Fifteen years of bone tumor cryosurgery: A single-center experience of 440 procedures and long-term follow-up


The National Unit of Orthopedic Oncology, Tel-Aviv Sourasky Medical Center and the Sackler Faculty of Medicine, Tel-Aviv University, 6 Weizman Street, Tel-Aviv 64329, Israel

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Abstract

Background: This summary of a single center’s extensive cumulative experience in bone tumor cryosurgery assesses the long-term outcome of bone conservation surgery in which adjuvant cryosurgery plays a pivotal role.

Materials and methods: We performed 440 cryosurgical procedures between January 1988 and December 2002. Two-thirds of the series comprised a variety of primary benign-aggressive and low-grade malignant lesions, and one-third were primary high-grade and metastatic bone tumors. The anatomical locations included almost every bone of the skeleton. Two methods of bone cryosurgery were used: Marcove’s “open” direct-pour system using liquid nitrogen (1988–1997) and Meller’s “closed” argon-based system (1998 to the present).

Results: The study cohort consisted of 214 males and 191 females (age range 5–82 years). The median follow-up was 7 years (range 3–18). The overall local recurrence rate was 8%: fractures = 1%, infections = 2% and skin burns = 1.3%. There were three cases of transient nerve palsies in areas other than the sacrum, and four cases of late osteoarthritis of an adjacent joint. The functional outcome for the 372 patients with no evidence of disease was almost 100% “good” and “excellent” (American Musculo-skeletal Tumor Society System). Only two patients needed secondary amputations.

Conclusions: Bone cryosurgery is a safe and effective limb-, joint- and even epiphysis-sparing surgical technique in suitable types of bone tumors, temporarily or permanently obviating the need for resection surgery.

Keywords: Bone tumor; Bone sarcoma; Metastases; Cryosurgery; Limb-sparing surgery

Introduction

This presentation of the clinical experience of a single center’s series of 440 cryosurgical procedures in 405 patients with various bone tumors and long follow-up (3–18 years) illustrates our conviction that conservation is superior to resection surgery in the treatment of skeletal masses and cavities (Fig. 1). Cryosurgery plays a key role in implementing this approach.1–3

Cancer surgery contends that a tumor-containing organ or tissue must be removed in its entirety and with disease-free margins in order to achieve local control and cure. There are essentially two conservative surgical approaches for such cases, with the intent to minimize or eliminate the risk of local recurrence: resection or conservation (Fig. 1). Resection surgery means excision of whatever is necessary to achieve ridding the site of recurrence risk: bone, adjacent joint, muscles, tendons, arteries, veins, nerves and skin. This can be accomplished by amputation (requiring later artificial external limb prostheses), or by limb-sparing surgery (LSS) (followed by internal reconstruction). Since the latter does not resemble the natural anatomy, conservation surgery, where feasible, appears an attractive option, especially for young patients. Conservation surgery contends that by killing remaining tumor cells after debulking the tumor (i.e., intrallesional excision), the skeleton will be “sterilized” without sacrificing the natural frame. The adjuvant modalities available include extensive mechanical burr drilling after curettage, radiation therapy, chemicals (phenol, alcohol, zinc chloride), exothermic acrylic bone cement, hyperthermic modalities (cauterization, radiofrequency ablation),

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* Corresponding author. Tel.: +972 3 6974688; fax: +972 3 6974690. E-mail address: imortonc@tasmc.health.gov.il (I. Meller).

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local chemotherapy (loaded in bone cement or through isolated limb perfusion), cryosurgery with different coolants, and combination(s) of the above. After the removal of the malignant content and sterilization of the walls, the remaining challenge is to effectively fill the bone defect, accomplishable by autogenous bone graft, allogenic bone graft, synthetic bone substitutes, bone cement, hardware and combinations thereof.

Conservation surgery preserves a great deal of the anatomy (especially the adjacent joint and even the epiphysis), it is not a “burning bridge” technique, and resection after conservation is still possible. This is important with respect to the long-term function and quality-of-life. It does not, however, presume to replace traditional resection surgery in all cases; conservation surgery should be used only if the rate of local recurrence after this “intralesional” approach is less than or equal to traditional resection surgery.

The purpose of this presentation is to describe the achievability and advantages of preserving bone and joint segments without violating the principles of bone cancer surgery.

**History and physics of cryosurgery**

The history of bone cryosurgery and its scientific basic features are beyond our scope. Briefly, cryoablation induces tissue necrosis via rapid cooling (induction of intra- and extra-cellular ice formation), temperature (−40 °C or below), slow thawing (creating intracellular recrystallization), repetitive freeze–thaw cycles, and maintaining tissue in a frozen state for 5–10 min.

**Materials and methods**

This is a retrospective, consecutive and cumulative experience of a single center and one orthopedic oncologic team, using cryosurgery in the management of a heterogeneous series of bone tumors, starting from January 1988 until January 2002. A total of 440 cryosurgical procedures were performed on 405 patients. Most (90%) patients underwent diagnostic procedures, staging studies and treatments in our institution. The diagnostic procedures included imaging-guided core-needle biopsy, open incisional biopsy, or open excisional biopsy. We performed open excisional biopsies only in unequivocal clinical and radiological situations (such as in clear-cut evidence of giant cell tumor [GCT] of bone). The remaining 10% of the patients had been diagnosed and treated elsewhere, but were referred to our institution due to local recurrences of the tumors.

The anatomical distribution of the bone tumors is displayed in Table 1; the diagnoses of the study cohort are listed in Table 2. According to the American Musculoskeletal Tumor Society (AMSTS; Enneking’s) surgical staging system, all the primary benign-aggressive and low-grade malignant bone lesions were at stage IA or IB (determined by the existence of a soft tissue component), while the primary high-grade malignant tumors were at stage IIA or IIB, or even stage IIIA or IIIB.

**Methods of bone cryosurgery**

Two methods of bone cryosurgery with modifications or combinations are described in the literature: Marcove’s...
“open” direct-pour system using liquid nitrogen, and Meller’s “closed” argon-based system. All the operations are carried out with the patient under general anesthesia.

Two-hundred operations (1988–1997) were done using Marcove’s approach; the ensuing 240 Meller’s approach; several patients required the combination of several adjuvant modalities in the same operation.

Each cryosurgical procedure comprises two phases:

**Phase a:** conservative “resection” of the tumor material (i.e., intralesional operation); **Phase b:** reconstruction/filling of the defect/cavity. The only real difference between the two cryo methods is the technique of the delivery of the coolant and its control.

**Phase a: intralesional excision of tumor**

A standard skin incision is used. Wide retraction of the skin edges of the soft tissues and especially of the adjacent neurovascular bundles is required in order to prevent inadvertent freezing of these tissues and subsequent necrosis, dehiscence and infection. The tissues and nerve bundles are retracted and protected, insulated and sealed-off using wet Gelfoam, wet warm dusters and continuous copious wound irrigation with warm saline during, and immediately after, the cryo procedure. Whenever feasible, a tourniquet is used to decrease the heat-sink effect of the circulation and prevent tumor bleed into the cavity. Blood in the cavity is indicative of not having achieved dry walls: this makes adequate freezing more difficult and reduces the freezing potential on the walls which contain residual microscopic tumor cells. This is the reason for packing the cavity with H2O2 solution or other drying materials (e.g., coagulating factors) just before pouring the coolant. An earlier curettage of the tumor is performed through a “window” (fenestration) in the bone. The site of the “window” is very important: it should be located as far as possible from important extralesional structures, such as neurovascular bundles. In addition, its size should be large enough for the optimal use of curettes and burr drills so that they can reach every corner of the cavity. The use of fiber optic light is mandatory. The shape of the “window” is also critical for the coolant to be able to reach every hidden piece of the wall of the cavity and have perfect contact with the bone space. Because there are no two bony cavities with equal geometrics, especially in flat bones, the position of the limb and body is changed several times during surgery, by moving the table, thus directing the flow of the coolant to all parts of the cavity. An excessively large “window” will expose the cavity too much and make it difficult to seal it off with the coolant during the cryo procedure.

### Table 1

<table>
<thead>
<tr>
<th>Anatomical location of 405 bone tumors</th>
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<tr>
<td>Pelvis and Spine (n = 72)</td>
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<tr>
<td>Sacrum</td>
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<tr>
<td>Vertebrae</td>
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<tr>
<td>Pelvic bones: sacroiliac joint, iliac bone, acetabulum, ischium, pubis</td>
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<tr>
<td>Upper limb and shoulder girdle (n = 90)</td>
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<tr>
<td>Humerus (n = 59)</td>
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<tr>
<td>Proximal humerus</td>
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<tr>
<td>Distal humerus</td>
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<tr>
<td>Humeral shaft</td>
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<tr>
<td>Forearm (n = 17)</td>
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<tr>
<td>Proximal radius</td>
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<tr>
<td>Distal radius</td>
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<tr>
<td>Proximal ulna</td>
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<tr>
<td>Distal ulna</td>
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<tr>
<td>Hand</td>
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<tr>
<td>Shoulder girdle (n = 5)</td>
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<tr>
<td>Clavicle</td>
</tr>
<tr>
<td>Coracoid</td>
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<tr>
<td>Acromion</td>
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<tr>
<td>Lower limb (n = 243)</td>
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<tr>
<td>Femur (n = 143)</td>
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<tr>
<td>Proximal femur</td>
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<tr>
<td>Distal femur</td>
</tr>
<tr>
<td>Femoral shaft</td>
</tr>
<tr>
<td>Tibia (n = 77)</td>
</tr>
<tr>
<td>Proximal tibia</td>
</tr>
<tr>
<td>Distal tibia</td>
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<tr>
<td>Tibial shaft</td>
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<tr>
<td>Fibula (n = 6)</td>
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<tr>
<td>Proximal fibula</td>
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<tr>
<td>Distal fibula</td>
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<tr>
<td>Foot</td>
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<tr>
<td>Patella</td>
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</table>

### Table 2

<table>
<thead>
<tr>
<th>Diagnoses of 405 patients with bone tumors (BTs)</th>
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<tbody>
<tr>
<td>Primary benign-aggressive BTs (n = 246)</td>
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<tr>
<td>Giant cell tumor/aneurysmal bone cyst</td>
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<tr>
<td>Chondroblastoma</td>
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<tr>
<td>Chondromyxoid fibroma</td>
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<tr>
<td>Osteoblastoma</td>
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<tr>
<td>Hemangioma</td>
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<tr>
<td>Schwannoma</td>
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<tr>
<td>Fibrous dysplasia</td>
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<tr>
<td>Ossifying fibroma</td>
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<tr>
<td>Desmобlastic fibroma</td>
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<tr>
<td>Eosinophilic granuloma</td>
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<tr>
<td>Primary low-grade malignant BTs (n = 80)</td>
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<tr>
<td>Enchondroma&lt;sup&gt;a&lt;/sup&gt; and chondrosarcoma grade I–II&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Hemangioendothelioma</td>
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<tr>
<td>Chordoma</td>
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<tr>
<td>Ependymoma</td>
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<tr>
<td>Primary high-grade malignant BTs (n = 21)</td>
</tr>
<tr>
<td>Ewing’s sarcoma</td>
</tr>
<tr>
<td>Osteosarcoma</td>
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<tr>
<td>Myeloma</td>
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<tr>
<td>Metastatic bone “disease” (n = 58)</td>
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<tr>
<td>Renal cell carcinoma</td>
</tr>
<tr>
<td>Other metastases&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> Seven eventually progressed to high-grade chondrosarcomas.

<sup>b</sup> It is almost impossible to differentiate between benign and low-grade malignant cartilage tumors except in the hands and feet.

<sup>c</sup> Breast, lung, colon, thyroid, soft tissue sarcoma, melanoma, bladder transitional cell carcinoma, squamous cell carcinoma, prostate and liver.
thereby both reducing the effect of the coolant and risking the extra-cavity tissues to injury. Thorough curettage of the tumor material is done with hand curettes and high-speed burr drilling, taking care not to push tumor material into the medullar canal, the joint, or the soft tissues outside the bone or joint.

Marcove’s technique. Liquid nitrogen is used as the coolant. A metal funnel is placed in the bony window and the base is sealed with wet Gelfoam (Fig. 2). The coolant is poured directly into the cavity via the funnel. The size of the funnel and its position depend on the size and depth of the cavity and window (i.e., the geometry of the space). The initial pour of the nitrogen lasts only 1–2 min in order to obtain a seal of the spout of the funnel with the bone edges and Gelfoam. The wet Gelfoam quickly freezes and produces a seal at the base. Thermocouples are used to monitor the temperature in the cavity walls and adjacent tissues, as necessary. From 1 to 3 freeze–thaw cycles are performed, depending on the type of tumor, its size and geometry, and its proximity to an epiphyseal plate or articular cartilage. A freeze–thaw cycle consists of direct freeze with recorded temperatures below −40 °C (usually between −80 °C and −120 °C) for 5–10 min and a spontaneous thaw until the temperature of the walls rises to above 0 °C, a process which takes 1–3 min. The surgeon can abandon the use of the thermocouples after gaining sufficient experience.

Meller’s technique. The CRYO-HIT system (Galil Medical, Yokneam, Israel) is used for cryoablation. It comprises a workstation, which includes a monitor, control panel and housing unit for six gas cylinders (five containing freezing gas [argon] and one containing thawing gas [helium]), connecting cables and metal probes of differing sizes to accommodate different volumes of tumor cavity (Figs. 3 and 4). It is a closed system, delivering argon gas through a metal probe that is not in contact with the ablated tissue, and has a default temperature of −190 °C. Using the same probes and delivery system, helium gas with a default temperature of 35 °C is introduced to produce thawing. The temperature at the tip of each probe is measured separately. Up to three probes can be positioned within the cavity, depending upon its volume (Fig. 3). The probes are then removed, and the cavity is filled with a viscous surgical sterile gel (Surgilube, Fougera, Melville, NY), routinely used in urology and gynecology and is composed of chlorhexidine gluconate, a water-soluble, non-staining, and biologically inert substance. Care is taken to prevent spillage over the rim of the cavity. The probes are then repositioned within the gel and a thermocouple is positioned along the inner walls of the tumor cavity, whereupon cryoablation is begun. A controlled flow of argon gas is delivered through the probes. The temperature falls rapidly and an ice ball composed of frozen gel grows in a centripetal fashion towards the walls of the tumor cavity until it fills the entire space (Fig. 4). Cryoablation continues for 5–10 min after the temperature around the walls of the tumor cavity reaches −40 °C or below. During cryoablation, the surrounding soft tissue is irrigated with warm saline solution to limit the possibility of spillage and thermal injury.
Thawing is then started by introducing warm helium gas through the same probes. The freeze–thaw cycle forms an ice ball that melts within 2 min; the probes are then removed and the tumor cavity is irrigated with saline to remove the remaining gel. Copious rinsing of the cavity with H2O2 solution is performed throughout the entire procedure.

Cryosurgery adjuvants. There are adjuvants implemented in all kinds of bone cryosurgery: the use of re-curettage and cauterization of the walls at the end of freezing, the use of freezing sprays, the combined use of other adjuvant “sterilizing” modalities, such as phenol application, and augmentation of a shallow cavity by adding bone cement walls in order to allow the safe use of cryosurgery, especially in flat bones.

Phase b: reconstruction of the defect
This is the phase in which reconstruction/filling (RF) of the cavity is carried out. The type of RF depends on the size of the bony defect, its location in the skeleton (an upper non-weight-bearing extremity versus a lower weight-bearing one, a long tubular bone versus a small and flat one), and the age of the patient. The five types of RF measures are described in Table 3 and Fig. 5.

Postoperative management of bone cryosurgery
The bone is the best insulating tissue in our body. The cryo-necrotic area in the bone cortex reaches a longitudinal diameter of up to 2 cm. These features explain why the popliteal neurovascular bundle is not harmed during the freezing process of a cavity in the distal femur, even one with a thin cortex (i.e., 1 mm). At the same time, however, freezing temporarily weakens the bone as if 10,000 Rads were applied to it at once — and that is why Marcove

![Figure 4. Meller’s technique of bone cryosurgery.](image)

![Figure 5. Illustrated type of bone reconstruction after cryosurgery using combinations of hardware, bone cement and bone graft in a distal femoral lesion.](image)

<table>
<thead>
<tr>
<th>Type of RF</th>
<th>Hardware:</th>
<th>Bone grafts:</th>
<th>Bone cement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>rods, nails, plates, screws</td>
<td>autogenous, allogenous, bone substitutes</td>
<td></td>
</tr>
<tr>
<td>I No RF</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>II Bone graft only</td>
<td>–</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>III Composite RF</td>
<td></td>
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<tr>
<td>(A)</td>
<td>+</td>
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<td>(B)</td>
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<td>(C)</td>
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<td>+</td>
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<tr>
<td>IV Bone cement only</td>
<td>–</td>
<td>–</td>
<td>+</td>
</tr>
<tr>
<td>V Two-stage RF</td>
<td>(a) Temporary RF using type III B for fractures through bone tumors</td>
<td>as needed, after cryosurgery</td>
<td></td>
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<td></td>
<td>for pathological 3 months–2 years without cryosurgery</td>
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<td></td>
<td>(b) Final R/F, via type II or III</td>
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</table>

Type explanations of RF:
Type I = dispensable and/or non-weight-bearing bones at any age.
Type II = especially in young children + Type I.
Type III = A: children in ideal cases for cryosurgery; B: adults in ideal cases for cryosurgery; C: borderline cases for cryosurgery.
Type IV = as in type I and adults.
Type V = reserved only for pathological fractures at presentation where cryosurgery will obviously cause a nonunion.

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Types of reconstruction/filling (RF) of the bone cavity after cryosurgery</th>
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<tr>
<td>Type of RF</td>
<td>Hardware:</td>
</tr>
<tr>
<td>I No RF</td>
<td>–</td>
</tr>
<tr>
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<tr>
<td>(A)</td>
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<td>(B)</td>
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<td>(C)</td>
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</tr>
</tbody>
</table>

Figure 4. Meller’s technique of bone cryosurgery.

Figure 5. Illustrated type of bone reconstruction after cryosurgery using combinations of hardware, bone cement and bone graft in a distal femoral lesion.
reported 40% fractures and 30% infections after cryosurgery in the early days. The bones remain brittle and fragile for 6–12 months and therefore must be protected until remodeling has been achieved. At the end of each cryo procedure, it is essential that good soft tissue and not merely subcutaneous coverage be placed over the frozen bone.

Intravenous perioperative antibiotics (cephalosporins) are routinely used, usually until the removal of the drains (48–72 h), and continued orally for 2 weeks. Postoperative management is different in each case, depending on the mechanical characteristics of the defect, its location and type of RF. The main considerations to bear in mind are the special nature of wound healing in this setting (it is slower after cryosurgery), and maintaining the bone under protected non-weight-bearing conditions for 6 weeks or more, using casts or braces as needed.

**Results**

The demographic picture of our cohort is reported in Table 4. Six patients had multifocal (synchronous or simultaneous) cryosurgical procedures in up to six different anatomical locations for metastatic lesions of renal cell carcinoma, and one had a rare case of multifocal GCT of bone.

**Local recurrence**

The overall rate of local recurrence (LR) in the 440 cryo procedures was 8%; >90% of them occurred during the first two postoperative years. LRs (25/35) occurred in primary benign-aggressive and low-grade malignant bone tumors; 10 were among high-grade malignant bone sarcomas and metastatic bone disease. Despite the heterogeneity of the cohort, stratifications well represent both the capabilities and limitations of cryosurgery.

**Infections and fractures**

There were nine cases of wound infection, six were deep and three were superficial. There were four cases of fractures and six cases of skin burns, mostly from spillage of the liquid nitrogen. There were no associated vascular complications. There were three cases of transient/partial peroneal palsy in areas other than the sacrum. During the follow-up period, there were four cases of late osteoarthritis of an adjacent joint which became symptomatic and required surgery.

Fractures in the frozen and internally fixed bones, which occur during the first 12 postoperative months, were first managed conservatively. Out of the four fractures in our entire series, three were united and one needed bone grafting.

**Functional results**

The functional outcome of the reported patients according to the AMSTS system depicts mostly 372 patients with no evidence of disease who kept their natural bone and joint, and scored “good” to “excellent”. The scores of 45 patients retreated for LR and/or complications depended on the type of salvage procedures: 35 had LR, six had deep wound infections and four had late osteoarthritis. The salvage operations included re-cryosurgery, resection and endoprosthesis reconstruction, resection and arthrodesis and two cases of amputation.

**Discussion**

This retrospective analysis of a highly heterogeneous and diverse series of patients permits generalized conclusions and recommendations. There is, however, an element of homogeneity in this work stemming from the fact that it summarizes 15 consecutive years of clinical experience of a single surgical team in one institution, where a strict protocol was followed in every decision-making process and in every operative procedure.

**Criteria for bone cryosurgery**

Based on our experience, the ideal case for cryosurgery would be a young adult, involvement of a long bone, a benign-aggressive or low-grade malignant bone tumor, a good cavity with >75% of it having sufficiently thick surrounding walls, none or minimal soft tissue component, and at least ±1 cm of subchondral bone left near a joint surface after curettage and burr drilling.

A borderline case for cryosurgery would be a pediatric patient (epiphyseal plate) or an old person (osteopenia, tumors; 10 were among high-grade malignant bone sarcomas and metastatic bone disease. Despite the heterogeneity of the cohort, stratifications well represent both the capabilities and limitations of cryosurgery.
adjacent osteoarthritis), involvement of flat bones or vertebral, a high-grade malignant and metastatic bone disease, a pseudo-cavity (shallow) with thinned, membranous, balloononed cortices of >50% of the surface area of the bony walls, a large soft-tissue component, and almost no residual subchondral bone, so that the joint cartilage “looks back at you”.

A case for which cryosurgery is contraindicated is one in which any of the above characteristics of the borderline case is more severe.

Algorithm for bone cryosurgery

The deciding difference between the ideal case and the borderline case is whether more complex techniques of RF are needed in order to reduce the anticipated higher rate of LR. This means bigger operations, more complications and longer rehabilitation time. Here, factors such as age and type/grade of tumor play a key role. For example, a huge GCT of the distal femur in a 30-year-old male in whom \( \sim 40\% \) of the subchondral bone is destroyed (the joint cartilage of a condyle “looks at you”) requires the usual RF (hardware and bone cement) plus the building of a new subchondral plate with autogenous corticocancellous bone graft taken from the iliac crest. The same pathology in a child will need a huge amount of bone graft, almost no hardware and no bone cement, while the same lesion in a 70-year-old patient can be dealt with by subchondral bone cement filling only.

Given the above definitions, and taking into account the patient’s age, type/grade of tumor and anatomical location, we constructed an algorithm for treating virgin cases, LRs and complications, bearing in mind that bone cryosurgery is a limb-, bone-, joint- and epiphysis-sparing procedure. This includes four steps in the following order if the preceding one fails: (1) up to two cryosurgery procedures, (2) resection with endoprosthetic reconstruction, (3) resection and gap arthrodesis and (4) amputation.

Conclusions

Bone cryosurgery is a safe and reliable technique for conservative limb-, bone-, joint- and even epiphysis-sparing surgery in suitable types of bone tumors of patients of different ages. It can often obviate the need for resection surgery, temporarily or permanently. Cryosurgery’s 3% rate of LR in GCTs is better than 10–60% previously cited.\(^{10}\) The open direct-pour liquid nitrogen approach drawbacks were difficult in performance, hazardous to adjacent soft tissues, cumbersome to execute and inability to accurately control freezing parameters (temperature, rate, time and location of the freeze—thaw cycles). It was also gravity-dependent, thus not applicable in various locations and tumor shapes. Since there was no clinical difference in our patients’ outcome between the two periods and the Marcove’s versus Meller’s cryo methods, Meller’s approach proves oncological efficacy without Marcove’s disadvantages. Accuracy of temperature, freezing time and cycle, rate, and freezing of any geometrical cavity is currently obtained.

Summary

Every effort should be made to develop techniques of conservational surgery of bones, joints and epiphyses: hyperthermia, irradiation or photodynamic therapy.\(^{11,12}\) Our experience testifies to the emergence of cryosurgery as the optimal mode of treatment for tumors in almost every bone of the skeleton.

Conflict of interest

The authors have no financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Specifically, there are no potential conflicts of interest with regard to employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding related to the submitted manuscript.

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