini M, Ratano S, Bondoux L, Mihov K, Bonnin MP (2021) Custom TKA enables adequate realignment with minimal ligament release and grants satisfactory outcomes in knees that had prior osteotomies or extra-articular fracture sequelae. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s00167-021-06619-3
6. Dobbelaere A, Müller JH, Aït-Si-Selmi T, Gousopoulos L, Saffarini M, Bonnin MP (2022) Sagittal femoral condylar shape varies along a continuum from spherical to ovoid: a systematic review and meta-analysis. Arch Orthop Trauma Surg. https://doi.org/10.1007/s00402-022-04613-z
7. Gousopoulos L, Dobbelaere A, Ratano S, Bondoux L, Tibesku CO, Aït-Si-Selmi T, Bonnin MP (2023) Custom total knee arthroplasty combined with personalised alignment grants 94% patient satisfaction at minimum follow-up of 2 years. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s00167-023-07318-x
8. Hirschmann MT, Behrend H (2018) Functional knee phenotypes: a call for a more personalised and individualised approach to total knee arthroplasty? Knee Surg Sports Traumatol Arthrosc 26(10):2873–2874
9. Hirschmann MT, Friederich NF, Becker R, Karlsson J (2019) Personalised medicine in knee arthroplasty: we need more science! Knee Surg Sports Traumatol Arthrosc 27(5):1357–1358
10. Hirschmann MT, Hess S, Behrend H, Amsler F, Leclercq V, Moser LB (2019) Phenotyping of hip-knee-ankle angle in young non-osteoarthritic knees provides better understanding of native alignment variability. Knee Surg Sports Traumatol Arthrosc 27(5):1378–1384
11. Hirschmann MT, Moser LB, Amsler F, Behrend H, Leclerq V, Hess S (2019) Functional knee phenotypes: a novel classification for phenotyping the coronal lower limb alignment based on the native alignment in young non-osteoarthritic patients. Knee Surg Sports Traumatol Arthrosc 27(5):1394–1402
12. Jones WN (1969) Mold arthroplasty of the knee joint. Clin Orthop Relat Res 66:82–89
13. Kim AG, Bernhard Z, Acuña AJ, Wu VS, Kamath AF (2022) Use of intraoperative technology in total knee arthroplasty is not associated with reductions in postoperative pain. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s00167-022-07098-w
14. Kuo AW, Chen DB, Wood J, MacDessi SJ (2020) Modern total knee arthroplasty designs do not reliably replicate anterior femoral morphology. Knee Surg Sports Traumatol Arthrosc 28(9):2808–2815
15. Li K, Saffarini M, Valluy J, Desseroit MC, Morvan Y, Telmon N, Cavaignac E (2019) Sexual and ethnic polymorphism render prosthetic overhang and under-coverage inevitable using off-the shelf TKA implants. Knee Surg Sports Traumatol Arthrosc 27(7):2130–2139
16. MacDessi SJ, Oussedik S, Abdel MP, Victor J, Pagnano MW, Haddad FS (2023) The language of knee alignment : updated definitions and considerations for reporting outcomes in total knee arthroplasty. Bone Jt J 105(2):102–108
17. Matar HE, Platt SR, Gollish JD, Cameron HU (2020) Overview of randomized controlled trials in total knee arthroplasty (47,675 patients): what have we learnt? J Arthroplasty 35(6):1729-1736.e1721
18. Moret CS, Hirschmann MT, Vogel N, Arnold MP (2021) Customised, individually made total knee arthroplasty shows promising 1-year clinical and patient reported outcomes. Arch Orthop Trauma Surg 141(12):2217–2225
19. Müller JH, Li K, Reina N, Telmon N, Saffarini M, Cavaignac E (2020) Sexual and ethnic polymorphism result in considerable mismatch between native trochlear geometry and off-the-shelf TKA prostheses. Knee Surg Sports Traumatol Arthrosc 28(12):3871–3878
20. Müller JH, Liebensteiner M, Kort N, Stirling P, Pilot P, Demey G (2021) No significant difference in early clinical outcomes of custom versus off-the-shelf total knee arthroplasty: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s00167-021-06678-6
21. Ranawat AS, Ranawat CS (2012) The history of total knee arthroplasty. In: Bonnin M, Amendola A, Bellemans J, MacDonald S, Ménétrey J (eds) The knee joint: surgical techniques and strategies. Springer, Paris, pp 699–707. https://doi.org/10.1007/978-2-287-99353-4_63
22. Rivière C, Iranpour F, Harris S, Auvinet E, Aframian A, Parratte S, Cobb J (2018) Differences in trochlear parameters between native and prosthetic kinematically or mechanically aligned knees. Orthop Traumatol Surg Res 104(2):165–170
23. Rivière C, Lazic S, Boughton O, Wiart Y, Vïllet L, Cobb J (2018) Current concepts for aligning knee implants: patient-specific or systematic? EFORT Open Rev 3(1):1–6
24. Rivière C, Lazic S, Villet L, Wiart Y, Allwood SM, Cobb J (2018) Kinematic alignment technique for total hip and knee arthroplasty: The personalized implant positioning surgery. EFORT Open Rev 3(3):98–105
25. Sappey-Marinier E, Tibesku C, Selmi TAS, Bonnin M (2020) Custom total knee arthroplasty. In: Rivière C, Vendittoli PA (eds) Personalized hip and knee joint replacement. Springer, Cham (CH), pp 255–264. https://doi.org/10.1007/978-3-030-24243-5_22
26. Valentino M, Pavlica P (2016) Medical ethics. J. Ultrasound 19(1):73–76
27. Zhang Z, Liu M, Wen X, Liu S, Zhang G, Yang C (2020) The relationship between the posterior tibial slope and the sagittal femoral condylar shape: two circles and ellipses. Clin Anat 33(7):1075–1081