# Robotic-assisted unicompartimental knee arthroplasty performed with Navio system: a systematic review

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**Abstract. – OBJECTIVE: Robotic-assisted arthroplasty is a relatively modern concept, quickly arising in its use. The aim of this systematic review is to assess, according to the existing literature, which are the functional and clinical outcomes and component positioning and implant survivorship of unicompartmental knee arthroplasty surgery performed using an image-free hand-held robotic system. Moreover, we analyzed whether there are significant differences and advantages compared to conventional surgery.**

**MATERIALS AND METHODS: A systematic review has been performed on studies published between 2004 and 2021, on the electronic library databases, according to the Preferred Reporting Items of Systematic Reviews and Meta-analysis (PRISMA) statement. The inclusion criteria were all studies described as unicompartmental knee arthroplasty performed with the Navio robotic system.** 

**RESULTS: Fifteen studies were included, and 1,262 unicondylar knee arthroplasties were analyzed. These studies showed a satisfactory recovery of joint function, with a good range of motion (extension <5° and flexion which ranged from 105° to 130.3°) in patients of the NAVIO group. The revision rate was <2% while the infection rate <1%; no postoperative transfusion was needed in all UKA implanted.**

**CONCLUSIONS: The use of a robotic tool for unicompartmental knee arthroplasty (UKA) could lead to a better implant positioning and joint alignment than conventional surgery. There is still limited evidence to support that the use of this robot in unicompartmental knee arthroplasty is a greater survivorship than other systems or conventional techniques; therefore, a longterm follow-up is needed.** 

*Key Words:*

Robotic-assisted, Arthroplasty, Knee, Unicondylar osteoarthritis.

## Introduction

Unicompartmental knee arthroplasty is a surgical procedure, born in the '50s, in order to treat patients affected by unicondylar osteoarthritis (OA). According to recent studies<sup>1</sup>, unicompartmental OA is the most common form of osteoarthritis in the knee. The advantages of this procedure in comparison to total knee arthroplasty are several: quicker recovery, lower complication rate and higher capability to return to preoperative activity level2,3. Furthermore, UKA ensures preservation of unaffected bone, cruciate ligaments and patellofemoral joints, providing near-normal kinematics<sup>4</sup> and increased range of motion (ROM)<sup>5,6</sup>.

Despite the good premises, the effectiveness of this procedure has often been controversial, because of a higher midterm rate of revision, compared to total knee arthroplasty  $(TKA)^{7,8}$ . According to Niinimaki et al<sup>9</sup>, in a review based on the Finnish Arthroplasty Register, the survivorship of UKA was 89.4% and 80.6% at 5 and 10 years respectively, while the survivorship of TKA was 96.3% and 93.3%.

Many studies<sup>10,11</sup> recommend precise indications and patient selection in order to achieve good results in this kind of surgery. In 1989, Kozinn et al $^{12}$  published their recommendations about UKA: increased weight (over 82 kg) and age (over 60) were considered contraindications, and similarly the presence of patello-femoral arthritis and knee pain were considered shortcomings as well. Nowadays these are not anymore considered contraindications, but only risk factors for UKA failure. Another crucial point of controversy is the deficiency of anterior cruciate ligament (ACL): implanting a medial UKA on a knee with a degenerative ACL deficiency secondary to osteoarthritis has lower failure risk than performing the same operation in a knee with OA secondary to a traumatic ACL deficiency with secondary OA<sup>13,14</sup>.

To achieve proper patient selection, scoring systems like the Unicompartmental Indication Score  $(UIS)^{15}$  were proposed. In this system, multiple variables are taken into account: age, BMI, ACL clinical function, ROM, affected and contralateral compartment status, cause of symptoms (OA, osteonecrosis, inflammatory, etc.). For each of these, up to 3 points can be assigned. An UIS<20 was considered by the authors a contraindication to UKA, while UIS>25 meant that performing a UKA was a good choice.

Robotic-assisted arthroplasty is a relatively modern concept, quickly arising in its use<sup>16</sup>. According to the Australian Joint Replacement Registry, unicompartmental knee replacements using robotic assistance had risen from 6.9% in 2015 to 30.3% in 2019. The precision in performing the surgical act and accuracy of execution of the surgical plan, make robotic-assisted arthroplasty an attractive method for joint replacement<sup>2</sup>. Superiority of robotic-assisted surgery in implant alignment is believed to be a possible advantage, in order to obtain better functional results and decrease number of revisions.

The NAVIO™ System (Smith and Nephew, Pittsburgh, PA, USA) is a semi-active robot that uses hand-held boundary-controlled instrumentation to perform knee prosthetic surgery. At the moment this is the only robotic system available in Europe for UKA, which is not based on preoperative imaging. The computerized systems currently available to assist the orthopedic surgeon are divided into two major groups: direct and indirect. The first group comprises autonomous robots, which make the surgical plan guided by the operator and then make the cut directly; semi-autonomous or boundary-controlled robots, on the contrary, are partially controlled by human hand. The other major category, the indirect system, is formed by navigation and computer-assisting machines, helping the surgeon in the placement of cutting jigs and giving a template of the motion of the limb, without making cuts.

The Navio Precision Free-Hand Sculptor, differently from the majority of other systems, is not based on a preoperative CT-scan. After surgical exposure, two-pin bicortical fixation is obtained on both femur and tibia. Then, tracking arrays are mounted on the pins, in order to obtain communication between the camera, the handpiece and the bone of the patient. Being an image-free device, the system is projected to create a virtual representation of the anatomy and the kinematics of the knee by collecting ROM and bone surface mapping, with no preoperative image needed.

Until now, as far as we know, there is only a systematic review by Clement et al<sup>17</sup>, which evaluated the accuracy and the outcomes of this image-free robotic system in performing both TKA and UKA. In the view of the authors, a review analyzing the use of this system in UKA, was considered mandatory, because of the cited differences between TKA and UKA, especially regarding surgeon-related failure rates and clinical outcomes.

Therefore, the aim of this systematic review is to assess, according to the existing literature, which are the functional and clinical outcomes and component positioning and implant survivorship of unicompartmental knee arthroplasty surgery performed using an image-free hand-held robotic system and if there are significant differences and advantages compared to conventional surgery.

## Materials and Methods

#### *Study Settings and Design*

We conducted a systematic review of literature focused on robotic unicondylar knee arthroplasty using the NAVIO system. It has been performed on studies published between years 2004 and 2021, on the electronic library databases PubMed, Cochrane, Medline and Google scholar, according to PRISMA statement 2020. Keywords used for the research were "Robotic unicompartmental knee arthroplasty" and "unicompartmental knee arthroplasty" and their MeSH terms in any possible combinations using the logical operators "AND", "OR" and NOT "total". The search was reiterated until September 1, 2021. The study was designed according to the PICO scheme: population (P), intervention (I), control (C) and outcome (O). In particular, we evaluated the component positioning and implant survivorship (O) of patients affected by unicompartimental OA (P), treated with robotic UKA  $(I)$  in comparison with those treated with other surgical techniques (C).

The research on Google scholar and other databases identified 2250 articles responding to "robotic unicompartmental knee arthroplasty", while on PubMed we identified 144 records.

#### *Inclusion and Exclusion Criteria*

The studies published as full-text articles in indexed journals concerning unicompartmental



Figure 1. PRISMA Flow-chart.

knee arthroplasty performed with the NAVIO robotic system were included in the present review. Exclusion criteria were TKA or PFA as the main topic of the paper, and surgery performed with other robotic systems. Articles with not fair scores according to guidelines of the National Institute for Health Quality Assessment Tool for Observational Cohort were excluded. Only articles written in English were included. No date limits publication was established. Expert opinions, studies on animals, unpublished reports, *in vitro* investigations, abstracts from scientific meetings and book chapters were excluded from review.

## *Data Extraction and Analysis*

Two independent reviewers (LF and LA) collected the data from the included studies. Any discordances were solved by consensus with a third author (FL). The research analyzed demographics data, study type, follow-up, side of UKA (lateral or medial), outcomes, clinical results, radiographic findings, satisfaction rate and adverse events of robotic UKA reported in the Tables I-IV. Data analysis was also compiled for preoperative and postoperative range, mean hospital stay, learning curve for robotic surgery, pain value, and implant alignment all performed with the NAVIO system. Numbers software (Apple Inc., Cupertino, CA, USA) was used to tabulate the obtained data. Categorical variables are presented as frequency and percentages. Continuous variables are presented as means and standard deviation. Only one decimal digit was reported and was rounded up.

## Results

#### *Search Results*

As reported in Figure 1, we identified 2,238 articles after duplicate removal. 2,206 were excluded by relevance of title and abstract. 32 articles were assessed for eligibility and only 15 studies responded to our inclusion criteria: unicondylar





Ems: endometriosis; PLR: platelet-lymphocyte ratio; NLR: neutrophil-lymphocyte ratio; OE: ovarian endometriosis; BMI: body mass index; LRT: likelihood ratio test; COVID-19: coronavirus disease 2019.





knee arthroplasty, manuscripts written in English, prosthesis positioning performed with NAVIO system.

Twelve studies were clinical studies conducted in different centers, while three were cadaveric studies conducted on fresh bones. Ten of these

Author (year)	<b>Preoperative clinical score</b>	Postoperative clinical score	<b>ROM</b>
Sephton et $al21$	OKS 24.5 (10-43)	N/A	$105.8^{\circ}$ (SD = 18.4)
Di Benedetto et al <sup>25</sup>	IKDC score 74.3 KSS score 58.6	IKDC score 89.9 (NS) KSS score $83.2$ (NS)	(POST-op) $EX < 5^\circ$ FLEX 127° average
Batailler et al <sup>19</sup> Mergenthaler et al <sup>20</sup>	Leelasestaporn et al <sup>26</sup> KFS score 65.5 $p=0.515$ KSS score 70.3 $p=0.265$ N/A N/A	KFS score 99.9 $p=0.203$ KSS score 96.9 $p=0.457$ IKSS-F 92.6±13 [50; 100] IKSS-K 90±11 [51; 100] KSS- F score $92.8 \pm 13.4$ [35; 100] KSS- K score $91.9 \pm 10.6$ [50; 100]	$(POST-op) EX 0°$ FLEX 130.3° (SD=5.6) N/A N/A
Negrín et al $37$	N/A	OKS 45 (37-47) [41-47]	N/A
Crizer et $al27$	KOOS-JR $57 \pm 14$ KSS activities $48 \pm 18$ ; expectations $13 \pm 3$ ; satisfaction $16 \pm 7.5$ ; symptoms $12 \pm 6$ VAS pain $44 \pm 22$	KOOS-JR $86.2 \pm 17$ KSS activities $82 \pm 17$ ; expectations $11 \pm 3$ ; satisfaction $34 \pm 9$ ; symptoms $21 \pm 5$ VAS pain $16 \pm 16$ (12 weeks post-op)	Pre-op $116 \pm 8^{\circ}$ Post-op $131 \pm 11^{\circ}$
Canetti et al <sup>23</sup>	IKSS-O $66.3 \pm 8.9$ IKSS-F $84.6 \pm 11.3$	IKSS-O $97.2 \pm 5.9$ IKSS-F $96.4 \pm 9.2$	N/A

Table III. Clinical outcomes.

studies were retrospective studies, two prospective cohort studies and three cadaveric studies; the year of publication ranged from 2015 to 2021. A total of 1,262 unicondylar knee arthroplasties performed with the robot system NAVIO were analyzed.

## *Hospital Stay and Surgery Time*

Four studies evaluated the hospital stay which ranged from 19.5 hours to 4.8 days, two studies noticed no postoperative transfusion needed in all UKA implanted. The mean time of surgery was calculated in five different studies with a range from 75.9 to 139 minutes as shown in Table II. Several studies reported the learning curve demonstrating lesser surgery time just after some arthroplasties.

#### *Adverse Events and Revision Rate*

Surgery performed with the robotic guidance showed a lower rate of reoperation or revision than conventional surgery. Different studies did not report any adverse events or cases of revision. Battenberg et al<sup>18</sup> (2020) reported four cases (3.1%) of adverse events related to Navio system, with stress shielding, incision pain with deep infection and anterior knee pain. In the same studies, sixteen cases could be related to knee implant: synovial hypertrophy with quadriceps atrophy and knee pain, persistent soft tissue pain, general soreness, femoral osteolysis, and eleven cases of non-progressive radiolucent lines.

Batailler et al<sup>19</sup> reported four revisions  $(5\%)$  of the implants and their conversion to TKA: three cases of aseptic loosening without malposition and one of unexplained pain, all revisions took place in the first year after surgery. Other cases of reoperation were three arthroscopic partial lateral meniscectomies, one arthrotomy and lavage for early infection, two arthroscopic arthrolysis and one polyethylene change with a thicker one.

Mergenthaler et al<sup>20</sup> noticed three cases  $(1.5\%)$ of aseptic loosening without implant malposition, one case (0.5%) of aseptic loosening with implant malposition and one deep hematoma (0.5%) in the early post-operative period. Sephton et  $al^{21}$ , Negrín et al<sup>22</sup>, Iñiguez et al<sup>5</sup>, Canetti et al<sup>2</sup> did not record any cases of adverse events during surgery or revision and reoperation rate.

Lonner et al<sup>24</sup> evidenced six cases  $(0.6\%)$  of complications related to pins after robotic surgery performed with both Mako and Navio systems, without any distinction between the two different systems: one pseudoaneurysm of a branch of the tibialis anterior artery; one tibial metaphyseal fracture; and four pin sites that displayed irritation and delayed healing. There were three cases of early peri-incisional cellulitis, too. There were

Author (year)	<b>Tibial slope</b>	Joint Line and Radiographic Findings
Di Benedetto et al <sup>25</sup>	Variance for tibial slope is $\pm 1.7^{\circ}$ (NS)	Variance for joint line $\pm$ 1.1 (NS)
Leelasestaporn et al <sup>26</sup> N/A		Preoperative mechanical axis 165.7 (7.5) Postoperative mechanical axis 180.1 (2.2)
Batailler et al <sup>19</sup>	Tibial slope $(°)$ (mean $\pm$ SD) Lateral UKA $86.1^{\circ} \pm 3$ Medial UKA $86.4^{\circ} \pm 2$	$HKA$ ( $\degree$ ) (mean $\pm SD$ ) Lateral UKA $182.3^{\circ} \pm 4$ Medial UKA $175.2^{\circ} \pm 2$
Negrín et al <sup>22</sup>	Slope before surgery 8.2 $(2.1 \text{ to } 13.8)$ [6.5 to 9.9] Slope after surgery $6.4$ [0.6 to 14.7] (4.3 to 8.3)	Tibial resection 6.2 (3.1 to 8.7) [5.3 to 7.1]
Negrín et al $37$	4.4 $(1.7-7.0)$ [3.3-5.1]	aMDFA 98 (95-101) [97-99] aMPTA 86.9 (83-92) [85-88] Sagittal femoral angle 46 (42-57) [44-47]
Herry et al <sup>28</sup>	N/A	joint line distalization 1.4 mm $\pm 2.6$
Savov et $al^{29}$	Slope before surgery $4.5 \pm 3.0$ Slope after surgery $5.3 \pm 2.5$	HKA pre-op $175 \pm 3.5$ ; post-op $178 \pm 2.4$ Joint Line distalization (mm) $1.3 \pm 1.6$ aMPTA pre-op $87 \pm 2.1$ ; post-op $89 \pm 1.6$

Table IV. Radiographic findings.

two late hematogenous deep infections that occurred six months and 12 months after surgery that required staged revision to TKA. Three patients required manipulation under anesthesia within three months after surgery.

The survivorship of the implant was >96% in each study, except for one where it was 82%; with a total revision and reoperation rate <2%.

## *Functional Results*

Four studies<sup>21,25-27</sup> evaluated the post-operative range of motion (ROM) of the knee in patients of the NAVIO group. They showed a good extension  $(<5^{\circ}$ ) and a flexion which ranged from 105 $^{\circ}$  to 131°. Several studies also evaluated preoperative and postoperative clinical scores showing better outcomes after surgery than conventional surgery groups. Leelasestaporn et al<sup>26</sup> compared 33 implants homogeneous for demographics, clinical scores and method of anesthesia performed with two robotic tools Navio *vs.* Mako. The clinical follow-up of 12 months found no significant differences of Knee Functional Score (KFS) and Knee Society Score (KSS) at 1 year between both robotic groups. Satisfaction rate was estimated in two studies Canetti et al<sup>23</sup> (2018) and Mergenthaler et al<sup>20</sup> 81.8% and 82% respectively. Crizer et  $al<sup>27</sup>$  evaluated KSS score in a robotic and a conventional cohort of patients with no differences at the pre-op baseline, finding a significant improvement in all KSS elements (functional activities, patient expectations, satisfaction, symptoms) in the robotic cohort at a 2-year follow-up.

## *Radiographic Findings*

Several studies evidenced how robotic-assisted UKA gives a better rate of joint line restoration due to less femoral component distalization than conventional UKA, some of them reported the radiographic findings analyzing the anatomical axis of femur and the height of joint line.

Di Benedetto et al<sup>25</sup> showed how robotic surgery is effective in terms of subjective and radiographic outcome and improving patient initial conditions.

Iniguez et al<sup>5</sup> compared angular change in prosthesis alignment between robotic and conventional group, denoting differences in medial distal femoral angle, medial proximal tibial angle, tibial slope, and sagittal femur angle with a significant difference between the two groups, thus showing a greater precision in component positioning in the Navio group.

Joint-line height was a major concern in the studies which analyzed radiographic findings and their effects on implant survivorship: Herry et al28 evidenced that restitution of joint-line height was significantly improved in the robotic-assisted group compared than the control group: +1.4 mm  $\pm$  2.6 *vs.* +4.7 mm  $\pm$  2.4 (*p* < 0.05), and +1.5 mm  $\pm 2.3$  *vs.*  $+4.6$  mm  $\pm 2.5$  ( $p < 0.05$ ) as assessed using by two methods. Also, Savov et  $al^{29}$  underlined the importance of joint line restoration in order to obtain better survival of the implant: in particular they observed that robotic tools (both Navio and Mako were used in the study) allowed low-volume surgeons to better control joint line (JL) distalization.

In the Mako group mean JL distalization was  $1.8 \pm$ 0.9, while in the Navio group was  $1.3 \pm 1.6$ .

Negrin et al<sup>22</sup> found that distalization of the femoral component was higher in the conventional group, resulting in a distalized joint-line: in particular, the proportion of patients that achieved femoral component positioning at 2 or less millimeters from the joint line was 75% in the robotic cohort, while in the conventional technique cohort was between 22 and 54% according to the measurement method.

## **Discussion**

The key findings of this systematic review were: 1) use of a semi-active robotic for UKA implanting is safe and reliable. 2) There is still limited evidence for supporting the use of this robot instead of other systems or conventional techniques. 3) Clinical outcomes are good, but with fair evidence. 4) Radiographic findings are good, especially when compared to those obtained with conventional surgery. 5) Evaluation of these implants' survivorship needs longer follow-up. 6) No data reporting cost-benefit analysis.

The level of evidence obtained is weak due to the heterogeneity of data reported and the short follow-up available. For the same reason, the authors were not able to make a meta-analysis about clinical outcomes, radiographic findings and implant survivorship.

Currently the major issues concerning UKA are the relatively high revision rates, and how the use of a robotic tool affects these rates, through better implant positioning, it is still not clear.

Surgical volume has a fundamental role in conventional UKA mid- and long-term results and outcomes<sup>2</sup>. Robertsson et al<sup>30</sup> found that orthopedic units with less experience had higher revision rates, and according to Liddle et al<sup>31</sup> surgeons with less than 10 UKAs per year had an 87.9% survival rate, while surgeons with more than 30 had a rate of 92.4% at 8 years.

Implanting a UKA, a surgeon has to evaluate and respect a number of parameters that influence clinical and radiographic outcomes. Christ et al<sup>2</sup> analyzed in a review the surgical variables that can be controlled by a robotic tool, helping the surgeon in performing UKA and the variables independent of the same tool. In the first group they identified parameters like: implant positioning, soft tissue balance, lower limb alignment and proper sizing of prosthetic components. On the

other hand, in the group of independent parameters there were: patient selection, soft tissue handling, implant design and fixation technique.

In a meta-analysis, published in 2019, Chin et al<sup>32</sup> found statistically significant differences in implant positioning between conventional and robotic UKA, especially concerning tibial components, with an important superiority in short-term clinical outcomes for the robotic group; differently, between conventional and robotic TKA, component positioning was still superior in the second group, but there was no difference in clinical outcomes. The optimization of joint line restitution in robotic UKA (r-UKA) is another advantage of this technique<sup>5</sup>. Many biomechanics studies showed the importance of joint line for prosthetic knee kinematics and survivorship. Deep tibial resection is believed to cause higher load on the tibial tray33 and minor resistance to compression forces. Furthermore, it causes higher bone loss, which represents a potential problem in case of revision into a TKA.

Concerning revision rates in the analyzed literature, the most important limitation was the follow-up available in the studies (range from 1.5 to 34 months). Merghenthaler et  $al^{20}$  reported one (0.5%) case of revision due to aseptic loosening with implant malpositioning in the group treated with r-UKA and six (3.5%) cases in the group of conventional UKA. Although not statistically significant, these data suggest what could be the advantages of better implant positioning of UKA performed with a robotic system.

An important finding was the presence of adverse events related to the robotic system. In two different studies Battenberg et al<sup>18</sup> and Lonner et  $al<sup>24</sup>$ , reported cases of complications possibly related to the use of NAVIO. Battenberg et al<sup>18</sup> did not discuss the direct cause of the complications, while Lonner et al<sup>24</sup> described the cases as pin related, the majority of which were soft-tissue problems, demonstrating that great attention is needed during this surgical procedure in the act of exposing tissues and inserting the trackers. Except for these cases, the overall soft tissue lesions were lower than those reported in literature for conventional UKA. The intraoperative surface mapping, the constant control of the robotic tool by the hand of the surgeon and the boundary limited modulation of burr operated by the computer, are certainly effective safety mechanisms $34$ .

Surgery performed with robotic systems allows surgeons to evaluate, intraoperatively, soft tissue tensioning and component positioning, constantly showing the possible alternative outcomes. In a meta-analysis performed by Kunze et al<sup>35</sup> in 2021, data from three prospective trials showed significantly better tibiofemoral alignment after robotic UKA, compared to computer-assisted and conventional ones.

In this review, radiographic findings after robotic surgery were analyzed in six clinical and two cadaveric studies. Restoration of anatomical axis and joint line, femoral and tibial angles were generally reported, with good results, but comparison between the studies often resulted difficult, for non-homogeneity of measures reported. A difference in prosthesis positioning between conventional and robotic UKA was found by Iniguez et al<sup>5</sup>, showing that robotic assistance improves radiographic results after this procedure.

Currently, the major limitation for systematic use of robotic-assisted surgery are the related costs: the MAKO system costs around 1 million \$ for the machine and the software for UKA, while the NAVIO is around 500 thousand \$. Furthermore, being image-free based software, a preoperative CT scan is not needed for NAVIO, thus further related costs are limited. Yeroushalmi et al<sup>36</sup> analyzed in 2020 the cost-effectiveness of the Smith & Nephew's robot, finding that it depended especially on surgical volume and that the incremental cost-effectiveness ratio (ICER) was 14,737\$ per revision avoided in 100 patients per year $36-42$ . In this review a cost-effective analysis was not possible, but according to the authors, minor costs related to an image-free system could be an advantage.

#### *Limitations*

The main limitation of the review is the small number of large and well-designed prospective studies on the issue. Moreover, there is a lack of patients and clinical reported outcomes, avoiding performing any objective statistical comparison of the different surgical techniques.

Further limitations are due to the included cadaveric studies which offer high evidence about radiographic results but no data about clinical outcomes.

#### Conclusions

This review reported encouraging data about performing UKA with an image-free robotic system. Although with weak evidence, according to current literature the NAVIO seemed to be able to improve functional and radiographic results of UKA implants, when compared to conventional technique. An interesting finding were certainly the causes that brought to reoperation, especially those related to the system itself. Whether the improvements brought by the use of this robotic tool could bring to better survival and lower revision rate is still not clear. Being revision rate the greatest concern about UKA surgery, high evidence of this kind of data is mandatory. Current literature about UKA performed with NAVIO is still dominated by retrospective and cadaveric studies, while large prospective controlled studies, with possibly medium-long follow-up, are needed in order to obtain better knowledge about the effectiveness of this procedure.

#### Conflict of Interest

The Authors declare that they have no conflict of interests.

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None.

#### Authors' Contributions The authors contributed equally.

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Not applicable.

#### Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

#### Ethics Approval

All procedures performed in the current study were in accordance with the 1964 Helsinki Declaration and its later amendments. The study design was approved by the Orthopedic and Traumatology Institute and School Council "Policlinico Universitario Agostino Gemelli IRCCS".

#### Informed Consent

Written informed consent was obtained from all individual participants included in the study.

#### Consent for publication

All consents for publication have been collected. All the patients gave written consent for their personal or clinical details along with any identifying images to be published in this study.

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