steeper
Creating life's turning points, together

Clinical Evaluation Summary

CES **OSS** K05

Össur - NOH5/NKH5 knee

Warranty period - 3 Years

Weight Limit - 100kg (NOH6/NKH6 – 136kg)

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

This knee appears to provide excellent geometric stability in stance phase, a smooth and controllable swing phase, good levels of durability and reliability, and a very low build height option, especially in the NKH5 form. Even in this form it is alignable. It also has an exceptionally good range of flexion, limited most often by the socket itself.

Indications

The NKH5 is particularly suited for application where a very short build is required, but where some alignment would still be desirable.
The NOH5 still provides a lower build option than many other knees.
Active users of a free knee who would benefit from a high level of geometric stability in the stance phase.
Active users of a free knee who would benefit from greater control of the swing phase.
Free knee users who would benefit from increased reliability and durability from their prosthesis.
Where a high flexion angle is required.
Cyclists*.

Contraindication

Patients whose activity level is below that where a free knee is appropriate, or who need a manual lock on occasions.

Patients who currently use a hydraulic knee with a yield facility, in order to descend stairs or steep slopes leg over leg.

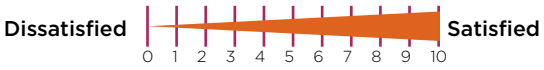
*We would hesitate to suggest that this knee unit be prescribed for use on a dedicated cycling prosthesis, since it is not possible to bypass the hydraulic system and the constant effect of the hydraulics would make the action of pedalling less efficient and constant high cadence cycling for any length of time may overheat the hydraulic fluid.

Evaluation Patients

Patient Details

Patient 1	Knee Dis	67 kg	21 year old male	Police/Clerical	Sigam F
Patient 2	Transfemoral	82 kg	30 year old male	Pharmacist	Sigam F
Patient 3	Transfemoral	85 kg	26 year old male	Office Worker	Sigam F
Patient 4	Transfemoral	68 kg	27 year old male	Unemployed	Sigam F
Patient 5	Knee Dis	75kg	28 year old male	Office Worker	Sigam F
Patient 6	Transfemoral	58 kg	24 year old male	Unemployed	Sigam F

Evaluation Result



Current Prescription

Patient 1	Laminate socket with the load shared between end bearing and ischial bearing, to Total Knee 2001 and Seattle Lightfoot
Patient 2	Silicone self suspending socket with lanyard with High Activity Total Knee and OB 1D10 foot
Patient 3	Laminate socket with Iceross liner, High Activity Total Knee 2100 and Variflex foot.
Patient 4	Primary prescription
Patient 5	Laminate self suspending socket with Blatchfords 4 Bar knee with PSPC. Seattle Lightfoot
Patient 6	Primary prescription

Prosthetist's Comments

Patient 1 – Actually a young man with an extremely short congenital transtibial absence, who has always been dealt with as a knee disarticulation and who therefore requires as short a build above the knee as possible. The Total Knee had served him very well indeed, apart from the fact that the knee ball kept coming loose and making a noise. Since unit one had reached the end of its life, following a fall into the sea, the opportunity was taken to trial the NKH5 in an attempt to provide an even shorter build.

Patient 2 – The patient was chosen in an attempt to provide a more dynamic gait. The prosthetist observed that the NOH5 was easy to assemble, smoothly finished and gave a good flexion angle. The adjustment of spring assist and hydraulic swing phase control he found "tricky" 4.

Patient 3 – A good user of the Total knee, this patient's second prescription gave opportunity to trial the NOH5 knee. The prosthetist found it easy to set up 4 and did not need to change anything from the factory settings. A pivot screw came loose after 6 months, but was serviced under warranty without question.

Patient 4 – Due to the length of the residual limb, an NKH5 was prescribed as his first issue prosthesis, the prosthetist finding it easy to fit, with a wide range of alignment and swing phase control. It appears stable throughout the stance phase and has proved reliable and durable.

Patient 5 – Technically a congenital absence of the fibula, the very short tibia would not allow the use of a transtibial prosthesis. The distal section does allow the socket to be self suspending, but also present a problem since the patient likes a high degree of flexion to enable him to kneel. The Blatchfords unit allowed this, but didn't tolerate the activity level of the patient. The Total knee wouldn't allow the flexion required, so the NKH5 was chosen. The alignment wedges, though requiring a certain level of "mental gymnastics", do make it easier to align than the other units.

Patient 6 – Previously fit and active prior to his amputation, but wishing to return to full time employment and to pursue his sporting and leisure activities, the prosthetist chose the NOH5 knee in the hope of helping him achieve a smooth, natural, cadence responsive gait. There were no problems with the technical instructions, fitting and alignment, and two months after delivery, no maintenance or adjustment has been required.

Patient's Comments

Patient 1 – Initially a little unsure of the knee, since the level of stability was such that he had to be more precise in his action when flexing the knee to sit, he scored it at 3, having scored the Total Knee at 4. By the review date 3 months later, he didn't even mention this issue, commenting only that it felt more stable and safer on stairs. He particularly liked the increased flexion. After 6 months he scored the knee at 5. No durability problems to date.

Patient 2 – Though he had scored the Total Knee at 4 and we did have some problems getting the swing phase speed correct on the NOH5, he still gave it 4 as well. The first unit developed a hydraulic leak, but a loaner was provided and the refurbished unit has been fine since. He likes it for cycling especially, but still seems to want it to be faster in swing phase.

Patient 3 – The patient made very little comment, but liked the look of the unit, thought it felt lighter and more stable. He requested it rather than a second Total knee and is still using it as his preferred prosthesis.

Patient 4 – Having no other experience against which to judge the knee, the patient scored it a cautious 3, stating that "I can do everything I need to". His only difficulty was in learning to sit, at which point the excessive stability of the unit initially proved awkward.

Patient 5 – The patient has found this unit very reliable and apart from a slight noise that developed in the hydraulics, has had no need of repairs whatsoever. He also appreciates the high degree of flexion available.

Patient 6 – This enthusiastic young man, despite having nothing with which to compare his prosthesis, scored it 5 at the start and the end of the two month evaluation. He is delighted with its performance, having used it on an exercise bike, walked over uneven ground and been on nights out with his friends. He tends go down slopes by taking a diagonal route, not because the knee has ever let him down, but because he lacks confidence. He wants to start running, but he is still at an early stage in his prosthetic rehabilitation.

This picture shows the flexion angle achieved on patient 5