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Analysis of Versafitcup®
Double Mobility wear rates

M. Bernardoni, F. Siccardi, I. Quagliana, E. Spadini
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Castel San Pietro, Switzerland

Abstract

The dual mobility concept was first proposed by Prof. Gilles Bousquet in 1976. The Bousquet concept divides two interfaces articulating a metallic head with a UHMWPE liner, the latter also articulating with a polished inner surface of the metallic acetabular shell.

A test was carried out in order to analyze the wear rates obtained with the Versafitcup® Double Mobility by Medacta®, used in combination with conventional UHMWPE and Highcross® (cross-linked polyethylene by Medacta®) liners. The test was conducted in unfavorable conditions, using metal heads and forcing more than the usual movement of the liner within the acetabular shell.

The results of the test demonstrate that the linear regression for the Versafitcup® Double Mobility conventional UHMWPE liners gives an average wear rate of 35.57±2.15 mg per million cycle. The linear regression for the Versafitcup® Double Mobility Highcross® UHMWPE liners gives an average wear rate of 2.30±0.74 mg per million cycle. Medacta®’s Versafitcup® Double Mobility liners made of Highcross® highly cross-linked UHMWPE (ETO sterilized) show a 94 % reduction in volumetric wear rate compared to the same liners fabricated of ETO sterilized, conventional UHMWPE. This is due to the enhanced properties of cross-linked polyethylene.

In conclusion we can confirm that the Versafitcup® Highcross® Double Mobility liner shows, in in-vitro hip wear simulator tests, a very low wear rate, comparable to wear characteristics of Metal-on-Metal and Ceramic-on-Ceramic bearing combinations, eliminating the risk of liner fractures, squeaking and the release of metal ions.

Introduction

The dual mobility concept has been first proposed by Prof. Gilles Bousquet in 1976. The basic idea is to couple two concepts: decrease wear according to the low friction concept of Charnley and achieve an intrinsic stability of the articulation utilizing a femoral head of bigger size, more similar to patient’s anatomy as advocated by McKee-Farrar. The Bousquet concept divides two interfaces articulating a metallic head (usually of diameter 22.2 or 28 mm) with a UHMWPE liner, the latter also articulating with a polished inner surface of the metallic acetabular shell. Hence the system is basically composed of a press-fit acetabular shell realizing two distinct concentric articulations:

• The femoral head within the polyethylene liner (small articulation)
• The liner within the metal shell (great articulation).

The UHMWPE liner represents, according to the different sizes, approximately 5/8 of a sphere and it is invariably designed with a retentive mechanism for the femoral head. Stress reduction has been observed and documented over the years and at least three publications of Aubriot et al. [1], Farizon et al. [2] and Leclercq et al. [3] have been dealing with this issue. Altogether more than 380 patients have been followed up for a period of more than 10 years. Results were excellent with an implant’s survival curve exceeding 95%. Even in those cases where a mobilization of the implant led to revision, this was never in association with loss of bone stock suggesting an optimal distribution of stresses.

Several other authors have been addressing the issue of implant stability, early dislocation in relation to a double mobility or bi-articular cup [4, 5, 6, 7].

Early dislocation remains the main complication after hip replacement surgery, and its origin is most often multifactorial including surgical mistakes, errors in orientation or lateralization of the implants, length of the
limb, muscular insufficiency, lever effect, neurological disturbances etc. In the above mentioned literature review, patients with recidivant dislocation or at high risk of dislocation have been satisfactorily treated with this kind of implant. In terms of safety, Leclercq et al.\cite{6} complains of only 1 dislocation on 1100 implants over a period of more than 10 years, which corresponds to a percentage of 0.1%.

### Material and methods

The purpose of this study was to analyze the wear rates obtained with the Versafitcup® Double Mobility by Medacta®, used in combination with conventional UHMWPE and Highcross® (cross-linked polyethylene by Medacta®) liners. The UHMWPE raw material, used both for conventional UHMWPE and Highcross®, is Chirulen 1020 (Quadrant PHS Deutschland GmbH), conforming to ISO 5834-2 type I and ASTM F648. The Highcross® UHMWPE was gamma irradiated at 100 kGy and thermally stabilized at 150°C with controlled cooling, to optimize the crystallinity of the material. The liners of each were manufactured by turning compression molded UHMWPE bars and were finished products that followed all the manufacturing process flow including final sterilization.

The test was carried out according to ISO 14242-1, ISO 14242-2 and ASTM 732-00 (International & US standards for wear testing). The test was conducted under a multi-axial hip joint simulator for 5 million cycles, measuring the wear at 0.5, 1, 2, 3, 4 and 5 million cycles.

The servo hydraulic test machine (Endolab GmbH Rosenheim, fig.1) offers six wear stations plus two reference stations, which aim is to control the soak level. This machine is able to reproduce the following force and movements:

- Compression load
- Flexion/extension movement
- Abduction/adduction movement
- Rotational movement.

![Fig.1 - Six stations hip simulator (according ISO 14242-1)](image)

To perform the test we used the worst case configuration, that consists of:

- Metal acetabular shell 64 mm, CoCr (ISO 5832-12) ball head 28 mm size M, double mobility liner 64/28, 12.9 mm thick.

Three liners of each type were tested. The implants above mentioned are finished products that followed all the manufacturing process flow, including the final sterilization.

The worst case has been identified considering that the wear production is proportional to the contact surfaces: a bigger contact surface will create a higher volumetric wear rate, even though the cup is subjected to a smaller load distribution in this case. This concept has been demonstrated also in literature for the femoral heads \cite{8,9}, and implies that most of the wear production is caused by the relative movement between the liner and the acetabular shell.

For this reason the test was performed forcing the liner moving. Thanks to a special attachment system (fig.2), during one gait cycle the liner is forced to move versus the acetabular shell starting from the 25% of the total Range of Motion allowed (which is 48°), which is more restrictive than standard conditions, where the liner movement starts at roughly 50% of the entire Range of Motion (which is 140°).

The system is composed by an attachment ring which is fixed on a metal taper, and during flexion/extension the ring gets contact with the UHMWPE liner. Articulation versus the ball head results from the lower lever arm of the frictional moments.
Results

The linear regression for the Versafitcup® Double Mobility conventional UHMWPE liners gives an average wear rate of 35.57±2.15 mg per million cycle (fig.3). The corresponding volumetric wear is 37.05±2.23 mm$^3$ per million cycle (fig.4).

The linear regression for the Versafitcup® Double Mobility Highcross® UHMWPE liners gives an average wear rate of 2.30±0.74 mg per million cycle (fig.3). The corresponding volumetric wear is 2.39±0.77 mm$^3$ per million cycle (fig.4).

A soak control has been used in the test, in order to measure the augmentation of liners weight due to the soak in the embedding medium. The embedding medium was composed by bovine serum with a 30g/l protein content and deionized water. It was filtrated before doing the test and maintained at 37°C. The serum has been replaced every 0.5 million cycles.

The in vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

Fig.2 - On the top: attachment system, composed by: metal acetabular shell (1), UHMWPE liner (2), CoCr ball head (3), metal taper (4), attachment ring (stainless steel) (5). On the bottom: detail of the attachment system, showing the attachment ring (5) in contact with the UHMWPE liner (2). The attachment ring has a chamfer with a radius of 1 mm.

Fig.3: Linear wear of the conventional UHMWPE and Highcross® liners vs number of cycles (Three liners of each type were tested, the graphic shows the linear regression for each type).

Fig.4: Volumetric wear of the conventional UHMWPE and Highcross® liners

Fig.5: Volumetric wear of Hard-on-Hard bearing (data coming from literature\textsuperscript{[106]})
Discussion

Medacta®’s Versafitcup® Double Mobility liners made of Highcross® highly cross-linked UHMWPE (ETO sterilized) show a 94% reduction in volumetric wear rate versus the same liners fabricated of ETO sterilized, conventional UHMWPE, thanks to the enhanced properties of cross-linked polyethylene.

Furthermore, the test has been conducted in unfavorable conditions, forcing the liner to move versus the acetabular shell more than in standard usage and using metal heads. It is well known from several publications that using a ceramic ball head can significantly reduce the wear rate [11].

Conclusions

The Versafitcup® Highcross® Double Mobility liner shows a very low wear rate and is a valid alternative to Metal-on-Metal and Ceramic-on-Ceramic bearings, because:

- Avoids the risk of liner fracture and squeaking observed with Ceramic-On-Ceramic
- Eliminates the risk of metal ions release observed with Metal-On-Metal
- Adds the important advantages of a large Range Of Motion and a low dislocation rate.

Wear characteristics of Metal-on-Metal and Ceramic-on-Ceramic bearing combinations, are summarized in fig. 5 where historical data coming from literature are reported [10].

<table>
<thead>
<tr>
<th>ROM in Flexion/Extension</th>
<th>Versafitcup® Double Mobility</th>
<th>Conventional Cup Head ø28mm</th>
<th>Conventional Cup Head ø32mm</th>
<th>Conventional Cup Head ø36mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>141°</td>
<td>125°</td>
<td>132°</td>
<td>137°</td>
</tr>
</tbody>
</table>

Additional information

Please note that the tests have been performed with a reduced Range Of Motion, in order to force the liner to move against the acetabular shell. The following table (fig.6) compares the real ROM of the Versafitcup® Double Mobility size 64mm with a Conventional Cup size 64mm, with different Head sizes (28mm, 32mm, 36mm).

Thanks to the Double Mobility concept, the Versafitcup® has a Head/Neck Ratio close to 3.25 for the smallest size growing up to 4.80 for the biggest size: that explains the increased Range of Motion of the Versafitcup®.

References


[12] Data on file Medacta®
Mechanical stability of the AMIStem
a standardized in-vitro analysis

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Abstract

In vitro studies are the first steps in evaluating the behavior of an orthopedic prosthesis. The purpose of this study was to analyze the mechanical stability of the AMIStem femoral stem by Medacta® International and to demonstrate that the product offers an easy introduction with AMIS® approach. The AMIStem was developed to improve the femoral component implantation during AMIS® (Anterior Minimally Invasive Surgery). It is based on straight rectangular stem design and clinical experience. Specific features are a reduced shoulder and a shortened shaft.

The stability test was carried out at the Heidelberg Institute where a standardized setup is used with a machine which applies an axial torque to the stem pre-implanted into a synthetic femur. Measurements at different sites, on both the stem and the femur allow the evaluation of relative micro-motions, thus providing results in terms of mechanical stability. Prostheses from different manufacturers had already been tested by the same method, which made it possible to have comparative results.

In conclusion, the AMIStem shows good primary stability and the typical fixation pattern of a proximal two thirds anchorage stem. The shortening is a benefit for rotational stability, whereas the fixation modus is not affected by the distal stem reduction. The reduction of the shoulder allows for easier implantation with the AMIS® approach.

Introduction

Among approaches for Total Hip Replacement claimed to be MIS, the anterior minimally invasive approach is the only one that follows a path which is both intermuscular and internervous thus providing all the possible benefits for the patient [1].

The AMIStem femoral stem (Medacta® International SA) has been developed to improve the femoral component implantation during AMIS® (Anterior Minimally Invasive Surgery, Medacta® Int. SA).

The AMIStem is based on the Quadra® stem (Medacta® International SA) design and clinical experience [2].

Building on the advantages inherent in the Quadra® stem design, the AMIStem has been designed to offer more bone preservation and easier introduction in the femoral canal preserving effective mechanical stability. The Quadra® stem is a straight rectangular stem successfully implanted since 2003 with more than 40'000 THA up to December 2009.

In addition, the stability of the Quadra® stem was evaluated in 2005 by a mechanical study at the Heidelberg Institute [3]. This study classified the Quadra® stem as a proximal two thirds anchorage stem that follows closely the torsion of the bone, therefore demonstrating mechanical stability and confirming the good clinical results.

In order to offer the surgeon more bone preservation and an easier implantation with MIS techniques, especially the AMIS® technique, the Quadra®-AMIS®* stem (Medacta® Int. SA) was designed with a reduction of the shoulder [4]. The Quadra®-AMIS®* was introduced in 2007 in two hospitals (Uniklinik Balgrist, Dr. Claudio Dora and Dr. Fabian Kalberer; CMC Paris V, Dr. Frédéric Laude) for clinical evaluation purpose reporting no revisions [5].
Following this intermediate step, the AMIS stem was designed with a 15% reduction of the length to improve bone preservation and stem introduction. The mechanical test was carried out in 2008 and in April 2009 the first AMIS stem was implanted.

This paper aims to present the AMIS stem and its results in terms of mechanical stability and easy introduction.

Material and methods

The purpose of this study is to analyze the mechanical stability of the AMIS stem and to show the results in terms of easy introduction. The AMIS stem prosthesis is a straight triple tapered stem made of Ti-6Al-7Nb (ISO 5832-11) and designed to have a metaphyseal fit.

The stability test has been carried out at the Heidelberg Institute, by the Laboratory of Biomechanics and Implant Research where different prostheses from different manufacturers have already been tested with the same method, providing a comparison background to evaluate the results.

The tests are performed with synthetic femur (composite bone 2nd generation, #3106, Sawbone) that closely resembles the human femur in mechanical properties and dimensions. Four bones are usually used to collect data. For consistency, the stems are always implanted by the same surgeon. The bones are then assembled onto a machine that applies an axial torque to the stem and therefore to the bone (Fig. 3).

This torque is time dependent ranging from -6Nm to +6Nm with a 0.16Nm step. The axial torque twists and bends the bone and the stem and produces differential movements between them. Moreover, a ventro-dorsal torque of maximal 3.5Nm was applied onto the prosthesis stem to evaluate possible tilting. To track this complex behaviour it is necessary to measure the spatial motion at different sites (Fig. 4). The lesser trochanter is used as the reference system. Measurements are carried out at five different sites: two of them are located on the implanted stem (#1: shoulder and #2: stem apex) and the other three on the synthetic bone (#3: 8cm below the lesser trochanter, #4: at the same level of stem apex and #5: 20cm below the lesser trochanter).

*Not FDA Cleared
The average movement for the four samples is the final outcome of the test in term of rotational stability and medio-lateral stability. For the rotational stability, a linear interpolation of the points for both stem and bone can be shown graphically and the differential movements can be compared.

Results

The final outcome of the rotational stability test is a graph with the Distance from the lesser trochanter as the ordinate and the Normalised angle of rotation as the abscissa (fig. 5). The broken line represents the movements of the stem while the solid line represents the bone. The identification of the points is as in fig. 4.

Remembering that each point in the chart comes from the average of the four samples tested, we can estimate the average relative movements between the stem and the synthetic femur.

Where both lines are present, we can evaluate the behavior of the stem and the bone. At the level of the lesser trochanter, which has been taken as the reference system, the average relative motion is 5.20mdeg/Nm whereas at the apex it is -9.97mdeg/Nm. Following the standards of the Heidelberg protocol, these values are sufficient to guarantee rotational stability. Furthermore, the shortening is a benefit for rotational stability, whereas the fixation modus is not affected by the distal stem reduction [6].

The fixation modus is confirmed also by the imprints of the dye test: strong and constant imprints within the proximal area of the stem and little contact at the edges on the cancellous bone in the distal part of the stem. Therefore the AMIStem shows the typical pattern of a proximal two thirds anchorage and follows closely the torsion of the bone.

Moreover, the tilting has been evaluated with the mean movements of stem and bone in medio-lateral direction showing good medio-lateral mechanical stability. These measurements also allow the elastic behavior of the stem to be considered. The average movements at the shoulder and at the tip of the stem are respectively 0.69mdeg/Nm and 0.18mDeg/Nm. This can be considered as a threshold behavior with respect to other stems evaluated with the same method. Considering the fixation modus, that shows little imprints at the distal tip, and the results of the first year implantations [7], that show no tilting, we can conclude that there are no concerns also about the flexibility of the AMIStem.

As far as the introduction of the stem during AMIS® is concerned, it is very easy to measure the space required to insert the stem. It is sufficient to measure the height of the shoulder where the apex of the stem virtually touches the femoral canal following the ideal curve of insertion (Fig. 6).

Using size 4 stems as reference, the AMIStem requires 41mm while for the Quadra® stem 60mm is required. The insertion of the AMIStem is therefore 33% easier [8]. It is important to point out that easier insertion means also less release of soft tissue, providing better results for the patient.

Discussion

Following the experience of Quadra® stems it has been possible to demonstrate the primary stability of the AMIStem. Both stems are suitable for every approach with promising long term results. The use of the AMIStem is particularly appropriate for the AMIS®
approach due to easier insertion that allows to reduce the release of soft tissues. The shortening of the stem and the reduced shoulder in comparison with a standard straight rectangular stem design is clearly related to bone preservation, especially in the lateral part of the greater trochanter.

Clinical evaluations are planned to confirm the mechanical results. The outcomes of the first year implantations are promising [7].

Conclusions

The AMISstem is a bone preserving implant suitable for every approach. Features are the reduction of the shoulder and the shortening of the shaft compared to the design of a standard straight rectangular stem.

The AMISstem shows good primary stability and the typical pattern of a proximal two thirds anchorage, such as the CLS stem (Zimmer Inc) [6] and Quadra® stem. The shortening is a benefit for rotational stability, whereas the fixation modus is not affected by the distal stem reduction [6].

The reduction of the shoulder allows an easier insertion for MIS approaches and especially for the AMIS® approach.

References


[8] Data on file: Medacta®
Abstract

Since the introduction of the low-friction total hip arthroplasty (THA) by Sir John Charnley, polyethylene wear has been a primary issue in hip arthroplasty, as it is associated with the risk of osteolysis. A particular kind of wear is backside wear, that can be described as relative motion between the external surface of a polyethylene liner against the metal acetabular shell socket. As backside wear is generated by the presence of micro-motions, a stable locking mechanism between liner and shell is essential to prevent backside wear. Versafitcup® CC Trio has a combined locking mechanism, composed by a clipping system and a multiple teeth crown. In order to assess the stability of this locking mechanism, mechanical tests have been performed under strong load conditions, well beyond the forces involved in the physiologic behavior of a human hip. The results of tests demonstrate that the Versafitcup® CC Trio has a stable mechanical connection between liner and shell, which even improves its strength properties under load conditions, avoiding the risk of liner rotation and micro-movements, which are the main factors for the development of backside wear.

Is backside wear a real issue in modern design cups?

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Backside wear in THAs

Since the introduction of the low-friction total hip arthroplasty (THA) by Sir John Charnley, polyethylene wear has been a primary issue in hip arthroplasty [1], as it is associated with the risk of osteolysis.

Wear is the removal of material, with the generation of wear particles, that occurs as a result of the relative motion between two opposing surfaces under load. [2] In complex mechanical-biological systems such as total hip and knee replacements, there can be many types of wear.

A particular kind of wear occurs from motion at two nonbearing surfaces. Examples of this phenomena include fretting at a Morse taper between the prosthetic femoral neck and head and backside wear. [1] Backside wear can be defined as relative motion of the external surface of the modular polyethylene liner against the metal acetabular shell. Literature reports that relative motion at the liner/shell interface may contribute to osteolysis. [3]

Many authors report that backside wear is especially related to acetabular shell designs with poor locking mechanisms, that allow significant motion between the polyethylene liner and the concave surface of the acetabular shell. [1,3,4,5]

In-vitro studies [5] demonstrate that a stable locking mechanism significantly reduce the shell-liner micromotion and backside wear. As a result, for the good outcome of a hip prosthesis, it is crucial to avoid the risk of backside wear using an effective locking mechanism design at the interface of shell and liner.
Mechanical tests have been performed to assess rotational stability under dynamic load of Versafitcup® CC Trio acetabular shell coupled with UHMWPE polyethylene liner.

Material and methods

The purpose of the study is to demonstrate that the Versafitcup® CC Trio, used in combination with UHMWPE liner has an effective locking mechanism, stable even under dynamic load, minimizing micro-movements (which are responsible for backside wear). Rotational stability of the liner has been assessed through torsion and push-out tests performed before and after a dynamic load of 10 million cycles.

The tests were carried out according to ASTM F1820-97 standard and the PI-11:98-01 Endolab GmbH accredited internal procedure: Compression test static/dynamic insert.

Implants tested were: 3 Versafitcup® CC Trio acetabular shell size 46 mm, coupled with 3 standard flat UHMWPE liners and a CoCr femoral head size M, 28 mm. The sizes were selected according to the identified worst case.

The UHMWPE raw material is Chirulen 1020 (Quadrant PHS Deutschland GmbH), conforming to ISO 5834-2 type I and ASTM F648. The liners were manufactured by turning compression molded UHMWPE bars and were finished products that followed all the manufacturing process flow including final sterilization. The parameter used for the dynamic load are the following:

- Max force: 14 kN
- Min force: 0.5 kN
- Frequency: 10 Hz
- Cycles: 10 million

The maximum force applied of 14 kN is well beyond the loads and charges involved in a human hip, according to Bergmann et al. [7].

The embedding medium for dynamic tests was a Ringer’s solution, a solution of recently boiled distilled water containing sodium chloride, potassium chloride, and calcium chloride in the same concentrations as their occurrence in body fluids. The solution was at room temperature.

For the torsion test a metal femoral head has been glued into the polyethylene liner and a constant feed rate of 7.5°/min without axial preload has been used. The schematic set-up of the test is reported in figure 3.

For the push-out test the assembly was placed upside down on a metal idler ring. The push-out load was applied by means of a 5 mm circular punch through the central hole on the backside of the acetabular shell. A constant feed rate of 51 mm/min has been used for pushing-out. The schematic set-up of the test is reported in figure 4.

The in vitro hip wear stimulator tests have not been shown to quantitatively predict clinical wear performance.
Results

The value of Push-Out and rotational stability were measured before and after dynamic load, and are reported in the table below (Tab. 1).

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Before Dynamic Load (N)</th>
<th>After Dynamic Load (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Push-Out</td>
<td>1328 Average 36 Mean Std Deviation</td>
<td>1812 Average 21 Mean Std Deviation</td>
</tr>
<tr>
<td>Torsion Test</td>
<td>13.4 Average 1.6 Mean Std Deviation</td>
<td>17.9 Average 0.9 Mean Std Deviation</td>
</tr>
</tbody>
</table>

Tab.1 – Results of Push-Out and Rotational Stability of Versafitcup® CC Trio before and after dynamic fatigue test and push out

After the test we performed also a visual inspection of the Polyethylene liner, and here below you can find the picture of the sample used (Fig.5).

Fig.5 – Pattern generated by the Versafitcup® CC Trio locking mechanism after dynamic load

The black color has been used to underline the pattern generated by the Versafitcup® CC Trio locking mechanism on the polyethylene liner.

Discussion

Torsion and push-out tests have been carried out in order to assess the stability of the Versafitcup® CC Trio locking mechanism. The results of both tests show that after 10 million cycles the Versafitcup® CC Trio is still stable.

In addition, the results are even better after the dynamic load, demonstrating that the connection strength between liner and shell has a progressive improvement under load conditions stronger than the standard charges that can be found in a human hip. The progressive improvement of the locking mechanism guarantees an adequate mechanical stiffness of the connection, avoiding the risk of micro-motion.

Looking at the pattern on the backside of the liner after the tests, it is possible to see all the marks, still separated, left by the spikes of the locking mechanism during the impaction. This is a sign of absence of motions, which has been identified in literature as root cause for backside wear. \[5\]

Conclusions

The Versafitcup® CC Trio has a combined locking mechanism for UHMWPE liners, which is composed by a clipping system and a multiple teeth crown. The results of tests demonstrate that this mechanical connection between liner and shell is stable, and even improves its strength properties under heavy load conditions, minimizing liner rotations and micro-movements, which are the main factors for the development of backside wear.

References

[1] Bezwada HP et al., Acetabular Wear in Total Hip Arthroplasty. eMedicine Orthopedic Surgery 2009 Apr; 15
Analysis of Versafitcup® CC Trio Acetabular shell deformation during impaction

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Abstract

Nowadays ceramic liners’ adoption is becoming greater thanks to the reduced wear. In contrast to bearings with conventional and highly crosslinked polyethylene, for ceramic-on-ceramic bearings with bigger diameters the wear-rate does not increase. On the other side, ceramic liners are the most sensitive to acetabular shell deformation and, considering cups with reduced wall thickness, the shell deformation is the main feature which must be taken into account during impaction. Thin wall thickness could induce cup deformation during the impaction phase, compromising the correct seating of the liner and potentially bring to the ceramic liner rupture [1, 2].

The Versafitcup® CC Trio is the latest development in the Versafitcup® System, which offers a complete product range (including ceramic, conventional and crosslinked polyethylene liners) for any requirement. Coming from the experience of Versafitcup® CC* and Versafitcup® CC Light* (implanted since year 2004), the Versafitcup® CC Trio has the same external characteristics of the system with an inner shell restyling, providing a reduced wall thickness for some shell sizes. This allows the use of bigger heads to better meet the needs of patients and surgeons and better restoring biomechanics.

This paper aims to evaluate Versafitcup® CC Trio shell deformation after impaction and to demonstrate that the registered deformation is not relevant, despite the reduced cup thickness.

In order to assess shell deformation, mechanical tests have been performed. Test results demonstrate that shell impaction causes just a slight geometric deformation of the implant, always within the tolerance values. Furthermore, this deformation has no evident influence on the manual insertion and on the correct final seating of the ceramic liner used in this study.

In conclusion, according to these results, it is possible to assert that no deformation risk occurs during shell impaction phase.

Introduction

Thanks to the reduced wear, ceramic liners adoption is rapidly growing. Considering ceramic liners, the wear-rate does not increase in case of bigger diameters for ceramic-on-ceramic bearings, in contrast to bearings with conventional and highly crosslinked polyethylene.

Nevertheless, considering acetabular shells with reduced wall thickness, the cup deformation is the main feature which must be taken into account during impaction. Thin wall thickness could induce cup deformation during the impaction phase, compromising the correct seating of the liner and potentially lead to ceramic liner rupture.

The Versafitcup® CC Trio (Figure 1a) is the latest development in the Versafitcup® System, which offers a complete product range for any requirements. Coming from the experience of Versafitcup® CC* and Versafitcup® CC Light*, the Versafitcup® CC Trio shell provides different solutions according to the patient’s need: flat and hooded liners in standard or Highcross® crosslinked polyethylene and ceramic liners (Figure 1b) can be adopted. Moreover, it can be supported or not by screws. This new product is a range of press-fit acetabular shells made of Titanium Vanadium alloy (Ti6Al4V) whose surface treatment consists of a titanium plasma spray coating (Ra=100µm) and an hydroxyapatite plasma spray coating (Ra=90µm). For some sizes, the Versafitcup® CC Trio shell is thinner than Versafitcup® CC* and Versafitcup® CC Light* to allow the use of bigger heads to better meet the needs of patients and surgeons and better restoring biomechanics.
As mentioned above, the Versafitcup® CC Trio shell has a thinner structure than well performing Versafitcup® CC* and Versafitcup® CC Light*. This new design provides the use of bigger femoral heads thus increasing the range of motion. Aiming to assess shell deformation after impaction, specific tests have been carried out.

Shell impaction should not cause any significant shell deformation which could compromise the correct seating of the ceramic liner.

Material and methods

The purpose of this study is to assess that the acetabular shell impaction does not cause a significant Versafitcup® CC Trio shell deformation. In first analysis high deformation values could prevent the correct seating of the liner, particularly the ceramic* one.

The test is performed on the Versafitcup® CC Trio shell Ø50 mm manufactured in titanium alloy Ti6Al4V (ASTM F1580) impacted on solid rigid polyurethane foam blocks (Sawbones, Ref.: 1522-04), then manually coupled with a Ceramtec BIoLOX® delta ceramic liner* E Ø36/44G. In fact, among the shells, the worst case is represented by the one with the minimal thickness of the equatorial wall, which is the acetabular cup Ø50 mm, as demonstrated by a Finite Element Analysis. Among the liners, the worst case is represented by the ceramic liner*, since it is the more rigid and therefore the more sensitive to shell deformation. The impaction test [3] is conducted on five specimens and it is carried out as described below.

1. A dimensional control of five acetabular shells is performed before impaction. Dimension A, B, C, circularity and straightness are verified as reported in Figure 2. Every specimen is measured using a CMM Zeiss Contura G2 according to the ISO 7206-2:1996.

2. Five solid rigid polyurethane foam blocks are reamed (Figure 3a) to create a suitable seat for the acetabular cup according to Jin et al. [4]. To finally ream the block an acetabular reamer Ø50 mm and a reamer handle (Precimed) are used.

3. The acetabular shell is connected to a specific cup impactor and then it is impacted in the polyurethane foam block using an hammer (Figure 3b, 4). The impaction is performed until reaching the expected depth.

4. After impaction, the dimensional control of the acetabular shell is carried out and the values are compared to those relative to prior impaction.

As defined by the protocol, the shell deformation must be controlled in order to verify the correct ceramic liner fitting with the acetabular shell and thus the final correct seating of the component. Five ceramic liners* E Ø36/44G are used to perform this test. Each liner is inserted manually in the shell and then gently impacted with the dedicated instrument.

*Ceramic liners, the Versafitcup® CC and the Versafitcup® CC LIGHT are not FDA cleared.
Results

The values of A, B, C, Circularity\(^{(i)}\) and Straightness\(^{(i)}\) dimensions before and after impaction are summarized and reported in Table 1. It is important to underline that deformation values are within the dimensional tolerance range.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Status</th>
<th>A (mm)</th>
<th>B (mm)</th>
<th>C (° ' '')</th>
<th>Circularity (mm)</th>
<th>Straightness (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nominal value</td>
<td>39.100</td>
<td>44.000</td>
<td>18° 55’ 00''</td>
<td>0.010</td>
<td>0.010</td>
</tr>
<tr>
<td>1</td>
<td>Before impaction</td>
<td>39.120</td>
<td>44.019</td>
<td>18° 51’ 7’’</td>
<td>0.004</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>After impaction</td>
<td>39.109</td>
<td>44.022</td>
<td>18° 51’ 10’’</td>
<td>0.039</td>
<td>0.000</td>
</tr>
<tr>
<td>2</td>
<td>Before impaction</td>
<td>39.117</td>
<td>44.014</td>
<td>18° 51’ 4’’</td>
<td>0.004</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>After impaction</td>
<td>39.082</td>
<td>44.019</td>
<td>18° 51’ 17’’</td>
<td>0.084</td>
<td>0.001</td>
</tr>
<tr>
<td>3</td>
<td>Before impaction</td>
<td>39.111</td>
<td>44.013</td>
<td>18° 51’ 57’’</td>
<td>0.007</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>After impaction</td>
<td>39.082</td>
<td>44.016</td>
<td>18° 51’ 50’’</td>
<td>0.069</td>
<td>0.001</td>
</tr>
<tr>
<td>4</td>
<td>Before impaction</td>
<td>39.110</td>
<td>44.008</td>
<td>18° 51’ 36’’</td>
<td>0.005</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>After impaction</td>
<td>39.094</td>
<td>44.009</td>
<td>18° 51’ 25’’</td>
<td>0.047</td>
<td>0.001</td>
</tr>
<tr>
<td>5</td>
<td>Before impaction</td>
<td>39.137</td>
<td>44.029</td>
<td>18° 51’ 30’’</td>
<td>0.003</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>After impaction</td>
<td>39.117</td>
<td>44.031</td>
<td>18° 51’ 47’’</td>
<td>0.055</td>
<td>0.001</td>
</tr>
<tr>
<td>Avg</td>
<td>Before impaction</td>
<td>39.119</td>
<td>44.016</td>
<td>18° 51’ 26’’</td>
<td>0.005</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>After impaction</td>
<td>39.094</td>
<td>44.019</td>
<td>18° 51’ 30’’</td>
<td>0.059</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Table 1. Comparison of Versafitcup® CC Trio shell geometrical values before and after impaction.

After dimensional control each ceramic liner* is manually inserted in the shell and gently impacted with the dedicated instrument.

After the manual insertion the liner rim lies on the same level of the shell rim and after the impaction phase the liner rim lies 0.3 mm under the plane of the shell rim. This demonstrates that the hit sinks the liner of about 0.3 mm.

<table>
<thead>
<tr>
<th>Versafitcup® CC Trio Shell</th>
<th>Ceramic Liner E</th>
<th>Manual Insertion</th>
<th>Final Seating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>LOT 617868</td>
<td>Easy(^{(ii)})</td>
<td>Good(^{(iii)})</td>
</tr>
<tr>
<td>2</td>
<td>LOT 617868</td>
<td>Easy(^{(ii)})</td>
<td>Good(^{(iii)})</td>
</tr>
<tr>
<td>3</td>
<td>LOT 617868</td>
<td>Easy(^{(ii)})</td>
<td>Good(^{(iii)})</td>
</tr>
<tr>
<td>4</td>
<td>LOT 617868</td>
<td>Easy(^{(ii)})</td>
<td>Good(^{(iii)})</td>
</tr>
<tr>
<td>5</td>
<td>LOT 617868</td>
<td>Easy(^{(ii)})</td>
<td>Good(^{(iii)})</td>
</tr>
</tbody>
</table>

Table 2. Results of ceramic liner insertion and final seating test in Versafitcup® CC Trio shell.

\[^{(i)}\] Circularity and Straightness are geometrical parameters used to define the inner cone accuracy.

\[^{(ii)}\] i. e. the ceramic liner stops when its rim lies on same plane of the shell rim.

\[^{(iii)}\] i. e. the ceramic liner rim sinks 0.3 mm under the shell rim.

* Ceramic liners, the Versafitcup® CC and the Versafitcup® CC LIGHT are not FDA cleared.
Discussion

Test results demonstrate that Versafitcup® CC Trio acetabular shell Ø 50 mm impaction causes just a slight geometric deformation of the implant and it is to underline that deformation values are within the dimensional tolerance range. Furthermore, this deformation has no evident influence on the manual insertion and on the correct final seating of the ceramic liner* E Ø36/44G, which has been adopted to evaluate the worst case. According to these results, the dimensional test can be considered passed.

Conclusion

The Versafitcup® CC Trio is the latest development in the Versafitcup® System. Coming from Versafitcup® CC* and Versafitcup® CC Light* implants, it has the same external characteristics of the system with an inner shell restyling to allow the use of bigger heads to better meet the needs of patients and surgeons and better restoring biomechanics. The Versafitcup® CC Trio shell is for some sizes thinner than Versafitcup® CC* and CC Light* implants, providing the adoption of bigger heads with respect to the same external diameter of the cup, performing an increased range of motion.

Hereby described mechanical tests have been performed to assess the lack of deformation risk during impaction phase, giving successful results: all deformation values are within the dimensional tolerance range. According to this study Versafitcup® CC Trio acetabular shells can be used without suffering of significant geometrical deformation values after impaction, providing no difficulties in liner correct seating and no risk in case of ceramic liner* adoption.

References


* Ceramic liners, the Versafitcup® CC and the Versafitcup® CC LIGHT are not FDA cleared.
Global Medacta® Knee Prosthesis GMK® Primary 1 Year Clinical Outcomes

Prim. Dr. W. Anderl [i], Dr. J-P. Canciani [ii], Dr. F. Chalencon [iii], Dr. P. Du Plessis [iv], Dr. P. Lambert [v], Dr. V. Leon [vi], Dr. J-L. Meriaux [vii], Dr. J-L. Meystre [viii], Dr. R. Mendelin [ix], Dr. P. Vieber [x], Dr. J-R. Wootton [xi]

GMK® International Evaluation Group

Abstract

The clinical surveillance of GMK® Primary total knee prosthesis is currently being investigated in 11 centers belonging to the International Evaluation Group. The 1-year follow up collected on 322 GMK® Primary total knee replacements (TKRs) performed on 313 patients, shows encouraging results both in terms of implant performances and patients’ satisfaction.

The 1-year survival rate for all GMK® Primary versions studied (fixed and mobile) is 100% considering aseptic loosening as end point and 99.4% considering any reason for revision. From a radiological analysis it has been assessed that all the prosthetic components are stable and well fixed. No critical radiolucencies bigger than 2 mm have been reported neither for cemented nor for uncemented implants. Moreover, 95% of patients declared an excellent or good rate of satisfaction. The Knee Society Score (KSS) significantly improved after surgery for all the subjects included in the study.

Pain reported before surgery has been post-operatively reduced or completely eliminated and the joint mobility properly re-established. Clinical evaluation will continue with a second follow up scheduled at 2 years.

Introduction

Medacta® International has set up a multi-center study in collaboration with an International Evaluation Group of surgeons to monitor the GMK® Primary* total knee prosthesis performance. Currently, eleven (11) centers are involved in the clinical evaluation of the GMK® Primary* total knee prosthesis with, to date, a mean follow-up of 12 months.

Each subject had a pre-operative clinical and radiological examination. Following implantation, there were clinical and radiological examinations at several periods of time.

The parameters kept into consideration are both physical and subjective. The Knee Society Score (KSS) both as general value and as functionality and grade of pain reported has been evaluated [1]. The range of motion, reported both as active and passive one, has been considered satisfactory if the subjects can reach at least 100° of motion, from 0° in extension to 100° in flexion.

From the radiological point of view, particular attention has been paid to the presence of radiolucency. The area around the tibial and the femoral component has been divided into different zones as reported in Figure 1. Radiolucencies smaller than 2 mm were not considered

Figure 1. Areas with possible radiolucency around the tibia (left) and around the femur (right)
as critical, as by the literature many authors consider radiolucencies as a sign of probable aseptic loosening in the future only if they are bigger than 2 mm [2].

Subjective data, such as patient satisfaction, have been reported too. The survival rate has been computed considering the aseptic loosening as endpoint.

These data represent a frame of reference to evaluate functional recovery of the prosthetic knee and overall patient satisfaction.

**General Data**

The study involved 11 centers and 313 patients, 38% male and 62% female, corresponding to 322 prosthetic knees implanted from January 2007 to March 2010 (Table I). 85% implants were all cemented, 13.8% implants were uncemented* and 1.2% implants were hybrid (cementless* femoral component on cemented tibia or vice versa). The mean follow-up is 12 months (371 ± 83 days).

<table>
<thead>
<tr>
<th>Tibial Baseplate</th>
<th>n. of cases</th>
<th>Insert Type</th>
<th>n. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed</td>
<td>84</td>
<td>STD</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>UC</td>
<td>82</td>
</tr>
<tr>
<td>Mobile*</td>
<td>238</td>
<td>STD</td>
<td>190</td>
</tr>
<tr>
<td></td>
<td></td>
<td>UC</td>
<td>48</td>
</tr>
</tbody>
</table>

Table I. Number of cases for each insert type

The subject population under survey presents a mean age at time of surgery of 72 years, ranging from 45 to 95, and reports a mean body mass index (BMI) of 29.88 Kg/m² [20.1 – 48.9].

The main reason for surgery was primary osteoarthritis as underlined by the following pathology distribution:

- 87% primary osteoarthritis
- 28% rheumatoid arthritis
- 9% secondary osteoarthritis
- 0.6% osteonecrosis
- 0.3% failed unicompartmental arthroplasty
- 0.3% fracture
- 0.6% other

The sum of percentage reported is over 100 since certain patients did present co-morbidity.

**Statistical Analysis**

Descriptive analysis was performed with use of univariate statistics for the continuous variables and frequency distribution for the categorical variables.

Results are reported as means and standard deviations. In order to evaluate the difference between preoperative and postoperative group paired Student’s t-tests were performed. The results of these comparisons are reported as p-value (<0.05).

**Implants size distribution**

By a first analysis of the distribution size of all components, we can observe a good fit of the system to the presenting patient’s knee joint morphology.

The central sizes (from 2 to 5) are the most frequently used for both tibial and femoral component (see Figure 2, Figure 3).
Figure 4 and figure 5 show the thickness distribution of the inserts used with the mobile* and fixed tibial baseplate.

Intra-Operative Complications

2% of patients experienced some intra-operative complications without major consequences:
- 2 malposition
- 4 other:
  - 1 bone defect of the anterior cortical (necessitating a bone graft);
  - 1 excessive femoral distal cut
  - 2 not specified.

Preliminary results

Generally, the results show a successful functional recovery for most of the subjects. The mean KSS improved 80 points for mobile* tibial baseplate implants and 81 for fixed tibial baseplate implants. In table II, the mean score is counted for three implants groups: mobile* bearing with standard insert, mobile* bearing with ultracongruent insert and fixed bearing with ultracongruent insert. The group with fixed bearing and standard insert hasn’t been taken into account for statistical analysis since it’s too a small sample group.

The data shows that the KSS score is significantly higher compared to its respective pre-operative score (Table II), regardless of tibial baseplate and insert type group.

<table>
<thead>
<tr>
<th></th>
<th>Pre-op. KSS</th>
<th>Post-op KSS (mean follow-up 12 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobile* UC</td>
<td>98.4* ± 24.9</td>
<td>179.7± 23.1</td>
</tr>
<tr>
<td>Mobile* STD</td>
<td>98.9* ± 23.4</td>
<td>178.4± 26.2</td>
</tr>
<tr>
<td>Fixed UC</td>
<td>97.6* ± 24.9</td>
<td>178.2± 21.4</td>
</tr>
</tbody>
</table>

Table II. Pre-operative and post-operative kss
* significant difference between pre and postoperative group (p<0.05)

After intervention a general improvement of the mobility of the joint was reported; the contracture in extension significantly decreases, flexion increases allowing patients to reach a greater range of motion for both passive and active movements, pointing out a significant statistical difference with standard insert in comparison to preoperative group and a significant statistical increment of passive flexion with ultracongruent insert in only fixed tibial baseplate type (Table III and IV).

By the data analyzed, all subjects were able to reach satisfactory outcomes. Extension was improved, with...
most of the patients being able to reach the 0° and the active flexion was higher than 120° in 68% of patients for insert standard and 47% for insert ultracongruent, reaching also a maximum value of 140° with both inserts. These results show that the implant itself isn’t a limiting factor for flexion for obese patients, as represented in Figure 7. This figure shows that the obese subjects were able to attain 130° of flexion like overweight and normal weight patients do.

A radiological analysis permitted us to evaluate the eventual presence of radiolucencies all components seem stable and well fixed. At mean follow-up of 12 months; no radiolucencies bigger than 2 mm were present in any zone for both cemented and uncemented* implants. No cases of bone penetration, tibial insert wear (medial/lateral), subsidence or implant breakage occurred. Some local and systemic complications have been reported during follow-up. 2.8% of patients experienced pain localized at patella or tibia, in particular for one patient with fixed tibial bearing and UC insert implanted, the surgeon resurfaced the patella.

These results show that the implant itself isn’t a limiting factor for flexion for obese patients, as represented in Figure 7. This figure shows that the obese subjects were able to attain 130° of flexion like overweight and normal weight patients do.

A radiological analysis permitted us to evaluate the eventual presence of radiolucencies all components seem stable and well fixed. At mean follow-up of 12 months; no radiolucencies bigger than 2 mm were present in any zone for both cemented and uncemented* implants. No cases of bone penetration, tibial insert wear (medial/lateral), subsidence or implant breakage occurred. Some local and systemic complications have been reported during follow-up. 2.8% of patients experienced pain localized at patella or tibia, in particular for one patient with fixed tibial bearing and UC insert implanted, the surgeon resurfaced the patella.

This preliminary data seems to be very promising with only a case of revisions reported, due to an infection.

### Table III. Active flexion and active extension pre and post-operative

<table>
<thead>
<tr>
<th></th>
<th>Active flex pre (mean follow up 12 months)</th>
<th>Active ext pre (mean follow up 12 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobile* STD</td>
<td>113.9* ±15.5</td>
<td>5.4* ±7.2</td>
</tr>
<tr>
<td>Mobile* UC</td>
<td>107.5 ±16.3</td>
<td>8.4* ±9.0</td>
</tr>
<tr>
<td>Fixed UC</td>
<td>110.5 ±11.7</td>
<td>5.6* ±8.2</td>
</tr>
</tbody>
</table>

* a positive value means a deficit in extension
* significant difference between pre and postoperative group ( p<0.05)

### Table IV. Passive flexion and passive extension pre and post-operative

<table>
<thead>
<tr>
<th></th>
<th>Passive flex pre (mean follow up 12 months)</th>
<th>Passive ext pre (mean follow up 12 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobile* STD</td>
<td>117.5* ±15.7</td>
<td>4.2* ±6.8</td>
</tr>
<tr>
<td>Mobile* UC</td>
<td>110.3* ±17.7</td>
<td>8.0* ±9.2</td>
</tr>
<tr>
<td>Fixed UC</td>
<td>112.7* ±11.7</td>
<td>4.9* ±7.6</td>
</tr>
</tbody>
</table>

* a positive value means a deficit in extension
* significant difference between pre and postoperative group ( p<0.05)
Conclusion

Generally, the results show a successful functional recovery for the majority of subjects at mean follow-up of 12 months: pain reported before surgery was reduced or eliminated and the joint mobility was re-established. KSS improved significantly after surgery for all subjects. From a radiological analysis all components are stable and well fixed. No critical radiolucency of more than 2 mm were reported both cemented and uncemented* implants.

95% of patients declared an excellent or good rate of satisfaction. According to the data collected to date, the 1-year survival rate for all GMK® Primary* versions studied is 99.4%, considering any reason for revision and 100% considering aseptic loosening.

To evaluate the trend of performance and of security of the GMK® Primary* total knee prosthesis in the future, it will be necessary to continue with the clinical evaluation. The number of subjects enrolled will be enlarged and outcomes at greater intervals of time after intervention will be collected.

References


Abstract
Surgical errors resulting in implant malpositioning are one of the most frequent causes of revision TKAs. A deviation from the neutral mechanical axis greater than ±3° is demonstrated to decrease the implant longevity. An analysis of 207 GmK® for total knee replacements performed through iMNS™ Medacta® Navigation System reported that 95% of cases are positioned respecting the acceptable range of ±3°, showing how this procedure may potentially increase implant survival rate.

Introduction
Total knee arthroplasty (TKA) is a well-established procedure that generally results in relief of pain, improved physical function and a high level of patient satisfaction. TKA is conventionally performed with the use of intramedullary or extramedullary alignment guides and achieves a high rate of success. However, it has been suggested that the most common cause of revision TKAs is the surgical error resulting in malpositioning of the components, which leads to poorer post-operative outcomes. Restoration of the coronal mechanical axis within 3° is thought to be optimal for a better outcome [1,2]. Based on the theoretical assumption that the use of computer-assisted systems (CAS) in TKA may improve implant alignment and thus improve implant longevity, the use of this technology has become popular.

Currently, four (4) centers are involved in the evaluation of axial alignment restoration during total knee prosthetic surgery with computer assisted technology. The performance of CAS system was investigated radiographically on the basis of axial alignment of the lower extremity measured preoperatively and postoperatively.}

General Data
From January 2008 to September 2010, 207 prosthetic knees (GmK® Primary, Medacta®) were implanted using a navigation system (iMNS™, GMK®-Evolis® 4.0 software) (Figure 3) on 198 patients, 68.7% female and 31.3% male, with a mean age at time of surgery of 72 years (46-87) and a mean body mass index (BMI) of 30.9 kg/m² (21.2-53.3). The study involved 4 centers. In 1 center, it was not possible to collect all radiographic data, in particular we’ve information about HKA preoperative alignment only for 20% of patients and CH angle was not evaluated in all cases.

45% of the surgeries with the navigation system were performed with a minimally invasive approach.

Statistical Analysis
Descriptive analysis was performed with use of univariate statistics for the continuous variables and frequency distribution for the categorical variables.

Radiological Measurements
Anteroposterior long leg radiographs were taken. The mechanical axes of the long leg before and just after operation were evaluated. Axial radiographs of the femur and tibia were taken too.

The mechanical axis of the femur (FM) is represented by a line from the center of the femoral head running distally to the mid-condylar point between the cruciate ligaments. In the case of the tibia, the mechanical axis (TM) is a line from the center of the tibial plateau (interspinous intercruciate midpoint) extending distally.

[i] Centre Clinical, Soyaux, France
[ii] Hospital de La Vega Lorenzo Guirao, Murcia, Spain
[iii] Merianiselinspital, Basel, Switzerland
[iv] Casa di Cura “Villa Salus”, Messina, Italy
to the center of the tibial plafond. The angle between these 2 axes is the hip-knee-ankle (HKA) angle. In the neutrally aligned limb the HKA angle approaches 180°. At this point FM and TM are colinear, pass through the knee center, and are coincident with the load-bearing axis, which is the line of ground reaction force passing from the ankle to the hip (Figure 1B). In a varus knee, the joint center is lateral to the load-bearing axis (Figure 1A), whereas in a valgus knee, the joint center is displaced medially (Figure 1C) [3].

The hip-knee-ankle angle is measured on a full length standing radiograph of the entire lower extremity. Based on simple geometric analysis the following elements usefully define in the frontal plane the geometry of the tibial and femoral surfaces and the angle between them when loaded in stance (Figure 2):

1. Condylar-hip (CH): the angle of the femoral condylar tangent with respect to the FM axis
2. Plateau-ankle (PA): the angle between the tibial margin tangent and the TM axis
3. Condylar-plateau (CP): the angle between the femoral and tibial joint surface tangents.

Results

Generally, the results of our investigation showed an improvement in the HKA alignment just after surgery, in comparison to values measured before. The percentage of patients with a neutral alignment, with a tolerance of ±3°, increased from 9% pre-operatively to 95% post-operatively (Figure 4).

Analyzing separately the condylar-hip and plateau-ankle angles showed the increased concentration of around 90° in comparison to measures taken before surgery (Figure 5 and 6). In particular before surgery, CH angle distribution is spread on all ranges, from minimum value of <84° to a maximum value of >96°. On the contrary, PA angle is more concentrated below 90°. After surgery 99% of knees show CH angle between 88° and 92° and 97% reports PA angle between 88° and 92°.

The same trend is confirmed when a minimally invasive approach is used.
Discussion and conclusion

Our results suggest that iMNS™ computer-assisted surgical navigation for total knee replacement is able to restore a good axial alignment. By the analysis of 207 TKR surgeries, 95% of the population showed a post-operative HKA neutral alignment.

Axial alignment of the limb with restoration of the HKA neutral axis is a determinant of the outcome in TKA surgery. In particular, a mechanical axis within a range of ±3° varus/valgus is thought to be associated with a better clinical outcome [1,2]. Regarding that there’s a well-established consent in literature and many studies compared the results obtained with CAS and conventional system, showing predominance of computer assisted surgery to the conventional: the mechanical axis within ±3° of neutral mechanical alignment is restored in around 90-95% of navigation cases in comparison to about 70-80% of the conventional cases [4, 5, 6, 7, 8].

On the contrary, there’s still not a general consent about the appropriate tibial and femoral prosthetic components positioning and their analysis is left out in most of the cases. There are only few studies that report an indicative tolerance range for tibial and femoral components. Molli et al. defined, only for tibial component, ±2° as acceptable deviation from the neutral tibial mechanical axis in the frontal plane [9]. In other studies, it has been considered a tolerance range of ±2° or ±3° for both tibial and femoral component [6, 10].

In conclusion, GmK® total knee replacement performed through iMNS™ Navigation System can be considered as a safe and reliable procedure that allows for an improvement in HKA alignment thus potentially increasing the prosthetic implant survival rate.
References


GMK® Primary
Posterior-Stabilized Implant: Design Rationale

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Medacta® International, Product Management department, Research & Development departments,
Castel San Pietro, Switzerland

Abstract
Medacta® is committed in developing orthopedic solutions in the complete respect of the natural anatomy and kinematics of the patient. The GMK® Primary System has been developed following this philosophy: bone preserving, anatomic femoral components and asymmetric tibial plateau are just few examples of our expertise.
This rationale aims to describe a particular version of the GMK® Primary System: the GMK® Primary Posterior Stabilized implant. Also for this implant, our priority is the respect for the patient, achieved through the bone preserving design of the femoral component.
Unlike the PS implants proposed by other companies, Medacta® designed a PS implant without a box in the femoral component which allows to sacrifice a minimum bone stock. Bone preservation is also allowed by minimal femoral resections: just 8 mm distal and posterior cuts for all sizes.
The absence of a box in the femoral component, allows to position the femoral implant performing just a small finishing of the intercondylar notch, without sacrificing a consistent bone stock.
Medacta® does not make you reach a compromise: with just a finishing of the intercondylar notch and without sacrificing a consistent bone stock allows the surgeon to meet the patient’s anatomy and expectations.
In the next pages you can read the results of the studies carried out to evaluate the performance of the GMK® PS fixed tibial inserts. Parameters such as range of motion, post performances, stability, hyperextension have been evaluated. Analyzing the results of the tests, it can be asserted that the GMK® PS implant offers good stability and natural kinematics without using a femoral box.

Introduction
A physiological flexor/extensor mechanism is fundamental to the function of the human knee. The aim of a posterior stabilized total knee replacement is the recovering of the normal function of the leg in relation to the daily activities of the patient and to reproduce the femur-tibial roll-back which is due to the posterior cruciate ligament (PCL) in the healthy knee.

When a PCL-substituting total knee replacement is performed, a restored physiological translation of the femur component over the tibial base-plate during knee flexion, referred to as femoral rollback, is associated with reduced quadriceps and patellar loads [1].
The PCL-substituting total knee replacement proposed by Medacta® is the GMK® Primary PS implant. The implant is composed by the GMK® PS femoral

Figure 1: GMK® PS femoral component and tibial insert. The posterior-stabilized mechanism is based on a posterior cam placed on the femoral component and a PS spine on the tibial insert.
Component and the GMK® PS fixed tibial insert. The GMK® posterior-stabilized mechanism is based on a posterior cam placed on the femoral component and a PS spine. Unlike the PS implants offered by many competitors, the GMK® PS femoral component does not have box and consequently requires a minimum bone stock sacrificing (Figure 1).

The GMK® PS femoral component is bone sparing also because is part of the GMK® system: the thickness of the distal and posterior condyles of all GMK® femoral components is only 8 mm, independently from the size being implanted.

In order to evaluate the performance of the GMK® PS fixed tibial inserts, a number of geometrical studies were carried out by means of a CAD software. The following parameters have been evaluated:

- Range of Motion
- PS cam and post performances
- Antero-posterior stability: Jump Over
- Hyper-extension and spine damage
- Static and fatigue endurance of PS spine and connection between insert and tibial tray
- Static medio-lateral stability
- Pull-off resistance.

**Range of motion (ROM) test**

During the ROM test, the PS femoral component was positioned with the PS cam surface tangent to the PS spine surface and the articulating surface tangent to the PS tibial insert. It was considered that the maximum flexion occurs when the highest point of the posterior wall exceeds the plane of the femoral posterior bone resection of 2.6 mm (Figure 2). The rotational freedom between the femoral and the tibial component was also obtained by means of the geometrical reconstruction of the articulating surfaces.

The study has been performed comparing GMK® TKR system with the Evolis® TKR system, which has 15 years clinical history. The theoretical ROM and the rotational freedom obtained in full extension for the GMK® PS, Evolis® PS, PFC-Sigma DePuy PS and Zimmer NexGen® LPS tibial inserts are shown in Table 1. Figure 3 shows the values of the theoretical ROM obtained with the Evolis® PS and the GMK® PS fixed tibial inserts.

<table>
<thead>
<tr>
<th></th>
<th>GMK® PS tibial insert</th>
<th>Evolis® PS tibial insert</th>
<th>PFC-Sigma DePuy PS tibial insert</th>
<th>Zimmer NexGen® LPS tibial insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theoretical ROM</td>
<td>138°</td>
<td>125°</td>
<td>125°</td>
<td>125°</td>
</tr>
<tr>
<td>Rotational freedom</td>
<td>+/- 10°</td>
<td>+/- 7°</td>
<td>+/- 7.5°</td>
<td>+/- 6°</td>
</tr>
</tbody>
</table>

Table 1: Values of theoretical ROM and rotational freedom in full extension for GMK® PS, Evolis® PS, PFC-Sigma DePuy PS and Zimmer NexGen® LPS tibial inserts [2].

When comparing the position of the PS spine in the GMK® PS and the Evolis® PS tibial inserts, it can be observed that the position of the GMK® PS spine is more anterior. Consequently at high flexion the posterior condyle of the GMK® femoral component is far away from the tibial insert posterior edge. Therefore, it can be
assessed that the position of the PS cam corresponds to a safer condition if compared to the Evolis® implant, but the ROM is not decreased.

Results (Table 1 and Figure 3) showed that the theoretical ROM and the rotational freedom of the GmK® PS tibial inserts are greater than the values obtained with the Evolis® tibial inserts and claimed by DePuy for PFC-Sigma PS tibial inserts [2]. As a result it can be assert that the GmK® fixed tibial inserts are expected to meet the patient expectation as well as the Evolis® inserts. Therefore, we may assert that the entire product range of the GmK® tibial inserts is substantially equivalent to the Evolis® whose success is proven by its 15 years clinical history with more than 35,000 implants and a low rate of revision [2].

In addition it has to be noticed that the GmK® PS tibial insert guarantees a good range of motion even without a specific femoral box: the GmK® PS femoral component requires only a finishing of the intercondylar notch and is therefore bone sparing.

PS cam and post performances

The degree of flexion when the GmK® PS femoral cam and the PS fixed tibial insert spine reach the contact was evaluated by means of a CAD software. The test consisted on positioning the femoral component in contact with the PS tibial insert and on flexing the femoral component without tibial intra-rotation.

Table 2 shows that the degree of flexion when the GmK® PS femoral cam and the PS fixed tibial insert spine reach the contact is similar to the competitors’ stabilized knee replacement ones.

<table>
<thead>
<tr>
<th></th>
<th>GMK® PS fixed tibial insert</th>
<th>PFC-Sigma DePuy fixed tibial insert</th>
<th>NexGen LPS tibial insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cam and post contact level</td>
<td>80°</td>
<td>80°</td>
<td>75°</td>
</tr>
</tbody>
</table>

Table 2: Cam and post contact level for the GMK® PS fixed tibial insert and the competitors’ implants [2].

The tibial femoral rollback was also evaluated by means of a CAD software. When the PS femoral component is positioned at 120° of flexion and 0° of intra-rotation with the PS cam surface tangent to the PS spine surface and the articulating surface tangent to the PS tibial insert, the rollback is identified as the distance between the position of the tibial-femoral contact point and the deepest point of the PS tibial insert articulating surface in the anterior-posterior direction (Figure 4).

The value of the rollback for the GmK® PS tibial insert (9 mm through 13 mm) is similar to the value recorded for the Evolis® PS tibial insert (11 mm through 15 mm) [2] and to the value of the physiological rollback of the knee recorded in the literature (12 mm on the average) [3-4].

Antero-posterior stability: jump over

When the PS femoral component is positioned at 90° of flexion and 0° of intra-rotation with the PS cam surface tangent to the PS spine surface and the articulating surface tangent to the PS tibial insert, the jump over is defined as the distance between the highest point of the PS spine and the contact point between the PS cam and the PS spine (Figure 5).
As shown in Table 3 the jump-over value of the GMK® PS fixed tibial insert is similar to the evolis® one (16 mm versus 15.7 mm respectively) and those of the main competitors. For this reason, can be assert that the risk of dislocation is as low as the evolis® one.

Compared to the femoral components of the competitors listed in Table 3, GMK® PS femoral component allows to sacrifice a minimum bone stock. It has been calculated that in the worst condition (GMK® PS femoral component size 6) GMK® PS femoral component requires to sacrifice only 10 cm³. On the contrary the competitors require to sacrifice a mean value of 25.4 cm³ (Figure 6) [2].

<table>
<thead>
<tr>
<th></th>
<th>GMK® PS fixed tibial insert</th>
<th>Evolis® PS fixed tibial insert</th>
<th>PFC-Sigma DePuy PS tibial insert</th>
<th>NexGen® LPS tibial insert</th>
<th>Vanguard Biomet stabilized tibia insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jump over value</td>
<td>16 mm</td>
<td>15.7 mm</td>
<td>16.3 mm</td>
<td>16 mm</td>
<td>17.3 mm</td>
</tr>
</tbody>
</table>

Table 3: Jump over value for the GMK® fixed tibial insert, Evolis® PS fixed tibial insert and the competitors’ implants [2].

Figure 6: Bone resection volume for GMK® PS femoral component and some posterior-stabilized femoral components of the competition. The GMK® PS femoral component requires to sacrifice only 10 cm³ because it does not have a femoral box [2].
Hyper-extension and PS spine damage

The breakage of the PS spine of the tibial insert is a complication which is recorded in the literature \([5-8]\) and is often due to the impingement between the anterior part of the PS spine and the femoral component intercondylar notch during hyper-extension movements.

<table>
<thead>
<tr>
<th>Hyper-extension</th>
<th>GMK(^\circ) PS fixed tibial insert</th>
<th>Evolis(^\circ) PS fixed tibial insert</th>
<th>PFC-Sigma DePuy stabilized tibial insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>(14^\circ)</td>
<td>(5^\circ) through (7^\circ)</td>
<td>(8^\circ)</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Hyper-extension value for the GMK\(^\circ\) PS fixed tibial insert, Evolis\(^\circ\) PS tibial insert and the competitors’ implants \([2]\).

The results of the geometrical study carried out show that the hyper-extension allowed by the GMK\(^\circ\) PS fixed tibial insert spine is higher (Table 4) than the Evolis\(^\circ\) one and the competitors’ stabilized knee replacement ones, whose successful experience is recorded in literature (Figure 7).

Figure 7: GMK\(^\circ\) PS fixed tibial insert and PS femoral component assembly at \(0^\circ\) of flexion (left); GMK\(^\circ\) PS fixed tibial insert and PS femoral component assembly \(14^\circ\) of hyper-extension (right).

Static and fatigue endurance tests of ps spine and clipping mechanism between insert and tibial tray

The resistance of PS spine and clipping mechanism of the GMK\(^\circ\) PS fixed tibial insert to the stress generated when the patient performs daily activities was tested by means of a static and a fatigue mechanical test.

The clipping mechanism between the GMK\(^\circ\) PS fixed tibial insert and the GMK\(^\circ\) fixed tibial tray consists in a peripheral wall, an anterior and posterior clip system and a fixing screw (Figure 8).

Figure 8: GMK\(^\circ\) PS fixed tibial insert; a) 3D view; b) sagittal view

The fixing screw, the tibial insert posterior clip and the insert spine have been tested in order to evaluate the static mechanical resistance during a test where an increasing anterior-posterior load was applied to the PS spine of the tibial insert by means of the PS femoral component during the simulation of the most critical daily activity: rising from a chair. During this activity the load transferred by the femoral component to the PS spine at \(90^\circ\) of flexion is maximum \([9]\), therefore the bending moment of the tibial insert generates the maximum stress on the tibial insert clipping system \([6]\).

Figure 9: GMK\(^\circ\) PS fixed tibial insert; direction of the applied load (left); the sagittal section shows the load application point which is the contact point between the PS cam of the femoral component and the PS spine of the insert (right).
When the GmK® posterior stabilized fixed tibial insert is loaded with an anterior-posterior load applied to the PS spine, the resistance towards the detachment from the tibial tray is given by the posterior clip mechanism and the fixing screw. The cross section of the posterior clip is minimal when the PS fixed tibial insert is from size 1. The maximal stress in the posterior clip and the fixing screw occurs when the distance of the load from the tibial tray surface is maximal: therefore the worst case is the PS fixed tibial insert size 1 height 20 mm.

The resistance of the GmK® PS fixed tibial insert was tested in the most critic condition (PS fixed tibial insert size 1 height 20 mm, femoral component at 90° of flexion and 0° of tibial intra-rotation). In addition, the static and fatigue endurance tests have been performed without fixing the components with the fixing screw.

Within the static test condition, the connection system of the GmK® has failed at a load of 1313 N, whereas the ultimate failure strength of the posterior cruciate ligament in vivo condition is 1280 N as reported by Kennedy et al. [10]. Therefore, it can be assessed that the connection system is able to resist the maximal anterior-posterior forces applied to the post ligament in vivo conditions.

During the dynamic test, the GmK® PS fixed tibial insert has been tested applying an increasing load to the PS spine by means of the femoral component. The mechanical resistance of the GmK® PS fixed tibial insert was evaluated during a fatigue endurance test. During the dynamic test a progressive load has been applied for 10 millions cycles to the PS spine of the tibial insert by means of the PS femoral component with a frequency of 10 Hz. The protocol has been chosen to simulate an expected implant’s life of 10 years.

Data shows that even with a peak load of 710 N, the connection system is still safe. Therefore, the dynamic test confirms that the GmK® connection system is substantially equivalent to the Evolis® connection which has withstand the cycled stress throughout the expected implant’s life [2]. The tests have been performed without fixing the components with the fixing screw, but actually the fixation screw is always foreseen within this configuration, making the modular device safer and more effective.

Static medio-lateral test

The GmK® PS fixed tibial insert was also tested to evaluate the ability to remain assembled to the tibial tray when a force is applied in the medial/lateral direction in the most critical condition. To reproduce the most critical condition the fixation screw has been deliberately omitted: therefore the fixation between the tibia insert and the tibia tray is only secured by the peripheral wall and the anterior/posterior clip mechanism. Moreover, considering the clearance between the intercondylar notch of the femoral component and the PS spine, the clearance is consistently reduced at 0° of flexion and the stress on the lateral side of the PS spine is increased. On the contrary, at 90° of flexion the clearance is larger and the stress is mainly concentrated on the posterior side of the spine (Figure 10).

Figure 10: Clearance between the intercondylar notch of the GmK® PS femoral component and the PS spine at 0° of flexion (left) and 90° of flexion (right)

When testing the GmK® PS fixed insert considering the most critical condition (connection not secured by the fixation screw, femoral component at 0° of flexion which corresponds to a reduced clearance) the insert failed at 1,814 N which is a value higher than the value obtained by the competitor testing the PFC® TC3 (1,495 N) [2].
Pull-off test

The ability of the fixed tibial insert to remain assembled to the tibial tray when a traction force is applied along the vertical axis direction was tested. The test was performed without using the fixation screw. The test confirmed the design integrity of the connection between the GmK® tibial insert and the matched tibial tray [2].

Conclusion

The solution proposed by Medacta® for a PCL-substituting total knee replacement is the GmK® Primary PS implant which is part of the GmK® system.

Unlike the implants proposed by many competitors, the GmK® Primary PS implant does not have a femoral box, requiring only a finishing of the intercondylar notch. The implant allows the surgeon to be bone preserving also because the thickness of the distal and posterior condyles is only 8 mm, independently from the size being implanted.

A number of tests have been conducted on the GmK® Primary PS implant in order to evaluate its performance. Parameters such as range of motion, post performances, stability, hyperextension have been evaluated. Analyzing the results of the tests, it can be asserted that the GmK® PS implant offers good stability and natural kinematics without using a femoral box. Medacta® does not make you reach a compromise: with just a finishing of the intercondylar notch and without sacrificing a consistent bone stock allows the surgeon to meet the patient’s anatomy and expectations.

References

Polyethylene in TKA: do we really need cross-linked polyethylene?

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Medacta® International, Product Management department, Castel San Pietro, Switzerland

Abstract

How important is polyethylene failure in TKA?: The most common causes of revision in total knee arthroplasty (TKA) are infection and loosening, followed by pain, instability and arthrofibrosis. Only 1.4% of TKA revisions is due to polyethylene failure [1].

What happens to the tibial inserts when polyethylene failure occurs?: In case of polyethylene failure in TKA, the tibial inserts are characterized by delamination [2]. Differently, in total hip arthroplasty (THA) polyethylene failure is characterized by adhesive or abrasive wear. This is due to the different conformity of the knee joint compared to the hip joint, to the higher contact stresses and to the different location of the maximum shear stress [3].

How to avoid delamination?: To avoid delamination it is fundamental to preserve the mechanical properties of polyethylene rather than increase the wear resistance [4].

What about cross-linked polyethylene in TKA?: Some orthopedic companies offer a cross-linked polyethylene tibial insert. While cross-linked polyethylene has become a golden standard in THA, its introduction into TKA is still controversial [5]. In fact, the cross-linking process allows an increase in polyethylene wear resistance but decreases the mechanical properties [4].

Does the sterilization process affect the mechanical properties?: Some sterilization methods are based on ionizing radiation which decreases the mechanical properties of polyethylene. Ethylene oxide sterilization is a well-known method which does not substantially affect the physical, chemical or mechanical properties of polyethylene and does not promote oxidation [6].

Why choose GMK® tibial inserts?: Medacta® GMK® tibial inserts are made of compression molded polyethylene GUR1020 with superior mechanical properties if compared to the cross-linked polyethylene. GMK® tibial inserts are sterilized with ethylene oxide and they do not undergo any irradiation or thermal process that can affect the mechanical properties and the oxidative stability of the material [7].

Polyethylene wear in revision TKAs

Primary total knee arthroplasty (TKA) is a successful operation associated with important improvements in quality of life and restoration of function for the patient. As a result of the success of TKA, its indications have widened to include younger and more active patients, increasing the demand for this procedure. As a consequence, the number of revision TKAs is also rising and it is estimated to increase to 601% from 2005 to 2030 [8].

The Australian Orthopaedic Association National Joint Registry reports the most common causes of revision TKA. The registry identifies loosening/lysis as the main reason for revision TKA (31.2%) followed by infection (22.2%), patello-femoral pain (14.3%), pain (9.1%), instability (5.5%), arthrofibrosis (4.6%), fracture (2.3%), malalignment (2.1%) and polyethylene failure (1.4%) [11].

Polyethylene failure mechanism in TKA prostheses was evaluated endoscopically by Kondo et al. [2]. The authors reported that the knees which had widespread, severe polyethylene wear were all characterized by delamination. A survey of the overall polyethylene surface showed deep erosion and fragmentation on the posterior site: this may lead to mechanical instability and, if not treated, risk of metallosis by metal-with-metal contact [2]. Lu et al. [9] assessed the severity of polyethylene failure in fixed-bearing and mobile bearing knee implants and reported that the polyethylene upper surface of the fixed bearing implants was characterized by scratching, pitting/metal embedding and delamination [9].

Therefore, it can be assessed that the most common causes of revision TKA are infection and loosening, while revision TKA due to polyethylene failure is only a small percentage of the total revision TKAs. When polyethylene failure in TKA occurs, it is often associated to delamination.
The Medacta® GMK® tibial inserts

The GMK® inserts are made of Ultra-High Molecular Weight Polyethylene (UHMWPPE), which is a compression-molded medical grade polymer for surgical implants according to ISO 5834 and ASTM F 648.

The low calcium GUR 1020 is the raw material from which the UHMWPE is obtained. The toxicity test has been conducted using the low calcium GUR 1020. The material was tested on mice and rabbits to demonstrate that the material meets the requirements of the USP guidelines for the Biological Test for Plastics (Class VI Certification) [7].

Starting from the low calcium GUR 1020, the UHMWPE bars are obtained by compression molding. Subsequently, the UHMWPE bars are cut and the inserts are obtained by milling. The UHMWPE used for the GMK® inserts is the same material used for the evolis® ones which shows a successful clinical history [7].

Polyethylene key features

The 3 main properties which characterize polyethylene are:

1) Wear resistance
2) Mechanical properties
3) Oxidative stability.

Polyethylene wear in total joint arthroplasty is generated through adhesive and abrasive wear which occur on the articular surface. Polyethylene wear produces small particles which can cause osteolysis. One of the features which characterize polyethylene is therefore wear resistance, which can be increased by irradiating the material with a ionizing radiation [8]. As shown in paragraph 1, polyethylene failure is the reason for revision TKA only for a small number of cases and it is characterized by delamination rather than adhesive and abrasive wear [2].

Delamination risk of the tibial insert may be increased by low mechanical properties for polyethylene [4]. The polyethylene mechanical properties influence not only delamination but also the whole tibial inserts resistance.

The most commonly considered mechanical parameters are:

- Yield Stress (point at which the polyethylene begins to deform plastically)
- Ultimate tensile strength (maximum stress that the material can withstand while being stretched)
- Elongation to Failure (strain at which a material region breaks).

In a highly conforming joint such as the hip, the contact stresses are relatively low because of the large contact area between the liner and the femoral head and the maximum shear stress occurs on the surface: in this condition, the adhesive and abrasive wear mechanisms predominate on delamination [3]. Therefore, in THA it is more important to privilege the polyethylene wear resistance rather than its mechanical properties.

On the contrary, in a less conforming joint such as a knee implant, the contact area between femoral component and tibial insert is smaller than in the hip, the peak loads are higher and the maximum shear stress occurs beneath the surface of the tibial inserts. As a consequence, delamination and pitting occur more typically on total knee components [3]. Therefore, in TKA the polyethylene mechanical properties are more critical than the wear resistance. It has to be noticed that polyethylene treatments such as irradiation, thermal and sterilization processes may reduce the mechanical properties of polyethylene and consequently generate delamination [4][10].

Oxidative stability influences the polyethylene mechanical properties in long-term. When the polyethylene is irradiated with ionizing radiation to increase its wear resistance, residual free radicals are generated within the material. Residual free radicals within the polyethylene which interact with oxygen lead to relevant changes in the mechanical properties of the polyethylene, including loss of fracture toughness, ductility, and embrittlement that worsens with time.

Traditional sterilization techniques of gamma irradiation in air produce residual free radicals and therefore cause oxidative degradation of the material [11]. Currier et al. [12] showed that the trend of oxidation of a gamma-air sterilized never-implanted polyethylene insert is exponential, with slower initial oxidation becoming much more rapid after 5 years of time.

Knowing the importance of the mechanical properties and the oxidative stability of polyethylene in TKA applications, the UHMWPE which constitutes the GMK® tibial inserts does not undergo any irradiation, thermal or sterilization process that could reduce its mechanical properties or oxidative stability [7].
Cross-linked UHMWPE

In the 1990s, cross-linked polyethylene was developed and is now widely used in THA. In vitro and in vivo studies of total hip prosthesis with highly cross-linked polyethylene have reported a significant increasing of wear resistance [13, 14]. On the other hand cross-linked polyethylene shows low mechanical properties, if compared to the nonirradiated polyethylene [15]. Crosslinked polyethylene in THA, where the wear reduction is more critical, is a golden standard.

Considering the reduced mechanical properties, the introduction of crosslinked polyethylene in TKA is still controversial [5].

The crosslinked polyethylene is produced starting from UHMWPE and following four important processing steps:

- Irradiation processing to promote crosslinking
- Intra or post-irradiation thermal processing step to remove the free radicals produced within the polyethylene during the irradiation process
- Cooling
- Sterilization processing.

Radiation allow the increase in wear resistance: for this reason, crosslinked polyethylene exhibits reduced wear if compared to conventional polyethylene [8]. On the other hand a higher degree of crosslinking results in a restriction of chain mobility in the amorphous region of the material, reducing the overall plasticity mechanisms [15]. Baker et al. [15] showed that increasing the crosslink densities in the polymer results in a decreased toughness and fatigue crack propagation resistance. Therefore the fatigue and fracture resistance of the cross-linked polymer in cyclic loading applications, such as a knee implant, might be critical. Moreover after the irradiation step some free radicals can cause oxidation which reduces the mechanical properties of the material in long-term (see paragraph 1).

To remove the free radicals that are in the material after the irradiation process, a thermal treatment is necessary. The two main thermal treatments used are melting (>137 °C) and annealing (<137 °C). Melting process eliminates the free radicals but reduces the mechanical properties of polyethylene (see Figures 2, 3 and 4).

Figure 1: The cross-linking processing is characterized by radiation at a dose level between 50 and 100 kGy to achieve cross-linking; melting process to extinguish the residual free radicals created during the irradiation process (eventually substituted by annealing); cooling process.

Figure 2: Modulus (defined as the ratio of tensile stress to tensile strain) for nonirradiated and cross-linked polyethylene. Subsequent melt stabilization for cross-linked polyethylene was performed at 170 °C. Adapted from Baker et al. [15].

*The value refers to a non irradiated polyethylene with characteristics similar to those of GMK® inserts polyethylene.
Figure 3: Yield stress (MPa) for nonirradiated and cross-linked polyethylene. Subsequent melt stabilization for cross-linked polyethylene was performed at 150°C. Adapted from Muratoglu et al. [19].
*The value refers to a non irradiated polyethylene with characteristics similar to those of GMK® inserts polyethylene.

Figure 4: Ultimate tensile strength (MPa) for nonirradiated and cross-linked polyethylene. Subsequent melt stabilization for cross-linked polyethylene was performed at 150°C. Adapted from Muratoglu et al. [19].
*The value refers to a non irradiated polyethylene with characteristics similar to those of GMK® inserts polyethylene.

Because the main disadvantage of melting is the reduction of the mechanical properties, a compromise solution is to heat the material to just below the melting temperature (annealing thermal process). This solution preserves the original crystal structure and retains mechanical properties (see Figures 5 and 6) but does not eliminate all the free radicals produced during the irradiation processing which are free to react with the available oxygen and cause the polyethylene oxidation [10].

Figure 5: Effect of post thermal treatment on yield stress. Yield stress (MPa) for nonirradiated and cross-linked polyethylene irradiated at 100 kGy. Adapted from Kurtz [8].
*The value refers to a non irradiated polyethylene with characteristics similar to those of GMK® inserts polyethylene.

Figure 6: Effect of post thermal treatment on ultimate tensile strength. Ultimate tensile strength (MPa) for nonirradiated and cross-linked polyethylene irradiated at 100 kGy. Adapted from Kurtz [8].
*The value refers to a non irradiated polyethylene with characteristics similar to those of GMK® inserts polyethylene.

The decreased mechanical properties of the highly cross-linked polyethylene which has undergone a melting process and the risk of oxidation of the annealed highly cross-linked polyethylene, may limit its use in high stress environment such a knee implant, where delamination occurs more frequently than adhesive and abrasive wear (see page 36).

Moreover, the reduced mechanical properties of the highly cross-linked polyethylene may influence the tibial post fatigue and decrease the ability of a tibial posterior-stabilized insert to sufficiently resist the forces generated in the knee.

Polyethylene in TKA: do we really need cross-linked polyethylene?
This may result in premature failure of the device\cite{17}. Tibial post fatigue tests conducted by Huot et al. \cite{17} demonstrated that cross-linked and remelted polyethylene (irradiated to 100kGy) tibial posts are less resistant than gamma air polyethylene.

Jung et al. \cite{21} presented 2 cases of X3 crosslinked polyethylene tibial post fracture in a posterior stabilized Scorpio Knee System (Stryker). The authors reported that in their hospital conventional UHMWPE polyethylene had been used in approximately 15,000 cases with no tibial post fractures. Tibial post fractures occurred only since they started to implant X3 crosslinked polyethylene \cite{21}.

Huot et al. \cite{17} analyzed also the impact toughness of irradiated and nonirradiated polyethylene and showed that the nonirradiated polyethylene is tougher than both the core and the outer of the irradiated polyethylene (Figure 7). This reduction in impact toughness may be critical in a knee implant where shocks frequently occur.

Polyethylene sterilization

Sterilization method is another treatment that can affect polyethylene mechanical properties. A number of sterilization techniques are used to sterilize and package the polyethylene inserts for TKA \cite{8}. The gamma air and gamma inert sterilization use the gamma radiation to sterilize the inserts and produce free radicals within the polyethylene \cite{11}. On the contrary, gas plasma and ethylene oxide sterilization does not produce free radicals within the polyethylene (Table 1).

The gamma air sterilized polyethylene inserts are stored in air-permeable packaging and sterilized with gamma irradiation. The oxygen is free to interact with the implant both during and after the irradiation process: for this reason oxidation starts during sterilization and continues during time in inventory \cite{12}. McGovern et al. \cite{18} analyzed the effect of ageing of gamma air sterilized polyethylene during storage and showed that the longer the shelf life, the shorter the time to revision was. All retrieved components showed oxidation and pitting and delamination on the surface (see paragraph 1).

Gamma inert sterilization method uses barrier packaging to exclude oxygen during both sterilization and shelf storage of polyethylene. This method is shown to be effective in preventing oxidation during shelf storage. If the problem of early fatigue failure seen in gamma air sterilized inserts with long shelf storage before implantation can be addressed by the gamma inert sterilization, the in vivo implantation could encourage the oxidation \cite{12}. A study showed that at longer time in vivo, retrieved gamma inert sterilized inserts showed severe fatigue damage and oxidation \cite{20}.

Gas plasma is a surface sterilization method which relies upon ionized gas for deactivation of biological organisms. The method does not substantially affect the physical, chemical or mechanical properties of polyethylene. Because of its recent introduction, data about in vivo implanted gas plasma sterilized components is not available yet \cite{8}.

The ethylene oxide sterilization method uses a highly toxic gas which neutralizes bacteria, spores and viruses. White et al. \cite{6} compared a number of retrieved tibial inserts with identical design that have been sterilized ether by gamma radiation or by ethylene oxide and showed that the component sterilized by ethylene oxide showed less surface damage and delamination than gamma radiation sterilized components. The gamma radiation components showed, on the contrary, decreased toughness and elongation to failure.
Comparing the different sterilization processes, the gas plasma and the ethylene oxide sterilization methods appear to be the only methods which do not encourage the polyethylene oxidation and do not substantially affect the physical, chemical or mechanical properties of polyethylene. For this reason, medacta® sterilizes all the GmK® tibial inserts using ethylene oxide, to guarantee the sterility of the implant together with the intact physical, chemical and mechanical properties of the material [7].

Conclusion

Polyethylene failure in total knee arthroplasty (TKA) is the cause of revision for only a small number of cases (1.4 %) [1]. Polyethylene failure in TKA is characterized by delamination [2]. Polyethylene delamination in TKA is the result of the knee joint kinematics and is affected by the mechanical properties of the tibial inserts [4].

If the polyethylene mechanical properties decrease, delamination increases. Therefore to avoid delamination it is fundamental to preserve the mechanical properties of polyethylene rather than decrease the wear resistance [4].

Cross-linked polyethylene was originally developed to reduce wear rate in acetabular bearings and is obtained by irradiating the conventional polyethylene with ionizing radiation. While cross-linked polyethylene has become a golden standard in THA because of the increased wear resistance, its introduction in TKA is still controversial [5].

It has been shown that the elevated radiation dose and thermal treatment to transform UHMWPE in cross-linked polyethylene reduce the mechanical properties of the material, potentially affecting delamination.

The mechanical properties of polyethylene are also influenced by the sterilization process. Between the different sterilization processes, ethylene oxide sterilization is a well-known method which does not substantially affect the physical, chemical or mechanical properties of polyethylene and does not promote oxidation [6].

Medacta® GmK® tibial insert are made of standard polyethylene (UHMWPE) sterilized with ethylene oxide and they do no not undergo any irradiation or thermal process that can affect the mechanical properties and the oxidative stability of the material [7].

Considering the short clinical history of cross-linked polyethylene, the reduced mechanical properties and the low rate of revision TKA caused by polyethylene failure, it can be stated that the application of this material in TKA is not a real clinical advantage but just a marketing tool.

Print in mind:

- Polyethylene failure is only 1.4% cause for TKA revision.
- Polyethylene failure in THA = abrasive/adhesive wear
- Polyethylene failure in TKA = delamination
- Crosslinked polyethylene shows increased wear resistance but reduced mechanical properties
- Reduced mechanical properties = increased risk of delamination
- Gamma radiation-based sterilization processes reduce the polyethylene mechanical properties
- Today there is no rationale to introduce crosslinked polyethylene in TKR
- Clinical results on crosslinked polyethylene should be carefully analyzed before the global introduction of this material
- GmK® tibial inserts do no not undergo any irradiation, thermal or sterilization process that can affect the mechanical properties of the material

<table>
<thead>
<tr>
<th>Sterilization process</th>
<th>Packaging type</th>
<th>Gamma radiation dose</th>
<th>Free radicals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma air</td>
<td>Gas permeable</td>
<td>25-40 kGy</td>
<td>Yes</td>
</tr>
<tr>
<td>Gamma inert</td>
<td>Barrier packaging, reduced oxygen atmosphere</td>
<td>25-40 kGy</td>
<td>Yes</td>
</tr>
<tr>
<td>Gas plasma</td>
<td>Gas permeable</td>
<td>None</td>
<td>No</td>
</tr>
<tr>
<td>Ethylene Oxide</td>
<td>Gas permeable</td>
<td>None</td>
<td>No</td>
</tr>
</tbody>
</table>

Table 1: Sterilization techniques used to sterilize and package the polyethylene inserts for TKA. Adapted from Kurtz [8].
# Addendum: Polyethylene in TKA

<table>
<thead>
<tr>
<th>Company</th>
<th>Poly name</th>
<th>Raw Material</th>
<th>Crosslinking</th>
<th>Thermal treatment</th>
<th>Sterilization</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>DePuy</td>
<td>GVF</td>
<td>GUR 1020</td>
<td>No</td>
<td>No</td>
<td>Gamma radiation</td>
<td></td>
</tr>
<tr>
<td>DePuy</td>
<td>Sigma XLK</td>
<td>GUR 1020</td>
<td>Radiation at 50 kGy</td>
<td>Remelted at 155°C for 24 hours and then annealed at 120° for 24 hours</td>
<td>Gas plasma</td>
<td></td>
</tr>
<tr>
<td>Smith&amp;Nephew</td>
<td>XLPE (Verilast)</td>
<td>GUR 1050</td>
<td>Radiation at 75kGy</td>
<td>Remelted at 150°C for 2 hours</td>
<td>Ethylene oxide</td>
<td>Used with Oxinium</td>
</tr>
<tr>
<td>Smith&amp;Nephew</td>
<td>Genesis Il</td>
<td>GUR 1050</td>
<td>No</td>
<td>No</td>
<td>Gas plasma</td>
<td>Used with Oxinium</td>
</tr>
<tr>
<td>Zimmer</td>
<td>Prolong</td>
<td>GUR 1050</td>
<td>Radiation at 65 kGy</td>
<td>Remelted</td>
<td>Gas plasma</td>
<td></td>
</tr>
<tr>
<td>Zimmer</td>
<td>Durasol</td>
<td>GUR 1050</td>
<td>Radiation at 95 kGy</td>
<td>Remelted</td>
<td>Ethylene oxide</td>
<td></td>
</tr>
<tr>
<td>Biomet</td>
<td>Arcom</td>
<td>GUR 1050</td>
<td>No</td>
<td>No</td>
<td>Gamma radiation</td>
<td></td>
</tr>
<tr>
<td>Biomet</td>
<td>E1</td>
<td>GUR 1020</td>
<td>Radiation at 100 kGy</td>
<td>No</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Stryker</td>
<td>N2Vac</td>
<td>GUR 1020</td>
<td>No</td>
<td>No</td>
<td>Gamma radiation</td>
<td></td>
</tr>
<tr>
<td>Stryker</td>
<td>Duration</td>
<td>GUR 1050</td>
<td>Radiation at 30 kGy</td>
<td>Annealed</td>
<td>Gamma radiation</td>
<td></td>
</tr>
<tr>
<td>Stryker</td>
<td>X3</td>
<td>GUR 1020</td>
<td>3 radiation steps at 30 kGy</td>
<td>Annealed for 3 times</td>
<td>Gas plasma</td>
<td></td>
</tr>
<tr>
<td>Medacta</td>
<td>UHMWPE</td>
<td>GUR 1020</td>
<td>No</td>
<td>No</td>
<td>Ethylene oxide</td>
<td></td>
</tr>
</tbody>
</table>
References


No differences in human knee morphometry and gender-specific clinical outcomes: a literature review

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Medacta® International, Medical, Product Management, Research & Development departments, Castel San Pietro, Switzerland

Abstract

Recently, some orthopedic manufacturers have been marketing gender-specific knee prostheses targeted at women. Zimmer claims that it has designed a total knee system specific for women “because women and men are different”. In response, Stryker has claimed that their “design closely matches the anatomy of a female knee”.

Are gender-specific knees just a marketing campaign or do they provide an actual advantage for surgeons and female patients? A literature review has been conducted and it shows that gender-specific knees are just a marketing campaign.

From the literature analysis, it appears clear that anatomical differences are related to the patient overall size and not the gender; moreover women do not have higher failure rates than men after traditional knee replacement surgery and a gender-specific total knee prosthesis does not confer any benefit in functional outcomes or patient satisfaction when compared with a standard prosthesis.

The gender-specific knees concept

A gender-specific total knee replacement implant is a prosthesis that is claimed to be specifically designed for either male or female. The size of the implant is slightly different and is supposed to accommodate the slight difference in size between men’s and women’s bones.

The idea behind this is that better replication of the anatomy, the joint replacement implants might allow for better function, as well as improved durability.

Companies promoting gender-specific knee prosthesis, state that gender-specific implants have been made using “average” size data, different for a man’s bone and a woman’s bone.

Are there really gender specific knee anatomic differences?

The gender-based anatomical differences claimed by those who support the female-specific knee implants are: 1) an increased Q angle, 2) less prominence of the anterior medial and anterior lateral femoral condyles and 3) reduced medial-lateral to anterior posterior femoral condylar aspect ratio (ML:AP aspect ratio). In survey published by Merchant et al., the authors concluded that the first two proposed differences disappear when corrected for the average height difference between men and women. Indeed, with reference to the ML:AP aspect ratio of the distal femur, the differences within groups of men and women are greater than the differences between men and women: the smaller ML:AP aspect ratio has no measurable clinical effect.

Also Bellemans et al. showed that there is anatomic variability between the same gender: women, for example, with identical antero-posterior femoral dimensions can have either wide or narrow medio-lateral dimensions.

This variability could be explained by morphologic variation.

Therefore, it can be stated that differences in patient anatomy have far more to do with the patients overall size, not their gender.

Do women have higher failure rates than men after traditional knee replacement surgery?

One can argue that if gender-specific implants are really necessary, there would be certain evidence that failure rates for women with traditional implants is higher than the failure rates measured between men. Data does not consistently show differences between men and women in most of the clinical outcomes of tricompartmental total knee replacement surgery.
To the contrary, data published in literature shows that women do better than men when looking at implant survival [4,5], patient satisfaction, wear related failure, revision risk and revision rates, range of motion and patient satisfaction [1]. In the study published by MacDonald et al., the authors showed that women in general had overall the greatest improvements in outcomes scores with a lower revision rate than men [6].

Do gender-specific TKA designs provide better functional survivorship, clinical outcomes and improved fit in women?

Gender-specific total knee implants do not seem to provide any benefit in terms of clinical outcomes, satisfaction or survivorship. Kim et al. analyzed the data obtained from 85 patients who received a standard LPS-Flex prosthesis in one knee and a gender specific LPS-Flex prosthesis in contralateral knee.

The authors found that the femoral component in the standard implant group fits significantly better than the one in the gender-specific implant group. In addition the early clinical radiographic outcomes, range of knee motion, patient satisfaction, revision rates and complication rates were similar in both groups. Analyzing the postoperative scores, the authors concluded that in women undergoing TKA, a gender-specific total knee prosthesis did not provide any benefit [7-8].

Conclusion

Differences in patient anatomy have far more to do with the patients overall size than just based on gender. Moreover, historical clinical data shows that women do not have higher failure rates than men after traditional knee replacement surgery. In addition, based on the available literature, there is no difference in the outcome of patients with a gender-specific knee arthroplasty, if compared to a traditional arthroplasty.

It appears clear that, rather than promote gender-specific knee implants, manufacturing companies should focus more on increasing the available range of their prosthesis in order to allow the surgeon to select more custom-sized components to allow for any individual’s unique anatomy [9].

References


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- Online Interactive 3D planning

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* data as of May 2011