Maturation of the distracted callus

Sonographic observations in rabbits applied to patients

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We measured the corticalization of lengthened callus in rabbits and humans with ultrasonography. In rabbits, the echo reflection value was correlated with the strength of the callus; when this value exceeded 70 percent of that of the normal cortex, the callus strength was equal to that of the normal tibia. Clinically, the lengtheners in 8 patients were removed when the echo value exceeded 70 percent, regardless of attained lengthening. Neither fracture nor collapse of the callus ensued. The time required from the end of the lengthening process until the echo reflection value reached 70 percent was correlated with the patients' age.

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In callus distraction (DeBastiani et al. 1987), poor callus strength with bending, collapse, or even fracture is a major problem after removal of the lengthener. A quantitative method of evaluation of the new cortex has long been needed in order to determine the safe timing for removal of the lengthener. Ultrasonography was recently introduced to evaluate the lengthened callus (Young et al. 1990, Maffulli et al. 1992). We used ultrasonography in rabbits to quantitatively evaluate the newly-formed cortex of lengthened callus and its correlation with the mechanical strength. Subsequently, the method provided a guide for safe removal of the lengthener in 8 patients.

Experiments in rabbits

One tibia in each of 12 adult male white rabbits was osteotomized at the tibio-fibular junction following fixation with an Orthofix M-100 mini-lengthener. After a waiting period of 1 week, lengthening was carried out at 1 mm per day (270° turn ×2) for 10 days. The rabbits were killed by intravenous injection of Nembutal® 10–70 days after the end of the lengthening period. The lengthened tibiae and contralateral normal tibiae were removed, cleaned of bulky muscles, submerged in a water bath, and subjected to ultrasonographic examination with an Aloca SSD650CL ultrasonograph. A 10-MHz mechanical sector probe was used without any special transducer or equipment. Both sagittal (Figure 1) and axial images of lengthened callus were obtained. The HIST-TRACE mode (Figure 2) was introduced; in this mode, the following 3 numerical values were calculated and displayed with the histogram for each area of interest:

T: The total number of unit areas included in the area of interest;

L: The commonest echo intensity in the area. On the histogram, the L value is that with the peak distribution on the X-axis on a scale of 1–64;

M: The number of unit areas contributing to the peak distribution on the histogram, which is displayed on the Y-axis of the histogram as 1.0.

The echo volume reflected at the cortical surface was defined as the difference between the L value of the superficial areas and that of the deep areas, and the percent echo reflection (ER), the relative reflection from the cortical surface, was calculated by the formula $(L_{superficial} - L_{deep}) / L_{superficial} \times 100$. The ER was obtained for 10 pairs of areas of interest obtained from 5 sagittal and 2 axial ultrasonograms, and their mean value was calculated. The theoretical value of ER of a normal bone is 98 percent ($L_{superficial}$ 64, L_{deep} 1), although the normal values obtained are usually below 95 percent due to dispersion of the echo into the deep area.

Callus strength

Following ultrasonographic evaluation, the tibia was placed horizontally with the entire lengthened callus supported by a steel plate (13 mm in length and 9 mm in width) which was molded to conform to the

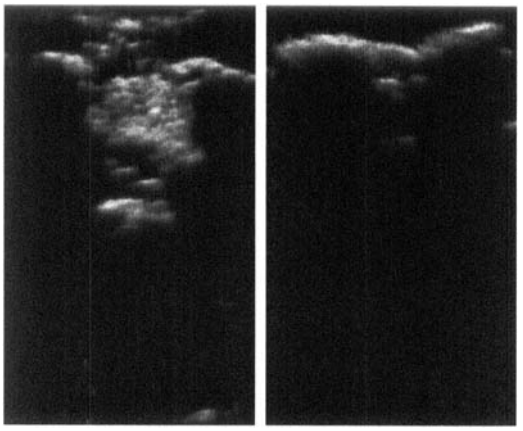


Figure 1. Ultrasonography of the lengthened callus of 2 rabbits at Day 0 (left) and Day 30 (right) after the 10-day lengthening process.

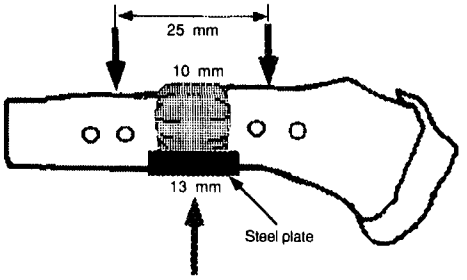


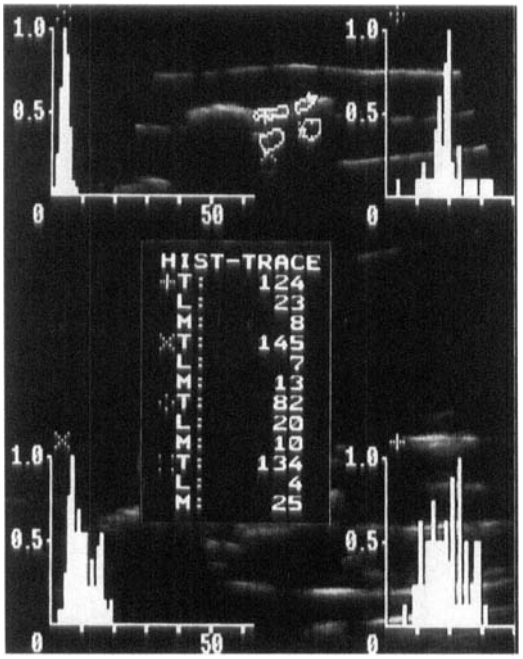
Figure 3. The bending test. A 13 mm steel plate is attached to support the whole 10 mm callus. The bending force is applied at the arrows with a distraction speed of 1 mm/min.

curvature of the callus. The 3-point bending strength test shown in Figure 3 was then applied via the steel plate and at two normal counter-portions with a distraction speed of 1 mm/min; the yield strength was recorded with a Simadzu AGS-500B autograph.

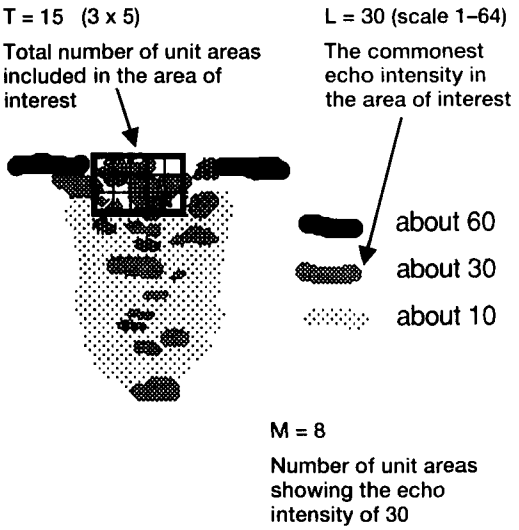
Observations in patients

5 femora and 4 tibiae in 8 patients aged 9–51 years were lengthened using the Orthofix instrument. For each patient, the etiology of shortening, lengthening (cm), healing index, and time required to attain 70

Figure 2. 4 histograms of the 2 surface and 2 deep areas calculated from the Day 30 ultrasonogram.



The L values are 23, 7, 20 and 4 , and ERs are (23–7)/23 =70% and (20–4)/20 = 80% for each pair.



The area of interest and 3 numerical values.

Table 1. 8 patients monitored by ultrasonography

Case	Age	Sex	Bone lengthened	Etiology of shortening	Length-ening (cm)	Healing index (mo/cm)	Time to reach 70% ER (wk)
1	9	M	Femur	Trauma	4	0.75	7
2	13	M	Tibia	Club foot	4	0.75	9
3	16	F	Tibia	Ollier disease	5	1.4	23
4	18	F	Tibia ×2	Achondroplasia	13	1	16
5	27	F	Femur	Trauma	3.5	1.1	12
6	32	M	Femur	Trauma	4	1.4	14
7	42	F	Femur	Trauma	4	1.7	18
8	51	F	Femur	CDH	2	4	24

percent ER after the end of the lengthening are shown in Table 1. The waiting period before the start of the lengthening varied with the patient's age from 1 week in the youngest patient to 3 weeks in the oldest.

Ultrasonography

Ultrasonographic examination was carried out weekly after the end of the lengthening process. Using a 5-MHz linear probe, 6 sagittal and 2 axial ultrasonograms of the most immature portion of the lengthened callus, where the cortex was still discontinuous, were obtained. Using histograms, 10 pairs of L values were obtained from the 8 ultrasonograms, and ER was calculated using the same formula as was used in the rabbits.

Results

The rabbits

In the more primitive callus, the echogenicity in the deep callus was higher than that at the surface, and ER initially had a negative value ($L_{superficial} - L_{deep} < 0$), and ER increased at a constant rate as corticalization took place.

There was a high correlation between ER and bending strength (r 0.92; $P < 0.001$) (Figure 4). The mean bending strength (SD) of the normal tibia was 52 (7) kg.f., and when ER exceeded 70%, the callus strength was equal to that of the normal tibia.

The patients

The change in ER after conclusion of the lengthening process in each case is plotted in Figure 5. ER ini-

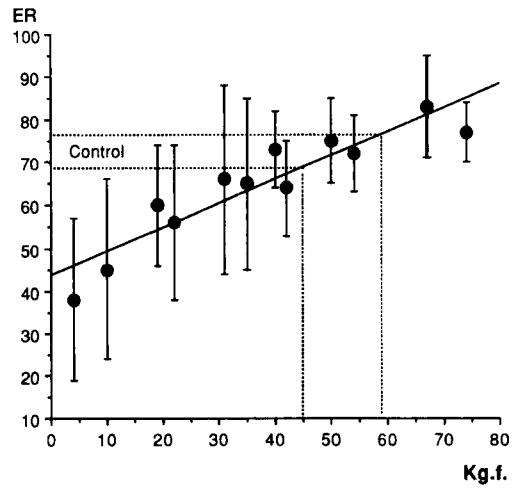


Figure 4. The distribution of ER at 10 points and bending strength of the 12 lengthened calluses. r 0.92, $P < 0.001$.

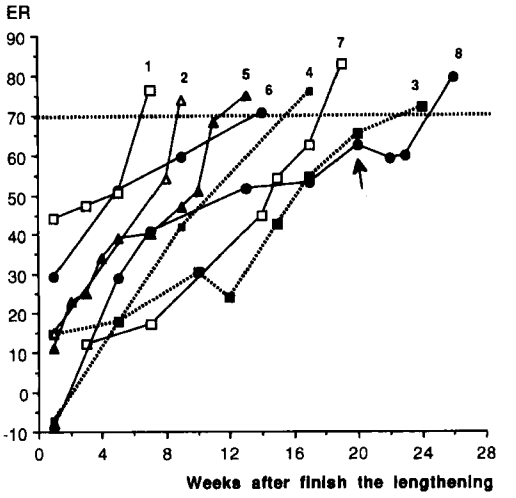


Figure 5. Change in ER after lengthening in the 8 patients. * Arrow; the lengthener was temporarily removed, and partial collapse of the callus ensued.

tially had a negative value in patients 4 and 5. The lengtheners were removed in all patients except one (patient 8) after it was confirmed that ER exceeded 70 percent. In Patient 8, the body of the lengthener was removed with the 4 screws left in the femur when the ER was 63 percent; the body was reattached when partial collapse of the callus became manifest 4 days after removal. In this patient, the lengthener was safely removed about 5 weeks later when ER was 80 percent. No fracture, bending, or collapse of the callus ensued in any other patient. The relationship between age and time for ER to reach 70 percent after the lengthening process was terminated is shown in Figure 6. After the data for patients 3 and 4, whose bones were considered to be pathological, were excluded, the correlation coefficient for the data in the remaining 6 patients was 0.99 ($P < 0.001$).

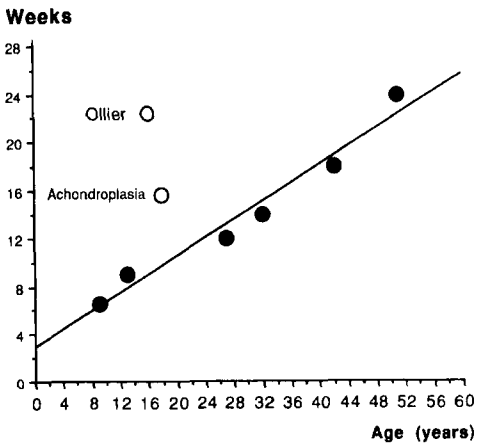


Figure 6. The age of patients and the number of weeks between the end of the lengthening process and the time when ER exceeded 70%. r 0.99.

Discussion

Ultrasonography can be used not only to detect early foci of ossification and to measure precisely the lengthening (Young et al. 1990, Maffulli et al. 1992), but also to obtain the numerical values for the commonest echo intensities at the superficial and deep areas. The echogenicity in the area beneath the surface decreases rapidly as the corticalization of the surface proceeds. ER, the value indicating the relative echo intensities of the corticalizing surface and the underlying callus, expresses the hardness of the surface more sensitively and reproducibly than does a value obtained using solely the echogenicity of the surface itself, which varies greatly depending on the gain level and probe direction. The mean ER for each tibia was experimentally confirmed to be highly correlated with the overall strength of the entire callus. In the present experiments, the bending strength was measured using a steel plate to support the entire callus throughout its entire length in order to disperse the bending force to the unlengthened normal cortex and to prevent focal invasion of the device into the soft callus tissue.

In the patients, 70 percent ER at the most central and immature portion of lengthened callus was also confirmed to indicate that the lengthener could safely be removed, regardless of the lengthening volume, which ranged from 2–13 cm. The time required after the end of lengthening until ER, 70 percent, was highly correlated with the age of the patient, in the absence of pathological bone (Figure 6).

References

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