

Does the type of Knee Replacement impact early postoperative pain?

A retrospective analysis of three Total Knee Systems

LSK PS knee pain relief precocity and superiority in the first 12 weeks post-op vs two competitive knees

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Introduction

Traditional evaluation of TKAs' success is based on surgeon-objectively-measured metrics such as Kaplan-Meier survivorship, Hazard ratios, revision rates, besides radiographic assessment and alignment/ROM. Contemporary TKAs are offering more than excellent survivorship being a well-proven procedure with more than 80% surviving at 25yrs f-u.¹ An emerging trend in Orthopaedics to measure TKAs' in-vivo outcomes complementing this objective approach is relying on subjective PROMs' collection,^{2,3} given the relatively high quota of post-operative dissatisfaction⁴ recorded even in unrevised patients^{5,6} and the residual pain following TKAs, even on younger patients^{7,8,6} which challenges the definition of "a successful TKA", given also the sometimes different criteria patients' vs physicians are adopting to judge and measure "success" based on different expectations.^{6,9-11} PROMs see today a widespread adoption by the majority of the international NJRs¹²⁻¹⁶ and growing publication rate¹⁷⁻¹⁹ when used as endpoints in clinical trials,²⁰ and work is ongoing to harmonize their usage to allow comparability.^{21,22} Their predictive value has been even recently demonstrated.^{23,24} When releasing a new TKA system

in the market is therefore crucial to collect also the unbiased voices of the patients to validate its clinical effectiveness.²⁵ This urgency holds true especially in the **immediate follow-up**, during the rehabilitation, a challenging phase where patients **have to recover as quickly as possible** setting the basis for future mobility, confidence (QoL) and associated satisfaction in time to come as well as excellent survivorship, which typically is not reported before 6 m to 12 m in the international NJRs, leaving the most critical rehabilitation phase poorly investigated, but **still so strategically important** for the patients. Evidences show in fact as persistent post-operative pain following TKAs still remains a large issue^{5,26} impacting 15% to 34% of patients even after 2 to 5 yrs post-op.²⁷ At once the Pain relief **precocity** in the first weeks (2 w to 8 w)^{28,29} of immediate post-op is crucial for the functional recovery and satisfaction later on seen in the follow-up at 6m to 2yrs^{30,31} and for the Pain relief itself at 3m to 6m.³² Fast pain responders may be identified very soon based on their pain trajectories in the immediate post-op and assessed for their impact on Pain relief and PROMs in the follow-up to come.

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Methods and Design

Single surgeon, 2 centres, retrospective review comparing **pain relief and painkillers** (opioid) dose up to 12 weeks post-operatively between 3 con-

temporary different primary TKAs implanted following the same surgical technique on comparable demographics arms (for age/gender/BMI/diagnosis) at baseline.

Timepoint

Focus **on the immediate recovery period**, as the most critical, from 2 weeks to 12 weeks post-op also collecting data at 6 weeks f-u.




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Implants used

299 TKAs in total performed from June 2020 to March 2022, distributed as in the table below, well-balanced arms.

The three TKAs represented different constraints (i.e. CR/UC/PS), kinematics (fixed vs mobile bearing) and fixations (i.e. fully cemented LinkSymphoKnee,

hybrid Evolution Medial-Pivot, uncemented PFC Sigma RP/CR) but the 3 arms exhibited no statistically-significant differences in pre-operative covariates and same surgical technique was used (i.e. tourniquet and median parapatellar approach).

| | Primary Knee Brand | N (knees) |
|---|---|-----------|
|  | LinkSymphoKnee PS, Waldemar Link | 94 |
|  | Evolution Medial-Pivot, Microport Orthopedics | 104 |
|  | PFC Sigma RP CR, Johnson & Johnson MedTech | 101 |

Study goal

The study goal is twofold: to identify which TKA offers

1. The largest Pain relief (change vs pre-op) and painkillers dose reduction
2. The quickest Pain relief and painkillers dose reduction

So quantity & rate are the key study objectives.

Primary endpoint: PROM- scale NRS Pain 0 to 10 at pre-op, 2w,6w,12w

Secondary endpoint: average daily dose of prescribed opioids (expressed as MME milligram morphine equivalent) at 2w,6w,12w only on opioid-naïve-patients (i.e not prescribed or using opioids 30 days prior to surgery, for each group 77 LSK PS, 89 MP, and 75 RP).

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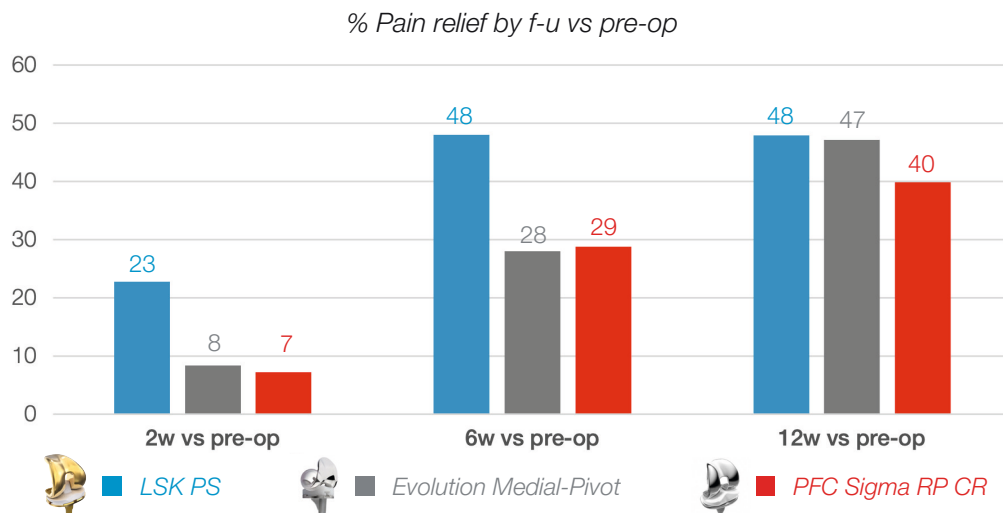
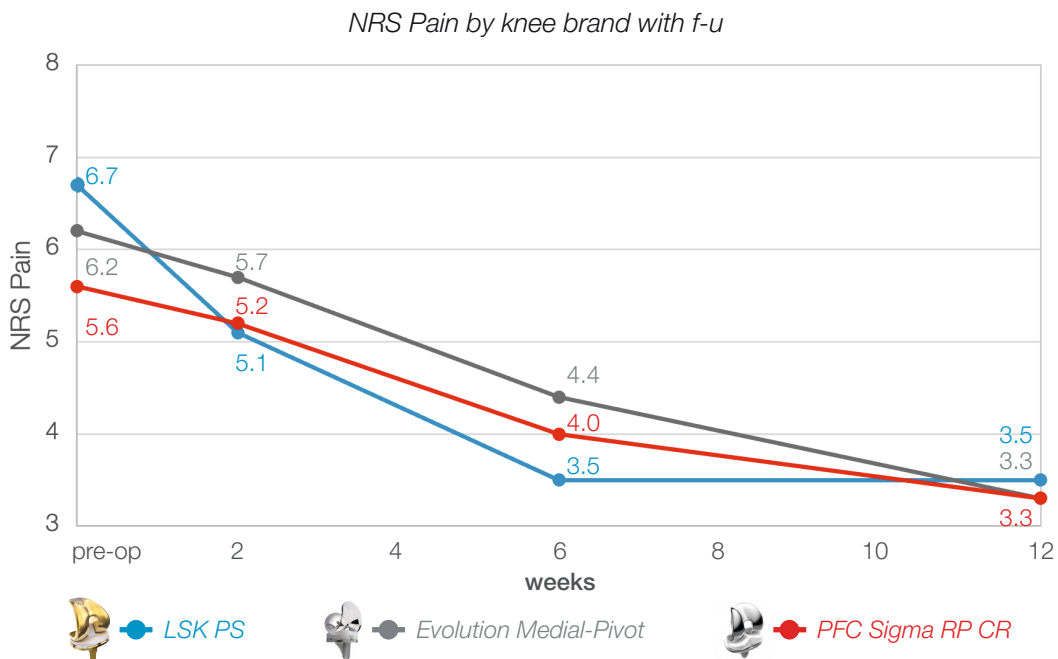
Results

• Pain relief

A statistically-significant different pain relief vs pre-op baseline was observed at 2w and at 6w for the LSK PS vs both MP and RP TKAs, with LSK PS able to offer

larger and quicker pain relief (23% vs 7-8% of RP/MP at 2weeks and 48% vs 28-29% for MP/RP at 6 weeks vs pre-op)

The bar charts below show % Pain relief achieved by knee brand at different timepoints vs pre-op.



Pain relief reached a plateau at 12 weeks f-u being the difference not any longer statistically-significantly different as normal with time differences were reducing among TKAs systems.

IMPORTANT TO NOTE:

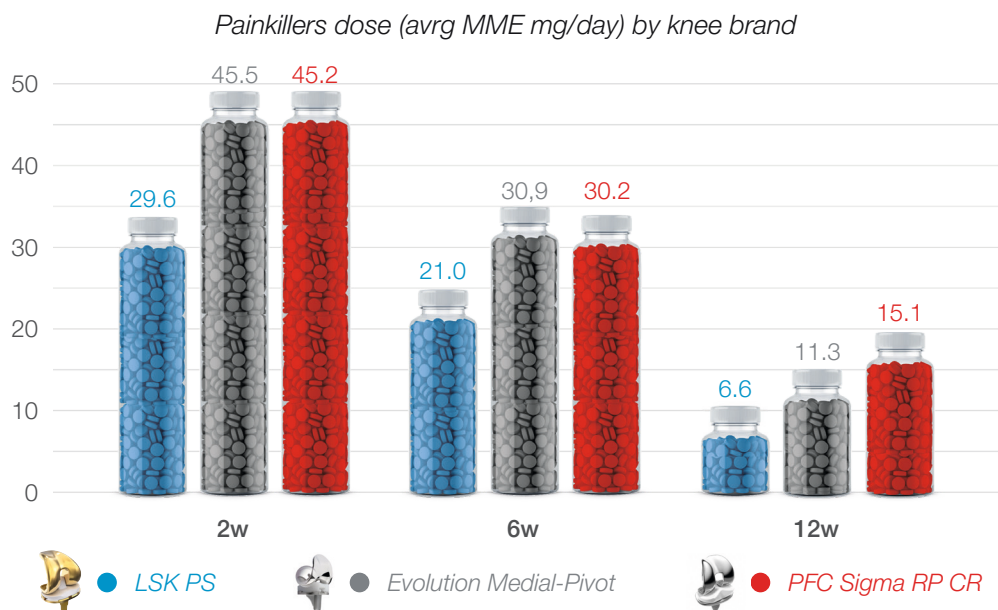
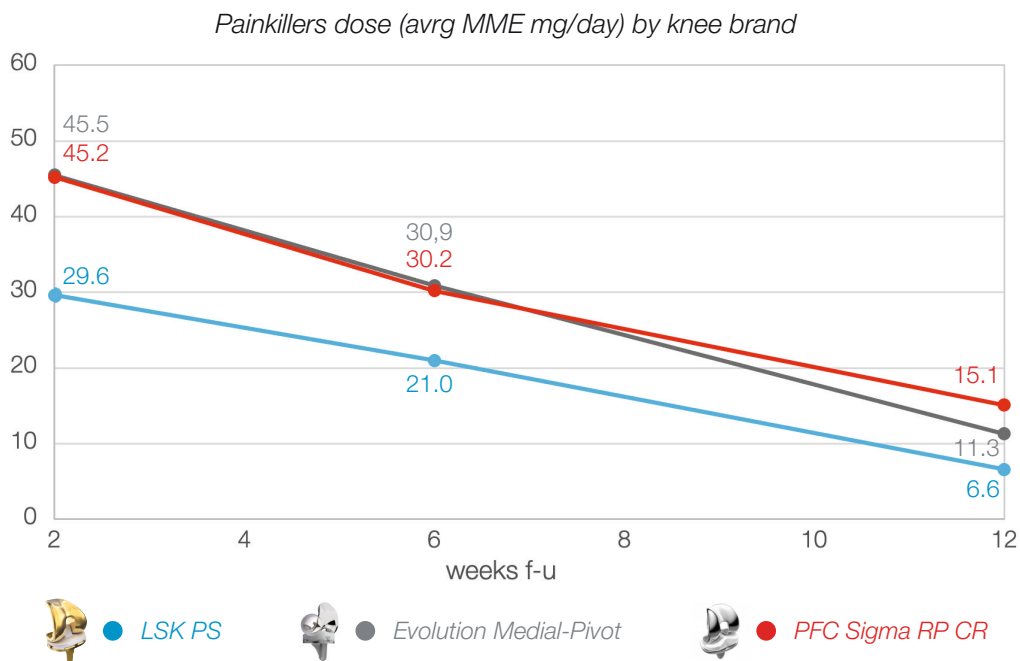
The benefit of LSK PS was brought exactly in the immediate f-u 2w to 6w **where it matters strategically more** for a patient own recovery/QoL restoration and mobility's confidence.

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• Painkillers reduction

A similar trend was found for the painkiller dose reduction, with LSK PS demonstrating a statistically-significant lower avrg opioid dose vs both MP and RP at 2w and at 6w f-u continuing offering a 78% reduction of painkillers at 12w vs 2w. The downhill painkiller dose trend was inversely correlated with an uphill Pain relief as logically expected.

Once again **the precocity** of Painkillers reduction was important vs competitors, meaning LSK PS patients not only needed a lower dose since the immediate post-op (largest % reduction -35% at 2w, -32% at 6w, -56% at 12w) but also reduced their doses **quicker** vs competitive knees



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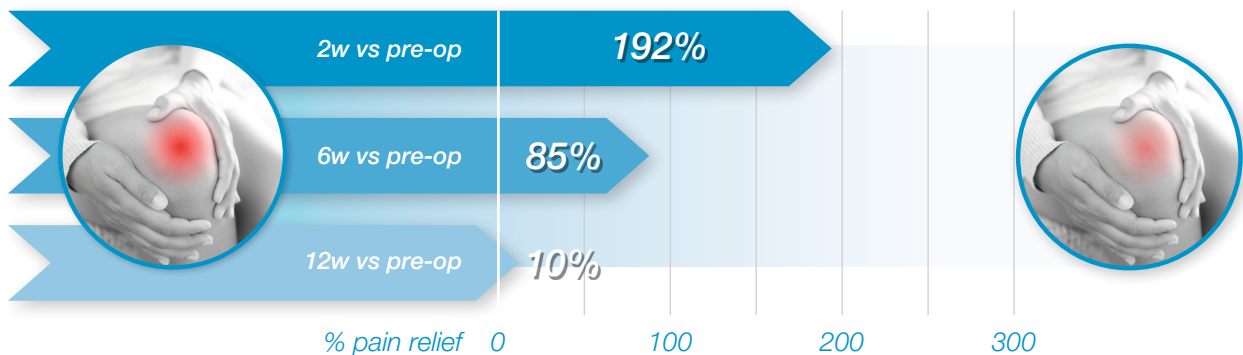
Benchmark LSK PS vs competitors

These data allow also a benchmarking of the LSK PROMs performances **at the shortest follow-up** vs either contemporary state-of-the-art knees, such as the Evolution MP, or vs long-time-validated primary

knee systems such as RP Sigma CR. The % Pain relief offered by LSK PS vs competitors at 2w/6w/12w vs pre-op is in fig. below:

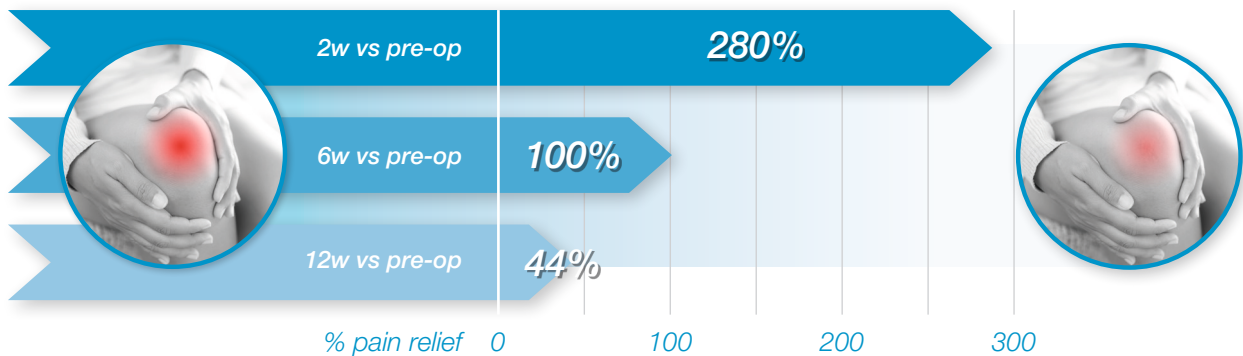
% avrg pain relief offered by LSK PS vs competitors

 **LSK PS** vs *Evolution Medial-Pivot* 



LSK already at **2 weeks f-u** can **relief x 3** the post-op Pain vs *Evolution Medial-Pivot*

 **LSK PS** vs *PFC Sigma RP CR* 



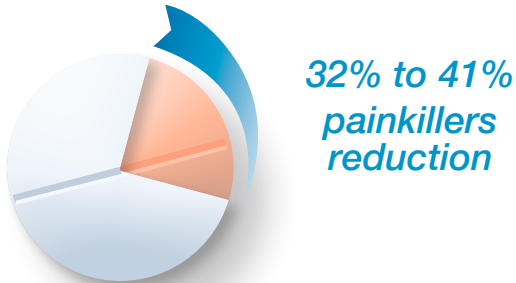
LSK already at **2 weeks f-u** can **relief nearly x 4** the Pain vs *the PFC Sigma RP CR*

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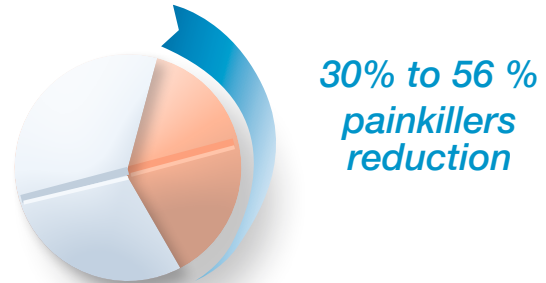
The 2w to 12w range of painkillers dose reduction range is shown in Fig. below:

Painkillers reduction - % reduction offered by LSK PS vs competitors between 2w to 12w f-u

LSK PS vs Evolution Medial-Pivot



LSK PS vs PFC Sigma RP CR



Conclusion

LSK PS significantly **outperformed at the shortest-term** follow-up during rehab two state-of-the-art contemporary knee systems being able to offer a **larger and quicker** Pain relief and associated Painkillers dose reduction. With less pain immediately recorded in the first weeks post-op, patient confidence and mobility can be increased having set the basis also for sustained pain relief in the months and years to come^{33,34}, allowing an earlier recovery, theoretically allowing shorter Length Of Stay (LOS) and larger outpatient TKAs quota, crucial points in the current value-based

healthcare scenario driven by patients' satisfaction maximization and resources' optimization at once. LSK PS has the potential, based on these PROMS study findings, of offering therefore significant values to patients and health care practitioners without having to wait too long for this value to impact patients' Quality of Life.

Further studies in the future, with larger cohorts, are deemed necessary to thoroughly investigate the reasons behind this promising short-term results and offer more clinical insights.



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