

# **EXTRA CORPOREAL SHOCKWAVE THERAPY**

**(Sonocur ®)**

**in Workers with Lateral Epicondylitis**

**EVIDENCE BASED PRACTICE GROUP**

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# 1. SUMMARY.

## **Medical-Conclusions**

The Cochrane Library systematic review (Level 1 quality of evidence) on the use of Extracorporeal Shock Wave Therapy (ESWT) in the treatment of lateral epicondylitis (Appendix A) suggests that:

- a) There are conflicting results in the literature
- b) Further clinical trials are necessary to clarify the value of this treatment modality.

A November 2002 prospective, randomized, multi center clinical trial (Appendix B) led the authors to conclude that ESWT should only be applied in further, high quality clinical trials until it is proved to be effective. They felt their study showed it was ineffective in treating lateral epicondylitis.

The ongoing WCB of BC lateral epicondylitis ESWT (Appendix C) study shows that 73% of workers who continue to work while receiving this treatment will remain at work 6 weeks after their last treatment. Approximately 27% of patients will stop work, because of their elbow problem.

Of those workers not working who receive ESWT treatment, 20% will return to work and remain at work 6 weeks after the last treatment. The majority (67%) of non-working lateral epicondylitis patients, however, will not return to work after ESWT treatment.

Recognizing that ESWT is, in fact, many different types of treatment, the literature describing this treatment is extraordinarily scattered and compares apples to oranges, making its interpretation difficult. Hence, while we have discussed ESWT in relation to epicondylitis, the WCB should extend its conclusions to all musculoskeletal conditions and not approve its use. The attached editorial outlines some further thoughts around this issue.

## **Corporate/Other-Conclusions**

Based on broad assumptions and limited data – if the Board were to broaden and expand the use of ESWT treatments there is likely a wide range of financial costs (savings) involved – from a 1.5 million dollars added cost, to a 160,000 dollar savings per year.

The WCB of BC should continue with its present policy of not approving ESWT treatment requests.

## ESWT Review EBPG Editorial

The enclosed documents relate to both our 'study' on low frequency ESWT in workers with lateral epicondylitis and other information on this technology. I believe it is necessary to editorialize and add to the enclosed and to outline what I feel is a reasonable 'outlook' on this whole issue.

ESWT, in itself, is not 'one' treatment. The literature and the manufacturers of the equipment all note that there are many technical differences between the various 'machines' presently in use. This, on its own makes any interpretation of the literature very difficult, as it appears that 'apples and oranges' are frequently being compared. Suffice it to say that most of the literature seems to be looking at 'high frequency and higher energy machines that (usually) need either local or regional anaesthetic (and occasionally general anesthesia) for their applications. An example of this would be the 'Ossatron' machine that did receive FDA approval in the U.S. In contrast, the 'Sonorex' machine in use in Vancouver is a lower energy machine, producing its impulses electromagnetically and requiring (usually) multiple treatments.

On top of the 'differences' noted above with the actual hardware, the literature is very diverse on what type of condition is the subject of any given study. Undoubtedly, most conditions studied are 'tendinopathies', but this still allows criticism when attempting to compare various studies. If one believes that the pathophysiology behind tendinopathies are similar, then perhaps this diversity of condition being studied is reasonable and not a critical point. However, it would seem to many that there are significant differences that cannot be directly compared. Is a finger flexor tendon 'trigger finger' ultimately the same as a calcific rotator cuff tendinitis or plantar fasciitis? I don't profess to know the answer to this but make these points only to note that when attempting to make sense of the literature in any systematic, evidence based way it is almost impossible. In fact, if one were to accept high level evidence based review principles, the vast majority of the literature does not even lend itself to scrutiny as it would not even pass minimal inclusion criteria standards necessary for a critical review.

Hence, at this point in time I believe the only honest comments that can be made are that:

- at present the literature is too 'scattered' with too many variables being present to suggest this modality of treatment is effective
- the WCB should not be the 'leading edge' in accepting new health technologies (assessment, treatment or otherwise) until the evidence is relatively clear that they are of benefit and such technologies are accepted and established within the medical / surgical communities
- the WCB should re-view this topic as the literature develops (which is quite rapidly doing so)

## **COCHRANE DOCUMENT STUDY**

**'Shock Wave Therapy for Lateral Elbow Pain' Buchbinder R et al.** (see Appendix A)

Attached is a Cochrane review of ESWT and lateral epicondylitis. It was recently added to the Cochrane database of completed systematic reviews.

The entire document is available for reading for those who have the interest and time. However, for those who do not, the following is a summary of what we feel the important points are.

This is a transparent, Cochrane systematic review. If one accepts that this 'group' is one, if not THE world experts on such reviews then this document should be viewed as having significant weight and scientific authority. It suggests the following:

- Only randomized or pseudo randomized\* controlled trials (the highest level of evidence) were considered for review.
- The majority of papers excluded (including one German systematic review, 2000) were case series reports.
- Data from the two randomized controlled trials was pooled and a meta-analysis of this aggregate data was undertaken
- The meta-analysis\* suggested the conflicting results in the two separate studies were no longer apparent. i.e.: the benefits of ESWT seen in the first trial became of no statistical significance when data from the one other study added and analyzed.

### **Conclusion**

As with many research papers the authors conclude the only decent papers on this subject show conflicting results. When pooled, both papers' data show no benefit – they suggest further research.

# Appendix A

## SHOCK WAVE THERAPY FOR LATERAL ELBOW PAIN

Buchbinder R, Green S, White M, Barnsley L, Smidt N, Assendelft WJJ.

Date of most recent update: 26 November 2001

Date of most recent substantive update: 7 November 2001

This review should be cited as: Buchbinder R, Green S, White M, Barnsley L, Smidt N, Assendelft WJJ.. Shock wave therapy for lateral elbow pain (Cochrane Review). In: The Cochrane Library, Issue 2, 2002. Oxford: Update Software.

### ABSTRACT

#### Background

This review is one in a series of reviews of interventions for lateral elbow pain. Lateral elbow pain, or tennis elbow, is a common condition causing pain in the elbow and forearm and lack of strength and function of the elbow and wrist. Shock wave therapy (ESWT) involves the application of single pulsed acoustic wave. Since the 1990's reports of benefit of ESWT in the treatment of tendon disorders have been appearing in the literature. A systematic review published in the German language appeared in 2000 ([Boddeker 2000](#))

#### Objectives

To determine the effectiveness and safety of ESWT in the treatment of adults with lateral elbow pain.

#### Search Strategy

Comprehensive electronic searches of MEDLINE, CINAHL, EMBASE and SCISEARCH were combined with searches of the Cochrane Clinical Trials Registrar and the Musculoskeletal Review Group's specialist trial database. Identified keywords and authors were searched again in an effort to identify as many trials as possible.

#### Selection Criteria

Two independent reviewers assessed all identified trials against pre-determined inclusion criteria. Randomized and pseudo randomized trials in all languages were evaluated for inclusion in the review provided they described individuals with lateral elbow pain and were comparing the use of ESWT as a treatment strategy.

#### Data collection and analysis

For continuous variables means and standard deviations were extracted or imputed to allow the analysis of weighted mean difference. Weighted mean difference using a random effects model was selected when outcomes were measured on standard scales. A fixed effects model was used to interpret results and assess heterogeneity. For binary data numbers of events and total population were analysed and interpreted as relative risk.

#### Main results

Two trials of ESWT versus placebo are included in this review (Rompe 1996, Haake 2001). Both trials included similar study populations consisting of participants with chronic symptoms who had failed other conservative treatment. The frequency of ESWT application and the doses and techniques used were similar in both trials. The first trial demonstrated highly significant differences in favour of ESWT whereas the second trial found no benefits of ESWT over placebo.

When the data from the two trials were pooled, the benefits observed in the first trial were no longer statistically significant. The relative risk for treatment failure (defined as Roles-Maudsley score of 4) of ESWT over placebo was 0.40 (95% CI, 0.08 to 1.91) at six weeks and 0.44 (95% CI, 0.09 to 2.17) at one year. After 6 weeks, there was no statistically significant improvement in pain at rest [WMD pain out of 100 = -11.40 (95% CI, -26.10 to 3.30)], pain with resisted wrist extension [WMD pain out of 100 = -16.20 (95% CI, -47.75 to 15.36)] or pain with resisted middle finger extension [WMD pain out of 100 = -20.51 (95% CI, -56.57 to 15.56)]. Results after 12 or 24 weeks were similar.

#### Reviewers' conclusions

The two trials included in this review yielded conflicting results. Further trials are needed to clarify the value of ESWT for lateral elbow pain.

This review should be cited as:

Buchbinder R, Green S, White M, Barnsley L, Smidt N, Assendelft WJJ. Shock wave therapy for lateral elbow pain (Cochrane Review). In: The Cochrane Library, Issue 2, 2002. Oxford: Update Software.

<http://www.update-software.com/newgen/newlibrary/ASP/Document.asp?docID=0&docN...>

## Appendix B

### Sonocur Study Analysis

Date of analysis	Total No. of participants in study		6 wks follow-up													
			Q.3 Has your elbow condition improved to the point where you could return to work?			Q.4 What is your work status now?										
			Total (n)	Completed 6 wks follow up (n)	Yes (n)	No (n)	No answer (n)	Full-time (n)	Full-time, duties changed (n)	Part-time (n)	Part-time, duties changed (n)	No Answer (n)	If not working, mainly due to elbow?			
Total (n)*	Yes (n)	No (n)											No answer (n)			
11-May-01	42	6	2	4	-	1	1	-	-		5	4	1			
22-Jun-01	66	16	5	10	1	3	3	1	-		10	8	1	1		
20-Jul-01	75	19	7	11	1	3	4	2	-		10	9	-	1		
22-Aug-01	84	37	12	22	3	9	4	2	1		21	19	1	1		
21-Sep-01	91	50	17	27	6	11	8	3	1		26	24	1	1		
19-Oct-01	100	56	32% (18)	57% (32)	11% (6)	21% (12)	14% (8)	5% (3)	4% (2)	4% (2)	52% (29)	46% (26)	2% (1)	4% (2)		
18-Jan-02	117	63	33% (21)	56% (35)	11% (7)	21% (13)	16% (10)	5% (3)	3% (2)	3% (2)	52% (33)	48% (30)	2% (1)	3% (2)		
07-Jun-02	137	81	28% (23)	61% (49)	11% (9)	21% (17)	15% (12)	4% (3)	3% (2)	4% (3)	54% (44)	49% (40)	2% (2)	2% (2)		

Note: As of October 19, 2001, the data is provided in percentages with raw data in (). Previous data only provides raw data.

\* Total N not working, mainly due to elbow / Total N completed 6 wks follow up.

## Appendix B (con't)

As of June 7, 2002		6 Wks Follow-up: Q.4 What is your work status now?								
		Total (n)	Full-time (n)	Full-time, duties changed (n)	Part-time (n)	Part-time, duties changed (n)	No Answer (n)	Not working: If not working, mainly due to elbow?		
								Yes (n)	No (n)	No Answer (n)
Pre-Treatment: Q.4 What is your work status now?										
Full-time (n)	12	8	1				1	2		
Full-time, duties changed (n)	14	2	7	1			4			
Part-time (n)	3	3								
Part-time, duties changed (n)	4		1	1			2			
No Answer (n)	2		1			1				
Not working: If not working, mainly due to Elbow?	Yes (n)	43	4	2	1	2	2	30		2
	No (n)	2						2		
	No Answer (n)	1						1		
<b>Total (n)</b>	<b>81</b>	<b>17</b>	<b>12</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>40</b>	<b>2</b>	<b>2</b>	
<b>Total in %</b>	<b>100%</b>	<b>21%</b>	<b>15%</b>	<b>4%</b>	<b>2%</b>	<b>4%</b>	<b>49%</b>	<b>2%</b>	<b>2%</b>	

Of those working pre-treatment (n=33):  
excluding No Answer

Post treatment, 73% (n=24) are still working.

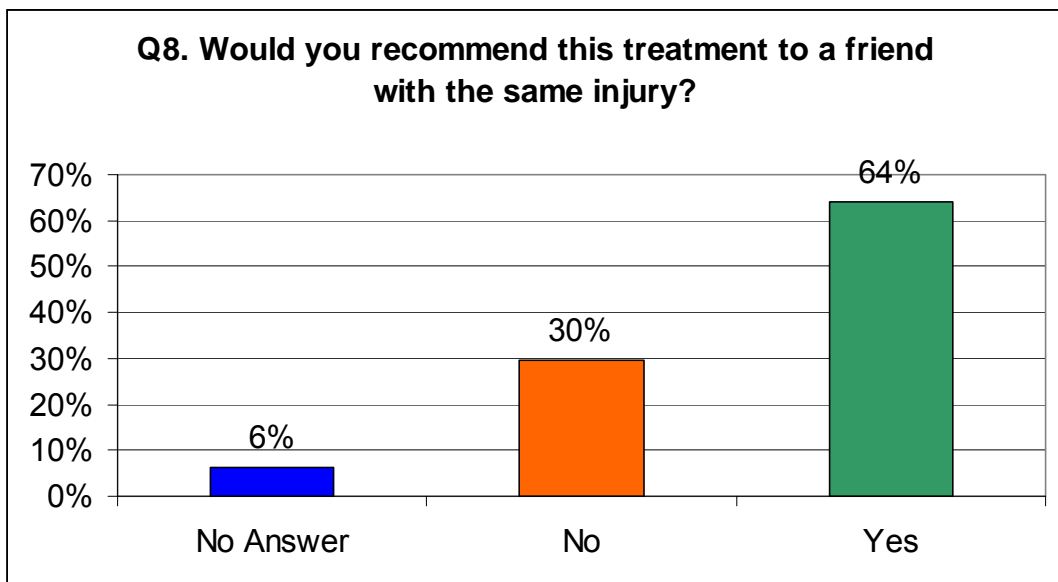
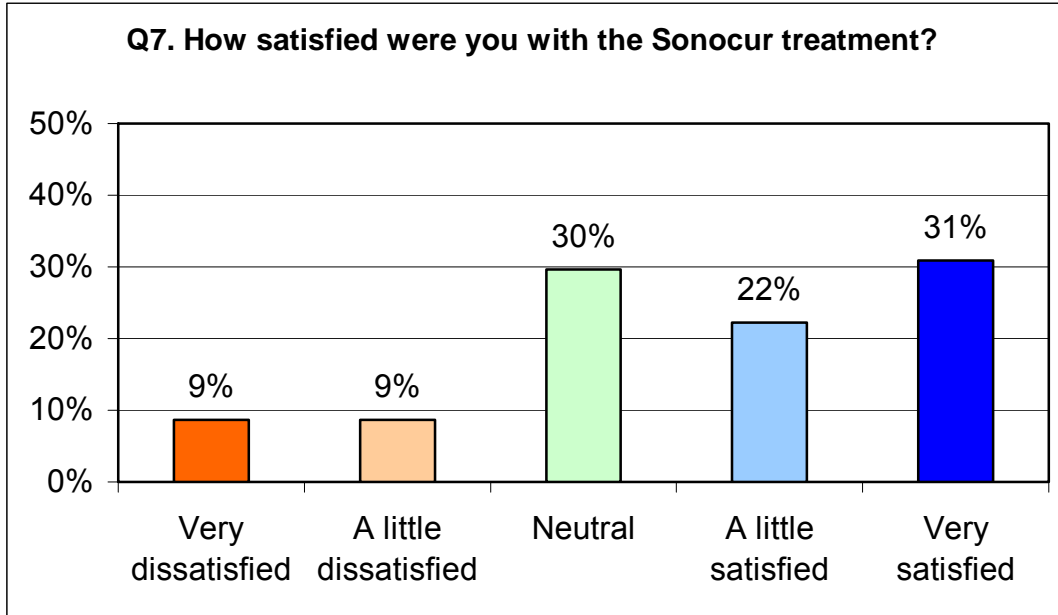
Post treatment, 27% (n=9) are not working, or 21% (n=7) are not working due to their elbow.

Of those NOT working pre-treatment due to elbow (n=45):  
No Answer

Post treatment, 67% (n=30) are still not working due to their elbow.

## Appendix B (con't)

As of June 7, 2002: From 6-wk follow-up questionnaire



## Appendix B (con't)

	07-Jun-02	
Q7.	N	%
Very dissatisfied	7	9%
A little dissatisfied	7	9%
Neutral	24	30%
A little satisfied	18	22%
Very satisfied	25	31%
Total	81	100%
Q8.	N	%
No Answer	5	6%
No	24	30%
Yes	52	64%
Total	81	100%

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