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SHORT TERM MECHANICAL EVALUATION OF THE NEXT GEN® IMPLANT

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Abstract: From the mechanical point of view, the knee implants should have great stability in complete extension (when is exposed to severe stress resulting from the body weight) and great mobility after a certain measure of flexion has been achieved. In our study we will refer to tricompartimental knee arthroplasty, with cemented prosthesis, using Nexegen Complete Knee Solution (ZIMMER) implant and different variants of biological cement. We assisted our 39 patients in the day before the operation and 7 days after the surgery (total knee arthroplasty), the main outcome measure being ROM (range of motion) measurement using a long-arm goniometer, for active extension and passive flexion. In normal weight patients the initial technical specification of the implant were found reachable and in those with overweight the initial implant specification were approximately 20 to 40 degrease less.

1. INTRODUCTION

The knee, mainly a joint with one degree of freedom, which allows the distance between the trunk and the ground to be varied, is the intermediate joint of the lower limb.

From the mechanical point of view, the knee implants should have great stability in complete extension (when is exposed to severe stress resulting from the body weight) and great mobility after a certain measure of flexion has been achieved [1,2].

2. MATERIAL AND METHOD

In our study we will refer to tricompartimental knee arthroplasty, with cemented prosthesis, using Nexegen Complete Knee Solution (ZIMMER) implant and different variants of biological cement.

The study (prospective study) was done during a three years period (01. 2007-07.2010) and had included a number of 39 cases, clinically and imagistic diagnosed with uni- and bilateral gonarthrosis, in advanced stages and it was done in Emergency Hospital of Oradea, Departments of Orthopaedics.

We assisted our 39 patients in the day before the operation and 7 days after the surgery (total knee arthroplasty), the main outcome measure being ROM measurement using a long-arm goniometer, for active extension and passive flexion.

This implant is composed of four elements: the femoral component, tibial component, the insert and the patellar component.

The femoral component is made of Co-Cr alloy, cemented, has three radii of curvature and has left / right variants. The design allows flexion to 130°, there is a posterostabilisation version , and has a maximal femoral-tibial congruency of 1.07-1.0. It presents many possibilities of femuro-tibial combinations, providing a great modularity (one size of the femur can be combined with 6 and even 8 sizes of the tibia, preserving joint congruency). Articular surface is polished and the implantation surface is rough. The sterilization is performed with Gamma radiation.

Figure 1. Femoral component

The tibial component, made of titanium alloy, respects anatomical shape of the tibia and is universal left / right. The design allows flexion to 130°. Tibial component presents the opportunity for suprastabilisation and transformation in revision prosthesis by attaching the extension rods, depending on the intraoperative needs. It presents a great modularity, extreme sizes of the tibia and femur can be combined together, keeping joint congruency, such as one size of the femur can be combined with 8 sizes of tibia. It presents peripheral attachment system of the polyethylene insert to the proximal side; the implant surface is matte and the modality of implantation is cemented. The sterilization is performed with Gamma radiation.

Figure 2. Tibial component

The insert, made of very high molecular weight polyethylene (UHMWPE) has the tibial anterior edge inclined to avoid patellar tendon impingement in full flexion. It presents a great modularity, extreme sizes of the tibia and femur can be combined together, keeping joint congruency, such as one size of the femur can be combined with 8 sizes of tibia. The method of implantation: removable insert with the insert peripheral attachment system, with elements of mechanical stabilization of the tibial piece type wedge. Sizes are

70 in total (each seven different heights for each of the 10 sizes of the tibia). The minimum thickness of polyethylene layer is 6, 5mm. It is sterilized with gamma radiation in nitrogen atmosphere.

The patellar component, made of very high molecular weight polyethylene (UHMWPE), is perfectly adapted to the femoral piece shape. There are 6 sizes described, common to left / right, denoted by 26, 29, 32, 35, 38 and 41mm and they present 3 spurs for cementing and implantation method is cemented and they are also sterilized with gamma radiation in nitrogen atmosphere.

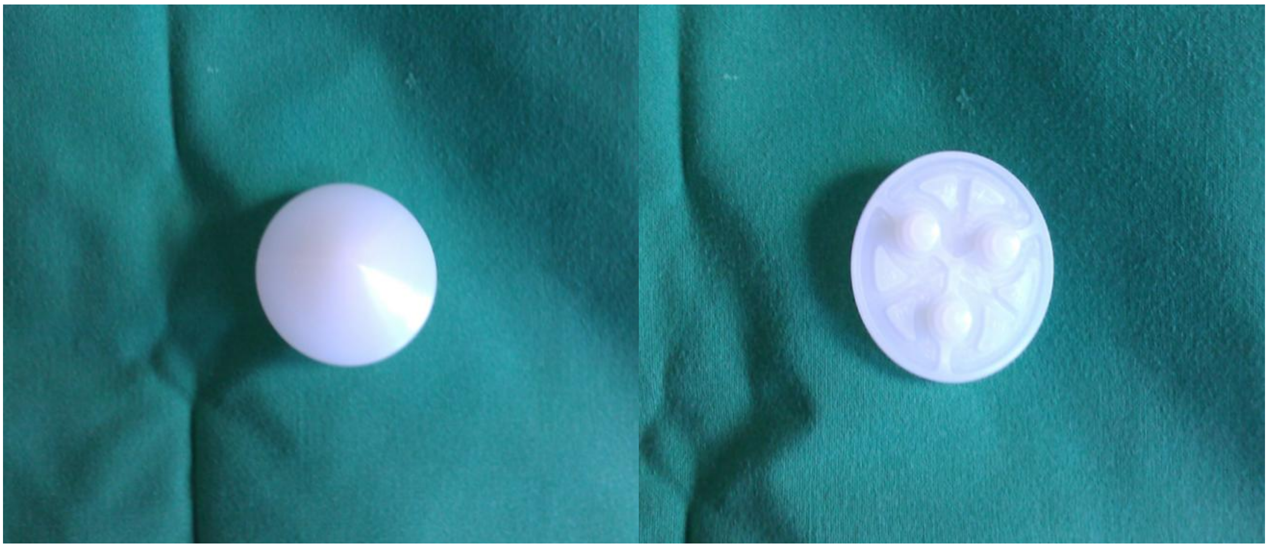

Figure 3. Patelar component

Figure 4. Complete implant, Zimmer_NexGen

Among the selected patients 74,3% were obese (grade II and III, according to the IMC).

NR.	INITIALS	SEX	AGE	PREOPERATORY Flexion/Extension measurements (°)	POSTOPERATORY* Flexion/Extension measurements (°)	GONARTHROSIS STAGE/SIDE	OBESITY BMI=G/(HxH)
1.	I.P.	F	67	85/170	100/180	3\left.	II
2.	S.G.	M	58	80/180	90/180	2\right.	III
3.	N.A.	F	80	80/170	100/180	3\left.	II
4.	D.V.	F	66	85/175	110/180	3\right.	II
5.	M.F.	M	71	90/180	110/180	2\left	II
6.	P.M.	F	58	90/175	110/180	3\right	II
7.	D.E.	F	56	90/180	110/180	2\left	II
8.	G.F.	F	63	95/180	110/180	2\left	II
9.	M.C.	F	75	90/180	100/180	3\left.	II
10.	G.F.	M	73	85/170	100/180	3\left.	III
11.	N.E.	F	65	80/170	90/180	3\left	III
12.	P.M.	F	79	80/165	90/180	3\right	III
13.	P.N.	M	62	85/180	110/180	2\right	II
14.	B.A.	F	64	85/180	110/180	2\right	II
15.	S.I.	F	75	85/170	100/180	3\right	II
16.	B.A.	M	67	90/170	110/180	3\right	II
17.	S.S.	F	71	95/170	110/180	3\left	II
18.	M.M.	F	59	75/165	90/180	3\right	III
19.	I.R.	F	62	80/170	95/180	3\left	III
20.	S.A.	M	58	90/180	100/180	2\left	III
21.	M.D.	M	65	90/180	100/180	2\right	II
22.	G.C.	F	57	90/180	100/180	2\right	III
23.	P.L.	F	69	85/170	100/180	3\right	III
24.	R.R.	F	72	80/170	95/180	3\right	III
25.	J.V.	F	68	75/170	90/180	3\left	III
26.	P.F.	M	68	85/175	95/180	3\left	III
27.	I.N.	M	71	90/170	110/180	3\left.	-
28.	N.F.	M	76	90/180	110/180	2\left	-
29.	M.G.	M	61	90/175	110/180	2\right	II
30.	P.P.	F	74	80/180	100/180	3\right	III
31.	C.R.	F	76	90/180	110/180	3\right	III
32.	S.S.	M	74	85/170	100/180	3\left	-
33.	C.T.	M	72	90/180	110/180	2\left	-
34.	R.N.	F	68	90/170	110/180	3\right	-
35.	C.N.	F	70	85/180	100/180	3\right	-
36.	D.P.	F	69	85/175	100/180	3\right	-
37.	M.E.	F	63	85/170	100/180	3\right	-
38.	D.C.	M	72	80/180	100/180	2\left	-
39.	R.Z.	F	69	80/170	95/180	3\left	-

*assessment of implant movement in vivo was done after 7 days postoperatively

3. RESULTS

The evaluation of the results was made by quantifying the functional benefit from the implant, related also to the daily activities of the patients.

All of them were able to perform the passive knee flexion over 90º (in sitting position).

All of them were able to perform the complete active knee extension (in dorsal decubitus position and also in orthostatic position).

In normal weight patients the initial technical specification of the implant were found reachable and in those with overweight the initial implant specification were approximately 20 to 40 degrease less.

4. DISCUSSION

Were made and there are many studies like ours, analysis aiming at assessing both individual and comparative benefits of these implants [3].

There are studies that support the idea that not only differences between the implants can influence the "lifetime" of them, but also the materials they are made of, or even the type of radiation used for sterilization may affect the functionality of implants or their component parts, as reported by Engh CA Jr. and collaborators, in an article published in January 2012 [5].

The use of the goniometer with long arms for measuring ROM for various joints has been reported in various studies over time, such as in studies of JZ Edwards and colleagues? (2004) or Anton F. Lenssen and colleagues (2007) [6.7]

Another important aspect that supports this study is the need to determine whether such implants can cope with demands similar to those physiologic, given that the age at which they are used tends to enter the interval in which people still work [8].

Last but not least we have to mention the intention to establish, as accurately as possible, the limits of the implant as with reference to our pre-existing studies and evaluations that have addressed other types of implants, idea that we also find in Matthew's C.L. at al, in a study published in 2012 [9].

5. CONCLUSIONS

Situations where the implant limits haven't been reached, most likely because of pervasive adaptation, the soft parts, mechanics prior to surgery, aspect that supports indication of physio-therapy sessions, both preoperative and post operative.

Knee implants represents a viable solution of treatment in advanced stages of biomechanical knee disorders.

The improvement of the quality of the actual implants, increased the longevity of knee prosthesis and the range of motion for degenerative advanced damaged knee, allowing us to suggest thse intervention to the patients who present an invalidant arthrosis, even if they are under 60 years old.

The success of the intervention and the implant functioning duration is up to the quality of the implant but also up to the patient selection by well established criteria.

Obesity is an important factor regarding both, the functionality of the implant and the general evolution in order to post operatory recovery and return to daily activities of those patients.

A normal walk, without distance limitation, allowing the patient to lead a normal life, is possible because of the significantly decrease of the pain and the functional recovery.

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