



Clinical Evaluation Summary

CES OSS K07

Össur - NOP5/NKP5 knee

Warranty period - 3 Years

Weight Limit - 125kg

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients, and shown in an abbreviated form overleaf. It is an attempt to give an overview of the product based on our experience to date and needs to be read in conjunction with the product literature supplied by the manufacturer.

Evaluation Summary

By referring to the design features of the knee the Clinical Support Group decided to evaluate the knee on moderately active patients that required little stance phase control and some swing phase adjustment. Polycentric in design and is therefore geometrically stable during stance phase, the knee includes a pneumatic swing phase control cylinder, offering the ability to adjust both flexion and extension resistance. The results of the evaluation conclude that the knee is smooth in action an easy and controlled transition from geometrical stability to free swing. The knee was found to be easy to adjust requiring no maintenance for the duration of the evaluation period.

Indications

- Any patient requiring a free knee with:
- A moderate amount of stance phase control typical of that offered by geometric stability
 - Swing phase adjustment offered by a pneumatic cylinder
 - The "fluid" swing phase with increased ground clearance at mid swing typical of a polycentric design
 - Short build height with alignment (K version)
 - A large degree of flexion

Contraindication

- A patient of low or very high activity
- A patient exceeding 125kg
- Where a wide range of speeds are required
- Individuals with a particularly aggressive gait

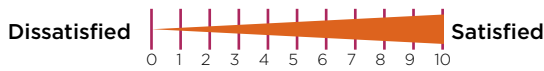
* It is imperative that the M.D.T assess very carefully the current limb use, not just the gait, but every aspect of the patient's activity before choosing to change any components.

Evaluation Patients

Patient Details

Patient 1	Transfemoral	82 kg	61 year old male	Caretaker/Groundsman	Sigam F
Patient 2	Transfemoral	90kg	56 year old male	Retired	SigamF
Patient 3	Transfemoral & Symes	83kg	50 year old male	Unemployed	Sigam E
Patient 4	Transfemoral	70kg	41 year old male	Badminton Player	Sigam F
Patient 5	Transfemoral	97kg	55 year old male	Company Director	Sigam F
Patient 6	Transfemoral	82kg	52 year old male	IT Manager	Sigam F

Evaluation Result



Current Prescription

Patient 1	Laminate socket with Ossur Seal-In liner 3R60 EBS Knee Multiflex foot (later converted to Trés)
Patient 2	OB 3R80 Knee
Patient 3	OB 3R106 Knee
Patient 4	Endolite Smart IP knee and Elite foot
Patient 5	Polypropylene Quadrilateral socket with DSPB, Endolite ESKPSPC, Multiflex foot/ankle
Patient 6	Polypropylene Conventional Suction socket, with a metal outer, conventional free knee, with no swing phase control and uniaxial foot

Prosthetist's Comments

Patient 1 - Easy to adjust swing phase control, a smooth and progressive swing. It appears stable at heel strike until mid-stance. Prosthetist noted that the patient was (in this instance) able to wear the trial the knee at factory setting "out of the box" and was then able to fine tune the settings according to the patients requirements. It was noted that it was not possible to discern if the addition of the cosmesis at delivery stage had altered the swing phase characteristics. The last feedbacks from the patient were taken via telephone conversations (the patient not feeling the need to attend the clinic) and it would appear that the knee has continued to perform as well as it had done after the first review appointment. (16/9/08) The Prosthetist was unable to determine if he would routinely prescribe this knee, preferring further experience with the knee before passing any conclusion.

Patient 2 - Described by the Prosthetist as a "robust gentleman" the patient "overpowered" the pneumatic cylinder and despite adjustment excessive heel rise was experienced. When compared to a knee (NOP4) manufactured by the same supplier, also with a pneumatic cylinder it was noted that it was possible with that unit to eliminate the excessive heel rise. It is thought therefore that the geometry of the knee was a feature that contributed to this experience, though his current prescription, being a hydraulic yielding knee, may also have contributed, since it allows a more aggressive gait, which was a characteristic of this gentleman's walking action.

Patient 3 - The Prosthetist noted that this gentleman preferred historically to have no swing phase control, but that it was possible to achieve good swing phase control with the NOP5, requiring little change from the initial factory setting of the pneumatic unit. Found to be a good knee when used in combination with a Trés foot.

Patient 4 - The Prosthetist was initially concerned that the lack of a weight activated stance phase control may be an issue for the patient (The Smart IP already having a weight activated stance phase control within its design) was pleasantly surprised to find that the unit performed well although the lack of stance phase control did "catch him out" once or twice. He would easily have learnt to control the knee, given more time.

Patient 5 - The Prosthetist commented that this patient was accustomed to having the sensitivity of the ESK reduced to a minimum and that he had a short residual limb. His current prescription was under review and so it was decided to trial the NOP5. It was found to be stable, but easy to transition into swing phase. He commented that the patient felt he "was in control of the point at which the transition takes place, such as when descending a slope, but that stability was retained until that point". Also he had found the technical literature easy to understand and concluded by suggesting that the knee would be appropriate for a patient requiring a medium level of stance control. Over the review period the knee needed no further alterations or maintenance.

Patient 6 - Having worn a prosthesis since suffering an accident when a child, this patient had always been reluctant to change his prosthesis, but problems with obtaining some components to service it, added to increasing back problems, possibly due to the exaggerated gait he'd developed in order to control the prosthesis, lead his prosthetist to persuade him to at least try to make a change and this knee unit seemed to be the most appropriate, based on experience with Patient 3.

Patient's Comments

Patient 1 - The patient described his opinion as being "very satisfied overall" and found the knee to be "comfortable and easy to use". He described the knee walking and stability as feeling good and "able to change from old leg to new and still be able to walk with confidence". At the last contact with the patient he described himself as being "entirely satisfied".

Patient 2 - No comments recorded.

Patient 3 - The patient benefited from the swing phase control offered but found the knee flexion angle excessive, preferring to rest onto the unit during kneeling (a stop would therefore need to be added in order to prevent this). It was noted however that the flat broad design of the knee unit made it a more stable platform when kneeling.

Patient 4 - The only note made was that the patient appeared to like the unit.

Patient 5 - The patient commented at the second review that the knee was "smoother and easier to walk with less energy required" and that he had found it easier to manage slopes, but the change in foot prescription had also contributed to the benefits he'd experienced.

Patient 6 - Though he understood the need to try and make a change to his prescription, the patient remained reluctant to do so right up to the delivery stage. He actually walked the new set up very well and this was commented on by other patients, but it wasn't until he returned to his original limb that he realized just how much better the new prosthesis was, at which point he became very enthusiastic about it.

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