Effects of high intensity focused ultrasound on the intervertebral disc

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● *Original Contribution*

MODELING OF THE HEAT DISTRIBUTION IN THE INTERVERTEBRAL DISK

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Abstract—The heat transfer equation was used to model the heat distribution in an intervertebral disk during ultrasound (US) exposure. The influence of thermal and acoustic parameters was studied to get a quantitative understanding of the heat transfer in the system. Heating of collagen to 65°C or above will lead to denaturation and is believed to stabilize and contract the outer part of the disk in a herniated disk. In our model, the US intensity was approximated by a Gaussian distribution and nonlinear propagation was excluded. The effect of self-heating and cooling of the transducer was also studied. The simulations were performed using the finite element method. From this model, it can be concluded that it is possible to heat parts of the disk to treatment temperature using a focused 5-mm diameter US probe. The physical constraints on the piezocrystal set the limit of the size of the treatment volume. (E-mail: johan.persson@ort.lu.se) © 2005 World Federation for Ultrasound in Medicine & Biology.

Key Words: **Focused ultrasound, Disk herniation, Finite element analysis, Thermal therapy, Linear propagation.**

INTRODUCTION

The incidence of low back pain has reached epidemic proportions in the Western societies, with employers experiencing more lost revenue from low back pain than from industrial action (Maetzel and Li 2002). It has been estimated that the total direct and indirect costs of low back pain in Sweden (nine million inhabitants) exceed $2 billion per year (Ekman et al. 2004). Low back pain is a symptom of different disorders. These can include disk degeneration and disk herniation, in which the outer wall of the disk often has a radial fissure and bulges onto neural tissue. Most patients recover from episodes of back pain after short periods of nonoperative treatment but, for some, the pain becomes severe and chronic. For such patients, surgery is often indicated.

The history of surgery of disk herniation goes back to the 1930s, when parts of the intervertebral disk were removed during open surgery (Mixter and Barr 1934). More recently, microsurgical and percutaneous techniques for mechanical (Maroon and Onik 1987; Postacchini 1999; Sharps and Isaacs 2002) or thermal (Choy et al. 1992; Quigley and Maroon 1994) removal of disk material have been developed, giving pain relief in some patients. In recent years, a minimally invasive thermal method for treatment of low back pain has been developed for both discogenic degeneration and disk herniation. In this method, called intradiskal electrothermal (or anuloplasty) therapy (IDET), the disk is heated with a navigable catheter containing a heating section that is inserted into the disk. The catheter is positioned adjacent to the posterior wall of the *anulus fibrosis* (the fibrous outer part of the disk surrounding the more gelatinous part, the *nucleus pulposus*) and heated to 95°C. In studies of ligaments, it has been shown that longitudinal shrinkage of collagen starts at a temperature of 65°C, and maximum shrinkage occurs at 75°C (Hayashi and Markel 2001). If this temperature range can be reached in the disk, there will be collagen shrinkage. Cell death also occurs if tissues are heated, but in a more complex way. The concept of thermal dose is often used to relate temperature and necrosis, in which the thermal effect is related to the equivalent effect as if the temperature had remained at a constant 43°C. Typically, the time required to achieve cell death halves for each 1°C temperature rise above 43°C.

An alternative method for heating tissue is focused ultrasound (US). As a step toward less invasive treatments of the intervertebral disk, the use of high-intensity

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focused US (HIFU) in the treatment of nonperforated disk herniation has been investigated (Persson et al. 2002). In theory, this can be completely noninvasive, but navigation of an US beam into the intervertebral disk between two vertebral bodies is complicated. Therefore, a minimally-invasive extradiskal approach has been studied, in which an ultrasonic transducer is placed on the external surface of the disk. The temperature distribution in an intervertebral disk during US exposure has been theoretically modeled. The aim of this work has been to optimize the design of a device for minimally-invasive thermal treatment and to study the effects of variation of physical parameters on performance of such a device.

METHODS

This work modeled the temperature distribution during US exposure in the intervertebral disk. The simulations were performed using the finite element program FEMLAB (FEMLAB version 3, Comsol, Sweden). The size of the US transducer is constrained to 5 mm in diameter by the height of the disk (Zhou et al. 2000) and practical surgical limitations. Other physical parameters of the US transducer, such as frequency and the focal length, should be optimized to treat as large as possible a volume as deep as possible. Others have measured the thermal conductivity and the specific heat capacity for the human intervertebral disk, but there is a large variation between different samples. It is, therefore, important to study what effect these parameters have on the treated volume. Ultrasound attenuation and absorption coefficients have not been measured in the disk, but there are published figures for the tendon (Goss et al. 1980) that we have used in our simulations. A focused US intensity distribution (I) was approximated by a circularly symmetrical Gaussian beam (Filipczynski et al. 1993; Hill et al. 1994). Linear wave propagation is assumed and plane-wave attenuation in the tissue was included in the model. This approximation produces a symmetrical field without any side-lobe effects according to:

$$I(z,r) = I_0 g(z) e^{\left[-2\left(\frac{r}{R_0}\right)^2 \cdot g(z) - 2A\cdot z\right]} \quad , \tag{1}$$

with

$$g(z) = \left[\frac{4z^2}{k^2 R_0^{\,4}} + \left(1 - \frac{z}{F}\right)^2\right]^{-1} , \tag{2}$$

where I_0 is the intensity at the US transducer center, z and r are the cylindrical coordinates. A denotes the pressure attenuation coefficient and F the focal distance. R_0 is given by the relationship:

$$R_0 = 0.75 \cdot a_t, \tag{3}$$

where a_t is the transducer radius. The wave number, k, is defined as:

$$k = \frac{2\pi \mathrm{f}}{c} , \tag{4}$$

where f is the frequency and c is the sound velocity. The intensity at the transducer center, I_0 is calculated from the Filipczynski et al. (1993) relationship between the radiated power, P, and I_0:

$$P = \frac{\pi I_0 R_0^{\,2}}{2} . \tag{5}$$

The heat transfer eqn (6) was used to model the temperature distribution in the disk. The influence of the thermal and acoustical constants on the temperature distribution in the disk was studied. Effects of nonlinear propagation were not taken into account in the model.

$$\frac{\partial T}{\partial t} = \frac{\lambda}{pC_s}\left(\frac{\partial^2}{\partial x^2} + \frac{\partial^2}{\partial y^2} + \frac{\partial^2}{\partial z^2}\right)T + \frac{Q}{pC_s} \tag{6}$$

Equation (6) describes the heat transfer in the system, where the temperature ($T(x,y.z,t)$) is a function of the position and time, $\partial T/\partial t$ is the rate of temperature change, λ the thermal conductivity, ρ and C_s are the density and heat capacity, respectively. Q is the heat source given by:

$$Q = 2\alpha I(x,y,z) \tag{7}$$

where α is the US pressure absorption coefficient. The attenuation coefficient (A) consists of two terms, absorption and scattering. In this model, it is assumed that the attenuation and the absorption coefficients are equal ($A = \alpha$). The model was simulated for a 3-D geometry with similar size and shape as a human lumbar intervertebral disk (Zhou et al. 2000) (see Fig. 1). The disk dimensions were set to 50 mm in the midsagittal plane, 60 mm in the frontal plane, and a height of 10 mm. The mesh used in the simulations was generated by FEMLAB. A finer mesh (maximum element size 1 mm) was used in the volume where the US field affects the disk, defined as a cylinder. Elsewhere, the mesh maximum mesh size was 15 mm, see Fig. 1.

An adaptive approach was used in the simulations, where the intensity was chosen so that the peak temperature after 120 s of US exposure was 95°C. This makes it possible to study the effectiveness of US in heating the disk. This temperature limit was chosen to avoid bubble formation (cavitation) in the tissue, which is hard to control and might cause tissue ablation. Because it has been shown that collagen shrinkage starts at 65°C (Hayashi and Markel 2001), the treated volume was defined

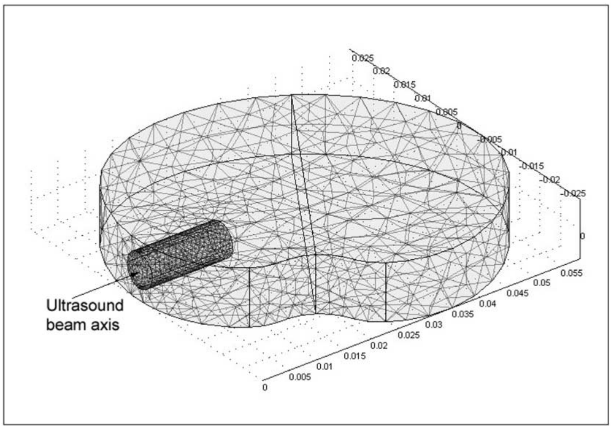

Fig. 1. The geometry and mesh used in the finite element simulations. The disk height used was 10 mm. The mesh is finer in the region of the US intensity field. The scale on the axis is in meters.

as the volume heated to 65°C or more. The temperature on the boundaries was kept at 37°C and the initial temperature, T_0, in the disk was chosen to be 37°C. Table 1 shows the geometrical constants of the US transducer and the properties of the disk used in the model when nothing else is mentioned. The transducer radius was set to 2.5 mm because of practical surgical limitations; the geometrical focal length was set to 15 mm, which is the distance to the nucleus. The density of the intervertebral disk was approximated to be similar to what is reported for human cartilage, 1100 kg/m^3 (Duck 1990). The value used for the sound velocity was 1540 m/s, which is a mean value for human tissue (Wells 1969). The value used in the model for the thermal conductivity, 1.2 W/(m K), was based on the measurements performed by Houpt et al. (1996) and the specific heat capacity was chosen to be 3200 J/(kg K) (Houpt et al. 1996).

Neither the US absorption nor the attenuation coefficients in disk tissue are known and, therefore, figures for the tendon have been used instead. These figures tend to have a large variation and we have chosen to use the value reported by Goss et al. (1980) for US absorption in bovine tendon as the standard value, 1.5 dB/(cm MHz). When the effect of the attenuation coefficient was studied, values up to 5 dB/(cm MHz) were included because Duck (1990) reports values for US attenuation in human tendon to be 4.7 dB/(cm MHz).

In Fig. 2, the size and shape of the applied acoustic field, with 4-MHz frequency, 3.05-W acoustic power and disk and transducer properties as shown in Table 1, are shown. Maximum intensity occurs 4.5 mm in front of the transducer (in the near-field region), although the geometric focus is at 15 mm. The half-maximum intensity width and length are 1.2 and 14 mm, respectively.

Self-heating of the transducer due to electrical inefficiency and conduction of the heat from the transducer to the tissue was also studied. This was done by setting a constant temperature on the boundary where the transducer is applied. To avoid harmful temperatures, both for the tissue and the piezocrystal, cooling water could be used in front of the transducer. Simulations were done with temperatures from 10 to 70°C on the transducer boundaries.

Table 1. Geometrical, thermal and acoustical properties used in the model

Constant	Value
Transducer radius (m)	2.5e–3
Geometrical focal length (m)	15e–3
Tissue density (kg/m^3)	1100
Sound velocity in tissue (m/s)	1540
Thermal conductivity (W/(m K))	1.2
Specific heat capacity (J/(kg K))	3200
Pressure attenuation (Np/(m Hz))	17e–6

RESULTS

In Fig. 3, the simulated temperature distribution in the disk after 120 s of US exposure with an acoustic field, as displayed and described in Fig. 2, is shown. The maximum temperature (95°C) is achieved 3.7 mm from the US probe. The length of the treatment volume (volume of tissue heated to above 65°C) is 12 mm

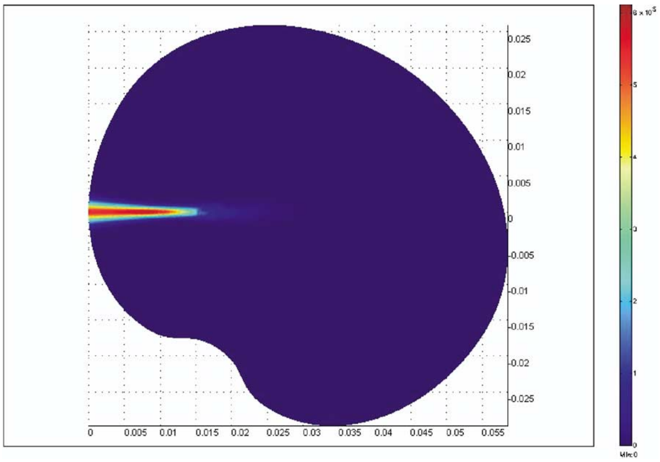

Fig. 2. A cross-section through the symmetry axis of the US beam that shows the applied intensity distribution in a disk with the properties shown in Table 1. The frequency used was 4 MHz and the acoustic power was 3.1 W. The unit of the color scale is in W/m^2. The maximum intensity occurs at a depth of 8.7 mm and the half-maximum intensity width is 1.2 mm.

and the width 4 mm; the total volume is 80 mm^3. From Fig. 4, it can be seen that the treatment temperature is reached in the temperature focus after less than 10 s of US exposure for frequencies in the range of 1 to 5 MHz. The heating is faster at higher frequencies. In Fig. 5, the influence of the frequency on the size of the treated volume can be observed when the US intensity is limited so that the peak temperature after 120 s is

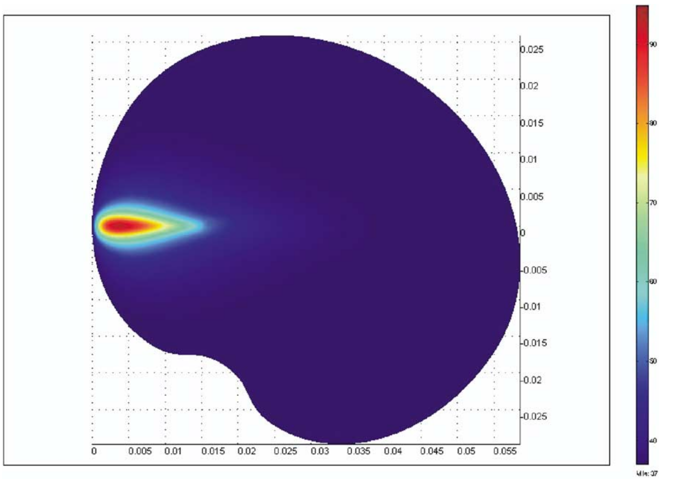

Fig. 3. The temperature distribution produced by the acoustic field shown in Fig. 2 after 120 s of US exposure. The units are in meters and in the scale at the right in°C. The length of the treatment volume is 12 mm and the width 4 mm for this simulation.

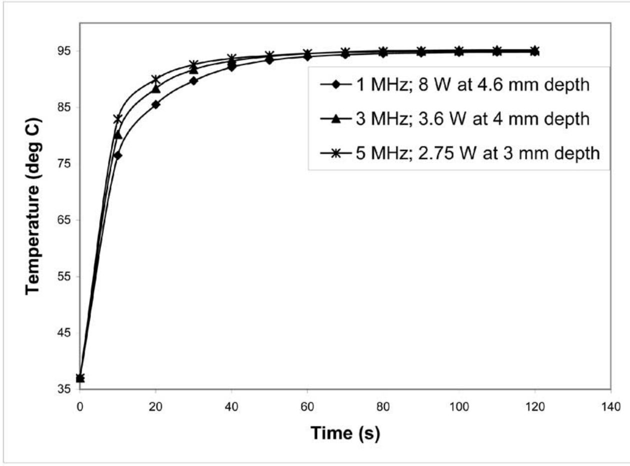

Fig. 4. Temperature as a function of time is shown in the point of maximum temperature for frequencies in the range of 1 to 5 MHz. The intensity was limited so that the peak temperature did not exceed 95°C.

95°C. The simulations show clearly that the size of the treated volume decreases with increasing frequency. Note that the output power needs considerably to be increased to reach a peak temperature of 95°C in the tissue when lower frequencies are used. The rate at which the treated volume increases is not dependent on the frequency during the first 10 s (Fig. 6). At later times, the volume increase reaches a plateau earlier for higher frequencies, resulting in a three times larger volume for 1 MHz than for 5 MHz.

The thermal conductivity (λ) does not affect the size of the treated volume as much as does the frequency. When the conductivity is varied by $\pm$ 50% from 1.2 N/(s K), the size of the treated volume is changed by less than 2%, and the output powers needed to raise the temperature to 95°C have to be increased or decreased by 50%,

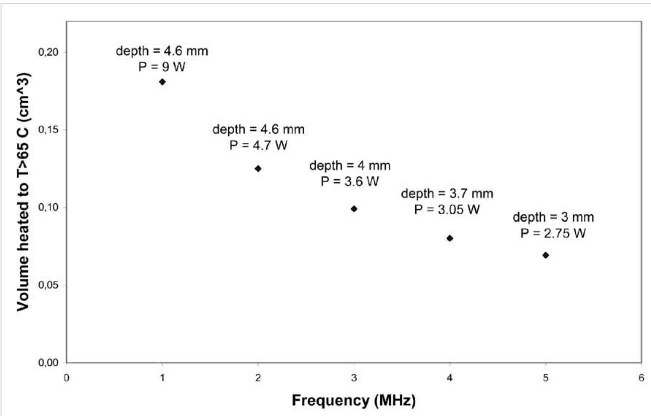

Fig. 5. The volume heated above 65°C vs. frequency with peak temperatures limited to 95°C after 120 s of US exposure. The depth at which the peak temperatures occur and the acoustic power used are also shown.

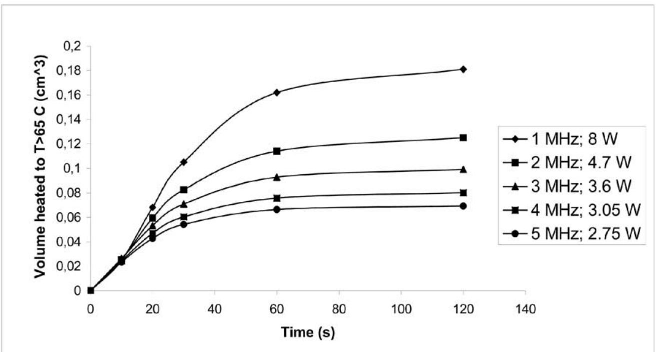

Fig. 6. The size of the treated volume vs. time for different frequencies, when the US intensity was limited to produce a peak temperature of 95°C. Lower frequencies result in larger treatment volumes.

respectively. In a clinical situation, when the exact thermal conductivity is not known and a fixed intensity is used, this might cause a problem. In Fig. 7, the influence of the thermal conductivity on the rate of the treated volume change is shown. For $\lambda = 0.3$ W/(m K), the combination of low output power and low thermal conductivity results in a longer time than 10 s being needed to reach treatment temperature in the disk. It can be observed that the size of the treatment volume increases faster for large values of the heat conductivity.

The second thermal constant, the specific heat capacity (C_s) does not affect the steady-state peak temperature. The effect of the specific heat capacity on the rate of temperature rise is small and 65°C temperature is reached within 10 s of the start of US exposure when the heat capacity is varied $\pm$ 20% from 3200 J/(kg K).

In Fig. 8, the size of the treatment volume after 120 s US exposure is shown as a function of US attenuation. It can be observed that the output power that is needed to increase the temperature to 95°C needs to be increased for lower values of the US absorption. This leads to a larger treated volume for small attenuation coefficients. It can also be concluded that the treatment volume does not increase considerably after 60 s of US treatment.

The focal length was initially set to 15 mm, with the aim of being able to treat the nucleus. However, it can be seen that the peak of the temperature occurs well before the geometric focus. Therefore, the effect

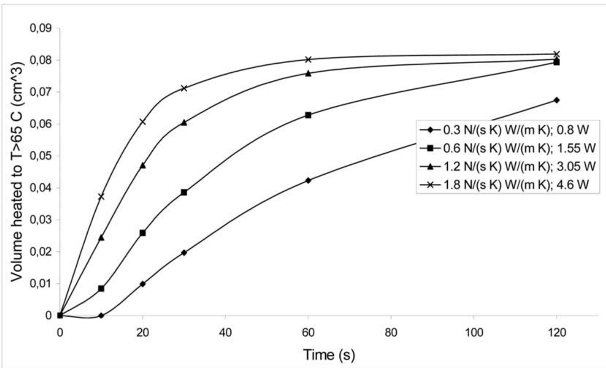

Fig. 7. The influence of the heat conductivity (λ) on the rate of treated volume change. The frequency was 4 MHz and the maximum temperature was limited to 95°C.

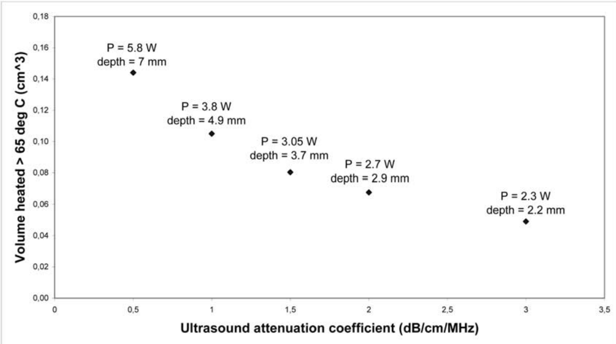

Fig. 8. The size of the treated volume as a function of the attenuation coefficient. The simulations were made for 120 s of 4-MHz US exposure with a peak temperature of 95°C.

of increasing the focal length was studied. In Fig. 9, it can be observed that an increase of the focal length increases the treated volume but decreases the depth for the maximum temperature.

The effect of self-heating on the maximum temperature in the tissue is small. The position of the temperature maximum, on the other hand, is affected more. A simulation with the transducer boundary temperature set to 20°C resulted in a decreased temperature maximum of 3 %, and the depth of the peak temperature increased by 17%. The size of the treatment volume decreased by 20% in this simulation (see Fig. 10).

To evaluate the robustness of the model, simulations with different time steps and mesh sizes were performed. Improving the time discretation or mesh size had a minor effect on the result.

DISCUSSION

In a clinical situation, it may be desirable to maximize the treatment volume and to minimize the treatment time. From this aspect, a low frequency should be used; by decreasing the used frequency from 4 to 1 MHz, the treated volume can be doubled (see Fig. 5). However, the output power from the US transducer needs to be increased threefold to maintain the same peak temperature at 1 MHz, as compared with 4 MHz. Because the size of the US transducer has been set to 5 mm in diameter, this

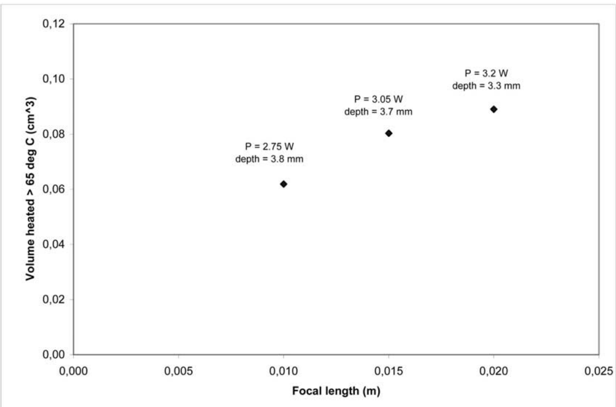

Fig. 9. The size of the treated volume after 120 s of 4-MHz US exposure as a function of the focal length, when the maximum temperature was limited to 95°C.

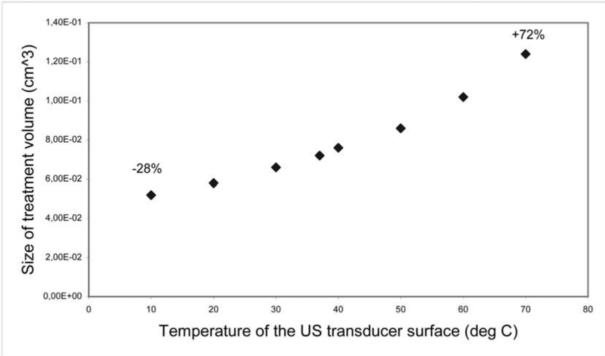

Fig. 10. The size of the treatment volume after 60 s of US exposure vs. temperature on the surface of the US transducer.

constrains on the output power from the transducer. At 2.75 W total output from the transducer, the equivalent power density is 14 W/cm^2. For many piezo materials used in ultrasonic transducers, an operating power density of 10 W/cm^2 is recommended and a maximum power density of 30 W/cm^2 is suggested by manufacturers. Therefore, operating characteristics of a practical device may need to be a compromise between frequency and power output. The maximum heated volume was achieved at 1 MHz but, because this required 9 W output, it would require a power density that may be difficult to realize practically.

Traditionally, the target tissue in treatment is the disk herniation, and the herniation is reduced by reducing the volume of material that is bulging inward onto the anulus. The volume of removed disk material during automated percutaneous diskectomy is on the order of 1 cm^3 (Gill and Blumenthal 1991). The simulations indicate that peak temperatures occur 3 to 5 mm into the disk, well within the anulus, and that, within the range of treatment area, it will reach farther into the nucleus. The treatment will not ablate tissue, as in laser diskectomy. However, other mechanisms may contribute to therapeutic effectiveness. Although the mechanisms of nonablative thermal treatment of chronic low back pain are not yet established, they are believed to be either denervation of the nerve endings that detect painful stimuli (nociceptors) in the anulus, collagen shrinkage of the disk or sealing of the fissures in the anulus. Local shrinkage of collagen in the region of a herniation could lead to reshaping of the external contours of the disk, relieving pressure on nerve roots. Sealing of annular fissures could also contribute to reduction of pressure on the nerve roots.

In chronic back pain that does not involve herniation, it is far more likely that pain relief is a result of denervation of nociceptors. In this case, effectiveness will depend on the thermal dose delivered to the tissues, rather than on reaching a threshold value for collagen shrinkage. The precise position of the nociceptors will need to be identified.

In these simulations, the peak temperature has been kept to 95°C as a standard reference, to compare the effect of parameter change on effectiveness of US in heating a disk. By adjusting power output to achieve this temperature, the effects of changing relevant parameters on the rate of heating and heated volume can be explored. Using a fixed output would have been somewhat arbitrary in simulations involving parameter sensitivity. However, in a practical situation, unless it is possible to monitor temperature *in vivo*, there may be a situation in which a device has a fixed output and it is necessary to know how variations in tissue characteristics may influence device efficacy or safety. In general, thermal data for the intervertebral disk are based on a small sample population and show wide variation. Houpt et al. (1996) have measured the thermal diffusivity in human intervertebral disks from three individuals who were 61, 32 and 27 y old to be $1.7 \cdot 10^{-7}$, $4.5 \cdot 10^{-7}$ and $3.0 \cdot 10^{-7}$ m^2/s with SDs up to $1.4 \cdot 10^{-7}$. Using the Houpt et al. estimation of the heat capacity in disk tissue of $3.5 \cdot 10^6$ J/(m^3 C), the value of heat conductivity will be 0.60 to 1.6 J/(s m K). Biologic variations, different water content and errors in the measurement model could explain the large deviation. The value of the heat conduction will affect the rate of temperature increase during the initial 60 s; the temperature will increase slower in a disk with a high heat conductivity. This is also valid for the size of the treatment volume (see Fig. 7). For exposure times longer than 60 s, there will be no large difference, whether the thermal conductivity is 0.60 or 1.6 J/(s m K). There do not appear to be published estimates of US attenuation or absorption coefficients for the intervertebral disk and we have used published figures for tendon in these simulations.

The small size of the US transducer, in combination with the continuous mode at which it will be run, will lead to considerable self-heating of the piezocrystal. To prevent the temperature maximum occurring on the surface of the disk due to heat conduction from the piezocrystal, a cooling system with flowing water in front of the transducer can be used. For this reason, simulations with different transducer surface temperatures were performed. The temperature at this boundary affected the depth of the peak temperature, but had only minor effect on the size of the heated volume.

The intervertebral disk itself is avascular, whereas the surrounding muscle tissue and vertebral bodies are well-perfused. In these simulations, we have used a boundary condition of a constant temperature of 37°C, both at the external surface of the anulus and at the endplates of the vertebral body. The simulations show that the heat flux across the boundary through a 1-mm diameter circle on the disk surface adjacent to the point of peak temperature into the vertebral body is just $2.5 \cdot 10^{-4}$ J/s after peak temperature is achieved. This justifies the boundary condition of a constant temperature of 37°C.

CONCLUSION

The heat equation was used to model the 3-D temperature distribution in a geometry typical for a human intervertebral disk. A Gaussian focused US field was used as the heat source and nonlinear effects were excluded.

When parameters were studied, the US intensity was limited so that the maximum temperatures did not exceed 95°C. Two device-specific parameters were studied, the frequency and the US transducer surface temperature. When a low frequency is used, a higher intensity can be used before the maximum temperature reaches 95°C. This leads to larger treated volumes deeper into the tissue. The temperature of the transducer surface can be controlled by the use of cooling water. This temperature affects both the treated volume and depth. The results showed that a high attenuation coefficient causes a smaller treated volume, because of the limitations on the temperature and also a more shallow treatment volume.

From our modeling, it can be concluded that it is possible to heat the disk to the target temperature (65°C) through an extradiskal minimally-invasive procedure. However, the depth of the treatment volume is shallow and it is not possible to increase this just by increasing the focal length.

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