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Prospective Clinical Trial Comparing Trapezial Denervation With Trapeziectomy for the Surgical Treatment of Arthritis at the Base of the Thumb

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ABSTRACT

Background: Trapeziectomy is considered to be the “gold standard” procedure for first carpometacarpal joint (first CMCJ) osteoarthritis. First CMCJ denervation offers the potential benefit of a shorter procedure with bone and joint preservation and swift postoperative rehabilitation. This trial aimed to compare functional outcomes, patient satisfaction, quality of life, and cost effectiveness following these treatments.

Methods: This study was a prospective clinical trial commencing December 2005 to November 2013. A range of functional outcomes assessments were used preoperatively at 6 and 12 mo and 5 y after surgery. These included measurements of strength/motion, visual analogue score, Michigan Hand Outcomes and the European Quality of Life-5 Dimensions questionnaires. Data were analyzed using a two-sample t-test and Mann–Whitney test.

Results: A total of 45 patients were studied of 55 recruited. Age ranged from 41 to 72 (mean = 59). Thirty-five patients underwent denervation and 10 initially had trapeziectomy. Nine patients were converted to trapeziectomy within an average of 6 to 12 mo. There was no significant difference in the functional outcomes at different points of follow-ups. Similarly, there was no significant difference in the time of return to work or cost effectiveness. Denervation achieved a success rate of just above 70%, whereas no revisions were required for the trapeziectomy group.

Conclusions: There was no difference between the two treatments. First CMCJ denervation does not appear to be superior to trapeziectomy. However, the advantage of rapid rehabilitation makes it more favored by patients but at the expense of 30% reoperation rate.

Level of Evidence: Level II.

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Introduction

Background to study

A variety of recognized surgical treatments are available to patients attending our hand surgery center. These include joint replacement, trapeziectomy, trapeziectomy with ligament reconstruction and tendon interposition, arthrodesis of the carpometacarpal joint, metacarpal osteotomy, and first carpometacarpal joint (first CMCJ) denervation.

Only in recent years, denervation techniques¹ have been applied to the first CMCJ to preserve skeletal integrity, yet reduce pain. First CMCJ denervation disrupts the nerve fibers that supply the joint and offers a number of theoretical advantages. These stem from it being a short operation in time requiring no postoperative immobilization thereby allowing for a swift postoperative rehabilitation with a relatively short recovery and brief time off work. In addition, the associated advantage of bone and joint preservation means that a prosthetic material or other reconstructive procedures are not required, and there is no compromise of further surgery. Having said that, there is no strong evidence to suggest that joint replacement or other reconstructive procedures improve outcomes in patients with first CMCJ osteoarthritis (OA).² Although denervation does not restore joint integrity or stability, there is equivocal evidence that motion should be improved by elimination of pain.³ However, in the authors' opinion, patients with disabling deformity or instability are not considered candidates for denervation and may be better treated with trapeziectomy.

In our experience, this procedure seems to be a good alternative to trapeziectomy. Previous research in conjunction with other units⁴ has shown that the results of trapeziectomy, trapeziectomy with soft tissue interposition, and trapeziectomy with ligament reconstruction and tendon interposition are indistinguishable at 3 mo and 1 y. Trapeziectomy is still considered to be the "gold standard" procedure in the hand surgery literature.⁴

First CMCJ denervation, however, offers an effective option for the treatment of first CMCJ OA with the advantage of rapid rehabilitation and a relatively low reoperation rate but at similar cost to both patients and the hospital.

Objectives

This trial aims to compare a relatively new procedure with what is considered a standard treatment as a method of treating basal thumb arthritis with a focus on the following four objectives: the functional outcomes; patient satisfaction; quality of life; and cost effectiveness of the two procedures.

Materials and methods

This study was initially designed as a prospective randomized clinical trial comparing first CMCJ denervation with trapeziectomy. This was in accordance with CONSORT guidelines. During the early stage of recruitment, patients were randomly assigned to one of two treatments. Although trapeziectomy is considered the "gold standard" in literature, both procedures

were routinely carried out in our center, and patients were informed of the possible treatments. However, they viewed denervation as a better option because of the perceived short recovery and subsequently considered randomization unacceptable. As a result, patients withdrew from the study because they were not receiving the treatment of their choice.

As under-recruitment was already taking place with patients self-selecting their treatment of choice in advance, it was considered that randomizing patients to both treatments would significantly undermine the established recruitment process. At the same time, it also became clear that the target number of patients would not be recruited within a practical timeframe. Therefore, the design of the study was modified with the approval of the ethics committee.

Power analysis was initially conducted by a clinical statistician on the original randomized study design suggesting that recruiting 55 patients in each of the two arms of the trial would provide a minimum effect size with 80% power, using $\alpha = 0.05$. An intention-to-treat approach was adopted to account for any dropouts or change in the treatment course (i.e., conversion to trapeziectomy).

The suggested number of patients was recruited from December 2005 until November 2013 and followed up over a period of 5 y. Patients included in the study were those who presented with OA at the base of thumb to our center and requiring surgery as their treatment. We excluded those who had undergone previous surgery for the condition on the same hand and who were unable to give informed consent. All patients were assessed preoperatively and treated using current treatment protocols. Once surgery was agreed, patients were allowed to choose one of the two surgical options.

A range of functional outcome assessments were performed by the hand therapists preoperatively and again at all three

Fig. 1 – First CMCJ denervation technique. Extensor tendons were lifted off the first metacarpal followed by elevation of the radial artery off the scaphoid. (Color version of figure is available online.)

Fig. 2 – First CMCJ denervation technique. Soft tissues were dissected off the first CMCJ joint capsule extending from the trapezoid dorsally to the carpal bones volarly beyond the trapezium. (Color version of figure is available online.)

points after surgery (6 and 12 mo and 5 y). Cost-effectiveness was only assessed at the 3-mo point after surgery.

At the preoperative assessment, patients underwent pre-local and postlocal anesthetic (LA) (block) measurements to establish their suitability for denervation. These assessments objectively and subjectively examine the functional status of the affected thumb and hand, the impact of surgery on time

off work and highlight changes in leisure interest. They are also deemed sensitive enough to detect changes over time. The instruments chosen have been validated and are known to be reliable:

- Strength: Three-point and lateral pinch strength, grip strength and work output using Jamar dynamometer,⁵ Preston pinch gauge,⁶ and BTE PRIMUS work simulator (BTE Technologies, Inc 7455-L New Ridge Road, Hanover, Maryland 21076-3105, United States).⁷
- Thumb range of motion: Span measurement and Kapandji opposition score.⁸
- Pain: Visual analogue score⁹
- Functional ability: Michigan Hand Outcomes Questionnaire (MHQ)¹⁰ and BTE PRIMUS work simulator.
- Patient satisfaction: MHQ.
- Quality of life: European Quality of Life-5 Dimensions questionnaire, which is a standardized and generic tool for assessing health-related quality of life.¹¹

A two-sample t-test was used to analyze measurements of strength, range of motion, pain and patient satisfaction from preblock to each of the three points following surgery to identify whether there was a significant difference in the change of measurements between thumb CMCJ denervation and trapeziectomy. The same test was also used to analyze cost-effectiveness of both procedures including any conversion from denervation to trapeziectomy. Similarly, the Mann–Whitney test was used to assess whether there was any significant difference in the quality of life.

Denervation technique

A single surgeon using the same technique performed all trapezial denervations in our series. This involved a single

Fig. 3 – The difference in change of measurements from preblock to every point of follow-up. No significance in change of measurements between the two groups for each point of follow-up and the preblock assessment because none of the P-values are less than 0.05. (Color version of figure is available online.)

Table 1 – Change in Michigan scores from preblock to 6 mo, preblock to 12 mo, and preblock to 5 y between denervation and trapeziectomy.

MHQ	Mean trap (n)	Mean den (n)	Difference mean	Standard error	95% CI	P-value
6 mo—preblock						
Function	7.86 (7)	2.25 (20)	5.61	8.82	–12.56, 23.78	0.5309
ADL	16.04 (7)	9.49 (20)	6.54	11.58	–17.30, 30.38	0.5769
Work	25.83 (6)	17.50 (22)	8.33	9.54	–11.28, 27.95	0.3904
Pain	–5.42 (6)	–6.25 (18)	0.83	9.86	–19.62, 21.29	0.9334
Esthetic	3.57 (7)	2.03 (20)	1.54	7.82	–14.56, 17.64	0.8454
Satisfaction	3.27 (7)	6.25 (20)	–2.98	11.33	–26.32, 20.36	0.7950
Overall	10.25 (6)	5.44 (17)	4.81	8.35	–12.54, 22.17	0.5702
12 mo—preblock						
Function	0.83 (6)	1.84 (19)	–1.01	10.90	–23.56, 21.55	0.9271
ADL	21.19 (6)	5.76 (19)	15.44	11.40	–8.14, 39.01	0.1888
Work	32.50 (6)	14.05 (21)	18.45	7.78	2.42, 34.48	0.0258
Pain	–4.00 (5)	–4.91 (18)	0.91	12.20	–24.47, 26.29	0.9414
Esthetic	–1.04 (6)	1.32 (19)	–2.36	10.42	–23.91, 19.20	0.8230
Satisfaction	–3.82 (6)	4.61 (19)	–8.42	14.84	–39.12, 22.28	0.5758
Overall	13.57 (5)	5.81 (17)	7.76	9.79	–12.65, 28.17	0.4372
5 y—preblock						
Function	–2.50 (6)	7.29 (12)	–9.79	8.93	–28.73, 9.14	0.2892
ADL	15.56 (6)	14.23 (12)	1.33	9.39	–18.58, 21.23	0.8892
Work	22.50 (6)	18.08 (13)	4.42	8.18	–12.83, 21.67	0.5955
Pain	3.33 (6)	–8.27 (13)	11.60	12.91	–15.63, 38.83	0.3812
Esthetic	5.21 (6)	7.67 (11)	–2.46	13.94	–32.16, 27.24	0.8621
Satisfaction	2.78 (6)	8.68 (12)	–5.90	15.03	–37.76, 25.95	0.6996
Overall	6.70 (6)	9.74 (11)	–3.04	9.36	–22.99, 16.92	0.7502

Whether there is a significant difference in the change of Michigan scores from preblock to 6 mo, preblock to 12 mo, and preblock to 5 y between denervation and trapeziectomy using a two-sample t-test.

dorsoradial incision preserving the terminal sensory branches of the radial nerve. The extensor tendons were lifted off the first metacarpal followed by elevation of the radial artery off the scaphoid (Fig. 1). Soft tissues were dissected off the first CMCJ joint capsule extending from the trapezoid dorsally to the carpal bones volarly beyond the trapezium (Fig. 2). The dissection was carried up onto the scaphoid and distally onto the first metacarpal, preserving the integrity of the capsule of the joint. A bipolar diathermy was then used around the periphery of the capsule ensuring that no nerve fibers remained attached to the first CMCJ capsule. Any branches that might have gone from the radial artery to the joint were ablated during elevation of the radial artery earlier in the procedure.

Results

A total of 96 patients with arthritis at the base of the thumb were assessed regarding the eligibility for the trial. Fifty-five patients were recruited for the trial after abandoning the randomization process. Of these, 10 patients did not wish to continue because of either declining surgery in preference of steroid injections or due to other health issues and therefore excluded.

Thirty-five patients underwent denervation and 10 initially had trapeziectomy. Of those who underwent denervation,

nine patients were converted to trapeziectomy within an average period of 6 to 12 mo at which point they were removed from the follow-up. Patients' age in the denervation group ranged from 41 to 72 (mean = 58) and gender ratio was (5:1) with 29 females versus 6 males, whereas in the trapeziectomy group, age ranged from 55 to 72 (mean = 61). Gender ratio was equal at 1:1.

There was no significant difference between denervation and trapeziectomy when considering the overall change in measurements from preblock to 6 and 12 mo or 5 y postop because all of the P-values were less than 0.05 (Fig. 3) (Supplementary Tables 1-3), except for one related to the Isotonic dynamic BTE 162&, work out-put assessment at 12 mo (P-value = 0.0141) (Supplementary Table 2).

Analyzing the MHQ in its components, there was found no significant difference when considering the overall change in scores from preblock to each of the three aforementioned points of follow-up, with the exception of one sporadic change in work scores at 12 mo (P-value = 0.0258) (Table 1).

Similarly, there was no significant difference in the change of visual analogue score between the two groups for each point of follow-up and the preblock assessment (Table 2).

The assessment of quality of life scores (European Quality of Life-5 Dimensions) showed again no significant difference between the two groups (Table 3).

Table 2 – Change in VAS from preblock to 6 mo, preblock to 12 mo, and preblock to 5 y between denervation and trapeziectomy.

VAS	Mean trap (n)	Mean den (n)	Difference mean	Standard error	95% CI	P-value
6 mo—preblock						
VAS	0.19 (6)	0.09 (29)	0.09	0.10	–0.11, 0.29	0.3527
12 mo—preblock						
VAS	0.21 (5)	0.13 (23)	0.08	0.11	–0.15, 0.32	0.4797
5 y—preblock						
VAS	0.15 (5)	0.10 (16)	0.06	0.14	–0.23, 0.34	0.6723

Whether there is a significant difference in the change of VAS from preblock to 6 mo, preblock to 12 mo, and preblock to 5 y between denervation and trapeziectomy using a two-sample t-test.

There was neither any difference between the two groups in terms of cost effectiveness although some variables did not have enough data to be tested (Table 4).

A large overlap in confidence intervals was noted in the time of return to work for both groups, which indicated no significant difference (Fig. 4).

Of the 35 denervations, nine patients were converted to trapeziectomy. This occurred mainly in the first year, indicating a success rate of just above 70%. No revisions were required for the trapeziectomy group throughout the period of the study (Fig. 5).

Table 3 – Change in EQ5D scores from preblock to 6 mo, preblock to 12 mo, and preblock to 5 y between denervation and trapeziectomy.

EQ5D	Number trap	Number den	P-value
6 mo—preblock			
Mobility	6	29	0.8967
Self-care	6	29	0.2581
Usual activities	6	29	0.5139
Pain/discomfort	6	27	0.1401
Anxiety/depression	6	29	0.8251
12 mo—preblock			
Mobility	5	23	0.5974
Self-care	5	22	0.1676
Usual activities	5	23	0.5311
Pain/discomfort	5	21	0.4980
Anxiety/depression	5	23	0.3269
5 y—preblock			
Mobility	5	16	0.3328
Self-care	5	16	0.2956
Usual activities	5	16	0.6331
Pain/discomfort	5	15	0.1716
Anxiety/depression	5	16	0.8895

Whether there is a significant difference in the change of EQ5D scores from preblock to 6 mo, preblock to 12 mo, and preblock to 5 y between denervation and trapeziectomy using a Mann–Whitney test.

Discussion

Trapeziectomy alone remains the gold standard procedure, particularly in the low-demand elderly patients with more advanced disease. This is despite the multitude of other surgical options.⁴ A recent systematic review has failed to identify any additional benefits of one procedure over another, particularly with respect to a number of the functional outcomes such as pain management, patient global assessment, range of motion, strength, and physical function. It is therefore recommended that trapeziectomy alone should be always used, unless indicated otherwise, as it has been found the simplest approach that is associated with fewer complications.^{2,12} More recent studies have supported this as the preferred technique due to its good long-term results.¹³

Thumb CMCJ denervation is commonly performed in our center, and it is popular among patients with OA at the base of the thumb because of the theoretical advantages discussed, in addition to the relatively short rehabilitation period after the procedure. However, standard trapeziectomy remained the ultimate procedure for those failing to improve following denervation. The length of postop rehabilitation, outcomes, reoperation rate, and cost-effectiveness generally influences the choice of a procedure over another. Therefore, it is crucial to establish whether a comparison could be drawn between the two options, and whether any difference actually exists, particularly that there is no recent study that has looked into such a comparison.

Analysis of functional outcomes, patient satisfaction, quality of life, cost effectiveness, and time to return to work for both trapeziectomy and denervation in terms of the treatment of the first CMCJ OA has demonstrated that there was no significant difference between the two procedures. The results of this study therefore support our hypothesis that was primarily based on both the theoretical advantages of denervation and patients' preference in our center. The demonstrated success rate of denervation in our series (70% at 12 mo) could reflect a relative degree of effectiveness in comparison to trapeziectomy in achieving the objective of treatment but at the expense of a possible 30% chance of reoperation after 12 mo postop.

It was also demonstrated that the "time to return to work period" was no different between either procedures, and there

Table 4 – Cost-effectiveness.

Group	Operation	N	Mean	Standard deviation	Standard error mean	95% confidence interval of difference	P-value
How long did it take for you to get to your appointment?	Trap	11	31.36	15.667	4.724	–13.82, 9.35	0.700
	Den	40	33.6	17.237	2.725		
How many miles did you travel to get there?	Trap	11	8.4091	4.90315	1.47836	–5.80, 5.14	0.538
	Den	39	8.7359	8.59735	1.37668		
How long did you spend at your appointment?	Trap	11	117.27	18.216	5.492	–9.35, 25.45	0.654
	Den	40	109.23	26.975	4.265		
How long did it take to get there?	Trap	10	48	74.729	23.631	–19.00, 40.52	0.058
	Den	38	37.24	28.157	4.568		
How many miles did you have to travel?	Trap	10	9.1	5.73876	1.81475	–6.45, 7.38	0.426
	Den	38	8.6382	10.40022	1.68714		

Whether there is a significant difference between denervation and trapeziectomy in terms of cost-effectiveness.

was a large spread in the data. This indicates that other factors determine when patients return to work other than the procedure they have had. These include the nature and type of occupation and advice from clinical staff. This does not necessarily signify that the recovery period is the same for both procedures. In addition, the fact that there was a large overlap in confidence intervals may suggest that there were insufficient patients to measure the difference that exists.

The results of this study were influenced by a number of limiting factors. The main one was focused around the issue of randomization. Initially, this led to under-recruitment resulting in a significant reduction in the number of patients who could be included in the study. This was primarily because patients were well informed about the two

procedures but showed a preference toward denervation based on the suggestion that it is a less aggressive procedure with a shorter rehabilitation period. The fact that 10 patients withdrew from the study has subsequently reduced the number of patients who were finally recruited, affecting the power of the trial. The assessment of quality of life was equally affected by the loss to follow-up especially in the trapeziectomy group (40% at 6 mo and 50% at 12 mo). Therefore, the second limiting factor is perhaps related to the need for larger more powered study.

The other factor in our series to be considered may be related to the preoperative assessment by the occupational therapists whereby patients were deemed suitable for denervation based on the improvement in their measurements from preblock to postblock. The use of the preoperative LA was highlighted in the published literature and has demonstrated conflicting results.³ The reported discrepancies in pain reduction after denervation have led some contemporaries to believe that the diffusion of the LA solution may be responsible for the postblock improvement in the measurements. Therefore, they did not consider the block test clinically relevant and thus influencing the eligibility for surgery.¹⁴ This may, to a certain extent, explain the 30% conversion rate to trapeziectomy in our series, which could also indicate that denervation may have been the wrong indication in those 9 patients. It is further possible that a degree of associated instability at the first CMCJ may have led those patients to present with an ongoing functional deficit after denervation and therefore requiring trapeziectomy. It is acknowledged that the denervation failure rate in our series was relatively higher than that quoted by Loréa³ and Arenas-Prat.¹⁵ This may potentially be related to the surgical technique in our series, which was limited to a single dorsoradial incision as opposed to two incisions³ or using Wagner approach.¹⁵ While the previously mentioned techniques may have provided a better access to perform an adequate denervation, the functional outcomes of which were not clearly explained.

The current literature does not include any studies that compare the outcomes of the two procedures. Therefore, it is

Fig. 4 – Return to work (time in days). A large overlap in the survival curve is noted between the two procedures indicating no significant difference. (Color version of figure is available online.)

Fig. 5 – Success rate. No revisions were required for the trapeziectomy group, whereas just over 70% of the denervations survived in the first-year follow-up. (Color version of figure is available online.)

difficult to draw comparisons. Several studies have looked into the outcomes of denervation for OA of the wrist, the results of which indicate major improvement in pain and patient satisfaction.^{16,17} Few studies have looked specifically into denervation of the first CMCJ referring to pain improvement but no reference to functional outcomes as such.^{3,18,19} One of these studies reported an average 84% overall improvement in pain after the procedure, in addition to a slight but significant increase in grip and pinch strengths.³

Salem and Davis reported that patients who undergo trapeziectomy achieve good pain relief in nearly 85% of the cases. However, despite this reliable outcome and maintaining a good movement, there was no major improvement in strength measurements found.²⁰ It has been shown that this outcome is sustainable in most patients without the need for any revisions. The vast majority of patients often require a minimum of a year to achieve a good outcome.^{21–23} This is mirrored in our results whereby none of the patients in the trapeziectomy group required revisions throughout the 5-y follow-up period.

The outcomes of both denervation and trapeziectomy were comparable for the period of this study and within the scope of the previously mentioned drawbacks. Therefore, it is reasonable to say that denervation is as good as trapeziectomy in the treatment of the first CMCJ but at the expense of possible reoperation in just fewer than 30% of the cases. In addition, denervation appeared to offer patients an adequate degree of pain relief and functional ability, facilitating return to work and usual daily activities at a similar cost to both patients and hospital. In addition, it is essential to state that, when given options of the surgical treatment of first CMCJ OA, patients appear to prefer denervation. However, it is acknowledged that some patients who really wanted a denervation procedure were so dissatisfied that they subjected themselves to a major second surgery, suggesting that

patients' enthusiasm for denervation may have been surgeon/recruiter driven rather than based on accurate scientific representation.

One of the problems with surgical randomized clinical trials is that the perceived cost to the patient in time and recovery plays an important role in the patient's willingness to participate and it may therefore not be possible to carry out a study of two very different techniques because of a low enrollment rate. Nevertheless, we believe that the results of this study have provided a platform for a larger more powered study. However, the feasibility of such a study is dependent on adequate and carefully planned sample size, which may be justified by our results. This is particularly important if a multicenter collaboration is ever considered.

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Authors' contributions: All authors have made substantial contributions to the conception and design of the study, in addition to acquisition, analysis, and interpretation of data. A.S. was responsible for research data entry, drafting the article, and dissemination and presentation of the work. R.H. was the clinical statistician involved in the study design, the statistical analysis of the data, and the review of the article. F.D.B. and C.H-P both are the senior authors overseeing the above and were responsible for the final review and revision of this article.

Disclosure

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jss.2019.01.011>.

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