Biologically Oriented Prostheses
BIOPRO

SUGGESTIONS CONCERNING TOTAL JOINT REPLACEMENT PROSTHESES

Prepared by Orthopedic Surgical Manufacturers Association

For the most current instructions for use and symbol glossary visit www.bioproimplants.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact orders@bioproimplants.com

The advancement of Total Joint Replacements, in conjunction with the use of polymethylmethacrylate bone cement, has provided the surgeon a means of restoring mobility and reducing pain for many patients. While these devices are largely successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal healthy bone.

In using total joint implants, the surgeon should be aware of the following:

A. The correct selection of the implant is extremely important. The potential for success in of the implant. No total joint replacement can be expected to withstand loads and activity levels of normal healthy bone. Total joint prostheses require careful seating and adequate bone support, and should be restricted to limited functional stress.

B. In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:

1. The patient's weight. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the appliance.
2. The patient's occupation or activity. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the cement, device or both.
3. A condition of senility, mental illness, or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
4. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, total joint replacement can only be considered a delaying technique or temporary relief.
5. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

C. The use of polymethylmethacrylate bone cement can be helpful in securing, supporting and stabilizing certain appliances in bone, but it neither replaces the function of sound bone for support nor eliminates the need for other support during healing. In using cement for implant fixation, care should be used to insure complete cement support on all parts of the appliance embedded in bone cement to help prevent possible stress concentration which may lead to failure.

D. The correct handling of the implant is extremely important. Contouring of the metal device is to be avoided where possible. If contouring is necessary, it should not be bent sharply, reverse bent, notched or scratched. These alterations can produce defects and stresses which may become the focal point for eventual failure of the implant.

E. A surgical implant should not be reused. Any implant once used should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns which may lead to failure. We urge you to use only new appliances of current design.

F. Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load-bearing, ranges of motion, and activity level permissible. Early load-bearing should be carefully controlled.

Additional information regarding a specific total joint system may be obtained from BIOPRO.

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