Recommendations to ensure the safe maintenance and use of Knee Ankle Foot Orthoses

This guidance is intended to aid governance within a clinical setting and should be read in conjunction with BAPO's Standards for Best Practice

Key principles relating to safe use

Knee Ankle Foot Orthoses (KAFOs) are essential to the mobility and well-being of many users of orthotic services.

KAFOs are a device that present one of the greatest risks to patient safety. The failure of the device may lead to a fall and consequent injury.

To ensure safe use, KAFOs must be safety checked. Safety checks must include the integrity of the structure and that the joint mechanisms are not excessively worn. Knee joint manufacturers' guidance and the frequency of checks must be adhered to.

BAPO recommends that all service providers ensure that their orthotic department has a clear policy and supporting information to ensure that KAFOs are checked at the required frequency, in line with manufacturers' recommendations.

Some aspects of these guidelines can be carried out in clinical areas or a clinic with limited workshop facilities, by appropriately trained personnel.

Such policies will require that records relate to each KAFO provided and that these are accurately documented to confirm the required safety checks have been completed.

Service users who do not follow the instruction given, to return their KAFO for a safety check, must in all cases be advised that the device must not continue to be used. To do so carries an unacceptable risk for the user.

Services must maintain accurate records that evidence all conversations that have occurred between the prescribing orthotist and service users, and that clear advice has been given by that orthotist regarding all matters relating to the safe use of all KAFOs.

Description

A Knee Ankle Foot Orthosis (KAFO) has been defined as an orthosis that encompasses the knee, ankle joints and the foot by the International Organization for Standardization[1].

1. Function

The function of a KAFO may include[2]:

1.1. To manage a deformity including a) the prevention of a deformity, b) the reduction of a deformity, and c) maintaining a deformity.

1.2. To alter the range of motion of the joint(s) including a) to limit the range of motion of a joint, and b) to increase the range of motion of a joint.

1.3. To change the dimensions of a limb segment including a) to improve the shape of a segment.

1.4. To manage abnormal muscular function including a) compensating for weak muscle activity, and b) controlling the effect of muscle hyperactivity.

2. Fabrication

2.1 The KAFO may be either custom-made or prefabricated[2].

3. Construction

3.1 A KAFO will comprise the following components[2]:

3.1.1 Interface components (in direct contact with the user and includes shells, pads, and straps).

3.1.2 Articulating components (permits or restricts motions of anatomical joints).

3.1.3 Structural components (connects the articulating and interface components and maintains the alignment of the orthosis and includes uprights and shells).

3.1.4 Cosmetic components (the means of providing shape, colour, and texture to an orthosis).

3.1.5 The orthosis may be made from a variety of materials such as plastic, steel, leather and composites or a hybrid of these materials.

4. Maintenance

4.1 All KAFOs must be appropriately maintained to ensure they remain safe for the service user. Clinicians must adhere to the manufacturer's guidelines on how and when to check components for safety. As a minimum, all KAFOs must be safety checked by the providing service every six months (or sooner if advised by the manufacturer) and on request should a service user report a safety issue.

4.2 The manufacturer, with whom the clinician places an order for the fabrication of a KAFO, must supply the prescribing clinician with all maintenance documentation pertaining to the KAFO's construction.

5. Maintenance and safety of a KAFO

The regular maintenance of a KAFO is essential to the safety of the device and the protection of the service user.

The clinician/service must ensure that they adhere to the following guidelines:

- All clinicians must be aware of the manufacturer's guidelines on the safe maintenance of all components used in the fabrication of a KAFO.

- The issuing department must have a local written policy/standard operating procedure for the safe maintenance of KAFOs.

- The issuing department must have a method of advising service users that their KAFOs are due a safety check. E.g., sending six-monthly reminder letters detailing that a safety check is due and what steps the service user must take to access the service for this purpose. Such letters must be recorded in the service users' files.

- The issuing department must have a method of identifying each KAFO issued to a service user. E.g., marking KAFOs with a unique identification number using a non-removable method. E.g., a permanent marker or ultraviolet (UV) pen, and ensuring this is recorded in the clinical notes at each service user contact. BAPO does not recommend engraving any identification into the structure of the KAFO as this can cause weakness in the device which may contribute to a safety issue. Manufacturers may use etching to mark an orthosis on the understanding that this task requires specialist knowledge, experience, and oversight in the manufacturing environment.

- All clinicians must ensure it is documented in the service user's notes that they have been advised that all KAFOs must be safety checked at least every six months by the department/service. The potential consequences of failing to have the KAFO safety checked and the fact that it is the service user's responsibility to bring the KAFO to the department to be safety checked.

- The department must have a dedicated service user information leaflet outlining the safe use of KAFOs and safety checks, with details on how to contact the department. It must be recorded in the service user's clinical notes that a KAFO information leaflet has been issued to the service user, or that they have declined the said leaflet. Details of how to care for the device, such as cleaning, must be included in the information leaflet. The information leaflet must also provide details of how the service user should check for general wear and tear daily and when and how to contact the issuing department should a problem occur before the KAFO is due to be safety checked.

  Where a KAFO has not been safety checked within the timeframe recommended by the manufacturer or in the absence of a guideline, within a six-month period, the service user must be advised not to wear the KAFO.

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This document has been through a consultation process with industry stakeholders and has been endorsed by:

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The National Orthotics Managers' Association Group (NOMAG)

References:

1. Standardization IO for. *Standardization IO for ISO 8549- 1:1989 Prosthetics and Orthotics - Vocabulary. General Terms for External Limb Prostheses and Orthoses. Geneva: International Organization for Standardization; 1989*.; 1989.
2. Standardization IO for ISO 13404 2007 (E). Categorization and description of external orthoses and orthotic components.Geneva: International Organization for Standardization; 2007.

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