THE REASONS FOR A CUSTOMIZED KNEE PROSTHESIS
STEPPING OUTSIDE THE SQUARE

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TOTAL KNEE REPLACEMENT – SUCCESS AND OUTCOMES

Total knee replacement (TKR) has become the standard treatment in severe degenerative joint disease of the knee [1], and the number of procedures is growing since its generalization in the late seventies [2].

Through constant advances in design and technology to improve results, TKR now has durable results, in terms of long-term fixation, wear and subsequent loosening. Reliability, as measured through survival rate with revision as the end point criteria for failure, is constantly improving [2].

But more recently, there is increasing emphasis on satisfaction and functional outcome as reported by validated outcome scores of the patient’s perspective, irrespective of the mechanical success and the longevity of the prosthesis reported by joint registries and surgeons [3, 4].

This approach in assessment has led to more disappointing functional results if compared with traditional “objective” knee scores, 5 or with other arthroplasty techniques such as unicompartmental knee replacement 6 and total hip replacement [7].

The main reasons for patient dissatisfaction are residual pain, (mainly anterior), instability or a limited range of motion, with inability to climb stairs or squat [8].

Outcomes can be affected by failure to technically achieve the surgical goal with surgeon volume being an important factor is success rate [9]. However outcomes of Total knee replacement are predominantly still unsatisfactory even in the best surgical hands, as the ultimate achievement of an appropriately aligned, balanced and naturally functioning knee is constrained by the limitations of current prosthetic design.

Improved preoperative planning and intra-operative navigation systems, and personalized cutting guides, have been developed as an attempt to improve the operator’s reliability. But the benefit of assisted surgery remains unclear, with both level 1 evidence studies and systematic reviews reporting contrasting results on improvement of accurate alignment and actual improvement of functional outcomes [10-19].
THE 180° TRADITIONAL ALIGNMENT AND BALANCING

Historically the proposed aim for coronal alignment, as measured by the mechanical femorotibial angle (MFT angle), has been within ±3° of 0 degrees, and the longevity of TKR has been traditionally associated with neutral or slightly valgus coronal alignment [20-23]. Studies have demonstrated improved functional outcomes with coronal alignment within 3 degrees of neutral [24, 25]. Achieving a mechanical alignment of 0° in the coronal plane requires the placement of the femoral and tibial components perpendicular to the femoral and tibial mechanical axes respectively. In the case of the femur the mechanical and anatomical axes are not coincident and form the femoral mechanical anatomical (FMA) angle. As such a distal valgus cut is made with respect to the anatomical axis, which should be equal to the FMA angle. Generally during conventional TKA with standard instrumentation most surgeons use the same fixed distal valgus resection angle (4°-7°) for all their patients, although variable jigs are available.

This goal of alignment also has consequences on balancing flexion and extension gaps notably at the femoral end [26]. Balancing the knee can be performed by utilizing measured resection techniques and setting the posterior joint line perpendicular to the anteroposterior axis of the trochlear groove, parallel to the transepicondylar axis, externally rotated 3° with respect to the posterior condylar axis or parallel to the tibial resection in 90° of flexion with the use of gap-balancing technique aligned internal-external rotation of the femoral component.

With measured resection techniques there is a wide range of femoral rotation, instability and femoral condylar lift off during flexion to 90 degrees [27, 28]. Gap balancing produces more accurate gap symmetry and minimal instability but can raise the joint line [29], and is accurate for gap balancing at 0 and 90 degrees but not necessarily in mid flexion [30]. Patients who perceive these changes in stability, limb alignment, and joint level alignment may be dissatisfied. The more accurate gap symmetry of gap balancing does not produce better functional outcomes in cruciate retaining or posterior stabilized prostheses [29, 31].

Fundamentally the current knee prostheses are designed with the concept that the bone cuts and the ligaments are balanced in order to modify the knee so as to fit the prosthesis to the knee along these alignment principles of 0 degrees and working with a 'square gap'.

Consequently, any intraoperative change in any one of factor of rotation, flexion, oversizing or balancing of components ultimately has consequences and compromises on the other parameters (fig. 1).

Fig. 1: Cascade of events resulting of traditional realignment in a typical varus knee. 1) The femoral perpendicular asymmetrical cut. 2) Tibial perpendicular asymmetrical cut. 3) MCL release to compensate extra-articular tibial deformity, thus changing the joint line level. 4) Grey rectangle underlying the posterior reference alignment, leaving an asymmetrical posterior gap. 5) Black rectangle showing external rotation where flexion gap balancing option is selected. 6) Broken line: increase of AP dimension as result of rotation with subsequent ML increase.

NATURAL ALIGNMENT AND BALANCING

The dogma of a target of an alignment of 180° crossing the prosthetic joint line perpendicularly
has been questioned as to whether it is essential to prevent failure [32], and it is not necessarily associated with better functional outcomes [33-36]. Some authors have promoted the restoration of a given degree of native deformity, especially when from femoral origin, along with the original joint line obliquity [37-42]. This concept may be reinforced by studies utilising CAS which have resulted in more accurate ‘traditionally’ aligned prostheses but without demonstrating superior functional outcomes [43, 44].

Moving closer to natural alignment may also be tolerated as improved prosthetic materials may tolerate variations in alignment in terms of wear rate [45].

The ideal rotational alignment is still the subject of controversy [46], and may be seen as a palliative attempt to offset an asymmetrical flexion gap and/or to make-up a poor patellar pace [47, 48].

THE RECENT ADVANCES IN PROSTHETIC DESIGN

Femoral Sizing and Shape

Independent from alignment factors affecting outcome, several publications have pointed out prosthetic design limitations regarding; sizing, AP/ML mismatch, and trochlear design [49]. AP sizing of the femur is dependent upon individual femoral anatomy and the degree of rotation and flexion of the femoral component chosen by the surgeon [50]. Selection of implant sizes between surgeons is variable depending on experience and philosophy [51]. Overhang of the femoral component is highly prevalent, occurring frequently and with greater severity in women. Overhang also increases as larger femoral component sizes are used in both sexes. Femoral component overhang can double the risk of long term knee pain [52, 53] and lead to worse flexion and function [53]. Aside from overhang, the cut surface of the femur is often not covered adequately by the definitive prosthesis, leaving sharp edges on which the soft tissue envelope abuts (fig. 2 & 3). As a result, the most recently released prostheses are showing an increasing number of sizes across the range – extreme sizes being delivered on demand – with optional narrower femoral components and extended options to allow femoral and tibial dissociation (Table 1). However significant increases of shear strain occurs in the peripheral proximal regions of the tibia when loaded with a larger versus a smaller femoral component, indicating the importance of a correct sizing relationship [54].

Fig. 2: Perfect AP/ML dimensioning in a female’s right knee with a modern design implant.

Fig. 3: Superior view of the same patient (figure 2) showing a lack of the trochlear coverage and subsequent sharp edges, despite perfect AP/ML dimensioning.
Table 1

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<th>Femoral sizes options</th>
<th>Tibial Size Options</th>
<th>Max. Compatibility Range between femur/tibia Size</th>
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<td>Journey</td>
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Whilst attempting to adapt design to improve function, the large range of sizes and expanding ability for femoral – tibial size dissociation inherently illustrates the difficulty in matching a patient’s specific anatomy and as such the potential risk in choosing the incorrect size for the femur and/or tibia of a given patient.

To further improve upon sizing issues, gender specific prosthetic sizes have been developed to counter the significant difference in distal femur proportions between men and women, as dimensions propagation of femoral components for TKA traditionally followed men’s distal femoral anatomy dimensions. In addition, sizing of modern femoral components was traditionally based on an assumption that ML dimension increases proportionally to AP dimension [55]. Despite best attempts to modify shape and size the problem has not been completely addressed, and there is still a tendency for ‘overhang’ and ‘underhang’. Analysis of six contemporary femoral components with multiple ML/AP shape offerings and an increased number sizes (Persona™, NexGen®, Sigma®, Genesis™ II, Triathlon®, Vanguard®) has demonstrated either persistent overhang or underhang characteristics of each prosthesis, despite some superiority of some prosthesis for greater cross ethnicity fit [56]. However these additional sizes for gender and enhanced ranges of size have previously not appeared to influence short-term outcomes [57].

Ongoing pain is also associated with soft-tissue impingement and may occur in up to 25%, of total knee arthroplasties. It is associated with a femoral component with a shallow trochlear groove or with a sharp transition to the intercondylar region of the implant, and poor patellofemoral tracking [58].

**Tibial sizing and shape**

Tibial sizing is an important issue as well. In any case, tibial tray or polyethylene liner overhang may lead to soft tissue impingement and subsequent pain (fig. 4). Asymmetrical

![Fig. 4: TKR revision for medial pain. Intra-operative view of the polyethylene liner medial that is overhanging in a rotating platform knee in external rotation. The metal tray is well aligned with the bone cut.](image-url)
tibial trays have also been emphasized, along with gentle 1 mm liner thickness increment. The tibiofemoral joint is asymmetric in shape and dimension, and correct positioning of the tibial component must accommodate both optimal bone coverage and satisfactory patellofemoral tracking. As such a compromise must be found during the operation to meet these two requirements, as best bone coverage often internally rotates the tibial tray [59]. Asymmetrical trays reflect the tibial torsion more accurately, and may offer the best compromise for optimal bone coverage and patellofemoral tracking [58]. However symmetrical trays have also been reported to provide the best compromise for coverage and more kinematic rotation and tracking [60, 61].

**Bony resection**

Irrespective of individual patient’s bone size and characteristics, bone resection requires a minimum bony cut that is not proportional to the patient’s anatomy, in order to accommodate the prosthesis and bearing. This has greater consequence in smaller bones as the resection is at a level of poorer bone quality and in closer proximity to the level of the collateral ligaments.

On the femoral side a fixed resection level can encroach upon the collateral ligament insertions in small femurs, with the potential risk of prosthetic impingement upon the soft tissue envelope. On the tibial side a relatively large distal resection level results in a smaller component size for that knee, and overall a relatively posterior and peripheral displacement of the implant, and strain increases significantly in the proximal tibia during loading [62]. The deep MCL is a distinct medial stabilizer and plays an important role in rotational stability. With a standard 9-mm tibial resection up to 54% of the deep MCL insertion area may be resected, and it is resected in at least 1/3 of cases of conventional TKA. However it may have implications in future designs of both unicondylar and total knee arthroplasty [63].

**Patello-femoral joint**

Patello-femoral function and stair climbing has been shown to improve with more anatomic trochlea designs of the femoral component [64]. Trochlear designs have also been gradually modified to better accommodate the patellar articular facets, with broad extended asymmetrical trochlear grooves. The literature has conflicting evidence how effective this is in improving patella tracking [65, 66].

**Patella resurfacing**

Anterior knee pain remains a factor in patient dissatisfaction, and furthermore the role of patella resurfacing during primary total knee arthroplasty remains controversial. Whilst resurfacing may reduce actual revision rates [67]. The literature has shown no benefit from resurfacing of the patella in terms of outcomes [67, 68, 69]. This may be by differences in design between TKA brands. However a review of five popular primary knee designs demonstrated that patella resurfacing has no improvement in overall knee function or anterior knee-specific function irrespective of TKA brand or for cruciate retaining versus sacrificing designs [70].

**Kinematics**

Aside from sizing variations there are many variations available to try and improve the kinematics and function of the knee replacement by different means. Orthopaedic device companies have developed technical differences including; single radius of curvature femoral components, graduated radius of curvature components, medial pivot designs, third condyle and high flexion femoral component designs to attempt to achieve kinematics matching the native knee. Third condyle designs have demonstrated similar anteroposterior and medial-lateral ligamentous stability compared to the native knee [71]. There is some evidence single radius designs
improve functional outcomes [72], however literature does not support any superiority of high flexion devices [73, 74].

The bearing platform itself has variations of posterior stabilized, cruciate retaining, rotating platforms and deep dished platforms to try and enhance kinematics such as deep flexion and maintain flexion stability. There is controversy over whether any are more superior. There appears to be no difference between fixed or rotating platforms [75], and they fail to achieve the anteroposterior stability of the native knee, furthermore some designs have failed to prevent paradoxical rollback/tibial external rotation. Cruciate retaining designs theoretically may improve function by maintaining proprioception [76], whereas posterior stabilized designs have evolved to enhance flexion. Whilst posterior stabilized knees may provide deeper flexion [77], the evidence in the literature shows that there is no difference in outcomes functionally between the two groups [77, 78, 79].

Overall, despite best attempts to improve the performance of knee arthroplasty, these modifications to existing implant design and rationale have not necessarily improved outcomes in active patients [80]. All in all, the trend that we all see is clearly an attempt to attain a prosthetic design that can better match the native knee, and current ‘off the shelf’ designs still utilize the model whereby the knee is made to fit the prosthesis, rather than the prosthesis fitting the knee, such that intraoperative modifications of one parameter will have consequences on another.

The question then remains, why are we not attempting to leapfrog these steps to a customized prosthesis?

THE CONCEPT OF CUSTOMIZED KNEE ARTHROPLASTY

The general idea of customization is to prevent the need for compromises that the surgeon is forced to make during standard TKR insertion and to minimize the accumulation of approximations from preoperative planning to final implant insertion. Customization is an appealing option but 3 principle questions arise: 1- What type of deformity can be addressed or what (native) residual alignment is acceptable? 2- What parts of a TKR may benefit from customization? 3- How to execute it at an industrial level?

Reaching the native alignment

The amount of acceptable native alignment (incorrectly termed “deformity”) is somewhat difficult to determine, but as mentioned previously, 3 to 5 degrees of residual alignment may be acceptable, as recommended in unicompartmental knee arthroplasty. This amount of angulation is acceptable provided that the ligaments (including the cruciates) are intact, and probably in patients under a maximum weight or BMI. These criteria would make the customized knee ideal for patients where both cruciates are intact. But in TKR the stabilization mechanism can be used to compensate for the absence of one or two cruciates, and thus customization can presumably be extended to more patients. On the other hand, fixed deformities, major ligament instability, or severe extra-articular deformities should be contraindications.

The native alignment does not cover the limb alignment alone but includes the joint line obliquity. In a customized knee concept this native angulation can be respected. This has consequences on ligament balancing, making it simpler because it does not create a flexion-extension miss-match from a femoral origin. Keeping the native joint obliquity results in restoring – or approaching – the individual medial-lateral femoral contours. In principle, in keeping the native knee contour there should be no further need for ligament release or it should be limited to address limited contractures (fig. 5). Such a design, while reducing the flexion extension imbalance may provide a smoother stability across the range of motion, thus reducing the mid flexion instability. Along
with better stability, keeping the ligament insertion intact and getting closer to the natural tension may reduce a significant source of potential residual pain.

On the tibial side, the accurate coverage of the bone surface not only protects against possible ligament impingement but also enhances implant fixation. The amount of resection, slope and the frontal obliquity of the cut do affect this surface, making the planning essential to approximate the ideal contour.

**Kinematics**

The kinematics of the knee is essentially guided by the articular surface contours but orchestrated by the ligaments. In the normal knee the femoro-tibial junction is subtly composed of cartilage and menisci that creates a complex and harmonious transfer across the range of motion. But in knee prostheses, the current necessity to use a stiff material that has a wear rate, namely polyethylene, prevents exact restoration of the native surface contour; whether it is standard or customized, even in presence of both cruciate ligaments. Thus one of the main design challenges in customized implants is to match the prosthetic femoral anatomical contour to the polyethylene in a form that can be reproducible and compatible with material resistance. In other words, there is still a need to maintain a given degree of conformity and to use a mechanism (such as a cam, post, third condyle, etc.) to provide a sufficient degree of congruency. It is possible to achieve this challenge through an algorithm that will match a particular type of stabilization mechanism with a given medial/lateral femoral contour from a number of knee sub-groups, based on a family of similar anatomical features. Thus the kinematics cannot be totally customized, but adopted and adapted, from a proven reliable solution.

Apart from femoro-tibial kinematics, patella tracking is probably the most important area which offers a large amount of room for improvement. The reproduction of the native patellar-trochlear anatomy is undoubtably one of the more promising areas of progress. In a

**WHAT TO CUSTOMIZE?**

**Bone coverage**

Aside from the customization of the femoral condyle contour to restore the biomechanics, the restoration of bony coverage is aimed to maintain the natural smooth transitions at the new articular surface - bone interface, including the bone cuts created to accommodate the prosthetic box. The miss-match resulting from the cuts and the implant generates either overhang of the implant in some areas or exposed sharp bony cuts in other places. These miss-matches are responsible for soft tissue impingement or overstuffing and may generate stiffness, irritation, or pain and discomfort that affect the clinical result. At the trochlea area the miss match is often large, due to proximal propagation of the cut, and the possible rotation or flexion of the cutting guide. Customization of the femoral contour, along with bony coverage, eliminates the AP/ML dissociation issue and many sources of impingement. The femoral box can also be designed in a more proportional and bone sparing way, especially in smaller sizes, where the miss match is increased when using a fixed, standard amount of resection.
custom implant the trochlear design and positioning is not compromised as in conventional techniques, by the variation of the femoral component positioning guided by flexion(extension gap balancing. The patellar resurfacing debate remains open, but more natural tracking should allow sparing of the native patellar surface more frequently.

**Fixation**

A strong and harmonious fixation is usually achieved in most of the patients with modern designs. The fixation may nevertheless be challenged in some situations. Typically in overweight females with small joints the fixation interface is reduced and fixation can be compromised. This can also occur when a residual deformity is present, especially a varus deformity. The use or addition of longer stems or fins is required in these situations. But the reduced surface resulting from the cut, or the lack of metaphyseal volume, or the presence of a narrow diaphysis can make the insertion of these extensions challenging. The shaft alignment may also be challenging since it is not always centered on the cut due to the local anatomy or in relation to the obliquity of the cut in both frontal and sagittal planes. In customized knees this can be anticipated, and the additional fixation extensions or devices, can be aligned and proportioned accordingly. The use of more proportional implant thickness allows the reduction of the bone resection in smaller patients, thus offering a wider and stronger bony site, typically on the tibial side. The femoral and inter-condylar boxes can also be reduced in order to maximize bone sparing whilst providing better fixation.

**HOW TO DO IT?**

**Technique**

The last but not least surgical challenge is the insertion of the implant. In customized implants there is no role for traditional instrumentations or intra-operative on the spot decision-making. The whole procedure and specific adjustments must have been anticipated during the planning and the implant design phase that will generate the patient specific cutting guides. The actual alignment and the various contributions to the deformity, including wear, ligament imbalance and native deformity must be determined as accurately as possible. From this analysis, the reducibility of the deformity must be calculated as accurately as possible to approximate the final limb alignment. So far there is no absolute way to predetermine the final alignment, this is why there should be some degree of patient selection and some room for intra-operative adjustments. The reducibility of the preoperative alignment can be estimated on stress x-rays and the overall analysis of the deformity based on a 3D model extracted from a CT-scan. Because the femoral implant is the key element in determining the future kinematics of the joint, its position cannot be adjusted much during the surgery, whereas on the tibial side it is easier to perform fine-tune by adjusting the cut in depth and direction. This option must be implemented in both the tibial design and the instrumentation (fig. 6).

[Fig. 6: Accuracy of a personalized femoral cutting guide along with the bony model that allows a final matching check before realizing the bone resection.]
Manufacturing process

In order to confirm the feasibility of such a project, we performed a limited series of 12 customized patient specific postero-stabilized total knees with a fixed bearing, after appropriate patient consent. Out of this preliminary experience we were able to demonstrate that the cutting guides were accurate and that the prostheses could accurately match the native knee. We do believe that building a customized implant is achievable (fig. 7, 8).

The real challenge is then to demonstrate a clinical relevance and durable advantage of this option in every surgeon’s hands compared to the modern range of implants. So far none of the current attempts have yet produced consistent published results.

Generalizing the process is another challenge. The implant design process requires several steps that cannot all be automated so far, including; clearance of osteophytes, estimation of cartilage wear, establishing suited kinematics, positioning of the posterior stabilization cam and alignment of the segments, etc. An individual surgeon cannot be asked to give his contribution for every single case plan. As such there is a need for detailed algorithm based upon large patient anatomic bases crossed with the design features.

Whether the image generation is CT based or MRI based is still a subject of debate. Also, collecting data with reliable imaging and transferring them in a safe way is another vast investment. Finally the manufacturing process is an additional new challenge; one cast for one patient is not currently a sustainable solution. Selecting the ideal and affordable manufacturing process along with subsequent specification requirements and legal compliance issues is not an insignificant hurdle.

Fig. 8: One year postoperative radiograph of a right customized TKR in an young and active female patient.

CONCLUSION

Custom made implants offer a chance to significantly improve both the life of the patient and the job of the surgeon. This fascinating adventure is a rather complex challenge. Ultimately, mailed delivery of a personalized implant, along with its specific disposable instrumentation in a single box will be a major improvement for the manufacturer, the surgical institutions and the payers. The question remains: is the initial investment worth the potential benefit? It is likely that successful surgical pioneers would agree!
LITERATURE


