Evaluation of a Medical Device for Assessment of Cartilage Degeneration After Impact Injury

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Introduction: Decision making in the operating room during arthroscopic procedures is complicated by lack of objective criteria for assessing cartilage quality and degeneration. The Arthro-BST is a medical device that measures streaming potential signals generated during indentation of the articular cartilage and calculates a quantitative parameter (QP) reflecting its electromechanical properties.[1-4] In this study a model of impact injury was used to create focal lesions in the medial femoral condyle that progressed to the surrounding cartilage surface to a variable degree. We examined the ability of the Arthro-BST to detect cartilage degeneration and loss across a broad range of lesion severity. The goal of this study was to determine whether there was agreement between Arthro-BST data and histological scores of osteoarthritic degeneration.

Materials and Methods: Focal impact injuries were made in both medial femoral condyles of ten adult sheep (age 2-6 years) using a hand-held impactor inserted through a 1 cm arthrotomy. Using a 4.5 mm diameter polished aluminum impactor tip, an injury of 35-40 MPa was created in the central weight-bearing portion of the medial condyle. Twelve weeks later the sheep were sacrificed for detailed assessments that included measurement with the Arthro-BST (Bio Syntech Canada Inc.) at three sites: the original impact injury site, an adjacent site 5 mm proximal, and the lateral condyle. Arthro-BST measurements were done with the distal femur immersed in lactated Ringer's solution. The device calculated QP values (in mV/mm3) by integration of the streaming potential distribution induced over its spherical indenter (radius of 3.175 mm) in the predefined range of compression amplitude from 100 to 300 µm. Each measurement was repeated twice and the average reported. Histological sections of the condyles were made after fixation in neutral buffered formalin, decalcification in formic acid, and staining with safranin-O. The OARSI osteoarthritis scoring system was applied to the index injury and the surrounding articular surface as well as the lateral femoral condyle.

Results: The injury created was a highly degenerate focal lesion in the medial femoral condyle that progressed centrifugally to involve a variable amount of surrounding articular surface at the three-month time point. The variability in progression was related to treatments and other factors not reported in this abstract. The lateral femoral condyle remained unaffected. Macroscopic and histological evaluations show that the degree of degeneration ranged from mild surface disruption with loss of safranin-O staining and superficial zone chondrocyte loss to severe full thickness fissures and full thickness cartilage loss. QP values measured at the lateral femoral condyle (OARSI score=1.0) are indicative of normal cartilage though some instances of mild, age-related degeneration were found. A paired student's T-test shows that QP values at the impact site were significantly lower than values at the adjacent ($p = 0.001$) or at the control site ($p = 5x10\text{-}6$). QP values in the surrounding of the impact sites are also statistically lower than the lateral condyle values ($p = 0.004$). A significant correlation ($p < 0.05$, $R = -0.56$) was observed between QP values at the impact site and the grade of the OARSI score.

Discussion: Arthro-BST measurements reflected the severity of osteoarthritis progression after impact injuries in two ways: 1) The depth of the lesion (OARSI grade) was proportional to depression of the QP values and 2) The centrifugal progression of less severe degeneration into the surrounding cartilage was reflected by moderately depressed QP values. Measured QP values at the impact sites were on average 16% of normal [5] for this site and species (12.5±7.7). Even in this low range, QP values were inversely proportional to the grade of the OARSI score. This suggests that the Arthro-BST could be used for quantitative evaluation of cartilage at an advanced stage of degradation. This large spread of QP values from highly degenerate to normal cartilage illustrates the wide dynamic range of the device, leaving considerable scope for detection of very early cartilage degeneration. While QP values for the adjacent site were on average 3 times higher than at the impact sites, they were still only half of the normal expected values. In future studies QP values in and around the impact site will be mapped in more detail to ascertain the spatial distribution and extent of degradation. In summary, the Arthro-BST was shown to be a useful device for the quantitative evaluation of articular cartilage from normal to highly degenerated stage.

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	BST Probe Data			OARSI Histological Score Medial Condyle			
Animal ID	Medial Condyle-Injury SPI	Medial Condyle-Surrounding SPI	Lateral Condyle SPI	Grade	Stage	Total Score	Comment
1L	1.4	9.6	10.6	1.5	1	**1.5**	Partial thickness focal lesion
1R	0.8	1.8	23.3	4.5	2	**9.0**	Full thickness large lesion
2L	3.5	7.4	14.9	1.5	2	**3.0**	Mild surface discontinuity-focal
2R	0.7	0.4	18.4	2.0	2	**4.0**	Surface discontinuity-large
3L	3.9	8.2	6.9	2.0	1	**2.0**	Surface discontinuity-focal
4L	0.7	18.0	14.3	3.0	1	**3.0**	Deeply fissured, focal lesion
4R	0.9	7.0	18.4	3.0	1	**3.0**	Deeply fissured, focal lesion
5L	0.5	1.9	1.2*	3.0	2	**6.0**	Surface discontinuity-difuse
5R	5.4	4.8	11.2	2.5	1	**2.5**	Surface discontinuity-focal
Y6L	0.3	5.1	18.0	3.0	1	**3.0**	Deeply fissured, focal lesion
6R	3.3	6.8	18.6	2.0	3	**6.0**	Surface discontinuity-focal
7L	0.3	3.4	7.4	3.5	2	**7.0**	Deeply fissured, focal lesion
7R	1.2	3.1	7.6	3.0	2	**6.0**	Deeply fissured, focal lesion
8L	3.9	2.9	18.4	2.0	3	**6.0**	Mild fissures, focal lesion
8R	1.3	2.5	5.6	4.0	3	**12.0**	Partial thickness focal lesion
9L	0.3	2.3	2.4	4.5	1	**4.5**	Partial thickness focal lesion
9R	2.5	10.3	6.8	3.0	2	**6.0**	Mild fissures, focal lesion
10L	4.2	10.6	5.9	2.0	1	**2.0**	Mild discontinity-focal
10R	1.3	1.2	6.4	3.0	3	**9.0**	Partial thickness, large lesion
Mean	**1.9**	**5.6**	**12.0**	**2.8**	**1.8**	**5.0**	
Stdev	1.6	4.4	6.1	0.9	0.8	2.8	
T-Test	Defect x Surr	SurrxLFC	DefectxLFC				
p<	0.0014	0.0038	0.000005				

* age-related degeneration



India ink stained impact injury



Safranin-O stained histological section
Magnification x 20